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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Vulnerability and Blood Donation: Enhancing Safety While Combating Stigma in Colombia

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Résumé
En 2022, la Cour constitutionnelle colombienne a ordonné la suppression de l'exclusion de 12 mois du don de sang pour les donneurs masculins potentiels qui ont déclaré avoir eu des relations sexuelles avec d'autres hommes au cours de l'année écoulée dans les lignes directrices nationales pour la sélection des donneurs de sang, afin de lutter contre la stigmatisation et la discrimination à l'encontre des diverses identités de sexe et de genre. Cet article explore la dynamique complexe de ce mandat et examine la tension entre les valeurs morales privées, telles que l'autodétermination et la liberté d'expression, et les valeurs publiques, telles que la non-malfaisance, l'égalité et l'approche de la vulnérabilité. L'analyse se penche sur les défis posés par le système d'hémovigilance colombien, les schémas épidémiologiques du VIH et le manque d'études à l'appui de ces changements de lignes directrices. Les contraintes structurelles et logistiques liées à la minimisation des risques transfusionnels sont mises en évidence, soulignant la nécessité d'améliorer les mesures de sécurité. Les implications de la réduction des délais d'ajournement pour les groupes à haut risque ne disposant pas de protocoles de test adéquats sont également abordées. La nécessité d'études nationales pour déterminer le risque réel posé par les différentes populations est soulignée, en plaidant pour des mesures de sécurité solides, y compris le test universel d'acide nucléique (TAN), pour protéger à la fois les donneurs et les receveurs. Il est essentiel de trouver un équilibre entre l'élimination de la discrimination et l'amélioration des pratiques de sécurité du sang afin de garantir la non-malfaisance et l'équité pour toutes les parties prenantes impliquées dans le processus de don de sang en Colombie. L'article souligne l'importance de protéger les individus et les communautés les plus exposés au risque d'absence de défense et d'insécurité dans le cadre de l'évolution des protocoles de don de sang.

Mots-clés
orientation sexuelle, maladies infectieuses, autonomie du patient, transfusion sanguine, Colombie, bioéthique

Abstract
In 2022, the Colombian Constitutional Court mandated the removal of the 12-month deferral for blood donation for potential male donors who reported having had sexual relations with other men in the past year in the national guidelines for blood donor selection, aiming to combat stigma and discrimination against diverse sex-gender identities. This article explores the complex dynamics of this mandate, and examines the tension between private moral values, like self-determination and freedom of expression, with public values, such as non-maleficence, equality and vulnerability approach. The analysis delves into the challenges of Colombia's hemovigilance system, the epidemiological patterns of HIV, and the lack of supporting studies for these guideline changes. Structural and logistical constraints in minimizing transfusion risks are highlighted, emphasizing the need for improved safety measures. The implications of reduced deferral times for high-risk groups without adequate testing protocols are also addressed. The necessity for national studies to determine the actual risk posed by different populations is underscored, advocating for robust safety measures, including universal nucleic acid testing (NAT), to protect both donors and recipients. Balancing the elimination of discrimination with enhanced blood safety practices is crucial to ensure non-maleficence and equity for all stakeholders involved in the blood donation process in Colombia. The article emphasizes the importance of protecting individuals and communities at greater risk of defenselessness and insecurity within the evolving landscape of blood donation protocols.

Keywords
sexual orientation, infectious diseases, patient autonomy, blood transfusion, Colombia, bioethics

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INTRODUCTION

In 2021, in the city of Cali, Colombia, two men took legal action after being denied the opportunity to donate blood at a hospital blood bank. Their case was based on the argument that existing regulations — specifically, Resolution 3212 of 2018 issued by the Ministry of Health and Social Protection (MHSP) and the Technical Guidelines for the Selection of Blood Donors established by the National Institute of Health (INS) — discriminated against them. At the time, these guidelines mandated a 12-month deferral period for men who have sex with men (MSM), given their significantly higher prevalence of HIV infection (estimated to be 36-42 times higher than that of the general population) (1,2).

The plaintiffs argued that this policy reinforced stigma and discrimination, particularly against gay, bisexual, and other MSM, and transgender individuals. Their claims were upheld by both the Eighth Family Court of Cali and the Superior Court of Cali, which ruled that the deferral guidelines were discriminatory. In 2022, the case was reviewed by the Constitutional Court, which reaffirmed its previous stance from Judgment T-248 (2012) and ruled in favour of eliminating donor selection criteria based on sexual orientation, instead advocating for an individualized risk assessment approach (3).

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While this decision represented an important step toward eliminating discrimination, it also raised significant concerns regarding the safety of blood recipients, who have no choice in their transfusion. Unlike donors, recipients rely on rigorous clinical and technical protocols to ensure that the blood supply is as safe as possible. Colombia has an estimated population of 52.6 million inhabitants and is served by 83 blood banks (29 public and 54 private). In 2023, these blood banks collected 999,545 blood donations from non-remunerated volunteers, yielding a national rate of 26.5 donations per 1,000 people. All blood banks adhere to guidelines established by the National Institute of Health, which manages the national hemovigilance program that gathers data from both blood banks and healthcare facilities that perform transfusions. It is important to note that, until 2025, the universal implementation of nucleic acid testing (NAT) for the detection of infectious agents potentially transmitted by transfusion was not mandatory in Colombia.

Given the unique epidemiological characteristics of HIV in Colombia and the challenges of implementing universal screening measures such as NAT, the absence of national studies validating the impact of these changes introduces a critical uncertainty: Could this policy modification increase the risk of transfusion-transmitted infections?

This article examines the implications of the Constitutional Court's ruling by analyzing four key aspects: 1) the evolution of donor selection policies in Colombia, 2) the functioning of the national blood system and current screening practices, 3) the epidemiological dynamics of HIV in Colombia, including risk factors and preventive strategies, and 4) the ethical and public health considerations surrounding this issue. We explore the balance between rights such as self-determination and non-discrimination and the fundamental principles of non-maleficence, equity, and the protection of vulnerable populations.

For the purposes of this article, we clearly distinguish between sexual orientation and sexual behaviour. An individual who identifies as gay or bisexual (orientation) may not engage in high-risk behaviours (e.g., they might be abstinent), meaning their risk profile differs from someone classified based solely on behaviour. This distinction is crucial because donor deferral policies may affect these groups differently depending on whether the criteria are based on identity or on behaviour.

Ultimately, we argue that while eliminating discriminatory practices in blood donation is a necessary step toward social equity, it must be accompanied by robust safety measures to ensure the protection of blood recipients. The principle of non-maleficence demands that any change in donor selection criteria be guided by scientific evidence and supported by comprehensive risk mitigation strategies, including the potential implementation of universal NAT testing. Without these safeguards, well-intended reforms risk unintentionally increasing recipient vulnerability rather than protecting public health.

FROM EXCLUSION TO INDIVIDUALIZED RISK ASSESSMENT: CHALLENGES OF BLOOD DONOR SELECTION CRITERIA IN COLOMBIA

The evolution of blood donor selection criteria in Colombia reflects a gradual shift from exclusionary policies to a more individualized risk assessment approach. This section examines key regulatory changes over the years, highlighting both advancements in reducing discrimination and persistent challenges in balancing inclusivity with blood safety.

In 1996, the MHSP introduced Resolution 901 (4) which adopted the Manual of Technical, Administrative, and Procedure Standards for blood banks. This document outlined the initial requirements to be eligible as a blood donor in the country. It also established a permanent deferral for individuals who disclosed having engaged in male homosexual relations within the last 15 years. In 2012, the Constitutional Court in Colombia issued Judgment T-248 (5) which established:

> among the risk factors that should be considered when qualifying a blood donor, sexual orientation should not be mentioned, but rather risky sexual behaviours, such as sexual intercourse without any kind of protection or with strangers, promiscuity, not having a permanent partner, etc.

In 2013, the INS published the Guide for the Selection of Blood Donors in Colombia with the aim to standardize and update the criteria for accepting or deferring potential blood donors across all blood banks operating in the country. Within this guide, question twelve was defined as follows: "Have you had sexual relations with individuals of the same sex? If the answer is affirmative, MSM since 1977 must be permanently deferred" (6).

At that time the Colombian guideline was aligned with the Guidelines on the Assessment of the Suitability of People for Blood Donation issued by the World Health Organization (7) and the Food and Drug Administration (8) of the United States, which recommended an indefinite deferral for all MSM (since 1977) from donating blood due to concerns regarding the potential transmission of HIV through transfusion.

Following the analysis, the Constitutional Court emphasized the need for the MHSP to review existing regulations regarding the reception and supply of blood components. The aim was to eliminate sexual orientation as a criterion for assessing the risk of transmitting infections like HIV and instead focus on investigating specific sexual risk behaviours. Additionally, the court ordered modifications to Resolution 901 to remove as exclusion criteria sexual orientation and belonging to the MSM population. These changes were intended to align the regulations with the understanding that HIV risk is not determined by gender identity or sexual orientation, but rather by individual risk practices.

To comply with the order of the constitutional court, in 2018 the MHSP issued Resolution 3212 (9). There, the behaviour of permanent deferral for MSM was changed to a deferral for 12 months, from the last sexual contact. In accordance with Resolution 3212, the INS published the Technical Guidelines for the Selection of Blood Donors in Colombia in 2018. This document updated the donor selection guide from 2012 and modified question twelve: “Have you had sexual relations with individuals belonging to any of the key populations, such as sex workers, people who inject drugs, street dwellers, men who have sex with men, and transgender women?”

If the answer was affirmative, a deferral period for twelve months after the last sexual contact with any member of these key populations was established (10). The Court established that the phrasing of the question assumed that having sexual relations with individuals from certain key populations (e.g., sex workers, MSM, transgender women) inherently carried a risk, without explicitly addressing actual risky behaviours. Therefore, this question generalized risk based on population group rather than behaviour. This was considered discriminatory by the court because it implies that all individuals within these groups were high-risk, rather than assessing risk based on specific sexual behaviours (e.g., multiple partners, unprotected sex, or sex with partners with known infections).

The implementation of a 12-month deferral period aligned with the policies adopted by various countries at that time, including the United States (11), Great Britain, Australia, and others (12). In Canada, for example, the lifetime deferral implemented in 2013 was later amended to a five-year deferral, allowing men to donate if they had refrained from sexual contact with another man for at least five years. This deferral period was subsequently shortened to one year in 2016 and further reduced to three months in 2019. In 2022, Canada removed the sexual orientation criterion and introduced a gender-neutral questionnaire focusing on sexual risk behaviour (13).

In August 2022, the INS issued an updated version of the Technical Guidelines for the Selection of Blood Donors (1) in response to the decision by the Superior Court of the Judicial District of Cali and the Constitutional Court Judgment T-171 (2022). The court determined that the 12-month deferral period for blood component donation by MSM, as stated in the 2018 INS Guidelines, could potentially violate fundamental rights when applied. As a result, the INS modified question twelve: “Have you had sexual relations with individuals belonging to any of the following populations: sex workers, homeless people, or individuals who inject drugs?”

On October 12, 2023, the MHSP issued Resolution 1676 of 2023 (14), thereby rescinding Resolution 3212 of 2018. Despite the persistence of epidemiological data highlighting an HIV epidemic concentrated in MSM, psychoactive substance users, transgender women, sex workers, homeless individuals, transgender men, and incarcerated individuals, this resolution omits any mention of populations with a prevalence of HIV infection greater than 1%. Instead, it introduces the following statement:

> It is incumbent upon individuals to practice solidarity self-selection. After receiving information about the requirements for blood donation, individuals are encouraged to assess their health status, habits, and behaviors that may constitute risk factors. Through this process, they can make a ‘voluntary, autonomous, conscious, and responsible decision’ to donate blood. The Ministry, the National Institute of Health, and Blood Banks will actively promote self-selection as a supportive behaviour.

Currently, after completing the donor selection questionnaire, there is a second step called self-exclusion. Here, potential donors are urged to think about the information they’ve provided to ensure the safety of blood components and recipients. Some blood banks still remind donors that providing false information during self-exclusion could be considered “spreading of HIV or hepatitis B,” according to Article 370 of the Penal Code. It’s crucial to note that Article 370 was declared unenforceable by Constitutional Court Ruling C-248 in 2019 (15). However, Article 369 (spread of epidemic) remains in effect.

Resolution 1676 of 2023 (14) also delineates certain criteria identifying individuals at risk for blood donation, including those engaged in specific sexual behaviours:

> [...] g) Individuals involved in any of the following risky sexual behaviours:
> - Having engaged in sexual relations (vaginal, anal, or oral) with more than two people within the last 12 months.
> - Changing sexual partners within the last 6 months.
> - Having sexual relations with individuals diagnosed with HIV, hepatitis, HTLV I-II viruses, and other biological agents known, through scientific evidence, to be sexually transmitted within the last 12 months. [...]
>
> [...] The deferral period for blood donation, when one or more of these risk factors are identified, shall align with the guidelines outlined in the ‘Technical Guidelines for the Selection of Blood Donors in Colombia’ established by the National Institute of Health. [...]
>
> [...] The questions and information solicited during the blood donor eligibility assessment shall focus on the risk factors defined in this resolution, without delving into matters of sexual orientation or gender identity. Blood banks, during the interview, must adhere to the questions stipulated in the ‘Technical Guidelines for the Selection of Blood Donors in Colombia. [...]’

> [...] The language employed throughout the blood donor selection process must be rooted in respect for human dignity, confidentiality, and the safeguarding of human rights. It should eschew any form of stigmatization or discrimination, seeking only information relevant to the fundamental technical purpose of ensuring blood safety. Furthermore, the reasons for deferring a donation in specific cases should be explained, guiding referred individuals to their respective health-promoting entities. [...]

In essence, the Resolution 1676 of 2023 advocates for the individualization of behaviours rather than generalization. This line of reasoning was supported by initiatives such as the FAIR screening criteria, promoted by the UK group For the Assessment of Individualized Risk (FAIR), which updated and emphasized the importance of assessing individual risk behaviours during the donor selection process. The aim of FAIR is to ensure a safe and equitable blood donation screening system that treats all individuals equally, regardless of gender identity or sexual orientation (16).

Resolution 1676 of 2023 (14) is significant for its endorsement of supportive self-selection and the individualization of cases. Nevertheless, within the Colombian context, certain instances highlight the inherent vulnerability of this approach. For example, in Colombia, it is regulated that a man can donate a maximum of four whole blood donations per year, with a minimum interval of three months between donations, while a woman can donate up to three times per year, with a minimum interval of four months between each donation. However, between 2018 and 2019, over 4,000 cases were documented in which individuals made whole blood donations at various blood banks within a period of fewer than 30 days, which violates national policy (17). Despite being informed, these people persisted in donating, prompting the need for strategies that can only be effectively implemented through a national framework, as opposed to relying solely on an individualistic approach. The identification of these cases raises concerns about the absence of studies quantifying whether these individuals belong to key populations or the general public. This critical limitation must be addressed as a priority before widespread national measures are implemented. While the primary intention is to reduce discrimination against specific groups, there is a risk of unintentionally amplifying the vulnerability to blood recipients. Recognizing that, in the Colombian context, a decrease in blood collections below 17.3 donations per 1,000 people is associated with higher mortality in vulnerable groups (18), it becomes imperative to meticulously evaluate both the positive and negative aspects of behaviours that may be in conflict at the present moment.

While Resolution 1676 of 2023 represents a significant step toward eliminating discriminatory deferral policies and emphasizing individual risk assessment, its reliance on self-selection raises concerns about enforcement and potential gaps in donor safety. The next section will explore the evolution of the Colombian hemovigilance system and the current challenges, particularly in light of legal changes.

NATIONAL HEMOVIGILANCE SYSTEM AND ITS CHALLENGES

This section outlines the evolution of serologic and NAT in blood donation screening, emphasizing its role in reducing transfusion-transmitted infections. While many countries have mandated NAT to enhance detection sensitivity, Colombia has yet to implement universal NAT screening, with less than 10% of blood banks adopting the practice. Understanding these testing strategies and their impact on the window period is crucial for evaluating the effectiveness of current screening policies and their implications for donor eligibility criteria.

Since the enactment of Decree 1571 in 1993, all blood units collected in Colombia are required to undergo serologic screening to identify HIV 1-2, hepatitis B surface antigen (HBsAg), antibodies against Hepatitis C Virus (HCV), and *Treponema pallidum*. Subsequently, Resolution 1738 of 1995 mandated the inclusion of serologic screening for antibodies against *Trypanosoma cruzi*, while Resolution 437 introduced mandatory screening for the presence of antibodies against hepatitis B core antigen (Anti-HBc) and Human T-Cell Lymphotropic Virus (HTLV). In 2023, most blood banks (95.2%) employed Chemiluminescent Immunoassays (CLIA), Amplified Electrochemiluminescence (ECLIA), or Chemiluminescent Magnetic Immunoassay (CMIA) HBsAg, Anti-HCV, Anti-*T. cruzi, T. pallidum*, Anti-HBc, and anti-HTLV I-II. The remaining 4.8% relied on fourth generation Enzyme-Linked ImmunoSorbent Assay (ELISA) (19).

The implementation of NAT aimed at detecting HIV, HBV, and HCV to reduce serologic window periods in blood donors started in 1997 in Germany (20). The window period refers to the time between the initial infection with a specific agent and the point at which the infection can be reliably detected by specific blood tests. The window period for HIV detection using NAT is approximately 3 to 9 days post-exposure, while for HCV is 1-7 days post-exposure (21). Conversely, for HBV, NAT can identify the virus within 10 to 23 days following exposure (22). In contrast, the window period extends from 18 to nearly 45 days for CLIA in HIV infections, and for HCV and HBV, CLIA can detect the viruses within 18 to 90 days post-exposure. Finally, the window period for HIV, HCV, and HBV with the ELISA test spans from 23 to 90 days after exposure (22). During this window period, the individual may be infected but still test negative (23). By the end of the 20th century, ten nations had adopted HCV detection through NAT in 100% of collected units, with four and three countries doing the same for HIV-1 and HBV, respectively. By 2010, 33 countries had extended their NAT testing protocols to include 100% of collected units for HCV and HIV, while 31 countries incorporated the same for HBV (20,24).

An international survey on NAT of blood donations from 1999 to 2009 showed that a total of 272,520,696 donations underwent screening using HIV-1 NAT, 303,196,074 underwent screening using HCV NAT, and 114,286,214 underwent screening using HBV NAT (20). Among these, 244 (0.9 per million) tested positive exclusively for HIV-1 through NAT, 680 (2.2 per million)

tested positive exclusively for HCV through NAT, and 1,884 (16.5 per million) tested positive exclusively for HBV through NAT. Consequently, there were 2,808 donations contaminated with viruses that tested negative in serologic screening, highlighting the potential transfusion of these units without the implementation of NAT (20).

Notably, in Latin America, Brazil stands out as the only country enforcing mandatory NAT screening on all collected blood donations (25). While other countries in the region have blood banks conducting NAT, the requirement to apply these tests to 100% of collected units is not obligatory. In the case of Colombia, the MHSP conducted a systematic review in 2016 to explore the introduction of NAT in blood banks (21). However, their findings did not deem it a mandatory requirement for widespread implementation, considering the prevailing characteristics of the Colombian blood donor population. At that time, 94% of blood donors were voluntary unpaid and 6% were family/replacement, and the selection process adhered to existing donor selection guidelines. This handbook prohibited the acceptance of populations identified by the MHSP with HIV prevalence exceeding 1%, where MSM and transgender women were included (26).

In 2018, the Institute for Health Technology Assessment (IHTA) conducted a comprehensive study evaluating the cost-utility of integrating NAT for the detection of HBV, HCV, and HIV into the conventional screening process for blood donations in Colombia (27). The findings of the study suggested the incorporation of NAT testing into the routine blood donation processing. This recommendation gained significance when considering clinical, ethical and social dimensions. Beyond the economic advantages derived from preventing infections in blood recipients, the decision to prioritize NAT testing was underscored by the imperative to safeguard the quality of life for individuals at risk.

Countries that have reduced deferral times for MSM typically implemented NAT across 100% of collected blood units simultaneously (28). However, the situation in Colombia presents a contrast. At the onset of the lawsuit initiated by the couple in Cali, less than 6% of the country's blood banks were conducting NAT procedures (29). As of November 2023, Colombia had not enforced the requirement for the inclusion of NAT in collected blood units, as noted by Bermúdez-Forero (30). Out of the 83 blood banks, only ten had integrated NAT for screening HIV, HBV, and HCV, comprising 12.4% of the total.

BEHAVIOUR OF HIV INFECTION IN COLOMBIA. TRANSFUSION-TRANSMISSIBLE INFECTIONS AND CURRENT LIMITATIONS

In this section, we review epidemiological studies conducted in Colombia on the incidence and prevalence of HIV, as well as the use and availability of antiretroviral therapy and post-exposure prophylaxis. The aim is to highlight the challenges the country faces in controlling the disease and the potential risks associated with relaxing restrictions in blood donor selection.

In 2002, the MHSP initiated studies to identify key populations in the country regarding HIV. In 2016, the MHSP published reports on the prevalence of HIV in MSM (26) and transgender individuals (31). The prevalence of HIV in the general population fluctuated between 0.2 to 0.6%, while in MSM it was between 5.6% and 24.1%. These studies revealed that Colombia was experiencing a concentrated HIV epidemic in MSM, psychoactive substance users, transgender women, sex workers, homeless individuals, transgender men and incarcerated individuals.

A 2019 study (32), which included a sample of 1301 individuals, aimed to assess the magnitude of the HIV epidemic and associated sexual behaviours among MSM aged 18 years and older in three Colombian cities (Bogotá, Medellín, and Cali), found that among participants queried about anal sex with a stable partner in the last 12 months, 92.8% acknowledged its occurrence. Regarding the frequency of anal sex (penetrative or receptive) in the last 30 days, 82.3% reported 1-5 instances, and 0.3% reporting none. Notably, 32.6% of participants consistently used condoms[1] during anal sex in the past 30 days, while 48.8% admitted to never using them. Conversely, when it came to anal sex with casual partners in the last 12 months, 91.8% of participants confirmed engagement. Importantly, 74.4% of participants disclosed using condoms during their last anal sex encounter with a casual partner. Of all participants, 3.3% reported taking pre-exposure prophylaxis (PrEP). The study determined a prevalence of HIV among MSM of 11.4% in Medellín, 23.4% in Cali, and 26.4% in Bogotá.

The 2023 report from the High-Cost Account in Colombia (35), highlighted that 62.12% of new HIV cases belonged to key population groups (i.e., people who inject drugs, transgender people, especially women, sex workers, MSM, people deprived of liberty, people living with HIV), with MSM accounting for 53.65% of these events.

It's essential to note that PrEP is a medication-based preventive strategy used to prevent HIV infection. When used correctly, PrEP is a highly effective method to significantly reduce the risk of HIV infection from sex. Additionally, studies have shown that individuals with an undetectable viral load cannot sexually transmit HIV. However, it is important to note that this does not apply to transfusion (36).

In 2015, the WHO recommended the use of tenofovir, in 2021, the dapivirine ring, and in 2022, long-acting injectable cabotegravir (37). In the Americas, 80% of PrEP users are in Brazil, where programs are free and easily accessible. In Chile, PrEP is distributed free to high-risk individuals under the National HIV/AIDS Plan. Peru confirmed the viability and safety of

[1] Condoms are 99% effective with perfect use but significantly less effective with typical use, with failure rates comparable to withdrawal. For instance, Smith et al. (33) reported that condom use reduces the risk of seroconversion by 63% to 72% in MSM, while Weller & Davis-Beaty (34) found a reduction of up to 80% in heterosexual couples.

tenofovir disoproxil fumarate alone, or in combination with emtricitabine in vulnerable populations through the iPrEx trial. In Mexico, despite a high intention to use PrEP, access is restricted due to cost. In Colombia, HIV prevention strategies focus on condom use and not sharing needles but do not fully reflect current advancements in combined prevention, including PrEP (29).

Colombia's "Clinical Practice Guidelines Based on Scientific Evidence for the Care of HIV/AIDS Infection in Adults, Pregnant Women, and Adolescents," effective since 2021 (38), recommend three PrEP options: a) Daily Tenofovir disoproxil fumarate/Emtricitabine or Tenofovir alafenamide/Emtricitabine for individuals over 12 at substantial risk of HIV; b) Dapivirine rings for women over 18 at substantial risk, subject to availability; c) Maraviroc for individuals over 18 at substantial risk when Tenofovir disoproxil fumarate/Emtricitabine or Tenofovir alafenamide/Emtricitabine are not viable, though not approved by INVIMA (National Regulatory Agency for Medicines) for prophylaxis. As of March 2025, only the first recommendation is available in the country. The use of lenacapavir is not yet available in the country.

In Colombia, only physicians can prescribe antiretroviral drugs, including PrEP (39) and one study showed that only 16.4% of physicians had any previous PrEP experience (40). Additionally, before enrolling in the PrEP program, an individualized assessment of the risk of HIV infection is required, considering social and access conditions (evaluated by a social worker) and the risk of conditions associated with or contraindicating antiretroviral prophylaxis. This assessment includes reviewing renal function, hematological profile, bone health, serologies for hepatitis, syphilis screening, and testing for HIV and other sexually transmitted infections (STIs).

Although PrEP reduces the risk of HIV transmission, a 2020 study involving 20 healthcare providers in Colombia identified several barriers to its effective implementation (41). Health Service Providers (the insurance companies of the health system) do not adequately transfer resources for PrEP implementation to Health Institutions. The lack of local studies on PrEP effectiveness in serodiscordant couples adds uncertainty. In rural areas, barriers include the cost and complexity of medications, limited availability of providers and service hours, and the absence of a national regulatory framework. PrEP is not included in the Mandatory Health Plan, complicating its administration and funding. Additionally, misinformation about approved medications, the stigma associated with HIV, and the lack of training for rural health professionals hinder PrEP acceptance and use. Adherence issues, negative perceptions about funding, and regional and economic inequalities are critical factors that need to be addressed.

According to AIDSinfo data, in 2021, 598 people received PrEP in Colombia, and in 2022 this number increased to 1,636, a rate of 3.2 per 100,000 inhabitants. This rate is low compared to other countries, in the same year: United States (114.7), Guatemala (89.7), Brazil (25.9), Canada (24.8), and Mexico (6.0) (42).

In 2022, a study on PrEP and its acceptance among transgender women found that 62.7% wanted to use it in the next 12 months, although only 26.6% had heard of PrEP. Participants reported difficulties attending medical check-ups and paying for PrEP and had concerns about changes in sexual behaviour and PrEP effectiveness (43). Another study identified seven main barriers to PrEP implementation from the perspectives of transgender women and gay/bisexual men: low awareness of PrEP, vulnerable social contexts, substance use affecting adherence, stigma, disapproval from partners, lack of training for health professionals, and discrimination in the healthcare system (44).

In Colombia, the HIV incidence rate has surged by 43% since the onset of the COVID-19 pandemic. In 2020, the rate stood at 23.5 cases per 100,000 inhabitants but by November 2023 it had escalated to 33.6 cases per 100,000 inhabitants (45). The cities registering the highest case numbers, along with their respective incidence rates, are as follows: Bogotá D.C., reporting 3,455 cases with an incidence rate of 8.4 per 100,000 women and 82.1 per 100,000 men; Medellín, documenting 1,385 cases with an incidence rate of 14.3 per 100,000 women and 97.2 per 100,000 men; Cali, recording 1,251 cases with an incidence rate of 18.2 per 100,000 women and 96.8 per 100,000 men (33). Despite findings by Scully (46), Bala et al. (47), and Saura et al. (48) establishing a higher risk of HIV infection in women compared to men, the latest HIV infection data reveal frequencies 9.8 (Bogotá D.C.), 6.8 (Medellín), and 5.3 (Cali) times higher in men than in women across the country's three major cities. The data suggest that men, specially MSM, may account for over 50% of new HIV cases in Colombia, which supports the possibility that this group continues to experience a disproportionately high risk of infection compared to other populations.

Despite the extensive measures implemented to enhance the safety of blood components for transfusion recipients, instances of HIV transmissions through transfusion have been identified (49,50,51). A notable case involves a repetitive voluntary donor whose actions in 2014 (17) resulted in the transmission of three HIV infections. Analysis of the accumulated data on transfusion-transmitted infections indicates that, during this period, one transfusion-transmitted infection occurred for every 160,755 transfused patients in Colombia (52). This figure represents a ninefold higher risk of transmission compared to rates reported in the United States and European countries (53).

It is worth noting that the national hemovigilance program in Colombia is still in the consolidation phase (49), and estimates indicate substantial underreporting of adverse reactions among donors and recipients, ranging from 60% to 95% (54). Additionally, there's a lack of post-transfusion monitoring for blood recipients to detect seroconversion caused by transfusion-transmissible agents. Moreover, blood banks currently cannot distinguish between blood components from the heterosexual

population and key populations like MSM or transgender women. Consequently, it's currently not possible to determine a distinct residual risk of transmitting viral agents to recipients based on these groups.

It is crucial to differentiate between the absence of evidence and a lack thereof. Studies conducted in the US (55) and France (56) have not identified an increased residual risk of HIV among heterosexual men and MSM, prompting a reconsideration of deferral policies for individuals from key populations. Notably, these countries conducted feasibility studies before modifying donation guidelines. However, in Colombia, these findings were applied without considering the differing epidemiological evidence across countries. One notable difference is the widespread implementation of NAT for all donations in the US and France. To the best of the authors' knowledge, there are no studies conducted in Colombia that quantify the residual risk of HIV or measure changes in reactivity and positivity rates of HIV tests conducted in blood banks between the heterosexual population and MSM or other key populations who self-identify as such during the donation selection process.

In Brazil, a multicentre study (57) found a strong association between a history of male-male sexual intercourse and having an HIV-positive sexual partner with being an HIV-positive blood donor. At the XII Colombian Congress of Blood Banks and Transfusion Medicine in October 2022, several blood banks presented evidence indicating an increase in transfusion-transmissible infections among blood donors, both before and after the 2021 changes to donor selection guidelines promoting non-discrimination towards the LGBTIQ+ population (58). Urbina et al. conducted a comparative analysis between the global residual risk per million donations from January 2011 to December 2015 and October 2021 to August 2022, revealing an increase from 5.11 to 12.43, representing a 2.4-fold rise after the Constitutional Court ruling (59).

As of the end of 2022, Colombia boasted a population of approximately 52 million people (60). The country maintained a network of 84 blood banks, comprising 29 public and 55 private establishments, which collected 963,423 blood donations in the course of the year (61). In 2022, after screening 56,769 donations, two donors were found to be in the window period (non-reactive serological tests but NAT-positive results), with one testing positive for HBV and the other for HCV. It was calculated that, maintaining that rate, screening one million donations would result in 53 window period cases. In 2023, after screening 77,173 donations, four donors were identified in the window period — exhibiting NAT-positive results despite negative serological tests — with two testing positive for HIV and two for HCV. It was estimated that, if 100% of the collected units had been screened with NAT, there would have been 52 similar cases per million donations, 50% of them for HIV (30). However, it remains unclear whether these infections indeed occurred or were false negatives.

The increase in transfusion-transmissible infections among donors, as observed after the 2021 changes to donor selection guidelines, raises important considerations. On one hand, the data suggest that Colombia's screening system is effective in identifying and removing potentially infectious donations when NAT is implemented. However, NAT is not mandatory, and only a few blood banks have voluntarily adopted it. This means that NAT-positive but CLIA/ELISA-negative cases can only be detected if NAT were applied universally across all blood banks. The rise in residual risk per million donations also highlights a critical question: does the potential increase in donors, following reduced deferral restrictions, justify the associated costs of additional screening and the potential risk of undetected infections? This trade-off underscores the need for a nuanced approach that balances inclusivity, blood safety, and financial sustainability, particularly given the existing gaps in confirming whether detected cases represent true infections or false negatives.

VULNERABILITY AND RIGHTS-BASED APPROACH

This section integrates a vulnerability and rights-based approach to underscore that eliminating sexual orientation-based exclusions in blood donation must be paired with rigorous safety measures to protect blood recipients, who are inherently vulnerable due to their lack of choice in transfusions. By drawing on feminist ethics and distinguishing between dispositional, situational, and pathogenic vulnerabilities, this text clarifies that addressing stigma and discrimination alone is insufficient when the healthcare system's safety protocols — such as universal NAT testing — remain inadequate. Consequently, the analysis strengthens the main argument by emphasizing that a balanced approach is necessary: safeguarding individual rights should not come at the expense of the principle of non-maleficence and the equitable protection of recipients.

Mackenzie, Rogers and Dodds (62) have proposed, from the perspective of feminist ethics, understanding the notion of vulnerability as one of the sources of moral obligations and duties of justice. In this regard, they propose a taxonomy of three sources of vulnerability (inherent/intrinsic, situational, and pathogenic) and two states of vulnerability (dispositional and occurrent). This taxonomy acknowledges the ontological vulnerability intrinsic to the human condition according to its life cycle (such as the need for food), while also allowing for the identification of context-specific (or situational) forms of vulnerability (social, economic, environmental, etc.). Pathogenic vulnerability arises when interventions aimed at mitigating vulnerability have the opposite effect, exacerbating the risk situation. This type of vulnerability can also manifest as paternalism or as violence and arbitrary discrimination. Dispositional vulnerability refers to a predisposition to be vulnerable under certain conditions (risk factors that need to be identified and intervened). Occurrent vulnerability refers to a form of vulnerability that is already present and requires immediate action, such as a person needing attention during an emergency. By distinguishing between these sources and states, we can identify responsibilities toward the "more than ordinarily vulnerable" and potential interventions to mitigate their effects. Intrinsic, situational, and pathogenic vulnerabilities are intertwined dimensions.

The concept of risk groups emerged during the North American epidemic in the 1980s, but has evolved to "key populations." The Joint United Nations Program on HIV/AIDS (UNAIDS) introduced this concept to identify groups that are highly vulnerable

to HIV and frequently experience inadequate access to services, compared to the general population (63). Although the specific key populations may vary depending on local epidemic dynamics, they generally encompass:

- People who inject drugs
- Transgender people, especially women
- Sex workers
- MSM
- People deprived of liberty
- People living with HIV

These groups encountered barriers in accessing promotion, prevention, and treatment services. Several factors contributed to their heightened vulnerability. These included the pervasive presence of stigma and discrimination, manifested through various means such as the criminalization of certain behaviours and practices, acts of violence (both from state and non-state actors), and the implementation of policies and restrictive laws. The purpose of labelling these groups as key populations was to concentrate efforts on preventing, controlling, and treating HIV infections (64). According to the UNAIDS report (2021) (63) the frequency of HIV infection was estimated to be 35 times higher among people who inject drugs compared to the general population. Among transgender individuals, particularly women, the infection rate was 34 times higher. Female sex workers were found to be 26 times more likely to contract HIV, while MSM faced a 25 times higher risk compared to the general population.

Within the spectrum of HIV transmission, different activities exhibit varying levels of risk, related to intrinsic and situational vulnerability. HIV can be transmitted through specific body fluids: semen, blood, human milk, pre-seminal fluid, and vaginal or rectal fluids. The primary routes of HIV transmission include anal or vaginal sex, sharing needles, syringes, or other drug injection equipment, and mother-to-child transmission. Epidemiological studies have shown that over 90% of new HIV cases are acquired through sexual acts. For instance, orogenital interactions without ejaculation carry a risk ranging from 0.01% to 0.05%. This risk increases to 0.05% to 1% for activities such as vaginal intercourse (with or without ejaculation), orogenital intercourse with ejaculation, and anal intercourse without ejaculation. The highest level of risk, approximately 1% to 3%, is associated with anal receptive intercourse with ejaculation (65), particularly in unprotected anal intercourse practices (66). This heightened risk is attributed to factors such as the greater density of lymphoid follicles in the rectal mucosa, the presence of intraepithelial pockets facilitating virus replication, and the increased susceptibility of rectal epithelial cells to abrasions. Of course, risk accumulation occurs with multiple partners, particularly in the absence of regular testing. Although the practice of anal sex is not exclusive to MSM, as it is also practiced among heterosexual couples, its prevalence is higher in the former group.

From a vulnerability approach, it is crucial to optimize the MSM risk management processes in the selection of blood component donors, considering the different dimensions of vulnerability mentioned. The Constitutional Court of Colombia, by eliminating references to sexual orientation and gender identity as risk factors, sought to eliminate the discrimination that perpetuates the stigmatization of certain groups. However, this action does not fully address the complexities of vulnerability. Dispositional vulnerability, which refers to the predisposition of certain individuals or groups to be more susceptible to specific risks, is evident in recipients of blood components, who critically depend on the safety of transfusions. We suggest that, from a rights-based perspective, it is important to move beyond selection criteria that reinforce the stigma against individuals and groups with greater vulnerability to HIV and other STIs. We propose addressing dispositional vulnerability as a characterization that helps identify opportunities for intervention to mitigate and prevent the materialization of risk, rather than as a category that fosters stigma and unjustified discrimination. We advocate for an active policy based on affirmative actions, rather than a punitive and discriminatory approach.

Additionally, situational vulnerability, which is contextually specific, affects both donors and recipients. MSM and other risk groups face both situational and pathogenic vulnerability due to stigma and discrimination that may lead them to conceal risky behaviours during the donor selection process. At the same time, blood recipients are in a vulnerable situation due to deficiencies in the Colombian healthcare system, such as the limited availability of NAT, pathogen inactivation processes for all collected blood units, and PrEP. This situation increases the risk of infection transmission through transfusions, which is particularly dangerous for those in critical condition or with compromised immune systems.

Understanding the dynamics of HIV infection acquisition necessitates an exploration of the interconnected social determinants that contribute to vulnerability. For instance, inequity (46) and gender-based violence disproportionately affect women, particularly in contexts where asserting condom use is challenging within patriarchal cultural norms (47). Additionally, forced displacement (67), socioeconomic inequality (68), educational gaps in understanding risk factors and practices (69), racial and gender discrimination (70), insufficient public policies addressing substance use disorders with a collective health and harm reduction approach (71), poverty (72) alongside the criminalization of individuals and communities with diverse gender identities, collectively amplify situational and pathogenic vulnerability to HIV infection (73).

The Constitution of Colombia guarantees that all individuals are born free and equal before the law, receiving equal protection and treatment from authorities, and enjoying the same rights, freedoms, and opportunities without discrimination based on sex, race/ethnicity, national or familial origin, language, religion, or political or philosophical opinion. However, it does not establish a right to donate blood. The Constitutional Court Judgment T-171 of 2022 describes the practice of donation as an intention of solidarity or an act of empathy (74). Decree 1571 of 1993 characterizes it as a duty of social solidarity (75). Thus,

under Colombia's legal framework, donating blood cannot be regarded as a legal or moral right. Instead, what must be ensured during the blood donation process is that potential donors are treated without discrimination based on their sexual orientation. This conclusion aligns with Franklin's perspective (76), as he has analyzed the interaction between rights, responsibilities, and expectations of the actors involved in blood component donation and transfusion. His analysis concludes that, although there is no explicit right to donate, rights, duties, and responsibilities are recognized for both donors and other participants in the process, with a special emphasis on the rights of patients receiving transfusions.

In other contexts, such as South Africa, where the pattern of HIV transmission differs from that of Colombia, the right of MSM to donate blood was established several years ago. However, some authors express their disagreement and advocate for prioritizing the rights of recipients (77). Another study highlights that, for many MSM, blood donation represents an act of citizenship that reflects values such as altruism and solidarity. For this reason, they advocate for a risk-based individualization approach rather than deferral based on sexual orientation. Nevertheless, there is no consensus within these communities regarding the "right to donate" (78).

At this point, it is important to draw a distinction. One meaning of the term "discrimination" refers to the ability to distinguish or discern, that is, the capacity to differentiate between various elements. In this sense, a discriminatory practice (understood as an exclusionary selection) can be either arbitrary or reasonable, depending on the strength of the justifications that support it in each case (79). A selection practice that discriminates between certain groups or practices is considered reasonable when it is based on fair, objective, proportional, and transparent criteria, while respecting fundamental rights (for example, in the case of blood donation, a person carrying a bloodborne condition). Conversely, selection based on criteria such as race/ethnicity, social status, age as an isolated factor, disability, sexual orientation, or gender identity may be arbitrary, according to the specific context. In the case of blood component donor selection, the Constitutional Court ruled that discrimination based on sexual orientation and gender identity constituted an unjustified practice.

In 1991, the Constitution of Colombia was updated to declare and protect the fundamental rights of the population (80). The request by the Constitutional Court to remove any mention of sexual orientation as a criterion for blood donation exclusion aimed to guarantee rights in the realm of private moral values, such as:

a) Self-determination: According to Article 18, freedom of conscience is guaranteed, where no one shall be harassed for their convictions or beliefs, nor compelled to reveal them or act against their conscience.

b) Freedom of expression: Article 20 ensures that everyone has the freedom to express and disseminate their thoughts and opinions, and to receive truthful and impartial information.

Article 16 of the current Constitution states that all individuals have the right to free development of their personality, with no limitations other than those imposed by the rights of others and the legal order. However, this protection of individual rights conflicts with essential public values due to several deficiencies in the Colombian healthcare system:

a) Non-maleficence: Article 11 declares that the right to life is inviolable. In Colombia, as described before, NAT for collected blood has not been fully implemented, pathogen inactivation techniques are not used, and there is a growing HIV epidemic concentrated in specific populations such as MSM. The lack of complete coverage of antiretroviral therapy for diagnosed HIV patients and the unavailability of free PrEP increase the risk of HIV transmission through blood transfusions.

b) Equality: According to Article 13, all people are born free and equal before the law and must receive the same protection and treatment from authorities. However, a patient undergoing a transfusion, especially in conditions of vital urgency, loss of consciousness, intellectual disability, or under 18 years of age, cannot choose whether to accept the transfusion. Allowing blood donation from a group with a high prevalence and incidence of HIV without adequate measures to reduce the transmission risk violates the principle of equality, endangering the lives of vulnerable recipients, such as pediatric patients, who may receive infected blood due to the HIV window period.

c) Vulnerability: The state has an obligation to provide special protection to people in circumstances of manifest weakness, according to Article 13. Not taking measures to reduce the risk of HIV transmission through transfusions exposes the most vulnerable to fatal consequences, contravening this constitutional mandate.

Therefore, while eliminating sexual orientation-based exclusion for blood donation aims to protect individual rights, this measure must be accompanied by significant improvements in blood donation safety practices. Implementing universal NAT and ensuring access to antiretroviral therapies and PrEP are essential steps to balance individual rights with public health protection and equity. Only then can we ensure the rights of all actors involved in the donation process and the safety of blood recipients, without compromising the integrity and lives of the most vulnerable members of our society.

CONCLUSIONS

While it is crucial to address practices that perpetuate stigma and discrimination against individuals based on their sexual orientation or gender identity, it is equally important to safeguard the safety of blood component recipients and uphold the

principle of non-maleficence. Unlike donors, recipients do not always have a choice in whether they receive a transfusion; they rely entirely on clinical criteria and technical guidelines to ensure that both donation and transfusion processes are safe.

The risk of HIV and other STIs is driven not by an individual's sexual orientation or gender identity but by specific high-risk behaviours. In light of this, we support the Constitutional Court's decision to review and modify donor selection criteria to eliminate discrimination against historically marginalized groups. However, given the unique epidemiological characteristics of the HIV epidemic in Colombia and the challenges inherent in ensuring the safety of the blood supply, the absence of studies validating these modified criteria raises significant concerns. These concerns are twofold: there is the potential for an increased risk of transfusion-transmitted infections, and there is the economic cost associated with implementing comprehensive safety measures — such as universal NAT testing — to mitigate such risks.

A clear cost-benefit trade-off emerges in this context. On one hand, broadening the donor pool by eliminating discriminatory deferral criteria may result in an increased supply of blood components. On the other hand, if these changes are not accompanied by robust safety practices — most notably, the universalization of NAT testing — the risk of undetected window period infections may rise, potentially compromising recipient safety. Economic considerations, including the cost of additional NAT testing, must be carefully balanced against the imperative to protect patients from transfusion-transmitted infections.

Pathogenic vulnerability arises when measures intended to reduce risk inadvertently exacerbate it. Therefore, while eliminating criteria based on sexual orientation is an essential step toward achieving equality and equity, it must be coupled with the universal implementation of rigorous safety measures and a continuous reassessment of associated risks. Only by integrating these strategies can we ensure that efforts to increase the blood supply do not inadvertently compromise its safety, thereby upholding the principles of non-maleficence, justice, and equitable care for both donors and recipients.

In conclusion, before implementing nationwide changes in blood donation policies, it is imperative to consider the complexity of the risks involved. We disagree with the Constitutional Court's decision which, in the absence of studies demonstrating a differential risk in the detection of infections between MSM and heterosexual individuals, assumes that both groups present the same risk. Although we agree that sexual orientation and gender identity alone do not determine the likelihood of acquiring infections potentially transmissible by transfusion, lifting the donor restriction without robust comparative studies is premature. Colombian epidemiological evidence — which shows that six out of ten new HIV cases occur among MSM and that the prevalence of HIV in men is 4.3 times higher than in women — indicates that specific sexual behaviours, such as anal intercourse, present a higher probability of transmitting infections like HIV compared to other practices, such as vaginal intercourse. Therefore, it is crucial to conduct studies that quantify and compare these risks to ensure that any modifications in donor criteria are accompanied by adequate safety measures, thereby safeguarding both the health of recipients and the integrity of the blood supply. In the absence of such studies, the widespread incorporation of NAT testing in all blood banks should be mandated to reduce the immunological window periods and mitigate the potential increased risk of transmission of infectious diseases that could result from removing one of the donor selection filters.

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REFERENCES

1. García Otálora MA, Herrera Hernández A, Bermúdez Forero MI. Lineamiento técnico para la selección de donantes de sangre en Colombia. Instituto Nacional de Salud. 2022.
2. Ministerio de Salud y Protección Social. Plan Nacional de Respuesta, ante las ITS, el VIH, la coinfección TB/VIH y las hepatitis B y C, Colombia, 2018-2021. 2018.
3. Herring C. National and worldwide blood shortage, we need blood! But we don't want YOUR blood! The Early Career Voice. 19 Jul 2021.
4. Ministerio de Salud Pública, Ministerio de Salud. Resolución 901 de 1996: Por la cual se adopta el Manual de Normas Técnicas, Administrativas y de Procedimiento para bancos de sangre. Diario Oficial No 4283; 1996.
5. Corte Constitucional. Sentencia T-248-12. M.P. Jorge Ignacio Pretelt Chaljub. Expediente T-3277032; 2012.
6. Osorio A, Melo A, Herrera-Hernández A, et al. Guía para la selección de donantes de Sangre en Colombia. Instructivo para el diligenciamiento de la encuesta. Instituto Nacional de Salud. Ministerio de Salud; 2012.
7. WHO. Blood donor selection: guidelines on assessing donor suitability for blood donation. Geneva: World Health Organization. 2012.
8. US Department of Health and Human Services. Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. Aug 2020.
9. Ministerio de Salud y Protección Social. Resolución 3212 de 2018: Por medio de la cual se modifican unos numerales del Manual de Normas Técnicas, Administrativas y de Procedimientos para Bancos de Sangre, adoptado mediante Resolución 901 de 1996 y se dictan otras disposiciones. 2018.
10. Instituto Nacional de Salud, Ministerio de Salud. Lineamiento técnico para la selección de donantes de sangre en Colombia. 2018.
11. FDA News Release. FDA Commissioner Margaret A. Hamburg's statement on FDA's blood donor deferral policy for men who have sex with men. HIV.gov. 23 Dec 2014.
12. Arora KS. Righting anachronistic exclusions: the ethics of blood donation by MSM. Journal of Gay & Lesbian Social Services. 2017;29(1):87-90.
13. Vesnaver E, Butler-Foster T, Goldman M, et al. Improved access yet inequitable experience: gay, bisexual and other men who have sex with men's views of more inclusive criteria for source plasma donation. BMC Public Health. 2023; 23:768.
14. Ministerio de Salud y Protección Social. Resolución 1676 de 2023 Ministerio de Salud y Protección Social. Diario Oficial No 52547; 2023.
15. Corte Constitucional. Sentencia C-248/19: M.P. Cristina Pardo SchlesInger. 2019.
16. FAIR Group. Can donor selection policy move from a population-based donor selection? Conclusions from the For the Assessment of Individualised Risk (FAIR) group. Dec 2020.
17. Bermúdez-Forero MI, Anzola-Samudio DA, Levi JE, García-Otálora MA. Prevention of multiple whole blood donations by an individual at the same month through the creation of a national Deferred Donor Registry (DDR). Transfusion and Apheresis Science. 2023;62(5):103767.
18. Bermúdez-Forero M, Delgado-López D, Anzola-Samudio D, Palomino F, García-Otalora M. Role of disruptions in O RhD negative donations in Colombia on increasing maternal mortality ratio from haemorrhage. Transfusion Medicine. 2024;34(2):142-53.
19. Aldana-Oyuela E, Herrera Hernández A. Programa de Evaluación Externa de Desempeño Directa En Inmunoserología Para Bancos de Sangre Peedd-Is. 2023.
20. Roth WK, Busch MP, Schuller A, et al. International survey on NAT testing of blood donations: expanding implementation and yield from 1999 to 2009. Vox Sanguinis. 2012;102(1):82-90.
21. León-Guzmán E. Revisión Sistemática de la literatura Sobre la efectividad de Las pruebas de Ácido Nucleico (NAT) para la detección de los virus de Hepatitis B, Hepatitis C y virus de inmunodeficiencia humana (VIH) en donaciones de sangre. Ministerio de Salud y Protección Social. Apr 2016.
22. Centers for Disease Control and Prevention. Understanding the HIV window period. 2024.
23. Gehrie EA. Transfusion-transmitted viral infections (TTVIs). In: Simon TL, Gehrie EA, McCullough J, Roback JD, Snyder EL, editors. Rossi's Principles of Transfusion Medicine. 6th edition. Hoboken, NJ: Wiley; 2022. p. 507-22.
24. Roth WK. History and future of nucleic acid amplification technology blood donor testing. Transfusion Medicine and Hemotherapy. 2019;46(2):67-75.
25. Agência Nacional de Vigilância Sanitária (ANVISA). Manual para o Sistema Nacional de Hemovigilância no Brasil. 2022.
26. Ministerio de Salud y Protección Social (MSPS) Colombia. Informe de Resultados Comportamiento Sexual y Prevalencia de VIH en Hombres Que Tienen Relaciones Sexuales Con Hombres En Siete Ciudades de Colombia (Bogotá, Medellín, Cali, Barranquilla, Cúcuta, Pereira y Cartagena). Mecanismo de Coordinación de País. 2016.
27. Vera Cala, LM, Cortés Aguilar A, Estrada Cañas I. Costo-utilidad de la adición de pruebas de Amplificación de Ácidos Nucleicos (NAT) para la detección de VHB, VHC y VIH al tamizaje convencional de las donaciones de sangre en Colombia. Instituto de Evaluación Tecnológica en Salud. Mar 2018.
28. Sturrock BR, Mucklow S. What is the evidence for the change in the blood -donation deferral period for high-risk groups and does it go far enough? Clinical Medicine. 2018;18(4):304-7.
29. Grupo de Estudio PrEP-Col. Implementación de la Profilaxis pre-exposición al VIH en Colombia. 14 Jan 2021.
30. Bermúdez-Forero M. Informe Nacional Bancos de Sangre 2023. Instituto Nacional de Salud. 11 de junio de 2024.

31. Ministerio de Salud y Protección Social (MSPS) Colombia. Resultados Del Estudio de Vulnerabilidad al VIH y Prevalencia de VIH En Mujeres Trans En Colombia. 2016.
32. Berbersi Fernández DY, et al. Comportamiento sexual y prevalencia de VIH en hombres que tienen relaciones sexuales con hombres en tres ciudades de Colombia: Bogotá, Medellín y Santiago de Cali, 2019. Bogotá, Colombia: ENTerritorio. Dec 2019.
33. Smith DK, Herbst JH, Zhang X, Rose CE. Condom effectiveness for HIV prevention by consistency of use among men who have sex with men in the United States. Journal of Acquired Immune Deficiency Syndromes, 2015;68(3):337-44.
34. Weller SC, Davis-Beaty K. Condom effectiveness in reducing heterosexual HIV transmission. Cochrane Database of Systematic Reviews. 2002;1:CD003255
35. Fondo Colombiano de Enfermedades de Alto Costo, Cuenta de Alto Costo (CAC). Situación del VIH/SIDA en Colombia 2023. Bogotá, D. C.: Fondo Colombiano de Enfermedades de Alto Costo; Jul 2024.
36. Gosbell IB, Hoad VC, Styles CE, Lee J, Seed CR. Undetectable does not equal untransmittable for HIV and blood transfusion. Vox sanguinis. 2019;114(6):628-30.
37. World Health Organization. Make PrEP simple, make PrEP differentiated! New WHO guidance, IAS policy brief and case studies from across the globe. WHO. 25 Aug 2022.
38. Ministerio de Salud y Protección Social, Empresa Nacional Promotora del Desarrollo Territorial ENTerritorio, Instituto de Evaluación Tecnológica en Salud. Guía de Práctica Clínica (GPC) basada en la evidencia científica para la atención de la infección por VIH/SIDA en personas adultas, gestantes y adolescentes. Guía para profesionales de la salud. Guía N° 39-2021. Bogotá. 2021.
39. Martínez-Cajas JL, Torres J, Mueses HF, et al. Applying implementation science frameworks to identify factors that influence the intention of healthcare providers to offer PrEP care and advocate for PrEP in HIV clinics in Colombia: a cross-sectional study. Implementation Science Communications. 2022;3(1):31.
40. Martínez-Cajas J, Alvarado-Llano B, Martínez-Buitrago E, et al. HIV care providers' familiarity, concerns, and attitudes about HIV PrEP in Colombia: insights from the PrEP-Col-Study. AIDS Care. 2022;34(11):1428-34.
41. Desarrollo de estrategias de implementación profilaxis preexposición a VIH en clínicas del VIH en colombia: protocolo de un estudio de implementación de método mixto. Corporación de Lucha contra el Sida. 2020.
42. The Joint United Nations Programme on HIV/AIDS. Combination prevention. People receiving pre-exposure prophylaxis (PrEP). AIDSinfo. 2022.
43. Mueses-Marín HF, Galindo-Orrego X, Alvarado-Llano BE, et al. Implementación de la Profilaxis pre-exposición al VIH en Colombia. Interdisciplinary Journal of Epidemiology and Public Health. 2021;4(2):e-8621.
44. Bolívar-Rocha M, Alvarado-Llano B, Martínez-Cajas J, Camargo-Plazas P, Gómez SB. Barreras para la implementación de PrEP desde las perspectivas de mujeres transgénero y gay/bisexuales - Estudio PrEP-COL. XIII Encuentro Nacional de Investigación en Enfermedades Infecciosas, Cali, Colombia, 18-20 Aug 2022.
45. Instituto Nacional de Salud. Dirección de Vigilancia y Análisis del Riesgo en Salud Pública. Boletín Epidemiológico Semanal. 2023;29.
46. Scully EP. Sex differences in HIV infection. Current HIV/AIDS Reports. 2018;15(2):136-46.
47. Bala AN, Azman A, Singh PSJ. The impact of gender discrimination and HIV stigma on women living in North Central Nigeria. Cogent Social Sciences. 2022;8(1):2027612.
48. Saura S, Jorquera V, Mascort C, Castellà I. Percepción del riesgo de infecciones de transmisión sexual/VIH en jóvenes desde una perspectiva de género. Atención Primaria. 2020;52(3):218-9.
49. Bermúdez-Forero, MI, García Otalora MA. Informe Nacional de Hemovigilancia 2016. Red Nacional de Bancos de Sangre y Servicios de Transfusión; 2018
50. Bermúdez Forero MI, García Otálora MA. Caso 1-2019: Notificación de una Infección Trasmitida por Transfusión (ITT)–Virus de Inmunodeficiencia Humana (VIH) identificada por genotipificación. Boletín Seguridad Transfusional, 2019: 1-11
51. Bermúdez Forero MI, García Otálora MA. Notificación de tres casos de Infección Trasmitida por Transfusión (ITT) – Virus de Inmunodeficiencia Humana (VIH) . Informe Nacional. 2019.
52. Instituto Nacional de Salud (INS). Reunión Nacional de la Red de Sangre. 2021.
53. Stramer SL, Galel SA. Infectious disease screening. In: Fung MK, Eder AF, Spitalnik SL, Westhoff CM, editors. Technical Manual. 19th Ed. American Association of Blood Banks; 2017. p. 161-206.
54. Bermúdez Forero MI, García Otálora MA. Informe de reacciones adversas a la donación (RAD) notificadas a SIHEVIINS© durante 2018. Bogotá: Instituto Nacional de Salud. Sept 2020.
55. Steele WR, Dodd RY, Notari EP, et al. HIV, HCV, and HBV incidence and residual risk in US blood donors before and after implementation of the 12-month deferral policy for men who have sex with men. Transfusion. 2021;61(3):839-50.
56. Pillonel J, Pelat C, Tiberghien P, et al. The evolving blood donor deferral policy for men who have sex with men: impact on the risk of HIV transmission by transfusion in France. Transfusion. 2020;60(3):525-34.
57. De Almeida-Neto C, Goncalez TT, Birch RJ, et al. Risk factors for human immunodeficiency virus infection among Brazilian blood donors: a multicentre case–control study using audio computer-assisted structured interviews. Vox Sanguinis. 2013;105(2):91-9.
58. Bermúdez Forero MI. Conductas de riesgo donantes. Instituto Nacional de Salud. 15 Oct 2022.
59. Urbina A. Conductas de riesgo y seguridad transfusional. In: Proceedings of the 12° Congreso Colombiano Acobasmet de Bancos de Sangre y Medicina Transfusional. Congreso Iberoamericano GCIAMT. Medellín, Colombia. 13-16 Oct 2022.

60. Departamento Administrativo Nacional de Estadística. Proyecciones de Población 2018-2070. DANE. 2021.
61. Instituto Nacional de Salud. Directorio Bancos de Sangre. 2025.
62. Mackenzie C, Rogers W, Dodds S, editors. Vulnerability: New Essays in Ethics and Feminist Philosophy. Oxford: Oxford University Press. 2013.
63. Programa Conjunto de las Naciones Unidas sobre el VIH/sida [ONUSIDA]. Confronting Inequalities. Lessons for Pandemic Responses from 40 Years of AIDS. 14 Jul 2021.
64. Programa Conjunto de las Naciones Unidas sobre el VIH/sida [ONUSIDA]. Orientaciones Terminológicas de ONUSIDA. 21 Sept 2015.
65. Andrade Forero L. Protocolo para la atención por exposición de riesgo biológico laboral o no laboral, ante las infecciones de transmisión sexual, el virus de inmunodeficiencia humana, el virus de la hepatitis b y el virus de la hepatitis c. Ministerio de Salud y Protección Social. 2017.
66. Díaz YMS, Orlando-Narváez SA, Ballester-Arnal R. Conductas de riesgo hacia la infección por VIH. Una revisión de tendencias emergentes. Ciênc saúde coletiva. 2019;24(4):1417-26.
67. Canadian UNICEF Committee. HIV/AIDS, Conflict and Displacement. Conference Report on the XVI International AIDS Conference Affiliated Event HIV/AIDS, Conflict and Displacement. Toronto, Canada. 12 Aug 2006.
68. Fox AM. The HIV–poverty thesis re-examined: poverty, wealth or inequality as a social determinant of hiv infection in sub-saharan africa? Journal of Biosocial Science. 2012;44(4):459-80.
69. Zhang H, Stanton B, Li X, et al. Perceptions and attitudes regarding sex and condom use among Chinese college students: a qualitative study. AIDS and Behavior. 2004;8(2):105-17.
70. Ramos SR, Lardier DT, Opara I, et al. Intersectional effects of sexual orientation concealment, internalized homophobia, and gender expression on sexual identity and HIV risk among sexual minority men of color: a path analysis. Journal of the Association of Nurses in AIDS Care. 2021;32(4):495-511.
71. Wodak A, McLeod L. The role of harm reduction in controlling HIV among injecting drug users. AIDS. 2008;22(Suppl 2): S81-92.
72. Mufune P. Poverty and HIV/AIDS in Africa: Specifying the connections. Social Theory & Health. 2015;13(1):1-29.
73. Magno L, Silva LAVD, Veras MA, Pereira-Santos M, Dourado I. Estigma e discriminação relacionados à identidade de gênero e à vulnerabilidade ao HIV/aids entre mulheres transgênero: revisão sistemática. Cadernos de Saúde Pública. 2019;35(4):e00112718.
74. Corte Constitucional de Colombia. Sentencia T-171/22. M.P. Gloria Stella Ortiz Delgado. 2022.
75. Presidente de la República de Colombia. Decreto 1571 DE 1993: Diario Oficial No 40989. 1993.
76. Franklin IM. Is there a right to donate blood? Patient rights; donor responsibilities. Transfusion Medicine. 2007;17(3):161-8.
77. Brooks JP. The rights of blood recipients should supersede any asserted rights of blood donors. Vox Sanguinis. 2004;87(4):280-6.
78. Grace D, Gaspar M, Klassen B, et al. *It's in me to give* : Canadian gay, bisexual, and queer men's willingness to donate blood if eligible despite feelings of policy discrimination. Qualitative Health Research. 2020;30(14):2234-47.
79. Pinto Bustamante BJ. ¿Triaje ético?. Colegio Médico Colombiano. Epicrisis; No. 30. 10 Dec 2023.
80. Constitución Política de Colombia. 2nd ed. Legis. 1991.

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Navigating Clinician-Researchers' Duties in Decentralized Clinical Trials

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Résumé
Les essais cliniques décentralisés (ECD) sont des essais cliniques dans lesquels certaines ou toutes les procédures liées à l'essai se déroulent en dehors des sites d'essais cliniques traditionnels. Les technologies numériques ont joué un rôle important dans la mise en place d'essais cliniques à distance et il est prévu que de nombreux essais cliniques adoptent des modèles décentralisés complets ou hybrides. Si les ECD présentent de nombreux avantages et opportunités pour rationaliser et améliorer la conduite des essais cliniques, leur mise en œuvre pose également plusieurs défis. Il s'agit notamment des risques liés à la vie privée et à la confidentialité, des défis liés à la supervision et au suivi des essais, ainsi que de la culture numérique et de la conformité des participants. Pour relever ces défis, il est essentiel de clarifier les obligations éthiques et juridiques des cliniciens-chercheurs, qui sont responsables de la conduite globale des essais cliniques. Cet article analyse ces obligations et identifie les facteurs clés qui devront être pris en compte pour faciliter l'adoption des ECD tout en garantissant la protection de la santé, de la sécurité et du bien-être des participants.

Mots-clés
devoirs des cliniciens, essais cliniques décentralisés, consentement éclairé, confidentialité et respect de la vie privée, surveillance à distance

Abstract
Decentralized clinical trials (DCTs) are clinical trials in which some or all trial-related procedures take place outside traditional clinical trial sites. Digital technologies have played an important role in enabling the remote conduct of clinical trials, and it is anticipated that many clinical trials will adopt full or hybrid decentralized models. While DCTs present many benefits and opportunities to streamline and improve the conduct of clinical trials, there are also several challenges in their implementation. These include privacy and confidentiality risks, challenges in trial oversight and monitoring, digital literacy, and participant compliance. To address these challenges, it is essential to clarify the ethico-legal duties of clinician-researchers, who are responsible for the overall conduct of clinical trials. This article analyzes these duties and identifies key factors needed to support the adoption of DCTs while safeguarding participants' health, safety, and well-being.

Keywords
clinician duties, decentralized clinical trials, informed consent, privacy and confidentiality, remote monitoring

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INTRODUCTION

Since the COVID-19 pandemic, the integration of technology into healthcare has increased dramatically. Faced with a rapidly spreading virus and the need for physical distancing, healthcare institutions across the globe adopted technologies to adapt to the key challenge of the pandemic to continue patient care while adhering to public health guidelines. For instance, telehealth involving the remote provision of healthcare services has experienced an unprecedented surge in use (1,2). Patients and healthcare providers alike adopted video consultations, online symptom checkers, and remote monitoring devices to ensure continuity of care when minimizing in-person contact. Furthermore, digital tools played a crucial role in contact tracing efforts, enabling the identification and tracking of potential COVID-19 exposures (3).

In addition to the clinical setting, technological innovations have been increasingly employed in research settings (4). The pandemic presented many challenges to clinical research, such as reduction of face-to-face study visits and delays in data collection and reporting (5). These constraints resulted in many research institutions suspending nearly all in-person interactions (6). Clinical trials were greatly affected by the pandemic, with sharp declines in participant enrollment and significant difficulties in conducting study procedures (7,8). Many sponsors, institutions, and contract research organizations (CROs) either delayed clinical trial initiation, suspended enrollment, or terminated their clinical trials altogether (9). Clinical trials are a fundamental tool in evaluating the safety and efficacy of new drugs, medical devices, and health system interventions in human participants (6). Given the need to continue clinical trials during the pandemic, a paradigm shift was required in their design and execution.

Digital technologies have featured prominently in this shift. Research teams and institutions began to conduct clinical trials remotely, in part or in full, using digital health technologies (DHTs) and other tools to facilitate research without physical contact between participants and the research team. Generally referred to as decentralized clinical trials (DCTs), these trials use digital tools and remote monitoring to allow participants to engage in trial activities from their homes, reducing the need for in-person

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visits. Activities that can be done remotely in DCTs include informed consent procedures, participant monitoring, home study visits, and sending investigational products, such as medications and wearable health devices, to participants' homes (10).

DCTs are not a recent phenomenon. The use of decentralization in clinical trials dates back to the 1980s, when mail-based methods began to be used for randomized clinical trials (11). In 2011, Pfizer conducted the first fully decentralized clinical trial, the REMOTE trial (12). REMOTE was a randomized, placebo-controlled, Phase 4 clinical trial that assessed the safety and efficacy of Detrol LA, a treatment for overactive bladder (12). The study included adult women in the United States who had experienced symptoms of overactive bladder for at least 3 months and had regular Internet access (12). It employed web-based digital technologies throughout the study cycle, from recruitment and informed consent to data collection (12). Additionally, study drugs were delivered to participants' homes via courier (12). While the study was terminated early due to inadequate enrolment — only 18 participants were recruited — REMOTE demonstrated the potential for DCTs to be successfully conducted within the framework of regulatory oversight and ethics approval. Furthermore, the lessons learned from REMOTE offered critical insights to help inform the design and development of future DCTs (12).

Despite growing interest in DCTs following REMOTE (13), uptake of decentralization was slow, mainly due to administrative, regulatory, and bureaucratic barriers compounded by high operational costs for both sponsor and site alike (7). Absent regulatory guidance on conducting DCTs also led to resistance in adoption (14). Regulatory bodies responsible for the oversight of clinical trials issued guidelines on the remote conduct of clinical trials to encourage continued trial conduct for those sites able to operationalize labour and resource redistribution outside brick-and-mortar settings (15-17).

Post-pandemic, researchers, institutions, sponsors, governmental institutions, and non-governmental organizations (NGOs) have retained interest in decentralization as a long-term possibility for clinical trials (6,18). In 2020, the Decentralized Trials and Research Alliance (DTRA), a non-governmental, not-for-profit organization in the US, was founded to expand awareness and advocacy surrounding the use of decentralized technologies in clinical trials and research (19). The Multi-Regional Clinical Trials (MRCT) Center, a policy and research centre associated with Brigham and Women's Hospital and Harvard University dedicated to promoting safe and ethical clinical trials, also works to address issues in the oversight and conduct of DCTs (20). In 2021, the Ministry of Economy, Innovation and Energy in Quebec, Canada, funded a large-scale, multi-institutional initiative to develop a digital platform for conducting fully remote clinical trials without the need for any in-person visits (21).

Although the use of DCTs is growing, they raise several challenges that require attention. For one, they raise important ethical issues, such as informed consent, participant safety, and privacy and confidentiality (10). There are also regulatory factors, such as compliance with privacy legislation and clinical trials regulations, that must be considered in DCTs (10,22). A growing body of literature has addressed the ethical and regulatory considerations raised by DCTs (10). However, there is one issue regarding DCTs that has yet to be fully explored: the nature and scope of clinician-researchers' duties.

Clinician-researchers are responsible for the overall conduct of a clinical trial (23). It is therefore important to clarify how their duties are engaged when the clinical trial is decentralized. Several of the challenges presented in DCTs may necessitate changes to the traditional way that trials are conducted in order for clinician-researchers to fulfill their duties. For instance, while all research requires the implementation of measures to protect participants' privacy and confidentiality, the use of digital devices in DCTs, such as wearables or mobile applications, may require additional safeguards or protections (24).

Insufficient understanding of the scope and content of clinician-researchers' duties in DCTs may prevent DCTs from realizing their full potential. Maintaining high standards of care, improving trial efficiency, and protecting patient safety all depend on clinician-researchers' understanding of the nature and extent of their responsibilities. Better-defined roles can help facilitate efficient use of DCT technologies while still ensuring regulatory compliance and ethical integrity. This article aims to address the existing gap in the literature by analyzing the scope of clinician-researcher duties within the DCT setting.

It is important to note here there is variation in the degree to which different components of a clinical trial are decentralized. Some DCTs may adopt a fully decentralized model, whereas others may employ a hybrid approach, with both decentralized and in-person elements. Different forms of decentralization can include electronic consent, remote recruitment through social media, virtual visits with members of the research team, and the use of digital devices for data collection (20). The use of digital devices, however, is not unique to DCTs; indeed, many in-person clinical trials are using digital devices as part of their protocols. Nevertheless, given their important role in enabling decentralization, our focus in this article will be on the use of digital devices in DCTs, particularly for informed consent and data collection and storage purposes.

In Section I, we outline some of the potential benefits and opportunities of DCTs, as described in the literature. In Section II, we discuss the key challenges raised by the use of DCTs, specifically privacy and confidentiality, safety monitoring, digital literacy, and participant compliance. While many of these challenges are already present in traditional in-person trials, decentralization can change the scope and nature of these challenges.

In Section III, we turn to the ethical and legal duties of clinician-researchers in the conduct of clinical trials. We consider the ethical duties of clinician-researchers as outlined in both Canadian and international research ethics guidelines, including the Declaration of Helsinki, Canada's Tri-Council Policy Statement (TCPS2), and the Guidelines for Good Clinical Practice (GCP), the latter of which establishes guidelines and best practice principles specific to clinical trials. In discussing the legal duties of clinician-researchers, we focus on Canadian law, which encompasses both the common law used by the Anglo-Canadian

provinces and the civil law used in the province of Quebec. Under both legal traditions, clinicians have legal and ethical duties, and these are largely similar between the two systems. We consider the unique position of clinician-researchers, whose ethico-legal duties encompass both clinical care and research but which have differing primary goals.

Subsequently, in Section IV we present key points to consider for DCTs, focusing on four specific clinician-researcher duties: to obtain informed consent from participants (the duty to inform); to maintain participant confidentiality (professional secrecy); to provide detailed instructions to participants concerning the completion of study procedures (the duty to instruct); and to maintain regular channels of communication with participants (the duty to follow up). While many other duties are relevant to the conduct of DCTs, we have chosen to focus on these four because, in our view, they are crucial to ensuring the integrity of DCTs and the protection of the rights and welfare of participants.

I. POTENTIAL BENEFITS AND OPPORTUNITIES OF DCTS

DCTs promise to be an important addition to the clinical trial ecosystem, providing many potential benefits, such as increasing flexibility in study participation, increasing diversity of study populations, and improving recruitment and retention of participants. Indeed, traditional clinical trials often face problems of insufficient patient recruitment, limited participant diversity, low participant retention, high costs, and other logistical challenges (25). By transferring the completion of study procedures from clinical sites to participants' homes, DCTs present an opportunity to address these challenges.

Nevertheless, there is limited empirical data on the purported benefits of DCTs (26). Furthermore, many of the purported benefits raise concurrent burdens and risks. Sugarman and Vayena (26), for instance, cite the example of remote monitoring, noting that while it may enhance data collection efficiency in some contexts, it can also entail a greater time commitment for some participants compared to traditional clinical trials. Moreover, many of the potential benefits of DCTs also depend on the specific study design (26). Lastly, not all clinical trials are amenable to decentralization, either fully or partially.

One of the purported benefits of DCTs discussed in the literature is their potential to "democratize clinical research" by providing access to individuals who would otherwise have been unable to participate due to geographical factors (27). Geographic accessibility has long been identified as a major access barrier to clinical trials (28). In Canada, 20% of the population lives in rural and remote settings, where travel time to urban healthcare institutions is a significant barrier to clinical trial participation (29). Rural participants also incur additional expenses to participate in trials, such as taking time off work and paying for additional childcare to attend in-person visits (30).

The significance of these barriers is demonstrated by the fact that rural patients are disproportionately underrepresented in Canadian clinical trials (31). By removing or minimizing the need for in-person visits, DCTs can help to reduce access barriers for patients who would otherwise have difficulties participating in clinical trials. Furthermore, improving accessibility to clinical trials can help reduce health and socioeconomic disparities between rural or remote populations and their urban counterparts (32). Shifting the completion of study procedures to the participant's location may remove some of these barriers, providing more equitable access to clinical trials (33,34). Moreover, by enabling remote participation, patients can avoid the burden of frequent in-person visits, reducing travel time and associated costs. Indeed, DCTs can reduce trial costs by up to 50% for participants (35).

DCTs have also been noted to potentially improve access to clinical trials for other underrepresented groups. Members of ethnic minorities and women — especially women of colour — are two examples of population groups underrepresented in clinical research (36). This lack of representation is a significant issue, as different people may respond differently to medications or other investigational products. This highlights the need for greater diversity and representation in clinical trials (37). Limited participation in clinical trials thus perpetuates existing health disparities and inequities. By removing the financial, geographic, and other barriers that disproportionately limit the participation of underrepresented groups in clinical research, decentralization may help to foster greater diversity in clinical trial participation (38).

Participant recruitment has long been a challenge in research generally; insufficient recruitment has been the principal cause of both delays in clinical trials and their premature discontinuation (39). Research has also shown that patients often perceive participation in clinical trials as burdensome. Patients have reported feeling burdened by the need for multiple study visits, their duration, and the perceived inconveniences associated with study procedures (40,41).

It has been suggested in the literature that DCTs can help remedy these inconveniences by giving participants more flexibility and autonomy in their completion of study procedures (34). Furthermore, some authors have proposed that the flexibility provided by DCTs fosters a more "patient-centric" approach to clinical trials participation (42). DCTs can give patients the opportunity to play a more active and engaged role in the completion of study procedures and, by extension, their healthcare. This increased engagement can, in turn, help patients improve their health literacy and autonomy (42,43). Furthermore, by leveraging digital technologies, DCTs provide patients with the ability to participate from the comfort of their homes or any other convenient location. This may help to make healthcare a more welcoming environment, as studies have shown that fear is an important barrier to seeking treatment (44).

Nonetheless, it should be noted that, while DCTs may improve accessibility to clinical trials, reduce burdens for participants, and increase participant engagement, decentralization alone is unlikely to fully address the complex, systemic barriers that

hinder equitable participation in clinical trials. Indeed, while Goodson et al (38) acknowledge the aforementioned perceived benefits of DCTs, they note that for certain minority groups, the most significant barriers are more likely rooted in structural racism rather than inconvenience. Technology alone is thus unlikely to remove these barriers (38).

Overall, despite limited empirical support for the benefits of DCTs, several authors have raised the potential to improve the conduct of clinical trials, making them more patient-centric and efficient (45). Nevertheless, while the use of DCTs may, in certain circumstances, be beneficial, these benefits are often accompanied by challenges that may negatively affect the overall feasibility and effectiveness of DCTs. These challenges require careful attention to adequately protect participants' rights, safety, and welfare. We address some of these challenges in the following section. In fact, the safety of participants has been identified as a component of DCTs that requires "increased ethical vigilance" (42).

II. CHALLENGES IN THE ADOPTION OF DCTS

While the literature discusses many of the challenges of decentralizing clinical trials, in this section, we will focus on three challenges and their corresponding duties: privacy and confidentiality; safety monitoring; and digital literacy and participant compliance. The issues of safety monitoring and privacy and confidentiality are by no means unique to DCTs; they pose challenges for all clinical trials. Nonetheless, decentralization may change the scope and nature of these challenges, necessitating different approaches to adequately address them. Furthermore, privacy and confidentiality, safety monitoring, and digital literacy and participant compliance are not the only challenges facing DCTs (10,27,43). We have chosen to focus on these three as they are likely to pose the most challenges for clinician-researchers in the exercise of their ethico-legal duties and, thus, warrant specific consideration.

Privacy and confidentiality

Clinician-researchers have a duty to protect the privacy and ensure the confidentiality of participants' personal information. In DCTs, digital technologies are often used to collect data. These increasingly sophisticated technologies can collect a wide range of information, from physiological data (such as heart rate, blood sugar, and respiratory rate) to patient-reported outcomes (PROs) (43,46). For patients, the use of digital technologies can provide greater autonomy and flexibility, avoiding or minimizing the need for in-person visits and giving them more control over their performance study-related procedures (43). For clinician-researchers and institutions, the use of digital technologies can help minimize the costs and time associated with clinical trials (43). The use of digital technologies, however, raises additional cybersecurity risks, such as unauthorized disclosures of confidential information (10,47).

Indeed, clinical trials, whether traditional or decentralized, involve the collection of personal, often sensitive, identifiable information. Personal health information is considered to be among the most sensitive of personal information (48). With the complex data flows inherent in the use of digital technologies, there are increased risks of data security breaches. Hacking and cybersecurity breaches are among the most frequent forms of unauthorized disclosures of health information in the digital era (49). Instances of data exposure in the healthcare industry can result in considerable harm to participants, including "potential discrimination, stigmatization, financial and psychological distress" (50). Although various measures such as deidentification and data encryption can help mitigate these risks (38), the diverse range of digital technologies used in DCTs, combined with the large volumes of data they collect, make it effectively impossible to eliminate all cybersecurity risks (51).

These risks may be heightened by the use of digital technologies that passively collect participants' data. Devices such as wearables or sensors collect data without requiring active input from participants, compared to other types of devices that require active engagement (34). While the vast volumes of data collected by passive-type devices can be beneficial by generating rich datasets for analysis, there is the risk that they may also capture irrelevant data that do not align with the study's purposes. For instance, depending on the devices used, passive data collection — such as audio, video, and location tracking — may occur without the participant's knowledge and consent, raising privacy risks for both participants and for third parties (42,52,53).

Privacy and confidentiality risks associated with the use of digital technologies are typically disclosed in documents such as Privacy Policies and Terms of Use (54). However, research has shown that few people read these documents and instead simply scroll to the bottom of their screens and accept the conditions (55). Moreover, these documents are generally designed to limit liability for software developers, rather than to educate or inform users in making informed decisions. Disclosing the privacy and confidentiality risks associated with digital health technologies will likely be an important component of clinician-researchers' duty to inform participants. We return to this point in Section IV.

Safety monitoring

Safety monitoring refers to the oversight of the progress of the clinical trial, ensuring that it is conducted in accordance with applicable protocols and regulations. Safety monitoring is an integral part of a clinical trial, as it helps to improve "the safety of the participants, the quality of the data and the trial integrity" (56). Importantly, safety monitoring helps ensure that study procedures are consistent and safe for participants throughout the clinical trial (56). It is therefore essential that there be "adequate oversight and monitoring during the trial" so that the safety and well-being of participants are maintained throughout its duration (56).

In traditional clinical trials, on-site visits allow researchers to monitor participants for potential adverse events or other safety issues. However, with limited in-person interactions in DCTs, there will be an increased reliance on participants' use of digital technologies to communicate safety information, which could pose a challenge to effective safety monitoring (57). In a study of the experiences and perspectives of European regulators on DCTs by de Jong et al. (57), respondents reported challenges regarding safety monitoring in DCTs. In particular, respondents stated that proper safety monitoring would typically require "in-person (on-site) visits to perform physical examinations". Furthermore, respondents stated that "timely and uninterrupted access to interpretable safety data" would be vital to facilitate safety monitoring in DCTs.

While safety monitoring is crucial to all clinical trials, the need for effective monitoring is particularly important in DCTs, as participants are responsible for completing most of the study procedures themselves. For instance, there are increased risks of physical harm to participants if they inappropriately or unsafely administer trial medications (11). For this reason, fully decentralized clinical trials are better suited to medications that are easy to use, have well-established safety profiles, and do not require complex medical evaluations, rather than those that are difficult to administer or need detailed medical assessments (58).

Safety monitoring using automated data collection may mitigate some of these risks and improve safety monitoring compared to traditional clinical trials, as "continuous monitoring of participants can flag safety issues and adverse events in real-time" (59). This can help research personnel better respond to adverse events when they occur (59). Continuous monitoring through the use of digital devices presents concerns regarding privacy and confidentiality, as discussed earlier. Nor does it necessarily help improve safety monitoring and oversight. Research personnel must therefore remain alert and responsive to potential safety issues. Remote safety monitoring procedures should thus be developed to allow for proper monitoring and responsive action. Furthermore, research personnel should be properly trained on how to identify and respond to potential safety alerts (60). Similarly, in situations where participants are responsible for communicating safety issues themselves, they must be properly trained in how to do so (60). We will return to the importance of participant training when we discuss clinician-researchers' duty to instruct in Section IV.

Digital literacy and participant compliance

DCTs rely heavily on the use of digital technologies. As an increasing number of clinical trials employ decentralized elements, unique technological challenges will likely arise. In Section I, we explored how decentralization may benefit participants, providing them with greater flexibility and autonomy, as well as removing many access barriers. However, the use of digital technologies can also create new access challenges for participants. Issues such as digital literacy, limited technological access, and participant overburdening have the potential to reduce participant engagement and affect data integrity (10). We address each of these issues in this section.

Digital literacy can be defined as "the ability to use information and communication technologies to find, evaluate, create, and communicate information, requiring both cognitive and technical skills" (61). The growing prevalence of digital technologies in everyday life has led to a "digital divide" (62). Limited technological proficiency is particularly common among the elderly and ethnic minorities, who disproportionately lack access to technologies or the Internet at home (63). Consequently, heavy reliance on digital technologies in DCTs may complicate participation for these groups or potentially exclude them altogether, further reinforcing existing disparities and inequities (64). It is therefore crucial for clinician-researchers, institutions, and sponsors to recognize that digital literacy varies across demographic groups. DCTs should not exclude these groups, who may require additional support throughout the study. We will revisit this issue when discussing the duties to follow up and to instruct in Section IV.

In addition to digital literacy and technological access, some studies suggest that DCTs may overburden participants by overwhelming them with different technologies and devices (57,65). Decentralization shifts more responsibility onto participants to complete study procedures that would typically be performed by the study team. This increased responsibility may place undue burden on participants. In their systematic review of methods used to conduct DCTs, Rogers et al. (11) highlight several aspects of DCTs that may overburden participants, including the high volume and complexity of trial activities, the burden of using and charging digital devices, and the emotional weight of responsibility for trial conduct.

As illustrated, the shift toward DCTs requires participants to take a more active role, adhering to remote data collection protocols and assuming responsibility for self-reporting crucial information. However, placing greater responsibility on participants may lead to reduced study engagement, non-compliance, and inaccurate self-reported data. Combined with limited or no in-person contact with the study team, depending on the type of trial, these added responsibilities may exacerbate the compliance challenges already present in traditional clinical trials (41). Indeed, Coyle et al. (13) identify participant overburdening as one of the main barriers to participant adherence to study procedures in DCTs and may affect the results of these studies.

In summary, while DCTs may provide solutions to many of the challenges facing traditional clinical trials, they also raise new challenges. Though many of these challenges are not unique to DCTs, decentralization can change their nature and scope. In this section, we specifically examined the challenges of privacy and confidentiality, oversight and monitoring challenges, and digital literacy. To address these challenges and mitigate the risks they pose to DCTs, in the next section we discuss the roles

and responsibilities of clinician-researchers that are likely to be engaged in DCTs. Based on these duties, we will propose considerations for clinician-researchers to help ensure that the key issues outlined above are effectively managed.

III. ETHICO-LEGAL DUTIES OF CLINICIAN-RESEARCHERS IN CLINICAL TRIALS

Investigators responsible for the conduct of clinical trials are generally required to "be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial" (23). Under Canadian guidelines, a qualified investigator is defined as an individual who is "entitled to provide health care under the laws of the province where that clinical trial site is located." The investigator is typically a physician, although in dental research dentists can also supervise clinical trials (65). Given that the investigator responsible for the conduct of a clinical trial must be a licensed clinician, we use the term "clinician-researcher" to refer to investigators of clinical trials.

Clinician-researchers are bound by ethico-legal norms applicable to both the provision of medical care and the conduct of research. The primary responsibility of clinician-researchers in clinical trials is to conduct research that both contributes to generalizable knowledge and protects the rights, safety, and welfare of participants (66). The duties of clinician-researchers are defined by their ethical obligations to research participants as well as their legal and deontological duties as members of the medical profession.

In this section, we focus on the duties of clinician-researchers within the research context. Nonetheless, their responsibilities as clinicians also influence their conduct as researchers, particularly regarding their legal obligations. As we will demonstrate, under Canadian law, clinicians' legal duties in the clinic also extend to research, with courts often imposing stricter standards in the latter context. Many of these duties are also both ethical and legal in nature. The duties to inform and to maintain confidentiality, for instance, stem from both ethical guidelines and the law. It is therefore important to understand how various, often overlapping norms govern clinician-researchers' conduct in the context of clinical trials. We offer a brief overview of the sources of these duties and some specific obligations imposed on clinician-researchers.

Norms governing conduct of clinician-researchers in clinical trials

Research Ethics Guidelines

Modern research ethics guidelines outline the principles and standards that govern responsible and ethical conduct in research, emphasizing participant welfare and rigorous scientific integrity. Compliance with research ethics guidelines is imperative for researchers, as it safeguards the rights, well-being, and dignity of research participants (67). These guidelines also ensure that research is conducted with integrity, transparency, and accountability, fostering trust within the scientific community and with the public (68). By maintaining the highest ethical standards, researchers not only contribute to scientific advancement but also uphold the fundamental values, such as beneficence, non-maleficence, autonomy, and justice, that guide responsible research conduct (69,70).

Researchers must comply with several research ethics guidelines at both the national and international levels. Nationally, regulatory bodies and funding agencies establish ethical guidelines and frameworks for researchers. Locally, institutions have Research Ethics Boards (REBs) or Institutional Review Boards (IRBs; in the US) to ensure that research is conducted in an ethically responsible manner. In Canada, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) is a joint policy of Canada's three federal research agencies — the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (68). In addition to the general principles governing research involving humans, TCPS2 includes a chapter that is dedicated specifically to clinical trials (Chapter 11) (71). TCPS2 is binding for the researchers receiving funding from the agencies forming the Tri-Council (71).[1] In the United States, most research involving human participants funded by federal agencies is subject to the Common Rule, a set of regulations governing the ethical conduct of research involving human participants (72). FDA regulations apply to clinical investigations that involve the testing of new drugs, biologics, and medical devices (73).

Alongside national guidelines, international research ethics guidelines also establish ethical standards for research. The World Medical Association's Declaration of Helsinki, first adopted in 1964, has been described as the cornerstone of modern research ethics, serving as the foundation for subsequent research ethics guidelines (74). It outlines the ethical principles and responsibilities of physicians and others involved in medical research with human participants. These principles include respect for autonomy, informed consent, privacy and confidentiality, and research ethics review (75). Similarly, the International Ethical Guidelines for Health-related Research Involving Humans (2016), published by the Council for International Organizations of Medical Sciences (CIOMS), also outline ethical guidelines for research involving human participants. These cover key issues such as study design, informed consent, vulnerability, privacy and confidentiality, data and biological material management, and community engagement (76).

Specifically, regarding clinical trials, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) adopted the Guideline for Good Clinical Practice (GCP), which is an internationally

[1] "As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the Application sections of the articles. Institutions must therefore ensure that research conducted under their auspices complies with this Policy. Researchers are expected, as a condition of funding, to adhere to the TCPS." (68)

recognized standard for ensuring the ethical and scientific quality of clinical trial design, conduct, recording, and reporting (23). While the ethical guidelines discussed above address research more generally, the ICH-GCP specifically focuses on clinical trials. Among its core principles, the ICH-GCP emphasizes that clinical trials should be "conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki" (23). As such, clinician-researchers are bound not only by the clinical trials-specific provisions of the ICH-CGP but also by the broader ethical principles outlined in the Declaration of Helsinki and other Helsinki-inspired research ethics guidelines.

These guidelines emphasize that the protection of the rights, safety, and well-being of participants lies at the heart of clinician-researcher duties in the conduct of clinical trials. This includes various measures designed to minimize risks and promote participants' welfare. These measures closely align with the legal duties of clinicians and include informed consent (23), rigorous study design (23), safety reporting[2], maintaining accurate records (21), overseeing the proper handling and administration of the investigational products (23), and ensuring participants receive appropriate medical care where necessary.[3] While certain responsibilities may be delegated to other research personnel, such as study nurses, clinician-researchers still retain ultimate responsibility for the delegated activities and are accountable for maintaining proper oversight of the clinical trial (23,77).

Legal Norms

Under Canadian law, clinicians have several obligations that derive from case law, legislation, and professional codes of ethics. These include the duties to inform, to instruct, to follow up, to diagnose, and to maintain patient confidentiality (professional secrecy) (78,79). We will address these duties in detail in the following section.

There is controversy as to whether the legal duties of clinicians also apply to the research context. There has been much written in the literature concerning the unique position of clinician-researchers as medical professionals who both conduct research and provide direct clinical care to patients. Much of this debate stems from the differing primary goals of clinical care and research. Clinical care focuses on the well-being of the individual patient. Clinical research, on the other hand, focuses on a group of patients with a certain disease or condition, aiming to generate knowledge that can help future patients (80). Consequently, in research, "the therapeutic best interests of a particular individual […are] not the main aim of the study" (81). Based on these differences, some authors have argued that research can be viewed as a natural extension of clinical care and, thus, generate similar duties (82,83). Prince et al. (82), for instance, argue that a researcher who is also the participant-patient's physician might owe that person a fiduciary duty, even with respect to the research aspects of the relationship. Conversely, other authors have argued that research generates its own distinct duties (83,84).

There has been limited case law on this question in Canada. Nonetheless, Canadian case law supports the view that the duties of clinicians in the clinical context also apply to research, albeit at more exacting standards than in the clinic (85). Indeed, courts have imposed stricter standards on clinicians when conducting research (86,87); and the highest standard of care expected of a clinician is when employing an experimental procedure (79). As in the clinical context, the relevance of each duty to research will depend on the specific circumstances of the study.

Relevant Canadian case law on this issue has focused on the duty to inform. In clinical care, prior to treatment, clinicians must provide patients with adequate information to help them make informed decisions (79). This includes disclosure of risks that either a reasonable person in the patient's position would want to know (the common law standard) (79) or that a reasonable physician would disclose in the circumstances (the civil law standard) (78).

In clinical trials, disclosure for research purposes and for medical care are treated differently to avoid therapeutic misconception. This occurs when participants do not properly understand that the primary goal of research is to produce generalizable knowledge and, thus, may not provide any therapeutic benefit (71). Given their dual role, clinician-researchers should "take all necessary measures to separate their role as researcher from their role as clinician" (71).

Because research is experimental in nature, Canadian courts have affirmed that the standard of disclosure in research is higher than for clinical care (86). In *Halushka v University of Saskatchewan*, for instance, the defendant physicians were conducting a research study that involved the administration of a new anesthetic drug. The plaintiff decided to participate in the study after being told by the defendants that the procedure was a "perfectly safe test" (86). However, the defendants did not inform the plaintiff of the risks of participating in the experiment. The plaintiff suffered cardiac arrest and sued the defendants for damages. The Saskatchewan Court of Appeal ultimately held that, because the plaintiff was a research participant who did not receive any therapeutic benefit from the experiment, he was entitled to a "full and frank disclosure of all the facts, probabilities and opinions" that a reasonable person might be expected to consider before consenting to the procedure (86). As a result, in research, investigators are obliged to provide patients with more detailed and precise information than in clinical settings (79,88,89).

[2] Safety reporting includes timely reporting of adverse events (unfavourable medical occurrences in a trial participant) and serious adverse events (unfavourable medical occurrences that are considered serious at any dose if they: 1) result in death; 2) are life-threatening; 3) require in-patient hospitalization or prolongation of existing hospitalization; 4) result in persistent or significant disability/incapacity; or 5) are a congenital anomaly/birth defect). Safety reporting also includes reporting deaths of participants (23).

[3] Both during and after the course of the clinical trial, the investigator or institution should ensure that "adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the trial". In addition, participants should be informed when medical care is required "for intercurrent illness(es) of which the investigator becomes aware" (23).

Having provided a brief overview of the sources of clinician-researchers' duties, in the next section we consider how some of these duties may be engaged in DCTs and what types of issues clinician-researchers should consider when conducting DCTs.

IV. CLINICIAN-RESEARCHERS' DUTIES IN DCTS: POINTS TO CONSIDER

In this section, we focus on four ethico-legal duties of clinician-researchers — to inform, to maintain participant confidentiality (professional secrecy), to follow up, and to instruct — and examine how these duties are likely to be engaged in DCTs. We have chosen to limit our discussion to these duties for several reasons. For one, much of the Canadian case law on research has focused on the duty to inform and the duty to maintain confidentiality, thus making them compelling points of analysis for DCTs. Furthermore, courts have stated that, in the context of clinical care, when clinicians delegate certain tasks to patients, they must instruct their patients on how to properly carry out these tasks (79). In addition, the challenges that DCTs pose for safety monitoring warrant consideration of how the duty to follow up may be engaged in this context. While these duties may not differ in kind in the DCT context, they may differ in degree and therefore require modulation for DCTs.

Informed consent

Consent to both clinical care and to participation in research must be fully informed and voluntary (71,86,90). Clinician-researchers have an ethical and legal duty to provide adequate information to enable informed decision-making. Research ethics guidelines require that prospective participants be fully informed of the objectives of the research, its methods, anticipated benefits, potential risks, and other relevant information (23,75). Furthermore, Canadian case law has established that prospective participants are entitled to "full and frank disclosure" of all relevant information that a reasonable person might be expected to consider before consenting to participate (86). This includes disclosure of all known risks, even if rare or remote, especially if they entail serious consequences for the prospective participant's well-being (87).

In addition to the known risks related to the investigational product and study procedures, the risks associated with decentralization should also be disclosed to prospective participants. As described in Section II, there are several privacy and confidentiality risks in DCTs associated with the use of digital technologies and more complex data flows. These include risks associated with passive data collection, location tracking, and data sharing with third parties. Prospective participants must therefore be thoroughly informed about these risks, the nature and scope of the data being collected, and who will have access to their data.

However, merely providing information to prospective participants is insufficient to obtain informed consent. Prospective participants must also thoroughly understand this information, and ensuring this is an essential part of the informed consent process (75). As discussed in Section II, many people have limited digital literacy or insufficient knowledge of how digital technologies work. Full comprehension and appreciation of the risks may therefore be difficult to achieve. However, difficulties associated with informed consent processes are not unique to DCTs nor to clinical trials more broadly. Traditional informed consent models, based on paper consent forms, are becoming increasingly complex, characterized by lengthy documents that contain technical and formal language (91, 92). Informed consent processes can nonetheless be more challenging in DCTs, especially if current practices involving lengthy and complex forms are translated "as is" to digital form (10,57).

DCTs provide an opportunity to simplify existing complex procedures by mobilizing remote consent models. The use of digital platforms can be customized to meet the specific needs of prospective participants. They can manage the information they get, modulating when, where, and how they receive it, such as by re-reviewing instructional materials, pausing and returning to the materials, or seeking advice from others (10,57). Moreover, research indicates that users feel more informed through the use of audio-visual tools and interactive platforms, rather than traditional written consent forms (10,57).

However, even with technological support, informed consent for DCTs should still involve face-to-face communication — whether in-person or remote — between the prospective participant and the clinician-researcher or a designated member of the study team. Face-to-face communication is essential to assess the prospective participant's capacity to provide informed consent. A voluntary and informed decision to participate may be compromised if the prospective participant is unable to comprehend information, communicate effectively, reason, or deliberate.

While legal capacity is presumed for individuals of full age, face-to-face communication allows the clinician-researcher to conduct an assessment if they suspect that the prospective participant may lack the capacity to provide informed consent (93). This can be done, for instance, by looking at visual cues or assessing the prospective participant's responsiveness. When informed consent procedures are done solely on digital platforms, the ability to assess capacity is more limited. Even in cases where capacity is established, face-to-face communication can enhance the prospective participant's comprehension, allowing a study team member to support the informed consent process in real time and supplement the use of digital tools and platforms.

Clinician-researchers are ultimately responsible for obtaining informed consent from participants. In the research context, this requires a high standard of information disclosure, particularly regarding risks. The risks associated with DCTs must be clearly explained, and prospective participants must fully understand the risks. While many of these risks stem from the use of digital technologies, these tools can also be leveraged to improve informed consent processes and enhance comprehension.

Privacy and confidentiality

Professional secrecy is the obligation of professionals to keep information shared by their patients or clients confidential. This duty is both ethical and legal in nature and applies to both research and clinical care. It is also enshrined in the medical codes of ethics across Canadian provinces and in Quebec's Charter of Human Rights and Freedoms (78,79,94-96). Provincial privacy legislation also reinforces this duty by requiring an individual's consent before their personal information can be disclosed to third parties, subject to certain exceptions (97,98). In both clinical care and research, the duty to keep information confidential arises from the trust relationship that exists between the patient or participant and the clinician-researcher, and which underpins the fiduciary nature of the clinician-patient relationship (99).

In the research context, clinician-researchers must take all necessary precautions to protect the privacy and confidentiality of participants' personal information (75). This duty applies across the full life cycle of the information: collection, use, dissemination, retention, and disposal (71). Any record of information that could identify a participant must be protected, in accordance with applicable regulatory requirements (23).

The duty to maintain confidentiality can be threatened or undermined when digital technologies are used to collect, store, and analyze personal information, notably due to increasingly common data breach events. In the US, for example, health care entities covered by the federal Health Insurance Portability and Accountability Act (HIPAA) reported more than 330 breaches affecting 41.4 million people in the first half of 2023 alone, according to the US Department of Health and Human Services' (HHS) Office for Civil Rights (100). Indeed, the potential for unauthorized data access, ransomware attacks, and potential misuses of sensitive personal information can significantly compromise participants' privacy if robust security measures are not implemented. Unauthorized disclosure or interception of participants' personal information poses risks to the patient's privacy and confidentiality (101). As outlined in Section II, disclosure of such information can be prejudicial to individuals, resulting in discrimination, stigmatization, and other types of harm (50).

With their heavy reliance on digital technologies for remote participation and data collection, DCTs may be particularly vulnerable to data security risks (10). While traditional clinical trials also entail privacy risks, the use of digital technologies may heighten these, thus requiring the implementation of stricter security safeguards (10). With the privacy and confidentiality challenges raised by DCTs, fulfilling the duty to maintain confidentiality will require additional efforts on the part of clinician-researchers and the study team.

Indeed, the ICH-CGP requires that records identifying the participant be kept confidential and not be made publicly available, to the extent permitted by applicable regulatory requirements (23). Given the unique privacy and confidentiality considerations raised by DCTs, additional safeguards will need to be implemented to safeguard participants' rights and interests (10). Depending on the trial and the types of digital tools or technologies used, measures such as data encryption, deidentification, and data minimization may be employed to mitigate privacy risks. Privacy impact assessments (PIAs) should also be conducted, where necessary, to identify potential impacts on participants (10). In certain cases, conducting a PIA may be a legal requirement in order to collect personal information (102).

In addition to risk disclosure, clinician-researchers should also be primarily responsible for ensuring that privacy risks are mitigated by implementing basic measures and safeguards such as those mentioned above. However, responsibility for mitigating privacy risks should also be shared with other stakeholders involved in the clinical trial. Institutions should be responsible for providing the infrastructure and resources to ensure that these measures are consistently applied throughout the trial. As in all clinical trials, sponsors are responsible for ensuring that the trial is conducted in accordance with both the protocol and applicable ethical and regulatory requirements.

The types of mitigation measures will vary by study and depend on applicable regulatory requirements. Nonetheless, clinician-researchers should remain aware of the privacy and confidentiality risks associated with DCTs, including data breaches, unauthorized access, and potential re-identification of participants, and should implement appropriate measures, such as robust encryption, secure data storage, and strict access controls to mitigate these risks.

Participant instruction

In DCTs, there is a shift of responsibility from the study team to participants. With this shift, there may be risks to participants if they do not perform certain study procedures or if they do not promptly report safety issues. Furthermore, participants will have different digital literacy levels, and many will likely require additional support during the trial. It is thus crucial that clinician-researchers (or other designated personnel) provide clear and detailed instructions to participants throughout the trial.

Under Canadian law, clinicians are responsible for giving clear guidance and proper instructions to make sure that patients understand and effectively perform any tasks that are delegated to them (103). Case law on the duty to instruct has focused primarily on postoperative clinical care, where physicians often delegate certain tasks to patients after discharge. The duty to instruct has yet to be judicially analyzed in the research context. However, given the shift of responsibility to patients in DCTs and the potential for risk of harm if certain study procedures, such as the administration of the study drug, are improperly executed, the duty to instruct is particularly relevant to clinician-researchers conducting DCTs.

In Section II, we highlighted safety monitoring as one of the key challenges facing DCTs. To mitigate associated risks, clinician-researchers (or other designated personnel) should provide detailed instructions on how participants should perform delegated study procedures (60), as well as how to report and respond to adverse events (60).

Alongside providing detailed instructions, the duty to instruct also includes verifying that participants have properly understood instructions and ensuring that they have the necessary tools to carry out their required tasks (104). For example, in the context of administering investigational products, Vayena et al. recommend offering participants "comprehensive instructions" via "dedicated apps or websites, with user-friendly communication tools, such as visual aids, infographics, and videos" (10). Considering that some participants may have limited digital literacy or have difficulty using digital technologies, the need for user-friendly, comprehensive instructions is imperative.

Furthermore, the duty to instruct requires physicians "to consider the patient's ability to understand and follow instructions" (104). Consequently, even if user-friendly communication tools are developed to aid participant comprehension, this does not automatically fulfill the duty to instruct. For certain individuals, participation in a DCT, whether fully decentralized or in hybrid format, may not be appropriate (60). Even with additional support, some participants may not be able to participate in a DCT. Clinician-researchers should therefore conduct thorough assessments to ensure that prospective participants have the capacity to understand and follow all necessary instructions. Clinician-researchers should also consider alternative measures to include patients who may not be able to participate in DCTs, such as by allowing more in-person check-ins with certain participants.

Overall, in clinical care, the duty to instruct requires that clinicians provide detailed instructions when delegating certain tasks to patients. In DCTs, where many trial-related tasks are delegated to participants, this duty becomes a critical component of clinician-researchers' responsibilities. Although Canadian courts have yet to analyze the duty to instruct in the research context, DCTs highlight its relevance in that particular setting.

Participant monitoring

In clinical trials, clinician-researchers are responsible for monitoring participant safety throughout the trial (71). They must take appropriate measures to minimize risks and burdens to participants and continuously assess these throughout the study (75). Both during and following the end of the clinical trial, adequate medical care must be provided to participants for any trial-related adverse events (23). Clinician-researchers must also develop plans for monitoring participant safety, evaluate the efficacy of the intervention, and establish criteria for withdrawing participants from the trial for safety reasons (71).

In traditional clinical trials, a participant's progress is typically monitored during in-person study visits. These may include physical examinations, reviews of study medications and symptoms, and any necessary laboratory tests. In DCTs, by contrast, participants can be monitored remotely by different means, such as telecommunications visits, data monitoring, or other remote modalities. As in traditional clinical trials, in DCTs clinician-researchers have the same fundamental monitoring responsibilities. However, the way in which these are carried out must be adapted to the remote context of DCTs. Clinician-researchers must therefore have systems in place to monitor the safety of participants, detect and report adverse events in a timely manner, and monitor participants' data for integrity and validity.

However, there may be challenges to monitoring how DCTs affect participants' safety and well-being. In their survey of European regulators, De Jong et al. (57) found that many respondents considered missing data to be a challenge associated with DCTs, one that could then raise issues with data interpretation. Furthermore, Daly et al. (105) note that DCTs can impose a higher burden on participants in relation to data monitoring, as they require participants to perform multiple data-related tasks themselves. This may not only burden participants and intrude within their daily setting but may also result in inconsistencies in the data collection process and, consequently, incomplete data. These gaps or inconsistencies not only compromise the scientific validity and operational conduct of the DCT but also negatively affect the safety and welfare of participants. Incomplete or missing data may delay the detection of adverse events or other clinically relevant changes and, thus, lead to delays in intervention or responses.

The duty to follow up is particularly relevant to participant monitoring in clinical trials. Under Canadian law, clinicians are responsible for following up with their patients concerning their treatment and care. Clinicians must use reasonable care in ensuring that important information, such as testing results or referrals, is communicated to patients and acted upon. This includes reviewing and responding to diagnostic tests in a timely manner, advising patients of significant findings, arranging appropriate follow-up appointments, and ensuring continuity of care when delegating or transferring responsibilities to other health-care providers (78,79). In clinical care, this duty ensures continuity of care and allows for the monitoring of patients' progress (78,79,94,106).

Some authors have suggested that follow-up might be easier in DCTs than in traditional clinical trials, as DCTs allow researchers to "analyze safety issues more continuously than in conventional trials, and possibly protect participants more effectively" (10). Because the need for study visits is reduced or eliminated, clinician-researchers (or other designated personnel) can follow up more frequently with participants, without the additional costs or burdens associated with in-person visits (43). Nevertheless, given the challenges that could be raised in monitoring participants in DCTs, it is crucial that clinician-researchers ensure adequate follow-up with participants throughout the trial's duration.

In clinical care, patient follow-up can involve the use of patient management software (107) for diagnostic testing result follow-up (108). These systems can play an important role in identifying patients who require follow-up based on abnormal test results or trends and help ensure that appropriate action is taken in a timely manner. For example, if a patient's test results fall outside of a normal range, the system can automatically generate an alert that triggers follow-up by the healthcare provider (109). These systems are increasingly being used to manage post-surgical follow-up through remote monitoring and identification of post-operative complications (110).

These types of follow-up systems can be informative for safety monitoring in DCTs. Ultimately, the level of monitoring required during a DCT will depend on the trial's levels of risk, size, and complexity, among other factors. The use of follow-up systems, as described above, may not be relevant or feasible for all DCTs. Nonetheless, the safety monitoring challenges raised by DCTs may, depending on the circumstances, require implementing novel solutions to monitor the safety and welfare of participants.

In addition to safety monitoring, clinician-investigators should also play a role in monitoring data for integrity and validity in DCTs, though other actors, such as the study sponsor and data safety monitoring boards (DSMBs), where relevant, should also play a role therein. This concords with ethical and normative guidelines in clinical trials. According to the ICH-GCP, clinician-investigators play a role in ensuring the "accuracy, completeness, legibility, and timeliness of the data" that they report to the trial sponsor in the CRFs and other required reports (23). Furthermore, according to the TCPS2, in their proposals researchers must include a comprehensive data and safety monitoring plan, specifying how safety, efficacy, and validity will be overseen, regardless of whether an independent DSMB is appointed (71). While the establishment of an independent DSMB is strongly recommended, especially for high-risk, multi-site, or blinded clinical trials and those involving vulnerable populations to ensure unbiased scrutiny of accumulating data, it does not absolve clinician-investigators of their obligations. DSMBs augment but do not replace clinician-researchers' monitoring responsibilities (71).

Clinician-researchers are thus responsible for ensuring the implementation of procedures that guarantee data integrity and validity. In DCTs, particular care is needed when participants' data is stored on personal devices, since it can often be connected with other sensitive details, such as contact information, location history, and audiovisual information (34). This not only raises privacy issues but can also affect the integrity and validity of participants' data. Robust data governance mechanisms and auditing and quality control processes should therefore be implemented. Other types of solutions can also be explored. For instance, recent research has recommended integrating personal health records (PHRs) into DCTs to enhance data integrity (111). The use of blockchain technology has also been proposed for data monitoring. Blockchain's use of algorithms can help enhance data security, protecting sensitive information from alteration, manipulation, and cybersecurity threats (112). This is especially important in clinical trials involving study drugs, where "the integrity of data directly impacts patient safety and trial outcomes" (112).

Overall, DCTs, as with all clinical trials, raise challenges regarding safety and data monitoring. The types of measures needed for safety, data integrity, and validity monitoring in DCTs will depend on the trial design and its specific features. For example, a fully decentralized trial relying on wearable devices and patient-reported outcomes may require stronger safeguards compared to a hybrid trial where some data are still collected in person at study sites. Similarly, trials involving vulnerable populations or higher-risk interventions may require additional safeguards, such as enhanced monitoring, independent data verification, or more frequent follow-up with participants. Monitoring measures should therefore be adapted to the nature of the study intervention, data sources, patient population, and degree of decentralization.

CONCLUSION

DCTs show great promise in the evolving clinical trials landscape. Growing evidence suggests that DCTs can help reduce costs, increase patient adherence, and improve data integrity, among many other benefits. However, DCTs also present several challenges. While not all of these are unique to DCTs, they may be amplified with decentralization. In this article, we examined three key challenges: privacy and confidentiality; oversight and monitoring; and digital literacy and participant compliance. If not properly addressed, these challenges may compromise the rights, safety, and welfare of DCT participants.

While there is growing scholarship on the ethical and regulatory challenges raised by DCTs, further attention is warranted to appraise the ethical and legal duties of clinician-researchers and how they are engaged in DCTs. As we demonstrated in this article, clinician-researchers are bound by several ethical, legal, and professional requirements that encompass their dual clinical and research roles. We focused on four duties encompassing clinician-researchers' roles in obtaining informed consent, ensuring privacy and confidentiality, providing instructions to participants, and conducting safety and data monitoring.

Understanding how these duties are carried out is crucial for addressing the challenges raised by DCTs, especially given the central role that clinician-researchers play in overseeing the conduct of clinical trials. Though many responsibilities may be delegated to other personnel, clinician-researchers are ultimately responsible for the performance of delegated tasks and their outcomes. Safeguarding the rights, safety, and well-being of participants in DCTs depends largely on the ethically and legally robust performance of these responsibilities. This article complements existing literature on the roles of clinician-researchers in DCTs. For instance, Besel et al. (113) enumerate the core competencies of clinical research professionals. The competencies, based on the Joint Task Force (JFT) Core Competency Framework, represent eight domains and are assessed

on proficiency levels ranging from fundamental to skilled to advanced: scientific concepts and research design; ethical participant safety considerations; investigational product development and regulation; clinical study operations (good clinical products); study and site management; data management and informatics; leaderships and professionalism; communications; and teamwork (113).

One limitation in our analysis that warrants mention is that our discussion of the legal duties of clinician-researchers is based on Canadian law. Our analysis of the clinician-researchers' legal scope of practice as they apply to DCTs may not be generalizable to other jurisdictions where legal and regulatory frameworks governing research could differ. As such, variations in local laws may limit the generalizability of our findings outside of Canada. Nonetheless, the use of international guidelines in our analysis, such as the Declaration of Helsinki and the ICH-CGP, which provide a unified and harmonized standard for clinical trial conduct, affords generalizability of findings to other settings that recognize these guidelines.

Furthermore, given the heterogeneity of the DCT landscape, we could not account for every possible variance in DCT design. The ways in which a clinical trial is decentralized can raise different challenges, which in turn may engage different duties or render some duties irrelevant. As such, not all Points to Consider in this article may be relevant to all DCTs. Nonetheless, there has been relatively limited scholarly discourse on the duties of clinician-researchers in DCTs. This article therefore fills an important gap in the literature and provides an important point of reference for future research and policymaking in the DCT field.

Finally, while the duties of clinician-researchers in DCTs are an important part of trial conduct, further attention must be given to the roles and responsibilities of other key stakeholders, such as sponsors, research institutions, CROs, regulatory agencies, and institutional review boards (IRBs), who may be less familiar with the ethical challenges of DCTs. Clarifying these roles and responsibilities will help ensure that DCTs can serve as an effective and sustainable model for future clinical trial design and conduct.

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REFERENCES

1. Bhatia RS, Chu C, Pang A, et al. Virtual care use before and during the COVID-19 pandemic: a repeated cross-sectional study. CMAJ. 2021;9(1):E107-14.
2. Johnson C, Dupuis JB, Goguen P, Grenier G. Changes to telehealth practices in primary care in New Brunswick (Canada): A comparative study pre and during the COVID-19 pandemic. PLoS ONE. 2021;16(11):e0258839.
3. Kleinman RA, Merkel C. Digital contact tracing for COVID-19. CMAJ. 2020;192(24):E653-56.
4. Rosa C, Marsch LA, Winstanley EL, et al. Using digital technologies in clinical trials: Current and future applications. Contemp Clin Trials. 2021;100:106219.
5. Nomali M, Mehrdad N, Heidari ME, et al. Challenges and solutions in clinical research during the COVID-19 pandemic: A narrative review. Health Sci Rep. 2023;6(8):e1482.
6. Loucks TL, Tyson C, Dorr D, et al. Clinical research during the COVID-19 pandemic: The role of virtual visits and digital approaches. J Clin Trans Sci. 2021;5(1):e102.
7. van Dorn A. COVID-19 and readjusting clinical trials. The Lancet. 2020;396(10250):523-24.
8. Ledford H. The COVID pandemic's lingering impact on clinical trials. Nature. 2021;595(7867):341-42.
9. Global Data Healthcare. Slow recruitment due to Covid-19 disruptions continues to climb in 2022. Clinical Trials Arena. 31 Jan 2022.
10. Vayena E, Blasimme A, Sugarman J. Decentralised clinical trials: ethical opportunities and challenges. Lancet Digit Health. 2023;5(6):e390-94.
11. Rogers A, De Paoli G, Subbarayan S, et al. A systematic review of methods used to conduct decentralised clinical trials. Brit J Clinical Pharma. 2022;88(6):2843-62.
12. Orri M, Lipset CH, Jacobs BP, Costello AJ, Cummings SR. Web-based trial to evaluate the efficacy and safety of tolterodine ER 4mg in participants with overactive bladder: REMOTE trial. Contemp Clin Trials. 2014;38(2):190-97.
13. Coyle J, Rogers A, Copland R, et al. Learning from remote decentralised clinical trial experiences: A qualitative analysis of interviews with trial personnel, patient representatives and other stakeholders. Brit J Clinical Pharma. 2022;88(3):1031-42.
14. Medrio. Hesitant to embrace decentralized trials because of regulations? Medrio; 12 Feb 2021.
15. Health Canada. Management of clinical trials during the covid-19 pandemic: notice to clinical trials sponsors. Health Canada; 27 Jan 2023.
16. Food and Drug Administration. Decentralized clinical trials for drugs, biological products, and devices: guidance for industry, investigators, and other stakeholders. FDA; Sept 2024.
17. European Medicines Agency. Guidance on the management of clinical trials during the Covid-19 (coronavirus) pandemic. Commission européenne/European Commission; 10 Feb 2022.
18. Innovative Medicines Initiative. Trials@Home. IHI; 1 Jan 2019.
19. DTRA. Decentralized trials & research alliance. DRTA; 2025.
20. Multi-Regional Clinical Trials. Oversight and implementation of decentralized clinical trials. MRCT Center. 1 Mar 2024.
21. Montreal Heart Institute. L'Institut de Cardiologie de Montréal se voit octroyer 9,35 M$ du Gouvernement du Québec pour piloter un projet d'envergure en essais cliniques virtuels. MHI; 13 Dec 2021.
22. Alper J, Khandekar E, Shore C, editors. Virtual clinical trials: challenges and opportunities: proceedings of a workshop. Washington, D.C.: National Academies Press; 2019.
23. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH harmonized guideline good clinical practice (GCP). ICH; 19 May 2023.
24. Tovino SA. Privacy and security issues with mobile health research applications. J Law Med Ethics. 2020;48(S1):154-58.
25. Chaudhari N, Ravi R, Gogtay N, Thatte U. Recruitment and retention of the participants in clinical trials: Challenges and solutions. Perspect Clin Res. 2020;11(2):64-69.
26. Sugarman J, Vayena E. Accurately understanding the potential benefits of decentralized clinical trials. The American Journal of Bioethics. 2025;25(5):81-83.
27. Andrews L, Kostelecky K, Spritz S, Franco A. Virtual clinical trials: one step forward, two steps back. J of Health Care Law and Policy. 2017;19(2):189-245.
28. Galsky MD, Stensland KD, McBride RB, et al. Geographic accessibility to clinical trials for advanced cancer in the United States. JAMA Intern Med. 2015;175(2):293-95.
29. Statistics Canada. Population growth in Canada's rural areas, 2016 to 2020. Government of Canada. 9 Feb 2022.
30. Sheridan R, Martin-Kerry J, Hudson J, et al. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. Trials. 2020;21:259.
31. Bharucha AE, Wi CI, Srinivasan SG, et al. Participation of rural patients in clinical trials at a multisite academic medical center. J Clin Trans Sci. 2021;5(1):e190.
32. Najarian M, Goudie A, Bona JP, et al. Socioeconomic determinants of remote patient monitoring implementation among rural and urban hospitals. Telemed J EHealth. 2023;29(11):1624-33.
33. Doroshow JH, Prindiville S, McCaskill-Stevens W, Mooney M, Loehrer PJ. Covid-19, social justice, and clinical cancer research. J Natl Cancer Inst. 2021;113(10):1281-84.
34. Petrini C, Mannelli C, Riva L, Gainotti S, Gussoni G. Decentralized clinical trials (DCTs): A few ethical considerations. Front Public Health. 2022;10:1081150.

35. Hanley Jr DF, Bernard GR, Wilkins CH, et al. Decentralized clinical trials in the trial innovation network: value, strategies, and lessons learned. Journal of clinical and translational science. 2023;7(1):e170.
36. Kaiksow FA, Carter J. Chapter 4: Barriers to representation of underrepresented and excluded populations in clinical research. In: Bibbins-Domingo K, Helman A, editors. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington, DC: The National Academies Press; 2022. p. 75-106.
37. Office of Minority Health and Health Equity. Clinical Trial Diversity. FDA; 12 May 2024.
38. Goodson N, Wicks P, Morgan J, et al. Opportunities and counterintuitive challenges for decentralized clinical trials to broaden participant inclusion. npj Digit Med. 2022;5:58.
39. Ali Z, Zibert JR, Thomsen SF. Virtual clinical trials: perspectives in dermatology. Dermatology. 2020;236(4):375-82.
40. Briel M, Elger BS, McLennan S, et al. Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany, and Canada. Trials. Dec 2021;22:844.
41. Henshall C, Narendran P, Andrews RC, et al. Qualitative study of barriers to clinical trial retention in adults with recently diagnosed type 1 diabetes. BMJ Open. 2018;8(7):e022353.
42. Coert RMH, Timmis JK, Boorsma A, Pasman WJ. Stakeholder Perspectives on Barriers and Facilitators for the Adoption of Virtual Clinical Trials: Qualitative Study. J Med Internet Res. 2021;23(7):e26813.
43. Gelinas L, Morrell W, White SA, Bierer BE. Navigating the ethics of remote research data collection. Clinical Trials. 2021;18(5):606-14.
44. Dubayova T, Van Dijk JP, Nagyova I, et al. The impact of the intensity of fear on patient's delay regarding health care seeking behavior: a systematic review. Int J Public Health. 2010;55(5):459-68.
45. Inan OT, Tenaerts P, Prindiville SA, et al. Digitizing clinical trials. npj Digit Med. 2020;3:101.
46. Weldring T, Smith SMS. Article commentary: patient-reported outcomes (pros) and patient-reported outcome measures (PROMS). Health Serv Insights. 2013;6:61-68.
47. Aizenberg M, Brandolini A. Confidentiality and privacy in digital clinical trials. In: Valdés E, Lecaros JA, editors. Handbook of Bioethical Decisions, Volume II. Cham: Springer International Publishing; 2023. p. 145-64.
48. Information and Privacy Commissioner of Ontario. Frequently asked questions: personal health information protection act. IPC; Sep 2015.
49. Seh AH, Zarour M, Alenezi M, et al. Healthcare data breaches: insights and implications. Healthcare. 2020;8(2):133.
50. Office of the Privacy Commissioner of Canada. Securing public trust in digital healthcare: resolution of the federal, provincial and territorial privacy commissioners and ombudspersons with responsibility for privacy oversight. OPC; 21 Sep 2022.
51. Organisation for Economic Co-operation and Development (OECD). Managing digital security and privacy risk. OECD; 1 Jun 2016.
52. Breslin S, Shareck M, Fuller D. Research ethics for mobile sensing device use by vulnerable populations. Soc Sci Med. 2019;232:50-57.
53. Carter A, Liddle J, Hall W, Chenery H. Mobile phones in research and treatment: ethical guidelines and future directions. JMIR Mhealth Uhealth. 2015;3(4):e95.
54. McGraw D, Mandl KD. Privacy protections to encourage use of health-relevant digital data in a learning health system. npj Digit Med. 2021;4:2.
55. Obar JA, Oeldorf-Hirsch A. The biggest lie on the Internet: ignoring the privacy policies and terms of service policies of social networking services. Information, Communication & Society. 2020;23(1):128-47.
56. Love SB, Yorke-Edwards V, Ward E, et al. What is the purpose of clinical trial monitoring? Trials. 2022;23:836.
57. De Jong AJ, Van Rijssel TI, Zuidgeest MGP, et al. Opportunities and challenges for decentralized clinical trials: european regulators' perspective. Clin Pharma and Therapeutics. 2022;112(2):344-52.
58. Robinson R, Sacks L. Decentralized clinical trials in the development of drugs and biological products. Ther Innov Regul Sci. 2024;59(6):1191-93.
59. Ghadessi M, Di J, Wang C, et al. Decentralized clinical trials and rare diseases: a drug information association innovative design scientific working group (DIA-IDSWG) perspective. Orphanet J Rare Dis. 2023;18:79.
60. Apostolaros M, Babaian D, Corneli A, et al. Legal, regulatory, and practical issues to consider when adopting decentralized clinical trials: recommendations from the clinical trials transformation initiative. Ther Innov Regul Sci. 2020;54(4):779-87.
61. Digital Literacy Taskforce. What is digital literacy? American Library Association; 2011.
62. Brisson-Boivin K, McAleese S. How digital literacy can help close the digital divide. Policy Options. 13 Apr 2021.
63. Velasquez D, Mehrotra A. Ensuring the growth of telehealth during covid-19 does not exacerbate disparities in care. Health Affairs Forefront. 8 May 2020.
64. Parks AM, Duffecy J, McCabe JE, et al. Lessons learned recruiting and retaining pregnant and postpartum individuals in digital trials: viewpoint. JMIR Pediatr Parent. 2022;5(2):e35320.
65. Health Canada. Guidance document for clinical trial sponsors: clinical trial application. Health Canada; 29 May 2013
66. Baer AR, Devine S, Beardmore CD, Catalano R. Clinical investigator responsibilities. JOP. 2011;7(2):124-28.
67. World Health Organization. Ensuring ethical standards and procedures for research with human beings. WHO; 2026.
68. The Expert Panel on Research Integrity. Honesty, Accountability and Trust: Fostering Research Integrity in Canada. Canadian Council of Academies; 21 Oct 2010.
69. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. New York: Oxford University Press; 2013.

70. Varkey B. Principles of clinical ethics and their application to practice. Med Princ Pract. 2021;30(1):17-28.
71. CIHR, NSERC, SSHRC. Tri-council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2. Government of Canada; 2022.
72. Office for Human Research Protections. 45 CFR 46 in Belmont Report. U.S. Department of Health and Human Services; 2019.
73. Food and Drug Administration. Regulations: good clinical practice and clinical trials. FDA; 21 Jan 2021.
74. Carlson RV, Boyd KM, Webb DJ. The revision of the Declaration of Helsinki: past, present and future. Brit J Clinical Pharma. 2004;57(6):695-713.
75. WMA Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. WMA; Dec 2024.
76. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Health-Related Research Involving Humans. CIOMS/WHO; 2016.
77. Barlow C. Human subjects protection and federal regulations of clinical trials. Semin Oncol Nurs. 2020;36(2):151001.
78. Philips-Nootens S, Kouri RP. Éléments de responsabilité civile médicale : le droit dans le quotidien de la médecine. Montréal: Éditions Yvon Blais; 2021.
79. Robertson G, Picard EI. Legal Liability of Doctors and Hospitals in Canada. Toronto: Carswell; 2017.
80. Kruger M, Nortjé N. The child with cancer: blurring the lines between research and treatment. In: Nortjé N, Bester JC, editors. Pediatric Ethics: Theory and Practice. Cham: Springer International Publishing; 2022. p. 379-86.
81. Czoli C, Da Silva M, Zlotnik Shaul R, et al. Accountability and pediatric physician-researchers: are theoretical models compatible with Canadian lived experience? Philos Ethics Humanit Med. 2011;6(1):15.
82. Prince AER, Conley JM, Davis AM, Lázaro-Muñoz G, Cadigan RJ. Automatic placement of genomic research results in medical records: do researchers have a duty? Should participants have a choice? J Law Med Ethics. 2015;43(4):827-42.
83. Henderson GE, Churchill LR, Davis AM, et al. Clinical trials and medical care: defining the therapeutic misconception. PLoS Med. 2007;4(11):e324.
84. De Melo-Martín I, Ho A. Beyond informed consent: the therapeutic misconception and trust. J Med Ethics. 2008;34(3):202-5.
85. Zawati MH. Chapter 12: Liability and the legal duty to inform in research. In: Joly Y, Knoppers BM. Routledge Handbook of Medical Law and Ethics. London: Routledge; 2014. p. 199-220.
86. Halushka v. University of Saskatchewan. 1965 CanLII 439.
87. Weiss v. Solomon. 1989 RJQ 731.
88. Freedman B, Glass KC. Weiss v. Solomon: a case study in institutional responsibility for clinical research. Law Med Health Care. 1990;18(4):395-403.
89. Largent EA, Fernandez Lynch H. Paying research participants: regulatory uncertainty, conceptual confusion, and a path forward. Yale J Health Policy Law Ethics. 2017;17(1):61-141.
90. Downie JG, Caulfield TA, Flood CM, editors. Canadian Health Law and Policy. Markham/Dayton: LexisNexis Canada; 2011.
91. Dankar FK, Gergely M, Dankar SK. Informed consent in biomedical research. Comput Struct Biotechnol J. 2019;17:463-74.
92. Nathe JM, Krakow EF. The challenges of informed consent in high-stakes, randomized oncology trials: a systematic review. MDM Policy & Practice. 2019;4(1):2381468319840322.
93. Dalpé G, Thorogood A, Knoppers BM. A tale of two capacities: including children and decisionally vulnerable adults in biomedical research. Front Genet. 2019;10:289.
94. Code of Ethics of Physicians. CQLR chapter m-9, r. 17.
95. Charter of Human Rights and Freedoms. 1975 CQLR c-12.
96. Professional Code. 1977 CQLR c-26.
97. Personal Health Information Protection Act. Sect. SO 2004, c 3, Sch A.
98. Health Information Act. RSA 2000 c H-5.
99. McInerney v. MacDonald. 1992 2 SCR 138.
100. Schumaker E, Leonard B, Paun C, Peng E. AMA president: AI will not replace doctors. Politico. 7 Oct 2023.
101. Gostin LO, Halabi SF, Wilson K. Health data and privacy in the digital era. JAMA. 2018;320(3):233-34.
102. Act respecting the protection of personal information in the private sector. 1993 CQLR c P-39.1 s. 3.3.
103. Rollin v. Baker. 2010 ONCA 569.
104. Peppler Estate v. Lee. 2019 ABOB 144.
105. Daly B, Brawley OW, Gospodarowicz MK, et al. Remote monitoring and data collection for decentralized clinical trials. JAMA Network Open. 2024;7(4):e246228.
106. Act respecting the governance of the health and social services system. CQLR c G-1.021.
107. Pampin M. Patient management software: what your care team needs to know. Welkin Health. 2020.
108. Kahlon (Litigation guardian of) v Vancouver Coastal Health Authority. 2009 BCSC 922.
109. Tarkan S, Plaisant C, Shneiderman B, Hettinger AZ. Reducing missed laboratory results: defining temporal responsibility, generating user interfaces for test process tracking, and retrospective analyses to identify problems. AMIA Annu Symp Proc. 2011;2011:1382-91.
110. Semple JL, Armstrong KA. Mobile applications for postoperative monitoring after discharge. CMAJ. 2017;189(1):e22-24.

111. Kim Y, Huh KY, Yu KS. Integrating personal health records to improve data integrity in trials with decentralized elements: a pilot study. Clin Transl Sci. 2025;18(6):e70267.
112. Kushwaha P, Srivastava N, Kushwaha SP. Enhancing clinical drug trial monitoring with blockchain technology. Contemp Clin Trials. 2024;146:107684.
113. Besel JM, Johnson EA, Ma J, Kiesow B. Reimagining the joint task force core competency framework for rural and frontier clinical research professionals conducting hybrid and decentralized trials. Front Pharmacol. 2023;14:1309073.

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ARTICLE (PEER-REVIEWED)

Ethical Issues in Humanitarian Work: Perceptions of Humanitarian Ethics Experts, Workers, and Non-Governmental Organization Members

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Résumé
Cet article documente empiriquement les perceptions et les expériences de divers acteurs du milieu humanitaire, y compris des travailleurs humanitaires, des membres d'organisations non gouvernementales (ONG) et des spécialistes en éthique humanitaire, concernant les enjeux éthiques du travail humanitaire. Nous avons réalisé quinze entrevues avec des personnes participantes, à partir desquelles nous avons dégagé quatre catégories d'enjeux éthiques : les tensions de valeurs, le manque de ressources, les considérations politiques et le néocolonialisme. Les tensions de valeurs recouvrent des questions éthiques liées aux conflits interculturels, à l'équilibre entre les soins, la sécurité et la collaboration, aux soins d'urgence et aux soins à long terme, ainsi qu'au silence éthique. Le manque de ressources comprend des enjeux tels que l'insuffisance de ressources financières et matérielles, le manque de préparation et l'absence de ressources éthiques, qui contribuent à des difficultés opérationnelles. Les considérations politiques concernent les enjeux éthiques liés aux opérations des ONG, notamment le décalage entre les décisions organisationnelles et les pratiques sur le terrain, l'inégalité de traitement entre le personnel local et le personnel expatrié, ainsi que les situations d'autoritarisme, de racisme et de corruption au sein des ONG et de leurs partenaires. Les enjeux éthiques liés au néocolonialisme mettent en lumière la persistance des idéologies occidentales et des dynamiques de pouvoir dans les organisations humanitaires. Ceux-ci se manifestent notamment par le paternalisme, le contrôle de la prise de décision par des personnes blanches et les déséquilibres de pouvoir entre les ONG et les gouvernements locaux, perpétuant un sentiment de supériorité de l'Occident sur les personnes non blanches. Enfin, ayant identifié le silence éthique et le néocolonialisme comme des enjeux éthiques importants de cette recherche, c'est-à-dire peu ou pas abordés dans la littérature empirique antérieure, nous proposons une réflexion sur les injustices structurelles et les inégalités systémiques qui traversent le travail humanitaire.

Mots-clés
problème moral, tension, dilemme, aide humanitaire, silence éthique, néocolonialisme, recherche empirique, recherche qualitative

Abstract
This study aims to empirically document the perceptions and experiences of diverse humanitarian actors, including humanitarian workers, NGO members, and humanitarian ethics experts, regarding ethical issues in humanitarian work. We conducted 15 interviews with participants, from which we extracted four categories of ethical issues: value-based tensions, resource scarcity, political considerations, and neocolonialism. The category of value-based tensions encompasses ethical issues involving intercultural conflicts, balancing care with security and collaboration, addressing emergency versus long-term care, and navigating ethical silence. Resource scarcity includes issues such as a lack of financial and material resources, insufficient preparation, and inadequate ethical resources, all of which contributing to operational difficulties. The category of political considerations highlights ethical issues related to NGO operations, including the disconnect between organizational decisions and field practices, the unequal treatment of local workers and expatriates, and instances of authoritarianism, racism, and corruption within NGOs and their partners. Ethical issues pertaining to neocolonialism highlights how Western ideologies and power dynamics persist in humanitarian organizations, manifesting in issues like paternalism, control of decision-making by white individuals, and power imbalances between NGOs and local governments, perpetuating a sense of Western superiority over non-white individuals. As well, having identified ethical silence and neocolonialism as key ethical issues in this study (i.e., undiscussed in prior empirical literature reviewed), we propose a reflection on structural injustices and the systemic inequities in humanitarian work.

Keywords
moral problem, tension, dilemma, humanitarian aid, ethical silence, neocolonialism, empirical research, qualitative research

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INTRODUCTION

Humanitarian work involves providing aid and protection to people adversely affected by crises such as complex emergencies arising from unstable political contexts, armed conflicts, and severe shortages of essential resources like food, medicine, and shelter. This work has evolved from immediate relief efforts to include long-term, meticulously monitored assistance (1-4). Humanitarian work is carried out by a diverse array of actors including national or international non-governmental organizations (NGOs), local populations, and governmental bodies, all working together to manage and alleviate crises. This has led to an ever-growing body of research and literature regarding its complexities and issues. Our previous study on the conceptualization of ethical issues in humanitarian work (5) highlighted the importance for humanitarian workers to identify and understand the ethical issues they may encounter. This understanding is crucial for assessing the associated risks and developing prevention

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and management strategies. In the current study, we define an ethical issue as any situation that potentially compromises the respect of one or more moral values or principles deemed important (6). Humanitarian workers face numerous ethical issues that are both complex and enduring (7). Research indicates that humanitarian work necessarily involves risks, especially given the high-pressure, resource-scarce environments in which workers often operate (8-13).

Our previous comprehensive review of the international literature on ethical issues in humanitarian work, conducted between 2018 and 2021, revealed a field dominated by descriptive or theoretical ethics (14). While valuable, there was a notable lack in comprehensive, empirically documented perspectives on the ethical landscape in humanitarian work; empirical research was sparse, with only 19 of the 84 articles we reviewed providing empirical data.

Table 1: Summary of empirical research on ethical issues in humanitarian work

References (2002-2020)	Country of researcher(s)	Study Design	Types of research participants
Michael & Zwi (29)	Australia / Data collection: Afghanistan	case study, document analysis, interviews with key informants, focus groups, and ethnographic coding analysis	nurses, patients
Hunt (26)	Canada	qualitative research design using a phenomenological approach	nurses, physical therapist, physician, social worker, director of a healthcare NGO
Hunt (27)	Canada	qualitative interpretive description	physicians, nurses, midwife, humanitarian NGOs human resources or field coordinators
Schwartz et al. (19)	Canada	qualitative study utilizing grounded theory methodology	healthcare professionals
Sinding et al. (20)	Canada	qualitative study, semi-structured interviews, and grounded theory analysis	physicians, nurses
Meldrum (2011) (15)	USA	qualitative research; phone interviews content analysis	physicians
Lopes Cardozo et al. (12)	USA	longitudinal	humanitarian aid workers
Schwartz et al. (13)	Canada	qualitative, in-depth individual interviews	healthcare professionals
Fraser et al. (23)	Canada	thematic and descriptive qualitative analysis in an interpretivist paradigm	humanitarian healthcare workers
Civaner et al. (4)	Turkey	qualitative approach based on grounded theory methodology	healthcare workers
Draper & Jenkins (17)	UK	qualitative research; interview analysis using Braun and Clarke's (2006) methodology	military healthcare personnel
Gotowiec & Cantor-Graae (24)	Denmark, Sweden	in-depth, semi-structured interviews; qualitative content analysis approach	healthcare professionals
Funk et al. (18)	USA, Canada / Data collection: Syria	qualitative content analysis	local and international humanitarian organizations members
Hunt et al. (11)	Canada	qualitative interpretive description	physicians, nurses, physical therapist (some with experience as NGOs policymakers)
Rubenstein & Robinson (22)	USA, Canada / Data collection: Jordan, Syria, Turkey	qualitative interview thematic analysis	management representatives from international and national NGOs, one UN agency and three independent groups
Asgary & Lawrence (16)	USA, France	qualitative descriptive approach	experienced humanitarian aid workers, from the field to headquarters
Hunt et al. (25)	Canada, USA	exploratory, qualitative interpretive description	national and international NGOs staff with experience of humanitarian health project closure
Hunt et al. (28)	Canada	exploratory, qualitative interpretive description	humanitarian policymakers and healthcare professionals
Gustavsson et al. (21)	Sweden	qualitative study using focus group discussions	Swedish nurses and physicians with international disaster healthcare experience

Table 1, which summarizes the key characteristics of these 19 empirical studies and formed the foundation of our previous conceptual work (5), here serves two purposes. First, it illustrates the limited scope of existing empirical research. Second, it highlights a crucial gap that motivated our present study: the perspectives of diverse humanitarian actors have not been sufficiently triangulated, with most studies focusing narrowly on healthcare professionals. This prior analysis convinced us of the need for more empirical research that engages with varied group of participants — including not only field workers but also NGO members and ethics experts — to develop a better understanding of the ethical issues at play.

The nineteen empirical studies reviewed comprise ethical issues pertaining to resource allocation, context, organizational and individual competency, impact and effectiveness of aid, corruption, professionalism, patient-healthcare worker relationships, emotional stress, palliative care, psychological impact, cultural and operational adjustments, high-risk settings, power imbalances, and sustainability.

Resource allocation and fair use are significant ethical issues that require tough decisions about prioritizing aid and managing often scarce resources (16-21). Ethical issues related to context involve public authorities' defensive attitudes and resistance to cooperation, the media's irresponsible coverage, and relief organizations' sometimes imperious approaches. These factors complicate effective humanitarian work and raise concerns about transparency and respect for the affected populations (4). Organizational and individual competencies also present ethical issues, including inadequate coordination and insufficient supplies, which can lead to compromised aid quality and inefficient resource use (4,16,22). Additionally, concerns about the

impact and effectiveness of humanitarian work focus on the perpetuation of dependency and inequity (16). Humanitarian work may inadvertently support undesirable governmental actions or misuse resources, complicating the identification of ethical duties (22).

Furthermore, corruption and ethical compromises, both local and systemic, can undermine the integrity of humanitarian work (16). Issues of professionalism and interpersonal responses include improper behaviour of humanitarian workers, which can compromise aid integrity (16,17,21). Patient-healthcare worker relationships encompass a range of ethical issues, such as the adequacy of healthcare workers' professional competence, the application of triage, limits of duty to care in dangerous conditions, respect for patient autonomy, and the preservation of confidentiality and privacy (4).

Humanitarian workers often face significant emotional and ethical stress due to exposure to extreme crisis situations. This stress can lead to feelings of isolation, burnout, depression, and guilt due to the moral implications of resource allocation and the emotional weight of providing or failing to provide adequate care (10,12,16,21,24). Similarly, ethical issues in humanitarian palliative care involve balancing life-saving treatments and alleviating suffering, causing moral distress among healthcare providers who struggle to ensure dignity for dying patients while managing limited resources, systemic constraints, and cultural sensitivities (10,25).

Cultural and operational adjustments further complicate ethical issues, especially in high-risk settings. Here, humanitarian workers must navigate operational hurdles and cultural differences while managing their ethical implications (17,21,26). In such settings, direct attacks on healthcare facilities, border closures, and access restrictions force workers to balance safety and care obligations (18,21,22). Ethical issues pertaining to power imbalances and cultural sensitivity require respectful and effective interventions. Humanitarian workers must manage their influence over program priorities and interactions to respect local cultures and avoid perpetuating colonial dynamics, ensuring mutual respect, and understanding in high-risk environments (17,27). Lastly, ethical issues concerning the sustainability and long-term impact of humanitarian work involve ensuring aid quality and sustainability, determining appropriate standards, and managing transitions responsibly to sustain benefits post-closure (28,29).

Given the dearth of empirical research, particularly studies that triangulate the views of different humanitarian actors, further investigation is required to facilitate a more nuanced understanding of ethics in this field. The reviewed empirical literature, as summarized in Table 1, has primarily focused on the experiences of healthcare workers and, to a lesser extent, NGO members. We have not found the perspectives of humanitarian ethics experts empirically documented. To address such blind spots, our study adopts a multi-perspective approach, triangulating the insights of humanitarian workers, NGO members, and humanitarian ethics experts. We specifically sought to engage individuals with diverse knowledge and experience, from on-the-ground practice to administrative oversight and academic reflection. We thus aimed to build upon the existing literature by providing a richer, more comprehensive empirical account. With these considerations in mind, we conducted an empirical qualitative study to answer the broad question, "What are the ethical issues in humanitarian work?", documenting the perceptions and experiences of a heterogeneous group of humanitarian participants.

METHODS

This section presents the methods used for the research in six parts. First, we present and justify the research design, then describe the sampling methods used to form the study sample, as well as the methods employed to recruit study participants. Subsequently, we specify the data collection and data analysis methods we employed. Finally, we outline ethical considerations.

Research design

Given the paucity of empirical research to date on the ethical issues raised by humanitarian work (14), and the scarcity of empirical studies in this field that have documented the cross-perceptions of different humanitarian actors, an inductive qualitative design was chosen (30,31). Since the phenomenological design is recommended for documenting the perceptions of various actors regarding the ethical issues arising from diverse practices (31), a descriptive phenomenological design inspired by Husserlian philosophy guided the present study (32,33).

Sampling

A purposive sampling approach was employed (34). To ensure a rich, varied, and comprehensive perception of the investigated phenomenon, a triangulation of sources was decided upon (35). This involved recruiting participants with diverse and complementary characteristics, particularly considering the social roles they occupy in the specific context of humanitarian work. Given that ethical issues may be perceived and experienced differently depending on an individual's social role (36), and that few empirical studies to date have opted for triangulation of their sources, the sampling strategy aimed to capture this diversity. Thus, three types of participants were sought: 1) humanitarian workers; 2) members of a humanitarian NGO; and 3) experts in humanitarian ethics, i.e., academics, philosophers or ethicists who teach humanitarian ethics, research humanitarian work or are considered thinkers with a specialization in humanitarian ethics.

Following Thomas and Polio's (37) recommendation to recruit between six and twelve participants to ensure data saturation when using this research design and taking into account that our sample would be heterogeneous, a number between nine and fifteen participants was targeted to ensure data saturation, i.e., between three and five participants per category. This meant recruiting three to five humanitarian workers, three to five NGO members and three to five humanitarian ethics experts. Finally, regardless of their role, to be included in the study, all participants had to be able to speak and understand English or French and had to be willing to take part in the study.

Participant recruitment

Several strategies were used to recruit participants. For humanitarian workers and NGO members, emails were sent to various NGOs to gauge their interest in participating in the study. To recruit humanitarian ethics experts, emails were sent to academics, philosophers, and ethicists known for their expertise in the field of humanitarian ethics, based on their reputation and published work on the subject. Additionally, individuals known to this research team members — whether humanitarian workers, NGO members, or ethics experts — were approached to participate in the study. Finally, participants were invited to identify others who might potentially be interested and share these contacts with the research team.

Data collection

Two tools were used for data collection: 1) a sociodemographic questionnaire; and 2) semi-structured qualitative individual interview guides designed specifically for this study. English and French versions of both documents were available, according to participants' preferences. The socio-demographic questionnaire collected data to describe the sample. Interview guides contained the same set of questions but were adapted to the specific role of the participants. This customization ensured that each question was relevant to participants' daily realities. When participants were contacted, they were asked in what capacity (role) they wished to take part in the research and agreed with the research assistant on a date and a time to take part in the interview.

Interview guides comprised two parts: an introduction and a section on ethical issues. The introduction consisted of general questions designed to put the participant at ease. For example, "Tell me what a typical working day is like for you". The section on ethical issues was designed to capture participants' perceptions of the phenomenon under study through questions such as these: "Tell me about any stories you've experienced in your humanitarian work that involve, in your opinion, an ethical problem or issue? In your opinion, what are the main ethical issues in humanitarian work? Please give examples." Finally, although some interviews were conducted in person, most were conducted online or by phone. Interviews were digitally recorded so that verbatims could be transcribed in full. Interviews lasted between 40 and 120 minutes, depending on the participants, with an average duration of 90 minutes.

Data analysis

Data collected via socio-demographic questionnaires were subjected to simple descriptive statistical analysis (i.e., totals and averages). The semi-structured interviews were analyzed qualitatively, following the steps proposed by Giorgi (38) to achieve a Husserlian phenomenological reduction. After collecting and recording the participants' narratives, research assistants transcribed the interviews in their entirety. Repeated reading of the verbatims enabled a team of analysts to draw up a synopsis, i.e., an initial extraction of the units of meaning, for each of the interviews. Each synopsis was then re-read and commented on by a second team of analysts. A third team of analysts analyzed the final version of all the synopses and verbatims. This team brought together all the analyses to generate and organize the final and unified units of meaning emerging from the qualitative narrative data. Given that several interviews were conducted in French, after full transcription of participants' narratives these were translated to English for publication purposes.

The final, unified units of meaning were organized into broader themes. This was an inductive process, grounded in the data itself, where we carefully compared and contrasted the verbatims from all participant interviews to identify recurring patterns and core concepts. To ensure both methodological rigour and clarity, and inspired by sociological approaches that analyze phenomena at different levels (39), we structured the resulting themes to reflect three distinct levels of analysis: the micro-level (individual, pertaining to issues experienced directly by individuals, such as value-based tensions), the meso-level (organizational, pertaining to issues related to organizational structures and practices, such as resource scarcity and political considerations) and the macro-level (structural, pertaining to overarching ideological and systemic issues, such as neocolonialism). This multi-level framework allowed us to present the findings in a structured manner, moving from the more personal experiences of humanitarian actors to the broader systemic forces that shape the ethical landscape of their work.

Ethical considerations

Before beginning participant recruitment, the principal investigator obtained ethical certification from the Comité d'éthique de la recherche avec les êtres humains of the Université du Québec à Trois-Rivières (UQTR). All members of the research team signed a confidentiality agreement. All research participants signed the consent form after reading the research information sheet, thus ensuring their free and informed consent.

RESULTS

This section presents the results of our study in two subsections: 1) a description of the study's participants, and 2) the ethical issues discussed.

Participants

This study included fifteen (n=15) participants, of whom ten (n=10) identified as female and five (n=5) as male. Participants' ages ranged from 28 to 63, with an average age of 35. The most frequent age for participants was 62 (20%), and over 50% (n=8) of participants were over 40 years of age. Moreover, 80% of participants were white (n=12) and most (n=12) were born in Western countries, predominantly Canada (n=7), while others were born in Asia (n=2) or Africa (n=1). Participants had occupied different humanitarian roles: humanitarian workers (n=8), ethics experts (n=4), NGO members (n=3). Of the humanitarian workers interviewed, five (n=5) were in nursing or other healthcare professions and three (n=3) were healthcare professional interns, and all NGO members worked in development aid. As for ethics experts, they had theoretical perspectives informed both by their hands-on experience in humanitarian field operations and by their relations with other people who do such work. Participants had been involved on average with at least 2 organizations, with 2 participants having worked with more than 6. The humanitarian work experiences ranged from 0.17 years (2 months) to 35 years; 40% of participants had less than 5 years of experience while 20% had more than 25 years of experience. In terms of education, 33% (n=5) of participants had doctorates, 27% (n=4) had bachelor's degrees, and 13% (n=2) had pursued postdoctoral studies; other participants (n=4) had qualifications including master's degrees, diplomas of specialized higher studies (DESS), certificates, and diplomas of college studies (DEC). Finally, twelve (n=12) participants have some knowledge of ethics, and three (n=3) do not. Nine (n=9) participants with ethics knowledge declared having taken one or many university courses entirely dedicated to ethics (n=6), having completed a few hours or days of ethics training (n=2) or holding a university degree dedicated to ethics (n=1).

Ethical Issues

This section groups our findings into four distinct themes of ethical issues arising in humanitarian work: 1) value-based tensions; 2) resource scarcity; 3) political considerations; and 4) neocolonialism (Table 2). These themes broadly encapsulate the ethical issues in humanitarian work on the micro-level (i.e., individual issues), the meso-level (i.e., organizational/institutional issues) and the macro-level (i.e., political and ideological issues). We discuss each in turn.

Table 2: Ethical issues in humanitarian work according to participant perceptions

Value-based tensions	Resource scarcity	Political considerations	Neocolonialism
• Intercultural value conflicts • Care versus collaboration • Ethical silence • Emergency versus long-term care • Care versus security	• Lack of preparation • Lack of ethical resources • Lack of financial and material resources	• Distance between organizational decisions and field practice • Asymmetry between local workers and expatriates • Authoritarianism, racism, and theft by NGOs and partners	• Paternalism, myopia, and white saviour complex • White people controlling decision-making positions • Power imbalance between NGOs and local governments

1. Value-based tensions

The theme of value-based tensions comprises ethical issues experienced by humanitarian workers in the field. They may arise in international missions, in NGO administrative offices, or in academic settings. Such issues involve making difficult decisions between conflicting values or requirements of the profession. In analyzing the data from the interviews, four concepts of ethical issues pertaining to value-based tension emerged: A) intercultural value conflicts; B) care versus protection of workers (NGO); C) care versus collaboration; D) emergency versus long-term care; and E) ethical silence (Table 3).

Table 3. Ethical issues related to value-based tensions

Units of meaning	Participants who discussed the issue
A) Intercultural value conflicts	P1, P2, P3, P4, P5, P6, P8, P12, P13
B) Care versus collaboration	P1, P2, P5, P14
C) Ethical silence	P1, P2, P4, P5, P12, P13, P14
D) Emergency versus long-term care	P1, P2, P4, P14, P15
E) Care versus security	P1, P2, P3, P4, P14

A) Intercultural value conflicts

Humanitarian workers often deploy in emergencies, which can range from war zones and disaster-stricken areas to regions affected by pandemics. When humanitarians work outside their home country, conflicts may arise between their values and those of local cultures. Such value conflicts may also arise between local NGO partners and international workers. Nine study participants highlighted the need to navigate intercultural value conflicts. For instance, one participant noted a significant ethical issue regarding local perceptions of sexual violence and the refusal of pregnancy termination for rape victims by local staff:

> *The final ethical dilemma is the different cultural perception of [...] people who are victims of sexual violence. In our team, we had a local staff who saw sexual violence in a certain light and refused, for example, to terminate the pregnancy of a woman who had been raped. There were obviously a lot of tensions concerning values and the status of women comparable to livestock in certain countries* (P1).

Another participant discussed the difficulty of respecting local culture while addressing practices perceived as unacceptable. This can lead to irreconcilable value conflicts, with colleagues insisting that such practices are part of the local culture, making discussions nearly impossible:

> *[...] how can we both assert respect for culture, and at the same time assert that there are practices that are not acceptable [...]. But there are a lot of misunderstandings here, and I've had practically impossible discussions with colleagues who said: "No, no, we won't get into it, it's part of the culture." A conflict of values that's hard to reconcile* (P2).

One participant also emphasized the need to set aside personal values for professional conduct:

> *You must put your own values aside [...]. I can have a very clear opinion on abortion, for example, but if I allow my perception to colour my speech, well, then I'm no longer being professional* (P8).

Conversely, another participant highlighted the operational needs of a hospital during Ramadan, critiquing the myopic view that could impede patient care, which should always be the top priority:

> *Like this is a hospital that has to run regardless [of Ramadan]. So, they had this very, like, I would say this myopic view of what is right or wrong. The patient care and the functioning of the hospital is priority number one* (P12).

Ultimately, then, intercultural value conflicts in humanitarian work require balancing respect for local cultures with addressing perceived practices and maintaining professional conduct.

B) Care versus collaboration in a context of corruption

Humanitarian NGOs often face ethical issues when operating in regions governed by local powers whose values and ways of proceeding may conflict with their own. To that point, four participants discussed the ethical issues arising from the need to collaborate with local authorities or, in some cases criminal organizations, to deliver essential care.

One participant noted the disproportionate allocation of government budgets, greater parts of it directed towards military expenditures than towards healthcare. Thus, NGOs were required to fill the gap:

> *Invariably, as a medical NGO, you end up providing the healthcare services that the government should be offering its population* (P1).

Another participant pointed to the prevalence of governmental corruption encountered by NGOs:

> *I've worked with NGOs that were very aware, among other things, that there was a lot of corruption at government level, that certain departments were supposed to hand over funds to us but weren't doing so* (P5).

Finally, another participant addressed the extreme measures required to operate in certain areas controlled by armed gangs. They raised a critical question regarding the ethical implications of engaging with such groups:

> *To enter these neighbourhoods, you must collaborate with armed gang leaders. Do we accept to engage, to deal, and to collaborate with armed gangs?* (P14)

Overall, participants' insights revealed that the provision of care often involves compromising with local powers that may not necessarily align with the NGOs' values and ways of working.

C) Ethical silence

Ethical silence, which corresponds to the tendency of a person to keep their ethical concerns to themselves for various reasons, may arise from complex reasons such as fear of personal consequences, notably job loss, and awareness of the overall benefits that NGOs provide despite their flaws. Workers may withhold reporting illegal or questionable activities due to the potential repercussions on them or others. Seven participants discussed this issue.

For instance, one participant explained that:

> *As far as ethical silence is concerned: for some years now, certain employees have been aware of a certain organized system of theft of medical equipment but were unable to denounce the situation. Because it put them in danger* (P1).

Similarly, concerns about losing one's job and facing negative judgments can suppress voices, especially in performance-driven organizational environments:

> *But of course, there was also the question of losing one's job, of negative judgment. That's a concern that's becoming very important in organizations where management styles are very much based on performance. [...] And that translates into isolation, ethical silence, or silence altogether* (P2).

Further, another participant pointed out that people who witness questionable management styles or decisions often remain silent to maintain their positions, despite recognizing irregularities:

> *I have been locked in a lot of bureaucracies for the last 5 years, rather than in the headquarters, rather very operational. I can see that in headquarters, I can see people keeping their jobs as they're not speaking out about often [authoritarian] management style or decision-making that seems strange to them or whatever* (P4).

Another participant (P5) explained that this silence was also prevalent when corruption was involved, with individuals refraining from speaking out due to fear of retaliation, such as repercussions on family members working in government or on personal benefits.

Moreover, one participant described how the hierarchical structure within NGOs can discourage whistleblowing:

> *Let's say local staff confide in you that such-and-such a person is doing malpractice, either stealing or abusing, sexual intimidation, and then not being able to talk about it [...]. That's right, because managers, at least at that time, weren't open to it. And even taking it up with the general manager was like bypassing the managers. In the end, there was a situation that went on for years, that everyone knew about, and nothing was done about it for a long time* (P14).

Additionally, another participant explained that international workers sometimes had to silence themselves to avoid conflicts or repercussions from host governments:

> *Sometimes […] we have not been able to speak out vey openly about our concerns about the Bangladesh government's sort of management of things, because of concern that they might not accept anymore visas or like withdraw NGOs or whatever* (P12).

These excerpts show how ethical silence can result from a combination of fear, external pressures, and sometimes problematic organizational cultures, which discourage workers from speaking out.

D) Emergency versus long-term care

Five participants also identified ethical issues arising from the need to prioritize between emergency and long-term care. Humanitarian NGOs typically operate with specific missions and may be active in the field for prolonged periods. However, when emergencies occur, immediate responses often become prioritized. This can result in the neglect of non-emergency issues, either because they fall outside NGOs' defined missions or due to limited resources, leading to a significant divide between emergency response and long-term care.

For instance, one participant noted the frequent challenges faced by the NGO she was working for at the time:

> *[There is a] difficulty for [this NGO] missions in managing chronic illnesses. Diseases such as diabetes, hypertension, non-infectious diseases that are still in their early stages [and] certain cancers. Of course, these are fairly typical cases* (P1).

Participant 4 highlighted another common issue: whether to prioritize long-term health support for a few people with chronic diseases or to focus on more immediate primary health care programs. Additionally, both participants 14 and 15 pointed out that in emergency situations, primary health care is often neglected, which can lead to deaths from other causes. Indeed, participant 14 expressed that:

> *It's classic to go into an emergency situation, but forget to provide primary health care, so people die of other things. We take care of the Ebola patients, and then we don't take care of other patients* (P14).

Overall, participants explained that humanitarian work unfolds in a complex ethical landscape, where urgency often overshadows the equally critical need for long-term disease care.

E) Care versus security

Humanitarian NGOs often need to operate in situations that require them to determine how much risk is acceptable for humanitarian workers to take in order to provide care. This issue is acute for field team leaders who must balance operational tasks with safety concerns. Five participants brought up this issue.

For instance, one participant underscored the extreme risks involved in their work, noting that their organization faced severe threats, assassinations, and kidnappings:

> *We've had several assassinations [...], but also hostages [...]. We currently have someone who has been a hostage for five or ten years, so these are extremely serious cases* (P2).

Another participant discussed the conflict between the responsibility to protect one's team and the imperative to meet the needs of the affected population:

> *It can be a conflict between the value of staff security, where you're wanting to protect your own team, and the good thing of going out and trying to give a food distribution to someone, but it's dangerous* (P4).

Similarly, participant 14 noted the tension between practicality and ethics in the tough choices humanitarian workers often have to make:

> *A major ethical issue, particularly as coordinator, is whether we are ensuring the safety of our staff versus meeting the needs of the population. There have been times when we've met people who've been in accidents on the road, and we've been told that we wouldn't stop to help them if they had Ebola. You're driving around in a car with the Red Cross logo on it, you have an accident and you drive right past it* (P14).

As reported by participant 3, ethical issues also extend to the personal sacrifices made by NGO workers, who must weigh their responsibilities to their families against their commitment to their mission, which adds another layer of complexity to the decisions about how much risk is justifiable in such perilous settings. Overall, participants noted the challenges of ethical issues faced by NGOs as they navigate the dual imperatives of providing care and ensuring staff safety.

2. Resource scarcity

The theme of resource scarcity encompasses various resource inadequacies that may arise in humanitarian work. We grouped these under the following ethical issues: A) lack of financial and material resources, B) lack of preparation, and C) lack of ethical resources (Table 4).

Table 4. Ethical issues related to resource scarcity

Units of meaning	Participants who discussed the issue
A) Lack of preparation	P1, P3, P4, P7
B) Lack of ethical resources	P1, P2, P5, P6, P11, P12, P14
C) Lack of financial and material resources	P1, P2, P3, P4, P5, P6, P8, P10

A) Lack of preparation

Four participants described their general lack of preparation for humanitarian work. As stated by participant 14: "There's not enough preparation". Specifically, they observed a significant gap between the predominantly theoretical training they received prior to their field experiences, and their actual needs. Such gaps often leave humanitarian workers without the appropriate strategies or knowledge necessary for effective operations. This can also lead to distress among workers and, at times, jeopardize the mission's success.

For instance, one participant discussed the clash between ethical ideals and reality in the field:

> *That's how I was trained, according to a certain code of ethics. And then we arrive [in the field], with very high standards in contexts totally different from ours [...]. So, there are clashes, with different capacities and resources* (P1).

Similarly, another participant mentioned that:

> *One of the biggest issues is […] the lack of training for practitioners. Either responders or researchers working […] try to deal with the ethical issues, [but] as a result of that [the lack of training] they're often […] left off to deal with them on their own or to maybe talk about [them] informally* (P3).

Finally, one participant explained that knowing how to prioritize and distribute resources was not easy in practice:

> *[…] they know how to do food distribution, they know technically what are a good practice and a bad practice in a food distribution, but it is very troubling to them which group of people they should prioritize in this situation because of various factors that are not about nutrition. They're about politics, access, capability, whatever* (P4).

A lack of practical preparation can leave humanitarian workers ill-equipped to handle ethical issues and operational challenges.

B) Lack of ethical resources

The lack of ethical resources described by participants include three different sub-categories: lack of a place to speak out (identified by six participants), lack of a clear ethical authority (three participants), and lack of standardized paths for decision-making (two participants).

First, some participants noted a significant gap in the availability of formal spaces dedicated to shared ethical reflection. Indeed, one participant noted the spontaneous emergence of such spaces within specific teams or under certain managers, but explained that these were not a standard feature across organizations:

> *Participant: [...] there's a real need to open up spaces, spaces that don't spontaneously exist, for shared ethical reflection, never alone, but in a group, to set up a deliberation group and a deliberation process.*
>
> *Interviewer: Did you say that these are spaces that don't currently exist?*
>
> *Participant: They exist spontaneously in many places. They often exist on a team's own initiative, from a manager, the team leader, etc., but I'd say at the ICRC or what I've seen in organizations [...] it doesn't exist. So, it's done in a sort of cobbled-together way, and when it's done well, it's great, but when it doesn't exist, there's always the risk of authoritarian drift* (P2).

Participant 5 further expressed that there were not more spaces to speak about ethics in academic settings than in the field:

> *[...] because I don't belong to an organisation, I don't have a place to speak. I tried to develop one at the [name of the university] when I worked there [...] but because humanitarian research and practice were not valued [there], it was never taken up. [...] So I wasn't able to create that space [and] within the organisations where I worked, there wasn't that space [...]* (P5).

Finally, one other participant noted that the consistent lack of designated spaces for ethical dialogue makes it difficult to foster a collective ethical environment:

> *Often we don't have that much space to talk about it, and that, I think, is a problem, because I think everyone needs to talk, at least to be heard, to express themselves* (P14).

Second, the ambiguity concerning who holds ethical authority in decision-making processes was also identified by three participants. These participants expressed confusion over whether decisions should be made internally within a group, or if they should rely on external authorities or donors. Namely, such confusion is compounded by the absence of clear guidelines on who should make these ethical decisions, as mentioned by participant 5:

> *And so, when there are ethical difficulties within a vulnerable group, people often tend to say, "Who can solve this situation for us?" They won't have the reflex to say: "We have the means; we can give ourselves the tools to resolve the situation." So [they'll] look for an ethical authority outside the group, and there's a real confusion about who can make an ethical decision. Can we make it ourselves? Should we defer to someone else, should we defer to the funders? And the guidelines for ethical authority are very vague* (P5).

The issue also extends to communication of sensitive and culturally relevant decisions across different contexts and individuals:

> *You know, there are still questions about who decides and how decisions get made, and in particular how are delicate and difficult culturally sensitive issues [can be] communicated across contexts and across individuals, or among individuals* (P6).

Third, two participants found the lack of standardized procedures for ethical decision-making to be particularly problematic. Participant 12 described the difficulty in determining when decisions should be made independently or when higher-level consultation is necessary:

> *[…] the line between the point when I can decide independently for my staff or with my staff versus when I need to consult my bosses is sometimes grey. […] It's an area that I've found complicated with [this NGO]. […] I've noticed that it's very hierarchical and I'm not used to that. […] I wouldn't say [this NGO] is formal, but there is this sense of like when you are deciding, you need to consult with the right people, and you need to keep the right people in the loop. But […] there's also this sense of [not wanting] to bother these people with these basic questions if I don't need to. […] It's probably one of the most stressful things of my job to be honest, navigating, should I make this decision on my own or not* (P12).

Participant 1 noted the inconsistent and potentially inequitable decision-making process:

> *We really did decide on an ad hoc basis. Case by case. [...] Some cases yes, some no, depending on how you saw the situation. I thought it was a bit unequal. On what basis?* (P1)

Overall, participants underlined the lack of structured resources for ethical deliberation and authority, as well as a need for clearer and more consistent decision-making processes in organizational settings.

C) Lack of financial and material resources

One of the ethical issues most frequently arising in this study, and discussed by eight participants, was the continuous lack of financial and material resources. Given the enormous demands for humanitarian work, available resources often seem insufficient. Participants highlighted the ethical issues which such scarcity imposes.

For instance, as participant pointed out:

> *What was difficult from an ethical point of view was that, first of all, the quantity of international equipment was limited. It was never at full capacity* (P1).

Similarly, participant 2 mentioned the constraints not only of material resources but also of time.

The challenge of insufficient resources forces humanitarian workers to make tough ethical decisions. As participant 3 noted, this often involves deciding how to distribute the limited resources:

> *[…] insufficient resources to address the problems and the challenges that they face and so often we'll have to make ethical decisions around what they can address and how do they address it and so on to meet the numerous* challenges (P3).

In fact, rationing and making allocation decisions was described by participant 4 as:

> *[…] one of the most profound areas is rationing, actually how we make decisions around the allocation of inevitably limited and probably insufficient resources* (P4).

To this point, participant 5 underscored the scale of the issues humanitarian workers encounter in the field compared to the scant resources to which they have access.

Finally, participant 6 reflected on how resource allocation issues arise almost systematically:

> *All of the stories would probably be quite different if there wasn't scarcity of access to treatments or a scarcity of access to personal* (P6).

3. Political considerations

Under the theme of political considerations, we group the ethical issues that deal with NGOs, their decision-making structures, and the way they operate. These are political considerations because, although the issues addressed by participants involve specific individuals or management practices, in reality these issues refer to deeper social and ideological questions. This theme comprises three ethical issues: A) distance between organizational decisions and field practices, B) asymmetry between local workers and expatriates, and C) authoritarianism, racism, and theft by NGOs and partners (Table 5).

Table 5. Ethical issues related to political considerations

Units of meaning	Participants who discussed the issue
A) Distance between organizational decisions and field practices	P1, P5, P6, P8, P11, P12, P13
B) Asymmetry between local workers and expatriates	P2, P3, P4, P6, P12, P13, P14
C) Authoritarianism, racism, and theft by NGOs and partners	P1, P2, P4, P5, P10, P14

A) Distance between organizational decisions and field practices

In many NGOs a disconnect often exists between organizational decision-making centres and the realities faced by field workers. This gap, which was described by 7 participants, is highlighted by discrepancies between on-the-ground needs and the strategic decisions made at the headquarters, which are often remote from the intervention areas.

For instance, one participant, in discussing challenges related to medicine procurement policies with the NGO she worked for, highlighted the distance that can develop between policies and how things actually work in the field:

> *Treatments and medicines were not always ordered or available. As far as the mission was concerned, I was working as a Canadian expert at the operational centre, but for the NGO operational centre. At the Operations Centre in [name of city]. With them, they didn't necessarily agree to buy medicines locally. It had to be of a certain quality, tested. When we could have found local medicines that have an impact on glycemia. You know, there's a lot of work to be done in this area* (P1).

Another participant described how bureaucratic challenges can overlook pressing local needs:

> *I work in South Africa, and my grants are to support AIDS orphans. [...] When I arrive in the field, what I realize is [...] that there is one group that is even more vulnerable: the children who still have their parents, but whose parents have developed all the pathologies associated with AIDS. [...] And because of the nature of my funds, I don't have the right to support these children, because technically, they're not orphans* (P5).

To this point, participant 5 mentioned "ethical myopia", which is the tendency of a person or an organization to impose their values on others or to assume that they share them, to discuss how some Western NGOs fail to engage with communities and thus hinder effective intervention and support:

> *[Ethical myopia is] very common in many Western NGOs, which don't bother to carry out field consultations. So there's a presumption that everyone agrees on fairness, that everyone agrees on the treatment of women, when that's absolutely not the case. People haven't checked what cultural mechanisms are in place on the ground* (P5).

One participant recounted instances of bureaucratic absurdities where field workers were unable to act in critical situations due to strict adherence to organizational rules:

> *There is bureaucratic nonsense [...] that is completely disconnected from the field and the needs of the field. I've seen cases where someone is literally dying, someone is dying between two street corners, and the [NGO] dude isn't allowed to do anything for X reason that I don't understand, that's beyond me. The guy's really pissed off, he wants to do something, but he can't. If he does, he could lose his job* (P11).

Finally, one participant discussed the complexities of using potentially lower-quality medications when that is all that is available:

> *The tricky part is that I just got an email from my colleague that our headquarters has concerns about the quality of this morphine, because it's pretty used in Bangladesh and they have actually said that we can't use it because they felt like it's not high-quality medication. […] I mean, it's not my decision, but I sort of a question: is a slightly less quality medication better than none?* (P12).

Participants underscored the tension between centralized organizational decisions and the dynamic, often critical conditions encountered by humanitarian workers in the field. Such disconnections can impede effective response strategies.

B) Asymmetry between local workers and expatriates

Seven participants mentioned a disparity in the treatment of local humanitarian workers and expatriate humanitarian workers within NGOs. As mentioned by participant 3, this issue reveals that local staff often receive inferior treatment compared to their international counterparts, who are provided with better accommodations and vehicles, and better resources or security.

One participant noted a significant evolution in employment contracts and professional status, which historically exhibit almost unnoticed discrimination between local workers and expatriates:

> *An enormous amount of work has been done [...] on employment contracts and professional status involving discrimination that was almost unnoticed [...]. Local employees and expatriates. Expatriates from Switzerland, Canada, France, etc. or Africans who go to Asia or Asians who come to Africa and who have a status, at the time it was a contract from the head office and there were a certain number of rules that were not at all the same as for local employees, with a contract with the local delegation. But that's changed. We now have a much more homogeneous system, which also allows us to move from one status to another* (P2).

Despite such improvements, power asymmetry remains a pervasive issue. Indeed, participant 6 explained that expatriates often reside in secure, gated compounds with personal transportation to work, in sharp contrast to that of local workers who may walk several kilometers to the same workplace. Similarly, participant 12 emphasized the privileges some workers have compared to others:

> *There are different layers of privileges there. Like this is why it's complicated, like it's not just that there's the oppressed group and the privileged group in this context. There's me that has the most privilege, you know like the international staff, even among us, there's like some international staff who are African, we have a couple of Cameroonians and Kenyan colleagues who face discrimination in Bangladesh that I don't experience. So even among international staff, there's this dynamic. And we often discuss this, like "oh of course he got held up at the border way more than I did." Like there's an awareness of we don't all have the same experiences. But they still have more access to resources and power than a lot of our national staff do. But then, within even a national staff, there's people from Dakar, like our doctors or nurses who are brought in externally. They are more highly educated then our staff that are hired from the local community. They have higher salaries and all the stuff, but they often feel lack of security* (P12).

This participant described the layered privileges in humanitarian work, not only between locals and internationals but also among the internationals themselves.

Moreover, one participant noted that local personnel sometimes experienced greater risks without corresponding recognition or protection: "[...] it was only local staff doing the most dangerous things" (P14). The discrepancy extends beyond individual treatment to broader social implications, contributing to a class difference within the humanitarian field. In fact, one participant described what they saw as elitism at both the international and national levels:

> *There is a sort of humanitarian elite and national local levels as well and to become member of a humanitarian organization and you're paid the biggest salary and government authorities and local people. You can end up in that situation of class difference* (P4).

This indicates that becoming a member of an NGO could significantly elevate one's social and economic status, often creating stark status contrasts between humanitarian workers, as participant 13 explained:

> *There's a big power difference of course between people. The humanitarian experts, I think, in general being much more flexible and, you know, have their security, etc. And people there, you know, like my health promotion team in Congo, there was the end of the mission and now I'm faithful, I remain in contact with these people, most of them don't work anymore* (P13).

Overall, participants expressed that power differences and layers of privilege challenge the equity of treatment between local workers and expatriates in humanitarian work.

C) Authoritarianism, racism, and theft by NGOs and partners

We group under malpractice from NGOs and their partners those behaviours that are unprofessional or even illegal, including theft and corruption, racism and stigmatisation, and authoritarianism in decision-making processes. While it is not always clear who is to blame in the cases mentioned by participants, it is nevertheless clear that these cases are the result of poor professional practice and conceal some major problems.

First, with regards to theft and corruption, one participant talked about an "organized system" of medical supply theft:

> *For some years now, certain employees had been aware of a certain organized system of theft of medical equipment, but they were unable to denounce the situation. [...] I could see that the allocation of positions and promotions was arbitrary, both for us expatriates and for the national staff. If you're friends with the project manager, he's connected. Also, a lot of racism* (P1).

Another participant mentioned corruption in drug distribution:

> *[…] when we know that if we don't have access to antiretrovirals, it can often be because of corruption on the part of certain organizations that will favour certain groups, even choosing not to distribute because it's too much work. With several of my partners, even the NGOs in the field saw no problem [...] in perpetuating violence against women. Then we realize that the clinics are lying to us. This often happens, where there's a kind of reappropriation of goods that should normally be offered free of charge. The same goes for food distribution in war zones* (P5).

Yet another participant explained how corruption underlies jobs attributions in NGOs:

> *If there's funding to pay a street worker, it's likely that, unfortunately, the person who's going to get the job won't be the person […] who believes in it and wants it, it'll be the person with the most influence and the best contacts, who may be completely useless at street intervention, but that's the person who's going to get the salary because the system over there will favour that, and we're still talking about corruption and abuse of power* (P8).

Second, participants also pointed to racism and stigma within NGO operations. As participant 4 noted: "Industrious [discrimination], yeah, racism, stigmatisation, yes, in your own organisation" (P4). Similarly, participant 6 described power imbalances that reflect systemic racism and which were visible in the leadership structure of most organizations:

> *[Racism] show itself out quite clearly in the power imbalances. Just look at leadership in most organization, and I think you'll see that there's still stigma and racism associated with how the organizations are* (P6).

Third, authoritative decision-making styles of NGOs was also criticized by participants. Namely, participant 2 expressed that such "authoritarianism of decision-making" was linked to performance-focused management, and which could have dire consequences for field work:

> *[...] the question of authoritarianism [...] is very strong today. [...] It's also linked to performance-based management methods and that sort of thing. [...] Authoritarianism in decision-making, within the same organization [...] if we haven't had a real ethical debate, people soon realize that it's difficult and that it may lead to disagreements, so we're in a dilemma. If you don't have the space to discuss it, you end up with a radicalized group. [...] You have decisions that are made, but which are not supported and which, in a hidden way, people will do a little differently from what they are asked to do. There'll be double talk, there'll be reports that don't correspond to reality, there'll be practices that are a little hidden and then, […] you'll have burnouts, people slamming the door, crises in teams, all that, it happens. These are things we've come across* (P2).

However, one participant considered that a certain degree of authority was inevitable, and even beneficial:

> *In [this NGO], there's a leader, a boss, a big boss. [...] But sometimes the way he manages things borders on dictatorship. But even for me, who often has trouble with authority, I've never had a problem with him because I trust him, I trust the man, I trust his profession and his decisions. [...] It's not fair, but I can't think of a better way to make it effective* (P11).

Finally, one participant described how problems like theft, abuse, and harassment were often overlooked in smaller organizations due to internal alliances and self-protection among staff, resulting, as seen above, in ethical silence:

> *Another ethical issue [...] is very frequent. When there are internal problems, we know about them, but we can't talk about them. That's not acceptable. Situations of theft, abuse, psychological or sexual harassment, and let's keep it that way. [This NGO], which I know a lot more about, is a small organization. People protect each other. [...] What I'm talking about are problems that local people experience all the time* (P14).

Overall, participants emphasized that misconduct within NGOs can encompass various forms of unprofessional and illegal behaviour, ranging from corruption and theft to racism and authoritative decision-making.

4. Neocolonialism

Finally, the theme of neocolonialism brings together ethical issues of an ideological nature that permeate organizations and their decision-making processes. "Neocolonialism" designates here a form of domination where, although not overtly colonizing, Western white persons perpetuate an ideological superiority over non-white persons. This dynamic mirrors historical colonialism, where colonizers sought to conquer peoples who they deemed lesser, inferior, or primitive through a lens of white supremacy. In contemporary settings, this manifests as the monopolization of knowledge and power by white persons, implicitly reinforcing the idea that non-white individuals are inherently inferior or incapable (39,40). This continuity of supremacist logic from old colonial structures to current socio-political interactions is why we discuss the issues in this section in terms of "neocolonialism." Under this theme, we group the following ethical issues identified by participants: paternalism, myopia, and white saviour complex, white people controlling decision-making positions, and power imbalance between NGOs and local governments (Table 6).

Table 6. Ethical issues related to neocolonialism.

Units of meaning	Participants who discussed the issue
A) Paternalism, myopia, and white saviour complex	P2, P3, P5, P6, P7, P8, P9, P11, P12, P13, P14, P15
B) Expatriates controlling decision-making positions	P6, P12, P14
C) Power imbalance between NGOs and local governments	P3, P4, P8, P13, P14, P15

A) Paternalism, myopia, and white saviour complex

This issue was raised by twelve participants and refers generally to the often-paternalistic attitudes exhibited by Western humanitarians. Such humanitarian workers often arrive in crisis regions assuming a managerial role without adequately understanding local dynamics, expertise, or cultural norms. This approach not only results in a lack of sensitivity to local realities but also fosters ethical and cultural myopia, undermining the potential for effective collaboration.

For instance, participant 2 noted the inherent danger of paternalism when Western agencies deliver aid in crises, emphasizing the ethical issues that can arise when local initiatives and capacities are overlooked. This is compounded when organizations fail to recognize existing local systems, potentially exacerbating ethical issues, as mentioned by participant 3:

> *I think that sometimes humanitarian responses can undermine local initiatives and local capacity development. If a humanitarian organisation goes in thinking there is no system there, it just might overwhelm whatever pre-existing and that could create ethical problems through the blindness to realizing that people have some of these abilities* (P3).

Similarly, one participant mentioned the fact that some organizations focus narrowly on specific treatments without considering broader community needs, which amounts to ethical myopia:

> *So, ethical myopia definitely arises in vertical programming, where an organization sends somebody in to do expressly one kind of treatment. And then in some of the perceptions research that we've seen, the community says: "well you know, we're really grateful that you came to treat the main injustice, but actually what was really a big issue in our community is something like kala-azar," which is one of the examples that did come up in the literature. So, we're glad that the organization is here, we would wish that you would be more responsive to our priorities instead of just sending what you think is what we need* (P6).

The imposition of Western values can also manifest in discriminatory practices in the field. For instance, participant 5 described a case of unequal service provision:

> *A large international NGO that receives funding from the UN, [...] but the way they do their work in the field is to tell disabled people: "You'll only have access to services if you convert to Christianity." [...] So there's a kind of tacit inequality because of religion, gender or the clan you belong to* (P5).

The perception of Westerners as benefactors merely distributing aid without substantial engagement further complicates relationships. For instance, one participant expressed that there seemed to be a culture of expecting Westerners to take charge when arriving in the field, or having locals set their own needs aside to conform to what they felt Westerners would want:

> *When we show up in Haiti to meet our fellow street workers, they have the unfortunate cultural reflex, I think, of looking at us and saying: "Tell us what to do, you [Westerners]." We're always saying that they've been like that for 300 years, in this culture where the white man comes in and says: "Do this, this, this and do it like that," and we're always saying: "Tell us what you want and what you need," and unfortunately we realize that sometimes, as we experienced in Guatemala too, we always had the impression that they were telling us what we wanted to hear. Don't tell me what I want to hear, tell me what you want. That takes a lot of time, and it really takes the solid foundations of a trusting relationship for the person to trust you enough to dare tell you what they want and what they think* (P8).

Further, another participant described how monetary donations, though well-intentioned, did not contribute significantly to sustainable development and might reinforce stereotypes of Westerners as wealthy outsiders:

> *Whether you come to see their village where they live and just drop in to do your business and leave, it's not necessarily helpful [...]. In [name of region], they collected money and we went there to give them things. But apart from that, we didn't do much. [...] It doesn't necessarily give a good image either, in the sense that there are a lot of people who think: "Oh well, we're white people, we come to give money and then we leave." In the sense that after that, people wonder why we're seen as rich or whatever* (P7).

To that point, participant 8 even compared Western workers' behaviour to "Santa Claus" and criticized the dispensing gifts and leaving shortly after as distorting perceptions and expectations:

> *It's this sort of habit of the workers, who, before leaving, would go to the local shopping mall and buy a whole bunch of toys, crayons, stickers, all the things kids might like. Then they'd play Santa Claus for a while, and on the last day before they left, they'd start handing out presents to everyone. For me, this raised questions and ethical issues, because once again, it really distorted children's perceptions. It got to the point where we'd been there for [some days] and then some of the kids would ask us: "When you leave, what are you going to give me?" Damn, I'm here for four months, you can't wait for me to leave because you know I'm going to give you a present when I go. Before we left, we bought things that we gave to the school, school equipment that was used at the school. We didn't give anything to anyone, we were the boring volunteers. We may have hurt some children's feelings, but it doesn't work to have this sort of perception that we just turned up and were like Santa Clauses* (P8).

Participants highlighted the necessity for Western humanitarian efforts to engage more deeply and respectfully with local communities, prioritizing genuine collaboration and responsiveness to local needs over the imposition of external solutions.

B) Expatriates controlling decision-making positions

Three participants pointed to a prevailing trend within NGO operations where individuals from the Global North — often with less experience — predominantly occupy leadership and decision-making roles. This dynamic may result in the oversight of local or more seasoned colleagues who may possess greater expertise, local knowledge, and cultural understanding.

For instance, one participant noted the disproportionate amount of power and respect granted to individuals from the Western world or the Global North:

> *[…] a lot of power and authority is placed in the Westerner or the person from the Global North, who might come in with very little experience compared to what the local practitioners have. But they're treated as, you know, so much more than that, given so much more respect just because of the colour of their skin or their accent or even the badge that they're wearing* (P6).

Another participant shared a personal account, expressing discomfort with the authority they held as a relatively inexperienced white Canadian nurse managing a hospital:

> *[…] after my first mission with [this NGO, I felt] a real discomfort [about being] a very inexperienced white Canadian nurse who was the manager of this hospital, managing, you know, 50-year-old men who have been there since 20 years in that context. And I felt very, very uncomfortable with that dynamic, like the authority that I had just by virtue of what, I don't know exactly* (P12).

Yet another participant pointed out that white Western expatriates often assumed team leadership roles shortly after completing their training, despite lacking on-the-ground experience:

> *You know, expatriates, [...] Westerners, whites, who arrive, who have no knowledge of the field, they're on their first mission, they've just finished their training a year ago and they're in charge of teams. But why? Why are they all team leaders? Well, that's beginning to change, but it's still happening [...] power relations, it doesn't make sense [...]. To perpetuate that in countries [...] with a history of colonization* (P14).

C) Power imbalance between NGOs and local governments

Power imbalances often manifest due to the political and economic authority that NGOs wield over local entities. Six participants highlighted this issue, explaining how such imbalances affect ethical practices and local perceptions. For instance, one participant noted that individuals in areas targeted by research might feel coerced into participating for fear of losing assistance on critical issues like visa applications or protection:

> *[…] around the research area somebody might be asked about being involved in research and they may be really fearful that if they don't agree to be a participant in the research that they might not get help to get a visa or protection. So that would be a way that somebody might stay silent about ethical concerns that they might have for being a research participant, among other fears* (P3).

Another participant discussed the broader concept of "humanitarian power," suggesting that many involved in humanitarian efforts may not fully grasp their influence over local communities and authorities:

> *I do believe in the notion of humanitarian power, and I think a lot of humanitarian agents just don't understand how powerful they are in the face of local communities, sometimes local authorities. There are real asymmetries of power between people with hard power like guns and weapons and humanitarians who are largely soft power. There is power asymmetry between humanitarians and suffering people and between humanitarians and conflict parties, foreign parties and politicians and donors, [etc.]* (P4).

Further illustrating the complexity of NGO influence, another participant recounted the experience of a friend who volunteered in Peru through an initiative funded by a Canadian mining company:

> *[...] I also have a very good friend who went to Peru as a volunteer engaged by [this NGO] to work in a village where there was a Canadian mining company. In the end, it was the Canadian mining company that gave [this NGO] the money to send a Canadian volunteer to help the people with the economic and social problems directly caused by the impact of the mine's installation in the area. It's a chicken-and-egg situation. Why am I here? I'm here to make a good impression, to make the mining company look good, which is subsidizing a volunteer to be here, when we know that they make billions in profits every year, and that they have absolutely no concern for environmental standards in these countries* (P8).

This participant described a paradox, where the volunteer's presence served to enhance the public image of the mining company, despite its ongoing extraction of vast profits and disregard for local environmental standards. Lastly, one participant touched on the substantial impact of NGOs in certain countries, raising questions about their accountability:

> *Because we're taking up so much space, NGOs are taking up so much space in certain countries, they're having such an impact that is it always the same thing? Are we just doing what we can without much accountability? It's time to rethink the responsibility of organizations* (P14).

Power imbalances between NGOs and local governments significantly affect ethical practices, local perceptions, and raise concerns about accountability and coercion in humanitarian efforts.

DISCUSSION

The purpose of this study was to document the perceptions and experiences of diverse humanitarian workers, ethics experts, and NGO members regarding ethical issues in humanitarian work. The interviews revealed a complex ethical landscape characterized by value-based tensions, resource scarcity, political considerations, and neo-colonialism. Below, we present a comparison between our findings and previous literature, a philosophical reflection on humanitarian work and structural injustices, and an overview of the study's strengths and limitations.

Comparison with literature

Prior empirical literature and interviews with the participants of our study highlight similar ethical issues concerning resource scarcity and allocation, corruption, cultural concerns, risks for workers, power imbalances, and long-term care and sustainability. Indeed, both prior literature and our study participants discuss the challenges of managing scarce resources effectively and ethically in the face of extensive needs. While the literature emphasizes the difficulties in prioritizing aid and managing scarce resources, often leading to tough decisions about who receives limited resources (16-20), our participants express that humanitarian workers often face a lack of preparation, lack financial and material resources, and lack ethical guidance, all of which exacerbate the issues pertaining to resource allocation and ethical decision-making in the field.

Further, issues pertaining to corruption and professionalism were highlighted for their impact on the integrity and effectiveness of humanitarian work. Prior empirical literature has explained how corruption can undermine humanitarian efforts, with improper behaviours of workers compromising aid integrity (16,17). Similarly, our participants discussed the ethical issues arising from the need to sometimes collaborate with local authorities or criminal organizations to deliver essential care. This could involve navigating governmental corruption, disproportionate budget allocations, and the ethical implications of engaging with armed groups.

Cultural concerns and operational challenges are also a source of ethical issues, in both the reviewed literature and our interviews. If the reviewed empirical literature discusses the need for humanitarian workers to navigate operational hurdles and cultural differences while managing their ethical implications in high-risk settings (17,22,26), our participants went deeper into specific conflicts, such as intercultural value clashes, the tension between respecting local customs and adhering to professional ethics, and the challenges of addressing unacceptable practices while maintaining respect for local cultures.

Speaking of risks and tensions, the prior literature we reviewed described the ethical issues faced by healthcare workers in conflict zones, including direct attacks on facilities, border closures, and the psychological burdens of making life-and-death decisions (18,22). Our participants echoed such concerns by highlighting the extreme risks, threats, and sacrifices at times involved in their work, and the ethical complexities of ensuring staff safety while meeting the needs of affected populations.

Power imbalances were identified as a significant ethical issue, with prior literature discussing the importance of managing influence and avoiding colonial dynamics in humanitarian interventions (17,27). To this point, participants addressed systemic issues like control over decision-making, racism, and the impact of these imbalances on local communities. They highlighted the unethical practices of NGOs and partners, such as theft, corruption, and authoritative decision-making, and the significant impact of NGO influence on local governments and communities.

Lastly, ethical issues concerning the sustainability and long-term impact of humanitarian work were discussed, focusing on the balance between immediate emergency interventions and sustainable healthcare solutions. Prior literature emphasizes the need for early planning for project closure, engaging with donors and stakeholders, and ensuring the sustainability of benefits

post-closure (28,29). Participants highlighted ethical issues pertaining to having to prioritize between emergency and long-term care, noting the challenges of managing chronic diseases and the neglect of primary health care in emergency situations. They stressed the importance of addressing both urgent needs and long-term health support to ensure comprehensive and sustainable humanitarian interventions.

Beyond these similarities, our study's multi-perspective approach surfaced two critical ethical issues largely absent from the prior empirical literature that we reviewed: *ethical silence* and *neocolonialism*.

The identification of ethical silence, by participants who described the reluctance of workers to speak out against unethical practices due to fears of repercussions, job loss, and negative judgments, suggests a systemic barrier to accountability within humanitarian organizations. This silence stems from a combination of fear, external pressures, and problematic organizational cultures that discourage transparency and accountability. While prior studies have noted emotional stress and burnout, they have not empirically documented the organizational pressures that compel workers to remain silent about various issues. Perhaps the inclusion of diverse humanitarian actors with varied perspectives helped gain a vantage point from which to see this phenomenon not just as an individual choice, but as an organizational and cultural problem. This finding suggests that without formal mechanisms to break this silence, many other ethical issues may remain hidden and unaddressed.

Neocolonialism, while addressed in terms of power imbalances and corruption in previous literature, was discussed by participants as the perpetuation of paternalism, the white saviour complex, and Western domination in decision-making. Participants noted that Western humanitarians often assumed managerial roles without understanding local dynamics, fostering cultural insensitivity and undermining collaboration. They also highlighted the disproportionate control of leadership positions by white individuals, which overlooks the expertise of non-white colleagues and reinforces power imbalances. The substantial influence of NGOs over local governments further exacerbates these ethical issues, raising concerns about coercion, accountability, and the effectiveness of humanitarian efforts. The significance here is that our study provides empirical evidence that such power imbalances are not just historical vestiges but instead active, ongoing structures that can perpetuate a sense of Western superiority. This finding challenges the humanitarian sector to confront not just its practices, but also the deeply ingrained colonial logic that continues to shape them. Participants stressed the need for genuine engagement and responsiveness to local needs over the imposition of external solutions.

Humanitarian work and structural injustices

Our findings, particularly those related to neocolonialism and the asymmetries between local and expatriate workers, strongly suggest that humanitarian work is deeply affected by structural systems of oppression. To better interpret and articulate the dynamics described by the participants, a theoretical lens can be instructive. The "coin model of privilege," developed by Stephanie A. Nixon (42), serves as a useful heuristic tool for this purpose: it is a framework that can help make sense of what the participants. Indeed, Nixon explains that societal structures inherently provide privileges (unearned advantages) to some while disadvantaging others. To illustrate, she invites seeing such privileges and disadvantages as a coin with two sides: privilege on top and oppression on the bottom. With this metaphor, she underscores that addressing structural inequities requires not only aiding disadvantaged groups but also dismantling the systems that create these disparities and inequalities in the first place. The fact that those on the top of the coin often do not realize their unearned privileges leads to a lack of awareness that perpetuates inequality, or a form of "willful hermeneutical ignorance" (i.e., the situation in which marginalized knowers develop suitable epistemic resources to […] explain their experiences[,] but […] dominantly situated knowers willfully refuse to acknowledge these […] resources" by ignoring, minimizing, mocking, or disregarding their importance (43,44). This invisibility of privilege maintains the status quo, as privileged groups may (un)consciously reinforce systemic injustices. Seeking to dismantling privileges and oppression, and to work against their invisibility requires "critical allyship", a process which, for Nixon, involves privileged groups recognizing their role in these systems, learning from marginalized groups, and actively working to dismantle oppressive structures (42).

In the context of humanitarian work, Nixon's model can help illuminate the root causes of the power imbalances and neocolonial attitudes that participants identified. Humanitarian organizations, often led by expatriates from Western countries, may unconsciously perpetuate neo-colonial practices and fail to effectively address local needs. Recognizing and addressing these structural injustices is crucial for creating more equitable and effective humanitarian interventions. Indeed, our study reveals several instances where structural injustices and the invisibility of privilege affected humanitarian work. Participants noted the disparity in treatment between local workers and expatriates, namely instances where expatriate workers received better accommodations, resources, and security. This aligns with Nixon's point about the unearned privileges held by those at the top of the coin, often leading to inequitable practices within organizations. Specifically, one participant described the discomfort of being a relatively inexperienced white Canadian nurse managing a hospital and overseeing experienced local staff. This is an example of differentially situated power dynamics, potentially fueled by privilege, where expatriates, despite their lack of experience, hold authoritative positions due to systemic biases. Additionally, participants highlighted ethical silence, where humanitarian workers refrain from reporting corruption or questionable practices due to fear of personal consequences. Such silence may in truth perpetuate existing (potentially oppressive) power structures and contribute to the invisibility of privilege, where those in positions of power may not recognize or challenge the systemic issues at play.

Nixon's coin model may be an interesting tool to develop a language aimed at better identifying and naming the structural injustices in humanitarian work, and to see that structural injustices involve more than just providing aid. Further, the model

encourages critical examination of the power dynamics within humanitarian organizations and a commitment to dismantling the systemic inequities that perpetuate these ethical issues. Nixon's approach could help develop more just and effective humanitarian practices, benefiting both workers and the communities they help.

Strengths and limitations

In terms of strengths, not only does this study enhance empirical research of ethical issues in humanitarian work, which has predominantly been theoretical (5,14), it also engages with diverse perspectives, including those of humanitarian workers, NGO members, and humanitarian ethics experts, facilitating a rich, nuanced, and triangulated understanding. Additionally, the impartiality of the research team, which specializes in (fundamental and practical) ethics without a background in humanitarian work, was complemented by the richness of the experiences shared by the participants involved, which was deemed significant. However, the study has limitations, including a lack of perspectives from humanitarian workers currently affected by the issues on the ground, which might render the developed portrait somewhat incomplete. Specifically, we see it as a limitation that the sample did not include national staff of NGOs, particularly since the results emphasize issues that are likely to be perceived differently by locally hired humanitarian workers. Moreover, despite achieving data saturation, the sample size remains small, and the transferability of this research is variable or limited.

CONCLUSION

This study aimed to empirically document the perceptions and experiences of diverse humanitarian workers, NGO members, and humanitarian ethics experts regarding ethical issues in humanitarian work. The participant interviews highlighted four categories of ethical issues: value-based tensions, resource scarcity, political considerations, and neo-colonialism. The category of value-based tensions encompassed ethical issues involving intercultural conflicts, balancing care with security and collaboration, addressing emergency versus long-term care, and navigating ethical silence. Resource scarcity included issues such as a lack of financial and material resources, insufficient preparation, and inadequate ethical resources, all of which contributing to operational difficulties. The category of political considerations highlighted ethical issues related to NGO operations, including the disconnect between organizational decisions and field practices, the unequal treatment of local workers and expatriates, and instances of authoritarianism, racism, and corruption within NGOs and their partners. And ethical issues pertaining to neocolonialism highlighted how Western ideologies and power dynamics persist in humanitarian organizations, manifesting in issues like paternalism, control of decision-making by white individuals, and power imbalances between NGOs and local governments, perpetuating a sense of Western superiority over non-white individuals. As well, having identified neocolonialism as a key ethical issue in this study (undiscussed in prior empirical literature reviewed), we proposed a reflection on structural injustices and the need for critical allyship to address systemic inequities in humanitarian work.

This study is likely to have implications for research, teaching, and practice. Documenting the various perceptions of ethical issues faced by various humanitarian actors represents a contribution to the research and literature on humanitarian ethics. While literature on ethical issues arising in humanitarian work is predominantly theoretical, empirical research on this topic is ever-growing. Such research may subsequently inform the training and education received by humanitarian workers confronted with these issues, equipping them with the ability to identify, label, and potentially respond to such issues in practice more effectively. Considering the insights articulated by participants, it may be beneficial to incorporate formal spaces for ethical deliberation and the resolution of discrepancies between local and expatriate workers into humanitarian work. Indeed, the interviews conducted revealed the crucial importance of addressing ethical issues once they are identified. While this topic was only briefly touched upon by some participants, it merits further attention in future research.

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REFERENCES

1. Rose J, O'Keefe P, Jayawickrama J, O'Brien G. The challenge of humanitarian aid: an overview. Environmental Hazards. 2013;12(1):74-92.
2. Terry F. The paradoxes of humanitarian aid. Agenda: A Journal of Policy Analysis and Reform. 1998;5(2):135-46.
3. Banatvala N, Zwi AB. Conflict and health: public health and humanitarian interventions: developing the evidence base. BMJ. 2000;321(7253):101-5.
4. Civaner MM, Vatansever K, Pala K. Ethical problems in an era where disasters have become a part of daily life: A qualitative study of healthcare workers in Turkey. PLoS one. 2017;12(3):e0174162.
5. Côté LP, Drolet MJ. Conceptualizing ethical issues of humanitarian work: results from a critical literature review. Canadian Journal of Bioethics/Revue canadienne de bioéthique. 2021;4(1):152-67.
6. Swisher LL, Arslanian LE, Davis CM. The realm-individual process-situation (rips) model of ethical decision-making. HPA Resource. 2005;5(3):1-8.
7. Slim H. Humanitarian Ethics: A Guide to the Morality of Aid in War and Disaster. London: Hurst; 2015.
8. Giannou C, Baldan M. War Surgery: Working With Limited Resources in Armed Conflict and Other Situations of Violence. Vol. 1. ICRC; 2009.
9. Haver K. Tug of War: Ethical Decision-Making to Enable Humanitarian Access in High-Risk Environments. Humanitarian Practice Network. 9 Nov 2016.
10. Hunt M, Chénier A, Bezanson K, et al. Moral experiences of humanitarian health professionals caring for patients who are dying or likely to die in a humanitarian crisis. Journal of International Humanitarian Action. 2018;3(1):12.
11. Hunt M, Pal NE, Schwartz L, O'Mathúna D. Ethical challenges in the provision of mental health services for children and families during disasters. Current Psychiatry Reports. 2018;20(8):60.
12. Lopes Cardozo B, Gotway Crawford C, Eriksson C, et al. Psychological distress, depression, anxiety, and burnout among international humanitarian aid workers: a longitudinal study. PLoS one. 2012;7(9):e44948.
13. Schwartz L, Hunt M, Sinding C, et al. Models for humanitarian health care ethics. Public Health Ethics. 2012;5(1):81-90.
14. Côté LP, Drolet MJ. Ethical issues arising in humanitarian work and possible responses to them: results from a critical literature review. Canadian Journal of Bioethics/Revue canadienne de bioéthique. 2023;6(3-4):16-32.
15. Meldrum H. Spirituality in medical practice: how humanitarian physicians draw their boundaries with patients. Integrative Medicine. 2011;10(3).
16. Asgary R, Lawrence K. Evaluating underpinning, complexity and implications of ethical situations in humanitarian operations: qualitative study through the lens of career humanitarian workers. BMJ Open. 2020;10(9):e039463.
17. Draper H, Jenkins S. Ethical challenges experienced by UK military medical personnel deployed to Sierra Leone (operation GRITROCK) during the 2014–2015 Ebola outbreak: a qualitative study. BMC Medical Ethics. 2017;18:77.
18. Funk KL, Rayes D, Rubenstein LS, et al. Ethical challenges among humanitarian organisations: insights from the response to the Syrian conflict. In: Ahmad A, Smith J, editors. Humanitarian Action and Ethics. London: Zed Books; 2018. p. 133-45.
19. Schwartz L, Sinding C, Hunt M, et al. Ethics in humanitarian aid work: learning from the narratives of humanitarian health workers. AJOB Primary Research. 2010;1(3):45-54.
20. Sinding C, Schwartz L, Hunt M, et al. "Playing God because you have to": health professionals' narratives of rationing care in humanitarian and development work. Public Health Ethics. 2010;3(2):147-56.
21. Gustavsson ME, Juth N, Arnberg FK, von Schreeb J. Dealing with difficult choices: a qualitative study of experiences and consequences of moral challenges among disaster healthcare responders. Conflict and Health. 2022;16:24.
22. Rubenstein LS, Robinson WC. Reality Makes Our Decisions: Ethical Challenges in Humanitarian Health in Situations of Extreme Violence. Center for Public Health and Human Rights; 2019.

23. Fraser V, Hunt MR, De Laat S, Schwartz L. The development of a humanitarian health ethics analysis tool. Prehospital and Disaster Medicine. 2015;30(4):412-20.
24. Gotowiec S, Cantor-Graae E. The burden of choice: a qualitative study of healthcare professionals' reactions to ethical challenges in humanitarian crises. Journal of International Humanitarian Action. 2017;2:2.
25. Hunt M, Nouvet E, Chénier A, et al. Addressing obstacles to the inclusion of palliative care in humanitarian health projects: a qualitative study of humanitarian health professionals' and policy makers' perceptions. Conflict and Health. 2020;14:70.
26. Hunt M. Ethics beyond borders: how health professionals experience ethics in humanitarian assistance and development work. Developing World Bioethics. 2008;8(2):59-69.
27. Hunt M. Moral experience of canadian healthcare professionals in humanitarian work. Prehospital and Disaster Medicine. 2009;24(6):518-24.
28. Hunt M, Eckenwiler L, Hyppolite SR, et al. Closing well: national and international humanitarian workers' perspectives on the ethics of closing humanitarian health projects. Journal of International Humanitarian Action. 2020;5:16.
29. Michael M, Zwi AB. Oceans of need in the desert: ethical issues identified while researching humanitarian agency response in afghanistan. Developing World Bioethics. 2002;2(2):109-30.
30. DePoy E, Gitlin LN. Introduction to Research: Understanding and Applying Multiple Strategies. St. Louis, Missouri: Elsevier; 2020.
31. Hammell KW, Carpenter C, Dyck I, editors. Using Qualitative Research: A Practical Introduction for Occupational and Physical Therapists. Edinburgh: Churchill Livingstone; 2000.
32. Husserl E. The train of thoughts in the lectures. In: Polifroni EC, Welch M, editors. Perspectives on Philosophy of Science in Nursing. New York: Lippincott; 1999. p. 247-62.
33. Husserl E, David. The Crisis of European Sciences and Transcendental Phenomenology: An Introduction to Phenomenological Philosophy. Evanston, USA: Northwestern Univ. Press; 1984.
34. Fortin MF, Gagnon J. Fondements et étapes du processus de recherche: méthodes quantitatives et qualitatives. Montréal: Chenelière Éducation; 2022.
35. Bogdan R, Biklen SK. Qualitative Research for Education: An Introduction to Theory and Methods. Boston: Allyn and Bacon; 2006.
36. Drolet MJ, Girard K. Les enjeux éthiques de la recherche en ergothérapie : un portrait préoccupant. Canadian Journal of Bioethics/Revue canadienne de bioéthique. 2020;3(3):21-40.
37. Thomas SP, Pollio HR. Listening to Patients: A Phenomenological Approach to Nursing Research and Practice. New York: Springer Publishing Company; 2004.
38. Giorgi A. De la méthode phénoménologique utilisée comme mode de recherche qualitative en sciences humaines: Théories, pratique et évaluation. In: Poupart J, Groulx, L. H., Deslauries JP, editors. La recherche qualitative: enjeux épistémologiques et méthodologiques. Montréal: Gaëtan Morin; 1997. p. 341-64.
39. Glaser JW. Three Realms of Ethics: Individual Institutional Societal: Theoretical Model and Case Studies. Lanham: Rowman and Littlefield; 1994.
40. Mills CW. The Racial Contract. Ithaca and London: Cornell University Press; 1997.
41. Mills CW. Black Rights/White Wrongs: The Critique of Racial Liberalism. New York: Oxford University Press; 2017.
42. Nixon SA. The coin model of privilege and critical allyship: implications for health. BMC Public Health. 2019;19(1):1637.
43. Applebaum B. "Listening silence" and its discursive effects. Educational Theory. 2016;66(3):389-404.
44. Pohlhaus Jr G. Relational knowing and epistemic injustice: toward a theory of willful hermeneutical ignorance. Hypatia. 2012;27(4):715-35.

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ARTICLE (PEER-REVIEWED)

Parental Comprehension of Standard and Simplified Information Consent Forms in a Pediatric Clinical Trial Simulation – A Randomized Controlled Study

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Résumé

Contexte : Les formulaires de consentement éclairé (FCE) sont une condition préalable obligatoire à la participation à des essais cliniques. Dans les études pédiatriques, le FCE est généralement signé par les parents de l'enfant. Les FCE conçus pour les essais cliniques sont souvent longs et complexes à comprendre. Nous avons mené cette étude afin de déterminer si un FCE simplifié améliorerait la compréhension des parents par rapport à un FCE standard. **Méthodes :** Un essai contrôlé randomisé, en simple aveugle, mené dans un seul centre et portant sur deux FCE fictifs, a été réalisé dans un hôpital universitaire tertiaire canadien spécialisé dans la santé maternelle et infantile. Les parents d'enfants hospitalisés ont été invités à lire soit un FCE standard, soit un FCE simplifié. La compréhension des parents a été évaluée à l'aide du questionnaire MICCA (Modular Informed Consent Comprehension Assessment). Le principal objectif de cette étude était d'évaluer la proportion de parents ayant obtenu un score MICCA de 75 % ou plus. **Résultats :** Cent cinquante participants ont répondu aux questionnaires de l'étude. Le critère d'évaluation principal a été atteint par 55,7 % des participants ayant lu le formulaire simplifié, contre 46,2 % dans le groupe ayant lu le formulaire standard (p = 0,303). Les scores MICCA moyens étaient respectivement de 17,87 et 17,75 points (p=0,847). Les thèmes mal compris par les deux groupes étaient les procédures de l'étude, les effets indésirables, les autres options thérapeutiques disponibles ainsi que les principaux avantages et l'objectif de l'étude. **Conclusion :** Cette étude randomisée contrôlée, monocentrique et en simple aveugle, a montré que la compréhension était similaire entre un formulaire de consentement éclairé simplifié et un formulaire standard. Cela suggère que l'utilisation de formulaires simplifiés n'améliore ni ne nuit à la compréhension des parents. Par conséquent, un formulaire simplifié devrait être utilisé aussi souvent que possible dans les projets de recherche pédiatrique.

Mots-clés
formulaires de consentement éclairé, simplifiés, compréhension, pédiatrique, questionnaire validé

Abstract

Background: Informed consent forms (ICFs) are a mandatory prerequisite for participating in clinical trials. In pediatric studies, the ICF is generally signed by the child's parents. The ICFs designed for clinical trials are often lengthy and complex to understand. We conducted this study to determine if a simplified ICF would improve parental understanding compared to a standard ICF. **Methods:** A single-centre, single-blind, randomized controlled trial featuring two fictitious ICFs took place in a tertiary Canadian mother and child university hospital. Parents of hospitalized children were assigned to read either a standard or simplified ICF. Parental comprehension was measured using the Modular Informed Consent Comprehension Assessment (MICCA) questionnaire. The primary outcome of this study was to assess the proportion of parents with a MICCA score of 75% or above. **Results:** One hundred and fifty participants answered the study questionnaires. The primary endpoint was reached by 55.7% of the participants who read the simplified ICF compared to 46.2% in the standard ICF group (p=0.303). The mean MICCA scores were 17.87 and 17.75 points, respectively (p=0.847). Themes that were poorly understood by both groups were the study procedures, the adverse effects, the other available treatment options as well as the main benefits and purpose of the study. **Conclusion:** This single centre, single-blind, randomized controlled study showed that the comprehension was similar between a simplified and a standard ICF. This suggests that using simplified ICFs does not improve nor impair parental comprehension. Therefore, a simplified ICF should be used as frequently as possible in pediatric research projects.

Keywords
information consent forms, simplified, comprehension, pediatric, validated questionnaire

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INTRODUCTION

The ethical process required to partake in clinical trials includes the informed and voluntary consent of the participants, a necessary prerequisite to ensure the respect of their autonomy and right to self-determination (1). A distinctive feature in the branch of pediatric research is that it is parents or legal guardians who generally consent on behalf of their children until they have the appropriate capacity to provide informed consent (1,2). In the Canadian province of Québec, consent must generally be given by a parent or guardian until the subject is 18 years old (3,4). However, a minor aged 14 and over who can understand the nature and consequences of the research should give written or at least verbal assent when possible. This assent is in addition to parental consent and does not replace it (3).

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To allow parents to make the best decision on behalf of their child, it is important, from an ethical standpoint, that they have a good understanding of the study's risks and benefits (5). Informed consent forms (ICFs) are legal-required documents that contain information about the research project. They should be concise and understandable so that parents can make an informed choice about whether they want to include their child in a study (6,7). Unfortunately, and mostly due to legal constraints, ICFs are often very lengthy (around 20 to 30 pages) and hard to understand (8-12), containing many complex medical terms as well as mandatory legal notices (7,12). A systematic review and a meta-analysis recently revealed that the undue complexity and length of ICFs can lead the readers to misunderstand the information they seek to provide (13,14). The themes that are the least understood include the benefits of a study, randomization, and the risks and the side effects of drugs being administered (14). Another meta-analysis established that participants' comprehension of ICFs had not improved over the last three decades, even for basic concepts such as the use of placebo or freedom to withdraw from the study at any time (15).

Some researchers have thus tried to improve participants' comprehension by using different ICF simplification strategies. These included modifying the readability, the text formatting (bullet points, font, bold or italic accents), the visual aspect (including more diagrams, tables, pictures) and the length of the text (16,17). Studies comparing standard and simplified ICFs suggested that the simplification increased patient comprehension (13,16,18-20). However, the literature supporting this claim is heterogenous, mostly due to the use of non-validated questionnaires. Moreover, there is limited data specifically concerning the pediatric population, where decisions must be made by an adult on behalf of their child.

The aim of this study is to determine whether a simplified ICF, compared to a standard ICF, improves comprehension in parents asked to consent to a clinical trial for their child using a validated questionnaire. We hypothesized that a simplified ICF featuring an improved layout and with less superfluous details would allow parents to better focus on the important items, thereby improving their comprehension of the essential key points for informed decision-making.

MATERIALS & METHODS

We conducted a single-blind, randomized controlled study featuring two different fictitious ICFs, a standard ICF and a simplified ICF, to determine parental understanding of research-related information. The study took place at the CHU Sainte-Justine, a 500-bed Canadian tertiary mother and child university hospital in Montreal, Quebec. The protocol and related documents received ethical approval from the institutional research ethics board.

Study population

Parents were included in the study if their child was aged between 7 days and 17 years old, and was hospitalized for a minimum of 48 hours on non-critical care units of the CHU Sainte-Justine. Participants had to be able to read in either French or English. For ethical concerns and to avoid bias, we excluded all parents who had type 1 diabetes or who had a child with this condition since our fictitious ICFs were focused on that disease. Only one of the child's parents could be enrolled and families could not be re-enrolled in the study if they were re-admitted at the hospital. Eligible parents were identified with support from the units' clinical pharmacists.

Study procedures

We randomly assigned parents to one of the two study groups (standard ICF vs simplified ICF) in a 1:1 ratio using a computerized multiple block randomization sequence. The randomization was performed by an online website (Sealed Envelope) in blocks of 4 or 6. Parents were blinded to the ICF they received. Participants had 24 hours to read their assigned ICF. No questions about the fictitious ICF were answered by the research team; participants were invited to write down any comments they had about their ICF. After 24 hours, an investigator collected the ICF and gave participants two questionnaires: one to assess their comprehension and another with supplementary demographic questions. The parents then had 2 hours to answer the questionnaires and they had no access to the ICF during that time. If needed, parents could be granted more time to complete these steps since we recognized that the hospital setting could be disruptive to the completion of the above tasks. Many precautions were taken during the recruitment, consent and participation phases to ensure that the parents would not be misled on their child's real diagnosis by the fictitious study we used. Precautions included clearly stating the nature of the study in the consent form, verbally informing participants at both the beginning and end of the study, and adding the watermark 'Fake Study' to the fictitious ICFs, as well as a cover page clearly indicating that the fictitious study did not apply to their child.

Informed consent forms

The fictitious ICFs were built around a fake medication called Insuperos, an oral treatment for type 1 diabetes. This study topic was chosen since there is a Modular Informed Consent Comprehension Assessment (MICCA) questionnaire specific to diabetes. In the province of Québec, standard joint legal clauses featured in the ICFs of research studies are negotiated at a government level to allow provincial standardization. The topics covered by the legal clauses are compensation, prejudice, confidentiality, participation and withdrawal, commercialization, contact information and signature. These clauses needed to be included in our fictitious ICFs, and their content could not be modified (21). The legal clauses amounted to 1570 words in French and 1421 words in English.

The standard informed consent form

Fifteen real-life ICFs were consulted as reference for the formatting and content of our standard ICF. Once the first draft was completed, the standard ICF was reviewed by different experts (clinical activities specialists, research ethics board members, pharmacists) to ensure that it would closely reflect a real-world informed consent form. The final version of the French standard ICF contains 8960 words (22 pages) whereas the English one has 8110 words (22 pages). Both versions feature two tables (Appendix 1). The LIX score, which measures readability, was 54 for the French version and 51 for the English version, corresponding approximately to a grade 11 to 12 reading level (22).

The simplified informed consent form

After the completion of the standard ICF, non-healthcare workers were consulted to target modifications for the simplified version and ensure that the content was clear and easily understandable by the general public. Senior members of the research team (many of whom serve in the hospital's research ethics board) also evaluated this version to ensure that all essential elements were preserved. We used simplification techniques suggested in several past guidelines and papers (16,17). Unnecessary repetitions of information were avoided, only elements essential to the comprehension of the study were included, and a simplified language was used. The following formatting techniques were used: more bullet point enumerations, italics, underlining, as well as bold characters for the important words and concepts. Supplementary diagrams were added.

The final version of the French simplified ICF contains 4914 words (17 pages) whereas the English version has 4459 words (17 pages). Both feature one table and five diagrams (Appendix 2). The LIX score was 52 for the French version and 50 for the English version, which is also equivalent to a grade 11 to 12 reading level (22).

Study instruments

Parental comprehension of their allocated ICF was assessed using a validated questionnaire, the diabetes-specific MICCA (23). This questionnaire was specifically chosen because it was built according to the ethical principles of different countries (including Canada) and its multiple-choice format allowed for an objective evaluation. The MICCA questionnaire is composed of 25 questions, 13 general interest and 12 that are trial-specific. Of these, 14 are true or false, 5 are simple multiple choices with only one possible answer, and 6 are complex multiple choices with more than one possible answer. Each question is worth 1 point (no partial points for the complex multiple choices), for a maximum score of 25. The MICCA also includes 7 supplementary questions about the participant's demographics (Appendix 3). As the MICCA was only available and validated in English, we translated it to French using forward and back translation (to ensure accuracy).

A subset of six questions regarding medication-specific outcomes were analyzed separately. Because there were only a few medication-specific questions, exceptionally partial points were awarded. The maximum total score was 6.

Additional information about the participants was collected with a supplementary questionnaire developed by our research team (Appendix 4). We asked participants about the time they needed to read the ICF and if they would consent to the fictitious study if it was real. Supplementary demographic questions were also included, and parents were invited to write any comments they had about the ICF.

Study outcomes

The primary outcome was the difference in the proportion of parents who obtained a MICCA score of 75% (19/25) or above, between the standard and the simplified groups. This score has been arbitrarily set and used in previous studies as a reflection of good comprehension (24). The secondary outcomes were the difference of mean score between the two groups for the whole questionnaire, the differences of proportion and mean score between the two groups for the medication-specific questions (6 questions, see Appendix 3) as well as the collection of the written comments in each group.

Data analysis

In an Ethiopian study that used the MICCA questionnaire, only 5% of participants who read an ICF obtained a score above 75% (24). Considering the results of that study as well as the differences between their and our study populations, we estimated that 15% of parents reading the standard ICF would score above 75%. Thus, using G*Power 3.1, we calculated that a sample size of 150 parents would allow us to detect a 20% difference between our two independent proportions of the primary endpoint (p_1=0.15 and p_2=0.35), with a power of 80% and significance level of 5%. We added a 10% margin for expected losses to follow up; consequently, our target sample size was 164 parents (82 in each study group).

The distribution of the results was assumed to be normal considering the sample size. For the primary outcome, the Fisher exact test was used to calculate the difference between the proportion of participants that obtained a score of 75% or above (19/25). To assess the robustness of our estimate, we conducted a sensitivity analysis with proportions of participants that obtained a MICCA score of 65% and 85%.

For the secondary outcomes, the difference in proportions was calculated with a Fischer exact test and the mean understanding differences were calculated with a Student T test.

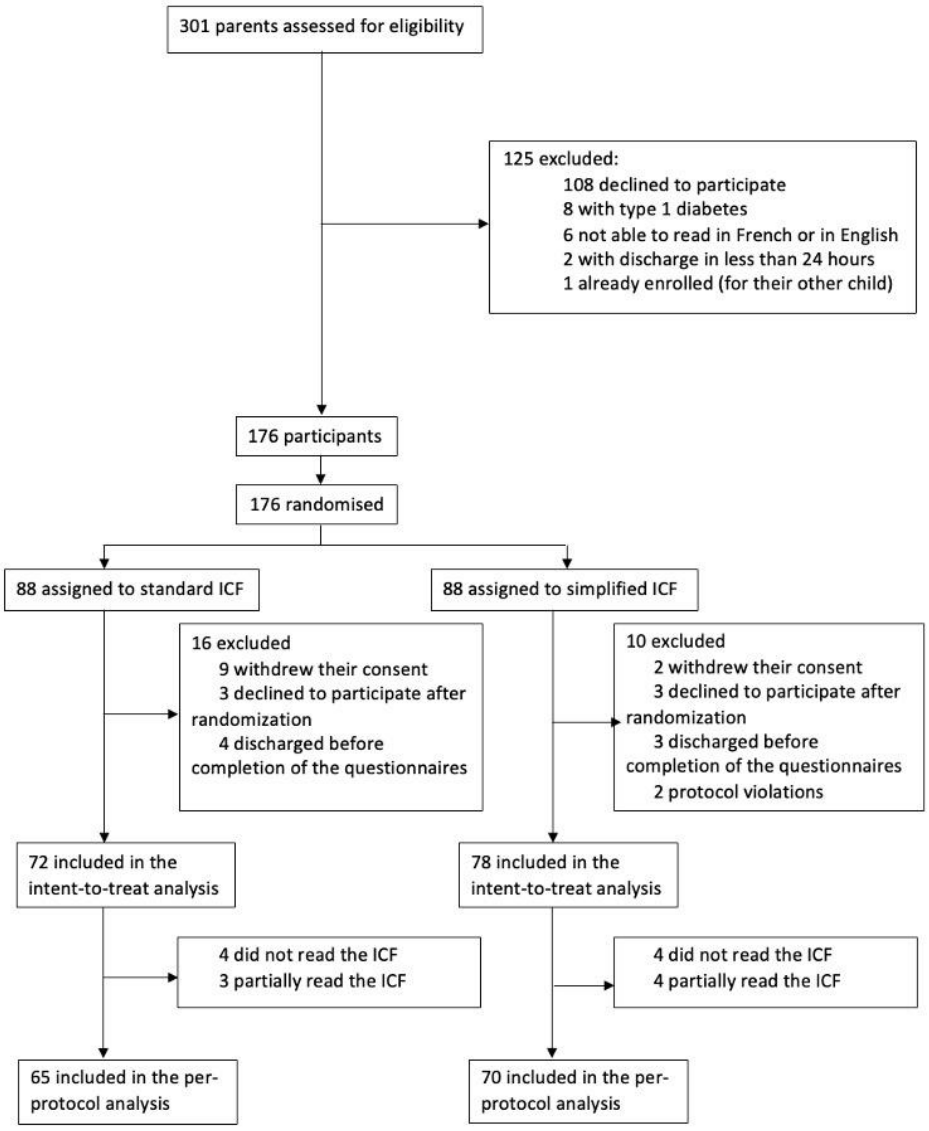
The statistical significance was set at alpha = 0.05 for all tests. Statistical analyses were performed using IBM SPSS version 27 (Armonk, NY). All the analyses for the total MICCA score and the medication-specific questions were conducted using the modified intent-to-treat and the per-protocol analysis. The modified intent-to-treat analysis included all the participants who answered the questionnaires, even if they did not read the ICF or read it only partially. The per-protocol analysis included only participants who read the ICF completely and answered the questionnaires.

The parents' reading notes and comments were grouped in common themes, to enhance our understanding of their subjective reading experience.

RESULTS

Between March and July 2023, 176 parents of children hospitalised at CHU Sainte-Justine were included in this study. The sample size was increased to compensate higher than anticipated losses to follow-up. Of the 150 who completed the questionnaires, 135 participants read the ICF completely (n=65 for standard ICF and n=70 for simplified ICF) (Figure 1).

Figure 1: Study schematic



Most of the participants were mothers, younger than 40 years old, spoke French and had an educational status higher than high school. Less than 20% of participants were healthcare workers (Table 1).

Table 1: Baseline characteristics of the intent-to-treat population

	Standard ICF (n=72) (%)	Simplified ICF (n=78) (%)
Age (years)		
< 40	48 (66.7)	56 (71.8)
≥ 40	22 (30.6)	18 (23.1)
Unknown	2 (2.8)	4 (5.1)
Sex		
Female	54 (75.0)	52 (66.7)
Male	16 (22.2)	22 (28.2)
Unknown	2 (2.8)	4 (5.1)
Preferred language for communication		
French	67 (93.1)	64 (82.1)
English	3 (4.2)	11 (14.1)
Other	2 (2.8)	2 (2.6)
Unknown	0	1 (1.3)
Highest educational level reached		
Primary school	1 (1.4)	0
Secondary school	5 (6.9)	9 (11.5)
Technical/vocational education	26 (36.1)	21 (26.9)
Some university education	5 (6.9)	7 (9.0)
Undergraduate degree	20 (27.8)	20 (25.6)
Higher graduate degree	12 (16.7)	16 (20.5)
Unknown	3 (4.2)	5 (6.4)
Healthcare worker		
Yes	14 (19.4)	14 (17.9)
No	58 (80.6)	62 (79.5)
Unknown	0	2 (2.6)
Participation to a clinical trial in the past		
Yes	9 (12.5)	17 (21.8)
No	60 (83.3)	57 (73.1)
Unknown	3 (4.2)	4 (5.1)

Upon analysis of the primary endpoint using the per-protocol model, 55.7% of participants in the simplified group obtained a total MICCA score ≥ 75%, compared to 46.2% in the standard ICF group (p=0.303) (Table 2). The pre-determined sensitivity analyses provided similar results (Table 3). There was no difference in the mean comprehension score between the 2 groups: 17.87 in the simplified group vs 17.75 in the standard group (p=0.512).

Table 2: Total and medication-specific MICCA scores, per-protocol analysis

		Standard ICF (n=65)	Simplified ICF (n=70)	RR	95% CI	P value*
Total score	Proportion of participants with a score of ≥ 75%	46.2%	55.7%	0.681	(0.346 to 1.343)	0.303
	Mean score (/25)	17.75 +/- 3.41	17.87 +/- 3.62		(-1.317 to 1.082)	0.847
Medication-specific questions	Proportion of participants with a score of ≥ 75%	30.8%	31.4%	0.970	(0.468 to 2.011)	1.000
	Mean score (/6)	3.485 +/- 1.25	3.414 +/- 1.24		(-0.354 to 0.494)	0.743

*Fisher exact for the difference between proportions and Student T test for the mean difference

When analyzing the comprehension of the medication-specific questions, the mean scores and the proportion of scores ≥ 75% were also similar between the 2 study groups (Table 2). Likewise, all these results were not statistically significant in the modified intent-to-treat model (Appendix 5).

Table 3: Sensitivity analysis for the total and the medication-specific MICCA scores, per-protocol analysis

		Standard ICF (n=65)	Simplified ICF (n=70)	RR	95% CI	P value*
Total score	Proportion of participants with a score of ≥ 65%	67.7%	74.3%	0.725	(0.344 to 1.530)	0.450
	Proportion of participants with a score of ≥ 85%	7.7%	11.4%	0.646	(0.200 to 2.086)	0.565
Medication-specific questions	Proportion of participants with a score of ≥ 65%	41.5%	44.3%	0.894	(0.452 to 1.769)	0.862
	Participation of participants with a score of ≥ 85%	10.8%	2.9%	4.103	(0.820 to 20.530)	0.088

*Fisher exact for the difference between proportions

In a post-hoc analysis, we compared the reported reading time between the two groups. The percentage of participants who took ≤ 1 hour to read their ICF was 60.0% for the standard group vs 73.9% for the simplified group (p=0.100). The themes of the questions that were failed by more than 50% of the participants in both groups were the study procedures, the adverse effects, the other available treatment options, as well as the main benefits and purposes of the study (Appendix 6).

When compiling the comments and suggestions made by the parents who read the simplified ICF, some participants identified the layout, with the bold words and point forms, as positive and useful. Others also commented that the simplified tables and figures helped make the text lighter. In the standard ICF group, some parents would have appreciated having this kind of layout and/or more tables. A point that stood out in the standard ICF was that parents found there were too many repetitions. In both groups, some parents reported that the ICF was too long and that the section about the risks associated with the procedures was too detailed and unnecessary.

A few parents made suggestions to help simplify future ICFs. They suggested adding a lexicon to define complicated words as well as providing complementary audiovisual explanations. They also suggested shortening the ICFs as much as possible and adding appendixes with supplementary information for parents who want more details.

DISCUSSION

To our knowledge, this is the first North American study to evaluate parental comprehension of a simplified ICF in a pediatric clinical trial simulation using a validated questionnaire. Our findings show that the comprehension of the simplified ICF was similar to that of the standard ICF. The absence of meaningful difference in comprehension applied to both the global questionnaire and the medication-specific themes. A shorter, more understandable document that does not compromise the quality of the informed consent process represents a valuable and positive result. Further, participants gave more positive feedback about the simplified ICF and more negative comments about the standard ICF, suggesting an enhanced perceived overall experience with the simplified ICF.

Our results differ from several studies which found that a simplified ICF was better understood than a standard ICF (16,20,24). It is important to consider certain key factors when comparing our study to others. First, most of the other studies in this field did not use a validated questionnaire, like we did, which makes it harder to compare and interpret the discrepancies between the results (25). Second, there is no standardized method for simplification of an ICF. However, some researchers did explore which methods could improve ICF comprehension. A combination of at least three different simplification techniques seems to be necessary to detect a difference in comprehension (16,17). Several of these recommended changes were used to create our simplified ICF, including four formatting techniques and three supplementary non-formatting changes, as well as additional diagrams. Finally, both our study groups achieved high comprehension scores in comparison to previous studies. For instance, a study using the MICCA questionnaire in Ethiopia showed that only 4.3% of the participants reached a comprehension score of more than 75% in the standard ICF group, compared to 46.2% in our study (24). The disparity in education levels is a contributing factor and likely plays a significant role, as approximately 50% of our study population had completed university studies, surpassing the 37% seen in the general Quebec population (26). Such a high score in the control group limits the chances to find statistically significant interventions in highly educated populations. Nonetheless, concerns remain for parents who do not achieve high comprehension scores.

Targeting parental interests and concerns may be a valid strategy. A study that evaluated parents' point of view on the important parts of an ICF showed that they considered the health benefits and the adverse effects of the drugs to be of the highest interest (27). In contrast to this, the results of a systematic review suggested that only a small minority of patients really understand the following elements of a research study: the concept of placebo, randomization, safety issues, risks and side effects (14). Similarly, in our study, 6 questions were failed by more than 50% of participants in both groups. These questions focused on study procedures, adverse effects, other available treatment options, and the main benefits and purposes of the study. Considering that these themes are the cornerstone of research projects, and are important for fully informed consent, greater efforts should be invested in making ICFs more accessible to the public — our results help target these areas for future improvement.

Our study shows that a simplified ICF is insufficient to achieve an optimal comprehension in all parents, even in a highly educated population. This highlights the importance of offering more guidance to potential participants in their reading of the ICF. A research team member who provides parents with supplementary explanations and answers their questions seems to be a key factor to promoting greater comprehension (28). Audiovisual or interactive content is another interesting avenue to improve the comprehension of study participants (13).

There were several limitations to our single centre study. First, comprehension was evaluated in a simulated study. Thus, parents may not have been as emotionally involved as those who would read an ICF to enroll their children in a real study. This issue is also described in other studies on this topic (13). Even though it would come with its own challenges, testing a simplified ICF in an active study would help to overcome this problem. Second, children and parents who had type 1 diabetes were excluded for ethical reasons. This could affect the level of comprehension in our study population because participants had less knowledge about the medical terms and procedures associated with that disease. Third, we did not respond to any questions the parents might have had reading the ICF, nor did we provide supplementary information on study-related

concepts. In a real clinical trial, the research team can answer any questions that arise. These limitations restrict our study's external validity, but they allowed us to focus exclusively on the ICFs.

Furthermore, our simplified ICF's text, while shorter than the standard version, was equivalent to a 11-12th grade level text, which is not comprehensible to a significant part of the North American population (29,30). We tried to shorten the simplified ICF as much as possible, as Tait et al. reported that longer ICFs were correlated with poorer verbatim understanding of risks and benefits (16). However, our province's legal requirements were an obstacle in the shortening of our form. A revision of the standardized legal clauses could allow for more intelligible text. Finally, our study did not consider the children's comprehension since they were hospitalized and the timing for a simulated research project was not appropriate. Their inclusion could be a significant point of interest for further studies since children who are able to understand a clinical study need to give their assent in order to participate.

CONCLUSIONS

Our single centre, single-blind, randomized controlled study showed that comprehension was similar between simplified and standard ICFs. Both groups were highly educated and achieved higher comprehension scores than what was previously described. This suggests that using simplified ICFs in pediatric research projects does not improve nor impair parental comprehension. A simplified ICF may enhance the parent's overall experience, due to its shorter length, use of bullet points and improved layout. Out of respect for participants and their families, a simplified ICF should therefore be used in research projects as frequently as possible. Other interventions, such as the use of audiovisual or interactive supplementary content, are also interesting avenues for supporting parental comprehension of clinical studies.

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REFERENCES

1. Roth-Cline M, Nelson RM. Parental permission and child assent in research on children. Yale J Biol Med. 2013;86(3):291-301.
2. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. JAMA. 2013;310(20):2191-4.
3. Code Civil du Québec. CCQ 1991.
4. Government of Canada. Comité d'éthique de la recherche: Processus de consentement. Ottawa; Health Canada-PHAC Research Ethics Board Secretariat; 2023.
5. Leibson T, Koren G. Informed consent in pediatric research. Pediatric Drugs. 2015;17(1):5-11.
6. Hazen RA, Drotar D, Kodish E. The role of the consent document in informed consent for pediatric leukemia trials. Contemp Clin Trials. 2007;28(4):401-8.
7. Grant SC. Informed consent—we can and should do better. JAMA Network Open. 2021;4(4):e2110848.

8. Kass NE, Chaisson L, Taylor HA, et al. Length and complexity of US and international HIV consent forms from federal HIV network trials. J Gen Intern Med. 2011;26(11):1324-8.
9. Berger O, Grønberg BH, Sand K, Kaasa S, Loge JH. The length of consent documents in oncological trials is doubled in twenty years. Ann Oncol. 2009;20(2):379-85.
10. Wen G, Liu X, Huang L, et al. Readability and content assessment of informed consent forms for phase ii-iv clinical trials in China. PLoS One. 2016;11(10):e0164251.
11. Epstein LC, Lasagna L. Obtaining informed consent. Form or substance. Arch Intern Med. 1969;123(6):682-8.
12. Beardsley E, Jefford M, Mileshkin L. Longer consent forms for clinical trials compromise patient understanding: so why are they lengthening? J Clin Oncol. 2007;25(9):e13-4.
13. Nishimura A, Carey J, Erwin PJ, et al. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Medical Ethics. 2013;14:28.
14. Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension—systematic review. Trials. 2021;22:57.
15. Tam NT Huy NT, Thoa LTB, et al. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Bull World Health Organ. 2015;93(3):186-98h.
16. Tait AR, Voepel-Lewis T, Nair VN, Narisetty NN, Fagerlin A. Informing the uninformed: optimizing the consent message using a fractional factorial design. JAMA Pediatrics. 2013;167(7):640-6.
17. Perrault EK, Keating DM. Seeking ways to inform the uninformed: improving the Informed consent process in online social science research. J. Empir. Res. Hum. Res. Ethics. 2018;13(1):50-60.
18. Koonrungsesomboon N, Teekachunhatean S, Hanprasertpong N, et al. Improved participants' understanding in a healthy volunteer study using the SIDCER informed consent form: a randomized-controlled study. Eur J Clin Pharmacol. 2016;72(4):413-21.
19. Koonrungsesomboon N, Tharavanij T, Phiphatpatthamaamphan K, et al. Improved participants' understanding of research information in real settings using the SIDCER informed consent form: a randomized-controlled informed consent study nested with eight clinical trials. Eur J Clin Pharmacol. 2017;73(2):141-9.
20. Koonrungsesomboon N, Traivaree C, Tiyapsane C, Karbwang J. Improved parental understanding by an enhanced informed consent form: a randomized controlled study nested in a paediatric drug trial. BMJ Open. 2019;9(11):e029530.
21. MSSS. Éthique de la recherche : Clauses légales. Gouvernement de Québerc; 2021.
22. Lix Score and readability. Lix score.
23. Buccini LD, Caputi P, Iverson D, Jones C. Toward a construct definition of informed consent comprehension. J Empir Res Hum Res Ethics. 2009;4(1):17-23.
24. Addissie A, Abay S, Feleke Y, et al. Cluster randomized trial assessing the effects of rapid ethical assessment on informed consent comprehension in a low-resource setting. BMC Medical Ethics. 2016;17:40.
25. Kon AA, Klug M. Methods and practices of investigators for determining participants' decisional capacity and comprehension of protocols. J Empir Res Hum Res Ethics. 2006;1(4):61-8.
26. Institut de la statistique du Québec. Niveau de scolarité; 2025.
27. Koonrungsesomboon N, Charoenkwan P, Natesirinilkul R, et al. What information and the extent of information to be provided in an informed assent/consent form of pediatric drug trials. BMC Medical Ethics. 2022;23:113.
28. Kadam RA. Informed consent process: A step further towards making it meaningful! Perspect Clin Res. 2017;8(3):107-12.
29. Statistics Canada. Literacy, numeracy - Average scores and distribution of proficiency levels, by labour force status, highest level of education and age group. Table 37-10-0049-01. 22 Jun 2015.
30. National Center for Education Statistics (NCES). Skills of U.S. unemployed, young, and older adults in sharper focus: results from the Program for the International Assessment of Adult Competencies (PIAAC) 2012/2014. In: US Department of Education, editor. Washington (DC): NCES; 2016.

APPENDIX 1: STANDARD FICTITIOUS ICF – ENGLISH VERSION

Available at external link

APPENDIX 2: SIMPLIFIED FICTITIOUS ICF – ENGLISH VERSION

Available at external link

APPENDIX 3: DIABETES-SPECIFIC MICCA - ENGLISH VERSION

Available at external link

APPENDIX 4: SUPPLEMENTARY QUESTIONNAIRE MADE BY THE RESEARCH TEAM IN ENGLISH

Contact pascal.bedard.hsj@ssss.gouv.qc.ca if you want to obtain the French version

Supplementary questionnaire

1. Approximately how much time did you spend reading the fictitious information and consent form:
    - 0 to 1 hours
    - > 1 to 2 hours
    - > 2 to 3 hours
    - > 3 to 4 hours
    - More than 4 hours

2. If the information and consent form you just read was not for a fake study, assuming your child had type 1 diabetes, would you accept that your child participate in the research project?

    REMINDER: THIS IS A FAKE STUDY. Your child does not have type 1 diabetes and will not take the Insuperos treatment or subcutaneous insulin. THIS IS A SIMULATION.

    - Yes
    - No

3. Are you a healthcare worker?
    - Yes
    - No

4. What is your preferred language for communication:
    - French
    - English
    - Spanish
    - Mandarin
    - Arab
    - Other (specify): _____

5. Do you have any comments about the fictitious information and consent form you read? (free text)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

APPENDIX 5: TOTAL AND MEDICATION-SPECIFIC MICCA SCORES, INTENT-TO-TREAT ANALYSIS

		Standard ICF (n=72)	Simplified ICF (n=78)	RR	95% CI	P value*
Total score	Proportion of participants with a score of 75% or more	41.7%	51.3%	0.679	(0.356 to 1.294)	0.256
	Mean score	17.21 +/- 3.741	17.36 +/- 3.987		(-1.401 to 1.100)	0.812
Medication-specific questions	Proportion of participants with a score of 75% or more	27.8%	30.8 %	0.865	(0.428 to 1.752)	0.722
	Mean score	3.347 +/- 1.310	3.269 +/- 1.367		(-0.355 to 0.511)	0.722

* Fisher exact for the difference between proportions and Student T test for the mean difference

APPENDIX 6: QUESTIONS THAT WERE FAILED BY MORE THAN 50% OF THE PARTICIPANTS IN BOTH GROUPS IN A PER-PROTOCOL ANALYSIS

Questions	**Percentage of participants who failed the question**
8. I will be told about new findings from the clinical trials so I can decide whether to continue to take part.	54.1%
20. Which describes the main purpose(s) of the clinical trial?	68.1%
21. Which procedure(s) will you be asked to take part in?	81.5%
23. Which side effect(s) might occur?	77.8%
24. Which describes the main benefit(s) of taking part in the clinical trial?	71.7%
25. Which describes the other treatment option(s) available to you?	59.8%

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Understanding How Canadian Physicians and Public Stakeholders Rationalize MAiD Amid Bill C-7: A Critical Analysis

Midori Matthew[a]

Résumé

Malgré sa légalisation, l'éthique de l'aide médicale à mourir (AMM) reste controversée en raison de l'évolution des critères d'admissibilité et des implications qui en découlent pour les personnes souffrant de maladies non terminales, notamment de troubles mentaux. Compte tenu de la disponibilité croissante de l'AMM, il est important de comparer les discours de la société et ceux des médecins afin d'éclairer l'élaboration de politiques et de lois en matière de santé qui reflètent les valeurs et les préoccupations des différentes parties prenantes. Cet article présente une analyse qualitative critique de deux types de données : 1) les réponses à des entretiens menés auprès de médecins canadiens concernant la pratique de l'aide médicale à mourir, et 2) les médias numériques canadiens, dans le but de déterminer les points de convergence et de divergence entre les discours des deux types de sources. Notre analyse a permis de dégager quatre thèmes généraux : 1) l'autonomie et le choix, 2) « mourir dans la dignité » et la réduction des risques, 3) le paternalisme et la vulnérabilité, et 4) la médicalisation de la souffrance. En général, si les médecins et les autres parties prenantes se disent attachés au principe de l'autonomie du patient, toutes les parties ont exprimé leurs préoccupations concernant les inégalités systémiques et le risque que l'AMM soit utilisée comme un substitut pour traiter les déterminants sociaux plus larges de la santé.

Mots-clés

soins palliatifs, méthodes qualitatives, aide médicale à mourir, AMM, projet de loi C-7, Canada, point de vue des médecins, opinion publique

Abstract

Despite its legalization, the ethics of medical assistance in dying (MAiD) remain contentious due to an evolving eligibility criteria goalpost and the subsequent implications for individuals suffering from non-terminal conditions, namely mental illness. Given the expanding availability of MAiD, comparing societal narratives with those of physicians is important to inform the development of health policies and laws that reflect a variety of stakeholder values and concerns. This paper presents a critical qualitative analysis of two types of data: 1) interview responses from Canadian physicians regarding the practice of MAiD, and 2) Canadian digital news media, with the goal of determining areas of convergence and divergence in the narratives of both source types. This analysis captured four overarching themes: 1) autonomy and choice, 2) "dying with dignity" and harm reduction, 3) paternalism and vulnerability, and 4) the medicalization of suffering. In general, while both physicians and other stakeholders express a commitment to the principle of patient autonomy, all parties raised concerns about systemic inequities and the risk of MAiD being used as a proxy for addressing broader social determinants of health.

Keywords

palliative care, qualitative methods, medical assistance in dying, MAiD, Bill C-7, Canada, physician perspectives, public opinion

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Due to an editorial oversight, this article was inadvertently omitted from the special issue, MAiD in Canada: A Sober Second Look.

INTRODUCTION

In 2016, Canada legalized medical assistance in dying (MAiD) following the Carter v. Canada ruling. Initially, MAiD was restricted to individuals facing a "reasonably foreseeable" natural death due to a grievous and irremediable health condition (1). However, the passage of Bill C-7 in 2021 in response to Quebec's Truchon decision expanded eligibility beyond those on the trajectory toward a reasonably foreseeable natural death to request MAiD under specific conditions (2). Despite its legalization, the ethics of MAiD remain contentious due to an evolving eligibility criteria goalpost and the subsequent implications for individuals who are suffering from non-terminal conditions, namely those suffering from mental illness (3). This expansion has intensified public discourse around ethical and medical questions about the role of MAiD in addressing suffering that reaches beyond physical illness, and how the law frames the lives of vulnerable Canadians at risk (4-7).

As the scope of MAiD's eligibility continues to grow, it is necessary to consider the insights of physicians affected by or participating in administering the procedure to examine the novel ethical terrain and practical implications post C-7. Physicians operate within a framework of professional ethics and medical standards and so may grapple with how MAiD compares with considerations of patient autonomy, non-maleficence, and the implications of liberalizing a terminal procedure in the face of crises such as affordability and a lack of social services for mental health and disability. Simultaneously, societal perspectives such as those offered by members of the general public, politicians, activists, and academics are iteratively shaped by concerns at the individual level (such as freedom of choice) and the macro level through considering the role of MAiD in an equitable society.

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The current body of bioethics research about the direction of MAiD in Canada does not adequately consider how the firsthand perspectives of clinicians involved in the practice compares with broader societal discourses. Given the expanding availability of MAiD, comparing societal narratives with those of physicians is important to inform the development of health policies and laws that are reflective of a variety of stakeholder values and concerns. This study examines how physicians conceive of MAiD in the wake of Bill C-7. The alignment or disjuncture between physician's firsthand perspectives and those put forth by stakeholders in digital news media (e.g., activists, politicians, and civilians) is analyzed to describe the climate of contemporary critical discourses. By examining these two data sources, this analysis brings attention to the ethical complexities that define the climate of MAiD in Canada.

METHODS

This paper presents a critical analysis of two types of data: 1) interview responses from Canadian physicians regarding the practice of MAiD, and 2) Canadian digital print news media, with the goal of determining areas of convergence and divergence in the narratives of both source types. A qualitative descriptive approach was used to elicit the perspectives of physicians across a variety of specialties to determine their moral rationalization regarding their decision to participate in or abstain from providing MAiD. Twenty-one in-depth semi-structured interviews were conducted with physicians practicing across Canada (see Table 1).

Table 1: Demographic characteristics of participants (n=21)

Area of medical specialty	Number	Percent
Family medicine	8	38.1
Palliative care	6	28.6
Obstetrics	1	4.8
Internal medicine	5	23.8
Psychiatry	1	5.8
Sex		
Male	7	33.3
Female	14	66.7
Years practicing medicine		
>30 years	12	57.1
21-30 years	4	19.0
11-20 years	2	9.5
6-10 years	2	9.5
1-5 years	0	0.0
<1 year	1	4.8
Geographic area of practice		
Southern Ontario	16	76.2
Northeastern Ontario	1	5.8
British Columbia	2	9.5
Manitoba	1	5.8
Saskatchewan	1	5.8

Age range	Number	Percent
18-29	1	5.8
30-39	1	5.8
40-49	2	9.5
50-59	5	23.8
60-69	8	38.1
70+	4	19.0
Involvement with WLT*		
Yes	19	90.5
No	2	9.5
MAiD provider		
Yes	14	66.7
No	7	33.3
Number of MAiD assessments		
0 (does not assess)	5	23.8
1-50	5	23.8
51-100	3	21.1
>100	8	38.1
Number of MAiD provisions		
0 (does not provide)	7	33.3
1-50	6	28.6
51-100	5	23.8
>100	3	21.1

WLT = withdrawing life-sustaining treatment

Interviews were conducted between October and December 2020 via Microsoft Teams. Recruitment was facilitated through an advertisement on the website of the Canadian Association of MAiD Assessors and Providers, along with convenience sampling of physicians known to members of the research team. A demographic survey, consent forms, and a document outlining the foci of the study were shared with participants prior to scheduling an interview. Interviews were transcribed verbatim and identifiers were removed to ensure participant anonymity. The duration of interviews ranged from 30 to 120 minutes. This project received ethics clearance from the University of Waterloo Office of Research Ethics (ORE #40801).

While the original goal of the interview guide was to elicit how physicians conceptualize MAiD provisions in comparison with their views of withdrawing life-sustaining treatment (WLT), the emergent nature of qualitative data revealed meaningful insights about how physician involvement in MAiD may be challenged in the wake of evolving laws, namely Bill C-7. To gain further insight and context regarding national social perspectives about this issue, a second data source — Canadian digital news media — was integrated into the analysis. Digital media sources consulted included English-language articles about MAiD and Bill C-7 published in Canadian news outlets since 2020, the year the Government of Canada published its legislative response to the Truchon decision, which found the "reasonable foreseeability of natural death" eligibility criterion unconstitutional. National, provincial, and municipal publications were included to capture a diversity of perspectives on Bill C-7 across the nation. The news media review was conducted from July to September 2024 in the wake of the federal government's delay, until 2027, in expanding MAiD access to individuals solely experiencing mental illness (8). Purposive sampling was applied to capture news media that was reflective of central political and social concerns about the law; in particular, those which addressed mental illness, disability, and poverty. Articles focusing exclusively on descriptive accounts without critical analysis of C-7's implications were excluded. The sample consists of thirty sources comprised of news articles, opinion editorials, and columns (see Table 2). The goal of this study was not to exhaustively capture each article published in this area since 2020, but to explore key themes about MAiD and C-7 by highlighting representative and detailed examples.

Table 2: Included sources in the digital news media review

Title	Source	Author(s)	Date
Canadian Senate passes Bill C-7, expanding assisted dying to include mental illness	Global News	J Bryden	18-Mar-21
As Bill C-7 reaches Senate, UN watchdog raises concerns about MAiD for persons with disabilities	CBC News	T Mahboob	02-Feb-21
Bill C-7, assisted dying and "lives not worth living"	Policy Options	JS Beaudry	14-Dec-20
Q and A with Heidi Janz: COVID-19 exposed ableism, assisted death Bill C-7 endangers those with disabilities	Edmonton Journal	L Boothby	25-Oct-20
How Bill C-7 will sacrifice the medical profession's Standard of Care	Policy Options	T Lemmens, MJ Shariff, L Herx	11-Feb-21
Senate amendment raises debate over medically assisted death for those with mental illness	CTV News	A Favaro, E St. Philip, AM Jones	10-Feb-21
Doctors condemn changes to Canada's assisted dying law as 'reckless'	CityNews	R Bernard	28-Nov-20
Canada's broken social safety net pushes people toward assisted dying	The Globe and Mail	B Murdoch	22-Apr-24
Doctors, disability advocates condemn parliamentary committee's recommendation to expand MAiD law	The Globe and Mail	E Anderssen	07-Mar-23
Quadriplegic Quebec man chooses assisted dying after 4-day ER stay leaves horrific bedsore	CBC News	R Watts	12-Apr-24
Manitoba woman devastated over delay in MAID for mental illness	CBC News	C Kemp	04-Feb-24
When harm reduction meets medical assistance in dying	National Post	C Selley	20-Oct-23
Opinion: Why I so desperately need a medically assisted death	Ottawa Citizen	J Scully	02-Feb-24
Calgary judge rules 27-year-old can go ahead with MAID death despite father's concerns	CBC News	M Grant	25-Mar-24
Misunderstanding of mental illness clouds MAID expansion, patient and psychiatrist say	CBC News	A Zafar	01-Feb-24
Ontario man not considering medically-assisted death anymore after outpouring of support	CityNews	C Mulligan, M Bond	17-Nov-22
Woman with chemical sensitivities chose medically-assisted death after failed bid to get better housing	CTV News	A Favaro	13-Apr-22
Police investigating medically-assisted death of B.C. woman	CTV News	A Favaro	26-Apr-22
Opinion: Canada will never be ready to expand assisted death to those with mental illness	Ottawa Citizen	D Zekveld	09-Feb-24
Opinion: If medically assisted death becomes more accessible for Canadians, we have a moral obligation to make living well — through housing, mental health supports — accessible too	Toronto Star	N Dosani	11-Feb-21
I am a MAID provider. It's the most meaningful — and maddening — work I do. Here's why.	Maclean's	M Li	13-Feb-24
Canadians with mental disorders shouldn't be excluded from requesting MAID	Maclean's	M Gupta	04-May-23
'Make it stop': Charter challenge launched against Ottawa for excluding mental illness from MAID	National Post	S Taylor	19-Aug-24
A timely reminder that the courts need to keep their noses out of individuals' medical decisions	The Globe and Mail	A Picard	02-Apr-24
Surge in medically assisted deaths under Canada's MAiD program outpaces every other country	Toronto Star	M Khalatbari	27-Jan-24
Opinion: I've seen what a good death looks like. I hope MAiD's future looks the same	The Globe and Mail	N Richler	01-Mar-24
Loneliness big factor in people choosing medically assisted death: Doctor	The Sudbury Star	L Stradiotto	03-May-24
MAID law on the right to die should respect individual choice: ethicist	CBC News	N Ayed	16-May-24
Spina bifida patient says Montreal hospital staff twice offered MAiD unprompted	CTV News	M Gilmour	05-Jul-24
'Catastrophic Pandora's box': Disabled Ontarians speak out against proposed MAiD law	TV Ontario	M Gilmore	03-Mar-21

A thematic analysis was completed by moving between reading the articles and reviewing interview transcriptions to identify dominant themes between sources. The goal was to determine whether the concerns presented by the news media were reflective of those expressed by physicians who are either involved in or proximate to MAiD in clinical practice.

RESULTS

The results of this analysis are representative of thirty digital news media sources and twenty-one interviews with Canadian physicians. Perspectives in the articles included those of disability rights activists, ethicists, academics, politicians, journalists, and physicians. The diversity of stakeholder perspectives included through news sources moved away from an exclusively clinical perspective on Bill C-7's impact and instead considered a nuanced perspective from a variety of societal actors. The analysis captured four overarching themes: 1) autonomy and choice, 2) "dying with dignity" and harm reduction, 3) paternalism and vulnerability, and 4) the medicalization of suffering.

Theme 1: Autonomy and choice

Patient autonomy was the most dominant theme across all sources analyzed. Arguments in favour of both MAiD in its original state as well as justifying its expansion post C-7 are typically based on the idea that access to the procedure provides patients experiencing grievous illness with the choice to end their lives as they see fit, thus allowing them a degree of control in an otherwise intractable experience. From the perspectives of the physicians interviewed, autonomy was a central consideration to ethical medical practice. Whether in cases where patients had non-foreseeable trajectories of death or those with a terminal diagnosis, many physicians expressed that access to MAiD was a means of respecting a patient's right to make self-directed choices about their medical care.

> *The patient has chosen to make an end-of-life choice that is consistent with all other life choices they make… the fundamental freedom we give to people to make choices about their life extends to MAiD [when] suffering exceeds present quality of life.* (Participant N, general practitioner, 30+ years of practice, provides MAiD)

Another physician challenged the notion posed by opponents that enhanced access to palliative care may negate the relevance of MAiD's expansion. They held that such arguments did not offer due recognition of the importance of patient choice:

> *There is critical importance in managing the autonomy of any patient… I challenge [those opposed] on the ridiculous notion that palliative care done well gets rid of the need for MAiD. Palliative care providers, in general, do a lousy job of managing that component of existential suffering.* (Participant J, palliative care specialist, 11-20 years of practice, provides MAiD)

In defence of Bill C-7, one Canadian senator expressed his support on the basis of autonomy, arguing that "our bodies and minds belong to us." (9) Arguing in favour of MAiD liberalization, one Canadian ethicist held that patient autonomy "…is a fundamental value for patients experiencing mental illness." (10) Articles reporting first-hand accounts by Canadians experiencing mental illness show similar sentiments. One individual with a mental illness felt that the expansion of MAiD would "liberate [them] from… crushing oppression of not having bodily autonomy," (11) thus depicting the availability of the procedure as giving them the ability to determine the trajectory of their own life. While recognizing the novel ethical terrain raised with Bill C-7, one physician shared that their commitment toward enabling patient autonomy remained:

> *I feel uncomfortable by the new bill [C-7], but I feel very strongly about patient autonomy. I would tread with great caution [during provisions], but I'm not sure if I could even follow through. I haven't faced that yet.* (Participant E, general practitioner, 30+ years of practice, provides MAiD)

There is debate within the medical community about how to balance autonomy with other ethical considerations, such as non-maleficence; namely, whether providing MAiD to patients with non-terminal illness may erode trust in the medical profession. Regarding this concern in the context of disability advocacy groups, one physician challenged this notion:

> *There's a lot of talk from disability groups that [Bill] C-7 will cheapen lives or reduce meaning in life, and I don't feel that way at all. I think it recognizes both their suffering and autonomy.* (Participant P, general practitioner, 30+ years of practice, provides MAiD)

Theme 2: "Dying with dignity" and harm reduction

A second core theme prevalent in physician interview responses was the concept of death with dignity and reducing potential harms faced by a patient who does not have MAiD as an option. The idea of dying with dignity refers to the belief that patients should have a right to make decisions about the end of their life in a way that aligns with their personal wishes and reduces grievous suffering. This view of MAiD is informed by principles of harm reduction, where the availability of the procedure minimizes the negative social or physical consequences that arise when an individual attempts to take their own life. Physicians in our sample shared cases where a patient had committed suicide due to MAiD ineligibility under the previous law, and argued that Bill C-7 would offer a better form of death:

> *A few of my patients have committed suicide, they were spiritually suffering… I was devastated. Those are not good deaths. For the family, it's devastating. I want deaths to be good not just for the patient, but for families as well. They carry scars for the rest of their lives.* (Participant P, general practitioner, 30+ years of practice, provides MAiD)

> *When a mentally ill person requests MAiD, some are very likely to die by suicide if you do not help them… the intent is to relieve suffering.* (Participant M, psychiatrist, 11-20 years of practice, assesses for but does not provide MAiD)

Though arguments regarding the moral permissibility of MAiD have never been without controversy, dichotomous opinions as to the appropriateness of this idea have heightened in the wake of Bill C-7. Several articles reviewed called the idea of dying with dignity under the new law into question. An article published in the Toronto Star stated that "…we don't give marginalized people a chance to live with dignity, but we are all too eager to provide a path in dying with dignity." (12) The Ontario Disability Justice Network was quoted as stating that any legislation that affords a right to die but does not guarantee the right to live is

"inhumane." (11) Without guarantees of access to a minimum standard of living, the expansion of the MAiD law puts vulnerable individuals "in circumstances where they [have] no other choice." (13) These concerns become reality in cases such as that of a quadriplegic man living in Quebec who developed a bedsore while awaiting care in a hospital, and who qualified for and then received MAiD due to the severity of his condition and fear of becoming burdensome (14). In other cases, the multidimensional nature of patient suffering is complicated by factors such as comorbid physical and mental conditions, resulting in poor conditions of living. The interplay of these factors is difficult to navigate in MAiD provisions, as shared by one physician:

> *I had a marginally housed patient… it was dirty, it was smelly, he had a chronic symptom burden and a severe personality disorder. I gave him the gift of a dignified death, which was very meaningful to me and his family. I wanted to treat him fairly, not dismiss him due to his terrible housing and economic situation, but also wanted to ensure these things weren't the main reasons [that] he was or wasn't found eligible.* (Participant C, general practitioner, 30+ years of practice, provides MAiD)

Theme 3: Paternalism and vulnerability

This theme explores the tension experienced by medical providers in protecting people from harm, particularly those who are part of vulnerable populations. The expansion of MAiD to individuals without a foreseeable trajectory to death has a marked impact on individuals who are physically disabled, severely mentally ill, or experiencing complications of chronic illness. Due to the widespread reporting of systemic injustices and inequitable treatment of vulnerable populations post Bill C-7, there are substantial ethical questions about the role of physicians in safeguarding the rights of marginalized individuals to engage in self-determination versus imposing unwelcome clinical judgment. Attending specifically to the potential of MAiD on mental health grounds, a psychiatrist interviewed by Maclean's held that "we can't say… how important it is to destigmatize mental disorders, and [then] pass laws that single out people with these disorders, portraying them as unable to make their own decisions… assessors may wrongly assume that they can't consent, or underestimate the severity of their suffering." (15) This belief was echoed by a physician respondent who does not participate in MAiD:

> *There is a conflict between forcing inpatient treatments of psychiatric patients who are trying to commit suicide and who don't want to go on living versus allowing patients with medical illness to terminate their life. There's a value judgment there, there's one person we trust and another we're exerting paternalism on, that we know better than them… there's a double standard. MAiD either needs to be abolished completely, or everyone should have equal access.* (Participant J, internal medicine specialist, <1 year of practice, does not provide MAiD)

Another physician interviewed by CBC News said that when MAiD was first introduced, she took patient requests at face value due to the basis of terminal illness. She now "discuss[es] transparently with a patient whether… MAiD is the right choice for them and help them understand [her] rationale and let them convince [her] that it is the right decision for them." (16) This refined approach, as suggested by participating physicians, aims to protect vulnerable individuals who may feel that they are being pushed toward a premature death due to a lack of access to social supports and comprehensive mental health care. Without such safeguards, there is concern that C-7 will "displace the… professional rule of the standard of care, which obligates physicians to apply their… intricate knowledge to a patient's clinical circumstances and replace it with patient choice." (17) The "standard of care" is informed by the idea that physicians have scientific expertise rooted in evidence-based medical research and standards set by professional organizations. The informational asymmetry between patient and provider places clinicians in a position of power in which they have a commitment to offer the safest and most suitable care option to a patient. Challenging the notion that providers of MAiD would do away with clinical discretion in the face of the evolving law, one physician respondent argued:

> *The language used by psychiatrists implies that we would see a patient and immediately accept their [MAiD] request without doing our due diligence or trying everything else that we possibly can. It's strange and quite offensive to me.* (Participant M, psychiatrist, 11-20 years of practice, assesses for but does not provide MAiD)

Theme 4: The medicalization of suffering

Without supports to offer a minimum standard of living for individuals to live well within society, vulnerable individuals may be inclined to apply for MAiD due to lacking access to resources that enable them to live a good life. This theme addresses perceived implicit ableist assumptions in the expansion of the MAiD regime that subtly imply that the lives of disabled people are worth less than those who are able-bodied. The new bill is described as "part of an incomplete and harmful approach to justice for people who are sick, old, or disabled" (18) and attempts to apply medical solutions to social problems. In a highly publicized case of MAiD gone awry, a St. Catharines, Ontario, man with chronic back pain applied for the procedure due to his inability to subsist on ODSP (Ontario Disability Support Program) and fear of homelessness (19). While support from community organizations enabled him to meet his financial needs, he stated that "governments should be focused on fixing the issues causing poverty rather than the moral ramifications of those in poverty seeking MAiD" (19), gesturing to the importance of upstream solutions to health inequities. As the passage of Bill C-7 had overlap with the COVID-19 pandemic which resulted in a public health-led national vaccination campaign to reduce mortality rates, one physician interviewed pointed to the stark contrast between the issues:

> *In the middle of the COVID pandemic and we're so worried about keeping everyone alive, yet the long-term facilities are filled with abuses — and we want to provide more people with MAiD? It's just schizophrenic.* (Participant B, palliative care specialist, 30+ years of practice, does not provide MAiD).

In an interview with the CBC, the United Nations watchdog for people with disabilities expressed concern about the liberalization of Canada's MAiD laws amid a lack of community services and affordable living options for those with disability. His worry was with regards to an "architecture of choice, [where] the various inputs into making our decisions will be… rigged when it comes to people with disabilities because of a lack of access to basic services to enable them to live with their condition." (20) Recounting cases of MAiD requests which were countered with treatment to the social determinants of health, particularly income, housing, and social inclusion, one palliative care physician stated that "…it should be reasonable to expect that the same energy put into passing MAiD will also be put into addressing the upstream factors that lead to poor health, like a national housing strategy, improving harm reduction services, implementing basic income strategies, and pharmacare." (21) One physician found that by addressing feelings of loneliness and social isolation, many patients withdraw their MAiD requests, thus validating the importance of community-based supports (22). Several articles included in this analysis also point to the fact that not all Canadians have equal access to palliative care, particularly those who are structurally vulnerable (22-25). These same concerns were reflected in our interviews with physicians:

> *How can we go forward with C-7 when we don't even provide universal access to palliative care or access to [social] resources? We don't have full psychosocial resources available*. (Participant D, palliative care specialist, 6-10 years of practice, does not provide MAiD)

> *I struggle when people suffering come to the health care system… and sometimes I wonder if only we could get them better housing, more supports in the home, or psychotherapy, and not making decisions from emotional distress. Sometimes, we can't do anything, and a poor person is going to die of something else anyway, and there are no active remedies for the situation. This causes me a lot of grief — is the cause of their condition social suffering or illness? Our system lets people down.* (Participant F, general practitioner, 30+ years of practice, provides MAiD)

DISCUSSION

This comparison of physicians' firsthand perspectives and digital news media provides important insights into the evolving health policy landscape of MAiD in Canada. By integrating both data sources, this study offers a textured, though not exhaustive, account of the current tensions and ethical considerations. While these narratives do not fully capture the nuance, diversity, or dynamism of the ongoing social debates surrounding MAiD in Canada, they nonetheless raise key themes across professional and public-facing discourse that can inform more responsive policy development.

The results showed that autonomy lies at the core of MAiD considerations, particularly from the perspective of physicians involved in the practice. This is consistent with the findings of recent research about MAiD in Canada (3,4,26,27). Many physicians felt that enabling access to MAiD is part of the fundamental freedom of self-determination and making decisions reflective of a patient's own values and lives, regardless of whether death was foreseeable. Texts capturing the perspectives of politicians, academics, and Canadians experiencing mental illness upheld autonomy as the central consideration in the expansion of MAiD laws, using the language of 'liberation' and 'empowerment' to justify expanding eligibility criteria. These opinions work on the underlying assumption that individuals are able to engage in medical decision-making free from the constraints of broader social structures, such as access (or lack thereof) to the resources necessary for ensuring the minimum standards of a good life. Autonomy-based perspectives, both in interviews and textual documents, typically did not consider the coercive influences of structural vulnerabilities such as poverty, a lack of access to community-based support, or other treatments that constrain the range of choices available through end-of-life care. Such responses show a static rather than relational conception of autonomy, wherein the right to 'choice' is taken at face value without recognition that autonomy may be enhanced or undermined through social context (28,29). Social commentaries and academic pieces have noted the disproportionate weight placed on autonomy in the development of MAiD legislation, to the detriment of values such as protection of the vulnerable (26,30,31). As self-determination necessitates that individuals are free from oppression and exist in a state of relative social equality (32), it is questionable whether such conditions are experienced equally across Canada.

Notably, physicians in our sample disagreed on the common policy assumption that expanding access to high-quality palliative care would reduce MAiD requests. Some providers emphasized that many of their MAiD-eligible patients were already receiving exemplary palliative care services yet continued to experience intolerable psychosocial suffering. This challenges the view that palliative care expansion alone could resolve MAiD-related distress. However, other physicians and commentators advocated for strengthening community care infrastructure under the presumption that MAiD requests may emerge from systemic gaps. This difference in perspective highlights how professional experiences and disciplinary norms shape understandings of suffering and the boundaries of medicine.

While harm reduction is a policy approach that is typically advanced in response to public health issues (e.g., drug use), recent scholarship has demonstrated its transferability to other contexts (33). Harm reduction is grounded in a recognition that the recommended solution to a complex problem is imperfect, and that as such, the option resulting in the least harm to an individual may be the best course of action. The findings of this study show that harm reduction arguments were advanced

alongside those holding that MAiD provides a dignified death for individuals experiencing intractable suffering. At the core of these views is the possibility that if denied access to a controlled medically assisted death, an individual may resort to harmful means to take their own life. Physician respondents spoke of encountering such cases in their respective medical practices, and articles written about Canadians experiencing non-terminal or mental illness cited their histories of suicidal attempts (34,35). The current literature contradicts this perspective, with one systematic review of international assisted suicide programs concluding that "…there is no evidence… to support the hypothesis that [MAiD] reduces non-assisted suicide." (36) Other textual sources questioned how Canadian society can express commitment toward dying with dignity when vulnerable individuals fail to receive the support necessary to live a minimally good life (11,12).

Paternalism, or the idea that select patients may be trusted while others are questioned, was considered. Most physicians felt that to prevent the development of a double standard with regard to patients deemed trustworthy and worthy of self-governance and those who are not, MAiD should not be restricted to the nature of the underlying condition. This follows from longstanding bioethical debates that situate autonomy and paternalism as oppositional constructs (37-39), with the false dichotomy that only one may prevail. Considerations of paternalism were given less attention by the writings of non-medical stakeholders (e.g., politicians, academics, or social commentators), which follows from the role that a physician plays as a 'healer' and a purveyor of medical expertise. There is a dissensus in the medico-ethical literature about the role of paternalism in MAiD. One perspective emphasizes the importance of case-by-case variability, arguing that sound clinical judgment should guide eligibility determinations regardless of whether death is reasonably foreseeable (4,40,41). Another contends that the medical standard of care requires physicians to withhold a terminal procedure if they believe other support measures could provide adequate relief. While these positions are not necessarily mutually exclusive, tension arises when clinical judgment leads to approving MAiD despite the availability of alternative interventions, highlighting an ethical conflict between respecting patient autonomy and adhering to professional obligations (17).

The final theme, the medicalization of suffering, underscores the risk of MAiD being perceived as a 'solution' to systemic failures, such as inadequate social services, rather than focusing on providing comprehensive support that allows individuals to live well. In general, the perspectives offered both by the physician sample and those analyzed through the digital media analysis achieved consensus on the reality of this issue. As one respondent noted, there is a distinctive contrast between the public health initiative to reduce mortality during the COVID-19 pandemic and the simultaneous expansion of MAiD — a juxtaposition that calls into question the consistency of societal values regarding which lives are worth saving. This critique of MAiD as a tool of medical ableism is echoed in recent literature (30,42). Critical responses to the post C-7 climate are troubled by the role of systematic inequalities as precipitating factors driving MAiD requests, and so argue that government instead focus on evaluating opportunities for improved services rather than continuing to expand the law (30,43). Concurrently, some participants argued that suffering is not always reducible to social context. For instance, looking to countries such as the Netherlands, where social safety nets are more extensive, some respondents noted that assisted death remains in demand even under more equitable conditions. Caution must thus be exercised in reducing MAiD requests to failures of policy, with recognition that conceptions of suffering are deeply subjective.

Together, the findings of this study contribute to naming the significant ethical quandaries that permeate the revised MAiD regime in Canada. The growing emphasis on autonomy, while central to respecting individual rights, can obscure the structural vulnerabilities that limit meaningful choice for many. As eligibility criteria continue to expand, policymakers must balance the imperative to respect patient preferences with a commitment to reducing inequality and bolstering the broader health care and social service systems. Rather than viewing these goals in conflict, a responsive MAiD policy must recognize that autonomy is only valuable when supported by the conditions necessary to live and die with dignity.

CONCLUSIONS

The expansion of MAiD through Bill C-7 has introduced considerable ethical, medical, and societal challenges in extending eligibility criteria to those whose deaths are not reasonably foreseeable. A joint analysis of physicians' perspectives and dominant narratives in digital news media found four central themes of concern: autonomy and choice, dying with dignity and harm reduction, paternalism and vulnerability, and the medicalization of suffering. While both physicians and public stakeholders emphasized a commitment to patient autonomy, participants expressed unease regarding the role of structural inequities and the risk that MAiD may be used as a response to unmet health and social needs. As such, effective health policy must move beyond legal eligibility frameworks to confront the systemic conditions that drive MAiD requests. While this analysis offers valuable insights into prominent discourses, it does not claim to capture the full complexity of the ongoing MAiD debate, which continues to evolve across cultural contexts. Policymakers must prioritize upstream solutions, such as strengthened mental health services, affordable housing, and robust social supports to ensure that all individuals have both the right to die with dignity and the opportunity to live well.

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REFERENCES

1. Government of Canada. Legislative background: medical assistance in dying (Bill C-14). 2016.
2. Government of Canada. Bill C-7: An Act to amend the Criminal Code (medical assistance in dying). 2020.
3. Coelho R, Maher J, Gaind KS, Lemmens T. The realities of medical assistance in dying in Canada. Palliat Support Care. 2023;21(5):871-8.
4. Wiebe K, Mullin A. Choosing death in unjust conditions: hope, autonomy, and harm reduction. J Med Ethics. 2024;50(6):407-12.
5. Kaiser A, Grant I, Lemmens T, Sheehy E. Opinion: MAiD bill is an affront to equality. Toronto Star. 11 Mar 2021.
6. Quinn G, De Schutter O, Mahler C. Disability is not a reason to sanction medically assisted dying — UN experts. UN Office of the High Commissioner; 2021.
7. Levitz S. Assisted dying bill sends wrong message to young Indigenous people, advocates argue. The Canadian Press. 24 Nov2020.
8. Government of Canada. Canada's medical assistance in Dying (MAiD) law. 2024.
9. Favaro A, St. Philip E, Jones AM. Senate amendment raises debate over medically assisted death for those with mental illness. CTV News. 11 Feb 2021.
10. Ayed N. MAID law on the right to die should respect individual choice: ethicist. CBC News. 16 May 2024.
11. Gilmore M. 'Catastrophic Pandora's box': Disabled Ontarians speak out against proposed MAiD law. TV Ontario. 3 Mar 2021.
12. Khalatbari M. Surge in medically assisted deaths under Canada's MAID program outpaces every other country. Toronto Star. 27 Jan 2024.
13. Gilmour M. Spina bifida patient says Montreal hospital staff twice offered MAiD unprompted. CTV News. 5 Jul 2024.
14. Watts R. Quadriplegic Quebec man chooses assisted dying after 4-day ER stay leaves horrific bedsore. CBC News. 12 Apr 2024.
15. Gupta M. Canadians with mental disorders shouldn't be excluded from requesting MAID. Maclean's. 4 May 2023.
16. Zafar A. Misunderstanding of mental illness clouds MAID expansion, patient and psychiatrist say. CBC News. 1 Feb 2024.
17. Lemmens T, Shariff MJ, Herx L. How Bill C-7 will sacrifice the medical profession's Standard of Care. Policy Options. 11 Feb 2021.
18. Beaudry JS. Bill C-7, assisted dying and "lives not worth living." Policy Options. 14 Dec 2020.
19. Mulligan C, Bond M. Ontario man not considering medically-assisted death anymore after outpouring of support. CityNews.16 Nov 2022.
20. Mahboob T. As Bill C-7 reaches Senate, UN watchdog raises concerns about MAiD for persons with disabilities. CBC News. 2 Feb 2021.
21. Dosani N. Opinion: If medically assisted death becomes more accessible for Canadians, we have a moral obligation to make living well - through housing, mental health supports - accessible too. Toronto Star. 11 Feb 2021.
22. Stradiotto N. Loneliness big factor in people choosing medically assisted death: Doctor. The Sudbury Star. 3 May 2024.
23. Anderssen E. Doctors, disability advocates condemn parliamentary committee's recommendation to expand MAiD law. The Globe and Mail. 6 Mar 2023.
24. Boothby L. Q and A with Heidi Janz: COVID-19 exposed ableism, assisted death Bill C-7 endangers those with disabilities. Edmonton Journal. 25 Oct 2020.
25. Richler N. Opinion: I've seen what a good death looks like. I hope MAiD's future looks the same. The Globe and Mail. 1 Mar 2024.

26. Brassolotto J, Manduca-Barone A, Zurbrigg P. Medical assistance in dying: a review of related Canadian news media texts. J Med Humanit. 2023;44(2):167-86.
27. Durant KL, Kortes-Miller K. Physician snapshot: the forming landscape of MAiD in northwestern Ontario. Palliat Care Soc Pract. 2020;14:2632352420932927.
28. Mackenzie C, Stoljar N, editors. Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self. New York: Oxford University Press; 2000.
29. Veltman A, Piper M, editors. Autonomy, Oppression, and Gender. New York, Oxford University Press; 2014.
30. Grant I, Benedet J, Sheehy E, Frazee C. A conversation on feminism, ableism, and medical assistance in dying. Can J Women Law. 2024;35(1):31-72.
31. CBC Radio. 'Cold comfort to be offered the choice to die' when not offered support to live, says disability advocate. The Current. 19 Nov 2020.
32. Mackenzie C. Three dimensions of autonomy: A relational analysis. In: Veltman A, Piper M, editors. Autonomy, Oppression and Gender. New York: Oxford University Press; 2014. p. 15-41.
33. Dea S, Weinstock D. Harm reduction: a research agenda. Health Care Analysis. 2020;28(4):299-301.
34. Scully J. Opinion: Why I so desperately need a medically assisted death. Ottawa Citizen. 2 Feb 2024.
35. Kemp C. Manitoba woman devastated over delay in MAID for mental illness. CBC News. 4 Feb 2024.
36. Doherty AM, Axe CJ, Jones DA. Investigating the relationship between euthanasia and/or assisted suicide and rates of non-assisted suicide: systematic review. BJPsych Open. 2022;8(4):e108.
37. Husak DN. Paternalism and autonomy. Philos Public Aff. 1981;10(1):27-46.
38. Brock DW. Paternalism and autonomy. Ethics. 1988;98(3):550-65.
39. Scoccia D. Paternalism and respect for autonomy. Ethics. 1990;100(2):318-34.
40. Dembo J, Schuklenk U, Reggler J. "For their own good": A response to popular arguments against permitting medical assistance in dying (MAID) where mental illness is the sole underlying condition. Can J Psychiatry. 2018;63(7):451-56.
41. Downie J, Schuklenk U. Social determinants of health and slippery slopes in assisted dying debates: lessons from Canada. J Med Ethics. 2021;47(10):662-69.
42. Janz H. Plagued to death by ableism: What the COVID-19 pandemic and the expansion of eligibility for MAID reveal about the lethal dangers of medical and systemic ableism in Canada. Can J Bioeth / Rev Can Bioeth. 2023;6(3-4):137-41.
43. Whitelaw S, Lemmens T, Van Spall HG. The expansion of medical assistance in dying in the COVID-19 pandemic era and beyond: Implications for vulnerable Canadians. Can J Gen Intern Med. 2022;17(2):17-21.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Does Allowing Track 2 MAiD Harm Disabled People?

Nicholas J. Abernethy[a]

Résumé
En 2021, en réponse à la décision de la Cour supérieure du Québec dans l'affaire Truchon c. Canada, le Parlement canadien a modifié le Code criminel afin d'autoriser l'aide médicale à mourir (AMM) pour certaines personnes qui n'ont pas de « mort naturelle raisonnablement prévisible ». Cette modification fait l'objet d'un vif débat. Certains universitaires et militants soutiennent notamment qu'elle devrait être abrogée car elle est discriminatoire à l'égard des personnes handicapées. En 2024, ces arguments ont été présentés dans le cadre d'une procédure judiciaire canadienne ; deux personnes handicapées et quatre organisations de défense des droits des personnes handicapées ont intenté une action en justice devant la Cour supérieure de justice de l'Ontario, contestant la modification. Dans cet article, j'analyse de manière critique les arguments centrés sur le préjudice présentés dans l'avis de demande des requérants (qui cristallise l'opposition plus large à la modification). Pour ce faire, je m'appuie sur l'analyse des deux côtés du débat éthique sur la modification. En fin de compte, je conclus que les arguments des requérants — et ceux des autres opposants à la modification — ne sont pas recevables. Certaines de mes objections récurrentes sont que les effets néfastes allégués de la modification sont soit 1) néfastes uniquement si les hypothèses éthiques douteuses des requérants sont vraies, 2) non attribuables à la modification, soit 3) inexistants, négligeables ou improbables. Pour défendre la modification, j'explique en quoi elle respecte l'autonomie des personnes et évite l'instrumentalisation.

Mots-clés
aide médicale à mourir, discrimination, handicap, Canada, autonomie

Abstract
In 2021, in response to the Superior Court of Quebec's decision in Truchon v. Canada, the Canadian Parliament amended the Criminal Code to allow Medical Assistance in Dying (MAiD) for some people who don't have a "reasonably foreseeable natural death." Debate rages over this amendment. In particular, some academics and activists argue that it should be repealed because it discriminates against disabled people. In 2024, these arguments appeared in a Canadian court proceeding; two disabled individuals and four disability rights organizations filed a lawsuit in the Ontario Superior Court of Justice, challenging the amendment. In this paper, I critically analyze the harm-centric arguments in the applicants' notice of application (which crystallizes the broader opposition to the amendment). In doing so, I draw on analysis from both sides of the ethical debate over the amendment. Ultimately, I conclude that the applicants' arguments — and those from other opponents of the amendment — don't succeed. Some of my recurring objections include that the alleged harmful effects of the amendment are either 1) harmful only if the applicants' dubious ethical assumptions are true, 2) not attributable to the amendment, or 3) nonexistent, negligible, or unlikely. In defence of the amendment, I discuss how it respects people's autonomy and avoids instrumentalization.

Keywords
medical assistance in dying, discrimination, disability, Canada, autonomy

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INTRODUCTION

Since 2016, Medical Assistance in Dying (MAiD) has been legal in Canada for some people whose "natural death has become reasonably foreseeable" (alongside other eligibility criteria) (1). In 2021, the Canadian Parliament amended the *Criminal Code* to allow MAiD for some people whose "natural death is not reasonably foreseeable" (2). Since then, many academics and activists have argued that this change should be undone because it discriminates against disabled people, in the sense of constituting harmful differential treatment. Some critics have gone as far as saying that "MAiD for people not at the end of their lives… is a modern form of eugenics against people with disabilities" (3, p.39).

In September 2024, two disabled individuals and four disability rights organizations filed a lawsuit in the Ontario Superior Court of Justice, challenging the amendment to the *Criminal Code* (4). In this paper, I will critically analyze the applicants' arguments in their notice of application, which crystallizes the broader academic and activist opposition to the amendment. However, it is beyond the scope of this paper to determine whether the applicants' arguments are legally strong, i.e., whether they succeed in showing that the amendment violates the *Canadian Charter of Rights and Freedoms*. Instead, I explore whether they are strong merely as arguments about harmful differential treatment (although, of course, this exploration will have legal relevance). In doing so, I draw on analysis from both sides of the ethical debate over the amendment. Ultimately, I conclude that the arguments made by the applicants — and other opponents of the amendment — don't succeed.

LEGAL BACKGROUND

In 2016, in response to the Supreme Court of Canada's decision in *Carter v. Canada*, the Canadian Parliament passed Bill C-14, which legalized providing MAiD to people who meet the following eligibility criteria:

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> being an adult (at least 18 years old) who is mentally competent ("capable") to make health care decisions for themselves; having a grievous and irremediable medical condition (as defined under subsection 241.2(2)); making a voluntary request for medical assistance in dying which does not result from external pressure; giving informed consent to receive medical assistance in dying; and, being eligible for health services funded by a government (1).

Subsection 241.2(2) defines "having a grievous and irremediable medical condition" as follows:

> having a serious and incurable illness, disease or disability; and, being in an advanced state of irreversible decline in capability; and, experiencing enduring physical or psychological suffering, due to the illness, disease, disability or state of decline, that is intolerable to the person and cannot be relieved in a manner that they consider acceptable; and, where the person's natural death has become reasonably foreseeable (1).

The notion of a reasonably foreseeable natural death has been the subject of some interpretative disagreement, but, in practice, it means that "there is sufficient temporal proximity to death (it is coming soon), and/or that the trajectory towards death is predictable from the person's combination of known medical conditions and potential sequelae" (5, p.1). A precise timeline is unnecessary. When MAiD is provided to someone who satisfies all of Bill C-14's eligibility criteria, this is known as Track 1 MAiD (4).[1] For this track, the most common medical condition is cancer (6).

In 2021, in response to the Superior Court of Quebec's decision in *Truchon v. Canada*, the Canadian Parliament passed Bill C-7, which changed MAiD eligibility to no longer require a reasonably foreseeable natural death (4). When MAiD is provided to someone whose natural death isn't reasonably foreseeable, this is known as Track 2 MAiD (4). For this track, the most common medical conditions are "Neurological conditions and 'other' conditions (such as diabetes, frailty, autoimmune conditions, chronic pain)" (6).

EXPOSITION AND CRITICAL ANALYSIS

Perhaps the most important claim made by the applicants in the 2024 lawsuit is that all grievous and irremediable medical conditions (as defined by Bill C-7) are disabilities, so everyone who is eligible for either Track 1 MAiD or Track 2 MAiD is disabled (4). Some academics make the same claim (7,8). By contrast, Bill C-7 seems to define "disability" more narrowly. It says that a grievous and irremediable medical condition is an illness, a disease, *or* a disability, so it implies that not all grievous and irremediable medical conditions are disabilities.[2] Also, as I will discuss later, most MAiD recipients don't self-identify as disabled. However, for the sake of argument, I concede that the applicants are correct about the non-legal meaning of the word "disability." Given this, allowing Track 2 MAiD straightforwardly constitutes differential treatment vis-à-vis disabled people; it changes the MAiD eligibility of a subset of them, and it doesn't change the MAiD eligibility of anyone without a disability (4).[3] So, the real question is whether this differential treatment *harms* disabled people.

The applicants say yes. Specifically, they say that "Bill C-7's addition of MAiD Track 2 imposes a burden and denies a benefit in a manner that has the effect of reinforcing, perpetuating, and exacerbating the disadvantages faced by persons with disabilities" (4, p.12). The applicants identify many ways in which allowing Track 2 MAiD supposedly harms disabled people. I have sorted the harms into five bundles: 1) causing premature deaths, 2) legitimizing death as an appropriate response, 3) demeaning disabled people, 4) decreasing healthcare options, and 5) decreasing trust in the healthcare system. For each bundle, I will critically analyze the applicants' associated argument. Some of my recurring objections to these arguments include that the alleged harmful effects are either i) harmful only if the applicants' dubious ethical assumptions are true, ii) not attributable to allowing Track 2 MAiD, or iii) nonexistent, negligible, or unlikely.

Throughout my critical analysis, I will assume that Canadian MAiD providers follow the legal and professional requirements regarding MAiD (e.g., discussing the possibility of MAiD only with people who may be eligible) (9). This is for two main reasons. First, the available evidence strongly suggests that violations of these rules are vanishingly rare in Canada (10). Granted, there have been news stories of alleged rule violations, but such allegations have been repeatedly debunked (10-13). Second, in cases where MAiD providers don't follow the rules, there may well be discrimination against disabled people, but it seems incorrect to attribute this discrimination to allowing Track 2 MAiD (rather than attributing it to the rule violators and/or the rule enforcers who failed).[4] With this in mind, let's turn to the bundles of supposed harms.

[1] To be clear, the notion of "tracks" came after *Truchon*.
[2] This implication follows from the presumption against interpreting statutes as including redundancy.
[3] By this logic, allowing Track 1 MAiD also constitutes differential treatment vis-à-vis disabled people.
[4] Furthermore, I agree with the following point made by Eric Mathison: "we also know that unethical acts transpire in other forms of end-of-life care, or in other aspects of health care, and it would be a mistake to conclude that those other forms of health care should be banned because of rare problems. By analogy, the existence of drivers who break the law doesn't justify banning driving" (12).

Bundle #1: Allowing Track 2 MAiD Causes Premature Deaths

The applicants argue that allowing Track 2 MAiD "increases the risk that [disabled people] will end their lives prematurely" (4, p.13). The applicants' conception of premature death seems to include any deaths caused by Track 2 MAiD; they assert that "Death should not be a solution for disabled people who experience intolerable suffering but are otherwise not at the end of their lives" (4, p.9). Similarly, "There is no deprivation that is more serious and more irrevocable than causing someone who is not otherwise dying to die" (4, p.14). According to the applicants, the risk of premature death is exacerbated by both 1) how Track 2 doesn't make MAiD eligibility contingent on exhausting all available treatment options, and 2) how MAiD is — or is portrayed as — easier, less painful, more accessible, and more effective than other options (4).

There are many different conceptions of premature death inside and outside the academic literature (14), and the applicants don't specify which they have in mind. Fortunately, all that matters for my purposes is that they seem to believe that premature deaths are *harmful*. So, for the sake of simplicity, I will engage with their premature death argument as an argument about harmful death. Essentially, what the applicants are saying is that people who choose to receive Track 2 MAiD are making a choice that is bad for them, so Track 2 MAiD should be disallowed.

I have two main objections to this argument. The first is that it is very unclear whether the deaths caused by Track 2 MAiD are actually harmful. The second is that what would be much *more* harmful is violating currently eligible people's autonomy by preventing them from being able to choose Track 2 MAiD.

Objection #1: Are the Deaths Themselves Actually Harmful?

The main reason why it is very unclear whether the deaths themselves are harmful is because people who receive Track 2 MAiD were experiencing intolerable suffering. In 2023, over 70% of these people reported suffering from a "loss of dignity," and over 95% reported suffering from a "loss of ability to engage in meaningful activities" (6).[5] In most (if not all) cases, eligible patients request Track 2 MAiD because they judge that their life is very low-quality. They have unique epistemic access to their quality of life, so we should believe that this judgment is probably correct. Thus, receiving Track 2 MAiD deprives them of the continuation of a harmful life; arguably, such deprivation is beneficial (so long as it is consensual).[6] Furthermore, as bioethicist Udo Schüklenk contends, "not terminal patients are arguably worse off than those who do suffer from a terminal illness, because potentially they could be forced to suffer unbearably for many decades" (16, p.611).

In the Track 2 literature, there are two main arguments that can function as responses to this objection. The first holds that because Track 2 recipients are disabled, it is ableist to say that death may be better for them than continuing to live with their condition. According to legal scholar Isabel Grant, "the state offering death as a solution to the suffering of disability for those not at the end of life is inherently ableist and based on the discriminatory premise that disability *can be* worse than death [emphasis added]" (7, p.262). In the same vein, she condemns "an ableist stereotype that life with a disability *may be* worse than death [emphasis added]" (7, p.307). Almost identically, legal scholars Quinn et al. claim that it is "reiterating [an] ableist stereotype" to say that "significant disability *can be* worse than death [emphasis added]" (8, p.6).

This response has unacceptable implications. Both Grant and Quinn et al. share the applicants' view that a grievous and irremediable medical condition is a disability (7,8). So, Grant and Quinn et al. would have to affirm that an intolerably suffering late-stage cancer patient is reiterating an ableist stereotype and a discriminatory premise when they say that life with their condition (a significant disability) is worse than death because of their extreme pain.[7] However, affirming this would be deeply implausible. Furthermore, Grant and Quinn et al. would have to affirm similarly counterintuitive things about some people who are eligible for Track 2 MAiD (e.g., someone with severe transverse myelitis, causing paralysis and extreme pain).

Fortunately for the applicants, the second possible response to my doubting of the harmfulness of the deaths themselves is more prima facie plausible. According to this response, the deaths caused by Track 2 MAiD are harmful because even if the recipients' lives were very low-quality at the time, their lives would have improved if they had stayed alive. Thus, receiving Track 2 MAiD deprives them of beneficial futures. In the literature, Track 2 opponents provide two main reasons for why people's lives would improve if they were denied access to Track 2 MAiD.

The first reason is that many of the people in question would adapt to their disability. As Quinn et al. argue, "a major concern must be that persons with a disability (and perhaps especially those with newly acquired impairment) may opt too readily for assisted dying… even before having the chance of coming to terms with and adapting to their new disability status" (8, p.5). For example, physician and bioethicist Quentin Genuis highlights a case where "a previously able-bodied individual experienced sudden, inexplicable neurological illness that caused significant disability and chronic pain" (17). This individual was "paternalistically" denied access to Track 2 MAiD, so he stayed alive, and he is now grateful for this denial (17). Similarly, Track 2 opponents Coelho et al. adduce how "In a recent Canadian study, which followed patients with spinal cord injuries, half of the participants reported suicidal ideation during the first 2 years of experiencing their injury. However, in retrospect… none wanted MAiD after they had time to adjust to living in the community" (18, p.874). Presumably, after adapting, these people's lives were no longer very low-quality.

[5] Later I discuss the argument that this suffering is caused by systemic ableism, but what matters for this section is that suffering is harmful regardless of its cause.
[6] For debates on this topic, see the philosophy of death (15).
[7] Saying that one's own disability is worse than death directly entails that disability can be worse than death.

The main problem with this reason is that it seems to apply to only a small subset of people who receive Track 2 MAiD. In 2023, more than 50% of Track 2 recipients had lived with their grievous and irremediable medical condition for over five years, and fewer than 5% had lived with their condition for under a year (6). This evidence suggests that Track 2 recipients generally aren't people who haven't had the time to get used to their condition; recall that MAiD eligibility requires "enduring" suffering (2). As an aside, note that someone would be ineligible for Track 2 MAiD if the newness of their condition precluded confirming that they have decision-making capacity, enough information for informed consent, an irreversible decline in capability, suffering that can't be alleviated in a way they consider acceptable, etc.

The second reason provided for why eligible patients' lives would improve if Track 2 MAiD was disallowed is that eligible patients who have refused some of the available treatment options would try these options if they were denied access to Track 2 MAiD (19). For example, researcher Alexander Raikin points to "patients who become fixated on MAID, who under different circumstances, before MAID was a part of our culture, would have… pursued treatment options with a reasonable chance of success even though doing so would be temporarily unpleasant or uncomfortable" (20). Furthermore, Track 2 opponents Lemmens et al. argue that such cases are especially concerning vis-à-vis Track 2 because "In the non-end-of-life context, combining treatment refusal with a request to active ending of life raises the stakes" (21). Presumably, on average, such requesters risk losing more years of post-successful-treatment high-quality life (compared to Track 1 requesters who have refused some treatment options). In a similar vein, bioethicists Martin Gunderson and David Mayo say that "there is a much greater likelihood that a nonterminal patient who wishes to die could be restored to a meaningful existence, and hence a much greater chance that physician-assisted death would be a mistake for that patient, than would be the case for a patient near death" (22, p.22).

There are two main problems with this second reason, both of which flow from the fact that eligibility for Track 2 MAiD requires trying all available treatment options that one considers acceptable (1). The first problem is that, for eligible patients who have refused some treatment options, it is highly uncertain whether they would try these options if they were denied access to Track 2 MAiD. This is because there are four other things that they might do instead. The first is continuing to consider the options unacceptable, continuing to refuse them, and continuing to experience intolerable suffering (perhaps for many more years). The second alternative is suicide. Tragically, some people resort to this option when they are denied access to MAiD (23). Thus, allowing Track 2 MAiD may avoid some severe harms that some people would experience during suicide attempts and/or afterwards (in the event of a failed attempt) (24).[8] The third alternative is dying via methods like requesting the withdrawal of life-sustaining treatment or voluntarily stopping eating and drinking.[9] Again, such deaths can be more harmful than deaths caused by Track 2 MAiD (26). The fourth alternative is becoming eligible for Track 1 MAiD (and then receiving it) by expressing the intention to engage in the third alternative. As legal scholar Jocelyn Downie explains,

> patients can meet the "reasonably foreseeable" criterion if they have demonstrated a clear intent to take steps to make their natural death happen soon or to cause their death to be predictable… For Julia Lamb [a B.C. woman with spinal muscular atrophy], this means indicating a certain intent to stop BiPAP [a sleep breathing machine] and then refuse antibiotics for the pneumonia that will inevitably result from the lack of ventilatory support. By logical inference, for others it will mean indicating a certain intent to refuse regular turning, then refuse skin care for the inevitable bedsores, and then refuse antibiotics for the infections that will inevitably result from the untreated bedsores. For still others, it will mean indicating a certain intent to refuse all food and liquids (27).

Track 2 opponents fail to show that people would choose to try treatment options that they consider unacceptable rather than one of the above four alternatives.

The second main problem with the "people would try more treatment options" reason is that even for people who would do so if Track 2 MAiD was disallowed, it is uncertain whether these options would improve their quality of life to such an extent that living would become better for them than death, so it remains uncertain whether receiving Track 2 MAiD would harm them. As Downie and Schüklenk explain, "some decisionally capable persons with disabilities… reject the treatments, supports and services proposed by their clinicians (because they view life with them as worse than death)" (28, p.666), and it is questionable whether these people are incorrect in viewing things thusly. After all, MAiD eligibility requires being informed about all rejected treatment options.

For illustration, imagine a treatment option with a low chance of a significant increase in quality of life and a high chance of severe adverse effects (on top of prolonging pre-existing intolerable suffering). Understandably, someone seeking Track 2 MAiD might refuse this option because they consider it unacceptable. Would it harm this person to receive Track 2 MAiD rather than suffer through this other option? Track 2 opponents fail to show that the answer is yes.

There is one remaining criticism of Track 2 MAiD that is worth considering in this section on the deaths themselves. Namely, Coelho et al. condemn that, for Track 2 eligibility, "There is no requirement that standard best-practice treatments… are accessible" (18, p.874). The main problem with this criticism is that it has no bearing on whether the deaths caused by Track 2

[8] For more on this in the context of Track 1 MAiD, see *Carter*.
[9] By putting Voluntarily Stopping Eating and Drinking (VSED) in this third category rather than the second category, I am implying that it isn't suicide. I recognize that this is a controversial view (25). Fortunately, nothing in my argument depends on whether VSED counts as suicide.

MAiD are harmful. As Schüklenk explains, for a “patient who is failed by an unresponsive health care system,” “The health care system will be no more responsive if they are denied access to MAiD” (16, p.612). For reasons I will discuss later, disallowing Track 2 MAiD wouldn’t make standard best-practice treatments more accessible.

In summary, the applicants (and other Track 2 opponents) fail to show that the deaths caused by Track 2 MAiD are harmful.[10]

Objection #2: Disallowing Track 2 MAiD Would Violate People’s Autonomy

In this section, I argue that disallowing Track 2 MAiD would harm the people who would otherwise receive it because denying them access to Track 2 MAiD would violate their human right to autonomy over their lives. This right covers choosing Track 2 MAiD over other options (even more beneficial ones) as well as choosing Track 2 MAiD based on considerations like ease, painlessness, and efficacy.[11] The autonomy argument for MAiD in general has been made many times (and affirmed by the Canadian courts) (26,29), so I won’t repeat it. Instead, I will rebut objections that hold that the autonomy argument doesn’t work in the case of Track 2 MAiD.

But before doing so, it is worth explaining how the autonomy argument interacts with the previous section on the deaths themselves. Consider the following three possibilities. First, suppose that the previous section managed to show that the deaths caused by Track 2 MAiD aren’t harmful. If so, one should believe that denying people access to Track 2 MAiD definitely harms them — because of the harm of the autonomy violation. Second, suppose that the previous section managed to show merely that it is *unclear* whether the deaths caused by Track 2 MAiD are harmful. If so, one should believe that denying people access to Track 2 MAiD probably harms them, on balance, because of the clear and severe harm of the autonomy violation. Third, suppose that the previous section was utterly unsuccessful in resisting the view that the deaths caused by Track 2 MAiD are harmful. If so, one should believe that whether denying people access to Track 2 MAiD harms them, on balance, depends on the relative severity of the harm of the death vs. the harm of the autonomy violation. Although it is beyond the scope of this paper to rehash old debates over the following, my stance is that the latter harm would outweigh the former harm, so denying people access to Track 2 MAiD would harm them, on balance, even if the deaths themselves are harmful.

One might complain that the above paragraph is insufficiently granular. Perhaps the previous section managed to show that *some* of the deaths caused by Track 2 MAiD are probably harmless, whereas others are probably harmful. For example, perhaps one thinks that the deaths are probably harmless in the >50% of cases where a Track 2 recipient had lived with their condition for over five years, and probably harmful in the <5% of cases where a Track 2 recipient had lived with their condition for under a year.

The problem with this perspective (vis-à-vis the aim of the applicants) is that *at most* it could justify something like disallowing Track 2 MAiD for people who have lived with their condition for under five years.[12] Among other reasons, this perspective couldn’t justify disallowing Track 2 MAiD across the board because, in the words of philosopher Lawrence Nelson, disabled people should be “treated as unique individuals and not as some anonymous ‘disabled person’ lacking a character or personal history” (30, p.3).[13] Indeed, even some Track 2 opponents condemn “failure to recognize the particularities of disabled people’s lives” (7, p.329). However, one of the starkest examples of such failure would be disallowing Track 2 MAiD for all currently eligible patients on the basis that receiving Track 2 MAiD would be harmful for a subset of them.

With all of the above in mind, there are two main objections that contend that the autonomy argument doesn’t work in the case of Track 2 MAiD. The first is the Internalized Ableism Objection. According to this objection, denying someone access to Track 2 MAiD often wouldn’t violate their autonomy because people who choose Track 2 MAiD often do so non-autonomously, driven by internalized ableism (8,31).[14] In the words of disability ethicist Heidi Janz, “The prevalence of… ableist medical and social messaging is resulting in increasing numbers of… disabled people ‘choosing’ MAID as a final capitulation to ableism” (33, p.138). More specifically, as summarized by Track 2 defenders Kayla Weibe and Amy Mullin, the concern is that disabled people are choosing death in large part because “they have internalised an incorrect belief that life with a disability is less worthy than life without one” (34, p.410). On philosopher Danny Scoccia’s reconstruction of the Internalized Ableism Objection,

> What makes [such beliefs] tainted, inauthentic, or nonautonomous is their origins in an oppressive society, not their falseness per se. The reason why the option of [assisted dying] provides only the illusion of freedom is that the preferences it allows disabled people to satisfy were molded under conditions of unfreedom (35, p.485).[15]

[10] This failure is especially damning because, if Track 2 MAiD was disallowed, then a practitioner who provides Track 2 MAiD regardless would be guilty of murder. They could be given a life sentence for causing a harmless (and consensual) death, and this punishment seems unjust.
[11] If someone is misinformed about the degree to which MAiD possesses such features, then they can’t provide informed consent, so it would be illegal to provide MAiD to them.
[12] To be clear, I deny that the perspective would actually justify this, given the harm of the autonomy violation.
[13] This was affirmed in *Truchon.*
[14] For an example that shows that not all people who choose Track 2 MAiD are driven by internalized ableism, I encourage the reader to research the story of artist and disability advocate April Hubbard, who intends to receive Track 2 MAiD because of her increasingly debilitating disabilities (32). She would reject, in the strongest possible terms, that life with a disability is less worthy than life without one.
[15] As Scoccia correctly observes, “saying that preferences are nonautonomous if they rest on normative error [would be] fundamentally dishonest” (35, p.484).

There are three main problems with the Internalized Ableism Objection. The first is that even if many disabled people are choosing Track 2 MAiD because of internalized ableism, preventing them from doing so would still be a violation of their autonomy (so long as they have decision-making capacity). By analogy, it seems that it would be a violation of someone's autonomy to prevent them from dieting (or prevent someone else from helping them diet), even if this prevention was done on the basis that their desire for dieting is driven by internalized fatphobia. Similarly, it would be a violation of a woman's autonomy to prevent her from getting a facelift, even if this prevention was done on the basis that her desire for the surgery is driven by internalized ageism (and/or internalized sexist beauty standards).[16] The same would be true for preventing a homophobic bisexual man from dating only women, even if this prevention was done on the basis that his desire for doing so is driven by internalized homophobia.

The second main problem with the Internalized Ableism Objection (as reconstructed by Scoccia) is that its underlying assumption — that beliefs and preferences are inauthentic when they originate from oppression — is utterly untenable. For example, experiencing oppression can make someone develop an authentic preference for fighting oppression. Feminist theorist Serene Khader adduces how "a Salvadorian anti-poverty activist called 'Maria' describes the hunger and extreme poverty in which she grew up as motivating her to fight these conditions" (36, p.183). Obviously, it would be a severe violation of Maria's autonomy to prevent her from fighting poverty, even if this prevention was done on the basis that her preference for fighting poverty was molded under conditions of unfreedom.

The third main problem with the Internalized Ableism Objection is that it has implausible implications. Suppose that it is correct that denying a competent person access to a way of dying wouldn't violate their autonomy if their desire for death is driven by internalized ableism. This entails that involuntarily treating an intolerably suffering disabled person (or even force-feeding them) wouldn't violate their autonomy if their desire to refuse life-sustaining treatment (or to stop eating and drinking) is driven by something like internalized contempt for dependence on others. However, this conclusion seems false. As Downar et al. explain, "while many patients request MAID today for reasons that are criticized as 'ableist,' [e.g., a loss of independence] the same rationale is accepted without comment or judgment when used to justify withdrawal of life support or a discontinuation of life-prolonging therapies" (37, p.896).

In summary, the above three problems show that the Internalized Ableism Objection fails to prove the existence of cases where denying a currently eligible patient access to Track 2 MAiD wouldn't violate their autonomy. Even for eligible patients suffering from internalized ableism, denying them access to Track 2 MAiD would be a severe violation of their autonomy (and thus highly harmful).[17] Of course, it would be a different story for patients whose internalized ableism impairs their decision-making capacity.

The second main objection to the autonomy argument in the context of Track 2 MAiD is the Structural Coercion Objection. This objection holds that denying someone access to Track 2 MAiD often wouldn't violate their autonomy because people who choose Track 2 MAiD often do so non-autonomously, driven by structural coercion to die (7,18,39). According to physician and advocate Ramona Coelho, this is because "societal structures, such as governments, create and sustain the predicaments that can make death an attractive choice for those who would have instead benefitted from greater resources and care" (40). More specifically, the applicants say that disabled people often experience intolerable suffering because of various forms of marginalization (including poverty, homelessness, and isolation), and disabled people often lack access to societal supports (particularly state-funded supports) that could make their suffering tolerable (4).[18] According to the applicants, this is especially true for disabled people who are also female, trans, non-binary, or indigenous (4). For a typical explanation of why the structural states of affairs in question are coercive, consider the following quote from Quentin Genuis about the aforementioned individual with a neurological illness, who was denied necessary mobility supports:

> He was clear that his "higher" desire was to live; his request to die would be retracted if his circumstances changed. His request for MAiD was not the choosing of a preferred option. He requested MAiD because, in his unjust context, it seemed to be his only choice. He felt as if he had no choice. His circumstances were straightforwardly coercive (17).

There are three main problems with the Structural Coercion Objection. The first is that it has implausible implications like those of the Internalized Ableism Objection. Suppose that the Structural Coercion Objection is correct that denying a competent person access to a way of dying wouldn't violate their autonomy if their desire for death is driven by structural coercion. This entails that involuntarily treating an intolerably suffering person (or even force-feeding them) wouldn't violate their autonomy if their desire to refuse life-sustaining treatment (or to stop eating and drinking) is driven by a societally-caused lack of acceptable alternatives. However, this conclusion seems false.

[16] It is beyond the scope of this paper to engage with the feminist literature on adaptive preferences.
[17] A better approach to dealing with internalized ableism can be found in Khader's work: "Noncoercive interventions, such as those involving… incitements to question prevailing beliefs, seem appropriate public responses to agents… who experience local value distortion… without fully compromised autonomy" (38, p.313). In the context of Track 2 MAiD, such interventions could involve checking for signs of internalized ableism and connecting afflicted patients with professionals who could help with eliminating their internalized ableism.
[18] It is beyond the scope of this paper to determine whether, for example, a disability causing homelessness that causes intolerable suffering legally counts as the disability causing the suffering. So, I will focus on cases where it seems that a disability causes intolerable suffering but could be prevented from doing so via societal supports.

The second main problem with the Structural Coercion Objection is that its framing of marginalization and lack of support paints a misleading picture. As Downar et al. explain, “In every country with available data, [assisted dying] is more common in people with higher income and education,” and “relatively few people from socioeconomically disadvantaged demographics pursue [assisted dying]” (10, p.1175, 1177). The available evidence suggests that this trend is holding true for Track 2 MAiD in Canada (41). Furthermore, in 2023, across both tracks, “In a small number of cases (n=5) disability support services were required but were not accessible to the person” (6). Even if all five of these cases were Track 2 rather than Track 1 (which is exceedingly unlikely), this would still be fewer than 1% of all Track 2 cases in 2023. Moreover, it is unclear how often societal mistreatment is the *tipping point* for making someone’s suffering intolerable.

The third main problem with the Structural Coercion Objection is that thought experiments show that denying freedom of choice is a severely anti-autonomous way to respond to structural coercion in analogous cases. Consider the following two.

I present the first using the language of the Structural Coercion Objection. Imagine someone who wants to flee their home country (and become a refugee) because the government oppresses their ethnic group, causing them extreme suffering.[19] Their “higher” desire is to stay in the country they love; their desire to flee would change if their circumstances changed. Their desire to flee isn’t the wanting of a preferred option. They want to flee because, in their unjust context, it seems to be their only choice. The government made fleeing an attractive choice for them, even though they would have benefitted from the cessation of oppression. Their circumstances are straightforwardly structurally coercive. Now imagine that the government — via walls and border patrol — prevents them from fleeing. If someone said that denying them the option of fleeing doesn’t violate their autonomy because their desire to flee is driven by structural coercion, this would be absurd.

The second thought experiment comes from philosopher Eric Mathison. As he explains, many women choose to get abortions because of financial considerations (e.g., the high cost of childcare) (11). Some socioeconomically disadvantaged women would no longer desire an abortion if they were wealthier; the socioeconomic system makes them see abortion as their only choice. Again, there is a sense in which this is structural coercion, and again it would be a severe violation of their autonomy if the government denied them access to abortion on the basis that their desire for abortion is driven by structural coercion (11).

The counterintuitiveness of the Structural Coercion Objection can also be shown by thought experiments involving non-structural coercion.[20] Consider the following three.[21] The first comes from Danny Scoccia. He asks us to imagine that

> The Gestapo has captured a British spy, whom it will torture and then execute soon unless he swallows a capsule in his possession that will kill him instantly and painlessly. His choice to swallow the capsule is “forced” and involuntary; the alternative to not swallowing it is horrible. There is a priest in the same holding cell as the spy, concerned that the spy will go to hell if he commits the mortal sin of suicide. He cannot free the spy, but he can take the capsule away from him. Surely if he does that for what he thinks is the spy’s own long term good, he violates the spy’s autonomy (35, p.489).

Suppose the spy wants to swallow the capsule. He wants to die because, in his unjust context, he sees death as his only choice. Nevertheless, it would be a severe violation of his autonomy if the priest prevented him from swallowing the capsule, even if this prevention was done on the basis that his desire to die is driven by coercion.

The second thought experiment also comes from Scoccia. He asks us to imagine a cancer patient with a bleak prognosis who volunteers for a clinical trial involving an experimental cancer drug (35). They see trying this drug as their only choice.[22] Nevertheless, it would be a violation of their autonomy to prevent them from trying the drug, even if this prevention was done on the basis that their desire for the drug is driven by coercion (in some sense).

The third thought experiment comes from bioethicist Daryl Pullman. It is designed to be anti-Track-2, but, as I will argue, it fails in this regard. Pullman sets the stage as follows:

> Imagine you are a parent and a ruthless criminal has taken you and your child hostage. The criminal offers you a tragic choice. She will let either you or your child go free, but only on the following condition; you must kill either yourself or your child. If you kill your child, you will go free; if you kill yourself, your child will go free. If you choose to do neither your deranged tormentor will kill both you and your child. You decide to kill yourself (43).

[19] Assume that fleeing would be irreversible for one reason or another.
[20] Although I believe that the thought experiments involving structural coercion are sufficient to prove my point, I am providing additional thought experiments to show the universality of my point.
[21] In his illuminating article on the topic, Brent Kious considers similar thought experiments, but he reaches conclusions that are less pro-MAiD than mine (42). Most relevantly, he says that “Whether MAID should be permitted depends, too, on how easily law and policy can be changed in order to ameliorate the injustices in question” (42, p.421). Although I disagree with this view, I won’t rebut it because Kious would probably agree with me about the cases that I am considering in this section. According to him, “Law and policy could change now, making circumstances better. But the effects of these changes may not be realized for years, even decades, and so are not likely to reduce the suffering of persons who have been harmed by these injustices so far. The fact that this injustice cannot be remedied in a way that quickly improves their circumstances suggests that they should still be permitted to access MAID” (42, p.421).
[22] If the reader thinks that the following matters, suppose that the patient has cancer because of an injustice (e.g., illegal dumping of toxic waste).

Pullman's main takeaway is that this choice isn't meaningfully autonomous; although he doesn't use the language of coercion, this is clearly what he has in mind (43). He claims that the choice in the thought experiment is analogous to "individuals opting for MAiD when they are unable to find adequate social supports to relieve the burden of their day-to-day existence" (43).

I agree that these two cases are to some degree analogous, but this analogy provides no intuitive support for the Structural Coercion Objection's claim that denying a structurally coerced eligible patient access to Track 2 MAiD wouldn't violate their autonomy. This is because it seems that somehow merely preventing the parent from killing anyone (in which case the criminal would kill both innocents) would be much worse, autonomy-wise, than allowing the parent to kill themself (and thereby save their child). In large part for this reason, it seems that preventing the parent from killing themself would harm them (on the supposition that the innocents won't be rescued in time). This provides intuitive support for my claim that denying a structurally coerced eligible patient access to Track 2 MAiD would harm them by violating their autonomy (on the realistic assumption that Canadian poverty, homelessness, isolation, etc. won't disappear anytime soon).[23]

In summary, the Structural Coercion Objection fails to prove the existence of cases where denying a currently eligible patient access to Track 2 MAiD wouldn't violate their autonomy. As shown, disallowing Track 2 MAiD would violate people's autonomy, so, for previously discussed reasons, it would harm them. Furthermore, given that people who desire Track 2 MAiD because of structural coercion have already had their choices restricted in a wide range of ways, it would be especially harmful to violate their autonomy by narrowing down their options even more. Track 2 opponents are right that the cases in question are deeply tragic, but their proposed solution would only make things worse. Ultimately, neither the Internalized Ableism Objection nor the Structural Coercion Objection can save the applicants' premature death argument from the autonomy argument for MAiD.

Bundle #2: Allowing Track 2 MAiD Legitimizes Death as an Appropriate Response

Next, the applicants argue that allowing Track 2 MAiD "has legitimized the idea that death is an appropriate response to" the following experiences: 1) some disabled people's intolerable suffering, 2) losses of things like dignity and the ability to engage in meaningful activities, and 3) feeling like a burden (4, p.10, 14). In some places, the applicants use the phrase "reasonable solution" in lieu of "appropriate response" (4, p.10). For the purposes of this paper, I assume that "legitimizing" means "making something seem true or permissible." With this in mind, I have two objections to this argument (and one objection to a related argument).

Objection #1: Is There Actually Legitimization?

My first objection is that it is doubtful whether allowing Track 2 MAiD has legitimized that death is an appropriate response to experiences 1 to 3. This is for two main reasons. The first is that the available evidence suggests that, between Bill C-7's passage and now, there hasn't been an increase in the number of Canadians who think, for example, that death is an appropriate response to the intolerable suffering of people who are eligible for Track 2 MAiD. Between the month after Bill C-7's passage (in 2021) and June 2023, Ipsos polls found a 4% increase in the number of Canadian adults who *oppose* allowing Track 2 MAiD (44,45). If anything, this suggests an increase in the number of Canadians who think that death is an *inappropriate* response to the intolerable suffering of people who are eligible for Track 2 MAiD. Of course, this type of evidence is inconclusive,[24] so what really matters is that it definitely doesn't support the applicants' legitimization argument.

The second main reason for doubting the alleged legitimization is that both inside and outside the context of MAiD, when Canadian law allows competent people to choose a treatment option, it doesn't seem that the law legitimizes the option as an "appropriate response" or a "reasonable solution." For example, Canadian law allows competent people to refuse blood transfusions (usually done for religious reasons) (46), but it doesn't seem that, in doing so, the law legitimizes refusing blood transfusions as appropriate. Instead, it seems that if the law legitimizes anything, it legitimizes that it is appropriate that competent people get to decide how they are treated (within some limits), even if their decisions are objectively unreasonable (or seem unreasonable from a practitioner's perspective).

Besides, even if allowing Track 2 MAiD *does* contribute to legitimizing that death is an appropriate response to experiences 1 to 3, the margin of change (relative to allowing only Track 1 MAiD) would be unclear. For example, because over 95% of Track 1 recipients reported suffering from a "loss of ability to engage in meaningful activities" (6), if allowing Track 2 MAiD legitimizes death as an appropriate response to this loss, then so does allowing Track 1 MAiD. Given that over 95% of MAiD deaths are Track 1 (6), it would be implausible to say that allowing Track 2 substantially increases the degree to which Canadians buy into a message that, if sent, is sent by both tracks.

Objection #2: Is There Actually Harm?

My second objection to the applicants' legitimization argument is that even if allowing Track 2 MAiD *has* legitimized that death is an appropriate response to experiences 1 to 3, it is doubtful whether this would be harmful because it is doubtful whether death is an objectively inappropriate response to these experiences. As a general rule (though not an exceptionless one), if X

[23] Recognizing that Canadian society's structural coercion will almost certainly continue into the near future doesn't constitute endorsing this. To use the uncharitable words of Track 2 opponent Isabel Grant, I am not actually "suggest[ing] that the state, through the medical profession, has an obligation to provide access to death but no obligation to make life tolerable for a Charter-protected group" (7, p.269). Like many other Track 2 defenders, my view is that the state has both obligations.

[24] The polls' credibility intervals are both ±1.9% (44,45).

is an objectively appropriate response to Y, it isn't harmful to legitimize X as an appropriate response to Y. So, it seems that the applicants are implicitly relying on assumptions that hold that death is an objectively inappropriate response to each of the three experiences. All three assumptions are dubious.

Let's begin with 1 and 2. Whether death is an objectively inappropriate response to some disabled people's intolerable suffering — and losses of things like dignity and the ability to engage in meaningful activities — depends on the correctness of parts of the applicants' premature death argument. However, I have already problematized these parts. Regarding 3, it is doubtful whether death is an objectively inappropriate response to feeling like a burden in cases where this feeling is correct. For example, imagine an altruistic Track 2 requester who wants to die partly to decrease the strain on the Canadian healthcare system. The applicants provide no reasons for why this type of ethical decision-making would be inappropriate.

However, in the disability studies literature, a reason is provided: choosing death to stop being a burden is based on the false ethical premise that life isn't worth living when one is dependent on others (47).[25] Against this, psychiatrist and bioethicist Brent Kious shows that being merely dependent on others is different from being a burden on others (which involves imposing severe net harms), so "it could sometimes be reasonable for a person to choose to hasten her death to avoid being a burden" (49, p.15). Ultimately, choosing death to stop being a burden on others isn't based on the premise that life isn't worth living when one is dependent on others; as many disability scholars emphasize, everyone is dependent on others.

Some Track 2 opponents would reply by arguing that death is an objectively inappropriate response to feeling like a burden because it is a non-autonomous response (for a heretofore undiscussed reason).[26] Namely, they would argue that choosing this response involves two types of anti-autonomous "felt pressure" (50, p.2). The first comes from burdened caregivers pushing someone to choose MAiD (7,8,51). However, the existing eligibility criteria and safeguards deal with this. As Eric Mathison explains, "MAID assessors spend a lot of time going over the reasons someone has for wanting MAID, including looking for evidence of coercion or undue influence" (52). Besides, some people are pushed by their families to *refuse* MAiD — and some people "refuse MAID because they perceive it as a burden on their families" (50, p.4) — but we don't react to this by disallowing MAiD refusals.

The second type of alleged felt pressure comes from mere knowledge of the burdening (51). However, it is unclear why we should think about this any differently (autonomy-wise or otherwise) from how, for example, mere knowledge of extreme poverty can engender felt pressure to donate to charity. Against this, bioethicists Stoll et al. would say that "a person's preference for MAID should not be driven by external factors" (50, p.2), but we don't hold other major life decisions to this high standard. As Eric Mathison and philosopher Jeremy Davis argue, "not all autonomous choices have to be self-regarding or self-interested. The decisions we make affect others, and we often make our most important decisions with consideration toward its effects on those we care about most" (53, p.346). Besides, feeling like a burden has an internal dimension; as Stoll et al. observe, "the patient's perception that they are a burden for caregivers may form part of the intolerable suffering" (50, p.2). In fact, the external vs. internal distinction arguably breaks down in many of the cases in question. As disability scholar Michael Gill argues (albeit not in the context of Track 2 MAiD),

> Consider, for instance, a patient's desire for her loved ones' memories to be mainly of her as vibrant, engaged, loving, and caring, rather than for their memories to be dominated by thoughts of her going through an agonizing dying process in a significantly compromised condition. That desire could be described as self-oriented and unrelated to burden: she does not want people to think a certain way about her. Or it could be described as burden-based and altruistic: she does not want her loved ones to carry burdensome memories. But probably the more accurate thing to say is that the distinction between self-oriented and burden-based is in this case inapt (48, p.319).

Now, regarding cases where the feeling of being a burden is *incorrect* (e.g., someone falsely believes that they are a burden on their family), I have three comments. First, it is unclear how common such cases are. As Michael Gill notes, "Recent studies have also found that that there is generally moderate correspondence between patients' self-perception of burden and actual caregiver burden" (48, p.321).

Second, as Stoll et al. explain, "When these unrealistic perceptions [of burdensomeness] contribute significantly to the individual's understanding of relevant information in deciding to seek MAID, it can be argued that their competence to make that decision is impaired" (50, p.3). Thus, they may be ineligible for MAiD.

Third, regarding cases where someone's competence is unimpaired despite falsely believing that they are a burden, I would have to fall back on my earlier objection that questions whether there is legitimization. Specifically, I maintain that allowing Track 2 MAiD doesn't legitimize anything harmful in the cases in question because allowing Track 2 MAiD doesn't legitimize that death is an appropriate response to feeling like a burden. Recall my earlier objection's discussion of the lack of evidence of legitimization, as well as the analogy to blood transfusion refusals.

[25] Michael Gill thoroughly refutes the associated arguments, largely by showing that they are guilty of the naturalistic fallacy (48).
[26] Some Track 2 opponents (e.g., legal scholar Elizabeth Sheehy) would say that "the whole notion of being a burden on society or loved ones is grounded in ableism" (3, p.59). Against this, I would repeat my responses to the Internalized Ableism Objection.

Objection #3: Is There More Rumination?

To conclude this section on legitimization, I explore another alleged harm of the legitimization: unhealthy rumination. According to Isabel Grant, "some perceive Track 2 MAiD as a 'monkey on their back' constantly throughout their struggle to deal with the realities of… disability in Canada. They are constantly in a position of re-evaluating whether their lives are worth living" (7, p.311). In the words of legal scholar Martha Minow (as quoted by Grant), this is because "the option of medical assistance in dying would alter the menu for all involved. It would turn the continuation of living into a question, open for debate, doubt, and persuasion" (7, p.318). Of course, there is a sense in which the discontinuation of living is always "on the menu" — regardless of whether Track 2 MAiD is allowed — for anyone capable of unassisted suicide, but the alleged key difference (as I understand it) is that allowing Track 2 MAiD has made more people see the discontinuation of living as a reasonable solution for them (and thus a live option, which triggers rumination).

However, Grant fails to show that the unease that allowing Track 2 MAiD may engender in some people outweighs the ease it engenders in others. As Ian Ball (the medical chair of a hospital MAiD committee) and Scott Anderson (a MAiD provider) observe,

> A recurring theme is that patients' moods are tremendously improved with the knowledge that MAiD gives them control over their disease… the availability of MAiD has improved the outlook of many patients who have not chosen the procedure. The knowledge that MAiD is an option, should symptoms become unbearable, is very reassuring for patients (54, p.372).

In fact, making MAiD available to people can comfort them so much that they see their life as worth living again. For example, in a 2015 study of Belgian patients with psychiatric disorders,

> Among all 48 patients whose euthanasia requests were accepted… 11 patients decided to either postpone or cancel the euthanasia procedure. Of the latter 11 patients, 8 explained (by phone or mail) that knowing they had the option to proceed with euthanasia gave them sufficient peace of mind to continue their lives (55, p.5).

Given such evidence, the burden of proof is on Track 2 opponents to show that, on balance, allowing Track 2 MAiD harms eligible patients' mental health. They fail to show this.

In summary, the applicants (and other Track 2 opponents) fail to show that allowing Track 2 MAiD has perniciously legitimized death as an appropriate response.

Bundle #3: Allowing Track 2 MAiD Demeans Disabled People

The applicants argue that allowing Track 2 MAiD "devalues the lives of people with disabilities" (4, p.14). Although the applicants make this claim multiple times, they do little to flesh it out, so I will steelman[27] them by drawing on legal scholar Deborah Hellman's demeaningness-centric theory of wrongful discrimination, which aligns with how some other Track 2 opponents (e.g., Isabel Grant) develop the devaluation argument (7). According to Hellman's theory, discrimination is wrongful when it demeans someone, i.e., when it treats them "in a way that denies [their] equal moral worth" (56, p.29). Whether drawing a distinction between people is demeaning depends on this distinction's socially understood meaning, which in turn depends largely on culture and context (56). In particular, drawing a distinction based on traits that define a mistreated and disadvantaged group is more likely to demean because of the distinction's social significance (which emerges largely from how such distinctions have been drawn in the past) (56).[28]

Returning to MAiD, the applicants could argue that allowing Track 2 MAiD devalues disabled people's lives by demeaning them because killing disabled people is socially understood to connote treating them as lesser, given the mistreatment of disabled people by Canadian society, especially the Canadian healthcare system. For an example of this mistreatment, consider how the rate of unmet healthcare needs is much higher for Canadians with disabilities than Canadians without disabilities (57). It would be understandable for such mistreatment to colour the ways in which people interpret how Canadian society treats disabled people differently (e.g., by making more of them eligible for MAiD).

The main problem with this argument is that a fuller picture of the history of the mistreatment of disabled Canadians reveals that it is doubtful whether allowing Track 2 MAiD is socially understood to connote treating them as lesser. In particular, this is because one of the main manifestations of this mistreatment has been the violation of the autonomy of disabled Canadians, especially by the Canadian healthcare system. Examples include forced sterilization and mass institutionalization (58,59). So, giving more disabled Canadians more control over their lives represents a repudiation of this historical mistreatment rather than a continuation of it. These considerations lend credence to the view that *disallowing* Track 2 MAiD would demean disabled people by being socially understood to connote treating them as "incompetent, easily coerced, and inclined to end their lives" and thus "plac[ing] them in the roles to which they have been confined by disability discrimination" (60, p.684). As philosopher

[27] A steelman is the opposite of a strawman. In other words, I am strengthening their argument before rebutting it.
[28] Also, Hellman says that demeaning someone requires having more power or status than them (56). This is because demeaning someone puts them down, so the demeaner has to be in a position such that their expression of disrespect can subordinate the victim (56).

Christopher Riddle argues, “Denying people with disabilities the right to exercise autonomy over their own life and death says powerfully damaging things about the disabled, their abilities, and their need to be protected” (61, p.487). Importantly, such ideas were key in *Truchon*; as Justice Christine Baudouin emphasized, “society often perceives the disabled as being incapable, due to their physical disability, of making the… ‘right decisions’ concerning their body and their life, hence their vulnerability and need for state protection from their… ‘poor choices’, including, for example, a request for medical assistance in dying motivated by the disability” (26, para.672).

The above problem with the demeaningness argument is even more acute vis-à-vis disabled Canadians who are also female, trans, non-binary, indigenous, or part of any other marginalized community because Canadian history is full of violations of the autonomy of members of these groups, especially by the Canadian healthcare system. Examples include non-consensual medical experiments and examinations, as well as barriers to accessing reproductive healthcare and gender-affirming healthcare (62-65).

Furthermore, the socially understood meaning of allowing Track 2 MAiD is presumably shaped partly by the context of the modern philosophy of the Canadian healthcare system. Specifically, given the triumph of patient autonomy over practitioner paternalism (66), allowing some disabled Canadians to choose Track 2 MAiD may be socially understood to connote treating them as morally worthy agents free to exercise self-determination over their lives. For illustration, Nicole Gladu (one of the disabled applicants in *Truchon*) interpreted the pro-Track-2 ruling as follows: “Now, it’s really a matter of personal decision. It’s up to me or it’s up to Mr. Truchon or other people like us to decide if we prefer the quality of life to the quantity of life” (67). As previously discussed, allowing Track 2 MAiD may legitimize that it is appropriate for people like Gladu to decide how they are treated.

This charitable interpretation is further supported by two legal provisions: 1) it is illegal to “discuss MAiD with a patient with the aim of inducing, persuading, or convincing the patient to request MAiD” (9, p.1) and 2) MAiD eligibility requires “making a voluntary request… which does not result from external pressure” (1). Arguably, these provisions express that disabled Canadians’ lives are valuable (and thus worth protecting from deaths that aren’t fully voluntary).[29] As Justice Baudouin put it in *Truchon*, “Respect for their individual freedom that is expressed thoughtfully, freely and clearly also contributes to the affirmation of the inherent value of their lives” (26, para.310).

Moreover, even if allowing Track 2 MAiD *did* demean disabled people, the margin of change (relative to allowing only Track 1 MAiD) would be unclear. Because everyone who is eligible for Track 1 MAiD is disabled (according to the applicants and others), if allowing Track 2 MAiD demeans disabled people, then so does allowing Track 1 MAiD (given my above steelman). So, because over 95% of MAiD deaths are Track 1, it would be implausible to say that allowing Track 2 MAiD substantially increases the degree to which disabled people are demeaned. It shouldn’t be forgotten that some disability rights groups (e.g., Not Dead Yet) have argued that limiting assisted dying eligibility to terminally ill people is ableist (35).

The applicants would probably respond to this margin-of-change challenge by arguing that allowing Track 2 MAiD is uniquely demeaning to disabled people because

> The exemptions carved out by MAiD Track 2 are based on a distinction between those who are disabled and those who are not. In contrast, the distinction between those who are eligible for MAiD Track 1 is based on a distinction between those who are dying (their natural death is reasonably foreseeable) and those who are not dying (4, p.9).

For context, the “exemptions” in question are exemptions to the *Criminal Code* sections on murder and aiding suicide (4). So, what the applicants seem to be saying in the above quote is that eligibility for Track 2 MAiD is determined by whether one is disabled, whereas eligibility for Track 1 MAiD is determined by whether one’s natural death is reasonably foreseeable.

However, there is no meaningful sense in which this is true. Yes, eligibility for Track 1 MAiD requires that one’s natural death is reasonably foreseeable, but it also requires that one is disabled (according to the applicants and others), and it requires many other aforementioned things (e.g., adulthood and decision-making capacity). Similarly, eligibility for Track 2 MAiD does require that one is disabled, but it also requires these many other things.[30] The applicants are arbitrarily setting aside most but not all of the eligibility criteria that the two tracks share. Moreover, both tracks’ eligibility criteria show that the Canadian approach to MAiD is individualized, rather than expressing sweeping generalizations about all disabled people or all disabled Canadians.

Now, some Track 2 opponents would respond to all of my demeaningness-centric analysis thus far by accusing me of missing the bigger picture. Sure, they would say, allowing Track 2 MAiD isn’t demeaning in isolation. However, it is demeaning *in conjunction with* something else.

[29] Arguably, a similar thing is true for the eligibility criterion that requires that the patient’s suffering can’t be relieved in a way they consider acceptable.
[30] Justice Baudouin emphasized this in *Truchon*.

The Conjunction Argument

The Conjunction Argument holds that allowing Track 2 MAiD (only for some disabled people) while disallowing MAiD — and offering suicide prevention — for all non-disabled people demeans disabled people by expressing that their deaths and their suffering are fundamentally different from those of non-disabled people.[31] Isabel Grant sets the stage as follows:

> if [MAiD] is about autonomy, why do we only care about disabled autonomy? Those with disabilities are not the only people who may want to die. Why do we not offer death on demand to all competent adults who wish to end their lives? Why only disabled lives?... Others argue that MAiD is fundamentally about alleviating suffering… But disabled people do not have a monopoly on intolerable suffering, especially when one includes in the definition of "suffering" factors like loneliness and being a burden to others. Why do we only offer death for disabled suffering? (3, p.42).

Grant's answer to such questions is that "The unspoken premise is that suicide is a benefit and a social good for people with disabilities whereas for others it is something to be deterred" (7, p.315). In other words, the Track 2 MAiD system rests on the assumption that, for disabled people and disabled people only, dying would be good for them and good for society. Thus, the system is "portraying disability as something to be avoided at all costs, even through death" (7, p.292). In the words of Heidi Janz, allowing Track 2 MAiD "enshrine[s] into law the quintessential ableist stereotype that it's better to be dead than disabled" (39, p.299). In a similar vein, disability activist Catherine Frazee argues the following:

> The foundational logic for Track 2 — that the suffering of disabled people warrants a special easing of eligibility thresholds for MAiD — builds from an ableist premise — namely, that disability suffering is inexorable, categorically distinct from the suffering of any non-disabled person, and remediable only by extreme medical intervention (3, p.70).

According to Frazee, allowing Track 2 MAiD doesn't just build from such premises; it also socially entrenches them (3).

There are two main problems with the Conjunction Argument. The first is that Bill C-7 made only a tiny percentage of disabled Canadians newly eligible for MAiD, so, if the law expresses anything about whether it is better to be dead or disabled, it expresses that it is better for the vast majority of disabled Canadians (who are eligible for neither track) to be alive.[32] The same goes for what the law expresses about disabled people's suffering. The vast majority of disabled Canadians are eligible only for non-MAiD remedies, including suicide prevention programs (if applicable) and non-extreme medical interventions such as standard pain management, so the law expresses that their "disability suffering" isn't "inexorable" or "remediable only by extreme medical intervention" (3, p.70).[33] Also, note that people who are eligible for Track 2 MAiD are still eligible for non-extreme remedies.

The second main problem with the Conjunction Argument is that whether a demeaning message is sent by the conjunction of allowing Track 2 MAiD and disallowing MAiD for non-disabled people depends on how this allowance and disallowance are socially understood. Grant, Janz, and Frazee implicitly assume (for reasons that will become clear soon) that Canadians generally agree that everyone with a grievous and irremediable medical condition has a disability. However, this assumption seems false; Canadian society seems to have a narrower conception of disability. Consider the following two pieces of (admittedly inconclusive) evidence. The first is that, as previously discussed, the Canadian government says that a grievous and irremediable medical condition is an "illness, disease *or* disability [emphasis added]" (1). The second is that, in 2023, "33.5% of Track 1 respondents self-identified as having a disability compared to 58.3% of Track 2 respondents" (6). This amounts to over 65% and over 40%, respectively, believing that *their own* grievous and irremediable medical condition *isn't* a disability. To be fair, it is possible that the rest of Canadian society understands disability much more broadly than both the Canadian government and Canadian MAiD requesters. However, if most Canadians have even a somewhat similar conception of disability, they wouldn't think that all grievous and irremediable medical conditions are disabilities. This matters because it means that, if they thought about it, they would probably think that both Track 1 and Track 2 make some non-disabled people eligible for MAiD. Thus, they probably wouldn't see either track (in isolation or in conjunction with anything else) as singling out disabled people, their deaths, or their suffering. Therefore, the Conjunction Argument fails to show that the conjunction in question expresses that disabled people's deaths and suffering are fundamentally different from those of non-disabled people. To be clear, I am not abandoning my earlier concession that all grievous and irremediable medical conditions *are* disabilities; I am just exploring the implications of the fact that most Canadians would probably disagree.

However, let's suppose for the sake of argument that I'm wrong. Perhaps most Canadians really do think that all grievous and irremediable medical conditions are disabilities. In this case, the Conjunction Argument could be correct that it is demeaning

[31] Parts of this argument can be found in the notice of application.

[32] This is why it is absurd to criticize Bill C-7 by saying, in the words of Quinn et al., that "if assisted dying is made available for all persons with a health condition or impairment, regardless of whether they are close to death, a social assumption might follow (or be subtly reinforced) that it is better to be dead than to live with a disability" (8, p.5). Assisted dying hasn't been made available for all people with a health condition or an impairment!

[33] Furthermore, many (if not most) *suicidal* disabled Canadians are eligible only for non-MAiD remedies. This is because many (if not most) suicidal disabled Canadians lack at least one of the following: decision-making capacity, an irreversible decline in capability, and suffering that can't be alleviated in a way they consider acceptable. After all, suicidality correlates with impaired decision-making capacity (68), and many disabilities (e.g., paraplegia and down syndrome) usually don't involve a continuous decline in capability (let alone an irreversible one), and many suicidal disabled Canadians' suffering can be alleviated in an acceptable-to-them way that they either haven't tried yet or are in the process of trying. Therefore, the law doesn't express that suicidal disabled people's deaths and suffering are fundamentally different from those of other people.

to limit MAiD eligibility to a subset of people with grievous and irremediable medical conditions. This would entail that the status quo system is in some sense problematic. Then the question would be what is the proper solution to this problem? There are three main options.

The first is merely disallowing Track 2 MAiD. However, this wouldn't solve the problem because, in a Track-1-only system, MAiD eligibility would still be both limited to a subset of disabled people (according to the applicants and others) and socially understood as being so (given what I have just supposed for the sake of argument). So, if allowing Track 2 MAiD demeans in conjunction with disallowing MAiD for all non-disabled people, then allowing only Track 1 MAiD would also demean in conjunction with this disallowance. Arguably, Isabel Grant implicitly admits this when she says that "By allowing medical professionals to provide death to *people with disabilities*, the [Criminal] Code sends the message that these disabled lives are less worthy of saving [emphasis added]" (7, p.308). Clearly, Track 2 isn't the real issue here.

Legal scholar Jonas-Sébastien Beaudry would probably respond by rejecting that a Track-1-only system would be demeaning. On the better-dead-than-disabled front, he makes the following argument:

> By limiting medical assistance in dying to patients whose death is due to occur soon… the state could in principle avoid making or condoning problematic quality-of-life judgments. This is because MAiD could be considered not as a kind of suicide, but as a modality of dying. Death being inevitable, MAiD patients would be perceived as choosing the modality of their death rather than as choosing to forego years of existence (69).

The fundamental flaw of this argument is that death is *always* inevitable, so choosing MAiD always constitutes both choosing a modality of death and choosing to forgo some duration of existence. Furthermore, despite Beaudry's claim to the contrary (69), allowing only Track 1 MAiD wouldn't limit MAiD eligibility to patients whose deaths are due to occur soon; some patients who are eligible for Track 1 MAiD could live for many more years (5).

So, what are the two options that could actually solve the problem that the Conjunction Argument identifies (if this problem exists)? The second option is disallowing MAiD altogether, and the third option is adding a third track by expanding MAiD eligibility to include some intolerably suffering people who are non-disabled (and socially understood as such). The applicants provide no reasons for favouring the second over the third option, and besides, the second option is a non-starter because it would violate the *Charter* (29). So, if anything, the Conjunction Argument may be more promising as an argument for further expanding MAiD eligibility.[34] By (loose) analogy, when Canada made voting available only to men, this was demeaning, but the proper solution was making voting available to more people rather than less.[35]

In summary, the applicants' demeaningness argument fails (even when buttressed by the Conjunction Argument).

Bundle #4: Allowing Track 2 MAiD Decreases Healthcare Options

The applicants argue that allowing Track 2 MAiD "narrows the range of options that are available… for dealing with suffering [disabled people] are finding intolerable" (4, p.11). According to the applicants, this is because practitioners may not pursue all available non-MAiD treatment options for people who are eligible for Track 2 MAiD (4).

The main problem with this argument is that it is highly doubtful whether practitioners are pursuing fewer non-MAiD treatment options for people who are eligible for Track 2 MAiD. After all, Track 2 MAiD providers are legally required to do the following:

> ensure that the person has been informed of [and has given serious consideration to] the means available to relieve their suffering, including, where appropriate, counselling services, mental health and disability support services, community services and palliative care and has been offered consultations with relevant professionals who provide those services or that care (72).

Furthermore, withholding or withdrawing treatment options to induce a patient to request MAiD would be illegal (for the aforementioned reasons). The applicants identify no incentives for practitioners to violate these requirements, and the applicants ignore the strong disincentives (e.g., the risk of imprisonment and losing one's license to practice). Besides, even if there are some violations, the harm would be attributable to the rule violators and/or the rule enforcers (rather than the eligibility change). Ultimately, it seems much likelier that allowing Track 2 MAiD expands — rather than narrows — disabled people's range of options for dealing with intolerable suffering (by giving some of them the option of Track 2 MAiD).

In response, the applicants could argue that allowing Track 2 MAiD has led (or will lead) to Canadian federal or provincial *governments* doing less to ensure that eligible patients can access non-MAiD treatment options. As Coelho et al. claim, "The rapid expansion of MAiD offers cost-savings for governments, creating arguably perverse incentives not to address the inadequacies of the healthcare system" (18, p.876). However, there is no evidence of such fears coming true in Canada (34), and similar predictions made about other jurisdictions that have legalized assisted dying (e.g., Belgium and Oregon) have

[34] For some arguments in this direction, see the work of Udo Schüklenk (70).
[35] One might respond to this entire demeaningness section by arguing that it sets the bar too high and that allowing Track 2 MAiD clears the lower bar for being merely offensive. However, Brent Kious shows that such offensiveness would be insufficient to justify denying people access to MAiD (71).

been proven wrong (28,48,60). For example, opponents of assisted dying in general predicted that it would lead to governments doing less to ensure that eligible patients can access palliative care, but, as philosopher Ben Colburn notes, "assisted dying tends to go hand in hand with greater support for palliative care, financially and otherwise" (60, p.685). Importantly, this trend has held true in Canada (28,73). Around the world, governments don't react to assisted dying eligibility expansions by doing less to ensure that eligible patients can access non-assisted-dying treatment options. The burden of proof is on Track 2 opponents to show that Track 2 MAiD is an exception to this rule, but they have failed to do so.

Furthermore, even if disallowing Track 2 MAiD would *eventually* lead to more access to non-MAiD treatment options, this wouldn't make it permissible. Most Track 2 recipients are over 75 years old (6), so, if Track 2 MAiD was disallowed tomorrow, most of the people who would be denied access wouldn't live long enough to reap the rewards of more access to non-MAiD treatment options if this progress came, say, ten years down the line (34). So, denying them access would constitute violating their autonomy and prolonging their intolerable suffering for the sake of other people's access to non-MAiD treatment options. Arguably, this would be impermissible instrumentalization (12,34,74). Justice Lynn Smith correctly condemned this type of "hostage-taking" in *Carter* (75, para.1274).

Bundle #5: Allowing Track 2 MAiD Decreases Trust in the Healthcare System

The applicants' fifth and final argument is that allowing Track 2 MAiD has decreased disabled Canadians' trust in the Canadian healthcare system (4). This is for three main reasons. First, Track 2 MAiD being allowed "can undermine the trust a person should have in their service providers" because "Death is presented as a form of medical treatment but only because they have a disability" (4, p.10). Second, many disabled people fear that a practitioner will recommend death to them, and this discourages them from accessing healthcare services (4).[36] Third, being offered MAiD communicates that the healthcare system won't help you because it doesn't care about you (4). Consequently, allowing Track 2 MAiD "narrows the range of options… that persons with disabilities may *perceive* as available… for dealing with suffering they find intolerable [emphasis added]" (4, p.11). Importantly, this could be true even if my previous section is correct that allowing Track 2 MAiD expands the range of options that are *actually* available.

The main problem with this argument is that it is doubtful whether allowing Track 2 MAiD has decreased many disabled Canadians' trust in the healthcare system. I have three justifications for this claim. The first is that the applicants' above reasons are weak so long as practitioners are following their legal and professional requirements. For example, it is doubtful whether someone would perceive that being "offered" Track 2 MAiD communicates (or evinces) that the healthcare system won't help them — or doesn't care about them — so long as the practitioner fulfills their professional obligation to discuss MAiD with the patient in a way that makes it clear that MAiD is just one option among all the "medically effective and legally available treatments" (9, p.4). Furthermore, it is doubtful whether someone would perceive that the practitioner is recommending death, so long as the practitioner heeds the ban on trying to induce, persuade, or convince patients to request MAiD. Note that some regulators (e.g., the British Columbia College of Nurses and Midwives) explicitly interpret the law as making it illegal for practitioners to "encourage… advise, [or] recommend" MAiD (76). Also note that a rule-following practitioner would bring up Track 2 MAiD for the first time not by literally *offering* it but by saying (or implying) that the patient *may* be eligible for it. As Eric Mathison explains, "Typically, providers don't say 'would you like MAID?' Instead, they offer info or to connect the patient with the MAID team" (52). Among other reasons, this is because the process for determining eligibility is long and complex (especially for Track 2).[37]

My second justification is that the available evidence conflicts with the applicants' trust argument. For example, a 2023 Ipsos poll found that over three quarters of disabled Canadians support allowing Track 2 MAiD (45). This would be hard to explain if a large percentage of disabled Canadians believed claims like the following: 1) death should never be a form of medical treatment for a disability (even a grievous and irremediable medical condition), 2) being "offered" Track 2 MAiD communicates (or evinces) that the healthcare system doesn't care about you, or 3) allowing Track 2 MAiD narrows disabled Canadians' range of options for dealing with intolerable suffering.

My third justification is that even if the applicants' reasons were plausible, the margin of change (relative to allowing only Track 1 MAiD) would be unclear. For example, imagine a disabled Canadian who loses some amount of trust in the Canadian healthcare system because of Track 2 MAiD presenting death as a form of medical treatment for some disabilities in some cases. Before Track 2 was allowed, this person probably already distrusted the Canadian healthcare system because of Track 1. After all, if Track 2 presents death as a form of medical treatment for some disabilities in some cases, then so does Track 1. For another example, imagine a disabled Canadian who uncharitably interprets being "offered" Track 2 MAiD as communicating (or evincing) that the healthcare system doesn't care about them. Before Track 2 was allowed, this person may well have already distrusted the Canadian healthcare system. After all, this pre-existing distrust would explain why they

[36] Isabel Grant adds that this may also "deter people from… fully disclosing the extent of their suffering" (7, p.311).

[37] My points in this paragraph are a large part of why I reject hope-centric arguments for disallowing Track 2 MAiD. For context, Coelho et al. claim that "Offering MAiD to a patient who has not raised it could be interpreted as an indication that their suffering will likely become intolerable, and that MAiD is the recommended way out, impacting patient hope" (18, p.873). Beyond what I have already said, there are two main problems with this argument. The first is that it couldn't justify disallowing Track 2 MAiD; it could only justify disallowing "offering" MAiD to patients who haven't raised it. The second is that in a world without Track 2 MAiD, patients who are told about it in the status quo would still be told if their suffering is likely to become intolerable (which, in practice, means "extreme") (77, p.20). Similarly, they would still be told if their condition is irremediable (or likely to be so). This is because these patients would still be making treatment decisions, and informed consent requirements would make practitioners give these patients the information in question. Thus, disallowing Track 2 MAiD probably wouldn't increase these patients' hope.

interpret the “offer” uncharitably. This pre-existing distrust could have many sources, including Track 1 and previous negative experiences with the healthcare system, which are much more common for disabled people (78,79).

The applicants could respond by arguing that even an unclear margin of change in how much the Canadian healthcare system is trusted by a small minority of disabled Canadians would be a major issue (given the severity of the harms associated with forgoing healthcare services).

I have two counter-responses. The first is that this alleged decrease in some disabled Canadians’ trust in the healthcare system could be outweighed by an increase in *other* disabled Canadians’ trust in the healthcare system (such that, on balance, allowing Track 2 MAiD increases disabled Canadians’ trust in the healthcare system). This is for two main reasons. First, many disabled Canadians may feel empowered by being given more control over their lives (see my earlier arguments for why allowing Track 2 MAiD is empowering and sends an empowering message), and this may help build — or rebuild — trust after infantilization by the Canadian healthcare system (and/or other systems). Second, some disabled Canadians want Track 2 MAiD or believe that they may want it eventually, and it is generally easier to trust a system that is willing to give you what you want. Many of these people would desire death — or foresee desiring death — because of their suffering-causing disability, so, contrary to what the applicants say, they probably wouldn’t mind death being presented as a form of medical treatment (or perhaps “medical intervention”) for some disabilities in some cases.

My second counter-response is that even if there has been an overall decrease in disabled Canadians’ trust in the healthcare system after the passage of Bill C-7, this harm may be overwhelmingly attributable to false or misleading information about MAiD (rather than to allowing Track 2 MAiD). For context, misinformation about MAiD is common on social media (80,81), and many MAiD cases have been misrepresented by the media (often to the dismay of the patients involved). For example, one patient said that his case was “hijacked by the right trying to spin it into their own agenda” (10, p.1176). It is certainly possible that some disabled Canadians’ understandings of how Track 2 works have been distorted by op-eds and news stories overgeneralizing from a select few cases in which practitioners *may* have violated their professional obligations. Here I have in mind the widely publicized case of a clinician who allegedly “discussed MAiD in positive terms” with one of the individual applicants (4, p.5), who was in a mental health crisis at the time (82).

By analogy, imagine a country in which misinformation convinces some of its disabled inhabitants that, because of a newly elected party, the healthcare system is providing much less support for disabled people. If this decreases the disabled inhabitants’ trust in the healthcare system and narrows their perceived range of treatment options, these harms are attributable to the misinformation rather than to the election of the party.

In summary, the applicants fail to show that allowing Track 2 MAiD has decreased disabled Canadians’ trust in the Canadian healthcare system.

CONCLUSION

One might object to this entire paper by arguing that it hasn’t *definitively* disproven that allowing Track 2 MAiD has caused premature deaths, perniciously legitimized death as an appropriate response to some experiences, demeaned disabled people, decreased their healthcare options, and decreased their trust in the healthcare system. This is true. As legal scholars Sarah Lazin and Jennifer Chandler correctly observe, there is a “lack of detailed information about the consequences of expanding MAiD access” (83, p.114), so it is probably currently impossible to conclusively prove or disprove the existence of these harms. However, all that this paper needs to have shown is that these harms are highly uncertain. If it is very unclear whether allowing Track 2 MAiD has caused these harms, then the Canadian government should default to respecting disabled people’s human right to autonomy over their lives. Furthermore, even if disallowing Track 2 MAiD would benefit some disabled people by mitigating some of these harms, the instrumentalization issue would arise again. Would this benefit justify violating many disabled people’s autonomy? The applicants — and other Track 2 opponents — fail to show that the answer is yes.

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REFERENCES

1. Department of Justice. Legislative Background: Medical Assistance in Dying (Bill C-14, as Assented to on June 17, 2016). Government of Canada. 2 Feb 2023.
2. Department of Justice. Charter Statement: An Act to amend the Criminal Code (medical assistance in dying) (C-7). Government of Canada. 21 Oct 2020.
3. Grant I, Benedet J, Sheehy E, Frazee C. A conversation on feminism, ableism, and medical assistance in dying. Canadian Journal of Women and the Law. 2023;35(1):31-72.
4. K.C., Kathrin Mentler, Inclusion Canada, Indigenous Disability Canada / The British Columbia Aboriginal Network on Disability Society, Council of Canadians with Disabilities, and Disabled Women's Network of Canada v. Canada (Attorney General). 2024 OSCJ CV-24-0072847-0000.
5. Canadian Association of MAiD Assessors and Providers. The Interpretation and Role of "Reasonably Foreseeable" in MAiD Practice. CAMAP. Feb 2022.
6. Health Canada. Fifth Annual Report on Medical Assistance in Dying in Canada 2023. Government of Canada. 11 Dec 2024.
7. Grant I. Legislated ableism: Bill C-7 and the rapid expansion of medical assistance in dying in Canada. McGill Journal of Law and Health. 2024;15(2):259-335.
8. Quinn G, Mahler C, De Schutter O. Mandates of the Special Rapporteur on the rights of persons with disabilities; the Independent Expert on the enjoyment of all human rights by older persons; and the Special Rapporteur on extreme poverty and human rights. Office of the United Nations High Commissioner for Human Rights. 3 Feb 2021.
9. Canadian Association of MAiD Assessors and Providers. Bringing up Medical Assistance in Dying (MAiD) as a clinical care option. CAMAP. Feb 2022.
10. Downar J, MacDonald S, Buchman S. Medical assistance in dying, palliative care, safety, and structural vulnerability. Journal of Palliative Medicine. 2023;26(9):1175-9.
11. Mathison E. Assisted dying and abortion are connected. Value Judgments. 1 Jun 2023.
12. Mathison E. Assisted dying in Canada is working great. Value Judgments. 16 Aug 2022.
13. Mathison E. Lack of housing is a housing issue. Value Judgments. 19 Oct 2022.
14. Sørheim P, Barra M, Norheim OF, Gamlund E, Solberg CT. Premature death as a normative concept. Health Care Analysis. 2024;32(2):88-105.
15. Luper S. Death. In: Zalta EN, Nodelman U, editors. The Stanford Encyclopedia of Philosophy. Winter 2024 Edition. 25 Aug 2021.
16. Schuklenk U. Argumenta ad passiones: Canada debates access thresholds to MAiD. Bioethics. 2022;36(6):611-2.
17. Genuis QIT. Hopeless hope, autonomy, and anthropology: a response to Wiebe and Mullin. Journal of Medical Ethics. 22 May 2024.
18. Coelho R, Maher J, Gaind KS, Lemmens T. The realities of medical assistance in dying in Canada. Palliative and Supportive Care. 2023;21(5):871-8.
19. Coelho R, Gaind KS, Lemmens T, Maher J. Normalizing death as "treatment" in Canada: Whose suicides do we prevent, and whose do we abet? World Medical Journal. 2022;70(3):27-35.
20. Raikin A. No other options. The New Atlantis. 16 Dec 2022.
21. Lemmens T, Shariff MJ, Herx L. How Bill C-7 will sacrifice the medical profession's Standard of Care. Policy Options. 11 Feb 2021.
22. Gunderson M, Mayo DJ. Restricting physician-assisted death to the terminally ill. Hastings Center Report. 2000;30(6):17-23.
23. Fichten L. As Canada delays medically assisted dying in mental illness cases, some find relief, others fear consequences. CBS News. 19 Nov 2024.
24. Moawad H. The effects of self-inflicted neck trauma. Verywell Health. 29 May 2022.
25. Downie J. An alternative to medical assistance in dying? The legal status of voluntary stopping eating and drinking (VSED). Canadian Journal of Bioethics / Revue Canadienne de Bioéthique. 2018;1(2):48-58.
26. Truchon v. Canada (Attorney General). 2019 QCCS 3792.
27. Downie J. A watershed month for medical assistance in dying. Policy Options. 20 Sep 2019.
28. Downie J, Schuklenk U. Social determinants of health and slippery slopes in assisted dying debates: lessons from Canada. Journal of Medical Ethics. 2021;47(10):662-9.
29. Carter v. Canada (Attorney General). 2015 SCC 5, 1 SCR 331.
30. Nelson LJ. Respect for the developmentally disabled and forgoing life-sustaining treatment. Mental Retardation and Developmental Disabilities Research Reviews. 2003;9(1):3-9.

31. Lemmens T. How Canada's medical assistance in dying law turned euthanasia and assisted suicide into a quasi-universal therapy for suffering. Journal de Droit de la Santé et de l'Assurance Maladie. 2024;39:110-22.
32. Chisholm C. Saying goodbye to April. CBC News. 17 Nov 2024.
33. Janz H. Plagued to death by ableism: what the COVID-19 pandemic and the expansion of eligibility for MAID reveal about the lethal dangers of medical and systemic ableism in Canada. Canadian Journal of Bioethics / Revue Canadienne de Bioéthique. 2023;6(3-4):137-41.
34. Wiebe K, Mullin A. Choosing death in unjust conditions: hope, autonomy and harm reduction. Journal of Medical Ethics. 2024;50(6):407-12.
35. Scoccia D. Physician-assisted suicide, disability, and paternalism. Social Theory and Practice. 2010;36(3):479-98.
36. Khader SJ. Adaptive preferences and procedural autonomy. Journal of Human Development and Capabilities. 2009;10(2):169-87.
37. Downar J, MacDonald S, Buchman S. Medical assistance in dying and palliative care: shared trajectories. Journal of Palliative Medicine. 2023;26(7):896-9.
38. Khader SJ. Must theorising about adaptive preferences deny women's Agency? Journal of Applied Philosophy. 2012;29(4):302-17.
39. Janz H. MAID to die by medical and systemic ableism. In: Kotalik J, Shannon DW, editors. Medical Assistance in Dying (MAID) in Canada: Key Multidisciplinary Perspectives. Cham, Switzerland: Springer; 2023. p. 299-308.
40. Coelho R. Medical assistance in dying overused in Canada even before expansion. The London Free Press. 9 Jul 2022.
41. Mathison E. MAID and marginalization. Value Judgments. 28 Oct 2024.
42. Kious BM. Hard choices: how does injustice affect the ethics of medical aid in dying? Cambridge Quarterly of Healthcare Ethics. 2024;33(3):413-24.
43. Pullman D. Moral and intellectual gymnastics in defense of Canada's out-of-control MAiD regime. Impact Ethics. 19 May 2023.
44. Ipsos. Support for Medically-Assisted Dying in Canada. Dying With Dignity Canada. 9 May 2022.
45. Ipsos. Support for Medically-Assisted Dying in Canada. Dying With Dignity Canada. 30 Jun 2023.
46. Banerjee S. Quebec coroner says Jehovah's Witnesses had right to refuse blood transfusions. Toronto Star. 14 Nov 2017.
47. Kittay EF. When caring is just and justice is caring: justice and mental retardation. Public Culture. 2001;13(3):557-79.
48. Gill MB. When is self-perceived burden an acceptable reason to hasten death? In: Cholbi M, Varelius J, editors. New Directions in the Ethics of Assisted Suicide and Euthanasia. 2nd ed. Cham, Switzerland: Springer; 2023. p. 315-36.
49. Kious B. Burdening others. Hastings Center Report. 2022;52(5):15-23.
50. Stoll J, Ryan CJ, Trachsel M. Perceived burdensomeness and the wish for hastened death in persons with severe and persistent mental illness. Frontiers in Psychiatry. 2021;11:532817.
51. Box G, Chambaere K. Views of disability rights organisations on assisted dying legislation in England, Wales and Scotland: an analysis of position statements. Journal of Medical Ethics. 2021;47(12):e64.
52. Mathison E. A look at the recent Charter challenge to track two MAID. Value Judgments. 3 Oct 2024.
53. Davis J, Mathison E. The case for an autonomy-centred view of physician-assisted death. Journal of Bioethical Inquiry. 2020;17(3):345-56.
54. Ball IM, Anderson S. Availability of medical assistance in dying can be therapeutic. CMAJ. 2017;189(9):e372.
55. Thienpont L, Verhofstadt M, Van Loon T, Distelmans W, Audenaert K, De Deyn PP. Euthanasia requests, procedures and outcomes for 100 Belgian patients suffering from psychiatric disorders: a retrospective, descriptive study. BMJ Open. 2015;5(7):e007454.
56. Hellman D. When Is Discrimination Wrong? Cambridge, Massachusetts: Harvard University Press; 2008.
57. Casey R. Disability and unmet health care needs in Canada: a longitudinal analysis. Disability and Health Journal. 2015;8(2):173-81.
58. Hopper T. The time when Canada's elite wanted to sterilize "insane" and disabled people. National Post. 16 Aug 2023.
59. Brown I, Radford JP. The growth and decline of institutions for people with developmental disabilities in Ontario: 1876-2009. Journal on Developmental Disabilities. 2015;21(2):7-27.
60. Colburn B. Disability-based arguments against assisted dying laws. Bioethics. 2022;36(6):680-6.
61. Riddle CA. Assisted dying & disability. Bioethics. 2017;31(6):484-9.
62. Burnett M. A history of abortion in Canada: The quest for women's reproductive rights. Journal of Obstetrics and Gynaecology Canada. 2019;41(supp. 2):S293-5.
63. James-Abra E. The road to inclusion: transgender health care in Canada. The Canadian Encyclopedia. 29 Jul 2014.
64. MacDonald NE, Stanwick R, Lynk A. Canada's shameful history of nutrition research on residential school children: The need for strong medical ethics in Aboriginal health research. Paediatrics & Child Health. 2014;19(2):64.
65. Gibson E, Downie J. Consent requirements for pelvic examinations performed for training purposes. CMAJ. 2012;184(10):1159-61.
66. Kilbride MK, Joffe S. The new age of patient autonomy. JAMA. 2018;320(19):1973-4.
67. The Canadian Press. MAID litigant says disability doesn't make her vulnerable to pressure to end her life. CTV News. 16 Dec 2020.

68. Sastre-Buades A, Alacreu-Crespo A, Courtet P, Baca-Garcia E, Barrigon ML. Decision-making in suicidal behavior: A systematic review and meta-analysis. Neuroscience and Biobehavioral Reviews. 2021;131:642-62.
69. Beaudry J-S. Bill C-7, assisted dying and “lives not worth living.” Policy Options. 14 Dec 2020.
70. Schuklenk U. Time to rethink assisted dying? Bioethics. 2024;38(4):273-4.
71. Kious BM. Disability, offense, and the expressivist objection to medical aid in dying. Journal of Medicine and Philosophy. 2024;49(6):532-46.
72. Health Canada. Model Practice Standard for Medical Assistance in Dying (MAID). Government of Canada. Mar 2023.
73. Canadian Institute for Health Information. Access to Palliative Care in Canada, 2023. CIHI. 2023.
74. Mathison E. The better world argument. Value Judgments. 17 Nov 2022.
75. Carter v. Canada (Attorney General). 2012 BCSC 886.
76. British Columbia College of Nurses & Midwives. FAQs. BCCNM.
77. Downie J, Chandler J. Interpreting Canada’s Medical Assistance in Dying Legislation. Institute for Research on Public Policy. Mar 2018.
78. Stainton T. Disability, vulnerability and assisted death: commentary on Tuffrey-Wijne, Curfs, Finlay and Hollins. BMC Medical Ethics. 2019;20:89.
79. Riddle CA. Medical aid in dying: the case of disability. In: Cholbi M, Varelius J, editors. New Directions in the Ethics of Assisted Suicide and Euthanasia. 2nd ed. Cham, Switzerland: Springer; 2023. p. 225-41.
80. Roley G. CBC headline on assisted suicide expansion is fake. AFP. 31 Jul 2024.
81. Goldin M. Canada isn’t pushing minors to end their lives. Current euthanasia laws don’t apply to them anyway. AP Fact Check. 24 Jul 2023.
82. Gamage M. She sought help in crisis and was suggested MAID instead. The Tyee. 9 Aug 2023.
83. Lazin SJ, Chandler JA. Two views of vulnerability in the evolution of Canada’s medical assistance in dying law. Cambridge Quarterly of Healthcare Ethics. 2023;32(1):105-17.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Beyond Beneficence: Moral Asymmetry and the Minimization of Suffering in End-of-Life Care

Adam Braus[a]

Résumé
Cet article examine de manière critique les fondements éthiques de la minimisation de la souffrance en fin de vie. La réduction de la souffrance constitue une préoccupation majeure dans le discours éthique relatif aux soins de fin de vie. Certains penseurs accordent une importance particulière au fait de réduire autant que possible la souffrance non désirée et inutile en fin de vie. Pourtant, beaucoup d'autres considèrent que la minimisation de la souffrance constitue une justification insuffisante, voire risquée, pour la prise de décision en fin de vie. Le désir de minimiser la souffrance est souvent considéré comme équivalent ou entièrement réductible à l'utilitarisme ou, en bioéthique, au principe de bienfaisance. J'argumente ici qu'il est erroné de fonder le désir de minimiser la souffrance en fin de vie sur l'utilitarisme ou la bienfaisance, puisqu'ils reposent sur une symétrie morale, alors que l'engagement à minimiser la souffrance est moralement asymétrique. Comme alternative, je propose et développe la doctrine du moindre mal évitable (DMME), fondée sur l'utilitarisme négatif, également appelé conséquentialisme moralement asymétrique. J'évalue la DMME au regard d'une série de traitements de fin de vie et montre qu'elle s'accorde bien avec les engagements éthiques de ceux qui souhaitent minimiser la souffrance en fin de vie. Je conclus que la DMME offre aux personnes, aux institutions et aux médecins une base théorique formelle, systématisée et défendable pour soutenir le désir de minimiser la souffrance en fin de vie.

Mots-clés
soins de fin de vie, compassion, conséquentialisme, asymétrie morale, soins palliatifs

Abstract
This paper critically examines the ethical foundations for minimizing suffering at the end of life. The reduction of suffering is a major concern in the ethical discourse of end-of-life care. Some thinkers privilege minimizing unwanted and unnecessary suffering at the end of life as much as possible. And yet, many others consider minimizing suffering an insufficient or risky justification for decision-making at the end of life. The desire to minimize suffering is considered equivalent to or entirely contained within utilitarianism or, in bioethics, the principle of beneficence. Here, I argue that it is a mistake to ground the desire to minimize suffering at the end of life in utilitarianism or beneficence, since these are morally symmetrical, and the commitment to minimize suffering is morally asymmetrical. As an alternative, I propose and develop the doctrine of least avoidable suffering (DLAS), which is grounded in negative utilitarianism — aka morally asymmetrical consequentialism. I assess DLAS against a series of end-of-life treatments and demonstrate that it aligns well with the ethical commitments of those who desire to minimize suffering at the end of life. I conclude that DLAS offers people, institutions, and physicians a formal, systematized, and defensible theoretical basis for the desire to minimize suffering at the end of life.

Keywords
end-of-life care, compassion, consequentialism, moral asymmetry, palliative care

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INTRODUCTION

The reduction of suffering is a major concern in decision-making at the end of life. Some thinkers privilege minimizing unwanted and unnecessary suffering as much as possible, and are generally in favour of palliative care, hospice, and the legalization of some forms of euthanasia. In this discourse, the moral obligation to minimize suffering has been considered equivalent to or entirely contained within the principle of beneficence, understood as the obligation to maximize benefits — including both minimizing suffering and maximizing positive welfare. The principle of beneficence is *morally symmetrical,* meaning unwanted and unnecessary suffering can be compensated morally by happiness.

However, the principle of beneficence alone is insufficient for end-of-life care if one's goal is to minimize suffering, as this principle may occasionally permit actions that increase suffering if they are outweighed by sufficiently large gains in overall welfare. If one is substantively committed already to minimizing suffering, one would need an ethical theory or framework that explicitly prioritizes the reduction of suffering rather than subsuming it under a broader utilitarian calculus. The commitment to minimize suffering could, I propose here, be more precisely and forcefully grounded in a *morally asymmetrical consequentialist* framework — one that categorically rejects avoidable suffering, regardless of how much it might be offset by increases in happiness beyond mere contentment (1-3).

In this paper, I argue for such an alternative ethical theory, which I call the *doctrine of least avoidable suffering (DLAS)*. While the principle of beneficence is rooted in utilitarianism, a symmetrical form of consequentialism, DLAS is grounded in negative utilitarianism, a morally asymmetrical framework, and entails a moral obligation to minimize avoidable suffering for the greatest number (1,3-7). Just as beneficence provides a systematic ethical structure for maximizing overall well-being, DLAS offers a formal and complete theoretical justification for prioritizing the alleviation of suffering over all other considerations.

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My aim here is not to argue in favour of the doctrine itself, but rather to introduce and formalize it as a meaningful contribution to the discourse. To illustrate how this doctrine aligns with the goal of minimizing suffering at the end of life, I examine its application in the context of various end-of-life treatments. My analysis demonstrates that DLAS not only provides a structured ethical commitment to reducing suffering but also offers a promising framework for end-of-life decision-making, with important implications for both research and practice. My discussion is primarily theoretical and is not intended to prescribe specific policies; the examples I present are exploratory rather than exhaustive, intended to showcase the doctrine's potential as a guiding ethical framework rather than to dictate its precise implementation.

The structure of this paper is as follows. In the first section, I make mention of those physicians and institutions that favour and even advocate for the position of minimizing unwanted and unnecessary suffering at the end of life. I then argue that neither beneficence nor any other major ethical approach adequately supports minimizing suffering. Following this, I define the doctrine of least avoidable suffering with various considerations and ground it in morally asymmetrical consequentialism. I then apply DLAS to various end-of-life treatments to show that it aligns well with the ethical commitments of end-of-life suffering-minimizers and can serve as a philosophical basis for this view. Finally, in the last section, I respond to various possible objections to DLAS.

THOSE WHO DESIRE TO MINIMIZE SUFFERING AT THE END OF LIFE

Death is commonly accompanied by significant pain and suffering, and various approaches to end-of-life decision-making prioritize the reduction of this suffering to different degrees. Some scholars, physicians, and institutions prioritize the alleviation of suffering in end-of-life care so strongly that they argue hastening death can be morally justified.

For instance, hospice care was founded in the US in 1967 with the goal of reducing suffering (8). To this day, "the overriding goal of care in the hospice setting is to relieve suffering" (9, p.26). In the 1990s, palliative medicine was introduced, which made the relief of suffering a primary goal. In 2004, the World Health Organization stated that palliative care advances quality of life through the "prevention and relief of suffering" (10). The American Academy of Hospice and Palliative Medicine and The Hospice and Palliative Nurses Association both state that reducing suffering is the goal of their organizations (11). The Oxford Textbook of Palliative Medicine has dedicated every edition to "suffering patients around the world" (12). Some notable figures who endorse a suffering-focused end-of-life approach include Timothy E. Quill from the University of Rochester School of Medicine's palliative care division and a board member of the American Academy of Hospice and Palliative Medicine, and Robert D. Truog from Harvard Medical School and Boston Children's Hospital. Another notable figure is Eric Cassell from Weill Cornell Medical Center, who is famous for claiming that the goal of all medicine ought to be the relief of suffering (13).

It might appear uncontroversial that "in the end-of-life context, alleviation of the suffering of a distressed patient is usually seen as a, if not the, central goal for the medical personnel treating her" (14, p.1). However, this view is not held by all and is, in fact, highly contested. Generally, one can presume there is a *pro tanto* obligation to reduce suffering; however, this common moral position still leaves open the chance that some other value might, in certain circumstances, morally compensate for additional unwanted and unnecessary suffering. In contrast, a strict commitment to minimizing suffering means that no other value can ever compensate for additional unwanted and unnecessary suffering.

This debate is especially controversial in end-of-life care, where minimizing suffering often entails sanctioning treatments that deliberately hasten a patient's demise. These forms of euthanasia include commonly accepted treatments, such as withdrawing life-sustaining treatments, and also more controversial methods like the voluntary stopping of eating and drinking (VSED), proportional palliative sedation (PPS), or medical aid in dying (MAID).[1] Many of these treatments are still illegal in the United States, such as providing MAID before someone is acutely dying, initiating VSED by advanced directive for incompetent people, or administering MAID by advanced directive and which is equivalent to voluntary active euthanasia (VAE). Those who promote minimizing patient suffering at the end of life generally advocate for expanding controlled access to some or all of these treatments.[2]

Some might object to including Dr. Quill and Dr. Truog in this group. The justifications for euthanasia these physicians have published are based on the argument from consistency. They argue that whether a physician withdraws life-sustaining medical treatment or administers lethal drugs, in either case a physician is taking an action that leads to the patient's demise and so there should be no moral or legal difference between these actions (16-18) not based on the moral demands to minimize suffering. However, one can gather from context that they made the argument from consistency to justify actions that had the goal of minimizing unwanted and unnecessary suffering at the end of life. And so, it is justified to include these physicians in the group of people that desire to minimize suffering at the end of life.

[1] MAID has also commonly been called physician assisted suicide (PAS). MAID is not merely a euphemism for PAS. The term MAID refers to a patient drinking lethal medication, whereas voluntary active euthanasia (VAE) refers to a physician administering a lethal injection. Both of these could be called "physician assisted suicide" so the term MAID provides a valuable distinction.

[2] For instance, in 1991 Dr. Quill prescribed MAID for a woman diagnosed with terminal leukemia in violation of the laws of New York state (15). This act resulted in him being made the plaintiff in the 1997 US Supreme Court case *Petitioners v. Timothy E. Quill et al* (16).

THE LIMITATIONS OF BENEFICENCE AND OTHER ETHICAL THEORIES FOR MINIMIZING SUFFERING

While the imperative to minimize suffering at the end of life may seem self-evident, its ethical foundations require closer examination. At first glance, it appears that the ethical imperative to minimize suffering is equivalent to or wholly contained within the *principle of beneficence*. The principle of beneficence, after all, entails maximizing welfare, which includes both minimizing suffering and maximizing pleasure and happiness (19-22). Since beneficence of this form is derived from utilitarianism, one might assume that developed utilitarian arguments support treatments that minimize suffering, including euthanasia (23).

However, beneficence (and, by extension, utilitarianism) does not prioritize minimizing suffering in every case and so is not a sufficient theoretical basis for the ethical goal of minimizing suffering. Beneficence is *morally symmetrical* — it sanctions increasing unwanted and unnecessary suffering so long as they are outweighed by a larger enough increase in happiness or pleasure. Therefore, both in theory and in practice, there will be cases where an increase in happiness or pleasure will outweigh an increase in suffering. For instance, there are many arguments that the unwanted and unnecessary suffering at the end of life is justified because it is part of a good death and can be meaningful for a person (24,25).

If suffering can be justified by its instrumental value in achieving greater happiness, then it is not an inherent moral wrong but rather a factor that can be weighed and, at times, sacrificed for a perceived greater good. For example, some arguments suggest that unwanted and unnecessary suffering at the end of life can be meaningful or even beneficial — whether by fostering spiritual growth, strengthening familial bonds, or contributing to a good death. From the perspective of those who are genuinely committed to minimizing suffering, such arguments are deeply problematic. They suggest that suffering can be morally instrumentalized — that it can be required, prolonged, or justified based on its potential to contribute to some greater happiness.

Perhaps the strongest evidence that the principle of beneficence does not prioritize suffering minimization is that it has been used to justify arguments *against* euthanasia. One argument is that death cannot possibly constitute a benefit at all (55). Various scholars argue that the unwanted and unnecessary suffering at the end of life is morally justified because it helps people reach greater happiness and fulfillment (25). In other words, many scholars use beneficence to justify requiring people to endure the unwanted and unnecessary suffering at the end of their lives because that suffering is instrumental in potentially gaining a great happiness or pleasure. One could argue that certain religious objections to euthanasia also rely on a form of beneficence, as they justify enduring unwanted and unnecessary suffering at the end of life by appealing to a greater good — whether it be increased holiness, spiritual fulfillment, or the sanctity of life (26,27). In each of these arguments, some greater happiness or superior state of being compensates for suffering — a position directly opposed by those who seek to minimize suffering as much as possible.

Alternative consequentialist frameworks for end-of-life ethics also often subordinate suffering minimization to other values in specific circumstances. Vitalism, whether religious or secular, accepts additional suffering when necessary for life preservation. Pure autonomy-centered approaches that advocate for unrestricted right-to-die policies prioritize self-determination over the suffering potentially involved in suicide or assisted death. Even attempts to balance autonomy with beneficence through combined positions or reflective equilibrium are problematic; these approaches provide no consistent safeguard against increased suffering that might be justified by appeals to either principle, depending on the specific circumstances. The resulting ethical framework remains vulnerable to permitting greater suffering based on whichever principle — autonomy or beneficence—is emphasized in a particular reflective equilibrium.

Among deontological approaches to end-of-life decision-making, there is still no guarantee that one will minimize suffering. One of the most prominent positions is the doctrine of double effect (DDE), which is commonly grouped together with its sister theory, distinguishing between killing and letting die (28). DDE does allow for the voluntary withdrawal of life-sustaining treatment and administering strong pain killers, but, at present, it prevents a physician from deliberately helping a patient to die even as a last resort to avoid irremediable suffering (19,29,30). The argument from consistency is a refutation of DDE and the killing/letting die distinction, but it also does not offer any guarantee to minimize suffering. It only expands physicians' latitude to do what they believe is right (17).

THE DOCTRINE OF LEAST AVOIDABLE SUFFERING (DLAS)

These ethical trade-offs one encounters with beneficence mean a different ethical basis is needed to defend the substantive ethical commitment to minimizing suffering at the end-of-life. Such a commitment must be *morally asymmetrical*, as it holds that no amount of happiness above contentment can morally compensate for unwanted and unnecessary suffering. The notion of moral asymmetry has gone by various names, including moral asymmetry (2,3,31-33), the compensation principle (34,35), and non-commensurability (35). Despite the differences in nomenclature, the idea is roughly the same: *suffering cannot be compensated for or outweighed by happiness*.

This concept explains many common moral intuitions. Consider how one might intuitively feel a moral obligation to make sacrifices to feed people who are starving or malnourished, but there is no such obligation to make sacrifices to feed people who are well-endowed or well-nourished. Similarly, one might consider it acceptable to torture a terrorist bomber who has

hidden a bomb that will explode tomorrow somewhere in an unknown, but heavily populated, city. However, arguably, one would not consider it acceptable to torture someone so that some large number of people could enjoy more convenience in their lives (e.g., slavery). Moral asymmetry sanctions trading a lesser suffering to avoid a greater suffering but rejects trading suffering — even a relatively small amount — to increase happiness above contentedness, no matter how much that happiness may be.

As an alternative to the principle of beneficence, I propose here *the doctrine of least avoidable suffering (DLAS)*, which may be stated succinctly as follows:

Always choose that action that will minimize unwanted and unnecessary suffering for the greatest number.

Like the principle of beneficence, DLAS is consequentialist. In other words, someone applying it will judge the moral worth of an action according to the outcome of that action. However, traditional forms of consequentialism are virtually all morally symmetrical since they sanction trading suffering for sufficiently large increases in happiness. DLAS, however, is morally asymmetrical and does not allow trading any amount of suffering to increase happiness beyond contentment and prioritizes minimizing suffering above all else. The most prominent form of morally asymmetrical consequentialism is called “negative utilitarianism” (1,37). While there is an important and ongoing philosophical discourse on the theoretical strengths and weaknesses of negative utilitarianism, here, I set many of the elements of this theoretical debate to one side and focus entirely on exploring how it might relate to the issue of end-of-life decision-making.

DLAS is applied to scenarios in much the same way as other consequentialist approaches. First, one separately evaluates the potential suffering and potential happiness that each course of action would produce. The morally preferable action is the one that results in the least suffering. For example, stealing a loaf of bread to feed a starving family might be justified, as the baker’s minor loss is outweighed by the family’s severe hunger. In cases where the suffering caused by different actions is equal, the amount of happiness produced serves as a tiebreaker (39). Further below I will apply DLAS to various end-of-life treatments.

The distinction between unwanted and unnecessary suffering may not be immediately clear. Would not those committed to minimizing suffering seek to eliminate all suffering entirely? Perhaps counterintuitively, some forms of suffering, while regrettable and tragic, are nonetheless morally tolerable. For instance, one would not object to someone voluntarily getting a tattoo or to the amputation of a gangrenous foot when medically necessary. Given that certain types of suffering are morally permissible, a structured, rules-based distinction between *morally tolerable* and *morally intolerable* suffering is essential to formalizing DLAS and avoiding arbitrariness. To that end, I propose the following three key factors for distinguishing between these categories. These factors will play a crucial role when evaluating how DLAS applies to end-of-life treatments. To judge if suffering is morally tolerable or intolerable, one must first consider the following:

1. **Consent:** For suffering to be morally tolerable, it must be voluntarily chosen. If an individual willingly undertakes distress or discomfort, it does not necessarily constitute suffering in the relevant moral sense. Since such experiences align with personal desires and preferences, they may even contribute to well-being, at least subjectively. This idea is captured in the principle of *volenti non fit injuria* (“to a willing person, no injury is done”). A clear distinction emerges when comparing consensual and nonconsensual suffering. While suffering imposed against one’s will is morally intolerable, suffering that is freely chosen is either not suffering at all or is at least morally permissible. For example, one would not equate a consensual boxing match with an unprovoked beating, a voluntary donation with theft, or rough sex with sexual assault. In each case, consent changes the ethical nature of the experience and shows that suffering — when freely chosen — does not necessarily require intervention.

There are two other conditions of morally intolerable suffering, which I label *capacity* and *exacerbation*.

2. **Capacity:** For suffering to be morally tolerable, it must be impossible for one to alleviate the suffering. It would be irrational for someone to have the moral obligation to do something out of their power, e.g., demanding one’s 90-year-old neighbour bring about peace in the Middle East. This intuition follows roughly the principle of *ad impossibilia nemo tenetur* or “ought implies can.” A good example from the end of life is when someone enters hospice care. One accepts that the suffering that must accompany the person’s death is now unavoidable and therefore must be tolerated even if it is regrettable and tragic.
3. **Exacerbation:** For suffering to be morally tolerable, any action meant to alleviate it must only cause greater suffering. It would be irrational to take actions that reduced a small suffering but caused a larger one, e.g., removing all your furniture to avoid stubbing your toe. As illustrated above by the gangrenous foot case, not amputating the foot will predictably only lead to greater suffering. And so, it is obligatory to endure lesser suffering that is instrumental in alleviating a greater one.

I accept that not everyone might agree with the importance of consent, capacity, and exacerbation in determining if suffering is morally tolerable or intolerable. There are, no doubt, edge cases that challenge the completeness of these three factors. Nevertheless, when applying DLAS to practical cases in end-of-life care, these three factors are important for understanding how DLAS works and aligns with the commitment to minimize suffering at the end of life.

APPLYING DLAS TO END-OF-LIFE CARE

In this section, I will assess the DLAS by applying it to various end-of-life treatments, progressing from the least to the most controversial. My purpose here is not to argue that these treatments ought to be available or that following this doctrine would necessarily constitute a moral improvement. Rather, my focus is on showing that physicians and ethicists who prioritize minimizing suffering at the end of life often advocate for the availability of these treatments — and that it aligns with and can justify controlled versions of them.

Through this analysis, I find that (a) DLAS sanctions voluntary forms of passive and active euthanasia as a last resort in cases of unwanted and irremediable suffering, (b) it maintains a moral distinction between killing and letting die but does not prohibit deliberate killing categorically, and (c) it does not sanction an arbitrary right to die. As such, I conclude that DLAS supports the commitment to minimize suffering at the end of life.

DNR, Withdrawing Life Sustaining Treatment, and VSED

Let's begin by seeing how one could use DLAS to justify the choice to comply with a DNR (Do Not Resuscitate) order or decision to withdraw life-sustaining treatments such as a ventilator. These two choices are legal and relatively uncontroversial in the US and traditionally have been justified by a patient's right to autonomy and bodily integrity combined with the killing/letting die distinction (40). In other words, the patient has the autonomy to refuse medical treatment, and a medical provider is not blameworthy for complying with these requests because they did not kill the patient but rather let the patient die. DLAS also justifies complying with these requests, but the justification does not require asserting someone's right to die or the killing/letting die distinction. Like the case of the nonconsensual tattoo above, if the patient does not consent to medical treatment, forcing that medical treatment becomes a form of nonconsensual, and therefore morally intolerable, suffering. Meanwhile, the suffering entailed in the patient dying is morally tolerable since it is consented to, and there is no action that one could take to prevent their dying (any life-saving or life-sustaining treatment) that would not only exacerbate unwanted and unnecessary suffering.

The same goes for the slightly more controversial option of a patient voluntary stopping of eating and drinking (VSED) (41). Again, VSED is commonly justified by reference to autonomy and killing/letting die, but VSED can be justified by using DLAS alone. If someone elects VSED to avoid irremediable suffering at the end of life, force feeding them (or even offering them food) would increase their suffering, because they do not consent to be fed. By contrast, force feeding or offering food to someone who is not facing irremediable suffering at the end of life (i.e., an anorexic) would be sanctioned, all things considered. Here, and in other cases, one can see how this doctrine sanctions deliberate forms of dying to avoid irremediable suffering at the end of life, but it does not sanction a right to die for any reason.

Proportional Palliative Sedation (PPS)

Proportional Palliative Sedation (PPS) is a legal practice of using strong drugs to render a patient unconscious when managing refractory pain at the end of life (42). PPS will usually hasten the death of the patient (especially if artificial hydration and nutrition are withheld, which is very common). Physicians justify PPS using references to autonomy, beneficence, and the doctrine of double effect (DDE) or killing/letting die. Justifications based on DDE or killing/letting die are what require physicians to only sedate patients in proportion to their pain. If the sedation is out of proportion with the patient's pain and hastens their death, then this would constitute active euthanasia and is considered morally wrong by many and illegal in the US and most other jurisdictions.

DLAS sanctions PPS since it consensually minimizes someone's irremediable suffering. But one might object that focusing solely on avoidable suffering would not require proportionality and would make no ethical difference between PPS and Voluntary Active Euthanasia (VAE). In other words, DLAS would not distinguish between (a) sedating a patient until they die of dehydration and (b) sedating a patient so strongly that it kills them outright. This is objectionable because there is a moral difference between killing and letting die. In response to this objection, I would argue that someone applying DLAS would still require using proportional sedation in cases of refractory pain and does still recognize a moral difference between killing and letting die, albeit different than is traditional.

While the patient is usually most at risk of suffering in an end-of-life scenario, someone using DLAS has the obligation to minimize suffering for everyone involved. There is also the suffering of other stakeholders, including a patient's loved ones and the medical providers. In the case of PPS, being very close to deliberately hastening someone's death risks causing moral injury, guilt, and blame for that person — all terrible forms of potentially life-long suffering. Hence killing someone is morally different from letting them die because it carries very real risk of moral injury. Proportional sedation is one way to prevent moral injury from leaking out and spilling onto those around the patient. Thus, DLAS would also advocate for proportionality when doing palliative sedation and maintaining a moral bright line between PPS and VAE (43).

Some might object that the presence of or risk of guilt and moral injury to those around the patient is not a strong enough reason to force DLAS to use proportionality.[3] Of course, in an end-of-life scenario, the patient is usually the one facing the greatest suffering — intense pain, debilitation, losing their life, and so on — and so the emphasis is on the patient, but it would

[3] Thanks to the comments from an anonymous reviewer for this objection.

be inconsistent if DLAS entirely ignored the suffering to those around the patient. While in the philosophical literature the discourse on end-of-life care is largely focused on the patient — namely, respecting their autonomous choices and doing them as much benefit as possible — in legal and clinical domains it is the DDE and killing/letting die arguments that hold tremendous sway.[4] These arguments hinge precisely on the risk of blame, guilt, and moral injury for medical providers. Moreover, considering the suffering of all involved ends up not being a weakness of DLAS but a strength. For instance, it is commonly agreed that medical care providers who feel they risk moral injury with a particular treatment ought not to be forced to perform it. If DLAS ignored all suffering except for the patient, it would sanction forcing medical providers to perform procedures they felt violated their conscience, and this is very objectionable. For these reasons, the consideration of the risk of moral injury to providers is a sufficient reason to maintain a moral difference between killing and letting die. However, whereas this moral difference is categorical for DDE (deliberately killing is prohibited), for DLAS, deliberately killing is permissible if it is the last resort for minimizing suffering.

Medical Aid in Dying (MAID)

Medical Aid in Dying (MAID) generally refers to a physician proscribing a single dose of lethal medication that must be self-administered by drinking by the patient (44). MAID is commonly justified today with arguments based on autonomy, DDE, and killing/letting die. MAID can be justified using DLAS alone without reference to DDE and killing/letting die by the same reasoning as justifying withdrawing life-sustaining treatment. The suffering of the patient is morally intolerable because it is non-consensual, there exists the capability to improve it (the lethal medication), and any other action would only make the suffering worse. Meanwhile, the suffering entailed in the patient dying must be tolerated because the death is consented to and there is no capability to select an alternative that would not exacerbate the suffering.

MAID is a controversial end-of-life treatments that is legal only in a few US states, and a handful of other countries. MAID laws in the US require a patient to have no more than six months to live, but they do not require irremediable suffering (45). In other words, as the laws are currently written, they simply allow people that are provably near the end of their lives the medical means to kill themselves painlessly. By contrast, the MAID laws of Canada, Belgium, and the Netherlands do require the patient to be facing irremediable suffering. As such, one could not defend the laws of the US using DLAS, but one could use DLAS to defend those of the latter countries. Once again, one can see that DLAS does not sanction an arbitrary right to die, even for terminal patients, since it requires irremediable suffering to justify any form of euthanasia.

Voluntary Active Euthanasia (VAE)

Voluntary active euthanasia (VAE) means treatments that directly bring about the demise of a patient. VAE is a controversial practice and is illegal in the US and in most countries, with notable exceptions being the Netherlands, Belgium, and Switzerland. One can think of VAE as the same as MAID but where a lethal medication is administered by a volunteer or physician. By similar analysis as MAID, one can use DLAS to justify VAE. However, since DLAS still makes a moral distinction between killing and letting die, VAE would only be justified as an absolute last resort and would require a physician or volunteer who agreed to administer the lethal medication, and even then, it would come at considerable moral risk. Both the patient and their physician must agree that there is no other way to minimize suffering. Some examples where VAE might be justified could be, (a) if the patient is competent and committed to taking MAID but there is some risk involved in self-administration (e.g., tremors, paralysis, or poor swallowing) or (b) if the patient is a candidate for MAID, VSED, or PPS but considers these as constituting greater suffering than VAE.

Switzerland's legal regulation of voluntary euthanasia could not be justified by DLAS directly because it does not require a patient to face irremediable suffering. However, one could use DLAS to justify the euthanasia laws of Belgium and the Netherlands since these do make irremediable suffering a requirement.

In conclusion, DLAS generally aligns with the commitments of those who wish to minimize suffering at the end of life, but not with those who advocate for an arbitrary right to die. It offers a middle way between disavowing any sort of euthanasia and allowing for "self-determination run amok" (46). DLAS treats any form of passive or active euthanasia as an absolute last resort against irremediable suffering. Moreover, DLAS treats forms of passive euthanasia (letting die) as morally preferable to forms of active euthanasia (killing), but it does not forbid active euthanasia categorically.

VARIOUS OBJECTIONS TO DLAS

One might object that DLAS is an absolutist moral approach, and therefore it does not admit of moral pluralism and runs the risk of being culturally colonial, which is objectionable. Many cultures and religious traditions interpret suffering in ways that do not align with a strictly harm-reduction perspective. For instance, some traditions may regard suffering as spiritually meaningful or necessary for personal growth, redemption, or preparation for the afterlife. If DLAS were to be applied without sensitivity to these perspectives, it could be criticized as imposing a Western-centric model of moral reasoning on suffering.

On the contrary, DLAS must embrace individual and cultural moral pluralism since failing to take into account cultural differences related to illness, dying, and death have already been identified as being a common cause of avoidable suffering. For instance, ignoring cultural differences causes conflict between medical providers and patients and their families, and can

[4] See the US Supreme Court case *Petitioners v. Timothy E. Quill et al* (16) where DDE, killing and letting die, and the argument from consistency are central.

even lead to physically or psychologically harming a patient or their loved ones (47,48). Consider the issue of a patient choosing their place of death. For many individuals and cultures, planning to die at home causes significantly less suffering than planning to die in a medical facility (49). So, all things being equal, DLAS requires that people have the option to follow their individual and cultural practices in choosing their place of death since this reduces avoidable suffering. While DLAS might run against some cultural practices, these are only practices that deliberately increased unwanted and needless suffering, for instance, female genital mutilation, tortuous human sacrifice, and the like, which are already significantly objectionable and extremely hard to justify solely on the grounds of moral relativism.

Another objection may hold that DLAS would sanction unacceptable violations of people's autonomy and theoretically enable a "slippery slope" from voluntary to involuntary forms of euthanasia (50,51). As it is defined so far, one might still suppose that DLAS *does* sanction involuntary euthanasia, since ostensibly the death of a patient might significantly reduce the suffering of caregivers or the burden on society — perhaps so much so that it could outweigh the suffering of violating someone's wish to live. While it is true that someone's death might reduce suffering for others, there are various reasons why DLAS directly defends people's autonomy (both directly and indirectly), forbids involuntary euthanasia, and therefore makes for a very "sticky slope" towards involuntary euthanasia.

First, as I argue above, suffering reasonably includes the frustrations of preferences, and so violations of autonomy and consent constitute suffering (52). Second, involuntary euthanasia runs the terrible risk of greatly increasing the injury and outrage of family members, loved ones, and concerned members of the public who might feel the person was murdered. This suffering would weigh heavily against the decision to commit involuntary euthanasia. Third, making involuntary euthanasia a legal medical practice would increase suffering greatly by reducing the number of those seeking medical care out of fear of being murdered. Moreover, no one would call a campaign of involuntary euthanasia (as the Nazi's pursued) or legal suicide or consensual homicide as moral acts aimed at minimizing suffering, rather these appear to be a moral scourge or depravity. Finally, if the caregivers of terminally ill people who wish to live are suffering so terribly with their care, the solution that leads to the least avoidable suffering is to provide them with greater support in the form of hospice and palliative care (which is not very costly and causes no additional suffering), not violating the wish of the terminal patient to live.

Another objection to DLAS is that perhaps it could never justify active forms of euthanasia — even though many who prioritize minimizing suffering support such interventions. The reasoning behind this objection is that killing, by definition, must constitute an increase in suffering; otherwise, if death were inherently preferable to suffering, DLAS would lead to pro-mortalism — the absurd conclusion that one be morally obligated to end all lives indiscriminately. In response, I would say that DLAS does not proscribe pro-mortalism. Like DDE or killing/letting die, DLAS offers a precise and non-arbitrary justification for when deliberately increasing suffering (perhaps by killing someone) is morally justifiable and even required. Only if an action leads to less suffering overall, then it is morally justifiable. As mentioned above, the amputation of a gangrenous foot would prevent the loss of the leg or the death of the patient. Similarly, if someone's consensual death is the only possible remedy to suffering at the end of life, DLAS would support this form of euthanasia since it replaces a greater suffering with a lesser.[5]

A final objection is that DLAS does not necessarily limit its application to those at the end of their lives; rather, it would justify intervention for anyone experiencing irremediable suffering, regardless of their life stage. This is true, but rather than a weakness, this is one of the doctrine's strengths. For instance, there are cases where it might be deemed the path of least suffering to withdraw life-sustaining treatments in tragic and hopeless neonatal and pediatric cases (53). Or cases where someone middle aged could continue to live with a ventilator but deems continued living greater suffering than dying (54). If DLAS only allowed for old people with aggressive terminal illnesses to die, then it would require additional unwanted and unnecessary suffering of young people in hopeless situations which is inconsistent and causes greater needless suffering.

CONCLUSION

In this paper, I introduced the doctrine of least avoidable suffering (DLAS) as a new potential ethical approach for those who desire to minimize suffering at the end of life. There are many people, physicians, and prominent and trusted organizations that are publicly and substantively committed to minimizing suffering at the end of life. I argued that this doctrine cannot be reduced to or contained within beneficence or utilitarianism because of fundamental differences in their moral symmetry. While beneficence and other ethical frameworks in end-of-life care might sometimes permit increases in unwanted and unnecessary suffering for the sake of other values, DLAS will always put the reduction of needless and unwanted suffering above other values.

I also fleshed out this new doctrine, grounding it in morally asymmetrical consequentialism and defining a systematic approach to its application. I highlighted three factors — consent, capacity, and exacerbation —to create a non-arbitrary process for distinguishing between suffering that obliges action and suffering that must be tolerated (even if it pains us). When applied to various end-of-life treatments — from DNR orders and withdrawal of life-sustaining treatment to more controversial interventions like MAID and VAE — DLAS yields positions that align well with the substantive ethical commitments of those who already prioritize suffering reduction. DLAS does not sanction an arbitrary right to die but treats euthanasia as a last resort against otherwise irremediable suffering. Moreover, it makes a moral distinction between killing and letting die but it does not absolutely prohibit killing. It makes the distinction between killing and letting die because deliberate killing can be a cause of

[5] For an excellent discussion of euthanasia for irremediable suffering at the end of life, see Greif, 2018 (20) and his scenario of a man trapped in a burning lorry.

suffering (fear and distress) to others, especially medical providers, friends and loved ones, and the public. In addition, DLAS also withstands various objections, including concerns about moral pluralism, the risk of a slippery slope to involuntary euthanasia, and questions about its scope.

While I have attempted to make a compelling ethical case for DLAS, my goal has not been to argue for the ethical superiority of DLAS over other approaches, but to help systematize an existing substantive ethical position. Many people, institutions, and healthcare professionals — particularly in palliative and hospice settings — already operate with an implicit or explicit commitment to enable the minimization of suffering at the end of life. What has been missing, however, is a philosophical account that fully, formally, and coherently justifies this substantive ethical position. DLAS provides this missing theoretical foundation and practical justification for a substantive ethical commitment that is already critically important and actively in use in end-of-life care practices in the United States and around the world.

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REFERENCES

1. Wolf C. O repugnance, where is thy sting? In: Tännsjö T, Ryberg J, editors. The Repugnant Conclusion: Essays on Population Ethics. Dordrecht: Springer; 2004. p. 61-80.
2. Mayerfeld J. The moral asymmetry of happiness and suffering. Southern Journal of Philosophy. 1996;34(3):317-38.
3. Popper KR. The Open Society and Its Enemies. Ryan A, Gombrich EH, editors. Princeton: Routledge; 1945.
4. Häyry M. Exit duty generator. Cambridge Quarterly of Healthcare Ethics. 2024;33(2):217-31.
5. Scarre G. Utilitarianism. New York: Routledge; 2020.
6. Smart JJC. Negative utilitarianism. In: D'Agostino F, Jarvie I, editors. Freedom and Rationality: Essays in Honor of John Watkins From his Colleagues and Friends. Dordrecht: Springer Netherlands; 1989. p. 35-46.
7. Smart RN. Negative utilitarianism. Mind. 1958;67(268):542-43.
8. Krisman-Scott MA. Origins of hospice in the United States: The care of the dying, 1945–1975. Journal of Hospice & Palliative Nursing. 2003;5(4):205-10.
9. Quill TE, Miller FG, editors. Palliative Care and Ethics. Oxford: Oxford University Press; 2014.
10. Davies E, Higginson IJ. Better palliative care for older people. Copenhagen: World Health Organization, Regional Office for Europe; 2004.
11. Dy SM, Kiley KB, Ast K et al. Measuring what matters: Top-ranked quality indicators for hospice and palliative care from the American Academy of Hospice and Palliative Medicine and Hospice and Palliative Nurses Association. Journal of Pain and Symptom Management. 2015;49(4):773-81.
12. Hanks GW, editor. Oxford Textbook of Palliative Medicine. New York: Oxford University Press; 2011.
13. Cassell EJ. The nature of suffering and the goals of medicine. Loss, Grief & Care. 1998;8(1-2):129-42.
14. Varelius J. Suffering at the end of life. Bioethics. 2019;33(1):195-200.
15. Quill TE. Death and dignity. In: Battin MP, Francis LP, Landsman BM, eds. Death, Dying and the Ending of Life, Vol. I–II. London: Routledge; 2019. p. 245-48.
16. Rehnquist WH; Supreme Court of the United States. U.S. Reports: Vacco v. Quill, 521 U.S. 793. Washington, DC: U.S. Supreme Court; 1996.
17. Miller FG, Truog RD, Brock DW. Moral fictions and medical ethics. Bioethics. 2010;24(9):453-60.
18. Bronner B. Two ways to kill a patient. Journal of Medicine and Philosophy. 2018;43(1):44-63.
19. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. New York: Oxford University Press; 1979/2001.
20. Greif A. The morality of euthanasia. Organon F. 2019;26(4):612-34.
21. Rigby B, Symons X. Abortion, euthanasia, and the limits of principlism. Medicine, Health Care and Philosophy. 2023;26(4):549-56.

22. Young R. Voluntary euthanasia. In: Zalta EN, Nodelman U, editors. The Stanford Encyclopedia of Philosophy, Summer 2024 Edition; 2024.
23. Singer P. Voluntary euthanasia: A utilitarian perspective. Bioethics. 2003;17(5-6):526-41.
24. Kass L. Life, Liberty & the Defense of Dignity: The Challenge for Bioethics. New York: Encounter Books; 2002.
25. van der Haak D. Death anxiety, immortality projects and happiness: A utilitarian argument against the legalization of euthanasia. Conatus – Journal of Philosophy. 2021;6(1):159-74.
26. Dworkin R. Life's Dominion: An Argument About Abortion, Euthanasia, and Individual Freedom. New York: Vintage; 2011.
27. Dyck AJ. Life's Worth: The Case Against Assisted Suicide. Grand Rapids: Wm. B. Eerdmans Publishing; 2002.
28. Norcross A. Killing and letting die. In: Frey RG, Heath Wellman C, editors. A Companion to Applied Ethics. Oxford: Blackwell Publishing; 2007. p. 451-63.
29. Mangan JT. An historical analysis of the principle of double effect. Theological Studies. 1949;10(1):41-61.
30. Bogatyńska-Kucharska A. The doctrine of double effect: A comparison of the version of Thomas Aquinas and contemporary accounts as formulated by Joseph Mangan and Joseph Boyle. Forum Philosophicum. 2020;25(2):273-92.
31. Harnad S. My orgasms cannot be traded off against others' agony. Animal Sentience. 2016;1(7):18.
32. Hurka T. Asymmetries in value. Nous. 2010;44(2):199-223.
33. Mayerfeld J. Suffering and Moral Responsibility. New York: Oxford University Press; 1999.
34. Parfit D. Reasons and Persons. 2nd ed. Oxford: Oxford University Press; 1987.
35. Wolf C. Person-affecting utilitarianism and population policy; or, Sissy Jupe's theory of social choice. In: Fotion N, Heller JC, editors. Contingent Future Persons: On the Ethics of Deciding Who Will Live, or Not, in the Future. Dordrecht: Springer; 1997. p. 99-122.
36. Goetz JL, Keltner D, Simon-Thomas E. Compassion: An evolutionary analysis and empirical review. Psychological Bulletin. 2010;136(3):351-74.
37. Ord T. Why I'm not a negative utilitarian. Toby Ord. 28 Feb 2013.
38. Arrhenius G, Bykvist K. Future generations and interpersonal compensations. Uppsala Prints and Preprints in Philosophy; 1995.
39. Truog RD, Campbell ML, Curtis JR, et al. Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American College of Critical Care Medicine. Critical Care Medicine. 2008;36(3):953-63.
40. Quill TE, Ganzini L, Truog RD, Pope TM. Voluntarily stopping eating and drinking among patients with serious advanced illness—clinical, ethical, and legal aspects. JAMA Internal Medicine. 2018;178(1):123-27.
41. Gurschick L, Mayer DK, Hanson LC. Palliative sedation: An analysis of international guidelines and position statements. American Journal of Hospice and Palliative Medicine. 2015;32(6):660-71.
42. Cassell EJ, Rich BA. Intractable end-of-life suffering and the ethics of palliative sedation. Pain Medicine. 2010;11(3):435-38.
43. Treem J. Medical aid in dying: Ethical and practical issues. Journal of the Advanced Practitioner in Oncology. 2023;14(3):207-11.
44. Padubidri JR, Antony Manoj M, Singh T. Euthanasia: A good death or an act of mercy killing? A global scenario. Clinical Ethics. 2022;17(2):118-21.
45. Callahan D. When self-determination runs amok. Hastings Center Report. 1992;22(2):52-5.
46. Crawley LM, Marshall PA, Lo B, Koenig BA. Strategies for culturally effective end-of-life care. Annals of Internal Medicine. 2002;136(9):673-79.
47. Kagawa-Singer M, Blackhall LJ. Negotiating cross-cultural issues at the end of life: You got to go where he lives. JAMA. 2001;286(23):2993-3001.
48. Gomes B, Calanzani N, Curiale V, McCrone P, Higginson IJ. Effectiveness and cost-effectiveness of home palliative care services for adults with advanced illness and their caregivers. Cochrane Database of Systematic Reviews. 2013;6(1):CD007760.
49. Buturovic Z. Embracing slippery slope on physician-assisted suicide and euthanasia could have significant unintended consequences. Journal of Medical Ethics. 2021;47(4):257-58.
50. Meier DE. The treatment of patients with unbearable suffering—the slippery slope is real. JAMA Internal Medicine. 2021;181(2):160-61.
51. Singer P. Practical Ethics. Cambridge: Cambridge University Press; 2011.
52. Chadwick A, Craig F. Withholding and withdrawing treatment in paediatric intensive care. Paediatrics and Child Health. 2024;34(2):69-73.
53. Gaul AL, Wilson SF. Should a ventilator be removed at a patient's request? An ethical analysis. Journal of Neuroscience Nursing. 1990;22(5):326-29.
54. Panayiotou P. Beneficence cannot justify voluntary euthanasia and physician-assisted suicide. Journal of Medical Ethics. 2024;50(6):384-87.

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ARTICLE (ÉVALUÉ PAR LES PAIRS)

Repenser l'assentiment des enfants de moins de 14 ans présentant une condition médicale complexe en regard des avancées médico-technologiques au Québec par l'approche écosystémique de Bronfenbrenner

Marina Trevisan[a], Hazar Haidar[a]

Résumé

Les avancées médico-technologiques ont amélioré la survie des enfants atteints de maladies graves, complexes et incurables. Toutefois, ces progrès s'accompagnent d'une complexification des décisions relatives aux soins médicaux pour ses enfants, dont les parents ou tuteurs sont généralement les décideurs principaux. Dans cet article, nous proposons de repenser l'assentiment des enfants mineurs de moins de 14 ans en intégrant l'approche écosystémique de Bronfenbrenner. Cette théorie permet d'examiner l'influence des contextes familial, social et institutionnel sur leur capacité à participer aux décisions médicales. Nous concluons qu'une prise en compte plus large de ces facteurs liés à l'assentiment des enfants pourrait transformer le processus décisionnel d'une approche plutôt dialogique que dichotomique, laissant une place à l'enfant pour participer activement aux décisions médicales qui le concernent.

Mots-clés

consentement, assentiment, approche écosystémique, Bronfenbrenner, éthique relationnelle, condition médicale complexe, Québec

Abstract

Medical and technological advances have improved the survival rates of children with serious, complex, and incurable diseases. However, these advances have been accompanied by increasingly complex decisions regarding medical care for these children, for whom parents or guardians are generally the primary decision-makers. In this article, we propose rethinking the consent of minors under the age of 14 by incorporating Bronfenbrenner's ecosystemic approach. This theory allows us to examine the influence of family, social, and institutional contexts on the ability of children to participate in medical decisions. We conclude that taking these factors related to children's consent into greater consideration could transform the decision-making process from a dichotomous to a more dialogical approach, allowing children to actively participate in medical decisions that affect them.

Keywords

consent, agreement, ecosystem approach, Bronfenbrenner, relational ethics, complex medical condition, Quebec

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INTRODUCTION

Les avancées médico-technologiques réalisées au cours des dernières décennies rendent désormais possible la survie d'enfants présentant des conditions de santé qui auparavant auraient été fatales. Bien que les traitements n'assurent pas la guérison de tous ces enfants, ceux-ci rendent possible la gestion des symptômes et prolongent la vie. Toutefois, ces progrès entrainent du même coup une complexification des soins ayant pour effet de transformer considérablement le quotidien des familles (1-3). Les parents se voient désormais offrir des choix qui auparavant étaient inexistants, et par le fait même, se voient placés devant des décisions difficiles et complexes. Mais qu'en est-il du regard des enfants sur ces décisions les concernant? Le Code civil du Québec est assez clair quant à l'incapacité juridique des enfants de consentir à leurs soins. C'est ici que la problème se complexifie. En effet, la Convention relative aux droits de l'enfant, qui est un instrument juridique international adopté par l'Assemblée générale des Nations Unies en 1989, se fonde sur quatre principaux piliers : la non-discrimination, la participation, l'intérêt supérieur de l'enfant ainsi que le droit à la vie, à la survie et au développement. Cela étant, il importe de bien définir ces quatre piliers, car l'interprétation qu'on en fait peut mener à prendre des décisions pour l'enfant plutôt qu'avec la participation de l'enfant. Qui décide de l'intérêt supérieur de l'enfant? Et, sur quelles bases déterminer cet intérêt supérieur? Dans le présent article, nous soutiendrons qu'il est éthiquement inacceptable que le consentement entourant les soins médicaux des mineurs de moins de 14 ans présentant une condition médicale complexe ne revienne qu'aux parents. Autrement dit, rechercher l'assentiment de ces enfants est un reflet de leur dignité humaine. Certes, ce consentement ne vient pas sans poser d'importants enjeux éthiques, notamment lorsque ces enfants sont exposés à des décisions médicales cruciales. L'argument développemental peut être invoqué pour contester une telle position. En effet, les enfants présentant une condition médicale complexe (CMC) sont susceptibles de présenter différentes formes de handicaps fonctionnels, autant physiques qu'intellectuels (4). Dans cette perspective, nous nous appuierons sur l'approche écosystémique (5) pour argumenter qu'il est possible de repenser la décision médicale relative aux soins médicaux de l'enfant comme étant dialogique plutôt que dichotomique.

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LE CONSENTEMENT AU QUÉBEC POUR LES SOINS MÉDICAUX

Afin de bien cerner les concepts éthiques en jeu, il importe de comprendre le cadre normatif entourant le consentement médical au Québec. D'abord, en regard du consentement des personnes, le Code civil du Québec stipule à son article 11 que :

> nul ne peut être soumis sans son consentement à des soins, quelle qu'en soit la nature, qu'il s'agisse d'examens, de prélèvements, de traitements ou de toute autre intervention. Sauf disposition contraire de la loi, le consentement n'est assujetti à aucune forme particulière et peut être révoqué à tout moment, même verbalement. Si l'intéressé est inapte à donner ou à refuser son consentement à des soins et qu'il n'a pas rédigé de directives médicales anticipées en application de la Loi concernant les soins de fin de vie (chapitre S-32.0001) et par lesquelles il exprime un tel consentement ou un tel refus, une personne autorisée par la loi ou par un mandat de protection peut le remplacer (6).

Ainsi, une personne a le droit d'accepter ou de refuser de recevoir des soins de santé et des services sociaux. La responsabilité incombe au professionnel de s'assurer que la personne consente avant de lui prodiguer quelque soin ou service. Pour que le consentement soit valide, il doit être libre et éclairé. On entend par « libre » qu'il soit exempt de toute pression, contrainte ou influence. Pour que le consentement soit éclairé, il est généralement admis que la personne doit pouvoir consentir sans menace ni promesse et sans que ses facultés soient altérées (7).

Concernant la forme que prend ce consentement, l'article 11 du Code civil reste assez vague en stipulant que « le consentement n'est assujetti à aucune forme particulière ». Cependant, le Code civil du Québec, à son article 14, vient baliser l'âge à partir duquel une personne est présumée apte à consentir pour elle-même : « le consentement aux soins requis par l'état de santé du mineur est donné par le titulaire de l'autorité parentale ou par le tuteur. […] Le mineur de 14 ans et plus peut, néanmoins, consentir seul à ces soins ». C'est ici que se dessinent trois catégories de personnes en fonction de leur capacité juridique à consentir, soit les majeurs (plus de 14 ans), les mineurs (moins de 14 ans) et les majeurs inaptes. Les droits et les devoirs associés à ces trois catégories renvoient à l'aptitude à être titulaire de ces droits, mais aussi à la capacité juridique, c'est-à-dire, à l'aptitude de les exercer soi-même. Le principe d'intégrité, garanti par la Charte des droits et libertés de la personne, est au cœur même des enjeux liés au consentement aux soins, car il relève de la dignité humaine. Au regard de ces explications, il est donc inexact d'user du concept de consentement en référence à l'opinion des enfants de moins de 14 ans. C'est pourquoi nous avons choisi de mobiliser le concept d'assentiment comme base d'expression des choix médicaux de cette catégorie de jeunes. Dans le cadre de cet article, l'intérêt sera porté plus spécifiquement sur les enjeux éthiques entourant le consentement des mineurs, donc des enfants de moins de 14 ans et qui présentent une CMC.

LES ENFANTS PRÉSENTANT UNE CONDITION MÉDICALE COMPLEXE

Il importe ensuite de définir les caractéristiques générales des enfants qui sont inclus dans la catégorie de la CMC. D'abord, le groupe de travail québécois sur les normes en matière de soins palliatifs pédiatriques (4) parle des enfants présentant une CMC comme « présentant des conditions progressives sans espoir de guérison. Les traitements offerts à ces enfants sont uniquement palliatifs et peuvent s'étendre sur des années ». Feudtner et ses collègues définissent la condition médicale complexe comme toute affection médicale, dont on peut raisonnablement estimer la durée à au moins 12 mois et qui affecte un ou plusieurs systèmes organiques différents, de manière suffisamment grave pour nécessiter des soins pédiatriques spécialisés ainsi qu'une hospitalisation dans un centre universitaire (8). Il s'agit généralement d'affections impliquant plusieurs morbidités et qui nécessitent l'attention de différentes disciplines et possiblement des soins à domicile. Cela implique de grandes exigences d'autogestion des soins ou une attention soutenue du soutien social, généralement des parents dans le contexte d'enfants malades (4). Le fait que ces soins complexes soient dispensés à domicile plutôt qu'à l'hôpital peut être source d'un grand soulagement dans la vie familiale, mais il ajoute également une charge supplémentaire au rôle parental. Les parents endossent alors un rôle qualifié de « parent-aidant », ce qui les expose à un risque accru d'épuisement parental, entendu comme un état de fatigue physique, émotionnelle et mentale lié à l'accumulation de responsabilités de soins et à la pression constante associée à la prise en charge de l'enfant (9). Dans ce contexte, des défis importants émergent, notamment lorsqu'il s'agit de prendre des décisions concernant la trajectoire médicale de l'enfant.

LES ARGUMENTS NORMATIFS

Pour en revenir à l'argumentaire portant sur le consentement des personnes mineures, nos sociétés occidentales reconnaissent généralement aux parents le fardeau décisionnel du meilleur intérêt de leur enfant. La principale critique adressée à cette approche éthique dominante est qu'elle conçoit les enfants uniquement comme des êtres vulnérables et nécessitant un besoin que leur meilleur intérêt soit protégé (10-12). En sous-texte, on comprend que ces enfants sont donc perçus comme incapables de comprendre et de participer aux discussions et aux décisions médicales qui les concernent, aussi complexes soient-elles. Ne deviennent-ils pas ainsi des « objets moraux », en ce sens où les parents et les intervenants médicaux décident pour eux, plutôt qu'avec eux?

Toujours d'un point de vue normatif, la Convention relative aux droits de l'enfant ratifiée par l'Organisation des Nations Unies en 1989 stipule à l'article 12 que chaque enfant a « le droit d'exprimer librement son opinion sur toute question l'intéressant, les opinions de l'enfant étant dûment prises en considération […]. À cette fin, on donnera notamment à l'enfant la possibilité d'être entendu dans toute procédure judiciaire ou administrative l'intéressant ». Bien que peu d'études se soient intéressées

à cette question d'un point de vue subjectif, les quelques études que nous avons recensées reconnaissent l'agentivité morale de ces enfants (13,14). La délibération morale de ces enfants menant à une décision médicale ou thérapeutique prenait en considération, non seulement ce qui était important à leurs yeux, mais aussi leur perception de ce qui était important pour leurs parents.

Un standard éthique bien reconnu s'appliquant à la santé des enfants est le principe du « meilleur intérêt » (15-18). Selon ce principe, toutes décisions ou actions en regard de la santé de l'enfant doivent tendre vers le meilleur intérêt de cet enfant. En général, ce principe s'opérationnalise au moyen de la balance décisionnelle entre le coût et les bénéfices pour l'enfant (15,18). Cette approche, qui tend vers l'utilitarisme, se veut surtout objective et elle s'intéresse peu à la subjectivité des enfants présentant une CMC. De plus, comment est-il possible d'être certain du rapport entre les coûts et les bénéfices dans un contexte humain présentant autant d'incertitudes vu la nature plutôt rare des conditions médicales de ces enfants? Il importe aussi de se rappeler que nombreux sont les enfants de cette population qui présentent des particularités au niveau de la communication limitant les opportunités et les moyens d'exprimer leur opinion. En conséquence, la vision de ces enfants est souvent peu sollicitée, ou lorsqu'exprimée, elle n'est guère prise en considération ou jugée comme invalide (13).

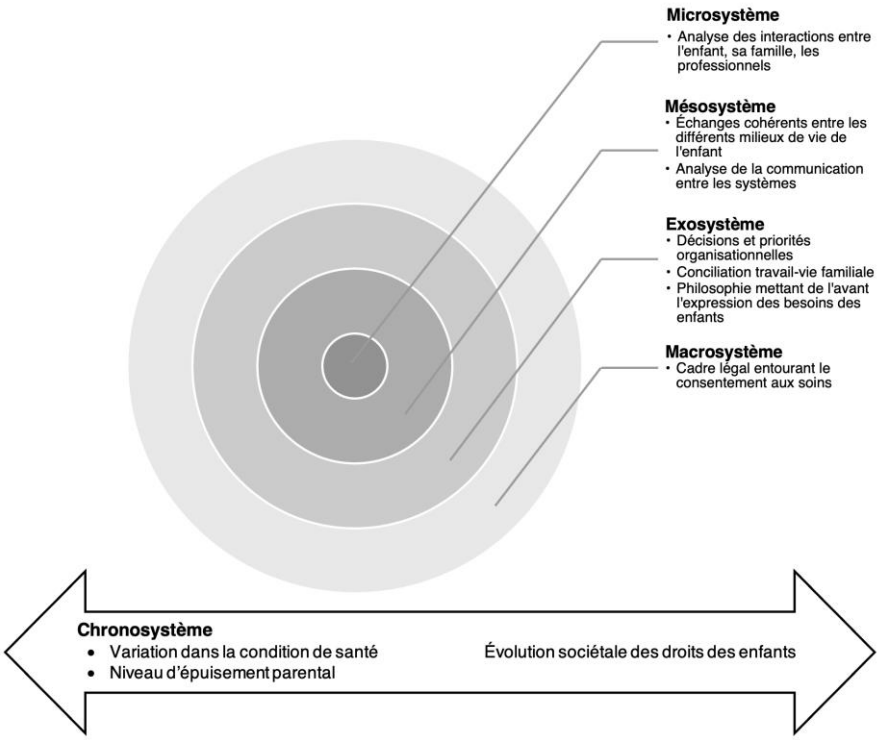
L'autonomie est un second principe (19-23) qu'il est possible de mobiliser afin d'étayer l'argumentaire. Ce principe, grandement inspiré de l'impératif catégorique de Kant, oblige à traiter tant sa personne que celle d'autrui, jamais simplement comme un moyen, mais toujours comme une fin. Autrement dit, il s'agit de considérer chacun comme un sujet libre, capable de juger et de se déterminer par soi-même. Le respect de l'autonomie de la personne réside ainsi dans le devoir de se conformer à ce libre choix, en s'assurant de son consentement éclairé. Cet argument suppose que la personne, en l'occurrence l'enfant, doit disposer de tous les éléments nécessaires pour se déterminer en connaissance de cause, et ce, sans subir de pressions externes (24).

Il n'en demeure pas moins que le bien-fondé de l'autonomie supposée peut être remis en cause sur plusieurs plans. D'abord, ce principe repose sur une conception de l'individu comme étant capable d'un calcul rationnel allant dans le sens de son meilleur intérêt, mais appliqué au domaine des soins médicaux. Or, considérer l'autonomie comme caractéristique fondamentale de l'humain, c'est aussi lui occulter toute la dimension de la vulnérabilité et de l'interdépendance, mise en lumière entre autres par les éthiques du care (25). Ainsi, être autonome n'implique souvent pas une autonomie réelle, indépendante, autant qu'il ne suffit pas de posséder tous les éléments factuels éclairant une décision pour faire un choix rationnel.

Fondée sur la prémisse d'interdépendance entre l'individu et son environnement, la théorie écosystémique, généralement associée au psychologue du développement Urie Bronfenbrenner (5), offre un socle cohérent avec l'éthique du care pour éclairer la problème précédemment exposée. Pour Bronfenbrenner, le développement est en fait le résultat de l'interaction entre différents systèmes qui s'interinfluencent (26). C'est ainsi que pour appréhender les sources d'influences réciproques d'une décision médicale, il importe de la contextualiser en comprenant la personne dans ses contextes familial, social, culturel, politique, et ce, à travers le temps. L'analyse écosystémique revient à non seulement identifier les composantes de chacune de ces structures, mais surtout d'en comprendre l'interinfluence. De manière plus spécifique, l'environnement est décortiqué en six structures s'emboitant les unes dans les autres (27).

Ce modèle a déjà été largement mobilisé dans les recherches portant sur les maladies rares et complexes ainsi que sur les soins palliatifs pédiatriques, notamment pour mieux comprendre comment les trajectoires cliniques, les dynamiques familiales et les contextes institutionnels et sociétaux s'entrecroisent dans l'expérience de la maladie et des soins (28-31). En nous inscrivant dans cette littérature, nous proposons d'étendre l'usage du modèle de Bronfenbrenner au cheminement décisionnel en soins pédiatriques complexes. Ce cadre écosystémique permet en effet de saisir comment les décisions médicales émergent de l'interaction entre les valeurs et la vulnérabilité de l'enfant, les ressources et représentations de la famille, les pratiques des équipes cliniques, l'organisation des services de santé et, plus largement, les cadres normatifs, culturels et politiques dans lesquels ces décisions prennent forme. Il offre ainsi une approche conceptuelle pertinente pour articuler l'éthique du care et l'analyse concrète des processus décisionnels en contexte de grande complexité clinique.

Figure 1: Penser l'autonomie de l'enfant et son assentiment par l'approche de Bronfenbrenner



Le microsystème fait référence aux sphères au sein desquelles la personne évolue directement. On peut penser à la famille, l'école ou le centre hospitalier. Différentes activités, relations interpersonnelles ou rôles s'inscrivent dans chacun de ces microsystèmes. Pour un enfant, on peut penser que la famille est un microsystème prenant une grande place dans sa vie. En ce sens, l'étude du microsystème familial pourrait s'attarder entre autres aux aspects physiques (la maison, le quartier), aux rôles familiaux, aux valeurs, aux caractéristiques culturelles, à la communication, aux interventions parentales. Dans le cadre des soins médicaux, le microsystème inclut les interactions directes entre l'enfant, les professionnels de la santé, ainsi que les membres de sa famille, particulièrement ses parents ou tuteurs légaux. Dans le but de renforcer l'autonomie de l'enfant à ce niveau, il est essentiel qu'il soit activement impliqué dans les discussions relatives à ses soins médicaux. Cela signifie que l'enfant doit être encouragé à poser des questions, exprimer ses préoccupations et participer au processus décisionnel en collaboration avec ses parents et les soignants.

Le mésosystème, quant à lui, se réfère aux interactions et aux liens qui existent entre les différents microsystèmes dans lesquels l'enfant évolue. Cela inclut, par exemple, la relation entre la famille et l'école, ou entre la famille et les professionnels de la santé. Dans le contexte des soins, le mésosystème concerne les échanges et la coopération entre les divers acteurs impliqués dans la vie de l'enfant tels que ses parents, les médecins, les psychologues, les travailleurs sociaux et les enseignants. Une approche intégrée et cohérente entre ces différents microsystèmes est cruciale pour favoriser l'autonomie de l'enfant. Par exemple, la communication régulière des enfants avec les professionnels de santé pour s'assurer que l'enfant comprend bien les choix qui lui sont offerts et que ses opinions sont prises en compte, cela établit un cadre favorable à son implication. Ce type d'interaction permet d'une part à l'enfant de se sentir soutenu, de développer une plus grande confiance en lui et d'être en mesure de participer activement aux décisions concernant sa santé et d'autre part, aux parents de s'assurer que leur enfant prenne la décision médicale qui reflète ses propres souhaits.

L'exosystème fait référence aux contextes sociaux, économiques, et institutionnels qui, bien que n'affectant pas directement l'enfant, influencent son environnement immédiat. Par exemple, il peut s'agir de décisions organisationnelles concernant l'octroi de services de soutien à domicile pour les enfants ou de l'ouverture du milieu de travail des parents à aménager les horaires de travail pour faciliter la conciliation des responsabilités de proche aidant. Ainsi la mise en place des protocoles qui permettent aux enfants de partager leurs besoins, d'exprimer leurs préférences lors des discussions relatives à leurs soins, ainsi que des politiques qui assurent une information adaptée à l'âge de l'enfant, contribuent à soutenir le développement de leur autonomie.

Le macrosystème désigne l'ensemble des croyances culturelles, des valeurs sociales, et des normes qui régissent une société. Les pratiques culturelles propres à des communautés forment aussi le macrosystème. Ce niveau d'analyse met en lumière la manière dont le consentement des enfants de moins de 14 ans est encadré par les cadres législatifs et les pratiques cliniques en vigueur. Comme mentionné précédemment, au Québec, la loi stipule que le consentement aux soins pour un enfant de moins de 14 ans doit être donné par les titulaires de l'autorité parentale. Cette règle reflète un macrosystème qui valorise la

protection du mineur et présume, de ce fait, son incapacité à participer aux décisions le concernant. Limiter ainsi sa participation à un assentiment revient à nier sa subjectivité et sa capacité, même partielle, de discernement. En revanche, si nous créons les conditions d'un dialogue adapté à son niveau de compréhension, dans lequel son point de vue est activement recherché et pris en considération, il devient possible de reconnaître pleinement sa place dans le processus décisionnel. En effet, une reconsidération de l'assentiment vient compléter les leviers identifiés aux niveaux micro, méso et exo pour renforcer l'autonomie de l'enfant et sa prise de décision.

Le chronosystème réfère à l'aspect temporel des changements et des continuités observés dans les environnements des individus. Il permet de comprendre les transitions vécues par une personne durant sa vie (26) telles que le passage à l'adolescence, ou dans le présent contexte, les variations dans son état de santé. Chez un enfant atteint d'une CMC, l'aggravation progressive de sa condition au fil du temps peut affecter sa capacité à participer activement aux décisions médicales qui le concernent. Dans un tel cas, le chronosystème permet d'évaluer de manière continue l'autonomie de l'enfant, en prenant en compte non seulement son développement personnel, mais aussi les défis liés à la détérioration de son état de santé, ce qui peut modifier ses capacités cognitives et émotionnelles et influencer sa prise de décision médicale. Le chronosystème permet aussi une analyse de l'évolution des différents systèmes autour de l'enfant. On peut penser à l'évolution de l'épuisement parental et ses effets sur la participation de l'enfant.

Réfléchir ainsi c'est de reconnaitre que l'humain est constamment en interaction avec son environnement, tant sur le plan individuel, culturel, social que politique. Ces relations sont imbriquées à un point tel qu'il devient difficile d'isoler ces interactions dans le cheminement décisionnel. Nous revenons ainsi à l'idée de dépendance mise en lumière par les éthiciennes du care qui est décuplée dans un contexte de soin à des mineurs présentant une CMC. Reconnaitre cette dépendance entre les êtres humains, et plus spécifiquement le lien de dépendance entre une personne mineure présentant une CMC et son parent soulève l'argument de la coercition implicite qui pourrait venir teinter le consentement des parents aux soins de l'enfant. Rappelons-nous que selon les balises du Code civil du Québec, le consentement doit être libre. Or, sommes-nous totalement libres et exempts de pression externe? On n'a qu'à penser à la perception d'être un fardeau pour ses parents, que peut entretenir un mineur présentant une amyotrophie spinale, par exemple. Comment cette perception viendrait-elle teinter son parcours de soins et services?

ARGUMENT DÉVELOPPEMENTAL

La maturité cognitive des mineurs a servi à déterminer l'âge légal du consentement aux soins à 14 ans. Cet argument développemental entourant la maturité cognitive vient justifier qu'à partir de l'âge de 14 ans, les enfants sont en mesure d'interpréter leur meilleur intérêt, et ce, de manière autonome. Le corpus de recherche en neuropsychologie sur le sujet est assez unanime à l'effet que le cerveau subit d'importants changements structurels et fonctionnels au cours de la période de l'adolescence, et ce, sans uniformité dans le temps (32,33). Le psychologue Steinberg conclut que tous les changements impliqués dans les systèmes cognitifs de base atteignent un niveau de maturité comparable à celui des adultes environ à la mi-adolescence, qu'il cible vers l'âge de 15 ans. Cette maturité intellectuelle s'installerait avant la maturité sociale ou émotive. Or, Steinberg est clair à l'effet qu'il est impossible d'établir avec précision, selon un âge déterminé, le moment de la maturité cérébrale. D'autres auteurs lient la maturité cognitive avec le processus de développement identitaire. Les jeunes enfants présentent de l'immaturité cognitive, car ils retiennent peu les souvenirs et ont une faible perception d'eux-mêmes (17). À l'instar des stades de développement cognitif de Piaget et des stades de développement moral de Kohlberg, ces approches positivistes occultent tout un pan des réalités vécues par les enfants. Les caractéristiques individuelles, familiales, socioéconomiques, culturelles, politiques, etc., viennent interférer avec le développement de la maturité cognitive des enfants (34). Il devient donc difficile d'attribuer un stade de développement en fonction de l'âge biologique, encore plus lorsqu'il est question d'enfants présentant une CMC.

L'idée de reconnaitre une « voix » aux mineurs qui font face à des choix médicaux permet justement d'ouvrir la discussion et défaire l'argument de la coercition implicite, mais aussi l'argument développemental. Cette « voix », qui reconnait la subjectivité de l'enfant peut, par ailleurs, s'exprimer à travers le concept d'assentiment. Il s'agit d'un terme utilisé fréquemment en éthique de la recherche dont l'extrapolation est possible en éthique médicale. L'énoncé de politique des trois conseils pour la recherche avec des êtres humains (35) reconnait que plusieurs personnes légalement inaptes à décider peuvent cependant exprimer leurs désirs, même si la manière dont ceux-ci sont exprimés ne correspond pas à toutes les exigences relatives au consentement légal. Ainsi, ces personnes sont tout de même capables d'exprimer oralement, physiquement ou par tout autre moyen de communication, leur assentiment ou leur dissentiment. Parmi ces personnes figurent notamment : « les personnes dont la capacité décisionnelle est en développement, comme les enfants, dont la capacité de jugement et l'autonomie sont en voie de maturation; […] les personnes dont la capacité décisionnelle n'est que partiellement développée, comme les personnes ayant une déficience cognitive permanente. » (35)

MODÈLE DE DÉCISION PARTAGÉE

Ces modèles principistes accueillent d'abord la critique de l'impossibilité d'être complètement libres et autonomes dans nos décisions. Appliquées aux enfants, à ceux présentant une CMC, mais aussi à toutes les populations « non-autonomes », ces approches peuvent perpétuer une vision individualiste centrée sur des normes procédurales pour déterminer qui est autorisé à parler au nom du patient, généralement la personne à qui revient le consentement substitué, sans pour autant tenir compte de cette signification éthique que portent les relations indivisibles entre les voix représentées. Il devient particulièrement

évident que les enfants, y compris ceux présentant une CMC, sont intégrés dans des relations humaines très complexes. Bien qu'ils soient reconnus comme agents, les enfants sont également légalement et moralement dépendants, en ce sens où ils sont non autonomes et ont droit à une protection. C'est ainsi qu'une conception en éthique relationnelle chez ces enfants permet de reconnaitre qu'ils peuvent être à la fois agents et dépendants. Cette éthique relationnelle est ici proposée comme un véhicule pour la communication entre les différents systèmes du cadre d'analyse de Bronfenbrenner.

En éthique relationnelle, « l'attention est portée sur l'espace moral créé par la relation à soi-même et à autrui […] L'espace relationnel, en tant qu'espace amoral, est le lieu où l'on exprime sa réactivité et sa responsabilité, non seulement pour soi-même ou pour autrui, mais aussi dans l'espace d'être pour et avec soi-même et autrui. » (36, p.296-97) Un cadre d'éthique relationnelle envisage les décisions dans le contexte des relations. Ce qui est éthiquement juste, se comprend par un dialogue constructif sur l'interdépendance entre les personnes.

En ce sens, lorsque considérés dans un cadre d'éthique relationnelle, les enfants en tant qu'agents ne sont pas compris comme des îlots moraux individuels dotés d'opinions indépendantes que des décideurs de substitution sont censés définir et représenter (37). Bien que reconnus comme dépendants, les enfants ne sont pas des vides moraux dénués de toute opinion et préférence moralement significatives que leurs « protecteurs » pourraient gérer sans tenir compte de leurs opinions. Dans le même ordre d'idées, les parents ne sont pas de simples représentants légaux de substitution, parlant au nom de leurs enfants, indépendants de ce qui est également important moralement pour eux en tant que parents. Les intérêts des enfants et des parents, ainsi que leurs croyances, valeurs, souhaits et espoirs, sont étroitement liés et interdépendants. Ceux-ci s'inscrivent aussi dans des contextes sociaux, historiques, politiques, économiques, culturels, etc. Les familles sont reconnues comme des microcosmes sociaux importants pour la culture et la transmission intergénérationnelles des récits familiaux. L'univers moral des enfants est profondément influencé par celui des parents; et il est de plus en plus reconnu que l'univers moral des parents est influencé par celui de leurs enfants (38).

Par conséquent, les conceptions binaires des enfants et des parents — qui supposent que l'un d'eux est l'arbitre ultime de ce qui est le mieux pour les enfants (c'est-à-dire leur intérêt supérieur) — sont profondément erronées. Elles dénaturent l'ancrage relationnel complexe et éthiquement significatif des enfants, des parents, voire de la famille élargie et de la collectivité au sein desquels s'inscrivent ces relations. Ces racines peuvent être partiellement identifiées lors de discussions avec les enfants et les parents, mais elles sont parfois liées à des contextes sociaux, culturels et politiques plus larges, qui peuvent inclure des oppressions systémiques et institutionnelles marginalisant les individus et les familles, et qu'il peut être difficile pour eux d'exprimer. Comprendre ces contextes plus larges peut nécessiter la consultation de personnes-ressources de la communauté (ex. : des dirigeants communautaires, des médiateurs/interprètes culturels, des universitaires).

CONCLUSION

En somme, les progrès technoscientifiques dans le domaine de la médecine placent les familles d'enfants présentant une CMC devant de nouvelles possibilités pour prolonger la vie. Ce genre de décision ne vient certes pas sans rayonnement sur la famille, voire sur la communauté. Il devient donc difficile à ce moment de concevoir la décision médicale comme binaire. Or, le cadre légal, mais aussi les principes généralement acceptés en bioéthique, sont sans équivoque sur la question. L'argument développemental vient aussi soutenir l'immaturité neurologique et les déficits fonctionnels importants que peuvent présenter les enfants atteints d'une CMC.

Dès lors se pose la question de la manière dont la participation des enfants et la reconnaissance de leur dignité peuvent être assurées dans une approche aussi dichotomique. Les approches principistes, bien qu'essentielles pour baliser l'action, peinent à rendre compte de la densité relationnelle et contextuelle des situations vécues par les enfants présentant une CMC. L'intégration d'une éthique relationnelle, conjuguée au modèle écosystémique de Bronfenbrenner, permet de penser l'assentiment des enfants de moins de 14 ans comme un processus relationnel, au sein duquel interagissent les parents, la famille élargie, la communauté, l'équipe soignante, et les valeurs sociétales. L'analyse de ces interactions à travers les différents contextes de vie de l'enfant offre une compréhension plus nuancée de la trajectoire décisionnelle.

Cette approche n'est toutefois pas exempte de limites. L'une des principales réside dans le niveau de développement requis pour que l'enfant soit en mesure de communiquer ses besoins, ses préférences ou son vécu. Dans cette perspective, le chronosystème de la théorie de Bronfenbrenner apparaît pertinent pour évaluer la capacité décisionnelle de l'enfant en prenant en compte l'évolution de son état de santé, de son développement et des répercussions sur les autres systèmes qui structurent son environnement. Reconnaître et composer avec ces incertitudes semble alors inévitable et témoigne d'une approche éthique attentive à la complexité, à la vulnérabilité et à la dimension relationnelle des soins pédiatriques.

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REFERENCES

1. Champagne M, Mongeau S. Les conditions de vie des familles ayant un enfant gravement malade. Dans : Champagne M, Mongeau S, Lussier L, éditrices. Le soutien aux familles d'enfants gravement malades : regards sur des pratiques novatrices. Québec : Presses de l'Université du Québec; 2014. p. 17-38.
2. Mongeau S, Champagne M, Carignan P. Au-delà du répit... un message de solidarité. Cah Francoph Soins Palliatifs. 2025:81-94.
3. Gabarro C, Dumas A. 2. Comprendre les difficultés des parents d'adolescents porteurs de maladies rares lors de la transition des soins. Dans: Gargiulo M, Mandel J, éditeurs. Maladies rares. L'apport des recherches en sciences humaines et sociales : L'apport des recherches en sciences humaines et sociales. Toulouse : Éditions Érès; 2023. p. 37-54.
4. Groupe de travail sur les normes en matière de soins palliatifs pédiatriques. Normes en matière de soins palliatifs pédiatriques. Gouvernement du Québec; 2006.
5. Bronfenbrenner U. The Ecology of Human Development: Experiments by Nature and Design. Cambridge : Harvard University Press; 1979.
6. Code civil du Québec. RLRQ, c. CCQ-1991, art. 11.
7. Bellot C. Les droits et le travail social: définitions, enjeux et perspectives. Québec : Presses de l'Université du Québec; 2020.
8. Feudtner C, Feinstein JA, Zhong W, et al. Pediatric complex chronic conditions classification system version 2: updated for ICD-10 and complex medical technology dependence and transplantation. BMC Pediatr. 2014;14:199.
9. Dubois AC, Seghers N, Van Dorsselaer I, et al. "Already too late" : A qualitative study of respite care among mothers of children with special healthcare needs and disabilities. J Pediatr Nurs. 2023;72:e114-21.
10. Bluebond-Langner M. The Private Worlds of Dying Children. Princeton : Princeton University Press; 1978.
11. Montreuil M, Carnevale FA. A concept analysis of children's agency within the health literature. J Child Health Care. 2016;20(4):503-11.
12. Lin N, Lv D, Hu Y, et al. Existential experiences and perceptions of death among children with terminal cancer: An interpretative qualitative study. Palliat Med. 2023;37(6):866-74.
13. Carnevale FA, Teachman G, Bogossian A. A relational ethics framework for advancing practice with children with complex health care needs and their parents. Compr Child Adolesc Nurs. 2017;40(4):268-84.
14. Chénard J. Trajectoires décisionnelles de parents d'un enfant ayant une condition médicale complexe. Thèse de doctorat, Faculté des arts et des sciences — École de travail social. Montréal : Université de Montréal; 2015.
15. Miller G. Pediatric Bioethics. Cambridge : Cambridge University Press; 2010.
16. Littlechild B, Housman C. Applying universal principles of 'best interest': practice challenges across transnational jurisdictions, cultural norms, and values. Children. 2023;10(3):537.
17. Baker J. Children's agency, interests, and medical consent. HEC Forum. 2013;25(4):311-24.
18. Browne A. Physician authority, family choice, and the best interest of the child. Camb Q Healthc Ethics. 2022;31(1):34-39.
19. Beauchamp TL, Childress JF. Les principes de l'éthique biomédicale. Paris : Les Belles Lettres; 2008.
20. Matthiesen A, Drumm N, Gerlach AJ, et al. Relational autonomy in pediatric healthcare: A scoping review. Nurs Ethics. 2025;33(1):225-44.
21. Gómez-Vírseda C, de Maeseneer Y, Gastmans C. Relational autonomy: what does it mean and how is it used in end-of-life care? A systematic review of argument-based ethics literature. BMC Med Ethics. 2019;20:76.
22. Jennings B. Reconceptualizing autonomy: a relational turn in bioethics. Hastings Cent Rep. 2016;46(3):11-16.
23. Le TD, Lin SC, Huang MC, et al. Factors impacting the demonstration of relational autonomy in medical decision-making: a meta-synthesis. Nurs Ethics. 2024;31(5):714-38.
24. Delassus E. Analyse critique du principisme en éthique biomédicale. HAL Open Science. 2017; fhal-01486803.
25. Tronto JC. Un monde vulnérable: pour une politique du care. Paris: Éditions La Découverte; 2009.

26. Tremblay G, Lizotte K, Lanciault LT, Thibault D. Fondements sociopolitiques du service social. Québec: Presses de l'Université Laval; 2015.
27. Damant D, Poirier MA, Moreau J. Chapitre 12 : Ça prend tout un village pour élever un enfant. Dans: Dorvil H, Mayer R, éditeurs. Problèmes sociaux - Tome II : Études de cas et interventions sociales. Sainte-Foy: Presses de l'Université du Québec; 2001. p. 319-36.
28. Boyden JY, Hill DL, LaRagione G, et al. Home-based care for children with serious illness: ecological framework and research implications. Children. 2022;9(8):1115.
29. Tsitsani P, Katsaras G, Soteriades ES. Barriers to and facilitators of providing care for adolescents suffering from rare diseases: a mixed systematic review. Pediatr Rep. 2023;15(3):462-82.
30. Lin N, Ren M, Xiang Y, et al. Exploring the life experiences of school-aged children afflicted by tethered spinal cord syndrome: an interpretative qualitative study. Health Expect. 2024;27(1):e13969.
31. Chénard J, Trevisan M. Quand décider rime avec complexité — une étude qualitative menée auprès de parents devenus proches aidants. Frontières. 2022;33(1).
32. Steinberg L. Does recent research on adolescent brain development inform the mature minor doctrine? J Med Philos. 2013;38(3):256-67.
33. Coleman DL, Rosoff PM. Adolescent medical decisionmaking rights: reconciling medicine and law. Am J Law Med. 2021;47(4):386-426.
34. Brabant B. Adolescents, neurosciences et prise de décisions médicales: devrions-nous revoir certaines dispositions du Code civil du Québec? BioéthiqueOnline. 2016;5:4.
35. Conseil de recherches en sciences humaines, Conseil de recherches en sciences naturelles et en génie du Canada, Instituts de recherche en santé du Canada. Énoncé de politique des trois conseils : Éthique de la recherche avec des êtres humains — EPTC 2 (2022). Gouvernement du Canada; 2022.
36. Bergum V. Relational ethics for health care. Dans: Starzomski R, Storch JL, Rodney P, éditeurs. Toward A Moral Horizon: Nursing Ethics For Leadership and Practice. Toronto : Pearson Education; 2012. p. 295-97.
37. Friedel M, Pallage S. "The day my son dies, I will die, too." Shared decision-making through game theory in paediatric palliative care: a clinical case scenario. Médecine Palliat. 2024;23(4):208-11.
38. Wall J. Ethics in Light of Childhood. Washington, DC : Georgetown University Press; 2010.

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ARTICLE (PEER-REVIEWED)

Understanding What Clinical Ethical Cases Are: A Review and Perspectives from a Canadian Collaborative Working Group

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Résumé

L'éthique clinique consiste en grande partie à comprendre des situations morales concrètes et à favoriser des discussions constructives à leur sujet afin d'identifier des solutions appropriées. Cependant, les concepts et les méthodes utilisés pour décrire les cas (ex. : les dilemmes, les situations, les récits) varient selon les auteurs et les méthodes d'analyse des cas. Nous avons entrepris une revue non exhaustive de la littérature — inspirée de la méthode d'analyse critique interprétative de McDougall — afin d'identifier une série d'idées influentes sur la manière de décrire les cas d'éthique clinique et les méthodes recommandées pour les comprendre. Nous avons identifié neuf familles de méthodes d'analyse de cas, qui varient considérablement en ce qui concerne la description de base des cas, les stratégies recommandées pour les comprendre et les caractéristiques supplémentaires à prendre en compte (ex. : les contextes, les dynamiques sociales et de pouvoir, les émotions). En tant que collectif d'éthicien(ne)s cliniques et d'universitaires, nous identifions cinq limites principales de ces méthodes et soulignons l'importance de développer des méthodes basées sur les connaissances pratiques des consultant(e)s en éthique clinique.

Mots-clés

éthique clinique, cas cliniques, méthodes, recherche participative, éthique vivante, pragmatisme

Abstract

Clinical ethics is largely about understanding concrete moral situations and supporting meaningful discussion on these to identify appropriate resolutions. However, concepts and methods used to describe cases (e.g., dilemmas, situations, stories) vary between authors and case analysis methods. We undertook a non-exhaustive literature review — inspired by McDougall's critical interpretive review method — to identify a range of influential ideas on how to describe clinical ethics cases and the methods recommended to understand these cases. We identified nine families of case analysis methods, which vary considerably with respect to the basic description of cases, the strategies recommended to understand cases, and additional features that should be considered (e.g., contexts, social and power dynamics, emotions). As a collective of clinical ethicists and academics, we identify five main limitations of these methods and underline the importance of developing methods based on the practical knowledge of clinical ethics consultants.

Keywords

clinical ethics, clinical cases, methods, participatory research, living ethics, pragmatism

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INTRODUCTION

Clinical ethics, as a field, is largely about understanding concrete moral situations in healthcare and supporting meaningful discussion on these to identify or suggest appropriate resolutions. For example, the third edition of the Core Competencies for Healthcare Ethics Consultation of the American Society for Bioethics and Humanities states that a chief goal of ethics consultations is “identifying and analyzing the nature of the value uncertainty or conflict that underlies the consultation” (1, p.4). This goal is seconded by the desire of “facilitating resolution of conflicts in a respectful atmosphere with attention to the interests, rights, and responsibilities of all those involved” (1, p.4). In fact, these conflictual situations, which are often referred to as “cases,” can be viewed as central to clinical ethics consultation processes. Key to clinical ethics is thus the (conceptual) understanding of what clinical ethics situations or “cases” are, and what practices can be used by clinical ethicists to discern the contents and causes of these situations, notably to facilitate their management or resolution. The conceptual understanding of cases thus sits (at least) at two levels. First, a case is an ontological entity: it possesses certain defining properties and is constituted by certain features which make up its contents. Taken together, they determine what is (or is not) a case. Second, for ethicists to understand what those properties and features are for any particular case, they need an epistemological framework and a set of corresponding practices to understand a given case.

Following the literature, we call “case analysis methods” those approaches to clinical ethics consultations that contain, explicitly or implicitly, ontological and epistemological commitments as described above. In the clinical ethics literature, concepts to further describe what cases are (e.g., dilemmas, situations, stories) and which epistemological practices to use (e.g., the role of values and principles in understanding the case) vary between authors and case analysis methods. Some of these differences are grounded explicitly in concepts and ethical theories, such as “dilemmas” for principlism, “morally problematic situations” for pragmatist theory, or “stories” in the context of narrative ethics. Adding complexity, while some methods describe what cases are primarily in terms of the ethical issue or conflict at hand and the ethico-cognitive process through which a picture of what is at stake is generated and by which the issue is resolved, other methods use a broader definition which more closely equates “case” with “the clinical ethics consultation” in its entirety — where and when it happened, what happened, who was involved, etc. Likewise, proposed epistemological practices to understand the contents and causes of cases also vary, tending to align with how cases are conceptually framed by the method or author, such as interpreting and weighing principles, attending to narratives to understand stories, or adopting a situational lens. Moreover, for some methods “practices” refers to the ethico-cognitive process described above (e.g., how to reconstruct a narrative of the situation and what that may reveal about the case), whilst for others, “practices” is a more expansive concept that includes the practical steps in a consultation (e.g., who to talk to, should discussions be conducted one-on-one or in a group). In other words, methods described in the literature have different ontological and epistemological commitments, or do not state explicitly (any, or all, of) their commitments, and suggest more or less expansive understandings of what these commitments amount to. The varying terms used to describe cases (e.g., dilemmas, situations) is a prima facie argument for the existence of such substantially different theoretical outlooks with respect to what clinical ethicists do.

It is plausible that these different theoretical outlooks on case analysis methods affect the concrete work of clinical ethicists. For example, viewing situations as “cases”, “dilemmas” or other alternate accounts could shape a number of practices, such as which factors are deemed ethically relevant, which steps are taken to try to resolve the situation, and what constitutes a “resolved” situation. In this study, we ask: how do the main case analysis methods in the clinical ethics literature characterize the ontological features of a “case” and the epistemological practices to understand and analyze a case, and how do these characterizations relate to the day-to-day practice of clinical ethicists? Although the concept of “case” is not used by all theories and methods, given its prevalent use in the literature (e.g., “case analysis methods”) we use it in this paper as a generic term to grasp the broad spectrum of concepts used to describe clinical ethics situations. To better document the range of ideas about what cases are in clinical ethics and related case analysis practices, we undertook 1) a non-exhaustive review of various contrasting case analysis methods in the literature, and 2) embarked on a critical and interpretive analysis based on experiential knowledge rooted in case analysis practices.

This paper is part of a broader and ongoing collaborative project aiming to help bridge and enrich theory, methodology, and practice in matters of clinical ethics consultation and deliberation methods in Canada (see Box 1). The review and process reported in this paper are part of subsequent objectives to document practices to understand cases and then identify promising clinical ethics practices. The underlying pragmatist orientation of the study invokes strategies that help illuminate how practices of clinical ethicists reflect embodied and contextual knowledge about how ethics consultations are done and should be done (2,3). Making this knowledge explicit and working from the resulting insights is envisioned as a promising way to enrich theory and methodology and structure a living ethics exercise (4). Living ethics is a stance which encourages the development of participatory, dialogue-based, action-oriented ethics. Given this orientation, participating clinical ethicists formed a collaborative working group with the shared goal of generating and testing the ideas articulated in this project.

Box 1: Collaborative improvement of moral deliberation methods: An exercise in living ethics

The five-year collaborative project, of which the current paper is part, is funded by the Social Sciences and Humanities Research Council of Canada (SSHRC). It incorporates the objective to start from 1) critical appraisals of existing literature and models in light of current Canadian practices (the focus of this paper), to then move toward 2) proposing promising practices from the repertoire of existing practices as well as creative and critical thinking, and then 3) test these practices and learn from this testing as part of an ongoing knowledge-generating and knowledge-sharing process. Practices are examined in light of three of the important tasks of clinical ethics (1): 1) describing how moral problems are understood (the subject of this paper), 2) illustrating how ethical deliberations can be structured as facilitated consultations, and 3) articulating the ways that outcomes of deliberations and consultations are assessed. The examination of activities falling under tasks 2 and 3 will be the subject of future work carried out as part of the collaborative research project.

METHODS

This paper reports on how clinical ethicists understand cases. It includes both 1) a non-exhaustive literature review of various contrasting case analysis methods in the literature and, 2) a critical interpretive review in the form of group discussion and participatory writing about the strengths and weaknesses of these influential methods and practices, in order to offer a critical analysis. Our process is inspired by McDougall's critical interpretive review (5), in keeping with the idea of a non-exhaustive review, but with the addition that the critical analysis was conducted by a group of 25 co-authors, all of whom are clinical ethicists in Canada, except for four research staff members. This helped root the exercise in case analysis experiences and practices used by the co-authors and lay the groundwork for the participatory five-year study (see Box 1). We amended McDougall's methodology to include extensive group discussions to highlight points of agreement and disagreement and to infuse the conversations with a plurality of perspectives. To some extent this mirrors the methodology of clinical ethics committees.

Literature review

Various exploratory search strategies were developed and piloted to scope the literature on case analysis methods. Given the goals of our group and our practical constraints, we could not review all possible literature on clinical ethics methods. In fact, initial efforts in this direction proved challenging in terms of setting rigorous and defensible search parameters (e.g., keywords, inclusion and exclusion criteria) given the lack of MeSH terms to precisely identify case analysis methods (there are no specific official keywords). Furthermore, our goal was to identify a range of influential ideas on how to describe clinical ethics cases and the practices recommended to understand these cases. Accordingly, we settled on identifying main families of methods (and representative publications) grouped according to common theoretical inspirations (e.g., casuistry, pragmatism, principlism, feminism) without claiming exhaustive or perfect representation. This then set the stage for subsequent group discussions in light of the day-to-day practices of clinical ethicists based on the existing offerings of influential methods as well as more local methods used by clinical ethicists in our Canadian group.

We began with a search for articles on the databases CINAHL, MedLine and PubMed to expand the database research process and ensure a broad reach. We chose these three databases because they cover most bioethics journals. The initial research design of the broader collaborative research project intended for three distinct literature reviews to be conducted at separate times, one for each of the important tasks of clinical ethics, and with this study focusing on the first task (see Box 1). However, we suspected, and the literature review later confirmed, that many articles would be relevant for more than one task; that some articles found through a literature review focused (i.e., by using tailored keywords) on one of the tasks might return articles relevant for one or both of the other tasks (e.g., the review for task 3 might return articles also relevant for task 1); and that given the lack of uniformity in the literature regarding the terms used to characterize what counts as the theoretical underpinning of various clinical ethics case analysis methods, both in terms of the ontology of (what are) "cases" and methods of analysis, the search might be prone to false positives (irrelevant articles selected) and false negatives (relevant articles missing). Three separate literature reviews would also be time-consuming. The initial plan was thus revised in favour of a single, exploratory, literature review conducted simultaneously for all three tasks of clinical ethics (with additional reviews to be carried out for tasks 2 and 3 in the future, if and when required to complement this initial review). For task 1, we used a combination of the keywords "moral case deliberation" OR "clinical ethics consultation" OR "ethics consultation" AND "method" OR "process". For task 2, we used a combination of the keywords "moral case deliberation" OR "clinical ethics consultation" OR "ethics consultation" AND "dialogue". For task 3, we used a combination of the keywords "moral case deliberation" OR "clinical ethics consultation" OR "ethics consultation" AND "outcome" OR "evaluation". Keywords targeted titles and abstracts.

A research assistant (AH) conducted the search in 2023 between October 3 and November 23, under the supervision of the principal investigator (ER). The search yielded a total of 495 articles: the sum of all articles found on the three databases amounted to, respectively, 255 articles for task 1, 76 articles for task 2, and 164 articles for task 3. This first set of 495 articles was reviewed by AH and ER to manually select, based on their titles and abstracts, articles relevant specifically for task 1 of clinical ethics (this paper's subject); articles in languages other than French or English and review articles were also excluded; in total, 363 articles were removed and 132 remained. Within this second set of 132 articles, ER and AH identified eight key articles most closely aligned with this study's objective, which would be later used for data-extraction piloting and testing purposes. AH took detailed content extraction notes on these eight key articles, which ER reviewed and approved.

A snowball method was then used: AH and GSB extracted from the second set of articles all references from their reference section, leading to a third set of articles. Relying on the detailed notes, AH and GSB reviewed the titles and abstracts of all

articles in this third set and eliminated review articles, articles in other languages than French or English, and articles irrelevant for the broader research project. Articles relevant for tasks 2 or 3 were set aside, and only articles relevant for task 1 were retained. At this stage of the review process, twenty-one co-researchers (clinical ethicists who are co-authors of this manuscript), were invited to send other references deemed relevant for task 1. Relevant references from the core research team's Endnote library (n=17) were also added. From this fourth set of articles, AH and GSB then created a preliminary typology of the main families of case analysis methods discussed in the literature based on a previous similar exercise by ER (2). The typology, and which articles best typified each method therein, were further revised through several rounds of refinement between ER, AH, and GSB to highlight the features and contrasts of different methods. Some methods were also excluded either because they were not case analysis methods, or because they were integrative methods which pulled from two or more families of methods, e.g., ASBH guidance and Core Competencies (1) and Jiwani's Practical Guide (6). These integrative methods were excluded to better delineate how each family of methods characterizes ethics cases. To refine the typology, the clinical ethicist co-researchers were consulted during the first set of small group meetings (see the section below) to ensure that no family of method was missed by the literature review, and that none were excluded from the final selection of methods in the typology.

The final content extraction strategy guiding the narrative synthesis was developed by the research team and adjusted based on the feedback of clinical ethicists, obtained through the group discussions described below. It was developed to extract content in ways that would reveal contrasting features of the various families of methods reviewed. The strategy ultimately included: 1) the description of cases with respect to 1.1) terminology and definitions and 1.2) the use of moral principles in understanding cases. It also considered: 2) practices to understand cases notably with respect to how 2.1) medical facts are handled; 2.2) the description of the process of understanding cases; 2.3) the consideration of issues related to interested parties, communication and social/power dynamics; 2.4) the accounting of context(s); and 2.5) the accounting and integration of emotions, values and preconceptions. Content extraction and narrative summaries were undertaken by one primary reviewer (GSB or AH), validated by a second reviewer (AH or GSB), and reviewed by the senior and lead researcher (ER). Group discussions provided further external validation by clinical ethicist co-researchers of the content extracted by the core research team. They confirmed the final narrative synthesis as accurately summarizing each method and as being faithful to their knowledge of the clinical ethics literature and their training (e.g., graduate studies, clinical ethics fellowships). In this review, we survey families of methods using representative publications for each family of method.

Participatory group discussion and writing

The active engagement and mobilization of clinical ethicists and the academic and practical knowledge they hold is central to this project. Participating co-researcher clinical ethicists were recruited via several targeted efforts: general announcements through the Canadian Bioethics Society (e.g., at events and through its newsletter), targeted invitations to colleagues suspected of being interested in the topic, and snowball recruitment based on recommendations of recruited co-researchers. Recruitment aimed at creating one French-speaking group for Québec and francophone Canada, a second group combining the Atlantic Canadian provinces (e.g., Nova Scotia, New Brunswick, Newfoundland, Prince Edward Island) and the province of Ontario, and a third group comprised of colleagues from the Western Canadian provinces (Manitoba, Saskatchewan, Alberta, British Columbia) for time-zone issues and geographical proximity. These groups were composed of respectively six, ten, and six colleagues in addition to the research staff who support and organize group meetings. The small group meetings were organized as distinct sessions of the three groups, while the forum meetings involved the three groups meeting as a full assembly of co-researchers. All meetings took place online using Zoom, for practical reasons (e.g., accessibility, convenience, costs).

The meetings had a dual purpose. First, to amend, as needed, the literature review and narrative synthesis carried out by the core research team to ensure no important methods were missed during the literature review, and that the narrative synthesis offered sufficiently nuanced interpretations of the methods. Second, to discuss the state of the literature on clinical ethics consultation and case analysis methods, as summarized in the narrative synthesis, and to gather the reactions of clinical ethicists to prepare the critical interpretative review; the discussion section of this paper is dedicated to this critical interpretative review. To maximize the input of clinical ethicists and make best use of their expertise and practical knowledge, this research project adopted a collaborative, iterative writing process for its academic outputs (i.e., research papers). The meetings served as group discussions and as brainstorming sessions on the manuscript's contents. Three sets of meetings were planned for this portion of the project. Before each meeting, the draft manuscript was shared in advance via Google Docs for online comments prior to the meeting. The first set of small group meetings occurred in late March 2024 to engage with the initial results of the literature review shared beforehand. As a result, the literature review was amended (result section of this manuscript) and some discussion points drafted to reflect the discussions. A second collective meeting of all three groups (forum meeting) occurred in May 2024 to discuss the draft manuscript and to elaborate the discussion section (i.e., the critical interpretative review). The manuscript was again amended to revise the results and significantly extend the discussion and propose a draft introduction and conclusion. A final set of small group meetings in June 2024 sought to identify any remaining gaps or concerns with respect to the interpretation of the results and discussion. A last round of edits occurred in the summer, and a final revised manuscript was shared with and approved by all co-authors in September 2024.

RESULTS

We identified nine families of case analysis methods (Table 1). These methods include various accounts of cases (e.g., moral dilemmas, cases, case stories, morally problematic situations) and practical orientations (principle-based inquiries, situational analyses and inquiries, dialogues).

Table 1 Families of case analysis methods and associated practices

Method	General account of cases	Practical orientation	Illustrative seminal publications
Principlist methods	Cases are moral dilemmas where interested parties are compelled to fulfill incompatible duties. There are many sources of moral disagreements leading to moral dilemmas, including competing views on how best to interpret relevant principles and their relative weight.	Use principles following a specification process (to substantiate the content of principles) to grasp the essence of a case.	(7)
Casuistic methods (casuistry)	Cases are made of circumstances (i.e., etymologically all that surrounds the case) and of maxims which express the nature of the moral problem.	Expose medical indications, patient preferences, quality of life and context.	(8,9)
Decision oriented methods	Cases are made of ideological intent (moral ideal) and objective context which include facts (e.g., who, when, where, how) as well as the values at stake.	Expose facts with conceptual patterns (abstraction, heuristics, proximate causation) as well as the value-structure of the situation.	(10)
Feminist methods	A case is a multidimensional situation involving (systemic) context, and the psychological and emotional aspects of the people involved.	Focus on values consensus, compromise, and a plurality of voices.	(11,12)
Pragmatist methods (clinical pragmatism)	Cases are morally problematic situations where the presumed best course of action is challenged by doubts or disagreements emanating from the particularities of that situation.	Grow a situational understanding of the case by engaging various parties to explore their assumptions and intuitions to make more transparent their implicit moral perceptions, and thus demarcate the disagreements that underline the moral problem.	(13-15)
Narrative methods	Cases are characterized and framed in terms of narratives and described as case stories.	Focus on the patient's perspective and values while understanding the overarching narrative of the case as recounted by the different stakeholders.	(16-18)
Scenario-based methods	A case is a difficult situation where a decision needs to be made.	Rely on guiding moral principles while taking into account the specificities of each case.	(19-21)
Deliberation-oriented methods	Cases are situations where conflicts of values and/or principles are exacerbated by instincts, emotions, fear and/or anxiety, leading stakeholders to uncritically take extreme and incompatible positions.	Consider values, facts, and principles, and define how minimalist (public) and maximalist (private) duties are at stake in the case. Start with deontological principles.	(22)
Hermeneutic methods	Cases as ambiguous stories where various understandings (which are interpretations of the situation based on preconceptions) collide.	Support the meeting of perspectives and interpersonal understandings, while calling for dispositions of openness and reflexivity, and methods of open communication, often in the form of dialogue.	(23,24)

Description of cases

In this section, we review and compare key elements that underline how different case analysis methods conceptualize what cases are: 1) the terminology to describe a "case" and how these are defined; and 2) the place of moral principles in different methods and how they are used.

Terminology and definitions

The terminology used to refer to the object of case analysis methods, herein referred to as "cases," varies greatly across methods, suggesting significantly different outlooks and practices.

Principlist approaches focus on "moral dilemmas." Beauchamp and Childress define moral dilemmas as situations "in which moral obligations demand or appear to demand that a person adopt each of two (or more) alternative but incompatible actions, such that the person cannot perform all the required actions" (7, p.11). However, this view has been called into question, for instance, by feminist and care ethics approaches. The latter challenge the framing of cases as ethical problems or dilemmas because these formulations already presume that a moral dilemma is at stake. Principlism has the consequence of reducing clinical ethics to specific moral issues, which leaves aside broader considerations of human flourishing or "the good life," and narrows the focus of ethics on decision-making (12).

In the context of casuistry, Albert Jonsen refers to "cases" (9) as "practical moral dilemmas" (8, p.1) or as "issues" (8, p.4). According to him, cases are made up of "circumstances" and "maxims." Circumstances (i.e., all matters that surround the case) are important in the conceptualization of cases since they provide context and nuance (9). Maxims which are "brief rule-like sayings that give moral identity to the case," (9, p.298) make up the core of the case. Casuistic methods propose to determine which maxim should direct the case (i.e., which moral direction the case should follow) and to what extent (9). "Issues" are defined by Jonsen as "the matter to be discussed in detail, the focus of attention, the knot that must be untied" (8, p.4).

Pragmatist approaches refer to “moral problems” or “morally problematic situations” which usually manifest through conflicts over, or doubts about, the best action to take in a given context (15). Clinical pragmatism brings attention to the process of “valuation” by which individuals form value judgements that are seen as reliable sources of guidance for regulating their conduct; when these value judgments prove themselves to be no longer reliable, individuals come to doubt these, which leads to moral problems where the appropriate conduct is uncertain (14).

In narrative approaches, cases are referred to as “case stories,” (16) or simply as “cases” which are seen as situations of “ethical concern” (18). Narrative approaches recognize that the process followed during a clinical ethics consultation shapes how the case is perceived (17). Cases are characterized and framed in terms of narratives: they are conceived as stories to be told and imply thus a form of linearity (i.e., they have a beginning, and an ending). Furthermore, narrative approaches recognize that the case story starts long before the beginning of the clinical ethics consultation and the healthcare encounter itself (16).

In scenario-based approaches, given the plurality of possible situations, a case can be an “ethically problematic situation” in line with pragmatist methods (19) or a “dilemma” in line with principlist methods (21). However, a distinction should be made between an ethically problematic situation (i.e., there are several moral principles at stake) and a moral dilemma (i.e., there are only two moral principles at stake) (19). Overall, an ethically problematic situation arises from a moral problem and is a situation where a decision needs to be made to resolve the problem at stake (21). Moral problems occur when interested parties are confronted with difficult choices or highly complex and often ambiguous situations (10,20). In sum, by framing “cases” as difficult choices between several moral principles, scenario-based approaches show similarities with principlism, though they differ from the latter in how cases are analyzed and what are understood to be the relevant factors therein.

Hermeneutic and deliberation-oriented methods both conceive of cases as grounded in lived experience: ethical problems stem from conflicts of values which stem from prior experiences and medical facts (22). Hermeneutic approaches, moreover, emphasize that one should use dialogue to make sense of the lived experiences of people (24). Feminist/care ethics approaches also highlight the embeddedness of cases in larger human relationships, which are themselves inscribed in power relationships and systems. Cases should be seen as “meaningful experiences and situations in general, which concern the fundamental questions of human life” (12, p.55).

Overall, some methods such as the principlist or decision-oriented methods adopt a more positivist stance and tend to view cases as situations that can be objectively described because they are made of data, facts, and values (10). These perspectives are criticized by feminist methods. Indeed, these methods advance that the presupposed “neutrality” of cases tends to erase their particular features and specificities (11). Hermeneutic methods posit that human actions are caused by a specific, embodied understanding of a situation. Each person thus has only a limited understanding of the situation, which emanates from their perspective, which is shaped by prior experiences. As such, the case is not something static nor neutral, but the sum of the stakeholder’s various and changing perspectives on the situation (24). Similarly, pragmatist methods underline the fallibility of value judgements, moral rules and principles, and the assessments of facts (14).

Use of moral principles in understanding cases

Case analysis methods reflect different perspectives concerning the nature and role of moral rules and principles in the conceptualization of what cases are. According to the original interpretation of principlism, principles (or moral norms) are sourced from “common morality,” that is, a “set of norms shared by all persons committed to morality [that] is applicable to all persons in all places, and we rightly judge all human conduct by its standards” (7, p.3). Accordingly, common morality is found in all cultures, and it contains general norms that are abstract, universal and content-thin. “Particular morality”, on the other hand, contains concrete, non-universal and content-rich norms that change according to cultures, groups and individuals, as it includes their respective responsibilities, aspirations, ideals, sympathies, attitudes and sensitivities (7). For principlism, “principles do not function as precise guides to action that direct us in each circumstance in the way that more detailed rules and judgements do” (7, p.13). Casuistry refers to principles as “maxims” (9).

In contrast, for clinical pragmatism, moral principles are not fixed or immutable; rather, they function as tools or “working hypotheses” that can be tested and revised (14). For scenario-based methods, there are different substantive principles at play in different situations which inform what is right or wrong, just or unjust. These principles help formulate general rules that could be applied to particular cases (21). In hermeneutic methods, general (moral) rules and principles are created through the abstraction of certain crucial elements in the stories of participants. They help formulate the ethical problem, but they always emerge from the consultations themselves and, as such, they are always related to a concrete case and the experiences of interested parties. Because hermeneutic methods engage as many people as possible in the consultation process, moral principles and other normative considerations evolve throughout the case (24).

Deliberation-oriented methods such Gracia’s (22) rely on deontological principles. Each case involves certain principles (namely autonomy, beneficence, nonmaleficence, and justice), which must be identified and analyzed according to the circumstances of the case. Gracia classifies nonmaleficence and justice as minimalist ethical duties and part of the domain of the “public,” whilst autonomy and beneficence are maximalist ethical duties and constitute the domain of the “private.” For Gracia, the prima facie obligation is to comply with the principles, but exceptions can be made on consequentialist grounds. In Martin’s decision-oriented method, norms and principles support the decision-maker’s decisions and are created by the action of the latter’s “intellect-value complex” on the “objective context” (10). The intellect-value complex is the combination of the

decision-maker(s)' 1) ability to make sense of a situation through abstraction and the creation of concepts and, 2) their own value structure. The objective context combines 1) the facts of the case, all data (bits of information observed or that have been reported on the situation that the ethicist recognizes as somehow important to understanding the event) and, 2) the values of the interested parties (each individual's specifically "personal ideology," interests and desires, behavioral norms and role-expectations prescribed by the parties' social interrelationships, and cultural identity). The principles that will orient the actions taken in a case, born of the interaction between the intellect-value complex and the objective context, are therefore specific to that case, and they differ from the moral and philosophical principles that characterize the cultures of the decision-maker and interested parties. In sum, principles serve various functions in different clinical ethics methods. These range from more foundational roles to ground and justify recommendations, all the way to more descriptive and interpretive roles, e.g., to name and express issues at stake.

Practices to understand cases

In this section, we review and compare the practices different case analysis methods recommended to understand the content and causes of cases, as they pertain to: 1) medical facts; 2) processes to understand situations; 3) interested parties, communication and social/power dynamics; 4) relevant contextual factors; and 5) emotions, values, and preconceptions.

Medical facts

Case analysis methods generally agree that having a clear understanding of the medical facts of a case is important to be able to make sense of a case. However, how important medical facts are and what their role is in understanding a particular case will vary relative to other factors. In deliberation-oriented methods, "[e]thical problems are always connected to conflicts of values, and values are supported by fact" (22, p.230) and as such, the medical facts must first and foremost be understood in detail to be able to make sense of a case. Casuistic methods also suggest that attention should be paid to the patient's medical indications, which includes a discussion of the patient's clinical condition (e.g., diagnosis, treatment, available interventions and their goals). These methods also add that the patient's quality of life should be considered carefully. Since the goal of any medical intervention is to improve the patient's overall quality of life, it is important to ask how the latter can be improved in the specific context of the case (8). Similarly, pragmatist methods insist on understanding and critically evaluating not only the medical facts, sensu stricto, but also the overall life situation of the patient which can include factors such as their beliefs, values, preferences, and needs (14). This explicit focus on the patient's overall life situation is shared with feminist, hermeneutic, and scenario-based methods.

Description of the process of understanding cases

The process through which cases are understood varies greatly between methods. Both pragmatist and hermeneutic methods propose an interactive and cyclical (iterative) process. The case analysis proceeds in phases within which new information is discovered and integrated into subsequent phases, leading to a progressively more detailed understanding of the case. There is continuous reanalysis and reinterpretation of the data as new information comes to light. In the hermeneutic method phases are distinct, but the iterative process can be both temporal and transversal: previous and new findings are integrated throughout the consultation process. Additionally, the design itself of the dialogue (the clinical ethics consultation) between the interested parties should not be pre-ordained by the ethicist(s) but emerge gradually from conversations to foster a sense of co-ownership. In pragmatist methods, the inquiry can be analyzed as a series of distinct steps or phases, but in reality, the process is continuous (14,24).

The hermeneutic, narrative, scenario-based, and feminist methods all appeal explicitly to narratives and stories as means to achieve understanding of a case. Hermeneutics alludes to a "narrative quest" in which the plurality of views of interested parties serve as a starting point for further exploration. Through the stories told, important patterns emerge, such as the issues that parties grapple with, their origins, and the ways parties attempt to deal with these issues (23). To adequately interpret a case, narrative methods propose paying attention to the "narrative frame" in which stories are told. This frame specifies, for instance, the protagonists of the case, the tellers of the stories, and the listeners (16). Scenario-based methods insist on the usefulness of narratives for carefully understanding a case; through stories, the complexity of a case can be reduced to its relevant components, a process known as "economizing" (20,21). Feminist methods also underline the usefulness of narrative as a tool to analyze cases, as they envision people's stories and relationships as central to ethics; resolving a case does not imply moral judgment, but the enhancement of empathy and development of these relationships (11,12).

Interested parties, communication and social/power dynamics

When understanding a case, scenario-based methods such as the Doucet method take into account the perspectives of all people concerned and emphasize the importance of moral pluralism (20,21). Indeed, understanding a situation requires understanding it in all its complexity, which is not only due to the biological, psychological, and technical facts but is also the result of interactions of a complex web of actors who pursue objectives according to both individual and shared group interests (20). Paying attention to all interested parties, and making sure that their voices are heard, is thus an integral part of the case description process. Most methods agree that all interested parties should partake in the discussion equally, thereby leading to a better understanding of a case. There are, however, some differences with respect to how the role of patients and other actors is viewed.

Similarly, narrative methods favour the adoption of a pluralist stance: for instance, they allow ethicists to avoid assuming that they know what is morally best by listening to the stories of people (18). Pragmatist, hermeneutic, and feminist methods also

highlight that it is important to connect with other people, to make an effort to understand their respective points of view, and to acknowledge and take into account alternative ways of framing the moral issue or concern by asking questions from different perspectives (11-13,24). Pragmatist methods insist, moreover, on the importance of reaching a moral consensus that can withstand moral scrutiny (13). Some methods highlight that a case cannot be resolved solely by expert judgment; all people involved in the clinical ethics consultation must have space to express their opinions, and other less factual forms of knowledge should not be dismissed (13,24). Feminist methods are particularly sensitive to how power and power asymmetries prevent some from voicing their concerns and their understandings of a situation and note how others' voices can be amplified (11). Hermeneutic methods insist more specifically on the importance of taking experiential knowledge into account when framing a case because the moral knowledge of people often stems from implicit feelings and lived experiences (24).

Hermeneutic methods emphasize the importance of paying deliberate attention to "silenced voices": "those whose interests are at stake but who remain unheard and are often hard to find because, for example, they want to remain anonymous or they fear sanctions" (24, p.240). Often, patients' voices are less taken into account in case analysis methods and some methods thus insist specifically on the importance of centring the patients' experiences. Narrative methods, and the idea of a narrative frame for the situation, create opportunities to centre the patient's perspective and values when framing the case: each case story is framed "by the patient's recollections and desires rather than by the health professionals' concerns or interpretations" (16, p.10). They allow patients to be seen in their full complexity rather than as one-dimensional characters based solely on factual information (18). The views and concerns of the medical team are also important but are listened to after the patient's story has been heard. This precaution helps the clinical team to understand that they are not the protagonists of the case story and that their role is to bring pertinent information to patients and their families (16). Decision-oriented methods see the patient as a particular, historically situated individual who provides additional value-oriented information about a case (10). Casuistic methods suggest that attention should be paid to the patient's preferences by taking into account their values and their evaluation of risks and benefits. In short, one asks the question "what does the patient want?" when framing a case. In the case where the patient is not able to answer this question, someone should be identified to be responsible for articulating the patient's perspective or values (8). Finally, pragmatist and feminist methods underscore that a democratic process and deliberate efforts to understand the points of view of all relevant parties will foster the inclusion of patients' experiences (11,14).

Context(s)

Context is accounted for in case analysis methods in different ways. Clinical pragmatism points to the importance of considering the social, institutional, religious, and familial contexts. Additionally, the environment where the discussions take place is important as it can make the patient and their family more or less comfortable, thereby impeding or enhancing the process of understanding the case (13). Narrative methods assert that a broad perspective on the patient's story is required, and to include this, close attention must be paid to the patient's family, community, and the social contexts that all shape the patient's story. Events that happened in the patient's remote past (e.g., childhood) may also be relevant. Similarly, Martin's decision-oriented method frames patients as historically situated individuals who create meaning and direction for their own world (life) through the combination of their value-structure and intentionality (value-intention) (10,16). In the scenario-based method, cases should be understood not only by careful description of the actual situation, but also by the repercussions that they can have for the healthcare team, and by the external factors that affect the case (21). For feminist methods, the framing of a case should include the context and the systemic conditions (e.g., socio-economic conditions) in which it has arisen (11). Casuistic methods consider the "external" impacts that can affect the patient when considering a case (e.g., legal, emotional, economic, religious) (8).

Emotions, values and preconceptions

The different emotions, values, and assumptions of interested parties can, to a large degree, influence the process of understanding a case during a clinical ethics consultation and many methods explicitly touch upon these themes to make sense of cases. Hermeneutic methods emphasize that every party comes to understand a case through their individual (e.g., cultural, social) background. Interpreting a case thus is always based on prior understandings and preconceptions (23). Decision-oriented methods also acknowledge that people making decisions have a preconceived set of values that influences their analysis of a case by providing them with a set of norms and principles that informs and supports the decisions they will take. These methods not only emphasize the healthcare professional's preconceptions, but also those of the patient. Martin suggests, for example, that the patient has a complex moral (and sometimes religious) value-structure that influences the way they perceive their pain, and what should be done to respond to it. Therefore, decision-oriented methods recommend considering values, as well as empirical facts, in order to understand a case properly (10). Narrative methods similarly argue that the clinical ethicist must remain as critical of their own interpretations as they are of other interested parties' interpretations during a case. Critical reflection is needed when understanding a case, but it is also necessary throughout the consultation process (17,18).

Because cases usually arise from complex situations, ambiguity and uncertainty are often present. The hermeneutic and pragmatist methods both maintain that ambiguity and uncertainty are not only an integral part of clinical ethics consultations, but that they also can be useful when understanding a case. As explained above, hermeneutic methods argue that making sense of a case is always based on pre-understandings and preconceptions. When a variety of actors, each with different preconceptions, are trying to make sense of a case, feelings of ambiguity necessarily arise. Hermeneutics proposes that the latter should not be regarded "as a hindrance to our understanding of the situation but as its very precondition" (23, p.57). Similarly, pragmatist methods emphasize that clinical ethics cases necessarily stem from situations that arouse perplexity and doubt and that one should therefore be "open to the intrinsic ambiguity and uncertainty that inevitably attends complex clinical

cases" (15, p.142). Preconceptions and ambiguity in clinical ethics consultations are thus not seen as negative per se: they are rather constitutive of moral problems, and resolving the latter involves being reflexive about preconceptions and about their roles in the case. Finally, narrative methods emphasize that the ethicist needs to pay attention to the silences in the case story: What is the patient not mentioning? What are the gaps in their story (16)?

Methods diverge significantly on the role of emotions in understanding a case. Scenario-based methods, for instance, stipulate that having some emotional distance from the case is important when talking about a case or discussing different scenarios (21), whilst pragmatist and feminist methods both suggest that emotions are important tools for understanding the case and so adopt a charitable framework. Feminist methods stress that the understanding of a case should include the psychological and emotional responses of all persons involved (11,12). Emotions are considered part of relationships and therefore implicated in clinical ethics cases which involve tensions in human relationships. Pragmatist methods highlight more specifically that when combined with empirical facts and logical reasoning, emotions can be a valuable source of moral insight and can thus help parties to better understand a situation (14,15). Emotions are thus seen as a valuable aspect of how we relate to and understand the world.

DISCUSSION

Understanding clinical situations is central to clinical ethics and case analysis, as evidenced by its centrality in various case analysis methods and practice guidelines. However, there are specific and variable views about what these consist of and how they should be incorporated. Our review and narrative data extraction strategy sought to analyze and contrast case analysis methods in terms of how they understand cases and recommend practices to better appreciate the nature of cases. The terminology and explicit or implicit epistemological commitments of these methods vary greatly. Principlism focuses on "dilemmas," hermeneutic and narrative methods on "stories" and "case stories," while pragmatist and scenario-based methods allude to "morally problematic situations." Pragmatist, and even more so feminist, methods highlight the importance of integrating the non-clinical and social dimensions of cases and draw particular attention to power asymmetries. For this reason, they explicitly call into question the narrowing down of situations into tidy dilemmas or cases. Likewise, our review reveals that practices that are recommended to make headway in understanding cases range in nature and scope. Some methods, such as casuistry or principlism, provide rather limited detail on how or by what processes ethics consultations should construct an understanding of cases. By contrast, feminist methods, for example, offer much more detail on why and how to do so (e.g., whether, why, and when consultants should meet with the parties involved).

Although there has been extensive discussion about case analysis methods, few attempts have been made to assess these critically in light of the real-world practice of clinical ethics consultation (25). Furthermore, the academic and practical knowledge of clinical ethicists is not systematically mobilized to build and evaluate these methods, although more recent literature has seen proposals emerging from concrete practices (26-28). In the following, we reflect on some of the gaps in the literature on case analysis methods, from the perspective of a sizable co-authoring group of clinical ethicists and researchers. We formulate our comments and critical analysis below to expose some of the more striking gaps, although several issues were raised in the critical analysis of the literature which we hope to tackle in the broader process of the project in which this contribution is embedded.

Restrictive terminology

A first critical observation is that the terminology found in the literature differs from that commonly used by the ethicists in our group in Canada. The word "case" is a common descriptor of clinical ethics situations in the literature, but in practice it can carry medical connotations and is sometimes avoided for that reason. While some routinely use the term in their practice, others do so more often in their teaching. The term "situation" is preferred by some, which can reflect a broader set of interested parties and points of view, such as patients and their circle, and professionals. Moreover, in chronic and long-term care — where the situation may be more akin to an ongoing story — the terminology of an "issue" arising within a broader narrative (personal, familial) context is a more common designation. Finally, some report that "requests" is the term that often-best captures how ethicists initially become involved in a case: through a request for a meeting by one of the stakeholders (e.g., a member of the medical team).

A possible explanation for this discrepancy between practice and theory is that the term "case" and its clinical connotations were originally introduced in clinical ethics (and clinical medical ethics) through medicine and medical ethics, to confer legitimacy at a time when clinical ethics was in its infancy (29). This emphasis on cases is exemplified by Siegler, Pellegrino, and Singer's claim that "[t]he goal of clinical ethics is to improve the quality of patient care by identifying, analyzing, and attempting to resolve the ethical problems that arise in the practice of clinical medicine" (30, p.5). At that time, there was also an eagerness in clinical ethics to take distance from principle-based bioethics — which had significantly influenced bioethics since its introduction to the field in the late 1970s — as it proved difficult to connect to clinical practice (31,32). Hence, emphasizing the medical aspects of clinical ethics, including its terminology and method, could have been a strategy to bring bioethics closer to medical practice. Medical jurisprudence might also have had an influence given its emphasis on the analysis of cases and policies (33).

When the term "case" was first introduced in clinical ethics, consultations were primarily focused on the issues that arose between patients and doctors. Yet, patients and doctors are not the only parties in a consultation; just as the ethicist's presence

and influence on the case came to be recognized as the practice of clinical ethics consultation grew, it is now understood that a variety of individuals (e.g., family members, nurses, and other healthcare professionals) can be considered interested parties within an ethics consultation, that is, parties who often have moral standing in a situation (1). In addition, organizational ethics is also of increasing importance to the field, and it can now be difficult to differentiate between clinical and organizational ethics (34). Tellingly, the term “clinical-organizational ethics” (“éthique clinico-organisationnelle”) is used in some Canadian practice settings, sometimes to reflect their interconnections. This could be an example showing how theoretical terminology lags behind the evolution of the profession’s reality, including its institutional and organizational dimensions (35-37). Due to its foothold in medicine, the term “case” may not capture the diversity of interested parties and ethical orientations involved in clinical and organizational ethics.

Gaps between theory and practice

A related observation is that current case analysis methods evince more theoretical sophistication (e.g., about terminology and theoretical commitments) than practice can integrate, amounting to a sizable gap between theory and practice. Ill-fitting or restrictive terminology may lead to misunderstandings and distortions with regard to understanding the issue at stake. For instance, if a situation is conceived of as a “case” in a narrower theoretical sense (e.g., following precepts of casuistry), this may leave in the shadow the informal preparatory work done to transform an issue into a case. It may lose sight of how a given situation is a narrative that started before the official case and will continue thereafter (16), or it may overlook the relationships that make up the moral situation, and which may express asymmetrical power dynamics (11). For example, when ethicists receive a request, they must assess whether the situation is one that necessitates a clinical ethics consultation; more specifically, they must assess whether there is an ethical problem at stake and ascertain what that problem may be.

This pre-consultation process will likely be iterative and intersubjective (6). Some situations may also require explorations of norms (clinical, legal, deontological) done in parallel with, or as part of, the ethics consultation process, to determine if the case is predominantly ethical, deontological (e.g., related to professional codes of conduct), or legal in nature. In contrast, the term “case” can imply — at least from the standpoint of certain methods — a relatively finite situation with a clear beginning and end. Warning against this possibility, the ASBH’s bioethics facilitation method points to “narrative reconstruction” as a means to clarify the issue at hand; it is important to recognize that when ethicists are approached with a new case, it is initially through the perspective of only one or some of the interested parties (1). Moreover, a given “issue” might span an extended period of time, and there may be changes that influence or change the nature of the situation. In fact, many ethical issues can be complex and long-lasting as is suggested by narrative ethics (16).

In the literature on case analysis methods, “cases” commonly refer to either salient or particularly illustrative ethical issues or dilemmas. Although these are useful for thinking more clearly about ethical issues, they may overshadow some aspects of daily ethics consultation practices. By focusing on these salient cases as examples, some methods may obfuscate more common and less dramatic ethical issues and therefore impede the development of conceptual tools and practical advice for resolving quotidian issues (38). In sum, the narrower theoretical understandings of moral situations (e.g., as dilemmas within principlism, or as cases as suggested in casuistry) do not squarely correspond to practices. In line with this observation about the lack of clear application or boundaries of certain theories, we note that some common theories and methods (e.g., principlism) have also been described as adapting in response to other approaches (e.g., pragmatism) (39).

Oversight of context

Several methods suggest, from a terminological and practical standpoint, that “cases” in a narrow sense are the unit of analysis, the foundational starting point. However, in ethics consultation practice, the boundary between specific cases and organizational and contextual issues is often blurred because of the connections between organizational culture and specific situations. Some methods (e.g., feminist methods) pay heed to the ways that contexts shape the nature of cases and speak directly to how a situation’s understanding is generated within clinical ethics consultation practice, but they do not all tackle this squarely. For example, it is well documented that people can receive suboptimal care because of various important social factors, such as socio-economic marginalization, racism, sexism, ageism, and other broad economic, political or ideological forces that contribute to shaping concrete situations (40). Such factors, which can lead to discrepancies with respect to standards of care, do not only represent an aspect of the situation, but a broader organizational and social issue — one which it may be beneficial or even crucial to integrate to understand the situation at hand. Recent proposals to supplement existing methods (e.g., casuistry) with additional layers of considerations (e.g., an awareness of the effects of anti-Black racism) are important steps in expanding the understanding of clinical ethics situations (40).

Cursory treatment of power dynamics and trust

A few methods (e.g., feminist, pragmatist) touch explicitly upon power dynamics while others tend to gloss over it (e.g., principlism, casuistry). Likewise, the ASBH explains that, when understanding a case, ethicists should be aware of power relationships between interested parties and should identify how these relationships influence how ethicists and stakeholders communicate (e.g., what information is emphasized or de-emphasized) (41). However, these methods offer limited detail to help guide efforts to identify and address power dynamics within the process of case analysis. Power dynamics can lead to the prioritization of certain relationships and voices over others. For instance, prioritizing the voice of a physician may lead to an emphasis on medical facts, whereas emphasizing the voice of a social worker may lead to a different focus (42). The

amplification of one voice over another can perpetuate negative power dynamics or result in a power imbalance which may itself be the cause of the actual ethical problem (43).

Related to the management of power dynamics is the cultivation and maintenance of trust by the clinical ethicist with regard to stakeholders. Trust ensures that stakeholders can express their uneasiness about a situation and discuss it openly. Yet the specific effects of trust and distrust between ethicists and stakeholders on case analysis and the consultation process is a topic seldom discussed directly by methods found in the literature. The topic surfaces most often when discussing the importance of communication skills. In our experience, the trust built by ethicists is central to their practices, notably because the ability to reach people and uncover salient information is vital to understanding situations fully. Trust cannot be built solely by offering high quality consultation services; training and education offered to the institution's personnel, presentations delivered during meetings, and recuring, positive, quotidian interactions with staff members, patients, and others, can greatly influence how much trust is afforded to individual ethicists within a clinical ethics consultation.

Ethicists may also need to maintain trust throughout the course of long-term relationships with the people for whom, and with whom, they are consulting if they are to remain credible agents. There may be instances in which a tension arises between, on the one hand, the desire to preserve trust, and, on the other hand, the desire to do rigorous work that may challenge existing relationships, such as when the case consultation raises disturbing questions about professional practice and attitudes. These conflicting obligations must be acknowledged, but existing methods offer little guidance on how to do so. Ideally, clinical ethicists are empowered to ask difficult questions and do rigorous work in ways that do not undermine the organization's ability to function but instead facilitate its functioning in alignment with its own fundamental values commitments. However, asking genuine ethical questions can disrupt the status quo and predetermined orientations. Trust is also often in flux — it can be built, and it can be undermined, and being aware of this ebb and flow is significant, for instance, if the ethicist is to be able to access the information needed to build a nuanced understanding of a given situation.

Limited awareness of the positionality of ethicists and stakeholders

Several methods recognize the influence of the ethicist's values and perspectives on their practice, including how they make sense of situations and the kinds of biases that can influence their understanding of various situations (11,16). However, the treatment of this aspect of the work could be enhanced significantly with increased attention to recent literature investigating ethicists' positionality (e.g., race/ethnicity, gender, age) and background, and why it matters. The ASBH argues that ethicists must be aware of their own values and their potential influence on their practice (41). But more work on what this means and how to achieve it is needed. We recognize that, beyond the perspective of individual clinical ethicists, they are recruited into institutions which entertain reasons and provide conditions for the establishment and use of clinical ethics services.

Ethicists are not free from bias, even if their work often involves uncovering or debunking bias and stigma (44). An intersectional approach would require an ethicist to be aware of and sensitive to their own positionality as a factor shaping their understanding of situations (45). For example, cases are situated within large-scale, systemic factors and issues (e.g., social construction of categories like race, ethnicity, gender to produce systemic phenomena like racism, transphobia, and sexism within the context of healthcare). An ethicist's history, experience, and positionality may influence how they see, or fail to see, aspects of the ethical problems arising in their professional context. The positionality of the ethicist is a variable that inevitably enters the intersubjective equation that factors into how situations are framed and understood, such that the ethicist's positionality not only affects their ability to understand the case but also the lens through which the process of framing the case occurs. For example, a situation framed as one involving a difficult patient might be better (re)framed as one involving a patient who has previously been subjected to racist attitudes and behaviours (40).

Furthermore, whilst some major bioethics journals have published special issues on the pervasiveness of Indigenous-specific racism, anti-Black racism, other systemic injustices, and there is widespread acceptance of the need for anti-oppressive practices and anti-bias training, these are only starting to be incorporated in the training of ethicists. On the same note, while case analysis methods have for a long time included considerations for all relevant aspects of the case, not all offer detailed resources to situate a case within larger systemic frameworks (36). For example, it is well known that pain treatment is biased toward under-recognition and under-treatment in non-white people, and that under treatment of pain is particularly pervasive in the care of Black people (46). Likewise, there is lingering stigma and health-related discrimination toward Indigenous patients in Canadian health settings (47,48).

Given these realities, understanding cases properly requires an expanded lens and closer attention to additional considerations. Whilst many methods highlight the importance of understanding the medical facts and the patient's demographic background, they may not be explicit enough in emphasizing the nuances and implications of socio-cultural identity and systemic oppression (49). By contrast, the practices in some clinical settings may reflect a deeper understanding of these systemic factors than is reported in the literature. For example, some Canadian hospitals now have "Indigenous Navigators" as well as Indigenous health programs. The existence of these resources supports responses that are more sensitive to socio-cultural factors and merit consideration in the context of clinical ethics consultation. Addressing the positionality of ethicists and interested parties may involve further consideration of how ethicists can work with other internal institutional supports (e.g., colleagues who have expertise in law, equity and human rights, cultural safety, social work, spiritual care) and how their work fits within overall health systems.

Limitations

Our efforts to review the literature and offer a critical perspective based on insights from clinical ethics experiences in the Canadian setting allowed us to structure a literature review in terms of practical considerations and to create a space where clinical ethicists can reflect on and share existing practices, in order to evaluate published accounts of case analysis methodology more critically. However, this exercise has several limitations. First, we could not embark on a systematic review of the literature due to methodological and practical reasons and theoretically, this did not fit the purpose of the project. Relatedly, some approaches (e.g., mediation, Indigenous knowledge generation and sharing) to resolving ethical issues may not fall under the label of case analysis methods and were therefore not included in our sample. Second, the representation of clinical ethicists in our authors' group, although broad, is certainly not exhaustive and reflects known challenges related to a lack of diversity in the field of bioethics as discussed above. Finally, this critical review is only a first step in our collaborative project; the initial critical analysis of the literature will serve to further document Canadian practices and develop more advanced and concrete practices.

CONCLUSION

Clinical ethics is largely about understanding and surmounting specific moral situations. Our review of the literature showed that diverse case analysis methods make wide-ranging proposals for terminology (e.g., "dilemmas," "cases," "scenarios," "stories") and practices to understand these situations (e.g., continuous, cyclical, iterative). However, based on our critical analysis and by drawing on our experience, we note that certain aspects of these proposals are quite distant from actual clinical ethics practice. Accounts of clinical ethics case analysis methods may offer insights on how to conduct an ethics consultation, but they rarely draw directly and explicitly from the practical experience of ethicists. Perhaps this is the case because several methods were developed prior to ethics consultation expanding significantly and the work has not received sufficient subsequent attention to revise theory in light of current practices. It is thus necessary to bridge gaps between clinical ethics methods and actual practice in ways that draw from both the clarity and simplicity of theory, and the wisdom and experiential knowledge of practice. There is also an important gap to address relative to the ways that clinical ethicists make decisions about which method(s) to use in specific cases given that many clinical ethicists work with a variety of approaches. At this time, there is a lack of metaethical theory that would help ethicists determine which methods they should be using in specific circumstances and contexts. As a next step in our collaborative work, we plan to document practices in clinical ethics case understanding to identify promising practices therein.

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REFERENCES

1. ASBH. Core Competencies for Health Care Ethics Consultation. 3rd ed. Schaumburg, IL: American Society for Bioethics and Humanities; 2025.
2. Racine E. L'éthique clinique, les émotions et le processus d'analyse de cas: Une étude qualitative et multi-site de comités d'éthique clinique québécois. PhD Thesis. Montréal: Université de Montréal; 2004.

3. Racine E. The Theory of Deliberative Wisdom. Cambridge, MA: MIT Press; 2024.
4. Racine E, Ji S, Badro V, Bogossian A, et al. Living ethics: a stance and its implications in health ethics. Medicine, Health Care and Philosophy. 2024;27(2):137-54.
5. McDougall R. Reviewing literature in bioethics research: Increasing rigour in non-systematic reviews. Bioethics. 2015;29(7):523-28.
6. Jiwani B. Clinical Ethics Consultation: A Practical Guide. Cham: Springer; 2017.
7. Beauchamp T, Childress J. Principles of Biomedical Ethics. Oxford: Oxford University Press; 2009.
8. Jonsen AR. Case analysis in clinical ethics. The Journal of Clinical Ethics. 1990;1(1):63-65.
9. Jonsen AR. Casuistry as methodology in clinical ethics. Theoretical Medicine and Bioethics. 1991;12(4):295-307.
10. Martin RM. A clinical model for decision-making. Journal of Medical Ethics. 1978;4(4):200-6.
11. DeRenzo EG, Strauss M. A feminist model for clinical ethics consultation: Increasing attention to context and narrative. HEC Forum. 1997;9(3):212-27.
12. Schuchter P, Heller A. The care dialog: The “ethics of care” approach and its importance for clinical ethics consultation. Medicine, Health Care and Philosophy. 2018;21(1):51-62.
13. Fins JJ, Bacchetta MD, Miller FG. Clinical pragmatism: A method of moral problem solving. Kennedy Institute of Ethics Journal. 1997;7(2):129-45.
14. Miller FG, Fins JJ, Bacchetta MD. Clinical pragmatism: John Dewey and clinical ethics. Journal of Contemporary Health Law & Policy. 1996;13(1):27-51.
15. Miller FG, Fletcher JC, Fins JJ. Clinical pragmatism: A case method of moral problem solving. In: Fletcher JC, Lombardo PA, Marshall MF, Miller FG, editors. Introduction to Clinical Ethics. Haggerstown: University Publishing Group; 1997. p. 21-34.
16. Charon R, Montello M. Framing the case: narrative approaches for healthcare ethics committees. HEC Forum. 1999;11(1):6-15.
17. Agich GJ. Narrative and method in ethics consultation. In: Finder SG, Bliton MJ, editors. Peer Review, Peer Education, and Modeling in the Practice of Clinical Ethics Consultation: The Zadeh project. Cham: Springer; 2018. p. 139-50.
18. Churchill L. Narrative awareness in ethics consultations: the ethics consultant as story-maker. Hastings Center Report. 2014;44(1 Suppl):S36-39.
19. Dion-Labrie M. Présentation d’une grille d’analyse pour la résolution de situation éthiques problématiques en réadaptation physique. Association des établissement de réadaptation en déficience physique du Québec; 2009.
20. Doucet H. Éthique clinique et analyse de cas. In: Birmelé B, editor. Des méthodes de travail pour un lieu de réflexion éthique. CHU Tours: Espace de Réflexion Éthique Région Centre; 1995.
21. Baertschi B. Les méthodes de résolution de cas. Bioethica Forum. 1998;26:4-11.
22. Gracia D. Ethical case deliberation and decision making. Medicine, Health Care and Philosophy. 2003;6(3):227-33.
23. Widdershoven G. Interpretation and dialogue in hermeneutic ethics. In: Ashcroft R, Lucassen A, Parker M, Verkerk M, Widdershoven G, editors. Case Analysis in Clinical Ethics. Cambridge: Cambridge University Press; 2005. p. 57-76.
24. Widdershoven G, Abma T, Molewijk B. Empirical ethics as dialogical practice. Bioethics. 2009;23(4):236-48.
25. Bell JAH, Salis M, Tong E, et al. Clinical ethics consultations: A scoping review of reported outcomes. BMC Medical Ethics. 2022;23:99.
26. Delany C, Feldman S, Kameniar B, Gillam L. Critical dialogue method of ethics consultation: Making clinical ethics facilitation visible and accessible. Journal of Medical Ethics. 2025;51(1):10-16.
27. Felder RM. Toward a new clinical pragmatism: Method in clinical ethics consultation. Medicine, Health Care and Philosophy. 2024;27(3):445-54.
28. Feldman S, Gillam L, McDougall RJ, Delaney C. How is clinical ethics reasoning done in practice? A review of the empirical literature. Journal of Medical Ethics. 2026;52(1):32-38.
29. Jonsen AR, Siegler M, Winslade WT. Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine. New York: McGraw-Hill; 1998.
30. Siegler M, Pellegrino ED, Singer PA. Clinical medical ethics. Journal of Clinical Ethics. 1990;1(1):5-9.
31. Singer PA, Pellegrino ED, Siegler M. Clinical ethics revisited. BMC Medical Ethics. 2001;2:1.
32. Siegler M. Clinical medical ethics: its history and contributions to American medicine. Journal of Clinical Ethics. 2019;30(1):17-26.
33. Berto M. The influence of medical jurisprudence on healthcare policy and legislation. Journal of Forensic Medicine. 2023;8(6):229.
34. Bean S. Navigating the murky intersection between clinical and organizational ethics: A hybrid case taxonomy. Bioethics. 2011;25(6):320-5.
35. Legault G-A. Professionnalisme et délibération éthique: Manuel d’aide à la décision responsable. Québec: Presses de l’Université du Québec; 1999.
36. Quintin J, Boire-Lavigne A-M. Exercer une délibération en éthique clinique avec le souci de l’expérience des personnes. In: Farmer Y, Bouthillier M-È, Roigt D, editors. La prise de décision en éthique clinique: Perspectives micro, méso et macro. Québec: Presses de l’Université du Québec; 2013. p.43-70.
37. Legault GA. La délibération éthique au cœur de l’éthique appliquée. Revue française d’éthique appliquée. 2016;26(1):37-44.
38. Zizzo N, Bell E, Racine E. What is everyday ethics? A review and a proposal for an integrative concept. Journal of Clinical Ethics. 2016;27(2):117-28.

39. Schmidt-Felzman H. Pragmatic principles--methodological pragmatism in the principle-based approach to bioethics. Journal of Medicine and Philosophy. 2003;28(5-6):581-96.
40. Vo H, Campelia GD, Olszewski AE. Addressing racism in ethics consultation: An expansion of the Four-Box Method. Journal of Clinical Ethics. 2023;34(1):11-26.
41. Clinical Ethics Consultation Affairs Committee. Improving Competencies in Clinical Ethics Consultation: An Education Guide. American Society for Bioethics and Humanities; 2015.
42. Doucet H, Larouche J-M, Melchin KR. Ethical Deliberation in Multiprofessional Health Care Teams. Ottawa: University of Ottawa Press; 2001.
43. Fricker M. Epistemic Injustice: Power and the Ethics of Knowing. Oxford: Oxford University Press; 2007.
44. MacDuffie KE, Patneaude A, Bell S, et al. Addressing racism in the healthcare encounter: The role of clinical ethics consultants. Bioethics. 2022;36(3):313-17.
45. Grzanka PR, Brian JD, Shim JK. My bioethics will be intersectional or it will be [bleep]. American Journal of Bioethics. 2016;16(4):27-9.
46. Gillis L. Report finds patients of colour less likely to get pain meds among racial issues plaguing health care. Ontario Health Coalition. 10 Jun 2020.
47. Boyer Y. Healing racism in Canadian health care. Canadian Medical Association Journal. 2017;189(46):e1408-9.
48. Conseil des Atikamekw de Manawan, Conseil de la Nation Atikamekw. Principe de Joyce. Nov 2020.
49. Linklater R. Decolonizing Trauma Work. Indigenous Stories and Strategies. Kjipuktuk: Fernwood Publishing; 2014.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Should People With a History of Psychosis Be Included in Psychedelic Research?

Khaleel Rajwani[a]

Résumé

L'exclusion de tous les patients ayant des antécédents personnels ou familiaux de psychose de la recherche sur les thérapies psychédéliques soulève d'importantes questions éthiques. Après avoir résumé l'imbrication et la séparation historiques de la recherche sur les psychédéliques et la psychose dans la psychiatrie occidentale, j'aborde certaines des raisons cliniques et socioculturelles importantes pour lesquelles les antécédents personnels ou familiaux de psychose sont devenus un critère d'exclusion standardisé dans presque toutes les recherches contemporaines sur les psychédéliques. Tout en reconnaissant qu'une grande prudence s'impose, je soutiens que l'exclusion des patients ayant des antécédents de psychose entraîne des préjudices importants en matière de sécurité, d'accessibilité, d'autonomie et d'équité. En m'appuyant sur le cas paradigmatique de l'exclusion généralisée des personnes enceintes de la recherche sur les médicaments, je soutiens que, plutôt que de prévenir les conséquences néfastes, une approche protectionniste et exclusionniste redistribue ces préjudices d'une manière éthiquement problématique. Les personnes ayant des antécédents de psychose méritent un accès équitable aux avantages de la recherche sur les thérapies psychédéliques. La production de données plus solides sur la sécurité, de recommandations posologiques et de directives thérapeutiques pour ce groupe améliorera la pratique clinique et réduira de manière générale les préjudices liés aux psychédéliques. J'explore également la littérature scientifique croissante qui suggère que les nouvelles thérapies psychédéliques pourraient jouer un rôle dans le traitement de la psychose, en particulier dans le cas des symptômes négatifs de la schizophrénie pour lesquels des traitements efficaces sont nécessaires de toute urgence. Enfin, je critique la pratique dominante d'exclusion liée à la psychose et défends l'idée qu'il est éthiquement impératif de mener des recherches cliniques prudentes sur les psychédéliques impliquant des personnes ayant des antécédents personnels ou familiaux de psychose. L'adoption d'une approche plus inclusive de la recherche sur les psychédéliques permettrait en fin de compte d'améliorer la sécurité, d'accroître l'accès, de réduire les inégalités et de prévenir les dommages à long terme causés par l'exclusion généralisée.

Mots-clés

thérapie psychédélique, schizophrénie, psychose, bioéthique psychiatrique, éthique de la recherche, médicaments psychoactifs

Abstract

The exclusion of all patients with a personal or family history of psychosis from psychedelic therapy research is a significant ethical concern. Beginning with a summary of the historical entanglement and disentanglement of psychedelic and psychosis research in Western psychiatry, I then discuss some of the important clinical and socio-cultural reasons why having a personal or family history of psychosis has become a standardized exclusion criterion in almost all contemporary research involving psychedelic drugs. While acknowledging that a high degree of caution is warranted, I contend that the exclusion of patients with a history of psychosis results in significant harms related to safety, accessibility, autonomy, and equity. Drawing on the paradigmatic case of the broad exclusion of pregnant people from drug research, I argue that, rather than preventing harmful consequences, a protectionist and exclusionary approach redistributes these harms in ethically problematic ways. People with a history of psychosis deserve equitable access to the benefits of psychedelic therapy research. Generating more robust safety data, dosage recommendations, and therapeutic guidelines for this group will improve clinical practice and reduce psychedelic-related harm broadly. I also explore the growing scientific literature that suggests novel psychedelic therapies could play a role in the treatment of psychosis, particularly in the case of negative symptoms of schizophrenia for which effective treatments are urgently needed. Ultimately, I critique the dominant practice of psychosis-related exclusion and defend the view that cautious clinical psychedelic research involving individuals with personal or family history of psychosis is ethically imperative. Adopting a more inclusive approach to psychedelic research would ultimately improve safety, increase access, reduce inequities, and prevent long-term harms caused by blanket exclusion.

Keywords

psychedelic therapy, schizophrenia, psychosis, psychiatric bioethics, research ethics, psychoactive drugs

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INTRODUCTION

Having a personal or familial history of psychosis[1] is one of the most common exclusion criteria in contemporary biomedical research involving psychedelic drugs. In this paper, I argue that the categorical exclusion of all patients with a personal or family history of psychosis from research into psychedelic therapies raises significant ethical concerns. I begin with an overview of the historical entanglement and disentanglement of psychedelic and psychosis research in Western psychiatry. I then survey and summarize the standard psychosis-related exclusion criteria incorporated in screening protocols for contemporary psychedelic therapy research. Several clinical justifications for these standardized criteria are examined, including the risk of adverse effects in this patient population, intensification of existing psychotic symptomology, hypersensitivity to persisting psychedelic-induced psychosis, and increased likelihood of long-term side effects including Hallucinogen Persisting Perception Disorder. Drawing on scientific literature and expert commentary, I acknowledge that these concerns warrant substantial precaution. However, I also contend that the prevailing perception of extreme risk in this patient group is likely amplified by historical propaganda, bias, stigma, and dated narratives linking psychedelic drugs with madness. Further, I consider the transcultural dimension of this ethical dialogue, noting that many indigenous cultures with living psychedelic practices have safely and meaningfully included people with lived experiences that may be categorized as psychotic in Western psychiatry. This perspective challenges the universality of current exclusionary frameworks in biomedical research and supports a transcultural approach to risk assessment and inclusion.

Next, the paper outlines the ethical implications of protectionist exclusion of patients with a history of psychosis from psychedelic research. First, blanket exclusion hinders the collection of qualitative and quantitative safety data that is relevant for clinicians prescribing psychedelic-assisted interventions in the real world. Many practical ethical issues are associated with excluding individuals who may be at higher risk of adverse effects related to psychedelics from clinical trials. Second, exclusion prevents certain individuals from accessing effective psychedelic-assisted interventions for treatment-resistant psychiatric disorders. It is plausible that the potential therapeutic benefits of evidence-based psychedelic therapies outweigh the risks for certain patients with a history of psychosis who are suffering from co-morbid diagnoses. Thirdly, blanket exclusion undermines autonomy by hindering the ability of people with a history of psychosis to weigh the risks and benefits of interventions and make informed decisions that could substantially affect their health. Fourth, psychosis-related exclusion has a direct negative effect on the participation of Black, indigenous, and racialized communities in psychedelic research. Marginalized people, including people with a history of psychosis, deserve equitable access to the potential benefits of innovative psychedelic research.

Drawing on the paradigmatic case of the exclusion of pregnant people from drug research, I argue that a paternalistic and exclusionary approach to psychedelic research does not prevent harmful consequences among a vulnerable population, but rather redistributes these harms temporally and demographically in morally problematic ways. Improving the evidence base by generating more robust dosage and safety data will have major long-term benefits for individual safety and autonomy, clinical practice, and public drug harm reduction. Blanket exclusion also forecloses the possibility of developing novel psychedelic therapies specifically targeted at schizophrenia and psychosis spectrum disorders. Emerging scientific literature suggests that psychedelic therapies could improve negative symptoms of psychosis, for which novel and effective treatments are urgently needed.

Ultimately, this paper critiques the dominant practice of psychosis-related exclusion and defends the view that inclusive and carefully supervised clinical psychedelic research involving individuals with personal or family history of psychosis is ethically imperative. A more inclusive approach to psychedelic research would improve safety, increase access, reduce inequities, and prevent long-term harms caused by protectionist exclusion.

PSYCHEDELICS & PSYCHOSIS: HISTORICAL ENTANGLEMENT AND DISENTANGLEMENT

Psychosis and psychedelic states of consciousness have long been entangled in the history of Western scientific and psychiatric discourse. In the early to mid-20th century, scientific discourses concerned with these two phenomena often overlapped, but research trajectories largely diverged in the aftermath of the 1960s US legal prohibition on psychedelic research (1). Despite this historical divergence, contemporary scientific interest in the overlap between psychedelic and psychosis phenomena has re-emerged in many disciplines, including clinical psychiatry, neuroscience, and psychopharmacology. Furthermore, interest in understanding psychedelic and psychosis as social, phenomenological, and pathological categories has re-emerged within contemporary critical discourses, including bioethics and madness studies, which critique the social stigmatization, pathologization, and ostracization of non-normative states of consciousness.

During the early to mid-20th century, “psychedelic” was just one term within a rich and contested taxonomy of psychoactive substances with the tendency to profoundly alter consciousness, perception of reality, cognitive functions, emotional experiences, and mood. Classic psychedelic drugs like psilocybin, mescaline, N,N-Dimethyltryptamine (DMT), and Lysergic acid Diethylamide (LSD) were also referred to as *psychotomimetic* (mimicking psychosis), *psychotogenic* (generating psychosis), *hallucinogenic* (generating hallucinations), and *psychodysleptic* (mind-disrupting) (1). These terms explicitly concretized perceived connections between consciousness-altering drugs and psychosis within prevailing social discourse. In the mid-20th century, leading researchers like Humphrey Osmond drew phenomenological comparisons between psychedelics and psychosis to develop models of madness and advance qualitative knowledge of hallucinatory phenomena. Comparative

[1] In what follows, the use of the term “history of psychosis” refers to “personal or familial history of psychosis”, unless specified otherwise.

research of that period included psychiatric studies as well as phenomenological analysis emerging from self-experimentation (1). Significant research took place using psychedelic drugs to understand and model psychosis, while clinical research investigated the use of psychedelics, particularly LSD, as a treatment for schizophrenia (2). As psychedelic drugs were introduced into psychiatric communities in the mid-20th century, an increasing number of clinicians and researchers argued that psychedelic therapy could be useful in the treatment of schizophrenia. Some also suggested that therapists should take LSD to help increase empathy with people experiencing schizophrenia (3,4).

However, the moral panic around psychedelic drugs in the 1960s led to the rapid closure of research programs around the world and marked a dramatic disentanglement of psychedelic and psychosis discourse (1). The proliferation of War on Drugs propaganda linking psychedelic drug use with madness coincided with a departure from scientific research and knowledge production that investigated psychedelic and psychosis experiences in parallel. Furthermore, the mid-20th century transformation of psychiatric discourse away from the dominant psychoanalytic paradigm, and towards biological and neuroscientific frameworks, meant that comparative phenomenological approaches were largely abandoned in favour of neurobiological and genetic research design (1).

Since the 21st century renaissance of research into psychedelic therapies in biomedicine, schizophrenia and psychosis have not been prominent therapeutic targets (2). However, some important neuroscientific and psychopharmacological research is ongoing. There is significant contemporary research interest in understanding the activation dynamics of serotonin receptors in the brain; decades of robust research have confirmed the historical speculation that changes in serotonin neurotransmission are important for understanding both psychedelic and psychotic experiences (5,6). As Geyer and Vollenwieder note, this agenda is closely linked with historical entanglements: “the fundamental idea that psychotic states seen in psychiatric disorders such as schizophrenia might be attributable, in part, to abnormalities in serotonergic systems began with the almost simultaneous discovery of lysergic acid diethylamide, psilocybin, and serotonin.” (6) Other topics of contemporary interest include the ways that antipsychotic drugs tend to block psychedelic experiences, similarities and differences between psychotic and psychedelic hallucinations, and the use of psychedelics in animal research to model and understand symptoms of psychosis (7-9). It is noteworthy that most contemporary scientific studies focus on using psychedelics to understand rather than treat psychosis.

Today, a broad range of psychedelic drugs are currently being investigated as part of innovative therapeutic interventions for mental illnesses such as post-traumatic stress disorder (PTSD), major depressive disorder, end-of-life anxiety, and substance use disorders. This includes classic psychedelics like psilocybin, LSD, DMT, and mescaline as well as non-classic psychedelics including ketamine, 3,4-Methylenedioxymethamphetamine (MDMA), and ibogaine.[2] As part of ongoing research, psychedelic drugs are generally prescribed and administered in a clinical setting under the supervision of trained therapists or healthcare professionals, and often as part of extensive psychotherapy.

Clinical trials involving psychedelic substances have been authorized by regulatory bodies in many global jurisdictions but remain at various stages of approval. Australia is the only country where MDMA and psilocybin have received regulatory approval as psychiatric medications for the treatment of treatment-resistant depression and PTSD. In the US, significant clinical research into psychedelic-assisted therapies is ongoing, but none have received regulatory approval; in a recent high-profile case, the US Food and Drug Administration rejected an application to approve MDMA-assisted therapy for the treatment of PTSD following phase 3 clinical trials (10). Other jurisdictions including Canada and some US states have increased access to therapeutic psychedelic use through compassionate access programs or decriminalization initiatives. In Oregon, Colorado, and New Mexico, psilocybin is legally accessible outside clinical settings through regulated adult use programs, and use is often supported by licensed facilitators.

PSYCHOSIS-RELATED EXCLUSION CRITERIA IN CONTEMPORARY PSYCHEDELIC RESEARCH

A personal or family history of psychosis is included as a criterion for exclusion from research when it is considered a comorbidity that could bias the results of the research or increase risk of adverse events (11). In contemporary psychedelic research, individuals with personal or family history of psychosis are generally excluded from clinical trials involving the administration of psychedelic substances as part of the therapeutic intervention (2). For example, in a study investigating psilocybin treatment of major depressive disorder with co-occurring alcohol use disorder at Johns Hopkins University the psychosis-related exclusion criteria were stated as follows:

- Current or past history of meeting DSM-5 criteria for schizophrenia spectrum or other psychotic disorders (except substance/medication-induced or due to another medical condition), or Bipolar I or II Disorder
- Have a first or second-degree relative with schizophrenia spectrum or other psychotic disorders (except substance/medication-induced or due to another medical condition)
- Has a psychiatric condition judged to be incompatible with establishment of rapport or safe exposure to psilocybin (12).

[2] Classic psychedelics are typically defined as substances that are partial agonists of 5-HT2A receptors that produce substantially altered states of consciousness involving changes to affect, cognition, and perception. Non-classic psychedelics refer to substances which arguably share psychopharmacological and phenomenological similarities to classic psychedelics in certain dosages and contexts but may differ in their neurobiological mechanisms of action.

Similar or identical psychosis-related exclusion criteria were mentioned in my review of 115 actively recruiting clinical trials for psychedelic-assisted therapies on the US National Library of Medicine clinical trials database as of July 2024 (13).[3] Psychosis-related exclusion criteria were specified in trials with psychedelic-assisted interventions targeted at PTSD, obsessive compulsive disorder, major depressive disorder, generalized anxiety disorder, substance use disorders, burnout among frontline healthcare workers, and depression in people with autism spectrum disorder, mild cognitive impairment, or Alzheimer's disease. These psychosis-related exclusion criteria were specified regardless of the psychedelic substance being administered as part of the intervention: the 115 studies surveyed included interventions with psilocybin, psilocin, ayahuasca, mescaline, ketamine, esketamine, MDMA, LSD and N,N-DMT. Psychosis-related exclusion criteria were also included in 44 studies accepting healthy volunteers. In some studies, exclusion criteria specifically mentioned major depressive disorder with psychotic features, antisocial personality disorder or borderline personality disorder. In other studies, exclusion criteria more broadly mentioned any personal history of a severe mental illness or psychiatric condition, which includes schizophrenia and psychosis spectrum disorders (13).

As of July 2024, there was a single study in the US National Library of Medicine database that did not include psychosis-related exclusion criteria: a proposed study investigating the tolerability of MDMA as a treatment for schizophrenia-associated asociality. This study was not yet recruiting as of July 2024, and will be discussed further in a later section. Although my review of exclusion criteria involved clinical trials registered in the US National Library of Medicine database, some of the trials included centres outside of the US. Psychedelic studies in other jurisdictions, including Canada and Australia, often include similar or identical psychosis-related exclusion criteria as studies based in the US.

WHY ARE PEOPLE WITH A HISTORY OF PSYCHOSIS EXCLUDED FROM PSYCHEDELIC RESEARCH?

Clinical Considerations

Given the psychoactive, hallucinogenic, and consciousness-altering properties of psychedelic drugs, and prevailing understandings of psychosis, caution around including individuals with a personal history of psychosis is intuitive and unsurprising. Common features of psychedelic experiences include hallucinations, delusions, dissociation, depersonalization, ego-reduction, among other changes in mood, cognition, and consciousness, which could subjectively overlap with common symptoms of psychosis. Clinical researchers have justifiable concerns about adverse effects in this patient population, particularly because psychedelics could plausibly intensify or exacerbate existing psychotic symptoms among those with active psychosis spectrum diagnoses. Past experiences or family history of psychosis could also increase the probability of adverse effects, challenging psychedelic experiences and bad trips, or signify hypersensitivity to long-term effects such as persisting psychedelic-induced psychosis or hallucinogen persisting perception disorder (HPPD). Considering these notable adverse effects, and the potential risks of compounding psychedelic experiences with psychosis experiences, precautionary exclusion of this group of individuals appears quite intuitive and sensible.

Even in otherwise healthy individuals, psychedelic drugs could precipitate drug-induced psychosis, which occurs when drug use triggers acute psychosis-like experiences or psychosis symptoms such as paranoia, delusions, and hallucinations. Sometimes these experiences are transient and sometimes they are lasting, and it may be initially difficult to discern psychedelic drug effects from psychosis symptoms. In perhaps the only published methodical survey on the topic, Malleson found episodes of psychedelic-induced psychosis were largely transient, and that examples of prolonged psychosis related to clinical LSD use were rare. In a survey of clinicians covering 50,000 LSD dosing sessions, he found that with clinical supervision the rate of psychotic reactions lasting greater than 48 hours was very low: 1.8 per 1000 patients and 0.8 per 1000 experimental participants (14).

Although there may be an intuitive association between psychedelic use and the intensification of psychosis symptoms, research is far from conclusive. A recent longitudinal study on the associations between psychedelic use and psychotic symptoms in the US and UK found no association between self-reported psychedelic use and a change in the number of psychotic symptoms within a two-month study period (15). Furthermore, psychedelic use was associated with a decrease in the number of psychotic symptoms in respondents with a personal history of psychosis (15). However, the researchers found an increase in psychosis symptoms associated with psychedelic use in people with a personal history of bipolar disorder, and a similar but weaker association with a family history of bipolar disorder (15). Another study of over 16,000 adolescent twins found that psychedelic use was associated with lower rates of psychotic symptoms when controlling for other drug use (16). Although we cannot conclude much due to the significant limitations of these methodologies, researchers in the field have suggested that more studies are warranted, and that psychedelics could exert less influence on psychosis symptoms in individuals with a personal or family history of psychosis than many speculate (15).

However, other researchers have observed that in some cases individuals who experience substance-induced psychosis go on to develop a persistent psychotic condition, such as schizophrenia spectrum disorder (17). According to a meta-analysis of 3 studies, the likelihood of transition from an episode of hallucinogen-induced psychosis to a diagnosis of schizophrenia was

[3] Informal author-conducted search of the ClinicalTrials.gov registry (US National Library of Medicine) conducted in July 2024. The search reviewed 115 actively recruiting interventional studies investigating psychedelic or psychedelic-assisted therapies. Each study record was examined for exclusion criteria referencing schizophrenia or psychosis-spectrum disorders. This search was exploratory and not a systematic review.

roughly 26%, which was estimated to be higher transition rate than from opioid-, alcohol-, or sedative-induced psychosis, but lower than cannabis-induced psychosis (17). Researchers argued that there is a substantial risk of transition to schizophrenia from substance-induced psychosis related to hallucinogen use (17). Another study found that familial psychosis history predicted progression from substance-induced psychosis to schizophrenia (18). Of course, one difficulty of assessing this research involves understanding whether the individuals would have developed psychosis without psychedelic drug use, and whether a substance-related trigger is a central precipitating factor. Kendler et al. (18) suggested that "schizophrenia following substance-induced psychosis is likely a drug-precipitated disorder in highly vulnerable individuals, not a syndrome predominantly caused by drug exposure." Transition from episodes of psychedelic-induced psychosis to long-term psychosis should be considered a risk of psychedelic use for people with a personal or family history of psychosis and must be factored into research ethics considerations and informed consent practices.

Some historical evidence shows that people with psychosis may have different dose sensitivity or altered dose response to a variety of psychoactive drugs, including psychedelics. For example, in one of the first documented trials of psychedelics in schizophrenia patients in 1947, researchers found that in schizophrenia patients, the onset of LSD experiences was delayed, and visual effects and euphoria were subdued compared to "nonpsychotic" participants.[4] According to the researchers, psychedelic drug effects were generally experienced as different from underlying psychosis, and none of the patients experienced a worsening of their mental illness (2,19). Other studies in the mid-20th century confirmed a general need for higher doses of LSD than nonpsychotic patients to elicit psychedelic effects: certain psychedelic drug effects including euphoria, nausea, and headaches were found to be lower in patients diagnosed with schizophrenia (2,20). In another study, researchers administered LSD-25 to "paranoid" and "undifferentiated" patients with schizophrenia, as well as nonpsychotic participants and compared responses to a questionnaire about their subjective experiences. The study found that the patient group experiencing "undifferentiated" schizophrenia reported lesser subjective effects overall, while the responses of patients with paranoid schizophrenia, and baseline participants without psychosis, were qualitatively and quantitatively comparable (21). There are significant methodological limitations in analyzing historical research involving psychedelic use among individuals experiencing schizophrenia, particularly because studies before DSM III (1980) that reference schizophrenia or psychosis subtypes (e.g., paranoid, undifferentiated) are considered to have unreliable overlap with contemporary diagnostic criteria. However, these historical studies support the notion that certain patients with schizophrenia may react differently to psychedelics than patients without psychosis or healthy volunteers, including differences in dose sensitivity and differences in the subjective psychedelic-associated effects like euphoria (2).

Despite deeply held intuitions and practical consensus that people with a personal or family history of psychosis have substantially greater risks of adverse psychedelic effects, there is a notable lack of contemporary scientific literature investigating the risk profile of psychedelic use among this group. This knowledge gap is obviously exacerbated by widespread exclusion of this patient group from the renaissance of Western clinical psychedelic therapy research in the 21st century. However, some analysis of historical and contemporary evidence challenges widely-held beliefs about the severity of risks of psychedelic use for individuals with a history of psychosis — beliefs which often ground exclusion of this patient population from modern psychedelic research. A recent analysis of clinical research involving psychedelics and schizophrenia taking place from the 1950s prior to the prohibition of research in the early 1970s, noted that although psychedelics were occasionally destabilizing to individuals with schizophrenia, results were highly variable, and studies were conducted by practitioners who were not well-equipped to establish supportive therapeutic settings (4). Furthermore, the authors noted that despite the nearly unanimous view that psychedelics can destabilize or exacerbate schizophrenia, both historical accounts and current survey-based research include instances where psychedelics have been reported to have a beneficial impact on individuals with psychosis. Researchers hypothesize that psychedelic-induced increases in neural plasticity, changes in cognition, psychopharmacological effects, and supportive set and setting could all contribute to beneficial therapeutic effects. Researchers have argued that a low dose or a microdose of a classic psychedelic drug like psilocybin could be a viable treatment for the negative symptoms of schizophrenia, and that more neuroscientific and clinical research is warranted (4).

Complementing this assessment of historical data, recent population-level research has also contributed to the ongoing discussion regarding the risks of psychedelic use among individuals with psychosis-related risk factors. A retrospective analysis of emergency department (ED) data found an increased incidence of schizophrenia spectrum disorder among individuals who presented to the ED and had used hallucinogens in uncontrolled, non-clinical settings (22). However, the study had important limitations, including the broad definition of "hallucinogens" and the lack of specificity regarding the type, dose, and context of use. Despite these limitations, this data underscores the potential risks associated with unsupervised psychedelic use, particularly among those with psychiatric co-morbidities or psychosis-related risk factors, and supports the importance of generating more robust, context-sensitive safety data in controlled clinical research settings.

Although historical and contemporary literature indicates that people experiencing schizophrenia may experience different subjective effects or require different dosages to elicit psychedelic experiences, researchers have argued that the current literature does not indicate that schizophrenia patients are necessarily hypersensitive to classic hallucinogen-associated psychosis (2). Scholars have pointed to clinical observations and surveys of clinicians working with patients to argue against the notion that psychedelic use is highly likely to cause long-term schizophrenia (4). Researchers have also challenged the view that patients with a history of psychosis are more susceptible to the long-term negative effects of HPPD, a rare clinical

[4] Studies cited from this era included terms like "nonpsychotic participant," "undifferentiated schizophrenia," and "paranoid schizophrenia," which may be considered dated. These terms are emphasized with scare quotes when used for the first time in the paper to indicate dated, contested, or problematic nomenclature.

condition in which people who have used hallucinogenic drugs like psychedelics experience prolonged or re-occurring perceptual changes that are reminiscent of acute drug-induced effects (23). One preliminary study compared two groups of people with schizophrenia with prior LSD use: those who were diagnosed with HPPD, and those who were not. The study found no differences in socio-demographic or clinical characteristics between the HPPD and non-HPPD groups (24). However, researchers concluded that "very little is known about the co-occurrence of schizophrenia and HPPD or the associated clinical implications" and that further research is needed (24).

In the absence of robust scientific data and clinical evidence, consulting credible experts in scientific, clinical, and ethical fields is an essential resource for assessing the practical risks of including people with a history of psychosis in psychedelic-assisted therapy research. In a recent project on the topic of psychedelic-assisted therapy for people with psychopathological psychotic experiences and psychotic disorders, La Torre et al. (25) consulted the opinions of experts in the fields of psychiatry, clinical psychology, medicine, and psychedelic drug use. The experts highlighted the complex clinical expertise and institutional resources required for supporting people with a history of psychosis in psychedelic therapy contexts, but ultimately found consensus that while the exclusion criteria may be justified for psychedelic protocols that provide minimal psychological support, psychedelic-assisted psychotherapy is not necessarily contraindicated for all individuals within this group (25). Their analysis suggested that offering psychedelic-assisted psychotherapy under the right conditions could potentially benefit people experiencing psychosis-related conditions (25). The experts stressed the need for more research related to risks, safety, and identifying critical factors for predicting treatment outcomes, including specific symptomology, duration of the illness, symptom severity, quality of therapist-client relationship, role of trauma in mental illness, and the quality of other supportive structures in the client's life (25). Yet, these important forms of research and knowledge production are exceedingly difficult or impossible today, given the blanket exclusion of people with psychosis from clinical psychedelic research.

Historical Narratives

Widespread concern around the risks of psychotic reactions to psychedelic drugs may be even more pronounced given historical narratives linking psychedelics with highly stigmatized accounts of psychosis and madness in the mid to late-20th century. Psychedelic researchers have argued that despite real possibilities of severe adverse effects, in general, "concerns about psychedelic use seem to have been based on media sensationalism, lack of information and cultural biases, rather than evidence-based harm assessments" (26). Furthermore, pervasive War on Drugs propaganda (disseminated primarily in the US) characterized psychedelic drugs as highly likely to lead to psychosis, madness, violence, and suicide in order to justify criminalization and political repression. Even as scientific discourses on psychedelic and psychosis phenomena disentangled, the connection between psychedelics and madness has maintained a deep influence within public opinion, biomedical research, psychiatric practice, and madness discourse.

The belief that LSD and other psychedelics frequently induce psychosis persists widely today. However, contemporary comparative research on psychedelics and psychosis has largely diverged from these outdated associations and overly simplistic views. For example, recent research demonstrates the highly complex differential neurophenomenology of hallucinations related to psychedelics and hallucinations on the schizophrenia spectrum, revealing a relationship that is far more nuanced and complicated than accounted for in historical models (27). Although, there is much less interest today in using LSD to model psychosis in research, the notion that psychedelic drugs provoke experiences of psychosis remains a factor for the persisting association between psychedelics and psychosis within clinical and social discourse. As Friesen argues, modern psychedelic research often seeks to rebrand by distancing itself from the stigmatized links between psychedelic drug use and madness, and the anti-establishment politics that were historically associated with psychedelic-using communities (1).

The scientific, medical, and bioethical community should be skeptical of any assertions made about links between psychedelic use and lasting psychiatric and psychotic effects without substantial evidence (26). The fact that both psychosis and psychedelic use are statistically prevalent in the population, and further, that the onset period of both typically occurs in early adulthood, may lead to mistaken causal inferences (26). It is also important to note that adverse effects, negative outcomes, and challenging experiences related to psychedelic use are relatively common even in patients without a history of psychosis. Furthermore, many people may attribute psychiatric and psychosis symptoms to the use of psychedelics drugs due to their striking and transformative subjective effects (26). The influence of War on Drugs propaganda campaigns linking psychedelic drugs with psychotic episodes may also lead to significant bias on the part of mental health professionals and policy makers.

Regulation and Research Ethics Oversight

In general, some instances of exclusion are rooted in regulatory or legal requirements, while others emerge through a culture of risk aversion within research design and research ethics review that often does not calibrate protectionist inclinations with real levels of risk (28,29). Psychosis-related exclusion from psychedelic research may be a regulatory requirement in specific legal contexts or certain jurisdictions, but in many instances, it falls in the latter category as a *de facto* form of exclusion practiced by researchers and ethicists. Furthermore, central regulatory frameworks in the US governing Institutional Review Boards (IRBs) have undergone very little revision or reform, despite bioethical consensus around the problems with protectionism and the importance of including marginalized communities in research. This often leaves IRBs to make decisions about inclusion and exclusion on a case-by-case basis (28).

Both de jure and de facto protectionism within contemporary research ethics largely emerged in response to high profile instances of unethical experimentation and human rights abuses involving vulnerable populations (28,30). Given the particularly disturbing histories of unethical, abusive, and exploitative experimentation throughout the history of Western psychedelic research, groups perceived as vulnerable or marginalized are likely to be subjected to a higher degree of caution, paternalism, and exclusion in contemporary research ethics review, including incarcerated people, people with a history of psychosis, and adolescents (31,32). However, emerging critiques within bioethics have challenged and problematized the concept of vulnerability, particularly as a justification for excluding entire populations from research (28). Scholars have argued that vulnerability is not a fixed trait but a context-dependent reality that may arise from various causes, such as impaired decision-making, social disadvantage, or situational coercion (28). These different forms of vulnerability require distinct ethical responses rather than blanket exclusion, and contemporary bioethical practice demands nuanced, context-sensitive approaches to vulnerability in research ethics that safeguard participants without perpetuating paternalism or undermining autonomy.

People with psychosis may be considered to have impaired capacity to consent to experimental interventions, particularly at higher levels of severity of psychosis. Research ethics review may take this into account, and there are already significant concerns and ongoing debates surrounding the ethics of informed consent in psychedelic therapy contexts (33-36). These ethical issues surrounding autonomy, consent, and caregiving in psychedelic research may be even more complex within the context of pathologies which deeply affect self-identity, which may include psychosis-related pathologies, as well as Alzheimer's and related dementias (37). The novel ethical issues and complexities posed by contemporary psychedelic research, as well as lack of time and material resources dedicated to the relatively new field of psychedelic ethics, can lead to further precautionary or protectionist exclusion by IRBs and other research ethics institutions (28)[5].

Resource Allocation

Even when an individual's history of psychosis is not a direct contraindication for a specific psychedelic intervention, healthcare institutions or therapy centres may not offer adequately supportive environments for individuals with psychosis-related diagnosis, psychotic symptoms, or complex co-morbidities. Due to systemic underfunding of mental health services and a lack of resources in many psychiatric and mental health institutions, individuals with a history of psychosis may not receive the care, support, attention, and resources that they need and deserve during the course of psychedelic therapy research. Experts have argued that psychosis-related exclusion criteria could be ethically warranted for psychedelic-assisted therapy protocols that provide limited psychological support for participants (25).

In the US and other global jurisdictions with significant profit incentives for drug development, there is little incentive for pharmaceutical companies to conduct trials in groups perceived as higher risk; this is true not just of psychedelic research, but of drug research more broadly (38). Incentives to include higher risk groups will decrease even further once psychedelic medicines move beyond clinical trials and are approved by regulatory bodies for clinical use (38).

Cultural Norms

Definitions of psychosis and madness are culturally bound. The categorization and pathologization of non-normative forms of consciousness reflects dominant colonial and biomedical power structures. In their discussion of the topic of psychosis-related exclusion from psychedelic research, La Torre et al. (25) emphasize the importance of accounting for the relationship between psychedelics and psychosis not only within the context of Western psychedelic research, but also in the context of living psychedelic traditions with histories and practices in Indigenous societies going back millennia. Western frameworks for understanding both psychedelics and psychosis are heavily influenced by historical and cultural context, and biomedical psychedelic therapy is largely indebted to the history of Indigenous psychedelic healing practices (39). Thus, engaging with these contexts and knowledge systems is an important tool for deconstructing exclusion and stigma in psychedelic and psychosis research. Furthermore, the preferential treatment of Western scientific and ethical frameworks reinforces colonial bias and perpetuates the oppression of Indigenous practices, knowledge systems, and worldviews (40,41).

In many Indigenous communities with rich shamanic traditions, such as those in the Amazon basin and Siberia, experiences and phenomenologies that may be categorized in Western psychiatry as psychotic are not necessarily pathologized or stigmatized. Instead, individuals who hallucinate are often considered epistemically privileged and endowed with spiritual abilities that make them well-suited to participate in psychedelic rituals, or even uniquely situated to take on the role of a shaman or healer in their communities (25,42,43). While this does not establish that psychedelics are safe for all individuals with psychosis, it supports the idea that some people with psychotic experiences may benefit, or may not be adversely affected, by psychedelic use (25).

The risks of psychedelic use among people within psychosis-related diagnostic categories in Western psychiatry may be different and even amplified — but these risks are not well understood or documented. Furthermore, psychedelic use in clinical settings has a radically different safety calculus than non-medical or unsupervised use: active biomedical supervision, specific psychotherapeutic practices, and other safety and accountability measures, can substantially reduce the risk of adverse effects and improve positive outcomes (2,14). Growing bodies of scientific, social scientific, and bioethical literature emphasize the

[5] For an overview of some of the key issues in contemporary psychedelic ethics see The Hopkins-Oxford Psychedelics Ethics (HOPE) Working Group Consensus Statement (36).

role of set and setting context in both psychotic and psychedelic experiences, which may play a significant role in reducing the likelihood of adverse events and orienting psychedelic-assisted interventions towards positive clinical outcomes (44-47). While sound research design, informed consent practices, and ethical oversight are essential to all research involving people with a history of psychosis, it is reasonable to hold that investigating psychedelic-assisted interventions in this group is not automatically unsafe in all cases.

THE HARMS OF PROTECTIONIST EXCLUSION OF PEOPLE WITH A HISTORY OF PSYCHOSIS

The exclusion of individuals with a history of psychosis from psychedelic research is often motivated by a legitimate concern for minimizing harm in the context of novel and potent therapeutic agents. Schizophrenia spectrum disorders are often chronic and persistent conditions, and the possibility that psychedelic use could trigger onset or exacerbate existing symptoms represents a serious concern. Thus, many clinicians, researchers, and ethicists adopt a risk-averse stance, guided by a desire to avoid unnecessary harm, particularly in early-phase trials where long-term safety data is limited. This cautionary approach reflects a broader ethos of protection within biomedical research, especially when working with populations that may be at elevated risk of negative consequences.

A personal or family history of psychosis can be an important risk factor for consideration in psychedelic research participation. It also may be an important exclusion criterion for sound observation and data collection within specific study designs. However, while scientists, clinicians, and ethicists will reasonably disagree on whether exclusion is justified in particular cases, effective critical bioethical inquiry demands that we question the broader ethical implications of dominant protectionist approaches and exclusionary practices.

As Friesen et al. note, the protection-inclusion dilemma faced by modern research ethicists inevitably involves difficult tensions between protecting potential participants from research-related harms and including under-represented or marginalized groups in research (28). Blanket exclusion can be ethically justified when the risks of an intervention are demonstrably significant and benefits are highly unlikely. Yet this is incredibly hard to establish when the risks of researching a drug are largely unknown, or when the research offers potentially intangible or unquantifiable benefits to current and future members of a population group. Friesen et al. argue that “while protectionism within research ethics stems from an important recognition of the harms that can befall certain individuals or populations as a consequence of research, over-protection, especially when it takes the form of exclusion from research, can lead to significant negative consequences as well.” (28).

For example, a growing body of critical bioethical literature has argued that the near-universal exclusion of pregnant people[6] from most forms of pharmacological research leads to significant and widespread ethical harms (48). The dominant and standardized practice of excluding pregnant people, which is often an unquestioned insertion in the development of study participation criteria, may not cause immediate issues, and may even reduce the likelihood of harm in the near term. However, this exclusionary practice, grounded in a protectionist approach, has resulted in widespread harms to pregnant people in healthcare related to safety, access to medication, informed decision-making, and health equity that have persisted for decades (48). Because of their historical exclusion, pregnant people have limited knowledge about drug toxicity and dosing, thereby reducing their knowledge and putting them at greater risk. Pregnant people may also be discouraged from accessing beneficial medications due to unknown risks, and further, off-label medication use exposes them to risk without the safeguards or disclosure practices of clinical trials.

Pregnant people have thus been harmed by protectionist practices, and the systematic exclusion of pregnant people from research is not ethically defensible (48). In many historical cases, research protocols unjustly excluded women of childbearing age who were treated as always “potentially pregnant”. The harms precipitated by near-universal exclusion continue to affect pregnant people today and will continue to cause harm to this group well into the future, even as bioethical critique advances and inclusive pregnancy-related research programs evolve. Ethical parallels also persist across research contexts; for example, analogous concerns about the harms of protectionism have been raised by ethicists and advocates in the context of adolescents and people with disabilities being excluded from research (31,49).

A high degree of caution in the study of any novel drug-assisted intervention is warranted. However, the paradigmatic case of excluding pregnant people from drug research demonstrates the broader ethical issues with acting on seemingly reasonable intuitions in ways that can lead to harmful long-term consequences. By surveying some of the most significant harms of protectionist exclusion in the case of people with a history of psychosis, the practical parallels between the case of pregnancy- and psychosis-related exclusion from drug research become clearer. Ultimately, this approach clarifies the ways that people with a history of psychosis are in fact substantively affected by exclusion.

Safety

Excluding people with a personal or family history of psychosis from psychedelic research is ethically problematic in many significant ways. Firstly, blanket exclusion prevents the collection of important safety data related to therapeutic psychedelic use among this group. Modern scientific inquiry into psychedelic therapies to date has largely been based on data from highly

[6] I have chosen to use the term “pregnant people,” a gender-neutral term which includes women and people of other gender identities that can or do experience pregnancy. I note the that the vast majority of pregnant people discussed in the context of this paper identify as women, and I acknowledge the diversity of views around using gendered terminology related to pregnancy within academic scholarship.

screened populations and excludes many individuals and communities that may bear increased risks of adverse outcomes (38). Appelbaum argues that although “it seems prudent to exclude people with personal histories of psychosis and mania from trials of a drug that mimics the symptoms of psychosis … in the real world of psychiatric treatment, people with [these diagnoses] that would have excluded them from the psilocybin trial are common [among psychiatric patients]” (38). Without a developed understanding of the complex safety profile for patients with a history of psychosis before psychedelics receive regulatory approval, psychiatrists will be left in the dark when psychedelic-assisted therapeutic tools are considered within complex practical clinical scenarios (38). Furthermore, the ethical urgency of modifying exclusion criteria is particularly time-sensitive, because once psychedelic therapies receive regulatory approval for clinical use, pharmaceutical companies will be far less likely to fund clinical trials involving groups perceived as high-risk (38).

Returning to the case of pregnancy-related research exclusion, scholars have noted that despite broad criticism from ethicists and international research bodies, data on the safety and efficacy of medications in pregnant people continues to be predominantly generated in post-marketing contexts rather than during clinical trials (48). Of course, all unstudied drugs have potential risk for adverse outcomes, particularly related to pregnancy, and critics often point to tragic cases like thalidomide and diethylstilbestrol (DES) which had devastating side effects on maternal and fetal health, including miscarriages, severe birth defects, and infant mortality. However, thalidomide and DES were not studied in controlled trials in pregnant populations prior to their approval, and because safety concerns were identified only after widespread use, the resulting harms affected a much larger number of people (48). This argument is generalizable to many cases of blanket research exclusion, including the exclusion of people with a history of psychosis from psychedelic research. Once approved for certain applications, psychedelic interventions are likely to be used off label in complex clinical situations, without any controlled safety data for this patient group. In the tragic case of thalidomide, the devastating consequences would have been much less widespread if safety trials had been conducted in small groups with well-established consent and disclosure processes (48). Similarly, if there are significant risks associated with certain psychedelic drugs in people with a history of psychosis, generating data and understanding within controlled research contexts can help contain and prevent wider harms.

There are two noteworthy disanalogies between these cases. Firstly, many people with a history of psychosis currently use psychedelic drugs in diverse non-medical settings. Furthermore, people with experiences that may be classified as psychotic have historically consumed psychedelic drugs across diverse Indigenous cultures for millennia. This was not the case with thalidomide or DES which were novel experimental drugs with no history of cultural, spiritual, or prior medical use. Secondly, in future contexts where psychedelic therapies are approved, a history of psychosis is likely to be included as a contraindication for many psychedelic-assisted interventions. However, inclusive research that can reduce psychedelic-related drug harm is still an important and ethically consequential benefit.

Recent developments in pregnancy-related research ethics offer promising examples of how research in historically excluded groups can be safely and effectively undertaken. In response to longstanding critiques of the exclusion of pregnant individuals from drug trials, researchers and ethicists have developed strategies that better balance precaution with inclusion. These include risk-tiered research models that prioritize initial safety assessments in non-pregnant populations before gradually expanding inclusion, the use of real-world evidence through observational registries, adaptive trial designs, and enhanced informed consent processes (50-52).

Drawing on these precedents, clinical psychedelic researchers can pursue analogous approaches to include individuals with a history of psychosis in studies, avoiding the long-term safety harms of exclusion. By critiquing and modifying strict exclusion criteria, the findings that emerge from psychedelic research will better reflect the practical clinical contexts in which psychedelic-assisted therapeutic interventions will be used. Inclusion of people with a history of psychosis in well-designed controlled clinical research with effective safeguards would improve knowledge about the safety and efficacy of psychedelic therapies and improve outcomes in the long run.

Accessibility

Blanket exclusion will continue to unjustly prevent certain individuals from accessing effective psychedelic-assisted interventions for other treatment-resistant psychiatric disorders, such as major depressive disorder and PTSD. As psychedelic-assisted interventions are destigmatized and more widely accepted in clinical practice, many patients with a personal or family history of psychosis will become interested in psychedelic-assisted treatments for a co-morbid psychiatric diagnosis (38). There is significant research demonstrating that patients with target diagnoses for novel psychedelic therapies are likely to have co-morbidities that would typically exclude them from psychedelic trials; for example, people with major depression are more likely to have a sibling with schizophrenia or bipolar disorder than the general public, are more likely to have attempted suicide, and are more likely to have borderline personality disorder, all of which could be contra-indicated for psychedelic therapies or match exclusion criteria for studies (38).

As psychedelic-assisted interventions gain regulatory approval and mainstream biomedical acceptance, patients with a history of psychosis who have been excluded from research may continue to be excluded from approved clinical interventions involving psychedelics.[7] Without controlled safety data, patients with a personal or familial history of psychosis may be discouraged from accessing beneficial psychedelic-assisted interventions due to fears of unknown risks and adverse effects.

[7] This may also apply to patients who have been excluded on the basis of past suicidality, bipolar disorder, or borderline personality disorder.

Even if this group is not excluded in clinical practice, these same patients may be exposed to unknown harms through off-label prescription without benefitting from the ethical safeguards and consistent health monitoring that are typical features of clinical trials (48).

As discussed, the view that including patients with a history of psychosis in these treatments would necessarily result in outsized risks for adverse events is not well demonstrated. Conversely, studies have shown some psychedelic interventions to be effective *despite* comorbidities. For example, MDMA-assisted psychotherapy for the treatment of PTSD was shown to be highly efficacious, even in patients with significant (non-psychosis) comorbidities (53,54). As new research findings and clinical knowledge emerge, it is plausible that the benefits of a novel psychedelic therapy targeted at a treatment-resistant diagnosis unrelated to psychosis will outweigh risks for patients with a history of psychosis even if the risks for the individual are considered elevated.

Autonomy

Protectionist exclusionary practices undermine autonomy by hindering the ability of people with a history of psychosis to weigh the risks and benefits of interventions and make informed decisions that could substantially affect their health. This applies both to autonomous individuals making an informed choice to participate in clinical research in a context of uncertainty, and for individuals in the future tasked with making decisions about pursuing approved psychedelic therapies as part of their healthcare.

Miller and Wertheimer argue that “hard” paternalism entails restricting the freedom of persons who are substantially autonomous to protect them from the potentially harmful consequences of their fully voluntary choices, without their consent (55). Completely preventing a particular group from freely consenting to experimental research thus constitutes a form of hard paternalism. In a practical ethical sense, hard paternalism appears to be ethically justified if there is strong evidence and expert consensus that (a) the risks of the action are substantial and (b) the decision-maker does not have the capacity to reasonably understand, assess, and consent to the risks. Today the scientific and clinical community lack the robust evidence and consensus demanded of criterion (a). And although there are complexities in assessing the capability of people with psychosis at increasing levels of severity to make informed decisions about experimental interventions (b), the ethical bar for establishing complete restrictions on free choice should be high. While many cases of psychedelic-assisted interventions involving people with a history of psychosis could meet this standard, and thus morally demand some form of paternalistic intervention like research exclusion, it is not evident that this paternalist and protectionist form of exclusion should be practiced universally across the incredibly wide spectrum of psychosis cases and clinical psychedelic interventions.

Let us imagine that after a robust set of studies, we find out that the risks of a MDMA-assisted therapy for PTSD are substantially higher for patients with a history of psychosis. Say for example that these participants are far more likely to experience acute adverse effects related to psychedelics than participants without a history of psychosis, and some experience a worsening of their psychosis symptoms, but the patients experience roughly the same positive long-term effects on PTSD outcomes. It does not follow that we *must* exclude these individuals from the therapy based on this additional risk factor. A specific clinical evaluation of the risks and benefits for an individual case will vary widely across diverse patients and differ based on the severity of the patient’s past and present mental illnesses, previous responses to treatments, past experiences with psychedelics, personal risk tolerance, therapeutic expectations, and accessibility of alternatives, among countless other clinical factors. Further, there are many other psychological and social factors that could increase individual risks for adverse effects and yet do not serve as a basis for exclusion. The threshold for acceptable or reasonable risk will vary greatly, and it should be up to patients, families, clinicians, and other relevant decision-makers to assess the specific risks of participating in a particular psychedelic-assisted intervention on a case-by-case basis — even when the risks may be substantially heightened for a particular patient with a history of psychosis.

Returning to the case of exclusion of pregnant people from pharmacological research, scholars have argued that blanket exclusion undermines autonomy by limiting the ability of the individual to assess the risks for themselves and decide if participation would be in their best interest (56). Additionally, the absence of robust evidence that has resulted from historical research exclusion creates barriers to making informed choices. This further undermines the autonomy of individuals from the excluded patient group who are tasked with making major decisions about their health (48). As Zur articulates: “it is not possible to properly weigh the risks and benefits and determine the option most in line with one’s values when information regarding these risks does not exist.” (48)

Decisions about psychedelic interventions for patients with comorbidities should not be made based on preconceived notions but should take into account established bodies of safety literature and considerations relevant to the specific therapeutic model, research design, and clinical delivery. Blanket exclusion can paternalistically halt the collection of data that illuminates the possible risks and benefits associated with psychedelic therapies — an important aspect for an *informed* consent process in dynamic and evolving clinical contexts. This ultimately prevent patients from making informed decisions about their own care. As empirical data about the risks emerges, it may be the case that specific and targeted precautionary exclusion of patients with a history of psychosis from particularly risky psychedelic-assisted therapies is justified. However, how to determine that threshold of risk is a difficult question that cannot be determined without an evaluative process grounded in patient-centred conversations and ethical consensus-building, backed up by more robust quantitative and qualitative data.

Diversity

Biomedical psychedelic research has systematically underrepresented racialized and Indigenous peoples, and research has largely neglected the complex role of racial trauma in psychopathology and the psychodynamics of psychedelic therapy (39,57). In an analysis of psychedelic studies conducted from 2000 to 2017, less than 6% of participants were racialized and less than 5% were Indigenous (39,57). Racialized and Indigenous peoples are more likely to be diagnosed with schizophrenia and psychosis spectrum disorders; for example, African American and Latin American individuals are diagnosed with psychosis spectrum disorders at rates 3 to 4 times higher than white Americans of European descent (25,58). As La Torre notes, psychosis-related exclusion in psychedelic-assisted psychotherapy has a direct impact on racialized and Indigenous communities' participation in psychedelic research (25).

Thus, racial injustice stemming from a lack of diversity in participation will be further exacerbated by broad exclusion of people with a history of psychosis. This significant ethical issue also applies to the exclusion of other diagnostic groups from psychedelic research, such as people with a history of bipolar disorder, which also correlates strongly with racialization and social marginalization. The systematic underrepresentation of racialized peoples in psychedelic research participation also casts doubt on whether psychedelic-assisted therapy evidence and theoretical frameworks are generalizable beyond a primarily white (male) European majority (39,57).

EQUITABLE DISTRIBUTION OF THE BENEFITS OF PSYCHEDELIC RESEARCH

Beyond extending harms, protectionist research exclusion is also an ethical failure when it contributes to an unjust distribution of healthcare research benefits between social groups in the long term (28). Exclusionary practices reduce participation and access but also hinder the possibility of developing novel therapies for people experiencing schizophrenia and psychosis spectrum disorders. The psychosis spectrum includes diagnostic categories with some of the most urgent need for innovative treatments, and yet people with a history of psychosis are largely excluded from the benefits of a new category of interventions that have been considered to have therapeutic promise for a range of applications for the treatment of psychosis symptomology and co-morbidities. Contemporary psychosis-related exclusion involves the entire spectrum of psychedelic interventions, which includes dozens of drugs with a wide range of possible clinical applications, psychopharmacological dynamics, and neurophenomenological nuances.

Novel Interventions for Schizophrenia and Psychosis Spectrum Disorders

The negative mental health outcomes of individuals diagnosed with schizophrenia and psychosis spectrum disorders represents a significant and ongoing public health crisis. Despite advances in psychiatric practice and mental health care in other domains, people with schizophrenia continue to face disproportionately poor outcomes, in terms of both morbidity and mortality. Individuals diagnosed with schizophrenia have a life expectancy of 20 years less than the general population, largely due to a combination of suicide (13 times more likely), high rates of cardiovascular disease, and other preventable physical health conditions; this gap has worsened in recent decades (59,60). The rate of sustained clinical or social improvement for people diagnosed with schizophrenia has remained stagnant for decades. Moreover, individuals with schizophrenia frequently experience social exclusion, unemployment, and homelessness, all of which exacerbate the challenges of managing the illness (61). This alarming crisis highlights the urgent need for more effective interventions and therapeutic models that benefit those living with schizophrenia and psychosis spectrum disorders.

In an influential review on the treatment of symptoms of schizophrenia, Correll and Schooler note that current antipsychotic treatments primarily target reducing the *positive* symptoms like auditory hallucinations, while the *negative* symptoms, like asociality and diminished expression, are more challenging to treat and constitute an unmet medical need for which new and effective treatments are urgently needed (62). Innovative and effective interventions for people with psychosis are ethically consequential and would greatly improve the quality-of-life of individuals and their families (4). Although effective interventions and standards of care exist, approved antipsychotic medications are associated with a range of therapeutic outcomes and can have significant adverse effects that vary among different patient groups and clinical contexts (4,63). There is a clear consensus around the need for action and innovation in the context of negative and treatment-resistant symptoms of psychosis; pharmacological developments and novel therapeutic interventions could substantively improve clinical outcomes and quality of life for many people with psychosis worldwide.

In a recent paper, Wolf et al. (2) argue that carefully considered research into psychedelic-assisted interventions has promising possibilities for the treatment of schizophrenia, grounded in sound psychopharmacological and neurophenomenological rationale. As mentioned above, expert analysis of historical research into psychedelic-assisted treatments for schizophrenia has already suggested that low-dose psychedelic administration could be an effective treatment for the negative symptoms of schizophrenia (4). Classic psychedelics are known for enhancing neural plasticity, which may have beneficial effects on a range of neuropsychiatric conditions, including schizophrenia and Alzheimer's and related dementias (2,4,37). The well-established neurogenic and synaptogenic properties of psychedelics, and the association between negative schizophrenia symptoms and cortical atrophy, could provide the foundations of a novel tool for treating schizophrenia (2). It is well established that 5HT-2A receptors mediate the psychedelic effects of classic psychedelic drugs, and these receptors are a key target in the treatment of depression, delusions, hallucinations, and other psychosis symptoms (2,27). It is reasonable to think that psychedelic psychopharmacology could play a role in the development of novel and efficacious pharmacological interventions

targeted at schizophrenia and psychosis spectrum disorders (2). Blanket exclusion from research and drug development prevents the possibility of further investigation into these therapeutic avenues.

Researchers and clinicians have specifically suggested that psychedelic interventions could help treat negative symptoms of schizophrenia and psychosis related to impaired social motivation or asociality. There are currently no accepted treatments for psychosis-related asociality, and impaired social motivation can radically reduce quality of life of people with psychosis-related diagnoses. Given the tendency for MDMA to increase social motivation, empathy, and bonding in healthy volunteers and participants in MDMA-assisted therapy, researchers from the University of California, Los Angeles, have proposed a study investigating the tolerability of MDMA in patients with schizophrenia. While antipsychotic medications can address many symptoms of schizophrenia, they are generally ineffective in treating deficits in social motivation which contribute to significant social impairment. Unlike traditional stimulants, MDMA enhances empathy, emotional closeness, and sensitivity to positive social cues, possibly due to its influence on oxytocin, a hormone linked to social bonding (64).

The researchers propose an exploratory model with safeguards, involving ascending dose administration over the trial period, which will be halted if patients experience increased psychotic symptoms. The researchers also propose exclusion criteria related to aggression or suicidality (64). This proposed study, with sound clinical and psychopharmacological rationale, expert clinical reasoning, and added safety precautions, reflects an ethics of cautious inclusion and tailored investigation that aligns with the inclusive bioethical approach that follows from the central argument of this paper. The results of the project would be a critical first step in understanding the safety profile of MDMA in patients with schizophrenia and setting MDMA dosage standards for future research in this patient group. Beyond this, the study will allow clinicians and researchers to better understand whether psychedelic compounds and psychedelic experiences could play an innovative role in addressing treatment-resistant social deficits related to schizophrenia and other psychiatric disorders.

Psychedelic-assisted interventions may also be a therapeutically useful tool for learning to navigate and process psychosis-related auditory and visual hallucinations. From a phenomenological perspective, both schizophrenia-related and psychedelic-induced hallucinations may be interpreted as experiences with spiritual or metaphysical meaning, despite significant etiological differences (27). Recent research on the connections between LSD, madness, and healing has suggested that the resemblance and shared mystical qualities of psychedelic and psychosis states of consciousness could offer tools for healing (65). Emerging literature suggests that the effects of psychedelic alterations to consciousness in supervised clinical settings would not necessarily overlap with, or worsen, everyday psychosis-related phenomenology. Despite the extremely vivid and immersive qualities of both psychedelic and psychotic hallucinations, people with psychosis using psychedelic drugs can typically distinguish between drug effects and everyday consciousness, and recognize sensory-perceptual changes as transient effects (27). Conversely, psychotic hallucinations tend to be reported as persistent over weeks or months, unpredictable, and harder to differentiate from everyday perception (27).

There may also be specific therapeutic effects associated with psychedelic experiences. Some studies of the mid-20th century using LSD in psychiatric patients with schizophrenia found that participation in group therapy increased while on LSD, and patients exhibited more positive social and emotional behaviour during psychedelic-assisted sessions than during placebo sessions. Participants also experienced other forms of positive affect and psychotherapeutic progress (66). Although no consensus on the therapeutic effects of psychedelics emerged in early studies of psychedelics in people with psychosis during the 1940s and 1950s, participants were generally all institutionalized patients in Europe and studies generally only administered LSD (2). Contemporary psychedelic research involves similar demographic and geographic limitations, which poses significant problems for generalizing negative or positive findings (67).

Psychedelic-assisted interventions targeted at psychosis spectrum disorders are likely to emerge in the mainstream model of psychedelic-assisted psychotherapy. When used in conjunction with evidence-based psychotherapeutic techniques and beneficial set and setting construction, the effects of psychedelic drugs could contribute to long-term decreases in psychiatric symptoms and improved quality of life, including altered self-perception, increased introspection, positive mood changes, and improvements in personality traits such as openness and empathy (68-71). However, other neuropharmacological and therapeutic models, including psycholytic, microdosing, and neuromodulation models, are worthy of preclinical and clinical research consideration as part of developing novel psychedelic-assisted treatments targeted at people with schizophrenia and other psychosis spectrum disorders (2).

Harm Reduction

While biomedical and bioethics scholarship largely focuses on clinical psychedelic-assisted interventions for individuals with specific psychiatric diagnoses, the vast majority of global psychedelic use takes place in non-clinical settings. This includes religious and cultural use, legal, decriminalized and criminalized non-medical use, as well as retreats and unregulated therapeutic use. Legal access to psychedelic therapy is rare and inequitable, and most psychedelic drugs remain controlled and criminalized worldwide. Given their exclusion from clinical research, people with a history of psychosis almost exclusively use psychedelic drugs in unsupervised and unregulated settings, for diverse reasons.

Harm reduction approaches focus on minimizing negative consequences of drug use, and promoting dignity, autonomy, and informed decision-making (72). Research investigating safety, dosage, and effects on psychosis-related symptoms is therefore critical for psychedelic drug harm reduction. Evidence-based harm reduction has been widely adopted in bioethics,

psychotherapy, and public health initiatives as a compassionate and ethical response to potentially risky behaviours like drug use and sexual activity (72).

In the short term, generating evidence on psychosis-related risks of psychedelic use will support individuals making decisions about psychedelic use, as well as therapists, facilitators, and first responders. Such research will also enhance transdiagnostic harm reduction models like the Psychedelics Harm Reduction and Integration model, which focuses on reducing harm among people using psychedelic substances in ceremonies, festivals, and underground therapy (73). Specific data on dosage and safety for people with a history of psychosis can also inform public health initiatives such as labels, warnings, and informational pamphlets in places with legal access to psychedelics. For example, cannabis labelling in Canada includes specific psychosis-related risk information because of research programs investigating the risks of cannabis consumption by people with a personal or family history of schizophrenia. Similar safety research into psilocybin and other psychedelics would substantially improve public health regulation and education in a growing number of jurisdictions with legal psychedelic drug dispensing.

FUTURE CONSIDERATIONS AND CONCLUSIONS

The development of clinical psychedelic therapies for people with a history of psychosis is interesting, controversial, and highly challenging. Due to widely held beliefs and assumptions about both psychedelics and psychosis, individuals with a history of psychosis, who are already marginalized in many ways, are often subject to protectionist exclusionary practices, and are unjustly denied access to equitable consideration within psychedelic research and discourse. People with present, past, or family history of psychosis deserve to be a part of the rapidly unfolding contemporary psychedelic therapy discourse. They deserve to benefit equitably from psychedelic-related research and innovation. Increasing the participation of people with a history of psychosis in psychedelic research is ethically important for current and future populations. Advocating for inclusion of people with a history of psychosis in contemporary psychedelic therapy discourse also adds to emerging literature that seeks to productively rebuild the historical bridge between psychedelic and psychosis discourse that largely deteriorated in the late 20th century (1).

In the complex context of psychedelic therapy research, developing a cautious inclusive approach is not as simple as lifting standardized exclusion criteria writ large. There are clearly substantial risks associated with psychedelic use among people with a history of psychosis, and not all people in this group will be suitable candidates for psychedelic-assisted interventions. However, in parallel with modern bioethics and social justice movements which advocate for more inclusion of marginalized groups within drug research, critically inspecting exclusion criteria, study methodologies, research ethics practices, and clinical frameworks will ultimately support autonomy, improve safety, and advance equitable access to the benefits of psychedelic research (48).

Initially, people with a personal or familial history of psychosis, but no active diagnosis, should be seriously considered for psychedelic-assisted interventions that could effectively address their existing mental illnesses. As neuroscientific and clinical research progresses, people with active psychosis-related diagnosis could be considered for inclusion in psychedelic therapies that target co-morbidities, as well as novel research that could substantiate innovative interventions for psychosis-related symptomology. Frameworks for increasing the participation of pregnant individuals in research, such as risk-tiered models, observational studies, and enhanced consent, show how the historically excluded populations can be included safely and responsibly in research. Psychedelic researchers should adopt similar approaches to include individuals with a history of psychosis, avoiding the long-term harms of blanket exclusion. Clinical case series, case-controlled studies, cohort studies, and population level investigations pose little or no health risk to participants but can generate more knowledge about the intersection between psychedelic use and psychosis-related risks.

There will inevitably be specific risks, both known and unknown, that must be addressed in depth as part of an ethical informed consent process for people with a history of psychosis wishing to participate in psychedelic therapy research. The question of how best to address unknown risks within informed consent practices is already an important conversation within psychedelic ethics but requires deeper bioethical inquiry and empirical research. A more inclusive approach to psychedelic research involving people with a history of psychosis also demands generating interdisciplinary expert consensus and developing research ethics frameworks that specify clinical ethical rationales for exclusion and shift the burden of proof towards justifying exclusion.

As research develops along this new frontier, there are further ethical concerns and considerations that will undoubtedly emerge. Patient autonomy in the context of psychosis ethics and madness discourse is an ethically complex issue, particularly in cases involving non-consensual institutionalization, and cases involving psychoactive drug use. Ethicists and clinicians have argued that the consent process for psychedelic-assisted therapies, which involve potentially transformative and ineffable experiences, as well as states of intense vulnerability, should be enhanced in ways that attend to the important differences between psychedelic-assisted and other kinds of interventions (33). In their recent work, Peterson et al. (37) flag important ethical considerations for psychedelic medicine research in the context of Alzheimer's disease and related dementias, which may have important similarities with the context of psychosis. One of the most important analogous ethical considerations involves the complexities of understanding how psychedelic experiences like "ego dissolution" can affect a person's experience of selfhood, particularly when both pathologies and psychedelic experiences can involve radical alterations in self-perception and self-processing. Other important parallels include age-related vulnerability and the potential exploitation of patient desperation (36). Furthermore, given the alarming history of flagrant unethical experimentation on institutionalized patients in

20th century psychedelic research, there is a magnified ethical gravity surrounding issues of agency, autonomy and consent involving institutionalized people with Alzheimer's and related dementias or psychosis spectrum disorders. Contexts involving people with psychosis or dementia also demand deep ethical consideration of how psychedelic-assisted therapies might influence the complex dynamics of caregiving (37).

A critical approach to bioethical inquiry is important in this case, given the historical mistreatment and abuse of people with lived experiences of psychosis in Western biomedical contexts, and intense social stigma compounded by broader social inequity and intersecting forms of oppression. Although this paper has briefly reflected on cultural norms and impacts of psychosis-related exclusion on diversity, much more must be said about the underexamined social consequences of exclusionary practices in biomedical psychedelic research.

Including people with a history of psychosis in clinical psychedelic research will have important long-term benefits for knowledge production, therapeutic care, and healthcare justice. Responsible and inclusive research will improve safety, increase access, reduce inequities, and prevent long-term harms associated with blanket exclusion. Deeper investigation into the relationship between psychedelics and psychosis has the potential to decrease drug-related harm, enhance autonomy, expand access to effective interventions for co-morbid mental illnesses, and substantiate novel treatments that could improve clinical outcomes and quality of life for countless people.

Table 1. Key Takeaways

Research Exclusion	• Blanket exclusion of individuals with personal or family history of psychosis from psychedelic research is ethically problematic and perpetuates harms that parallel other cases of research exclusion.
Historical Context	• Exclusionary practices are shaped by historical propaganda linking psychedelic drug use with madness and psychosis. • Critical review of this historical legacy is imperative.
Regulatory Oversight	• Many researchers and ethicists exclude people with psychosis as a standardized criteria in psychedelic research. • Ethical review should include justification for exclusion, rather than assuming it as default.
Risk Assessment	• While specific clinical risks exist, actual evidence is limited. • Intuitions may be based on outdated or biased assumptions. • Case-by-case evaluation of research is warranted.
Protectionist Harms	• Overprotection can cause significant long-term harms, such as in the case of excluding pregnant people from drug trials. • Inclusivity, with due caution and safeguards, aligns with a critical bioethical approach.
Safety	• Exclusion prevents collection of critical safety and dosage data. • Without research, future off-label or unsupervised use may pose greater harms.
Autonomy	• Exclusion undermines patient autonomy and informed consent. • People with decision-making capacity should be allowed to make an informed assessment about research participation and risks. • Lack of evidence further hinders informed decision-making in this population group in future clinical contexts.
Access & Justice	• Exclusion reduces access to promising therapies for co-morbid or treatment-resistant conditions. • Racialized and Indigenous communities are disproportionately affected by exclusion due to diagnostic disparities. • All people deserve equitable access to the benefits of psychedelic therapy research.
Cultural Sensitivity	• Many cultures with psychedelic practices have safely included people with experiences that may be considered psychotic or pathological within Western psychiatric frameworks. • Risk assessments should consider cultural context and transcultural safety evidence.
Therapeutic Potential	• Emerging literature suggests that psychedelic therapies have promise for treating negative symptoms of schizophrenia. • Carefully designed studies could lead to novel therapeutic interventions for people with treatment-resistant psychosis spectrum disorders.

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REFERENCES

1. Friesen P. Psychosis and psychedelics: Historical entanglements and contemporary contrasts. Transcultural Psychiatry. 2022;59(5):592-609.
2. Wolf G, Singh S, Blakolmer K, et al. Could psychedelic drugs have a role in the treatment of schizophrenia? Rationale and strategy for safe implementation. Molecular Psychiatry. 2023;28(1):44-58.
3. Blewett DB, Chwelos N. Handbook for the Therapeutic use of Lysergic Acid Diethylamide-25 Individual and Group Procedures. OCR by MAPS, Edits by Erowid. 1959.
4. Haden M, Woods BA, Paschall SA. Psychedelics and schizophrenia: A mystery in history. Journal of Psychedelic Studies. 2023;7(3):174-83.
5. Nichols DE. Hallucinogens. Pharmacology & Therapeutics. 2004;101(2):131-81.
6. Geyer M, Vollenweider F. Serotonin research: contributions to understanding psychoses. Trends in Pharmacological Sciences. 2008;29(9):445-53.
7. Hartogsohn I. American Trip: Set, Setting, and the Psychedelic Experience in the Twentieth Century. Cambridge, MA: MIT Press; 2020.
8. Langlitz N. Neuropsychedelia: The Revival of Hallucinogen Research Since the Decade of the Brain. University of California Press; 2013.
9. Carhart-Harris RL, Kaelen M, Bolstridge M, et al. The paradoxical psychological effects of lysergic acid diethylamide (LSD). Psychological Medicine. 2016;46(7):1379-90.
10. Reardon S. FDA rejects ecstasy as a therapy: what's next for psychedelics? Nature. 13 Aug 2024.
11. Patino C, Ferreira J. Inclusion and exclusion criteria in research studies: Definitions and why they matter. Jornal Brasileiro de Pneumologia. 2018;44(2):84.
12. Johns Hopkins University. Psilocybin treatment of major depressive disorder with co-occurring alcohol use disorder (PsiloMDDAUD) (NCT04620759). ClinicalTrials.gov. US National Library of Medicine.
13. US National Library of Medicine. ClinicalTrials.gov Database.
14. Malleson N. Acute adverse reactions to LSD in clinical and experimental use in the United Kingdom. The British Journal of Psychiatry. 1971;118(543):229-30.
15. Honk L, Stenfors CUD, Goldberg SB, et al. Longitudinal associations between psychedelic use and psychotic symptoms in the United States and the United Kingdom. Journal of Affective Disorders. 2024;351:194-201.
16. Simonsson O, Mosing MA, Osika W, et al. Adolescent psychedelic use and psychotic or manic symptoms. JAMA Psychiatry. 2024;81(6):579-85.
17. Murrie B, Lappin J, Large M, Sara G. Transition of substance-induced, brief, and atypical psychoses to schizophrenia: a systematic review and meta-analysis. Schizophrenia Bulletin. 2020;46(3):505-16.
18. Kendler KS, Ohlsson H, Sundquist J, Sundquist K. Prediction of onset of substance-induced psychotic disorder and its progression to schizophrenia in a Swedish national sample. American Journal of Psychiatry. 2019;176(9):711-9.
19. Stoll WA. Lysergsaure-diathylamid, ein Phantastikum aus der Mutterkorngruppe. Schweizer Archiv für Neurologie und Psychiatrie. 1947;60:279-323.
20. Katzenelbogen S, Fang AD. Narcosynthesis effects of sodium amytal, methedrine and LSD-25. Diseases of the Nervous System. 1953;14(3):85-8.
21. Langs RJ, Barr HL. Lysergic acid diethylamide (LSD-25) and schizophrenic reactions. Journal of Nervous and Mental Disease. 1968;147(2).
22. Myran DT, Pugliese M, Xiao J, et al. Emergency department visits involving hallucinogen use and risk of schizophrenia spectrum disorder. JAMA Psychiatry. 2025;82(2):142-50.
23. Orsolini L, Papanti GD, De Berardis D, Guirguis A, Corkery JM, Schifano F. The "endless trip" among the NPS users: psychopathology and psychopharmacology in the hallucinogen-persisting perception disorder. A Systematic Review. Frontiers in Psychiatry. 2017;8:240.
24. Lev-Ran S, Feingold D, Frenkel A, Lerner AG. Clinical characteristics of individuals with schizophrenia and hallucinogen persisting perception disorder: a preliminary investigation. Journal of Dual Diagnosis. 2014;10(2):79-83.

25. La Torre JT, Mahammadli M, Faber SC, Greenway KT, Williams MT. Expert opinion on psychedelic-assisted psychotherapy for people with psychopathological psychotic experiences and psychotic disorders. International Journal of Mental Health and Addiction. 2023;22:913-37.
26. Johansen PØ, Krebs TS. Psychedelics not linked to mental health problems or suicidal behavior: A population study. Journal of Psychopharmacology. 2015;29(3):270-9.
27. Leptourgos P, Fortier-Davy M, Carhart-Harris R, et al. Hallucinations under psychedelics and in the schizophrenia spectrum: an interdisciplinary and multiscale comparison. Schizophrenia Bulletin. 2020;46(6):1396-408.
28. Friesen P, Gelinas L, Kirby A, Strauss DH, Bierer BE. IRBs and the protection-inclusion dilemma: finding a balance. American Journal of Bioethics. 2023;23(6):75-88.
29. Ann BM. Harming through protection? New England Journal of Medicine. 2008;358(8):768-9.
30. Sessa B. The history of psychedelics in medicine. In: Handbuch Psychoaktive Substanzen Springer Reference Psychologie. Berlin: Springer; 2016. p. 2-18.
31. Rajwani K. Should adolescents be included in emerging psychedelic research? Canadian Journal of Bioethics / Revue canadienne de bioéthique. 2022;5(2):36-43.
32. Strauss D, de la Salle S, Sloshower J, Williams MT. Research abuses against people of colour and other vulnerable groups in early psychedelic research. Journal of Medical Ethics. 2022;48(10):728-37.
33. Smith WR, Sisti D. Ethics and ego dissolution: the case of psilocybin. Journal of Medical Ethics. 2021;47(12):807-14.
34. Marks M, Brendel RW, Shachar C, Cohen IG. Essentials of informed consent to psychedelic medicine. JAMA Psychiatry. 2024;81(6):611-7.
35. Jacobs E. Transformative experience and informed consent to psychedelic-assisted psychotherapy. Frontiers in Psychology. 2023;14:1108333.
36. Jacobs E, Earp B, Appelbaum P, et al. The Hopkins-Oxford Psychedelics Ethics (HOPE) Working Group Consensus Statement. American Journal of Bioethics. 2024;24(7):6-12.
37. Peterson A, Largent EA, Lynch HF, Karlawish J, Sisti D. Journeying to Ixtlan: ethics of psychedelic medicine and research for Alzheimer's disease and related dementias. AJOB Neuroscience. 2023;14(2):107-23.
38. Appelbaum PS. Psychedelic research and the real world. Nature. 2022;609(7929):S95.
39. George JR, Michaels TI, Sevelius J, Williams MT. The psychedelic renaissance and the limitations of a White-dominant medical framework: A call for indigenous and ethnic minority inclusion. Journal of Psychedelic Studies. 2020;4(1):4-15.
40. Rajwani K. Critiquing medical exceptionalism: towards a transcultural psychedelic bioethics. American Journal of Bioethics. 2025;(1):84-7.
41. Celidwen Y, Redvers N, Githaiga C, et al. Ethical principles of traditional Indigenous medicine to guide western psychedelic research and practice. The Lancet Regional Health - Americas. 2023;18:100410.
42. Dos Santos RG, Bouso JC, Hallak JEC. Ayahuasca, dimethyltryptamine, and psychosis: a systematic review of human studies. Therapeutic Advances in Psychopharmacology. 2017;7(4):141-57.
43. Taussig M. Colonialism, Shamanism and the Wild Man: A Study in Terror and Healing. Chicago: University of Chicago Press; 1987.
44. Hartogsohn I. Constructing drug effects: A history of set and setting. Drug Science, Policy and Law. 2017;3:2050324516683325.
45. Noorani T. Containment matters: set and setting in contemporary psychedelic psychiatry. Philosophy, Psychiatry, and Psychology. 2021;28(3):201-16.
46. Gukasyan N, Nayak SM. Psychedelics, placebo effects, and set and setting: Insights from common factors theory of psychotherapy. Transcultural Psychiatry. 2022;59(5):652-64.
47. Hartogsohn I. Set and setting, psychedelics and the placebo response: An extra-pharmacological perspective on psychopharmacology. Journal of Psychopharmacology. 2016;30(12):1259-67.
48. Zur RL. Protected from harm, harmed by protection: ethical consequences of the exclusion of pregnant participants from clinical trials. Research Ethics. 2023;19(4):536-45.
49. Walsh M, Stead V, Sawyer SM, O'Shea A, Watson JM, Anderson KLM. In pursuit of ethical and inclusive research: what ethics committees and disability researchers can learn from each other. International Journal of Qualitative Methods. 2024;23.
50. Krubiner CB, Faden RR. Pregnant women should not be categorised as a 'vulnerable population' in biomedical research studies: ending a vicious cycle of 'vulnerability.' Journal of Medical Ethics. 2017;43(10):664-5.
51. Blehar MC, Spong C, Grady C, Goldkind SF, Sahin L, Clayton JA. Enrolling pregnant women: issues in clinical research. Women's Health Issues. 2013;23(1):e39-45.
52. Helmreich RJ, Hundley V, Norman A, Ighedosa J, Chow E. Research in pregnant women: the challenges of informed consent. Nursing for Women's Health. 2007;11(6):576-85.
53. Smith KW, Sicignano DJ, Hernandez A V, White CM. MDMA-assisted psychotherapy for treatment of posttraumatic stress disorder: a systematic review with meta-analysis. Journal of Clinical Pharmacology. 2022;62(4):463-71.
54. Mitchell JM, Bogenschutz M, Lilienstein A, et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nature Medicine. 2021;27(6):1025-33.
55. Miller FG, Wertheimer A. Facing up to paternalism in research ethics. Hastings Center Report. 2007;37(3):24-34.
56. Shields KE, Lyerly AD. Exclusion of pregnant women from industry-sponsored clinical trials. Obstetrics & Gynecology. 2013;122(5):1077-81.
57. Williams MT, Reed S, George J. Culture and psychedelic psychotherapy: Ethnic and racial themes from three Black women therapists. Journal of Psychedelic Studies. 2021;4(3):125-38.

58. Schwartz RC, Blankenship DM. Racial disparities in psychotic disorder diagnosis: A review of empirical literature. World Journal of Psychiatry. 2014;4(4):133-40.
59. Laursen TM. Life expectancy among persons with schizophrenia or bipolar affective disorder. Schizophrenia Research. 2011;131(1):101-4.
60. Saha S, Chant D, McGrath J. A systematic review of mortality in schizophrenia: is the differential mortality gap worsening over time? Archives of General Psychiatry. 2007;64(10):1123-31.
61. Jääskeläinen E, Juola P, Hirvonen N, et al. A systematic review and meta-analysis of recovery in schizophrenia. Schizophrenia Bulletin. 2013;39(6):1296-306.
62. Correll CU, Schooler NR. Negative symptoms in schizophrenia: A review and clinical guide for recognition, assessment, and treatment. Neuropsychiatric Disease and Treatment. 2020;16:519-34.
63. Tandon R, Belmaker RH, Gattaz WF, et al. World Psychiatric Association Pharmacopsychiatry Section statement on comparative effectiveness of antipsychotics in the treatment of schizophrenia. Schizophrenia Research. 2008;100(1):20-38.
64. Bershad A. Tolerability of MDMA in schizophrenia. (NCT05770375). Clinical Trials.gov. 2023.
65. Wießner I, Falchi M, Palhano-Fontes F, Feilding A, Ribeiro S, Tófoli LF. LSD, madness and healing: Mystical experiences as possible link between psychosis model and therapy model. Psychological Medicine. 2023;53(4):1151-65.
66. Abramson HA, Hewitt MP, Lennard H, Turner WJ, O'neill FJ, Merlis S. The stablemate concept of therapy as affected by LSD in schizophrenia. Journal of Psychology. 1958;45(1):75-84.
67. Michaels TI, Purdon J, Collins A, Williams MT. Inclusion of people of color in psychedelic-assisted psychotherapy: A review of the literature. BMC Psychiatry. 2018;18:245.
68. Tupper KW, Wood E, Yensen R, Johnson MW. Psychedelic medicine: a re-emerging therapeutic paradigm. Canadian Medical Association Journal. 2015;187(14):1054-9.
69. dos Santos RG, Hallak JEC. Therapeutic use of serotoninergic hallucinogens: A review of the evidence and of the biological and psychological mechanisms. Neuroscience & Biobehavioral Reviews. 2020;108:423-34.
70. Reiff CM, Richman EE, Nemeroff CB, et al. Psychedelics and psychedelic-assisted psychotherapy. American Journal of Psychiatry. 2020;177(5):391-410.
71. Schenberg EE. Psychedelic-assisted psychotherapy: a paradigm shift in psychiatric research and development. Frontiers in Pharmacology. 2018;9:733.
72. Pilecki B, Luoma JB, Bathje GJ, Rhea J, Narloch VF. Ethical and legal issues in psychedelic harm reduction and integration therapy. Harm Reduction Journal. 2021;18:40.
73. Gorman I, Nielson EM, Molinar A, Cassidy K, Sabbagh J. Psychedelic harm reduction and integration: a transtheoretical model for clinical practice. Frontiers in Psychology. 2021;12:645246.

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ARTICLE (PEER-REVIEWED)

The Development of Bioethics at The Hospital for Sick Children: From Committee to Integration

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Résumé

Documenter l'évolution et les expériences des services de bioéthique contribue à constituer une base de données sur les réussites et les défis qui peut servir de ressource durable pour toutes les personnes impliquées dans le travail de bioéthique. Cette chronologie de la bioéthique à l'Hôpital pour enfants malades (SickKids) de Toronto, au Canada, est l'un de ces projets de documentation. Elle décrit les événements, les défis et les réussites qui ont contribué à l'évolution du département de bioéthique, qui est passé d'un comité d'éthique à un département de plus en plus intégré aux équipes et aux processus de l'ensemble de l'organisation. À partir d'une combinaison de sources primaires et secondaires, notamment des documents préparés pour des enquêtes d'accréditation cycliques, des coupures de journaux, des livres et des rapports, des notes de réunion, des témoignages directs, des témoignages oraux, des enregistrements vidéo, des communications personnelles et des documents d'archives, nous explorons le développement et l'intégration des activités de bioéthique à SickKids et la manière dont le personnel et les collègues ont abordé la place et l'objectif de la bioéthique au sein de l'institution depuis le début des années 1980 jusqu'à aujourd'hui. Chaque ressource de bioéthique hospitalière reflète et contribue au développement situé de la bioéthique dans des contextes locaux, nationaux et internationaux. Un examen approfondi du développement d'un service permet de préserver les contributions des personnes, des pratiques et des contextes qui ont marqué les étapes importantes de son développement et façonné sa culture organisationnelle. Ce type de travail de réflexion soutient le développement des services de bioéthique, garantit que les enseignements tirés des connaissances institutionnelles restent accessibles aux bioéthiciens actuels et futurs, et apporte des informations transférables qui peuvent éclairer d'autres services et le domaine plus large de la bioéthique appliquée.

Mots-clés

histoire, bioéthique pédiatrique, département de bioéthique, SickKids, Canada

Abstract

Documenting the evolution and experiences of bioethics services contributes to a repository of successes and challenges that can serve as a lasting resource for all involved in bioethics work. This chronology of bioethics at The Hospital for Sick Children (SickKids) in Toronto, Canada, is one such documenting project. It describes events, challenges and successes that contributed to the Bioethics Department's evolution from an ethics committee to a department increasingly integrated into teams and processes across the organization. Using a mix of primary and secondary sources, including materials prepared for cyclical accreditation surveys, newspaper clippings, books and reports, meeting notes, eyewitness accounts, oral testimonies, video recordings, personal communications, and archival materials, we explore the development and integration of bioethics activities at SickKids and the ways in which staff and colleagues navigated the place and purpose of bioethics within the institution from the early 1980s to the present day. Each hospital-based bioethics resource reflects and contributes to the situated development of bioethics across local, national and international contexts. A focused examination of one department's development can preserve the contributions of people, practices, and contexts that defined major milestones in its development and shaped its organizational culture. Reflective work of this kind supports bioethics service development, ensures the lessons embedded in institutional knowledge remain accessible to current and future bioethicists, and contributes transferable insights that can inform other services and the broader field of applied bioethics.

Keywords

history, paediatric bioethics, bioethics department, SickKids, Canada

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INTRODUCTION

Documenting the evolution and experiences of bioethics services contributes to a repository of successes and challenges that can serve as a resource for all involved in bioethics work. This chronology of bioethics at The Hospital for Sick Children (SickKids) in Toronto, Canada, is one such documenting project. It describes the events, challenges and successes that contributed to the department's evolution from an ethics committee to a department that is increasingly integrated into teams and processes across the organization.

The impetus of our project aligns with a characterization of bioethics articulated by scholars such as Onora O'Neill who describes it as "a meeting ground for several disciplines, discourses and organizations concerned with ethical, legal and social questions raised by advances in medicine, science and technology" (1). Among the many academic disciplines that inform bioethics, including philosophy, theology, law, medicine, nursing, social work, sociology, and anthropology, some scholars have articulated that one discipline remains conspicuously absent — history (2). While not a formal historical analysis, our project involves empirical and chronological narrative work[1]. We sought to describe the evolution of bioethics at SickKids using a variety of primary and secondary sources, including materials prepared for cyclical accreditation surveys, newspaper clippings, books and reports, meeting notes, eyewitness accounts, oral testimonies, video recordings, personal communications, and archival materials. Some primary source materials consulted are privately housed within the Department of Bioethics, while others are publicly accessible through academic or hospital archives.

This paper is the product of a learning experience in collecting, synthesizing, and analyzing primary and secondary sources of importance to bioethics at SickKids and the field of paediatric bioethics. This work is primarily a reflection of written documents and oral testimonies that recount events and the individuals who contributed to bioethics work at SickKids. We sought to make reflexivity a priority in our process. The information uncovered was frequently discussed by the first and last authors and through the unique and essential lenses of the multiple authors. This paper does not serve as the comprehensive historical record[2] of the SickKids Bioethics Department or the field of Canadian paediatric bioethics ethics itself, but rather as a rich chronology informed by many primary sources that acknowledges its inherent limitations. This descriptive chronology leans into the department's unique dimensions and complexities. We acknowledge its challenging experiences alongside its positionality and contextual features of being situated in an internationally renowned paediatric research hospital, and specific contributions of department staff to engaging in the work of paediatric bioethics.

Each hospital-based bioethics resource, the Bioethics Department at SickKids being one example, reflects and contributes to the situated development of bioethics across local, national and international contexts. This paper shares the insights garnered from an accounting of the development and integration of its bioethics activities as its staff and colleagues navigated the place and purpose of bioethics within the institution, from the creation of a formal ethics committee in the early 1980s to the present day. A focused examination of one department's development can preserve the contributions of people, policies, and practices that defined major milestones in its development and shaped its organizational culture. Reflective work of this kind supports bioethics service development, ensures the lessons embedded in institutional knowledge remain accessible to current and future bioethicists, and contributes transferable insights that can inform other services and the broader field of applied bioethics[3].

SICKKIDS: THEN AND NOW

The Hospital for Sick Children was founded in March of 1875 with the rental of an eleven-room two-story red-brick house on 31 Avenue Street that, by July of the following year, had treated 44 young patients (5). More than a century and a half later, The Hospital for Sick Children has evolved significantly. The 2024/2025 SickKids Annual Report reflects the scope of clinical care offered, reporting the average number of inpatient beds occupied daily at 293, emergency visits for the year totaling 62,964, and the hospital engaging in 12,241 operating room cases (6). In 2024/2025 the hospital staff, trainees, and volunteers totaled 15,119 (6). Supported by its academic affiliation with the University of Toronto, the hospital is competitive internationally for research intensity and output and is home to Canada's largest hospital-based child health research institute (7). The growing scope of the institution's activity over the years informed the rich range of ethical issues it faced. While its ethics supports were consistently resourced and engaged through the years, funding for bioethics staff and trainees were for the most part comparable with other Ontario bioethics services.

THE 1970s/1980s

The growth and institutionalization of bioethics at SickKids in the 1980s was informed by significant developments in the progression of the field of bioethics in the late 1970s. Several warrant brief reference in our exposition of the landscape in which discussions about bioethical issues took place at SickKids during this period. The Belmont Report was published in 1979 by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (8,9) to

[1] The authorship team drew inspiration from Berg and Lune's (3) methodological guidance for historical research, which outlines a process for identifying sources and evaluating their relative authority or insight to advance the aims of the historical inquiry.
[2] We apologize for any omissions of individuals or projects that were genuine features of the work and evolution of Bioethics at SickKids. We would invite individuals to share these omissions with us should there be opportunities to include them in future iterations of this chronology.
[3] Recent examples of this kind of reflective work in clinical ethics include: "1997: The Birth of ASBH in pictures and commentaries", a product of the American Society for Bioethics and Humanities (ASBH) History Project prepared by Loretta M. Kopelman (4) and made available publicly on the ASBH Website and "Moral Histories: Stories and Voices from the Founding Figures of Bioethics" a project of the Johns Hopkins Berman Institute of Bioethics that features interviews with founding figures of bioethics in the United States and Canada.

describe ethical principles that offer a foundation for the protection of vulnerable persons who participate in medical research. It has been suggested (10,11) that a historically overlooked task the Commission struggled with was how to apply the concept of autonomy to research involving children in a post-World War social landscape[4]. Ultimately, the committee landed on several essential guidelines for conducting research with child participants. These guidelines focused on the need for parental approval, the requirement to seek assent for children older than 7 years (10,11). These developments informed ethics integration with research at SickKids. The emergence of principlism also influenced the development of how the bioethics team approached clinical and research ethics consults in their early days, as well as the earliest iterations of its ethics frameworks. These important events were not only discussed but shaped the development of bioethics at the hospital.

As noted, the publication in 1978 of James Childress and Tom Beauchamp's first edition of The Principles of Biomedical Ethics gave rise to principlism as the predominant theory in applied ethics (10,12). Their theoretical framework for analyzing ethical issues in healthcare focused on respect for autonomy, nonmaleficence, beneficence, and justice (10). Beauchamp and Childress's Four Principles are now fundamental to current approaches to navigating ethical issues in healthcare (10,13). In the same year, Warren Reich published what is considered the first encyclopedia of bioethics — aptly titled the Encyclopedia of Bioethics — which formulated a widely accepted definition of bioethics as the interdisciplinary "systematic study of human conduct in the area of the life sciences and health care, insofar as this conduct is examined in the light of moral values and principles" (13). In addition, it articulated parameters for the scope of the field of bioethics as an academic discipline, provided one of the first systematized organizations of knowledge (in a Western context) of the field, and included a historical overview[5] of its development (13,14). In reflections on his work many decades later, Reich offered insight into his observations that bioethicists in the 1970s systematically neglected most problems related to children, aside from issues of consent, which were a popular topic of discussion at the time (14). One reason for this neglect, Reich believed (14), was the highly restrictive conceptual framework of bioethics developed in the 1980s which made it difficult to effectively address or include the experiences of children. One of the distinct features of the Bioethics Department at SickKids was being conscious of this gap and committed to redressing it by contributing to the developing canon of paediatric bioethics.

The early ethics committee

SickKids was an early adopter of the formalized ethics committee model. Its inaugural ethics committee, established in the early 1980s, was first chaired by Geoff Barker, who was Director of the hospital's Paediatric Intensive Care Unit (PICU) (see Appendix 1 for the bioethics roles of individuals listed throughout this paper). Research conducted in 1984 found only 18% of hospitals in Canada had such committees (15). By 1989, ethics committees were established in 70 of 120 (58%) English-language hospitals in Canada with over 300 beds (16). Storch and colleagues have suggested this phenomenon can be linked to a Canadian Hospital Association policy statement (17) and a change in the Guide to Accreditation of Health Care Facilities in 1986 (18), which proposed that health care facilities might establish a multidisciplinary committee to address the need for policies on biomedical ethical subjects. While the policy statement was put forward as a recommendation, it is possible that healthcare administrators may have taken it as an accreditation standard (16), which in the context of a public healthcare system can necessitate quick organizational action. Similarly, in the United States, the 1992 Accreditation Manual for Hospitals Supplement from the Joint Commission on the Accreditation of Healthcare Organizations endorsed the use of committees for consideration of ethical issues arising from patient care (19). By the end of the 1980s, the "ethics by committee" model was the dominant approach to ethics consultation in healthcare institutions across North America (15,16).

In the 1980s, SickKids began a fruitful relationship with scholars at the Westminster Institute for Ethics and Human Values, which had been established in 1978 in London, Ontario (20). The Director of the Westminster Institute, Abbyann Lynch, joined SickKids in 1986 as a consultant bioethicist and served on the newly formed ethics committee. The Committee's broad membership consisted of approximately 20 individuals drawn from diverse backgrounds, including medicine, law, social work, nursing, patient representatives, and hospital board members. In 1983, Jonathan Hellmann of the Division of Neonatology was appointed Committee Chair. Lynch was doing bioethics consultations from her first interactions at SickKids, mobilizing the ethics committee when she determined a consult would be aided by the diversity of their collective expertise and experiences. At full committee meetings, Lynch would briefly describe the clinical consultations she led, accounting for the issues about which she was being consulted. Together Lynch and Hellmann, sought to focus the efforts of the committee on establishing a standardized process for ethics consultation by ethicists and the enhancement of ethics education and ethically-informed policy development within the institution.

The merits of consultations by full committee versus the use of a single consultant bioethics model continued to be debated among healthcare organizations into the 1980s and 1990s. Some of the defenders of the ethics by committee model believed that consultation by an institutionally approved group sent an admirable message that ethics ought to be practiced in community, for the benefit of the community (21). On the other side of the debate, some organizations were choosing a single consultant bioethics model which allowed ethics consultations to be more flexible, performed as they were by a sole ethicist who could then engage with a committee when appropriate (22). Disagreement also existed about whether ethics committee compositions appropriately distinguished individuals with an interest in ethics from those with specific training and expertise in

[4] The Commission's deliberations took place during the post-World War II period of rapid change in the understanding of childhood and adolescence, brought on in part by school children's roles assuming risks in the polio vaccine trials, and the civil rights movement and evolving legal precedents that gave them additional safeguards in treatment access and research participation (11).

[5] The Encyclopedia also included a comprehensive history of the discipline — one of the credited contributors to this section, Abbyann Lynch, then an Associate Professor of Philosophy at St. Michael's College, University of Toronto, would become one of the foremost leaders in paediatric bioethics ethics at SickKids, as well as within the Canadian and International communities.

the discipline. General thinking at the time was that ethics committees should be constituted to ensure diverse representation of professional, cultural, political and social biases, as well as diverse values and belief systems (22). On this view, the strength of the committee's ethical expertise was not understood as being at an individual level but rather at a collective one. A committee's ability to navigate ethical issues would thus be enriched by the diversity of experiences and thought within the committee membership.

Over time, SickKids adopted a single consultant bioethics model which became a wide-spread norm for bioethics consultation in Canada and beyond. Within the ethics committee, a subgroup was formed which developed a consultation process open to anyone at the hospital. Committee members were supportive of moving forward with the model of consultation by bioethicists, even though it was different from the model of consultation predominantly used across North America at the time[6]. The committee was initially concerned about how medical staff would react if anyone on their team could request an ethics consult. They brainstormed about how to ensure that all hospital staff would be aware of this model and empowered to avail themselves of this bioethics service. It took time to disseminate the model and rationale, but it eventually became well accepted. In addition to patients and families, any staff member or trainee could request a consult without declaring their intention or seeking permission. The bioethicist would work out with the requestor who else should be involved with discussions. We understand that hospital staff found bioethicists Lynch and Baylis to be trustworthy and discreet.

Similar to many such services across Canada, at SickKids bioethics services worked with a range of documentation modalities in an attempt to capture the quantities and qualities of ethics consultations. At different stages documentation has included identifiable information, broad definitions of what constitutes a consultation, and narrower definitions. Over the years, bioethics consultation evolved to being available to any patient, substitute decision maker, staff, trainee or volunteer with an ethical issue linked to their experience at SickKids.

Child rights

To appreciate the landscape in which discussions of child rights would were taking place at SickKids, it is important to examine the 1989 adoption of the United Nations Convention on the Rights of the Child (UNCRC) by the United Nations General Assembly, an event that would shape the zeitgeist of human rights and bioethics (26). One of the first comprehensive articulations of children's rights in international law, the UNCRC had significant implications for how rights and interests of children were understood in healthcare settings. Specifically, the UNCRC charged member states with ensuring that basic survival requirements were met for all children, including food, clean water, and health care and strongly stipulated that children should be afforded rights of protection against neglect and exploitation. Crucially, the UNCRC emphasized that children have a universal right to education, access to information, and to express their views in all matters affecting themselves — with their views being given due weight in accordance with their age and maturity, in member states responsible for protecting and promoting these rights (27). The Convention was effective in entrenching, in the canon of children's human rights law, the importance of the parent-child relationship, children's positive right to protection and children being individuals in their own right rather than merely extensions of their parents (28). Underscored by the departmental documents reviewed for this project, these concepts would go on to be of enduring relevance to the care of children at SickKids, the work of Pro Bono Law Ontario at SickKids, and to cases where bioethics services were engaged.

The inclusion of the concept of the best interests of the child[7] as a guiding principle for all articles in the Convention was similar to the use of this concept in judicial cases across North America. Legal decisions addressing ethically complex issues in paediatrics and scholarship in paediatric bioethics have a long bi-directional relationship where each frequently informs the reasoning of the other. Cases which did so in the 1980s (and early 1990s) asked courts to weigh in on the rights of persons with mental disabilities to be protected from sterilization[8], the responsibilities of parents as substitute decision-makers[9], the interests of children in receiving religious instruction[10], and the substantive legal content of best interests as a guiding principle[11]. Bioethics services at SickKids have always worked in collaborative relationships with health lawyers and health law

[6] It should be noted the context for the development of ethics committees within healthcare institutions in the United States was influenced by concerns regarding the legal liability of physicians in cases were there existed significant ethical questions regarding the permissibility of withdrawing life sustaining care (23). A notable legal case which took up these questions was that of Karen Anne Quinlan, in 1976, and occurred as at a time when ethics committees were becoming more widespread (24); the issue has been revisited in several other cases in the US, including, notably, that of Nancy Cruzan in 1990 (25).

[7] The best interests of the child is generally expressed as a principle or standard in Canadian law and bioethics. The principle is considered a substantive right and guiding principle that covers all rights laid out in the UNCRC. Examples of express references to the best interests of the child in federal law adopted in the 1980s include the Divorce Act, 1985 (29), and the Citizenship Act, 1985 (30).

[8] Both the best interests standard and the *parens patriae* doctrine were discussed at the 1986 Supreme Court of Canada (SCC) in E. (Mrs.) v. Eve (31) regarding a mother's consent to the sterilization of her adult daughter who had disabilities. While this controversial case concerned substitute decision-making on behalf of an adult, it set a precedent that would influence the application of the *parens patriae* doctrine and best interests standard to future SCC cases on the rights of children.

[9] In 1983, guardians of an infant in New York born with significant disabilities challenged the legal theory behind a set of federal rules implemented in the early 1970s, that nontreatment for infants born with disabilities was discriminatory and an infringement on the civil rights of said infants. The case went to the US Supreme Court, which ruled these rules as unnecessary to protect the rights of infants with disabilities and as interfering with parental rights to consent or refuse treatment based on what they deemed to be in their infants' best interests (32). In response, the US Congress adopted an updated set of guidelines. As some scholars have pointed out, while distinct, both sets of rules are often associated and referred to as "The Baby Doe regulations." There has been vigorous academic debate on the inconsistency of these rules, presently, with the best interests of the child principle, individualized decision-making, and quality of life concerns (33-35).

[10] This issue was discussed in Young v. Young heard before the Supreme Court of Canada in 1993 (35). The court considered the best interests of children to be a child-centric analysis that should not strictly focus on the absence of harm.

[11] Several North American legal cases in the 1980s began to use and debate the substantive legal content of the best interests principle. For cases heard at the Supreme Court of Canada, see (31,36-44).

professors within and outside the organization, including hosting many Bioethics Grand Rounds where legal experts presented on a new piece of legislation or new legal decision that had an ethical dimension relevant to paediatrics.

The 1980s was a significant time for both the translation of legal and ethical thought into the rights and treatment of children in healthcare settings, and reflections on how the work of ethics consultants and committees in hospitals ought to meet the pressing challenges before them. The SickKids model had ethics consultations and adjacent activities led by experienced bioethicists with explicit background in philosophy and applied ethics. This model set the tone for the creation of a Department of Bioethics at SickKids in 1991.

THE 1990s

Founding the "Department of Bioethics"

SickKids founded its Department of Bioethics in 1991, embracing the recommendation of the ethics committee established almost a decade earlier. Abbyann Lynch was appointed Director and her prior colleague at the Westminster Institute, Françoise Baylis, joined the department as its first bioethicist. The bioethicist lineage that followed in the subsequent decade included Christine Harrison, Mary Rowell, Mona Sidarous, and Louis Charland in a part-time capacity. Research activities were supported by Louis Kunicki and several student volunteers and research assistants. The Bioethics Committee remained operational until 1993/4 when it was renamed the Bioethics Advisory Committee.

The Department was introduced to the wider hospital in the Department's inaugural newsletter, *Calyx: Ethical Issues in Paediatrics*, which was also established the same year,

> We look forward to working with others involved in the care of paediatric patients, and the study of ethical issues, hoping thereby to increase the awareness of staff and parents concerning ethical issues relating to the provision of health care to infants, children and youths (45).

Despite much enthusiasm for the announcement, not everyone in the institution responded positively. The presence of the new Department highlighted an underlying critique of bioethicists whose role was (anecdotally) misconceived by some as policing from a perceived moral "high ground." It is said that on the first day of the Bioethics Department's establishment, a sign was posted on a wall just outside a SickKids operating room saying, "The Ethics Police Have Arrived." This prompted recognition of the need to build relationships with different departments to integrate more closely with the wider multi-disciplinary teams and facilitate collaborations. The Department bioethicists throughout the decade would realize acceptance of their role. This was influenced, at least in part, by their efforts to navigate the unique practice cultures of different clinical departments in the hospital. Each subculture had a strong influence on the receptiveness of its members to ethics support offered by the Department. It would take time to understand the bureaucratic structures, individual personalities, and team dynamics, and this influenced the approaches taken by Lynch, Baylis, and later Harrison, Rowell, and Sidarous, to build a collaborative ethics program. As Director, Lynch led and contributed candidly to conversations occurring across Canadian healthcare institutions on the challenges of providing collaborative ethics support (46).

In 1991, the Bioethics Committee developed and published institutional guidelines for bioethics consultations (46). The guidelines highlighted the purpose and process for ethics consultations and represented a significant shift towards acknowledging and standardizing the role of bioethics consultations within the institution. The Department activities evolved throughout the decade and were ultimately organized under four pillars of activity across clinical, educational, and scholarly domains. They were, and continue, to include:

1. Ethics Consultation — seeks to identify, analyze and support the management of ethical issues.
2. Policy Development — seeks to support the management of ethical issues through policy and guideline development at an organizational level.
3. Education on Ethics and Ethics in Education — seeks to deliver ethics education, and to identify ethical issues in the provision of education across the hospital.
4. Research on Ethics and Ethics in Research — seeks to conduct bioethics research, bioethics scholarship and ethical review of research conducted by hospital staff and with hospital patients.

Tracking ethics consultations

Ethics consultations have consistently been a priority of bioethics services at SickKids, from the inauguration of the Department. Pervasive questions at SickKids, which continue to parallel broader debates in the profession (48-56) related to tracking consultations, included whether markers of quality would be consultation numbers increasing over time (indicating requestor satisfaction or limited learning) or reducing (indicating learning that could be applied in future cases or perceived limited utility). In its early years, tracking was conducted in paper form: each consult had a file, collation was done for Departmental priority setting and annual reporting and printed in a paper-bound bi-annual report. Records of this period with regards to ethics consults numbers were shredded during the hospital's move away from "shadow charts", recognizing the need to have all relevant consultant materials in the single patient chart. Due to these limitations, and despite our best efforts,

we are unable to meaningfully compare data sets for clinical consultation across the development of the Department. We return below to how, in the 2000s, data collection methods on tracking ethics consultations evolved as a priority for the Department.

Creating spaces for paediatric bioethics discourse

The Department had a consistent commitment to creating spaces to engage in multiple forms of ethics discourse. Department members have always supervised and mentored trainees in graduate programs, electives, fellowships and even volunteer opportunities. Members have taught formal courses through the University of Toronto and provide all forms of didactic and discourse education across the hospital. In conjunction with efforts to engage in education, the dissemination of scholarly work through publication emerged as a distinct priority for the Department during the 1990s. An oddity for a hospital at the time, SickKids ran an in-house publishing press which enabled the Department to produce several significant publications. Baylis led the development of several books published by the Department during the 1990s. The 1993 publication of *Paediatric Ethics in a Canadian Context* (57) and 1994 publication of *Institutional Policy in Paediatric Practice: Documenting Canadian Experience* (58) offer unique windows into the evolution of Canadian paediatric clinical ethics, and the latter which includes the then terms of reference for hospitals ethics committees across Canada. Similarly, *Codes of Ethics*, published first in 1992 (59), and then reedited in 1999 (60), detail the ethics and professional practices codes of many health disciplines and allied health professions during this period. From the additions and exclusions across both editions, it is possible to discern tonal shifts in the values prioritized by institutions over the decade. These books were well received, and often due to high demand, received second prints.

As part of its focus on producing high quality written work, the Department newsletter, “Calyx”, launched in 1991, became a popular publication within the hospital and continued to be published into the early 2000s. Many contributors to Calyx, including scholars, clinicians, and students worldwide, would go on to have careers in clinical and academic bioethics across North America. In searching through department documents for informative materials, we unexpectedly found an international mailing list which documented the broad reach of the newsletter (61). The thoughtful debate and dialogue in the pages of Calyx found its way into the hands of scholars, healthcare professionals, and bioethicists in Canada, the United States, Australia, China, Columbia, England, Israel, Russia, and Trinidad, among others. Notably, many core topics discussed in Calyx articles from the 1990s (62-67) — including determinations of best interests, the capacity of children to participate in clinical and research decision-making, and ethical distinctions between consent and assent — remain salient ethical issues in paediatric healthcare institutions today.

Departmental collaborations and communities of practice

Acknowledging the significance of ethical issues to paediatric clinical practice and decision-making, in 1991 the Bioethics Department launched the “Everyday Ethics” bioethics discussion series, which had wide participation from multiple clinical departments and often featured collaborative presentations between ethicists and healthcare providers[12]. The popularity of the series drew attention from other hospitals in the Toronto area and collaborations with those hospitals were facilitated through video conferencing, which would grow more reliable as the decade progressed. While collaboration was a priority for the team, being a standalone department also had its own distinct benefits; notably, it granted the Department significant agency over its activities and hiring practices while enhancing institutional engagement through active participation in decision-making committees. During this time, the Department championed numerous initiatives, including educational activities for staff and trainees, and broadening access of the ethics consult service to staff, parents, patients, trainees, and volunteers, thus allowing direct access to a bioethicist.

At the start of the 1990s, several bioethics departments within Toronto’s academic hospitals, including SickKids, were navigating their relationship with their common academic partner, the University of Toronto. In personal communications among department bioethicists, these hospitals were often collectively referred to as “The University Avenue hospitals,” reflecting their proximity on this downtown street. While the ethics committees and departments at the University Avenue hospitals had a record of collaboration, talks began with the University of Toronto to establish a more solidified partnership. Lynch had long been an ardent advocate for the development of a large-scale paediatric focused bioethics centre. However, after extensive discussions between SickKids and the University of Toronto about various models for bioethics collaboration, she would be disappointed as a different approach was ultimately adopted.

In 1995, SickKids, in collaboration with Sunnybrook Hospital, Mount Sinai Hospital, Toronto General Hospital, and the University of Toronto founded the University of Toronto Joint Centre for Bioethics, often known by its shortened moniker “The JCB” (62). The JCB marked a significant departure from traditional models of bioethics centres based either in universities or in healthcare institutions. Designed collaboratively in an attempt to bridge the gap between bioethics theory and practice, the centre sought to both advance bioethical thinking and enhance clinical ethics practices in healthcare (62). The JCB continues to maintain a strong relationship with the Bioethics Department at SickKids. Nevertheless, concerns that involvement with the JCB — given its broad range of focus areas — might overshadow the specific needs of paediatric bioethics remained

[12] The Bioethics Department maintains a record (68) of all the sessions that occurred in the series. A few notable examples include: *“Family Secrets: Preserving Confidentiality in the Practice of Genetic Counseling”* co-presented by J. Siegal (Genetics) and A. Lynch (Bioethics) in 1994; *“The Doctor will be with you in just a moment but not in person, the ethics of telemedicine”* co-presented by J. Cooper (Surgery), A. Paven (Telemedicine) and M. Rowell (Bioethics) in 1995; C. Harrison and C. Sass-Kortas in 1996 “Better or Worse? Proposed Changes to Ontario’s Consent Law”; and F. Baylis and A. Goldbloom (Bioethics/Law) in 1992 “Ontario’s proposed consent to treatment legislation: you, your patients, and their rights advisors.”

relevant throughout its history. SickKids bioethicists have advocated for strong paediatric ethics representation and education within the JCB, since its founding[13].

Also in 1995, the Royal College of Physicians of Canada issued a call to bolster bioethics education[14] among Canadian medical residents. Members of the SickKids Bioethics Department[15] collaborated with the Paediatric Ethics Network (PedEthNet) to create a first of its kind medical ethics curriculum for use in paediatric residency programs. The comprehensive curriculum, "The Good Paediatrician: An Ethics Curriculum", was published in 1996 (69). Despite the intention of its authors, the curriculum was never formally adopted by Canadian medical schools. In speaking with individuals who worked on the project, we learned that the team lacked sufficient support to demonstrate the value of the material to the interest groups responsible for curriculum design, monitoring, and decision-making in Canadian medical schools. While today the Government of Canada Tri-Agency funding programs emphasize and support robust knowledge mobilization plans, this is a relatively new development. If the anecdotal reports are correct, they underscore a pervasive issue in the funding of bioethics-oriented research projects — that regardless of the quality of the work produced, if insufficient support exists to engage interest groups and decision-makers the true value of this work remains unrealized.

Lynch's championing of paediatric bioethics was continued by her successor, Christine Harrison, who took up the position of Department Director following the end of Lynch's[16] tenure in the mid 1990s. Harrison created the Canadian Paediatric Bioethics Network (CPBN) to offer opportunities for bioethicists working with children and families to have collaborative dialogue with one another. The number of paediatric bioethicists was and continues to be relatively small in Canada. The CPBN offered a novel opportunity for an organized community of practice for colleagues working across broad geography and different provincial healthcare systems. Today, the Canadian Bioethics Society (CBS) supports several interest groups[17], but the CPBN, today recognized as the Canadian Paediatric Bioethics Interest Group, got its start in the mid 1990s[18]. In its earliest iterations the CPBN would connect via a telephone conference call several times a year and hosted an in-person group meeting at the annual Canadian Bioethics Society conference. The CPBN gained prominence over the decade hosting a popular pre-conference ahead of the annual CBS conference which for eight years[19] running (up until the COVID-19 pandemic). These paediatric bioethics pre-conferences were a unique feature for a general bioethics conference as they isolated explicit space for the conference theme to be examined through the lens of paediatric bioethics.

Engaging on issues of consent, capacity, and substitute decision-making

In the early 1990s, the Government of Ontario recognized the need to address healthcare consent issues comprehensively, particularly after concerns were raised regarding patient rights, the role of substitute decision-makers, and legal standards around consent. In 1992, Ontario introduced legislation specific to healthcare treatment decisions — the Ontario Consent to Treatment Act (72). This Act formalized the common law principle that decision-making ability is based on capacity rather than age; in Ontario there would be no age of consent for treatment. During this time, the Bioethics Department hosted several Everyday Ethics sessions on the impact of the legislation at SickKids, including a 1992 Everyday Ethics session hosted by Baylis and Goldbloom (73). Bioethicists at SickKids proposed recommendations to The Ministry of Health concerning these legislative changes that would be consequential to the creation of the Ontario Heath Care Consent Act (HCCA) which came into effect in 1996 (74). The HCCA remains the Ontario law that governs the ability of persons (regardless of age) to consent to healthcare treatments and admission to care facilities.

Reflecting provincial efforts to address healthcare consent issues, bioethicists at SickKids were engaged in a myriad of complex discussions regarding consent during this time. A particularly challenging question centred on how much responsibility lies with a hospital to contact former patients if new information suggests that they may have sustained unforeseen harm during treatment. Prior to 1985, Canada did not have a comprehensive testing program for the transmission of blood-born viruses, like HIV, HBV, or HVC, built into its voluntary blood donation system (75). In what is considered a significant public health failure, a great number of Canadians received blood products contaminated with HIV and Hepatitis C. The Government of Canada would overhaul the governance of the domestic blood supply following the "Krever Report" in 1997 (75). The Report directed hospitals to undertake reviews of their records in order to identify former patients who received blood and blood

[13] They have contributed to the education and training of over 400 students and fellows who participate in graduate programs, bioethics electives, and clinical ethics fellowships hosted at the JCB

[14] Broadly, the objectives were to integrate bioethics skills and knowledge into the clinical practice of residents in accredited programs, to assist postgraduate specialty and subspecialty programs in teaching bioethics to their residents, to develop model curricula for use within these programs, and to develop methods to evaluate the bioethics knowledge, skills, and attitudes of residents.

[15] Then SickKids staff members affiliated with the project included Abbyann Lynch (bioethics), Francoise Baylis (bioethics), Christine Harrison (bioethics), Jonathan Hellmann (neonatology), Robert Hillard (paediatrics), Mary Rowell (bioethics), Susan Tallett (medical education).

[16] Abbyann Lynch is remembered, following her passing in 2019, as a distinguished philosopher, bioethicist, mentor, and fierce advocate for the rights of children. She was a founder of the Canadian Bioethics Society and a charter member of the National Council in Bioethics in Human Research. In her lifetime she received multiple prestigious honours, including induction into the Order of Ontario (1993) and the Order of Canada (1997) (70).

[17] In an effort to support the role of the Canadian Bioethics Society and benefit from its engagement efforts across Canada, in 2025, the CPBN evolved into the Canadian Paediatric Bioethics Interest Group. As of August 2025, additional interest groups include: Indigenous Ethics, Rural and Remote Ethics, Ethics in Nursing, Environmental Ethics, Religion and Bioethics, MAiD and Bioethics, Disability Ethics, Practising Healthcare Ethicists, Artificial Intelligence and Healthcare Ethics, Global Bioethics, Moral Distress, and Mental Health and Substance Use Health (71).

[18] According to the information we were able to obtain, the CPBN was founded in the mid-1990s as ethicists, including Harrison, organically moved existing regular conversations and collaborations into a more formal network with recurring meetings, collaborative mentorship, and information sharing.

[19] This important streak ended when the COVID-19 pandemic put a stop to in-person events. However, the CPBN is still active, and at the latest Canadian Bioethics Conference (co-hosted with the International Conference on Clinical Ethics and Consultation) in Montreal (Spring 2024), the CPBN held an afternoon meeting with 60+ members in attendance.

products between 1978 and the end of 1985, and where such records were still in existence, to directly notify these patients to inform them about the risks of HIV infection and provide counselling about the advisability and availability of HIV testing.

Aside from the contributions the Department made to the creation of the HCCA, by the end of the decade, Everyday Ethics sessions also made space to discuss central issues such as what it means to navigate decision-making in the context of participatory rights, emerging autonomy of young people and bioethics principles such as best interests of the child[20]. Several influential decisions[21] at the Supreme Court of Canada (SCC) on questions regarding the rights of children and the value of the family structure demonstrate that these issues were, and continue to be, important to Canadians.

THE 2000s

Under the continued leadership of Harrison, the early 2000s marked a period of change within the Bioethics Department (see Appendix 2 for diagram of the Department's structure as of 2025). In 2001, Randi Zlotnik Shaul was hired as a bioethicist and became an active member of the Research Ethics Board at SickKids, building on the engagement of Lynch, Baylis, and Rowell in contributing to research ethics education and ethics oversight of hospital-wide research activities.

Reporting relationships and academic linkages

This new decade also ushered in changes in the Department's reporting relationship to the hospital's senior administrative team. The reporting relationship of an ethics service affects its activities and capabilities and is an under-discussed topic in organizational ethics[22]. Oral accounts indicated that in 1991, the Department first reported to the Executive Vice President and Chief Operating Officer, Alan Goldbloom, then later to the VP of Medical and Academic Affairs, Ronald Laxer, strengthening their relationship with physician groups within the hospital. In the early 2000s, the Department began reporting to the Chief of Nursing and Interprofessional Practice, Margaret Keatings, which presented a new opportunity to bolster engagement with interprofessional groups within the hospital. Pam Hubley followed Keatings in her role as Chief of Nursing and Interprofessional Practice. When Hubley's portfolio later expanded as she became VP of the SickKids Learning Institute and International Nursing, bioethics remained in her portfolio. The Department is currently benefitting from interprofessional relationships built over time as well as integration within medical teams facilitated by reporting to Lennox Huang, CMO and VP Medical and Academic Affairs. Similar to any bioethics service embedded within a large organization, the ability to provide support and have an impact is tightly linked to reporting relationships and the support garnered from executive leaders. Each period of the Bioethics Department's development is characterized by distinct institutional opportunities and challenges manifested by leadership support, available funds, and collaboration across hospital committees.

Impact and quality in academic health sciences centres are often recognized through academic designations. Consistent with their long-standing commitment to academic contribution and integration, departmental bioethicists have been supported in seeking academic appointments at the University of Toronto, fulfilling reporting and promotional requirements in the departments of Paediatrics, Family Medicine, the Institute for Health Policy, Management and Evaluation and the Dalla Lana School of Public Health; additional appointments were made in the School of Graduate Studies at the University of Toronto and, where pertinent other universities, to facilitate membership on graduate student thesis supervision committees. Given the relatively small number of non-physician hospital-based bioethicists that move forward for promotion in these university departments, each stage of the promotion pathway was somewhat novel for both the bioethics candidates and their reviewers in these departments[23].

Ethics engagement within and outside of SickKids

It was during this era that the Department adapted some of its educational activities to meet the evolving needs of the hospital. Everyday Ethics was rebranded "Bioethics Grand Rounds" to fit more comfortably into established language within the educational infrastructure of medical departments at SickKids. The Bioethics Grand Rounds[24] were not necessarily a new offering in terms of content or structure, but the new branding signposted to clinicians that the Department understood their educational culture and were crafting opportunities to engage in moral discussion with clinicians in a more familiar, and incentivized format (the Department sought and maintains a qualification to provide CME[25] credits). Given their popularity, several Bioethics Grand Rounds have become annual offerings. The "Bioethics Book Review" for example, discusses a pre-selected novel that engages with ethical health-related issues affecting young people, while the "Bioethics Year in Review" highlights key paediatric ethics issues that have made media headlines during the year.

[20] Everyday Ethics sessions hosted by the Department between 1995-99 discussed: the ethics of surgical sterilization of children with profound disability — *"Whose Needs are Being Met?"* (76); a child's right to refuse treatment — *"When Does No Mean No?"* (77); respectful involvement of children in research — *"Yes They CAN Understand!"* (78); and best interests in the use of alternative treatments — *"Who Decides What's Best?"* (79), among many others.
[21] The decision made in Young v. Young (36) situated the best interests of the child as child-centric analysis that should not focus strictly on harms. In 1999, Baker v. Canada (Minister of Citizenship and Immigration) (80), a significant administrative law decision of the Supreme Court of Canada, among other issues referred to the UNCRC in their analysis. In Gordon v. Goertz (81), the court considered the interests of children with a child-centric analysis.
[22] This relationship affects the type of issues they are informed of by senior leadership, the mechanisms by which the Department reports yearly activities, and which senior leaders are most up-to-date with bioethics activities throughout the hospital.
[23] Harrison, Zlotnik Shaul and Greenberg were promoted to Associate Professor in the Department of Paediatrics at the University of Toronto; in 2024, Zlotnik Shaul became a full professor in the Department of Paediatrics.
[24] Bioethics Grand Rounds at SickKids include a variety of formats throughout the annual series, with some focused on a clinical case, others on a broader conceptual issue with interdisciplinary dimensions, and a couple of specialty rounds including an annual year-in-review and book review.
[25] Continuing Medical Education credits.

In 2001, Bioethics Week was established, providing the opportunity for clinical teams and departments across the institution to host open events discussing ethical issues relevant to their context. The structure of Bioethics Week, conceptualized by Harrison, encourages each division or team to use their regular academic rounds or equivalent to focus on an ethics topic pursuant to their service. Individual services take the lead in selecting the topic, with the Bioethics Department supporting them with speaker selection and format if needed. During this innovative week, events are open to staff, trainees, and families to explore ethical issues in both new and familiar clinical areas and disciplines[26]. The week has become a key platform for discussing contemporary and longstanding ethical issues[27]. While in 2024, Bioethics Week held twenty-plus events with over one thousand attendees, the first Bioethics Week marked a humble (yet ambitious) beginning for the tradition, engaging in eight well-attended events. Notwithstanding the fact that the Department is situated within an organization with a large annual budget, the funds dedicated to the Bioethics Department have consistently called for careful allocation, aiming to be as effective as possible while managing hospital-wide budget cuts that led to the loss of Department staff and resources. Bioethics Week was a creative way to host a hospital-wide annual event without the need for much draw on the Department budget.

Accreditation Canada has priority standards about principle-based decision-making that call upon hospitals to have resources to recognize and support the identification, analysis and addressing of ethical issues. These resources together constitute the hospital's "Ethics Framework" and include the Bioethics Department and its services. The Bioethics Department engages in ongoing hospital-wide education and dissemination about the Ethics Framework.

With all this success, and evolving collaborations, we would be remiss to not also acknowledge the 1990s as a period where numerous passionate discussions occurred between bioethicists, at SickKids and beyond, regarding their responsibilities as members of a growing "non-professional-profession". One notable illustration of these debates emerged in the context of the Olivieri Affair, a controversy that later gave rise to a published exchange between two SickKids bioethicists.

Ethical controversy discussed publicly — the "Olivieri affair"

In 2004, The Journal of Medical Ethics featured a seminal exchange between two SickKids bioethicists, Baylis and Rowell, the latter who had been a bioethicist at SickKids during what became widely referred to as the "Olivieri affair"[28], and which was the catalyst for their exchange. In Baylis' initial commentary to the journal, aptly named "Where were the heroes of bioethics?" (86), she argued that the wider bioethics community had failed to play a pivotal role:

> Bioethicists in Canada failed Dr Olivieri and her colleagues at HSC. Why? Did they fear losing their jobs? There are few bioethicists who have the security of tenure. Did they fear being sued? Many of the individuals and organisations involved in this case had shown themselves willing to engage in litigation. Did they fear loss of reputation? Again, many involved in this case had shown themselves willing to make damaging public comments. Did they fear retribution and consequent damage to their careers? After all, bioethics in Canada is a very small and fractured community. I do not know the reason(s) for the ensuing silence. I do know, however, that by and large Canadian bioethicists failed to speak up when there was ample time and opportunity. As a responsible community, we must ask ourselves whether we could and should have done more (p.49).

In her reply (87), Rowell sought to contextualize the facts she believed were not accurately represented in Baylis's piece, and to clarify her role in the case. She stated that:

> My efforts to support Dr. Olivieri were often dismissed by the hospital administration and sometimes also by the media, who were perhaps seeking a more sensational account of the case than I felt it appropriate to provide, believing such an approach to be contrary to the best interests of children in research and contrary to support of Dr. Olivieri and her colleagues (p.50).

Baylis's response to Rowell (88) drew international attention to what she believed was an important lesson for the wider bioethics community to glean from the incident:

[26] Some of the activities included in Bioethics Week are a named lecture in memory of Christine Harrison, former Director of the Bioethics Department, and an academic poster display, where staff and trainees from across the hospital can showcase their bioethics-relevant work with an award named for the inaugural and current clinical bioethics associate, Jonathan Hellmann.

[27] These have included ethical dimensions of treating 2SLGBTQIA+ individuals and families following Canada's legalization of same sex marriage in 2005 under the Civil Marriage Act, the implications of truth-telling and confidentiality in paediatric care with the hospital's growing reliance on electronic records, and the extent to which paediatric care should be prioritized in society. Frequently, the ramifications of legal decisions, like A.C. v. Manitoba (Director of Children and Family Services), a landmark Supreme Court of Canada case adjudicated in 2009 on the rights of "mature minors", became fervent points of discussion (82).

[28] The "Olivieri Affair" was named after Nancy Olivieri (BSc, MD), who was the former head of the hemoglobinopathy program at SickKids. She was embroiled in a four-year legal battle involving SickKids, the University of Toronto, and Apotex Inc, a Toronto-based pharmaceutical company. In 1996, she broke the confidentiality agreement which governed her research sponsored by Apotex to share with patients and the wider scientific community her serious concerns that her findings demonstrated the potential dangers of using deferiprone to treat children with thalassemia. Apotex pulled its funding from the University, for which it was negotiating a $30 million dollar donation, and pursued legal action against Olivieri; she was then removed from her post at SickKids, though she would later be reinstated. Thorough accounts of the affair have since been published (83-85). A report published in 2001 into the affair commissioned by the Canadian Association of University Teachers (CAUT) exonerated Olivieri of any wrongdoing (84). The Olivieri Affair raised issues of research ethics and academic freedom that were illustrative of the growing pressure in the mid-1990s for universities, teaching hospitals and individual researchers to seek corporate sponsorship for projects (84). As the CAUT report detailed, public institutions were not conscious of the inadequacy of their policy infrastructures for protecting the public interest in this new environment, and policies and practices had not been changed to consider these new circumstances.

> The lesson for all of us in this is that speaking truth to power — the job of bioethics — is a daunting task and one that we are unlikely to succeed at if we do not learn to ask for and to accept, to offer and to provide, moral support and meaningful help (p.52).

This exchange offers a touchpoint to an ongoing existential debate in the profession that, we contend, goes much further back than the 1990s. This debate asks the community of practice to consider the purpose of a bioethicist, and further, what moral duties that purpose conveys. Is it possible for a bioethicist to serve institutions, individuals, and communities, particularly when the interests of these parties can be significantly at odds? These questions, which remain significant at SickKids and not without disagreement among bioethicists in Canada, are further complicated by increasing calls for the professionalization of clinical ethicists (89-91) and growing critique of the lack of intellectual and cultural diversity among North American bioethicists (92,94).

THE 2010s TO 2025

Between 2010 and 2025, the Department welcomed many new faces, and several novel roles reflective of a desire to create a team that increased complementary interdisciplinarity in academic and professional backgrounds. After being replaced through the structure of a Department, a Bioethics Advisory Committee was reinstated in 2017 to support the Bioethics Department and to serve as a forum for bringing multiple disciplinary lenses and vantage points to deliberations about challenging ethical issues facing the organization, as well as ethics capacity building for members as “ethics ambassadors”. Prior to Zlotnik Shaul being hired as the Director of the Department, a needs-assessment was conducted by two external experts in paediatric bioethics (one from Canada and one from the United States). They recommended that the work of the small department could benefit from the assistance of a Bioethics Advisory Committee. This new iteration of the committee is interdisciplinary, with at least 20 members representing roles across the institution. The inaugural co-chairs were critical care intensivist Peter Cox and Zlotnik Shaul; when Cox retired from SickKids, staff physician Kevin Weingarten took over as co-chair.

With respect to bioethicist roles, at the start of the 2010s, bioethicist Rebecca Greenberg (with a background in nursing and bioethics) joined the staff and Zlotnik Shaul followed Harrison as Director. Bioethicist Alison Williams joined for a one-year contract, bringing increased attention to ethical issues within hospital roles such as maintenance and environmental services, often overlooked in traditional bioethics services. Bioethicists within the Department have come from diverse disciplines — most commonly philosophy, but also law, health policy, spiritual care, nursing, neuroscience, pharmacy, and novel therapeutics[29]. A consistent feature of the team at SickKids has been the inclusion of a member with extensive philosophical training, offering a distinctive depth and critical perspective to the team. This sentiment was reaffirmed when bioethicist James Anderson joined in 2013. Anderson’s work at the intersection of ethics and epistemology would prove invaluable as the hospital’s strategic focus shifted to precision child health and the integration of artificial intelligence into clinical care. The addition of Melissa McCradden, completing the first fellowship in the Ethics of Clinical Artificial Intelligence at SickKids, at the end of the decade, further enhanced the Department’s ability to address the ethical challenges associated with AI. McCradden quickly established herself as a leading voice in AI ethics globally and put SickKids on the map as a leader in AI Ethics. However, the unprecedented speed with which AI has progressed, along with fever pitch excitement about its potential, has led to competitive pressures that strain hard won ethical commitments to responsible development and implementation of new technologies.

The role of the Clinical Bioethics Associate

Until 2010, roles within the Bioethics Department included only bioethicists, administrative staff[30], and students/trainees. In contrast with other regions, such as the US, Canadian bioethicists are generally not physicians but hold graduate degrees from academic backgrounds like philosophy, theology, health sciences, social work or law, and have completed a clinical fellowship in bioethics. In the early 2010s, however, the Department formally incorporated a new role, that of the Clinical Bioethics Associate (CBA) — a clinician who has completed a graduate degree in bioethics and is on a career path that formally or informally includes protected non-clinical time to engage in bioethics teaching, policy development and scholarship. This role provides bioethicists with clinical partners that broaden disciplinary expertise brought to Department deliberations, reach, and embeddedness across the organization. Development of the role also gives a formal anchor to clinicians interested in having bioethics as their academic and research foci. The Department adopted a “hub and spoke” model consisting of three primary bioethicists (the hubs) and seven CBAs (spokes) supported by a Bioethics Advisory Committee[31]. The CBAs bring clinical specialty and bioethics expertise to the Department and a bioethics lens to their clinical, educational, policy, and scholarly engagement across the organization. The CBAs during this period included Mary Campbell (cardiac critical care

[29] These bioethicists include: Abbyann Lynch (philosophy), Mona Sidarous (Law), Francoise Baylis, (Philosophy and Health Policy), Christine Harrison (Philosophy), Mary Rowell (Religion), Randi Zlotnik Shaul (Law and Bioethics), Rebecca Greenberg (Nursing and Bioethics), James Anderson (Health Policy and Philosophy), Melissa McCradden (Neuroscience and Bioethics), Maram Hassanein (Pharmacy and Bioethics), and Andrew McFayden (Novel Therapeutics and Bioethics).

[30] A sample of administrative professionals who have worked with the Department of Bioethics include: Micheline Cox, Desta Ramlackhansingh, Parviz Manji, Saima Navsariwala, Kathy Prokop, Gurleen Kaur, Samantha Singh, Hanifah Ahmad, and Han Banh.

[31] The Department established a bioethics advisory committee in 2017 made up of approximately 20 staff from across the hospital and co-chaired by the Director of the Bioethics Department, first with Peter Cox and then with Kevin Weingarten. The committee meets quarterly, providing input on pressing ethical issues facing the hospital that could especially benefit from the range of contextual and disciplinary lenses brought by this diverse membership.

nurse), Lauren Chad (geneticist), Jonathan Hellmann (retired neonatologist and the inaugural Clinical Bioethics Associate), Andrew Helmers (critical care intensivist). Roxanne Kirsch (cardiac critical care intensivist), Sarah Lord (palliative care and complex care physician), Kevin Weingarten (palliative care physician and oncologist). In 2023, the model was described by Roxanne Kirsch and SickKids bioethics colleagues in the Journal of Pediatric Ethics (94).

Quality improvement and models of care

In recent years, bioethicists and Clinical Bioethics Associates have become members of an increasing number of committees and team discussions, providing opportunities to engage with ethical issues before they warrant a full consultation. Recognizing these contextual features of bioethics consultation data at SickKids provides a window into the local experience as well as context for emerging metrics of the field. With the move to the most recent version of the hospital's electronic medical record (EMR), and the fact that bioethics consult notes are part of the EMR, metrics going forward should be more accessible. In 2025 the Department introduced a new tracking system previously developed and in place at another Toronto academic health sciences centre. The hope is this may allow for useful comparison of metrics over time and benchmarking with other paediatric centres in the future.

Discourse on the legal and ethical issues raised by care-models, such as family-centred care, child-centred care, and the model adopted at SickKids, child and family centered care (95), were at the heart of many bioethics consultations, and subsequently became an important area of research and consideration within the Department. Inquiry and research in this area led to Zlotnik Shaul's 2014 edited volume, *Paediatric Patient and Family-Centered Care: Ethical and Legal Issues* (96). The book featured 18 chapters by 31 authors from across Canada and varied healthcare specialties exploring the ethical and legal synergies and tensions these models can create in a range of different contexts[32]. Shortly after, in 2018 Greenberg, with colleagues Aviva M. Goldberg and David Rodriguez-Arias, edited and published *Ethical Issues in Pediatric Organ Transplantation* (97). The book was the first in a Canadian context to specifically address ethical issues in paediatric organ transplantation. Both books were very well received by Canadian and international colleagues in paediatric healthcare and bioethics.

Addressing the SickKids 'truths' of truth and reconciliation

During this period, a significant commitment of the Department involved considering institutional involvement in harms propagated against Indigenous peoples in Canada, as a first step towards reconciliation. This is an important term that entered the public consciousness of Canadians, following the 2007 Indian Residential Schools Settlement Agreement which mandated the establishment of the Truth and Reconciliation Commission[33]. One such harm distinctly tied to SickKids was its participation in nutritional experiments performed on Indigenous children in Canada at six residential schools between 1942 and 1952 (99). The Department of Indian Affairs Canada performed the experiments under the direction of two physicians, Percy Moore and Frederick Tisdall, the former a famed nutritionist and one of three paediatricians at SickKids who developed Pablum infant cereal in the 1930s (100). The impact of these experiments was documented by Canadian historian Ian Mosby (101) who found that Indigenous children participating in the study, without the informed consent of the children or their guardians, were denied adequate nutritional, medical, and dental care, leading to death and severe physical and mental trauma (101). SickKids acknowledged their involvement in a public apology issued in 2018:

> The Truth and Reconciliation Commission of Canada states that without truth, justice is not served, healing cannot happen, and there can be no genuine reconciliation between Indigenous and non-Indigenous peoples. It is with this belief in mind that SickKids wishes to acknowledge harmful aspects of the hospital's history with Indigenous peoples as a first step on the path of reconciliation. Between 1942 and 1952*, on behalf of the Department of Indian Affairs of Canada, SickKids physician Dr. Frederick Tisdall led nutritional experiments on malnourished populations in Indigenous communities and residential schools. During these experiments essential vitamins were withheld from children who needed them and regular physical examinations may have been confusing, painful, and potentially traumatic. The experiments were conducted without children or their parents' consent, and by modern standards of medical research ethics would not have been approved. Findings of the studies did little to alleviate the underlying causes of malnutrition for Indigenous children, and for most, the health risks experienced over the course of the studies outweighed any benefits received. As an organization, SickKids bears responsibility for having allowed this unethical research to occur (102).

The apology also acknowledged the 2015 closure of its Motherisk Drug Testing Lab after it was determined the lab's testing procedures, used by the Ontario child protection system, did not meet appropriate standards for forensic use. A report on the harmful effects of the reliance on hair testing in child protection court cases ordered by the Attorney General of Ontario found drug testing had been disproportionately imposed on Indigenous families in the provincial child protection system and in legal

[32] Featured topics in the book include child consent to research, resource allocation, cultural and religious conflict, decision-making in the Neonatal Intensive Care Unit, and partnerships when treating adolescent anorexia.
[33] The Commission gathered testimony from over 7,000 survivors of the Residential School System and published its entire six volume final report and calls to action in 2015. The National Centre for Truth and Reconciliation at the University of Manitoba maintains the public national record of their work (98).

proceedings (103). The apology echoes sentiments expressed by Indigenous children's rights activists, like Cindy Blackstock[34], who have expressed that, to serve the interests of Indigenous children, we need to challenge the myths we tell ourselves to justify past actions we deem abhorrent. By recognizing contemporary injustices against Indigenous peoples as deliberate choices and patterns, we have the power to disrupt and transform behaviours and relationships (105). Other healthcare institutions across Canada are also being called on to examine how they can reconcile their past relations with Indigenous children with their current efforts to build reciprocal relationships grounded in honesty about anti-Indigenous racism, and respect for Indigenous community-based knowledge and experiences (106,107). Today, the Bioethics Department continues to explore what the spirit of truth and reconciliation looks like, and what it calls us to do in our creation of practices, policies, and relationships. The Department has had membership on the hospital's Indigenous Health Council, engaged in external training, and collaborates by integrating Indigenous knowledge into offerings such as Bioethics Grand Rounds Book Reviews, Bioethics Year-In-Review, Bioethics Week, and Departmental activities in consultation, policy development, graduate student support, research and scholarship.

Medical assistance in dying

Another notable legal development in the 2010s was Canada's legalization of Medical Assistance in Dying (MAID), in 2016, following the SCC Carter decision (108). MAID legislation opened discussion to a myriad of ethical concerns. In 2016, the Canadian Council of Academies was tasked by the federal government with examining three categories left outstanding by the legislation. These included the use of advanced directives, requests wherein the sole underlying illness is a mental disorder, and the question of eligibility of mature minors. The Council selected experts from across Canada, including Zlotnik Shaul, to serve on the Expert Panel Working Group for MAID for Mature Minors. The group released their report on the mature minor question in 2018, "The State of Knowledge on Medical Assistance in Dying for Mature Minors" (109). In 2019, PhD candidate Carey De Michelis along with Adam Rapoport (Medical Director of Patient Advanced Care Team-PACT) and Zlotnik Shaul — as co-leads of the SickKids MAID Policy Development Working Group for legally eligible 18-year-olds — published a paper on the emerging legal and ethical landscape of MAID for eligible 18-year-olds receiving care in a paediatric hospital (110). Public discourse about MAID raised questions and concerns about the morality and capacity of a legally qualifying 18-year-old to access MAID. Discussions about whether an adolescent should be considered capable of making decisions linked to their death were not new questions for bioethicists at SickKids. Decades earlier in 1992, Lynch hosted two "Everyday Ethics" sessions on the topic (111,112). Canada continues to discuss the ethics of mature minors becoming eligible to access MAID at some point in the future. In 2023, Zlotnik Shaul was invited back to parliament to present on ethical issues associated with MAID for mature minors, as an expert witness on behalf of SickKids to the Senate's Special Joint Committee on MAID (113).

The responsible integration of artificial intelligence

During her postdoctoral fellowship at SickKids on the ethics of clinical artificial intelligence[35], McCradden and Anderson led the development of a research ethics-based pipeline for the responsible integration of clinical AI (114,115). McCradden was subsequently hired as a bioethicist with the Department in 2019, adding AI ethics expertise to the bioethics team at a critical time. SickKids centred precision child health, a mission which involves leveraging machine learning and big data to individualize diagnosis and treatment, as a cornerstone of their 2020-2025 Strategic Plan (116). In 2022, McCradden was appointed as the Director of Artificial Intelligence in Medicine at SickKids. Ethical dimensions of this work included public and patient/family perspectives on AI and the aforementioned work on clinical integration of AI in healthcare, among several others[36]. Collaborations with international colleagues produced guidelines for clinical trial protocols for interventions involving AI (138) and reporting guidelines for early-stage clinical evaluation of decision support systems driven by AI (139). In 2024, McCradden took on the role of Research Fellow in AI Ethics at the Australian Institute for Machine learning and AI Director at Australia's Women's and Children's Health Network, while retaining a research appointment at SickKids. In 2024, Anderson's responsibilities expanded to include Ethics Lead for Artificial Intelligence at SickKids, a leadership role in AI ethics consultation (clinical, organizational, research), AI ethics education, and the development of ethically informed frameworks, platforms and tools to facilitate the implementation of AI into clinical care. This journey reflects an institutional appetite for embracing AI to improve care and how the Bioethics Department acknowledged the importance of embedding ethics into this process by co-creating this fellowship and later committing to making ethics central to the development of AI at the hospital. This is another example of collaboration with other departments, and the desire to integrate ethics within all areas of the hospital.

One of the considerations within the bioethics team rests in the reflection around technological solutionism and the moral mandate of bioethicists to provide impartial, neutral ethical analysis in a situation where the institution has committed itself to a particular technology. With AI embedded in the 2025 SickKids Strategic Directions, the pressure to ensure it delivers value

[34] Cindy Blackstock, a member of the Gitxsan First Nation, is an Indigenous children's rights activist and Executive Director of First Nations Child & Family Caring Society of Canada, Associate Professor & Director of FNCARES (First Nations Children's Action Research and Education Service) at the University of Alberta and Professor in McGill's School of Social Work. Blackstock has collaborated with other Indigenous leaders to assist the United Nations Committee on the Rights of the Child in the development and adoption of a General Comment on the Rights of Indigenous children (104).

[35] To address contemporary issues and advancements, in 2018, SickKids partnered with Vector Institute for Artificial Intelligence, a Toronto based independent, not-for-profit organization affiliated with the University of Toronto to create a first-of-its-kind fellowship opportunity, a Postdoctoral Fellowship in the Ethics of Clinical Artificial Intelligence. The inaugural AI ethics fellow, Melissa McCradden joined The Department as a bioethicist in 2019.

[36] Other areas of research in the Department include informed consent by paediatric patients to the collection and analysis of data (117), reporting of "ethics methods" in clinical research (118,119), the ethics of whole genome sequencing in paediatrics (120-123), the ethical translation of novel therapeutics (124-126), algorithmic bias/equity-promoting solutions for point-of-care decision-making using AI (127,129), the explainability of AI algorithms (127), evidence for the promise of AI in psychiatry (129), the value of standards for health datasets in AI-based applications (130), and further nuances on the ethics of AI application in paediatric healthcare settings (114,115,131-137).

almost inevitably leans on not just bioethicists but all SickKids staff. Against this backdrop, bioethicists must navigate the competing tensions between delivering on the institution's strategic vision while holding the line of the profession in providing impartial ethical analysis.

The COVID-19 pandemic

On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic[37], urging countries to activate and scale up their emergency response mechanisms and prepare their healthcare systems (140). Circumstances created by the pandemic exacerbated existing ethical tensions in the Canadian healthcare system producing an environment which challenged the ethical judgment of providers, patients, and families. The ways in which the pandemic uniquely affected the paediatric population and their families prompted the Bioethics Department's involvement with related internal and external dialogue, policy, advocacy and scholarship. Examples include: the development of pandemic family presence policies, vaccine mandate policies, education, and strategies to navigate vaccine hesitancy (142), approaches to navigate moral distress among providers, the accommodation of adult patients in a temporary adult ICU, and consultation support on duty to care and resource allocation concerns in the paediatric surgery backlog (143,145). On a provincial advocacy level, Zlotnik Shaul was appointed to the Ontario Covid-19 Bioethics Table to bring the lens of paediatric ethics to support decision-making for the province on key pandemic related policies and recommendations affecting children and their families[38].

Precision child health, and expanding engagement in health equity & artificial intelligence

Precision Child Health (PCH) became a SickKids priority. It seeks to integrate patient and family data seamlessly into a responsive learning health system, advancing our capacity to deliver individualized care. This integration aims to enhance diagnostic speed, therapeutic precision, and predictive insight, ultimately refining how we meet each patient's specific needs. PCH leadership recognized that the ethical dimensions of this approach to care must be considered as the infrastructure and governance are being created. To that end, positions such as Ethics Research Analyst and Ethics Lead for PCH were established.

Alanna Goldstein was hired in 2022 as the Ethics Research Analyst. With expertise in health education and media literacy, Alanna works in partnership with the bioethics team to understand the ethical, legal, and equity issues that affect the SickKids' patient, family, and staff communities, and to ensure these issues are considered and addressed in the development and implementation of PCH initiatives. In 2024, the Department made significant additions to the team. Maram Hassanein joined as a bioethicist, bringing expertise and engagement at the intersection of healthcare ethics and religion, health equity, end-of-life care, pharmaceutical ethics (148), and global ethics. An Ethics Lead in PCH role was created and filled by Andrew McFadyen who brings expertise grounded in parental and advocacy experience with patients, families, governments, industry, hospitals and researchers along with bioethics training and international engagement to broadening access to novel therapeutics and PCH. In the short time since his arrival, McFadyen (working closely with Anderson, Pat Furlong, and PhD candidate Lucie Perillat) developed and published a model for the development, administration, and evaluation of individualized therapies (149). Each of these roles reflect recognition of, and the organization's investment in, specialized attention to some of the most ethically complex issues in paediatric bioethics.

CONCLUSION — LOOKING TO THE FUTURE

The process of researching and writing this manuscript enhanced our understanding of the contexts that have shaped paediatric bioethics within and beyond SickKids. As we delved into discussing the perceived ethics scandals in SickKids' history, we often paused to consider whose interests were prioritized and what this focus revealed about societal and institutional inequities. In recounting the work of the Department — be it in consultation, research, education, policy development, or training the next generation of bioethicists, clinicians, researchers, health lawyers and academics — we gained a deeper appreciation of the values prioritized by the Department and the institution more broadly. We recognized that the pervasive collaborative spirit across all members of the Department has consistently facilitated and enhanced bioethics work. Members appear to have always freely shared with one another insights from their own disciplinary training with respect and humility, raising the quality of Departmental output. The evolution of the Department's work engaged with societal and legal shifts regarding child rights.

Institutional memories and culture are often passed down from person to person, as was the case in the Department. Recognizing the importance of documenting the journey of the Department, we embarked on this project not only for our own learning but for future bioethicists, the SickKids community, and for potential scholars to have access to a window into the development of bioethics at SickKids. As the field of bioethics continues to move towards a form of professionalization, appreciating dimensions of its development becomes crucial for contributing to future trajectories. This project illustrates the significance of recording both achievements and challenges within bioethics; our hope is that other bioethics programs will be inspired to document and disseminate their own unique experiences. The examination and preservation of institutional culture, memories, policies, and practices can contribute to informing an intentional and mindful progression of the discipline.

[37] In July of 2020, a special task force led by the Chief Science Advisor of Canada released their report on the science concerning children as vectors for the spread of COVID-19 (141).
[38] The Bioethics Table produced briefs on consent for the vaccination of youth aged 12-17 (145), the ethics of paid sick leave during the pandemic (146), and priority setting for personal protective equipment, among others (147).

While lessons we have learned (and are still learning) through this unique inquiry will continue to crystalize, at this time we recognize that hospital-based bioethics is not a solitary activity. The impact or quality of the engagement is dependent upon the unique qualities of the bioethics team members, their relationships with patients, families, colleagues and trainees, the support of institutional leadership, the political climate and opportunities within and outside the institution, and the evolving culture of the organization. At a time when burnout of those working in healthcare is at an all-time high, we have come to better appreciate the significance of collegiality, trust and support between members of a bioethics team. Like with any healthcare team, SickKids bioethics team members have, over the course of their careers, experienced personal health issues, family challenges, the loss of loved ones, and a range of intersectional vulnerabilities. The collaborative team dynamic and nurtured relationships allowed members to work in their roles, supported by professionalism and compassion, while facing their personal circumstances.

As we envision the future, we anticipate learnings from this rich chronology being solidified through ethics work in AI, Precision Child Health, best interests of the child in the context of population diversity, leadership ethics, clinician and family wellbeing and more. The future of the Department is bolstered by the contributions of numerous staff and trainees both within and outside the Department. Service, collaboration, leadership, and adaptability have characterized the Department's history thus far and all indications point to it being the modus operandi of chapters to come.

No written chronology of a bioethics department can be fully comprehensive. There are significant conversations, "ah-ha" moments and even unspoken experiences of bearing witness that are too nuanced to fully capture or document. Yet these experiences strengthen the thread that links each generation of a bioethics service to the next. While the work of a bioethics department contributing to the multiple facets of complex health care organizations can be intellectually challenging, emotionally heartbreaking, and at times very stressful, the experience of working in community at the intersection of such profound human experiences is nothing short of a privilege. The gratitude that comes from looking back at the opportunity to work with others who responsibly carry the weight of such space with care, makes both the work, the looking back and the looking forward worthwhile.

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Conflits d'intérêts

Aucun à déclarer

Conflicts of Interest

None to declare

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REFERENCES

1. O'Neill O. Autonomy and Trust in Bioethics. Cambridge: Cambridge University Press; 2002.
2. Wilson D. What can history do for bioethics? Bioethics. 2013;27(4):215-23.
3. Berg BL, Lune H. Qualitative Research Methods for the Social Sciences. 8th ed. Boston: Pearson; 2012.
4. Kopelman LM. The birth of ASBH in pictures and commentaries; 1997.
5. Wright D, Kids TH for S, Haddad MJ. SickKids: The History of The Hospital for Sick Children. Illustrated edition. Toronto: University of Toronto Press; 2016.
6. The Hospital for Sick Children (SickKids). Annual Report 2024-2025. 2025.
7. SickKids. About SickKids.
8. Alsan M, Wanamaker M. Tuskegee and the health of Black men. The Quarterly Journal of Economics. 2018;133(1):407-55.
9. CDC. The Untreated Syphilis Study at Tuskegee Timeline. 4 Sept 2024.
10. Beauchamp TL, Childress JF. Principles of Biomedical Ethics: 7th Edition. 7th ed. New York: Oxford University Press; 2013.
11. Carroll TW, Gutmann MP. The limits of autonomy: The Belmont Report and the history of childhood. Journal of the History of Medicine and Allied Sciences. 2011;66(1):82-115.
12. Ducar D, Howard L. Careers in bioethics: An interview with James Childress. Voices in Bioethics. 2017;3.
13. Reich WT. Encyclopedia of Bioethics. Free Press; 1978.
14. Reich WT. Shaping and mirroring the field: The encyclopedia of bioethics. In: The Story of Bioethics: From Seminal Works to Contemporary Explorations. Washington, D.C: Georgetown University Press; 2003. p. 165-89.
15. Avard D, Griener G, Langstaff J. Hospital ethics committees: survey reveals characteristics. Dimensions in Health Services. 1985;62(2):24-6.
16. Storch JL, Griener GG, Marshall DA, Olineck BA. Ethics committees in Canadian hospitals: Report of the 1989 Survey. Healthcare Manage Forum. 1990;3(4):3-8.
17. Institutional Ethics Committees: Recommendations for Action. Ottawa: Canadian Hospital Association; 1986.
18. Guide to Accreditation of Canadian Health Care Facilities. Ottawa: Canadian Council on Hospital Accreditation; 1986.
19. Joint Commission on the Accreditation of Healthcare Organizations. Accreditation Manual for Hospitals Supplement from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). Oakbrook Terrace, Illinois; 1992.
20. Ferguson K. Western launches new Centre for Bioethics. Western News. 8 Dec 2025.
21. Ross JW. Case consultation: the committee or the clinical consultant? HEC Forum. 1990;2(5):289-98.
22. Baylis FE. Ethics consultation: The hospital for sick children initiative [Toronto, Ontario]. HEC Forum. 1991;3(5):285-92.
23. Annas G, Grodin M. Hospital ethics committees, consultants, and courts. AMA Journal of Ethics. 2016;18(5):554-9.
24. Re Quinlan. 70 N.J. 10 (1976), 355 A.2d 647.
25. Cruzan v. Director, Missouri Dep't of Health. 497 U.S. 261 (1990).
26. UNICEF Canada. About the Convention on the Rights of the Child.
27. Tang KL. Implementing the United Nations Convention on the Rights of the Child: The Canadian experience. International Social Work. 2003;46(3):277-88.
28. Ezer T. A positive right to protection for children. Yale Human Rights and Development Law Journal. 2004;7:1-51.
29. Divorce Act. R.S.C. 1985, c. 3 (2nd Supp.).
30. Citizenship Act. R.S.C. 1985. c. C-29.
31. E. (Mrs.) v. Eve. 1986 2 SCR 388.
32. Kopelman L. Rejecting the Baby Doe rules and defending a "negative" analysis of the best interests standard. The Journal of Medicine and Philosophy. 2005;30(4):331-52.

33. Kopelman LM. The best-interests standard as threshold, ideal, and standard of reasonableness. Journal of Medicine and Philosophy. 1997;22(3):271-89.
34. Hurst I. Baby Doe rules. Pediatrics. 2005;116(6):1600-1.
35. Young v. Young. 1993 4 SCR 3.
36. C.B. v. The Queen. 1981 2 SCR 480.
37. Paquette et al. v. Galipeau et al. 1981 1 SCR 29.
38. Racine v. Woods. 1983 2 SCR 173.
39. Novic v. Novic. 1983 1 SCR 696.
40. King v. Low. 1985 1 SCR 87.
41. Lamb v. Lamb. 1985 1 SCR 851.
42. Frame v. Smith. 1987 2 SCR 99.
43. C.(G.) v. V.-F.(T.). 1987 2 SCR 244.
44. New Brunswick (Minister of Health and Community Services) v. C. (G. C.). 1988 1 SCR 1073.
45. Calyx: Ethical Issues in Paediatrics. Summer 1991. The Bioethics Department at The Hospital for Sick Children Collection.
46. Lynch A. Medical professionalism: toward a contemporary Canadian model. Journal of Canadian Studies. 1992;27(1):107-17.
47. Baylis F. Guidelines for bioethics consultations at the hospital for sick children [Toronto, Ontario]. HEC Forum. 1991;3(5):293-7.
48. Greenberg RA, Anstey KW, Macri R, Heesters A, Bean S, Zlotnik Shaul R. Bioethics consultation practices and procedures: a survey of a large Canadian community of practice. HEC Forum. 2014;26(2):135-46.
49. Honan L, Heesters AM, Bianchi A, Salis M, Bell JAH. Key insights and priorities for evaluating the effectiveness of clinical ethics consultation. Canadian Journal of Bioethics/Revue canadienne de bioéthique. 2024;7(2-3):201-4.
50. Feldman SL, Riaz SH, Crites JS, et al. Answering the call for standardized reporting of clinical ethics consultation data. The Journal of Clinical Ethics. 2020;31(2):173-7.
51. Porter A. Documenting clinical ethics consultation. Canadian Journal of Bioethics/Revue canadienne de bioéthique. 2021;4(1):79-82.
52. Fox E, Duke CC. Ethics consultation in U.S. hospitals: determinants of consultation volume. American Journal of Bioethics. 2022;22(4):31-7.
53. Cohn F. Ethics consultation: data and the path to professionalization. American Journal of Bioethics. 2022;22(4):1-4.
54. Glover AC, Cunningham TV, Sterling EW, Lesandrini J. How much volume should healthcare ethics consult services have? Journal of Clinical Ethics. 2020;31(2):158-72.
55. Sanelli-Russo S, McBride Folkers K, Sakolsky W, Fins JJ, Neveloff Dubler N. Meaningful use of electronic health records for quality assessment and review of clinical ethics consultation. Journal of Clinical Ethics. 2018;29(1):52-61.
56. Bliss SE, Oppenlander JE, Dahlke JM, Meyer GJ, Williford EM, Macauley RC. Measuring quality in ethics consultation. Journal of Clinical Ethics. 2016;27(2):163-75.
57. Baylis F, McBurney C, editors. The Case of Children: Paediatric Ethics in a Canadian Context. Toronto: The Department of Bioethics, The Hospital for Sick Children; 1993.
58. Baylis F, Eckenwiler L, Kunicki L, editors. Institutional Policy in Paediatric Practice Documenting Canadian Experience. Toronto: The Department of Bioethics, The Hospital for Sick Children; 1994.
59. Baylis F, Downie J, editors. Codes of Ethics: Ethics Codes, Standards, and Guidelines for Professionals Working in a Health Care Setting in Canada. First Edition. Toronto, Canada: The Department of Bioethics, The Hospital for Sick Children; 1992.
60. Baylis F, Downie J, Dewhirst K, editors. Codes of Ethics: Ethics Codes, Standards, and Guidelines for Professionals Working in a Health Care Setting in Canada. 2nd ed. Toronto: The Department of Bioethics, The Hospital for Sick Children; 1999.
61. Mailing List for Calyx: Ethical Issues in Paediatrics.
62. Downie J. The Limits on Children. Calyx: Ethical Issues in Paediatrics. Summer 1991.
63. Belik J. Should I treat my patient as I would my child. Calyx: Ethical Issues in Paediatrics. Spring 1993.
64. Smith B. Sharing of quantitative risks with patients and families: A difference between prospective and retrospective risk ascertainment. Calyx: Ethical Issues in Paediatrics. Summer/Fall 1995.
65. McBurney C. Patient-focused care: who are we kidding. Calyx: Ethical Issues in Paediatrics. Winter/Spring 1996.
66. Harrison C. I spy… moral distress on the paediatric ward. Calyx: Ethical Issues in Paediatrics. Winter 1998.
67. Huyer D. Child abuse and neglect: reporting dilemmas. Calyx: Ethical Issues in Paediatrics. Spring 1999.
68. Compendium of “Everyday Ethics” sessions (posters and informational flyers) presented by the Department of Bioethics at The Hospital for Sick Children (SickKids).
69. Lynch A, Pediatric Ethics Network, editors. The Good Pediatrician: An Ethics Curriculum for Use in Canadian Pediatrics Residency Programs. PedEthNet; 1996.
70. Department of Philosophy. Dr. Abbyann D. Lynch 1928 - 2019. 1 Aug 2019.
71. Canadian Bioethics Society. Interest Groups.
72. Ontario. c 31 Consent to Treatment Act, 1992/Loi de 1992 sur le consentement au traitement. 1 Jan 1992.
73. Baylis F, Goldbloom A. Ontario’s proposed Consent to Treatment legislation: You, your patients, and rights advisors. Everyday Ethics - An Informal Discussion Series. 26 Oct 1992.
74. Health Care Consent Act. SO 1996, c 2, Sch A.

75. Krever H. Commission of Inquiry on the Blood System in Canada Final Report. Ottawa; 1997.
76. Reeder J. Surgical sterilization of the profoundly mentally retarted child - whose needs are being met? Everyday Ethics - An Informal Discussion Series. 23 Oct 1995.
77. Doyle J, Harrison C, Kenney D. The child's refusal of treatment: When does no mean no. Everyday Ethics - An Informal Discussion Series. 24 Mar 1997.
78. Abramovitch R, Harrison C. Respectful involvement of children in research: yes they CAN understand! Everyday Ethics - An Informal Discussion Series. 6 May 1998.
79. Harrison C, McNeill T, Weitzman S. Tyrell Dueck's "Choice": Who decides what's best? Everyday Ethics - An Informal Discussion Series. 29 Apr 1999.
80. Baker v. Canada (Minister of Citizenship and Immigration). 1999 2 SCR 817.
81. Gordon v. Goertz. 1996 2 SCR 27.
82. A.C. v. Manitoba (Director of Child and Family Services). 2009 SCR 181.
83. Shuchman M. The Drug Trial: Nancy Olivieri and the Scandal That Rocked the Hospital for Sick Children. Toronto: Random House Canada; 2005.
84. Thompson J, Baird P, Downie J. Report of the Committee of Inquiry on the Case Involving Dr. Nancy Olivieri, the Hospital for Sick Children, the University of Toronto, and Apotext Inc. Canadian Association of University Teachers. 2001.
85. Schafer A. Biomedical conflicts of interest: a defence of the sequestration thesis—learning from the cases of Nancy Olivieri and David Healy. Journal of Medical Ethics. 2004;30(1):8-24.
86. Baylis F. The Olivieri debacle: where were the heroes of bioethics? Journal of Medical Ethics. 2004;30(1):44-9.
87. Rowell M. The Olivieri debacle: where were the heroes of bioethics? A Reply. Journal of Medical Ethics. 2004;30(1):50.
88. Baylis F. Response to Mary Rowell. Journal of Medical Ethics. 2004;30(1):51-2.
89. Frolic A, PHEEP Steering Committee. Grassroots origins, national engagement: exploring the professionalization of practicing healthcare ethicists in Canada. HEC Forum. 2012;24(3):153-64.
90. ASBH. Healthcare Ethics Consultation Certification.
91. Wyzynski D. Professionalization of clinical bioethics: this is the way. Canadian Journal of Bioethics / Revue canadienne de bioéthique. 2024;7(1):58-60.
92. Baker R. Erasing blackness from bioethics. American Journal of Bioethics. 2022;22(3):33-5.
93. Chattopadhyay S, De Vries R. Respect for cultural diversity in bioethics is an ethical imperative. Medicine, Health Care, and Philosophy. 2013;16(4):639-45.
94. Kirsch R, Chad L, Helmers A, et al. Clinical Bioethics Associate: an innovative model of care nested in a paediatric bioethics department. Journal of Pediatric Ethics. 2023;3(1):20-26.
95. SickKids. Our Care Philosophy.
96. Zlotnik Shaul R, editor. Paediatric Patient and Family-Centred Care: Ethical and Legal Issues. 1st ed. 2014. New York, NY: Springer; 2014.
97. Greenberg RA, Goldberg AM, Rodríguez-Arias D, editors. Ethical Issues in Pediatric Organ Transplantation. Springer; 2016.
98. NCTR. National Centre for Truth and Reconciliation. 2024.
99. MacDonald NE, Stanwick R, Lynk A. Canada's shameful history of nutrition research on residential school children: The need for strong medical ethics in Aboriginal health research. Paediatrics & Child Health. 2014;19(2):64.
100. SickKids. History of Nutrition.
101. Mosby I. Administering colonial science: nutrition research and human biomedical experimentation in Aboriginal communities and residential schools, 1942–1952. Histoire sociale/Social history. 2013;46(91):145-72.
102. SickKids. Reconciliation statement on SickKids' History with Indigenous Peoples. 7 Aug 2018.
103. Beaman JC. Harmful Impacts: The Reliance on Hair Testing in Child Protection. (Report of the Motherrisk Commission). Ontario: Ministry of the Attorney General; Feb 2018.
104. First Nations Child & Family Caring Society. Who We Are.
105. DeLory A. Cindy Blackstock: Indigenous children are worth fighting for. Dalhousie News. 11 Feb 2022.
106. Leo G. Inside the brain school. CBC News. 10 Jun 2024.
107. Pelley L. Mistreated: Legacy of segregated hospitals haunts Indigenous survivors. CBC News. 12 Jun 2024.
108. Carter v. Canada (Attorney General). 2015 1 SCR 331.
109. The State of Knowledge on Medical Assistance in Dying for Mature Minors: The Expert Panel Working Group on MAID for Mature Minors. The Expert Panel Working Group on MAID for Mature Minors. Council of Canadian Academies; 2018.
110. DeMichelis C, Shaul RZ, Rapoport A. Medical Assistance in Dying at a paediatric hospital. Journal of Medical Ethics. 2019;45(1):60-7.
111. Lynch A. Allowing Death... at HSC? The Care of Nancy B. Everyday Ethics - An Informal Discussion Series. 22 Jan 1992.
112. Lynch A. The Adolescent Patient's Decision to Die. Everyday Ethics - An Informal Discussion Series. 23 Mar 1992.
113. Special Joint Committee on Medical Assistance in Dying. AMAD. House of Commons of Canada.
114. McCradden MD, Anderson JA, Stephenson EA, et al. A research ethics framework for the clinical translation of healthcare machine learning. American Journal of Bioethics. 2022;22(5):8-22.
115. McCradden MD, Stephenson EA, Anderson JA. Clinical research underlies ethical integration of healthcare artificial intelligence. Nature Medicine. 2020;26(9):1325-6.

116. The Hospital for Sick Children (SickKids). SickKids 2025 5-Year Retrospective. Feb 2025.
117. McCradden MD. Partnering with children and youth to advance artificial intelligence in healthcare. Pediatric Research. 2023;93(2):284-6.
118. Anderson JA, Eijkholt M, Illes J. Ethical reproducibility: towards transparent reporting in biomedical research. Nature Methods. 2013;10(9):843-5.
119. Sounderajah V, McCradden MD, Liu X, et al. Ethics methods are required as part of reporting guidelines for artificial intelligence in healthcare. Nature Machine Intelligence. 2022;4(4):316-7.
120. Anderson JA, Meyn MS, Shuman C, et al. Parents perspectives on whole genome sequencing for their children: qualified enthusiasm? Journal of Medical Ethics. 2017;43(8):535-9.
121. Anderson JA, Hayeems RZ, Shuman C, et al. Predictive genetic testing for adult-onset disorders in minors: a critical analysis of the arguments for and against the 2013 ACMG guidelines. Clinical Genetics. 2015;87(4):301-10.
122. Szego MJ, Meyn MS, Shuman C, et al. Views from the clinic: Healthcare provider perspectives on whole genome sequencing in paediatrics. European Journal of Medical Genetics. 2019;62(5):350-6.
123. Chad L, Anderson J, Cagliero D, Hayeems RZ, Ly LG, Szuto A. Rapid genetic testing in pediatric and neonatal critical care: a scoping review of emerging ethical issues. Hospital Pediatrics. 2022;12(10):e347-59.
124. Djordjevic D, McFadyen A, Anderson JA. Ethical challenges and opportunities in the development and approval of novel therapeutics for rare diseases. Journal of Medicine Access. 2023;7:27550834231177507.
125. Ganji N, Kalish B, Offringa M, et al. Translating regenerative medicine therapies in neonatal necrotizing enterocolitis. Pediatric Research. 2024;96(7):1609-15.
126. Perillat L, McFadyen A, Furlong P, Anderson J. A conceptual model and practical guidance for the development, administration, and evaluation of individualized therapies. Frontiers in Medicine. 12:1493832.
127. Bradshaw TJ, McCradden MD, Jha AK, et al. Artificial intelligence algorithms need to be explainable—or do they? Journal of Nuclear Medicine. 2023;64(6):976-7.
128. McCradden MD, Patel E, Chad L. The point-of-care use of a facial phenotyping tool in the genetics clinic: An ethics tête-a-tête. American Journal of Medical Genetics Part A. 2021;185(2):658-60.
129. McCradden M, Hui K, Buchman DZ. Evidence, ethics and the promise of artificial intelligence in psychiatry. Journal of Medical Ethics. 2023;49(8):573-9.
130. Arora A, Alderman JE, Palmer J, et al. The value of standards for health datasets in artificial intelligence-based applications. Nature Medicine. 2023;29(11):2929-38.
131. Thai K, Tsiandoulas KH, Stephenson EA, et al. Perspectives of youths on the ethical use of artificial intelligence in health care research and clinical care. JAMA Network Open. 2023;6(5):e2310659.
132. McCradden MD, Joshi S, Anderson JA, London AJ. A normative framework for artificial intelligence as a sociotechnical system in healthcare. Patterns. 2023;4(11):100864.
133. McCradden MD, Kirsch RE. Patient wisdom should be incorporated into health AI to avoid algorithmic paternalism. Nat Med. 2023;29(4):765-6.
134. McCradden MD, Anderson JA, Zlotnik Shaul R. Accountability in the machine learning pipeline: the critical role of research ethics oversight. American Journal of Bioethics. 2020;20(11):40-2.
135. McCradden MD, Stephenson EA, Anderson JA. Clinical research underlies ethical integration of healthcare artificial intelligence. Nature Medicine. 2020;26(9):1325-6.
136. Anderson JA, McCradden MD, Stephenson EA. Response to open peer commentaries: On social harms, big tech, and institutional accountability. American Journal of Bioethics. 2022;22(10):W6-8.
137. McCradden MD, Joshi S, Mazwi M, Anderson JA. Ethical limitations of algorithmic fairness solutions in health care machine learning. The Lancet Digital Health. 2020;2(5):e221-3.
138. Rivera SC, Liu X, Chan AW, et al. Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension. The Lancet Digital Health. 2020;2(10):e549-60.
139. Vasey B, Nagendran M, Campbell B, et al. Reporting guideline for the early-stage clinical evaluation of decision support systems driven by artificial intelligence: DECIDE-AI. Nature Medicine. 2022;28(5):924-33.
140. WHO. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020.
141. Government of Canada. COVID-19 and Children. 2020.
142. Helmers AJ, Anderson JA, Kirsch RE. Caregiver COVID-19 vaccination status in pediatric hospitals-ethics of exclusion. JAMA Pediatrics. 2022;176(5):441-2.
143. The Hospital for SickKids, Wiebe K, Zlotnik Shaul R, Kelley S, Kirsch R. Exploring the ethics of paediatric surgical prioritization in Canada: A survey of existing institutional guidance. Canadian Health Policy. Jul 24.
144. Wiebe K, Kelley S, Fecteau A, et al. Operationalizing equity in surgical prioritization. Canadian Journal of Bioethics / Revue canadienne de bioéthique. 2023;6(2):11-19.
145. Smith M, Bernard C, Blackman N, Zlotnik Shaul R, Ritchie Z. Vaccinating Ontarians aged 12-17: legal and ethical requirements for consent. Ontario COVID-19 Bioethics Table. 21 May 2021.
146. Ontario COVID-19 Bioethics Table. Ethics of Paid Sick Leave for the COVID-19 Pandemic. 23 Apr 2021.
147. Ontario COVID-19 Bioethics Table. Priority Setting of Personal Protective Equipment — Within Health Care Institutions and Community Support Services. 25 Mar 2020.
148. Hassanein M, Anderson JA. Refusal of animal-derived medical products in a paediatric setting: Ethical issues. Paediatrics & Child Health. 2020;26(2):99-102.
149. Perillat L, McFadyen A, Furlong P, Anderson J. A conceptual model and practical guidance for the development, administration, and evaluation of individualized therapies. Frontiers in Medicine. 2025;12:1493832.

APPENDIX 1

Last Name, First Name	Credentials	Role Linked to Bioethics Dep at SickKids
Anderson, James	MHA, MA, PhD, Philosophy	Bioethicist, Ethics Lead for AI
Barker, Geoff	MB, BS a	Chair Ethics Committee
Baylis, Françoise	CM, ONS, FRSC, FISC	Bioethicist
Campbell, Mary	RN, BScN, MHSc, cardiac critical care nurse	Clinical Bioethics Associate
Chad, Lauren	MDCM, MHSc, FCCMG, FRCP (C), geneticist	Clinical Bioethics Associate
Charland, Louis	PhD	Bioethicist
Cox, Peter	MBChB, DCH, FFARCS (UK), FRCP(C)	Inaugural co-chair Bioethics Advisory Committee
De Michelis, Carey	MA, PhD	PhD(c), research coordinator
Goldbloom, Alan	BSc, MD Associate Pediatrician in Chief, Exec VP & Chief Operating Officer	Executive lead for Bioethics Department
Goldstein, Alanna	MA, PhD	Ethics Research Analyst, Precision Child Health
Greenberg, Rebecca	RN, PhD, Bioethics	Bioethicist, Researcher
Harrison, Christine	PhD, Philosophy/Bioethics	Bioethicist, Director
Hassanein, Maram	RPh, MA, MSc, Bioethics, BPharm	Bioethicist
Hellmann, Jonathan	MBBCH, FCP(SA), MHSc Neonatologist	Clinical Bioethics Associate
Helmers, Andrew	MDCS, MHSc., FRCP (C) paediatrics intensivist	Clinical Bioethics Associate
Huang, Lennox	CMO, VP, Educ, Med & Academic Affairs	Executive lead for Bioethics Department
Hubley, Pam	MSc, BScN, VP Interprofessional Practice, Learning Institute	Executive lead for Bioethics Department
Keatings, Margaret	RN, MHSc, Chief of Nursing & Interprofessional Practice	Executive lead for Bioethics Department
Kirsch, Roxanne	MD, MBE, FRCP (C), FAAP cardiac intensivist	Clinical Bioethics Associate
Kunicki, Louis	RN	Researcher
Laxer, Ronald	MDCM, FRCPC Physician, VP Medical and Academic Affairs	Executive lead for Bioethics Department
Lord, Sarah	MD, FRCP (C), MHSc PACT, (palliative care), Complex Care	Clinical Bioethics Associate
Lynch, Abbyann	CM, OOnt, LMS, PhD, LLD (Hon.), DSL. (Hon.)	Bioethicist, Inaugural Director
McCradden, Melissa	PhD Neuroscience, MHSc Bioethics	Bioethicist, Director AIM
McFadyen, Andrew	BA, BEd, MHSc, Bioethics, HEC-C	Ethics Lead for Precision Child Health, Bioethicist
Perillat, Lucie	HBSc, PhD(c)	Trainee
Rapoport, Adam	MD, FRCPC, MHSc Bioethics, PACT	policy development co-lead - MAID
Ritchie, Zoe	MA, PhD	Trainee, research coordinator
Rowell, Mary	RN, MA nursing ed, MA ethics and law, cardiac critical care nurse	Bioethicist
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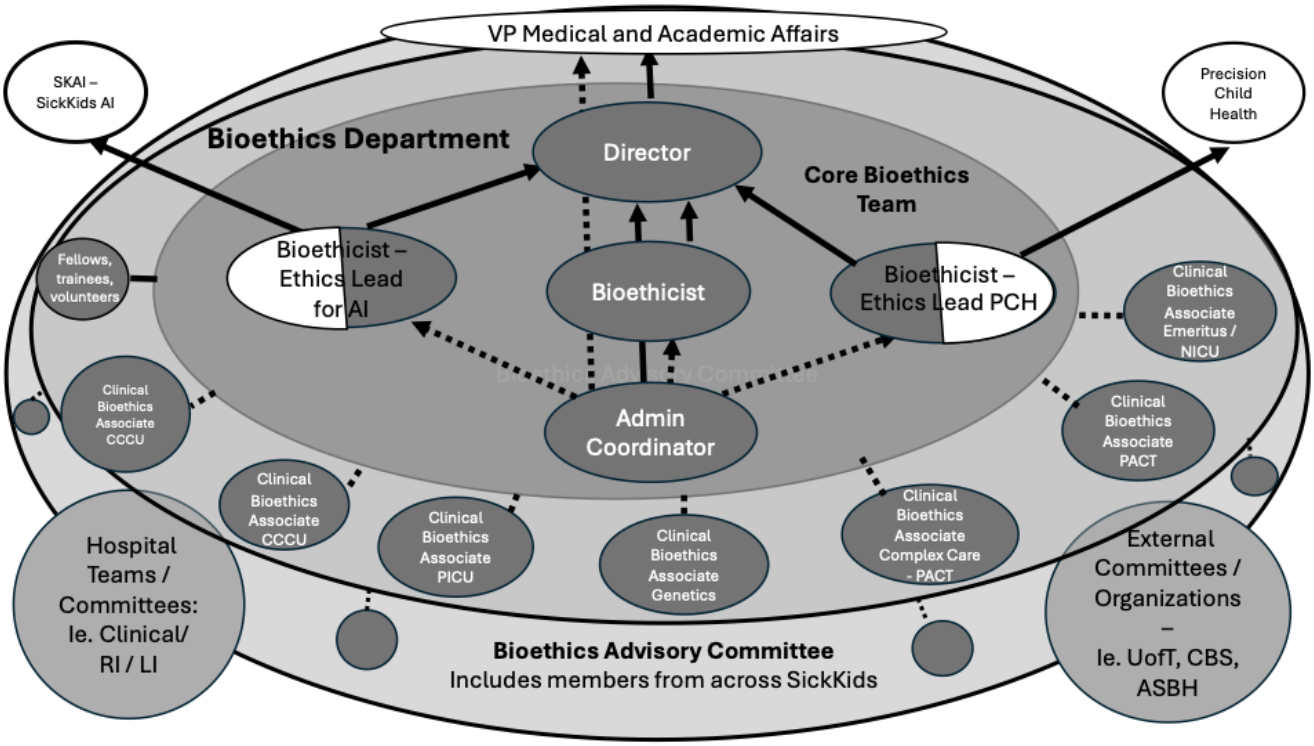
APPENDIX 2


VP Medical and Academic Affairs
SKAI – SickKids AI
Precision Child Health
Bioethics Department
Director
Core Bioethics Team
Fellows, trainees, volunteers
Bioethicist – Ethics Lead for AI
Bioethicist
Bioethicist – Ethics Lead PCH
Clinical Bioethics Associate Emeritus / NICU
Clinical Bioethics Associate CCCU
Admin Coordinator
Clinical Bioethics Associate PACT
Clinical Bioethics Associate CCCU
Clinical Bioethics Associate PICU
Clinical Bioethics Associate Genetics
Clinical Bioethics Associate Complex Care - PACT
Hospital Teams / Committees: Ie. Clinical/ RI / LI
External Committees / Organizations – Ie. UofT, CBS, ASBH
Bioethics Advisory Committee
Includes members from across SickKids

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CRITICAL COMMENTARY (PEER-REVIEWED)

Ethical Challenges in Deploying Large Language Model Chatbots for LGBTQ2+ Mental Health Support

Alexandre Ngoc Nguyen Teichmann[a], Jiayi Xing[b]

Résumé
Alors que les chatbots alimentés par l'IA deviennent de plus en plus courants dans le domaine des soins de santé mentale, nous explorons dans ce commentaire les préoccupations éthiques qu'ils soulèvent pour les personnes LGBTQ2+, des utilisateurs qui sont déjà confrontés à des obstacles systémiques et à une stigmatisation considérables. Nous examinons comment ces outils, bien qu'ils promettent un meilleur accès, peuvent involontairement perpétuer les préjudices par le biais de préjugés, de risques liés à la confidentialité et du technosolutionnisme.

Mots-clés
LGBTQ2+, grands modèles linguistiques, chatbots IA

Abstract
As AI-powered chatbots become more common in mental health care, we explore in this commentary the ethical concerns they raise for LGBTQ2+ individuals — users who already face considerable systemic barriers and stigma. We examine how these tools, while promising greater access, may unintentionally perpetuate harm through bias, privacy risks, and techno-solutionism.

Keywords
LGBTQ2+, large language models, AI chatbots

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INTRODUCTION

The emergence of large language model (LLM) chatbots, such as ChatGPT and similar artificial intelligence (AI)-driven conversational agents, has opened new frontiers in the delivery of mental health support, particularly in the context of increasing demand for mental health services. By offering on-demand and anonymous interactions at the very fingertips of users, these tools have immense potential in the realm of mental health, such as reducing barriers to care, especially in contexts where access is limited due to stigma, cost, or geographic isolation. However, the deployment of such technologies in mental health contexts raises significant ethical issues, especially amongst vulnerable populations. Marginalized and underrepresented populations require careful and specific considerations when it comes to healthcare needs and more importantly mental health needs, given historical mistreatment and barriers to access to care that remain deeply embedded in health systems. Notably, the unchecked deployment of AI technologies, such as general use LLM chatbots, have been shown to perpetuate biases, raising ethical concerns regarding the safety and equitable use of such technologies (1).

This paper addresses the ethical issues raised by LLM chatbots in mental health services, and more specifically amongst one community: LGBTQ2+ individuals. Pre-existing barriers such as discrimination, social stigma, and childhood adversities have been well-documented contributors to chronic stress in LGBTQ2+ individuals; there are particularly pronounced effects amongst transgender and nonbinary populations, who experience higher prevalence of anxiety and depression, as well as post-traumatic stress disorder (PTSD), non-suicidal self-injury, and suicidal tendency compared to cisgender peers (2,3). In LGBTQ2+ populations, disparities persist even after accounting for access to social support and negative social interactions, indicating that unmeasured aspects of systemic discrimination continue to drive elevated risk (4).

While LLM chatbots for mental health raise numerous ethical issues themselves, interaction with individuals from the LGBTQ2+ community involve specific considerations that pose additional ethical issues, given the nuanced and identity-related nature of the challenges faced by this community and established prevalence of mental health concerns. In this paper, we thus first explore the mental health considerations that influence mental health care delivery in LGBTQ2+ individuals. Secondly, we examine in depth three ethical issues that LLM chatbot use for mental health raise in this specific community: bias, safety and related privacy concerns, and technological solutionism.

MENTAL HEALTHCARE CONSIDERATIONS

Mental healthcare is unlike any other form of healthcare, in that its outcomes are extremely dependent on the phenomenology of the individual on the receiving end (5). From this perspective, there are several key considerations that must be integrated when delivering mental healthcare to the LGBTQ2+ community. First, it is important when delivering care to foster an environment that promotes affirmation and inclusive communication, through sensitive language, and a safe and inclusive environment. This has been shown to positively affect health outcomes (6) and is undoubtedly also a significant factor to

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consider in mental healthcare delivery, as addressing individuals who may already have a weakened or damaged sense of identity requires building a thoughtful therapeutic rapport.

Second, we must consider minority stress theory when discussing healthcare delivery, which in this context can be defined as the: “hypothesis that sexual minority health disparities are produced by excess exposure to social stress faced by sexual minority populations due to their stigmatized social status” (7). As LGBTQ2+ communities face systemic stressors that affect their mental health, the stigma and barriers present in the healthcare system demand special identification and intervention. This is linked to the concept of intersectionality, which also affects health outcomes and the care that these populations receive — particularly individuals with multiple marginalized identities (8). Systemic stress factors, such as discrimination, internalized stress, prejudice and perceived rejection must all be accounted for and evaluated in a health setting, as response to interventions are partly dictated by the external influence of those stressors (9). This applies heavily to mental health, where sensitive issues such as psychological vulnerabilities demand trust between patients and providers, which can only be fostered by meaningful understanding and non-prejudicial behaviour.

Additionally, interacting in a health care setting with individuals from the LGBTQ2+ community requires a thorough understanding of the traumas to which these individuals are frequently exposed, highlighting the need for a trauma-informed approach when delivering care. Researchers have highlighted the importance of promoting safety, trust, choice, collaboration and empowerment in a clinical setting (10). This also includes active screening for trauma, such as violence and ensuing psychological consequences (11).

Thus in the scope of our analysis, we are considering LLM chatbots as providers of mental health advice, but not as a modality possessing personhood nor a replacement for human therapists. In the context of providing such services, treating LLMs as anything more than sophisticated tools risks misleading users about their actual capacities.

Contemporary LLMs currently operate without consciousness, intentionality, culpability, or the ability to execute autonomous understanding; outputs are the result of probabilistic text prediction, not reflective thought or empathy (12). This distinction is essential in the mental health context, where therapeutic relationships rely on authenticity and trust. Similarly, we do not consider LLM chatbots to be replacements for human therapists. A recent control trial tested a generative AI chatbot called Therabot for mental health treatment in adults presenting with clinically significant depression, anxiety, or high-risk eating disorder symptoms. Participants reported high engagement and a therapeutic alliance score comparable to outpatient psychotherapy norms (13). Even with a notable reduction in participants’ symptoms, the study authors emphasized the continuing need for risk mitigation and close human supervision. Again, referencing minority stress theory, LGBTQ2+ individuals in whom therapeutic trust is often already fragile may face compounded risks if an LLM chatbot fails to recognize their lived realities and layered identities. Thus, despite the promise they show as supplemental tools, we do not regard LLM chatbots as replacements for human therapists.

Having laid the groundwork for responsible mental health care practices and considerations in this population, we now turn to the ethical issues raised by LLM chatbot use.

BIAS

LLMs are trained on immense datasets that stem from what is available on today’s internet, from books to articles, forums, and social media. While this provides the user access to an unfathomable quantity of data, it can also reflect prejudices, stereotypes, and systemic inequalities already embedded within these data sources. Consequently, when deployed in mental health contexts, LLMs may inadvertently reproduce harmful or exclusionary language, particularly toward marginalized groups such as the LGBTQ2+ community. Research has shown that LLMs can perpetuate gender, racial, and sexual orientation biases due to skewed or under-representative training data (14). Therefore, if we think of LLM chatbots as a provider of mental health support, they can have potentially negative consequences when compared to more impartial and trusted human support. In the LGBTQ2+ community, this could reflect unchecked biases embedded in various data sources, as opposed to a human clinician who could at least be aware and attempt to mitigate their own biases. As this community has faced and continues to be exposed to significant gender and sexual orientation biases and discrimination, biased LLM training datasets will reproduce these biases in their interactions with users (15). As Serravalle et al. explain, “These biases stem from the reproduction of historical cultural patterns that are inadvertently and often unintentionally transferred to the process of creating and developing technologies such as algorithms or automated systems.” (16) Further, identifying and correcting these biases will be even harder in LLMs, as the way they are trained is obscure and considered a “black box” (17).

Second, there is a risk that LLMs trained on more prevalent and dominating cultural narratives will exclude or misrepresent LGBTQ2+ subgroups, particularly those at the intersections of race, disability, or socioeconomic status. For example, LLMs have been found to present an underlying masculine bias (18), which can be particularly problematic in a community where many individuals already struggle with their gender identity and trauma. Such subtle but frequent harms compound the minority stress already experienced by these users and may contribute to therapeutic disengagement and systemic mistrust. Given the psychological vulnerability of LGBTQ2+ users seeking mental health support, such risks cannot be overlooked.

Therefore, if LLM chatbots perpetuate bias in an already stigmatized population, this poses a significant health equity problem (19). Tools intended to increase access and reduce disparities in mental health care could instead deepen inequities

by reinforcing harmful stereotypes and eroding trust. Research shows that biased interactions with LLMs decrease user trust in this technology more broadly, reducing their willingness to engage with it across other domains, such as education and professional development (20). Petzel and Sowerby highlight that AI prejudice disproportionately affects and harms marginalized groups, undermining their confidence in AI technologies. Though this research did not include LGBTQ2+ groups, it is reasonable to imagine that individuals in this community would be similarly affected, and so discouraged from using LLM-based tools even where they might be appropriate and beneficial, thus further widening structural inequalities. This risk becomes even more concerning if human mental health professionals are intentionally or unintentionally replaced by AI systems in efforts to reduce workload or costs, an issue explored later in this paper.

SAFETY AND PRIVACY-RELATED CONCERNS

It has been well established that individuals from the LGBTQ2+ community suffer from higher risk, than their peers, of compromised mental health, including dangerous behaviours such as suicidality and self-harm (21). So it is reasonable to assume that handling such situations would be one of the LLM chatbots primary tasks when integrated into mental health care amongst this community.

Up to now, LLM chatbots have not been subjected to clinical validation, unlike other medical devices, which is particularly problematic in a context of evidence-based medicine. Non-clinically validated “black box” technologies raise the possibility of expressing unpredictable outputs. When we are dealing with human lives in a high-stake environment, such as in a crisis management scenario, unsupervised outputs present a serious concern for potential danger. LLM chatbots should be able to systematically refer to tools such as hotlines where human intervention is essential in scenarios that it detects as being dangerous. Yet, LLM chatbots have had conflicting successes in this regard: on one hand, they have been shown to be slightly superior to human therapists when dealing with suicidality (22), but on the other hand, they have been shown to fail adequate crisis management, omitting elements such as sufficient inquiry or providing excessive directive advice (23). We are then faced with a problem of clinical validity. Is it possible to test an LLM chatbot in a real-world scenario, such as in an actual crisis situation? Would it be possible to perform those tests in an ethical manner, knowing that not offering the gold standard to an individual in crisis would be unethical? Additionally, carrying out such experiments in this specific community would perpetuate historic mistreatment, rendering this option non-viable and dangerous. We are led to consider what measures of validity should be implemented in LLM chatbots for mental health.

Second, if we are to consider the safety of such AI tools for mental health care in the LGBTQ2+ community, we must examine privacy-related safety concerns. LLM chatbots acquire and analyze immense quantities of data through their interactions. Many LGBTQ2+ individuals live in geographical and/or social contexts that are hostile to their identity. They may live in fear that their identity could be exposed, causing considerable ensuing psychological or even physical trauma (24). Thus, privacy issues are deeply concerning for LGBTQ2+ users who, in many regions, must guard their identities due to fear of discrimination, outing, or legal consequences. LLM chatbots designed for mental health support frequently encourage users to disclose intimate details about their emotions, identity, and personal history (25). If there are not robust security measures, safeguards, or regulations in place to prevent data sharing or leaks, this could put those individuals at greater risk. Moreover, depending on the political context, an ill-intentioned government or insurance agency having access to this type of data could easily enact discriminatory measures again those users, exposing them to additional harms. Recent litigation underscores the severity of these risks.

In the landmark 2024 US (Florida) case of *Garcia v. Character Technologies* (26), the mother of a 14-year-old boy alleged that her son died by suicide after a chatbot provided harmful advice, raising questions about legal liability in the use of LLM chatbots for mental health support. The company claimed that the chatbot should be protected under First Amendment free speech rights, echoing arguments raised in a prior case in 2023, Walters v. OpenAI, LLC (27), in which the court’s decision suggested that generative AI outputs may be entitled to First Amendment protections. If US courts are to continue endorsing such claims, developments in AI technology designed for mental health care require further amendment of existing legal doctrines and regulatory frameworks, to ensure adequate legal protections for vulnerable populations such as LGBTQ2+ users.

Furthermore, companies developing those tools often do not have incentives to implement safe data policies, as their main goal is profit, and currently there is a paucity of laws and regulations governing data availability, especially in North America. This creates a clear problem as companies handling sensitive data have insufficient motivation to protect that very data, thus exposing vulnerable health data to potential leaks. Moreover, it seems that chatbots currently used in the health setting lack even basic transparency about data security and privacy. A 2021 scoping review by May and Denecke, which included a significant number of mental health coaching chatbots, found that “the majority [of health chatbots] did not provide any information regarding security or privacy aspects” (28). This is particularly pertinent, as vulnerable users must understand how their sensitive data will be handled, especially the LGBTQ2+ community, who already experience systemic mistrust in the healthcare system. We acknowledge that certain data protections do exist in the US, including the California Consumer Privacy Act (CCPA) (29) which protects rights regarding the collection and use of consumer data, and the Health Insurance Portability and Accountability Act (HIPAA) (30) that widely regulates health data in clinical settings. However, these current frameworks do not adequately encompass the regulation of AI chatbots for mental health support. They do not impose proactive safeguards against inference based on sensitive issues, such as sexual orientation or gender identity, nor address the risks of secondary use of such data by insurers, advertisers, or state actors. HIPAA also applies only to “covered entities”, which leaves consumer

health apps and chatbots largely unregulated (30). There is thus a regulatory gap in the US that allows LLM chatbots to handle sensitive health-related data without necessarily falling under formal health service classifications and privacy guidelines.

TECHNO-SOLUTIONISM

The very concept of LLM chatbots for mental health support in a particularly socially marginalized community raises the issue of techno-solutionism, defined as the “oversimplified reduction of complex problems into technological puzzles” (31). In our context, it can be applied to healthcare and societal issues, and more specifically to the societal roots of the compromised mental health experienced by members of the LGBTQ2+ community. LLM chatbots may provide rapid access to support, but they do not address the structural issues that shape well-being: discrimination, economic insecurity, familial rejection, and societal stigma. Techno-solutionism in mental health is a significant concern as disproportionately marginalized subgroups within the LGBTQ2+ community face intersectional barriers linked to race, disability, socioeconomic status, and other identities. These compounded inequalities mean that introducing LLM chatbots without addressing systemic causes could create new barriers to accessing appropriate and supportive mental health care rather than removing existing ones. As Eubanks (32) highlights, technological “fixes” often obscure the very social injustices they purport to address, reinforcing inequality by shifting responsibility away from systemic reform.

Furthermore, there is a danger that these tools may be deployed as substitutes, rather than supplements, to human care. Mental health care relies not only on empathetic responses, but on rapport building and attunement (33). These qualities are critical in therapeutic interactions, particularly for LGBTQ2+ individuals whose mental health needs often involve identity affirmation and trauma-informed, sensitive support. Although research has found that patients may more readily disclose sensitive information (e.g., suicidal thoughts) to a chatbot than to a human clinician when facing stigma (34), AI-written content elicits less empathy from users than human-narrated content (35), highlighting the gap that would occur if we were to completely replace human clinicians with AI agents. LGBTQ2+ users, already marginalized in clinical settings, may find that chatbots not only fail to meet their emotional needs, but also inadvertently contribute to a sense of lack of validation, a key element in gender affirmation (36).

CONCLUSION

In this paper, we examined the ethical complexities of using LLM chatbots for mental health support within the LGBTQ2+ community. While these tools promise expanded access to care, particularly for populations facing barriers due to stigma, geography, or cost, they also raise serious concerns when deployed amongst marginalized users. We focused on three major areas of ethical risk: the reproduction of bias, safety and privacy vulnerabilities, and the broader issue of techno-solutionism. Tthese risks cannot be examined in isolation and require an intersectional lens that accounts for interdependent sources of harm when examining inclusion and exclusion. We explored how mental health considerations set an ethical baseline for AI development, emphasizing the importance of trust and therapeutic integrity. These considerations are inseparable from systemic bias that continues to influence which communities are excluded from care and whose needs are marginalized. For LGBTQ2+ communities, bias can manifest in misgendering, exclusionary language, or invalidation of identity, potentially leading to psychological harm. Concerns around safety and privacy amplify these exclusions, as risks of data misuse or harm are not evenly distributed but are rather disproportionately experienced by LGBTQ2+ individuals living in social or political contexts where disclosure of their identity could lead to real-world consequences. The current lack of transparent data handling practices, combined with limited regulation of AI tools, is at risk of augmenting an already present systemic mistrust. The lack of clinical validation and unpredictable outputs from these “black box” systems means that chatbot responses can be unreliable or even dangerous when users are in acute distress. With legal frameworks currently not equipped to hold LLM chatbots culpable to the same degree as human therapists, caution must be exercised appropriately in future developments. Techno-solutionist framing is the overarching structural risk that further obscures the inequities that shape access to care, prioritizing efficiency at the cost of trivializing the systemic challenges faced by vulnerable populations. While chatbots may provide rapid, anonymous support, they cannot replace the relational depth, empathy, and affirmation that LGBTQ2+ individuals often require from mental health care providers. There is thus a strong possibility that, in the name of innovation and cost-effectiveness, such tools will become substitutes for meaningful human care.

In the current healthcare worker shortage, LLM chatbots hold promise as an aid in mental health support. However, this promise can only be realized if these tools are developed and deployed with specific attention to the needs and vulnerabilities of the LGBTQ2+ individuals they aim to serve, such as through frameworks that can ensure the safety and quality of LLM chatbot responses (37). Without such care, these technologies risk reproducing the very harms they claim to alleviate. Employing an intersectional lens is a starting point that highlights how these dynamics are compounded, and it reminds us that future ethical deployment of LLM chatbots is less about producing rapid technological fixes than addressing the layers of inequities that shape mental health care.

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Aucun à déclarer

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None to declare

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REFERENCES

1. Xue J, Wang Y-C, Wei C, et al. Bias and fairness in chatbots: an overview. arXiv; 2023.
2. Inderbinen M, Schaefer K, Schneeberger A, et al. Relationship of internalized transnegativity and protective factors with depression, anxiety, non-suicidal self-Injury and suicidal tendency in trans populations: a systematic review. Front Psychiatry. 2021;12:636513.
3. Hainey KJ, Connolly DJ, Thomson R, et al. Mental health outcomes in transgender and nonbinary people: an umbrella review. JAMA Psychiatry. 2025;82(11):1142-51.
4. Kingsbury M, Findlay L. Mental health and access to support among 2SLGBTQ+ youth. Health Rep. 2024;35(11):12-22.
5. Ritunnano R, Papola D, Broome MR, Nelson B. Phenomenology as a resource for translational research in mental health: Methodological trends, challenges and new directions. Epidemiol Psychiatr Sci. 2023;32:e5.
6. Moore C, Dukes C. The value of identity: providing culturally-responsive care for LGBTQ+ patients through inclusive language and practices. Del J Public Health. 2019;5(3):6-8.
7. Frost DM, Meyer IH. Minority stress theory: application, critique, and continued relevance. Curr Opin Psychol. 2023;51:101579.
8. Gessner M, Bishop MD, Martos A, et al. Sexual minority people's perspectives of sexual health care: understanding minority stress in sexual health settings. Sex Res Soc Policy. 2020;17(4):607-18.
9. Comeau D, Johnson C, Bouhamdani N. Review of current 2SLGBTQIA+ inequities in the Canadian health care system. Front Public Health. 2023;11:1183284.
10. Sinko L, Ghazal LV, Fauer A, Wheldon CW. It takes more than rainbows: supporting sexual and gender minority patients with trauma-informed cancer care. Cancer. 2024;130(4):507-16.
11. Livingston NA, Berke D, Scholl J, et al. Addressing diversity in PTSD treatment: clinical considerations and guidance for the treatment of PTSD in LGBTQ populations. Curr Treat Options Psychiatry. 2020;7(2):53-69.
12. Browning J. Personhood and AI: why large language models don't understand us. AI Soc. 2024;39(5):2499-2506.
13. Heinz MV, Mackin DM, Trudeau B, et al. Randomized trial of a generative AI chatbot for mental health treatment. NEJM AI. 2025;2(4):AIoa2400802.
14. Mehrabi N, Morstatter F, Saxena N, et al. A survey on bias and fairness in machine learning. ACM Comput Surv. 2021;54(6):115.
15. Ten Tije M. Bias in, bias out? Why AI isn't as neutral as you think. Tilburg.ai; 2024.
16. Santa Serravalle R, Muñoz Alarcon C, Duran Herrera F. Gender bias in AI: uncovering the roots and shaping inclusive futures. Mondo Internazionale; 26 Mar 2025.
17. Manche R, Myakala PK. Explaining black-box behavior in large language models. Int J Comput Artif Intell. 2022;3(2):102-8.
18. Bartl M, Murphy TB, Leavy S. Adapting psycholinguistic research for LLMs: gender-inclusive language in a coreference context. arXiv:2502.13120; 2025.
19. Mirzaei T, Amini L, Esmaeilzadeh P. Clinician voices on ethics of LLM integration in healthcare: a thematic analysis of ethical concerns and implications. BMC Med Inform Decis Mak. 2024;24:250.
20. Petzel Z, Sowerby L. Prejudiced interactions with large language models (LLMs) reduce trustworthiness and behavioral intentions among members of stigmatized groups. Comput Hum Behav. 2025;165:108563.

21. Russell ST, Fish JN. Mental health in lesbian, gay, bisexual, and transgender (LGBT) youth. Annu Rev Clin Psychol. 2016;12:465-87.
22. McBain RK, Cantor JH, Zhang LA, et al. Competency of large language models in evaluating appropriate responses to suicidal ideation: comparative study. J Med Internet Res. 2025;27:e67891.
23. Scholich T, Barr M, Wiltsey Stirman S, Raj S. A comparison of responses from human therapists and large language model-based chatbots to assess therapeutic communication: mixed methods study. JMIR Ment Health. 2025;12:e69709.
24. Schwartz AP. Why outing can be deadly. National LGBTQ Task Force; 20 Feb 2014.
25. Gümüşel E. A literature review of user privacy concerns in conversational chatbots: a social informatics approach. J Assoc Inf Sci Technol. 2025;76(1):121-54.
26. Garcia v. Character Technologies, Inc., 6:24-cv-01903, (M.D. Fla.).
27. Walters v. OpenAI, L.L.C., 1:23-cv-03122, (N.D. Ga.).
28. May R, Denecke K. Security, privacy, and healthcare-related conversational agents: a scoping review. Inform Health Soc Care. 2022;47(2):194-210.
29. The California Consumer Privacy Act of 2018, CA Civ Code § 1798.100 (2018).
30. Office for Civil Rights. Summary of the HIPAA Privacy Rule (original ruling 1996). U.S. Department of Health and Human Services; 2025.
31. Cambridge Dictionary. Techno-solutionism.
32. Eubanks V. Automating Inequality: How High-Tech Tools Profile, Police, and Punish the Poor. New York: St. Martin's Press; 2018.
33. Beyene LS, Strand EB, Misund AR, et al. Conceptualizing healthcare professionals' relational competence in mental healthcare: an integrative review. Int J Nurs Stud Adv. 2024;7:100266.
34. Miles O, West R, Nadarzynski T. Health chatbots acceptability moderated by perceived stigma and severity: a cross-sectional survey. Digit Health. 2021;7:20552076211063012.
35. Shen J, DiPaola D, Ali S, et al. Empathy toward artificial intelligence versus human experiences and the role of transparency in mental health and social support chatbot design: comparative study. JMIR Ment Health. 2024;11:e62679.
36. Glynn TR, Gamarel KE, Kahler CW, et al. The role of gender affirmation in psychological well-being among transgender women. Psychol Sex Orientat Gend Divers. 2016;3(3):336-44.
37. Long Y, Ma Z, Mei Y, Su Z. AffirmativeAI: towards LGBTQ+ friendly audit frameworks for large language models. arXiv:2405.04652; 2024.

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CRITICAL COMMENTARY (PEER-REVIEWED)

Critique des droits négociables de procréation comme mesure de contrôle de la population

Georges-Philippe Gadoury-Sansfaçon[a,b]

Résumé
Cet article propose une critique féministe approfondie des droits négociables de procréation (DNP), une mesure proposée pour contrôler la croissance démographique mondiale. L'analyse démontre que les DNP renforceraient les injustices économiques et sociales, tout en introduisant une dimension eugéniste problématique. L'article souligne la nécessité d'élaborer des politiques démographiques respectueuses de l'équité, de la justice sociale et des libertés individuelles.

Mots-clés
droits négociables de procréation, contrôle démographique, justice sociale, eugénisme, politiques démographiques, bienfaisance procréative

Abstract
This article offers an in-depth feminist critique of Tradeable Procreation Entitlements (TPE), a measure proposed to control global population growth. The analysis demonstrates that TPEs would reinforce economic and social injustices while introducing a problematic eugenic dimension. The article highlights the need to develop population policies that respect equity, social justice and individual freedoms.

Keywords
tradeable procreation entitlements, population control, social justice, eugenics, population policies, procreative beneficence

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INTRODUCTION

L'essor récent des préoccupations entourant l'urgence climatique, la disponibilité limitée des ressources naturelles et les défis économiques liés à une population mondiale en forte croissance ravive les débats sur les politiques démographiques et leur justification morale. Alors que la planète approche du seuil symbolique de dix milliards d'individus (1), les questions d'alimentation, d'eau potable, de logement et d'accès aux soins de santé deviennent critiques, notamment dans les régions les plus vulnérables (2). Ces situations problématiques amplifient les inégalités existantes et poussent les autorités décisionnelles à envisager des interventions pour limiter la croissance démographique mondiale, souvent au prix de restrictions importantes des libertés individuelles, de la vie privée ou du droit à l'autodétermination reproductive.

Un exemple marquant d'une telle intervention est la politique chinoise de l'enfant unique, instaurée en 1979 pour contrôler une surpopulation alors perçue comme menaçant gravement les ressources économiques et environnementales du pays (3). Bien que cette mesure ait réduit de manière significative le taux de natalité à court terme, elle a aussi provoqué des conséquences sociétales profondes. En effet, le vieillissement rapide de la population chinoise, couplé à une diminution drastique de la proportion de jeunes adultes en âge de travailler, entraîne aujourd'hui une pression socioéconomique majeure, sans parler de l'impact sur l'équité et le ratio des sexes (4,5). Ce déséquilibre démographique compromet désormais la viabilité des systèmes sociaux et économiques qui reposent sur une main-d'œuvre jeune et active pour soutenir financièrement et matériellement une population âgée en pleine croissance. Cet exemple met en lumière les défis éthiques et pratiques associés à l'implantation de mesures coercitives de contrôle des naissances, soulignant la nécessité de réfléchir à des approches alternatives.[1] Ces approches devraient également être évaluées à la lumière des risques qu'elles posent pour les droits fondamentaux : toute politique visant à restreindre la procréation soulève inévitablement la question de savoir si l'État peut aussi contraindre certaines personnes à procréer, et dans quelles conditions. Cette tension entre contrôle nataliste et coercition procréative expose le potentiel totalitaire d'un tel système.

LES DROITS NÉGOCIABLES DE PROCRÉATION (DNP)

Déjà en 1964, Boulding proposait le concept de droits négociables de procréation (DNP)[2] à des fins de gestion des naissances, soulignant explicitement la possibilité de « set up a market […] in which the rich and the philoprogenitive would purchase them from the poor, the nuns, the maiden aunts, and so on. » (9, p.135-136). Les DNP reposent sur l'idée d'attribuer à chaque individu ou couple un certain nombre de droits reproductifs transférables, permettant ainsi de contrôler le taux de natalité tout en instaurant une logique marchande autour des choix reproductifs.

[1] Pour une étude approfondie de l'éthique des politiques démographiques, voir (6-8).
[2] Traduction libre de « Tradeable Procreation Entitlements » (9,10). Traductions alternatives considérées : « permis » ou « obligations ».

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Chaque droit correspond au droit d'avoir un enfant biologique vivant. Ces droits sont conçus comme négociables et échangeables sur un marché où les prix évoluent selon l'offre et la demande. Cela implique que les personnes disposant de ressources financières suffisantes pourraient acquérir davantage de droits, tandis que les moins fortunées pourraient être incitées à vendre les leurs.

Plus récemment, de la Croix et Grosseries (10) et Bognar (11) ont examiné la viabilité du concept de DNP, cherchant à adapter cette proposition au contexte contemporain et contribuant à renforcer l'argumentaire économique en sa faveur. Toutefois, cette mesure soulève plusieurs questionnements éthiques fondamentaux du point de vue de la justice sociale en raison de son potentiel discriminatoire. Par exemple, les DNP pourraient renforcer les inégalités économiques, en permettant aux plus riches d'acheter des droits supplémentaires tout en contraignant les moins aisés à vendre les leurs. Ces mécanismes pourraient aussi aggraver les discriminations de genre et raciales déjà existantes, affectant particulièrement les groupes économiquement vulnérables. Malgré ces préoccupations, ces enjeux sociaux et éthiques demeurent largement sous-développés dans la littérature existante.

Ce commentaire critique vise précisément à approfondir l'analyse éthique des DNP, soulignant comment ces droits pourraient exacerber les injustices sociales et introduire une dimension eugéniste problématique. Ces enjeux – discriminations, eugénisme et instrumentalisation économique de la vie – constituent quelques-unes des dimensions problématiques que soulève ce type de dispositif. Bien que l'analyse mette l'accent sur ces aspects, ils s'inscrivent dans un ensemble plus vaste de préoccupations éthiques liées au contrôle de la procréation, incluant notamment les atteintes aux libertés individuelles, à la vie privée et au consentement.

EXACERBATION D'INJUSTICES SOCIALES

Les politiques démographiques doivent être examinées au vu des principes de justice sociale et d'équité, notamment lorsqu'elles visent à encadrer ou à restreindre la capacité reproductive des individus (6). Or, les droits négociables de procréation s'inscrivent dans la catégorie des mesures démopopulationistes (7), c'est-à-dire celles s'attaquant aux enjeux existentiels par une intervention sur le nombre. Ce sont souvent celles dont bénéficient les mieux nantis au détriment des moins bien nantis, souvent au nom du bien commun (12-14).

Ce type de politiques inclut notamment le cas du Pérou qui, dans les années 1990, a imposé la stérilisation forcée à plus de 200 000 femmes issues principalement des communautés rurales, autochtones et défavorisées, dans le cadre d'une politique briguant des arguments de réduction de la pauvreté et de contrôle de la natalité (15). À Singapour, durant les années 1970, le gouvernement a mis en place un système agressif d'incitation à la stérilisation volontaire des femmes peu éduquées après leur deuxième enfant, en offrant notamment des compensations financières et des avantages liés au logement, limitant ainsi gravement la liberté reproductive des populations visées et renforçant les discriminations économiques et sociales existantes (16).

Imaginons une application hypothétique des DNP dans un pays où les inégalités économiques sont prononcées et où l'administration en place prend des décisions et exécute des coupures de services qui ont le potentiel d'exacerber ces inégalités. L'accès aux droits reproductifs supplémentaires deviendrait rapidement inaccessible pour les familles à faible revenu, exacerbant davantage les fractures sociales existantes et soulignant clairement le caractère problématique de cette mesure dans un contexte capitaliste contemporain.

En outre, cette mesure exacerbe les injustices raciales, de genre et de classe, puisque la capacité d'achat sur le marché des droits reproductifs est inégalement distribuée. Ainsi, l'accès effectif à ces droits dépendrait directement des moyens financiers, privilégiant automatiquement les groupes économiquement aisés. Comme illustré précédemment dans le cas fictif, la femme recevant initialement 1,5 DNP mais n'ayant pas les moyens d'acheter le demi-droit supplémentaire nécessaire pour un second enfant serait contrainte de vendre son droit restant. Cette situation limite clairement l'option d'avoir une famille plus grande aux individus capables d'assumer les coûts élevés imposés par le marché, renforçant ainsi les systèmes de pouvoir existants et aggravant les inégalités sociales déjà profondes.

Cet exemple permet aussi de mettre en lumière l'enjeu de consentement libre soulevé par les DNP. Supposons que la femme dispose de très peu de moyens financiers et que sa seule solution pour subvenir à ses besoins est de vendre son droit et demi de procréation, alors que si elle était dans une autre situation financière elle voudrait se prévaloir de son droit; il serait difficile ici de soutenir qu'elle consent librement à cette vente. Bien que les considérations financières poussent quotidiennement l'individu vers des décisions et des responsabilités non désirées (ex. : garder un emploi non stimulant pour subvenir à ses besoins) sans nécessairement compromettre sa liberté de choix, une compensation aussi significative a tout de même le potentiel de nuire de façon significative et existentielle à l'expression d'un consentement suffisamment libre.

La mesure est aussi teintée d'un eugénisme négatif par le fait qu'elle crée une limitation inégale des droits reproductifs de groupes précis — ici, ceux qui ne pourront pas se permettre l'achat de droits supplémentaires[3] ou qui n'auront pas d'autre choix que de vendre leurs droits. Les enjeux susmentionnés ont donc la possibilité de dissuader des groupes traditionnellement victimes de discrimination par rapport à la reproduction au profit des plus riches. La mesure s'inscrit donc dans le même ordre d'idées que plusieurs tentatives de supprimer la fertilité des uns et d'augmenter la fertilité des autres, ce qui renforce son caractère eugéniste.

[3] Pour une critique de la nécessité d'avoir plus d'un enfant pour répondre aux droits reproductifs, voir (17).

LA BIENFAISANCE PROCRÉATIVE ET L'ENJEU DÉMOGRAPHIQUE

En parallèle, Bognar (11) soutient que les considérations de justice sociale ne sont pas justifiées, et propose un contre-argumentaire passant par l'application du principe de bienfaisance procréative à l'enjeu démographique.

D'abord, il s'appuie sur des observations dans les pays développés selon lesquelles plus les individus deviennent riches, moins leur famille tend à être grande. Il suggère ainsi que la demande des plus riches serait beaucoup moins élevée que nous l'imaginions instinctivement. Néanmoins, considérant l'éventualité où cette observation s'avérait non applicable dans une situation de droits négociables de procréation, il réfère au modèle économique d'analyse de la mesure présenté par de la Croix et Grosseries (10). Ce modèle soutient que les inégalités seraient réduites à long terme puisque la situation des moins bien nantis s'améliore après la vente. En d'autres mots, la mesure contribuerait dans certaines circonstances à diminuer les disparités financières puisqu'elle entrainerait une redistribution progressive des ressources aux plus pauvres, ayant donc un effet positif sur la justice sociale à long terme. Il propose également que les gouvernements pourraient distribuer plus de ressources aux moins bien nantis pour leur permettre de participer au marché ou acheter les droits pour eux.

Il soutient également qu'au bout du compte, le principe de bienfaisance procréative, selon lequel nous avons l'obligation morale de sélectionner l'enfant ayant la plus grande chance de mener une meilleure vie, traditionnellement soulevé en lien avec le diagnostic préimplantatoire (18), s'applique à l'enjeu démographique et justifie les conséquences sociales potentielles.[4] Il affirme qu'en fin de compte, ce n'est pas une mauvaise chose si davantage d'enfants naissent de familles mieux nanties :

> If children are born to worse off parents, then they get a worse start in life than children who are born to better off parents. If social policy can affect the kind of start children get in life, then, arguably, it should do so; if it can make such an impact impersonally, then, arguably, it should do so too. (11, p.9)

Les premiers arguments présentés par Bognar s'appuient sur une évolution hypothétique des enjeux à long terme pour justifier l'implantation de DNP en matière de justice sociale, mais font par le fait même abstraction des enjeux individuels en découlant à court terme. Or, la considération de la situation et des droits (ici reproductifs) des individus est au cœur des réflexions d'égalité et d'équité propres à la justice sociale; proposer une diminution de la pauvreté à long terme par une pénalisation de la pauvreté va donc à l'encontre des convictions promues. L'idée qu'un paiement unique puisse faire une différence significative à long terme dans ce contexte est également questionnable en l'absence de mesures se penchant sur les déterminants structuraux de la pauvreté (21).

Le raisonnement présenté ne réussit pas non plus à justifier la transposition du principe de bienfaisance procréative à l'enjeu démographique. La prémisse composée selon laquelle de pouvoir agir sur le type de départ s'ensuit le devoir d'agir ne suffit pas à justifier que la politique sociale devrait spécifiquement agir par le biais de DNP. Bognar sous-entend également une conception capitaliste et eurocentrique de la bonne vie et du meilleur départ selon laquelle leur caractère « bon » est proportionnellement lié à l'argent. Ce faisant, il appose un faux dilemme entre la pauvreté extrême et la richesse et présente une généralisation abusive et une vision préjudiciable des conditions de vie des individus qui ne font pas partie des plus aisés.

CONCLUSION

Il apparait donc que les droits négociables de procréation ne constituent pas une mesure justifiable de contrôle démographique, principalement en raison de leur effet exacerbant sur les injustices sociales. Cette conclusion découle directement de l'analyse proposée, qui souligne comment ces mesures renforcent les inégalités déjà présentes dans les sociétés contemporaines. En permettant aux plus riches d'acquérir des droits reproductifs supplémentaires, les DNP introduisent non seulement une dimension profondément discriminatoire, mais également une forme d'eugénisme économique susceptible de limiter la reproduction des groupes les moins favorisés.

En outre, bien que les arguments en faveur de telles mesures, comme ceux de Bognar, puissent invoquer une amélioration hypothétique des conditions socio-économiques à long terme, ils négligent systématiquement les impacts individuels immédiats, lesquels sont pourtant cruciaux dans une perspective de justice sociale. L'application du principe de bienfaisance procréative dans ce contexte s'avère problématique, puisqu'elle présuppose une hiérarchisation des conditions de vie basée principalement sur des critères économiques réducteurs et eurocentriques, ignorant ainsi la complexité et la diversité des réalités vécues par les individus moins aisés financièrement.

En cela, les DNP ne représentent pas uniquement un enjeu de justice sociale, mais également un glissement possible vers une gouvernance biopolitique autoritaire, dans laquelle les corps reproducteurs deviennent des objets de régulation étatique ou marchande. Le fait d'instaurer un marché des naissances implique une surveillance constante, une gestion centralisée des droits reproductifs et de la contraception, et donc une réduction significative de la sphère privée.

Enfin, au-delà des DNP, plusieurs autres mesures démographiques méritent également un examen approfondi quant à leur justification éthique, particulièrement dans un contexte de population croissante. Des propositions frappantes comme l'installation obligatoire d'un implant contraceptif avant la puberté mettent en lumière la nécessité de développer des cadres d'analyse éthique rigoureux afin de prévenir les dérives potentiellement liberticides et discriminatoires.

[4] Pour une critique de la nature impersonnelle du principe de bienfaisance procréative, voir (19,20).

Il existe par ailleurs des leviers reconnus qui, sans imposer de restrictions, contribuent à soutenir des choix reproductifs réfléchis et autonomes. L'amélioration de l'accès à l'éducation, la disponibilité universelle de la contraception, ainsi que les politiques de soutien à la parentalité sont autant d'initiatives qui peuvent influencer les taux de natalité tout en respectant les droits et les libertés individuelles. Il demeure toutefois essentiel que ces interventions s'inscrivent dans une logique de promotion de l'autonomie et de justice sociale, et non dans une stratégie implicite de gestion démographique.

L'exploration attentive des implications sociales et éthiques des politiques démographiques demeure donc essentielle afin d'assurer que les approches choisies respectent véritablement les principes fondamentaux d'équité, de justice sociale et de respect des libertés individuelles.

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RÉFÉRENCES

1. United Nations. World Population Prospects 2024. New York: United Nations Department of Economic and Social Affairs, Population Division; 2024.
2. Lam D. The next 2 billion: can the world support 10 billion people? Popul Dev Rev. 2024;51(1):63-102.
3. Zhang J. The evolution of China's one-child policy and its effects on family outcomes. J Econ Perspect. 2017;31(1):141-60.
4. Li H, Yi J, Zhang J. Estimating the effect of the one-child policy on the sex ratio imbalance in China: identification based on the difference-in-differences. Demography. 2011;48(4):1535-57.
5. Zhang Y, Goza FW. Who will care for the elderly in China? J Aging Stud. 2006;20(2):151-64.
6. Andersson H, Brandstedt E, Torpman O. Review article: The ethics of population policies. Crit Rev Int Soc Polit Philos. 2021;27(4):635-58.
7. Bhatia R, Sasser JS, Ojeda D, Hendrixson A, Nadimpally S, Foley, EE. A feminist exploration of 'populationism': engaging contemporary forms of population control. Gend Place Cult. 2020;27(3):333-50.
8. Page EA. Justice between generations: investigating a sufficientarian approach. J Glob Ethics. 2007;3(1):3-20.
9. Boulding K. The Meaning of the Twentieth Century: The Great Transition. London: Routledge; 1964.
10. de la Croix D, Gosseries A. Population policy through tradable procreation entitlements. Int Econ Rev. 2009;50(2):507-42.
11. Bognar G. Overpopulation and procreative liberty. Ethics Policy Environ. 2019;22(3):319-30.
12. Bandarage A. Women, Population and Global Crisis: A Political-Economic Analysis. London: Zed Books; 1997.
13. Hartmann B. Reproductive Rights and Wrongs: The Global Politics of Population Control. Chicago: Haymarket Books; 2016.
14. Schultz S. Reproducing the nation: the new German population policy and the concept of demographization. Distinktion J Soc Theory. 2015;16(3):337-61.
15. Vasquez Del Aguila E. Precarious Lives: forced sterilisation and the struggle for reproductive justice in Peru. Glob Public Health. 2022;17(1):100-14.
16. Rowlands S, Regmi PR. The use of forced sterilisation as a key component of population policy: comparative case studies of China, India, Puerto Rico and Singapore. Indian J Public Adm. 2022;68(2):271-84.
17. Conly S. One child: do we have a right to more? J Popul Sustain. 2016;1(1):27-34.
18. Savulescu J. Procreative beneficence: why we should select the best children. Bioethics. 2001;15(5-6):413-26.
19. Stoller SE. Why we are not morally required to select the best children: a response to Savulescu. Bioethics. 2008;22(7):364-9.
20. Bennett R. The fallacy of the principle of procreative beneficence. Bioethics. 2009;23(5):265-73.
21. Winkler-Schor S, Brauer M. What happens when payments end? Fostering long-term behavior change with financial incentives. Perspect Psychol Sci. 2024;20(5):925-40.

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RÉPONSE À - ARTICLE / RESPONSE TO - ARTICLE

Between Human Extinction and the Extinction of Good Arguments: Placing Warning Signs for the Survival of Both

Murilo M. Vilaça[a]

Texte discuté/Text discussed: Torres ÉP. If artificial superintelligence were to cause our extinction, would that be so bad? Can J Bioeth/Rev Can Bioeth. 2025;8(3):74-85.

Résumé
Ce texte est une réponse à l'article de Torres sur la super-intelligence artificielle et l'extinction de l'humanité. J'émets quelques signaux d'alerte sur la trajectoire argumentative de l'auteur, affirmant que le sujet de l'extinction de l'humanité est pertinent et qu'il est donc nécessaire de rectifier le cap à plusieurs reprises.

Abstract
This text is a response to Torres' article on artificial superintelligence and human extinction. I place some warning signs on the author's argumentative trajectory, arguing that the topic of human extinction is relevant, so it is necessary to correct the course at several points.

Mots-clés
philosophie, bioéthique, revue de la littérature, faisceau d'idées fausses, bons arguments

Keywords
philosophy, bioethics, literature review, bundle of fallacies, good arguments

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In his article, "If artificial superintelligence were to cause our extinction, would that be so bad?" (1), Torres focuses on the question of human extinction through the risk posed by artificial superintelligence (ASI). According to him, "this is a topic that [...] bioethicists have not adequately examined" and "philosophers lack a robust theoretical framework for providing nuanced answers to this question" (p.74), Torres presents his aim as modest: "to encourage more vigorous debate about this topic among bioethicists, and to do this by applying the theoretical framework that I have developed elsewhere to the particular case of ASI" (p.74-5).

It may sound very promising when someone emerges who can fill important gaps in knowledge on a complex and relevant topic, in two areas — bioethics and philosophy — that no one has been able to fill before. This certainly catches the reader's attention, since, searching for ("artificial superintelligence" AND "theoretical framework") and ("artificial superintelligence" AND ethics AND "theoretical framework) on Google Scholar, we have the following results respectively: 259 and 174 (from 2000 to 2024, in the search carried out on December 4, 2025).

Here, then, it is appropriate to place a first "warning sign". Torres's assertions about the inadequacy of the approaches of bioethicists and philosophers create a burden of proof for him, namely to demonstrate that in all the relevant literature, nothing can be considered adequately examined, nor is there a robust theoretical framework. Insofar as he appears not to have adequately reviewed the literature, nor present the reasons for not reviewing certain texts, nor identified the authors of the texts by area of expertise (bioethics or philosophy), Torres may have committed a methodological error or, ultimately, may have petitio principii, since he begins the text with assertions (which may be the core of his argument) that he does not properly demonstrate. While we can assume that not all the results of the above searches are relevant to answering the author's question, the reader is not presented with anything to help them understand to what extent the texts not reviewed by the author would not change a scenario of the debate that he presents as incomplete. Instead of proving that there is no good answer to the question, he states that it doesn't exist and that he will provide one. Put another way, on what basis does the author make the above claims about the limitations of bioethicists and philosophers, in such broad terms?

This warning sign is a big one. In several paragraphs, Torres uses declarative sentences, offering few or no references (sometimes just one; sometimes that single reference is to himself). This cannot be called a literature review. Despite that, on p. 75, for example, he announces the "consensus view" (which, in footnote 4, he informs us he has already called the "default view"). We are on the second page, and we are already faced with a supposed consensus (which was a default) on this controversial topic. The author doesn't explain why the terminology changed. "Now [I] prefer the [new] term", he says (p.75). Personal preferences are not exactly a good way to achieve the conceptual robustness the author claimed to seek.

Based on a fairly limited number of texts, he writes sentences, creating a highly questionable overall effect. "Transhumanists [...] would say that [...]" (p.78), "the vast majority of pro-extinctionists accept [...]." (p.78), and so on. Torres's transhumanists are reduced to two texts by Nick Bostrom, which, for any expert on the subject, is not even remotely convincing in presenting the perspective of this transhumanist alone.

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According to Pirie, “the fallacy of composition occurs when it is claimed that what is true for individual members of a class is also true for the class considered as a unit” (2, p.31). Torres puts everything in the same “bundle” (3), as he states in footnote 12: “It is for this reason that one might wish to classify versions of transhumanism, longtermism, and other TESCREAL (Transhumanism, Extropianism, Singularitarianism, Cosmism, Rationalist, Effective Altruism, and Longtermism) ideologies as ‘pro-extinctionist’.” (1, p.80). Although he may claim that the “simple repetition of a point of view does nothing by way of supplying additional evidence or support” (2, p.111), Torres’s bundle becomes increasingly full of different things, and as a result, the conceptual gaps widen.

A second warning sign refers to Torres’s ASI and what I will call the epistemic gap. “Imagine” (1, p.75), the author proposes. Imagining is a wonderful human capacity. But, in an “ocean of possible imaginations” about what an ASI could be, a concept that has been used in very different ways, Torres seems to incur the lack of conceptual (and, I add, epistemic) robustness that he points out. Further on, in the “Equivalence Views” section, Torres ‘imagines’ two other extinction scenarios involving the ASI. It would be more coherent or prudent to write “involving an ASI” because, as he claims, “the details of Going Extinct are paramount” (1, p.79).

But there is another side to the epistemic gap that should be highlighted. In a recent publication, Agar and Vilaça (4) argued that human extinction via an ASI may be a “problem of charismatic extinction threats” and counsel the adoption of a “imagination insurance for an intrinsically uncertain future”. “We are, of course, free to imagine an ASI with such power [like Skynet]” (4, p.7), they note, but claim that “Imagination insurance offers a way to bring attention to extinction threats that overly focusing on [ASI] and other exotic extinction threats causes us to overlook. [...] Humanity needs imagination insurance in respect of extinction threats” (4, p.10-1).

Agar and Vilaça start from a fact to offer a relevant normative answer to a central question of our time: “how much of our finite pool of worry we should allocate to each extinction threat [?...]. Only then can we decide which threats to ignore and which to seriously prepare for” (4, p.11). The authors’ suggestion isn’t exactly groundbreaking, but given the current scenario, it proves to be very useful: We should focus on the intrinsic causes of a potential threat of extinction, that is, in [new] evidence. Without providing or addressing evidence, our imagination can take us far from what matters.

Although he promises to offer a solution to the problem of “lack a robust theoretical framework”, Torres surprisingly fails to consider that he may have been captured by the charisma of a threat that may be far from relevant to thinking robustly about the most fundamental part of his question: Would it be good if everyone on Earth (read: human beings) were killed? In this regard, Torres’s conclusion doesn’t sound so innovative:

> My hope is that this provides a helpful degree of clarity to a deceptively complex issue: nearly everyone — including most proextinctionists — would concur that the mass murder of everyone on Earth would be extremely bad (1, p.83).

For someone deeply interested in the topic of human extinction and concerned about the quality of the debate, Torres does not seem to have singled out the most threatened danger, nor to have offered major contributions to what he calls “consensus view”.

I conclude this commentary by highlighting a controversial characteristic of Torres’s argumentation in some of his texts (here is the third warning sign): labelling as eugenics what he wants to criticize. He uses this term frequently in his arguments. In another text, alongside Gebru, eugenic ideology was the very strong link between very different things: racism, xenophobia, classism, ableism, sexism, transhumanism, Extropianism, singularitarianism, (modern) cosmism, Rationalism, Effective Altruism, and longtermism (3).

In his text (1), in footnote 14, Torres uses the word, qualifying it in an innovative way: digital eugenics (1, p.80). Eugenics appears in footnote number 14, in which he states: “For a discussion about what our artificial descendants might be like, and the ethics of creating artificial descendants, see (49). Note that I object to the sort of “digital eugenics” [...] – that this paper explores.” (1, p.80). In another text, Torres states that “digital eugenicists want to do away with biology altogether” (5). The reference “49” in Torres’ article is a text by Lavazza and Vilaça (6). I invite the reader to read that article, in which, broadly speaking, the authors argue that in a hypothetical scenario of imminent and irreversible human extinction (the ultimate threat), it would be better to consider how to preserve some of the value of human beings by generating non-organic successors (based on silicon) than to do nothing. At no point in the text do Lavazza and Vilaça argue that we should do away with biology altogether, nor that this would be desirable or better, which eliminates any possibility of identifying the authors as digital eugenicists.

Torres uses the expression “artificial descendants” and correlates it with “digital eugenics,” stating that “I object to the sort of ‘digital eugenics’.” (1, p.80). In other words, Torres associates Lavazza and Vilaça with advocates of something like digital eugenics. But a clever reader will easily see that this is not true.Lavazza and Vilaça neither explore, much less defend, the creation of artificial descendants, postulating to do away with biology altogether. Therefore, the definition of “digital eugenicists” used by Torres himself does not apply to them. The authors are very clear: they are not advocating the extinction of humanity, nor its replacement by artificial descendants (who would be superior). Starting from the hypothetical premise “[...] that there is

an impending threat and that there is a will to address the issue of our potential extinction" (6, p.3), they propose that we consider what entity could succeed us, carrying as much of our human value as possible. The scenario clearly outlined by the authors does not allow any inference that their arguments are pro-extinction.

Transhumanists, pro-extinctionists, or anyone Torres wants to oppose sound reprehensible at the origin, when associated with eugenics, without even needing to explain in depth what this means in its various forms and contexts (2). Considering that labelling someone or some argument as eugenicist does not tend to legitimize them/it, it is important to pay attention to this strategy of the author, which can be framed in a myriad of fallacious ways.

In Torres's article, there are some interesting clues about the problems of the debate surrounding the question of human extinction, such as the different conceptions of what it means to be human. The overview presented (three main positions within existential ethics) may also be useful for introducing the debate, but the criteria for defining why these are the main ones are unclear. Perhaps the most important thing for advancing this debate is to address controversial issues in the most analytical way possible, and the least ideological or prejudiced. Instead of framing authors and perspectives within a preconceived framework, labelling them/it, we must identify how concepts, arguments, empirical evidence, and imagination can be combined to generate the best possible understanding of the topic.

Thinking about the threats to the presence of humans (and nonhumans) on Earth is crucial today. We need to unite the billions of minds around this (4). Imagination is precious, criticism is necessary, but we will not save humans at the expense of good arguments.

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REFERENCES

1. Torres ÉP. If artificial superintelligence were to cause our extinction, would that be so bad? Canadian Journal of Bioethics/Revue canadienne de bioéthique. 2025;8(3):74-85.
2. Pirie M. How to Win Every Argument: The Use and Abuse of Logic. New York: Continuum; 2007.
3. Gebru T, Torres, ÉP. The TESCREAL bundle: eugenics and the promise of utopia through artificial general intelligence. First Monday. 2024;29(4).
4. Agar N, Vilaça MM. On artificial superintelligence and the problem of charismatic extinction threats. Journal of Ethics and Emerging Technologies. 2025;35(2):1-12.
5. Torres ÉP. Digital eugenics and the extinction of humanity. Tech Policy Press. 11 Jul 2025.
6. Lavazza A, Vilaça MM. Human extinction and AI: what we can learn from the ultimate threat. Philosophy & Technology. 2024;37:16.

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COMPTE RENDU / REVIEW

Undoing Suicidism: A Trans, Queer, Crip Approach to Rethinking (Assisted) Suicide by Alexandre Baril

Juergen Dankwort[a,b]

Résumé
Il n'y a pas de sujet plus brûlant actuellement que l'examen critique des thèmes de la prévention du suicide et du suicide assisté. C'est ce qu'a accompli de manière exceptionnelle le Alexandre Baril dans son ouvrage *Undoing Suicidism: A Trans, Queer, Crip Approach to Rethinking (Assisted) Suicide* (2023). Bien qu'il s'agisse incontestablement d'une contribution majeure au domaine de la prévention du suicide et de l'aide à mourir, remarquablement explorée dans un seul ouvrage, le raisonnement approfondi et critique de l'auteur semble faire défaut lorsqu'il explore les approches existantes et évolutives du suicide assisté volontaire dans la deuxième partie de son ouvrage révolutionnaire.

Mots-clés
prévention du suicide, aide à mourir, politique de santé

Abstract
There is no more compelling a current issue than critically examining the topics of suicide prevention and assisted suicide. That has been exceptionally accomplished by Alexandre Baril in his book *Undoing Suicidism: A Trans, Queer, Crip Approach to Rethinking (Assisted) Suicide* (2023). While it is unquestionably a major contribution to the field of suicide prevention and assisted dying, remarkably explored in a single book, the author's thorough and critical reasoning appears to fall short where he explores existing and evolving voluntary assisted suicide approaches in the second part of his revolutionary work.

Keywords
suicide prevention, assisted dying, health policy

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There is no doubt that Alexandre Baril has upended prevailing approaches in suicide prevention. His approach is solidly grounded through a "queercrip" lens and relevant for practitioners, health beneficiaries, researchers, and others concerned with legal, medical, policy, and ethical implications. His contribution to the field of suicidality is profound and gives pause to notions that people must necessarily be deterred from attempting the act at all costs. The very idea of providing support in affirming assisted suicide for suicidal people appears at first blush to be counter-intuitive and contraindicated, that is, until one delves into his richly developed theoretical treatise, which is well-grounded, clearly explained, amply supported, and logical. Moreover, all of it is more convincingly offered by a scholar who has experienced suicidal ideation since his youth and had to hide his ideations for over a year from physicians to even obtain his DNR bracelet.

Undoing Suicidism (1) is both a remarkable protest and plea to understand how suicidal people experience pervasive forms of criminalization, incarceration, moralization, pathologization, stigmatization, marginalization, exclusion, and discrimination; it is anchored destructively, he argues, in a logic of misguided preventive care that demands an injunction to live in almost any conceivable situation. That flawed "abstinence" approach, he convincingly explains, accounts for massive failures in suicide prevention linked to a discourse and practice that "propel deaths by suicide rather than prevent them." Suicidal people are oppressed by what he coins "structural suicidism", an experience all too familiar for far too many, especially those who don't fit binary categories of gender and sexuality.

The second part of his book then opens the door to the recent right-to-die movement, now impressively grown to over 60 organizations located in 30 countries on several continents, according to the World Federation of Right to Die Societies (2). Not surprisingly, a dive into suicidism would not seem a stranger to those acquainted with the topic of assisted suicide. Yet he notes that neither field in its respective studies explores the other; there's a dearth of information in suicidism on assisted dying, and no discussion of suicidism among right-to-die proponents and researchers. The literature in both fields omits the other.

Baril critiques right-to-die societies for their stated objective to provide assisted dying that adheres to legislated boundaries established through laws within their jurisdictions (all of which require applicants for this provision to be ill or sick, yet competent, and of a certain senior age with few eligibility exceptions). He brings the reader back to his initial points which assert that this is ageist, ableist, and sanist. The older, the sicker, and the more "rational" you are, as established to the satisfaction of the medical profession, the more likely you will be granted access.

I welcome Baril's recognition of a crucial problem with the current prevailing models for assisted dying regimes around the world for the reasons he lists: just adding more people to the current regimes further entrenches a flawed and legislated pathway for this provision which is still based on the same exclusionary criteria; that is, marked by bifurcations of young/old, healthy/sick, and rational/irrational. In other words, even as current restrictions are challenged by applicants whose conditions

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are excluded from the provision, and therefore argue that they have been denied their constitutional rights, widening eligibility still falls short of addressing the lack of fundamental positive rights for suicidal people or those seeking assisted dying as a service.

In a remarkable recent decision by the German Federal Constitutional Court (3), the very notion of codifying eligibility criteria by government legislation to establish a life worth living — or not — for access to assisted dying has similarly been deemed unacceptable and incompatible with the values of liberal, pluralist societies. However, it differs from Baril's conception insofar as it was based on an established principle of person-state separation. This is perhaps not coincidentally clarified by a German court given that country's darkest chapters of the Third Reich, when persons deemed unfit for society were institutionally euthanized. The difference between Baril's objections and the determination of the court is that the latter did not focus on the -isms that Baril eschews; it rejects the process of institutionalizing criteria by the state that would determine which understanding of quality of life is deemed livable or the contrary. The contrast here is not merely academic. Baril later postulates that the way forward with assisted suicide is for it to be normalized legislatively and thus granted state approval.

While Baril's astute observations are not only original and potentially ground-breaking for creating a pathway to assisted suicide with important practice implications, he fails, however, to appreciate the profound difference between a service that sets out to support suicidal persons and one designed to assist them to commit suicide (voluntary assisted dying). Baril appears to conflate the two because of his focus on an anti-oppression agenda.

It occurred to me that there is more than a nuance in this difference between responding to persons presenting as suicidal and responding to a person seeking aid to end their life. In the former, no sanctioned provision is required or included other than a fully validating, respectful, position for the beneficiary. This certainly is essential for practitioners employing active listening and empathetic skills. In contrast, a request to end one's life with assistance through a provision necessarily means that the act be provided or denied, and that then involves a plethora of considerations respecting autonomy on the one hand and security for vulnerable persons on the other, with providers being held accountable for their involvement.

Baril's failure to distinguish the vastly different mandates, and societal implications, for each service also leads him to propose that assisted dying providers meet the same objectives, and accomplish the same tasks, that he identifies as essential to implementing the only productive and rights-based approach for both assisted dying and effectively supporting persons burdened with suicidal ideations. Although an argument can be made to support the claim that assisted dying services may in fact help prevent unwanted, violent, and desperate suicide when it is driven by a lack of any acceptable, sanctioned option, to place such added tasks on each service seems unrealistic and counterproductive. For example, with respect to other interventions, studies have consistently shown that the most successful strategies for stemming intimate partner and family violence have occurred through the provision of specialized services for victims and offenders each of which functions via a coordinated and integrated community approach, with each contributing a piece of the process with its own expertise. No single service has shown comparable positive results.

Baril recognizes an outlier in assisted suicide providers, namely Exit International (4), which renounces illness as a necessary criterion for access to the provision and thus avoids ableism in its mission, yet it still fails to meet his approval. He claims that Exit International approaches the matter from an individualistic and "underground" stance, which means that it fails his intersectional understanding for effective social change; that is, that it must attain legitimization through legislation.

With this stipulation, I argue that he errs in several ways: First, he omits to note other right-to-die associations, such as Final Exit Network (5) in the US, and NGO services in Switzerland and Germany, who have in fact garnered support for both the traditional assisted suicide path within respective regulations that permit either physician-assisted dying or assisted euthanasia by other means and providers, including, in some cases, information on self-deliverance outside of usually sanctioned parameters. Second, he lacks understanding about the ways that effective social change can and does occur by assisting individuals through the provision of direct services such as education, clothing, and food bank assistance that have functioned, for example, as crucial recruitment tools in enlisting welfare recipients in the work of citizens' groups, thereby galvanizing participation in anti-poverty movements in Canada, the US, and elsewhere. His critique, that an organization deemed "underground" fails the test of effective change-making is flawed as even a cursory review of movement development can show that historically such groups, sometimes revolutionary and having to function below the radar in order to survive, have later produced meaningful social change. And, lastly, his criticism that Exit International is ageist because it requires applicants seeking information and resources to be at least 50 years old leaves out the organization's acceptance of exceptional younger persons for compelling reasons.

When I was a young McGill University graduate social worker, publicly contesting a closure of a social service agency satellites in Quebec on the fabricated grounds that services were no longer needed there, I discovered that applying all of my training, education, and social work practice goals would not go unpunished. In this, my first job, I was targeted with industrial discipline for disloyalty to my employer. As a social worker, and Ottawa University associate professor, Dr. Baril will surely recognize that no practice occurs without institutional, medico-legal, and/or socio-political boundaries. There are restraints which I fully discovered in arbitration. That said, *Undoing Suicidism* is absolutely a must-read and one that I hope will rewrite the curricula of suicide prevention efforts while reinforcing the awareness of already proficient helpers applying or strengthening their active listening and empathetic skills. Beyond that, it may also serve as a cautionary tale with respect to replicating a prevailing, problematic, and controversial approach when creating a new assisted dying provision.

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REFERENCES

1. Baril A. Undoing Suicidism: A Trans, Queer, Crip Approach to Rethinking (Assisted) Suicide. Philadelphia: Temple University Press; 2023.
2. World Federation of Right to Die Societies. Members.
3. den Hartogh G. Decriminalising assisted suicide services: Bundesverfassungsgericht 26 February 2020, 2BvR 2347/15. European Constitutional Law Review. 2020;16(4):713-32.
4. Exit International. About Exit.
5. Final Exit Network. About.

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ART, CULTURE ET OEUVRE DE CRÉATION / ART, CULTURE & CREATIVE WORKS

My Haiku Practice

James Dwyer[a]

Résumé
J'étais très occupé. Souvent, je n'étais pas vraiment attentif au moment présent. Trop souvent, je pensais déjà à la prochaine tâche sur ma liste. J'ai donc commencé à écrire un haïku par jour. Je me suis dit que cela m'aiderait à être plus présent, plus attentif et plus réactif. Dans cet essai, je décris ma pratique du haïku. Au début, je voulais conserver mes haïkus et les classer par saisons, mais cela n'a pas fonctionné. Je les ai donc rangés dans les catégories suivantes : trajet pour aller au travail; nature et nature humaine; jeunes et vieux; vie conjugale; vie moderne; ordinateurs, IA et Internet; vie universitaire; monde médical; vie en période de pandémie; retraite; vie politique; pratique spirituelle; mort; et attitude face à la mort. J'explique ces catégories en donnant des exemples de haïkus que j'ai écrits. J'ajoute également une brève conclusion provisoire qui renvoie à mes objectifs spirituels : être plus présent, plus attentif et plus réactif. Ma pratique m'a aidé à être plus présent et plus attentif, mais je ne suis pas certain d'être devenu plus réactif. Je crois que, pour le devenir, je devrai développer de nouvelles habitudes — de nouvelles façons d'habiter le monde. Je termine en proposant quelques étapes susceptibles de m'aider à devenir plus réactif.

Mots-clés
haïku, pratique spirituelle, pleine conscience, réactivité, réflexion éthique, vie quotidienne

Abstract
I was busy. Often, I was not mindful of the present moment. Too often I was thinking ahead to the next thing on my list. So I began to write one haiku each day. I thought it might help to become more present, mindful, and responsive. In this essay, I describe my haiku practice. At first, I wanted to save my haiku and arrange them by seasons, but that didn't work. So I arranged them in these categories: walk to work; nature and human nature; young and old; married life; modern life; computers, AI, and the Internet; academic life; medical world; pandemic life; retirement; political life; spiritual practice; death; and attitude toward death. I explain these categories by giving examples of the haiku that I wrote. I also add a short, tentative conclusion that refers back to my spiritual aims: to become more present, mindful, and responsive. My practice did help me to become more present and mindful, but I'm not sure that I'm any more responsive. I believe that to become more responsive, I will need to develop new habits — new ways of inhabiting the world. I conclude with steps that might help me to become more responsive.

Keywords
haiku, spiritual practice, mindfulness, responsiveness, ethical reflection, daily life

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INTRODUCTION

I was busy. I had classes to teach, ethics consults to do, my own health problems to attend to, and people to care for and about. Often, I was not mindful of the present moment and what I was doing. Too often I was thinking ahead to the next thing on my list. So, I began to write one haiku each day. I wanted to be more mindful, present, and responsive. This is my report on the use of haiku as a spiritual, and ethical, practice.[1]

I followed Matsuo Basho (1644-1694) in using haiku as a form of spiritual practice (3,4). Indeed, Basho transformed linked poems that were courtly displays of intellectual skill into poems that embody a Zen spirit. He developed what we now call haiku. However, in acknowledging my debt to Basho, I want to be clear about two things. First, I am not claiming that my poems embody the skill and depth of Basho's. Second, although I embarked on writing haiku as a spiritual practice, I am not claiming that this practice is a sufficient and necessary condition to become a good person.

My haiku practice is simply one way to address a problem that I noticed in my own living. I don't think there is one way, with sufficient and necessary conditions, to becoming a good person. I think that good living has many aspects. The aspect that bioethics has focused on is deliberation and decision, but paying attention is an important part of moral life, and I've also come to sense that responsiveness is very important. I wanted to see if my haiku practice could help me pay attention, perceive more clearly, and respond more effectively. Later in my essay, I will try to explain responsiveness, the quality of responding to the situation or context.

I used my haiku practice to try to cultivate some Zen values: attending to the present moment, moderating intellectual abstractions, viewing the self in connections, and recognizing the impermanence of life. Although I admired these Zen values, I couldn't help but thinking about how Zen failed to address, criticize, and dampen the rise of militarism in Japan in the 1930s and 1940s (5). Like many institutionalized religions, Zen was often used to rationalize and justify forms of warfare.

[1] This is my third report on my haiku practice; for the first two, see (1,2).

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Classical Japanese haiku are very short poems of 17 syllables. Traditionally, they include a seasonal word (*kigo)* and a cutting word *(kireji*). The seasonal words set the poem in the natural cycle, and the cutting word helps to contrast the images in the poem. I had trouble with all these requirements. 17 syllables does not make sense in European languages like English and French. So, I was happy to free myself from that requirement. Although I tried at first to include a seasonal word, I realized that so much of my world works to keep out the seasons: the flu vaccine that I get every fall aims to keep out seasonal trends and to protect patients. I did try at first to contrast concrete images, but I note later how even that requirement proved difficult.

The journal *Modern Haiku* commissioned a panel of experts to come up with a definition of haiku. The panel failed. However, the journal does include this gloss on their website:

> Haiku is a brief verse that epitomizes a single moment. It uses the juxtaposition of two concrete images, often a universal condition of nature and a particular aspect of human experience, in a way that prompts the reader to make an insightful connection between the two. The best haiku allude to the appropriate season of the year (6).

Of all the problems with using haiku practice as a form of spiritual development, I found the avoidance of abstraction to be the most problematic. Although I tried to use concrete images in my verse, I realized how my lifeworld is permeated with abstractions: ideas about solidarity and justice, problems about futility and technology, and shortcomings in structures and systems. In my early years in bioethics, I thought in terms of universal theories, but now I think that the facts of the case are often decisive. I have become more of a particularist, and I use theories as tools or prompts to help me think about salient factors. However, Zen Buddhists and haiku practitioners are radical particularists. They don't believe in tools, but I am getting ahead of myself.

In this essay, I want to describe my haiku practice: what I did, what it helped me to do and become, and what it didn't help me to do and become. Every day I looked for a haiku moment and wrote one haiku in my notebook. At the end of the week, I reviewed them and saved many on my computer.

WALK TO WORK

My practice began on my walk to work. Instead of thinking about what I needed to do when I got to my office, I paid attention. I still remember the first haiku that I formulated on my walk to work:

first footprints
in the snow
except the squirrel's

With surprise, joy, and a touch of vanity, I saw that I was the first to walk through the new snow. Then I saw the squirrel's footprints tracking across the snow to the base of a tree. I realized that I was the second creature to walk there, just a small part of a larger web of life that will change over time.

On my walk to work, I also noticed the strange, auto-centric way we treat snow:

snowplows
clear streets
block sidewalks

In clearing the streets, the snowplows form a metre-high mound that blocks access to the sidewalks. If you are able to get to the sidewalk, you find it covered with snow, but the situation is worse. The problem is not the trudge through the snow. The problem is that under the snow that covers the sidewalk is a sheet of ice. The dilemma is to walk on the sidewalk and risk a fall or to walk on the street and risk a collision with a car. I often chose the street.

Another snowy haiku moment:

PT restroom
taking off long underwear —
automatic flush

On another morning, I walked by a church:

blue spruce
my church has
no office

Months later, as the snow changed to rain, I observed:

rainy morning
worms on the sidewalk —
dead

I also had haiku moments on the walk home:

libertarian
roofers held together
OSHA rope

I didn't really know that they were libertarians, but I liked the contrast. This was a case in which my guess affected — or infected — my haiku practice.

After a while, I had a lot of haiku saved on my computer. At first, I tried to save them according to the seasons: spring coming alive, then the long days of summer, then the crisp days of fall, and finally the snows of winter. But that didn't work out; classifying my haiku according to seasons tended to change their meaning. Since my life is too separated from the natural seasons, I found other categories to classify the meaning of my haiku. I will give some examples in each of the following categories.

NATURE AND HUMAN NATURE

My haiku practice helped me to attend to the natural world and my attitude toward it.

seems too early
for geese heading North —
evolution decides

I also saw my wishful thinking:

confidence:
the last snowstorm
of the year

My attitude toward the weather was part of the problem:

we need rain
but not on
my day off

But what troubled me was my own attitude toward nature:

a spider
in my space —
his space

Concerned about the domineering attitude that humans often assume, I formulated a very critical haiku:

a gaggle of geese
a zeal of zebras
a plunder of people

However, I tried not to adopt another extreme attitude, the misanthropy that I saw in myself and sometimes found in environmental ethics. I tried to view my own life as a small part of a changing web of life.

YOUNG AND OLD

I attended more to children than I had in the past, and I noticed differences between children and adults, at least in my culture. I noticed how children play:

children blowing
on dandelion puffs —
co-evolution

spring roll:
a grassy slope
with dandelions

One day, I ate at the local Korean restaurant, and listened to the son of the woman who owned the restaurant:

summer day
almost first grade
he says proudly

Then I came upon a social context, the dumpster outside the hospital:

children helping
their mother dig
through the dumpster

Then I wondered about the relationship between children and adults:

a child's question
launches her father's
prepared lecture

Next, I turned my attention to older people and my own aging:

a few years ago
turns out to be
fourteen

I used to admire
the oldest man in the gym
before he was me

planting a fruit tree
on her eightieth birthday —
justice between generations

At least I could still go to the gym and plant fruit trees.

MARRIED LIFE

Of course, married life is an important part of living:

grocery shopping
with a fasting wife
with ADHD

Married life always involves some pretending:

small pretense
acting as if I
like her haircut

I worried more about large pretenses:

topics we avoid
the after life
the present life

But I was devoted to married life:

begin to like
my silicon
wedding band

red maple leaves
a long walk with
my wife

MODERN LIFE

In this category, I notice just how strange modern life is:

laundry day
another sock
gone AWOL

the Milky Way:
billions of stars
obscured by lights

I take
half a pastry —
twice

Part of the strangeness of modern life was watching and reacting to what we call news:

a Turkish beach
a refugee child
washes ashore

I also noticed what we are losing:

lost to progress
hand-written
Thank You cards

About this loss, the so-called conservative parties have little to say. With my practice, I continued noticing aspects of modern life:

careful plans
spray painted on
the sidewalk

It was time for a vacation:

a real vacation:
a week without
political news

hike to
Balanced Rocks —
tripped on a root

And then there was a solar eclipse:

eclipse
sunglasses in hand
rain clouds in sky

And memories of other countries:

Mexican market
half-remembered words
familiar flavors

a whole country
bicycle trailers
to pull cellos

airport toilet
clean and neat —
in Japan

familiar
sounds of recess
in Taipei

But mostly I found my own environment strange:

workers pushing carts
use ADA push buttons
more often than …

stickers on laptops
a modern language
I don't comprehend

picnic blanket
with pale young women
in bikinis

Strange too were the tensions, conflicts, and contradictions in my own life:

aspirations
of minimalism
Amazon order

Indian
veggie bowl with
Bollywood music

COMPUTERS, AI, AND THE INTERNET

The machines that dominate my life, and provide both frustration and joy, are mostly computers. I don't really know how much of the frustration comes from the computers themselves, from my lack of skill, or from the social context in which computers function. In living, these frustrations are often mixed:

online chat with
a human being
who types a reply

I fail
two-factor authentification
twice as often

real cost
of a modest donation
daily emails

These computers, which include cell phones, were supposed to simplify my life, but they often left me with more things to do:

one more task
to block spam calls
on my cell phone

The frustration sometimes left me at a loss:

important matter:
long phone tree then
placed on hold

Google Maps sends me
in the wrong direction —
twice

Often, I blamed myself:

monastically
out of touch —
computers

But I was tempted to generalize about function:

disconnected by
all the ways to
stay connected

Internet
designed to attract
and distract

However, my computer life also left me with a smile:

friendship:
I check the weather
where he lives

ACADEMIC LIFE

My academic life included teaching, writing, doing ethics consults at the hospital, and much more. When the pandemic struck, I taught more online, but pandemic life deserves its own category. Here are some haiku from academic life:

continental divide
those who generate email
those who must respond

not my type
she actually likes
Track Changes

journal club
talk about everything
but the article

An important part of my work were ethics consults:

attitude test:
the pager beeps
Friday at four

I always tried to be clear about the ethical issues, but now I paid more attention to the patients themselves. I noted the variety of patients:

emergency nurse
struck in the eye —
by a patient

hasn’t seen a doctor
in thirty-five years —
now wants everything

wants to leave
Against Medical Advice —
to check on her dog

patient with
a rare disease —
dysfunctional family

Another aspect of my academic life was writing. This aspect had its own haiku:

hours of struggle with
the online submission —
the root problem is …

no easier with age:
rejection letter from
a journal

And I noticed things about myself that I didn't like:

shutting the door
only excludes
external distractions

Some aspects of academic life had nothing to do with ethics consults or writing. For example:

summer day at
university library
wool sweater

And my feelings when reading the world news:

the cunning
of history doesn't
seem so smart

Of course, there were meetings that I had to attend:

meeting
cancelled
a gift from God

the sun sets
through the window —
the meeting goes on

Yes, the sun was setting.

MEDICAL WORLD

I saw the medical world both as a worker and as a patient. My experience as a patient began with hematuria:

layers of
medical providers
same questions

"pink or red
or merlot?"
urologist asks

"bladder cancer"
I say it aloud
on the way home

they ask for
the copay now —
just in case

And yet I had a dumb sense that things would be all right:

I'll be okay —
it's only raining
in the puddles

My own experience of illness helped me to pay attention to the experience of others:

I shake
his cold hand —
Raynaud's

losing weight
unintentionally —
new problem

doctor's office
he brings his daughter
who looks sixty

outlines of an
oak leaf blown away —
Alzheimer's

I knew how close we all are to a sudden end:

a diagnosis
all it takes to realize my
days are numbered

Although I had a dumb sense that I would be all right, I was not hopeful about the larger social context:

Fox News on
the clinic's television —
sick twice

PANDEMIC LIFE

The seasons changed, and my lifeworld too. Soon the pandemic was upon us, and brought with it its own haiku moments:

still dark
footprints in the snow
approach the hospital

All classes shifted online to Zoom classes. The university was slow to shift back because it discovered how much money it could save. More haiku:

Zoom class went well
except for the student
in the waiting room

"end meeting"
I longed to click yes —
a year ago

I thought about the larger issues that the pandemic raised:

picnic tables
covered with snow —
vaccine waitlist

I want the vaccine
that helps me to live
with purpose

receding snow
white litter with
blue face masks

I noted the lack of solidarity:

they cherish
their liberty to
infect others

The pandemic went on and on, until it became the background in which we live.

RETIREMENT

There were many reasons, both negative and positive, why I decided to retire. Negatively, I lost all patience with the requirements of the medical school. I remember when they began to require us to write comments to and about students in a certain format. Probably that requirement made it easier for the dean to copy what we write into the dean's letter, but what got lost were educational goals and values. Also, I noted that the university discovered that it could save money by having us teach online. Again, there were no discussions of educational goals and values. Positively, I wanted to write a few things, without interruptions, and I wanted to find or create some meaningful forms of political engagement.

This phase in my life provided more material for haiku:

retirement fantasy:
email from people
I know

My retirement income was quite sufficient:

luxury of waiting
Social Security increases
8% per year

Downsizing was a long-standing practice of mine:

deep satisfaction
of giving another thing
to Goodwill

But I was surprised to notice a peculiar form of impatience:

I forget
how to sit
in long meetings

I was able to affirm my decision to retire when I rode the bus:

city bus
silent college students
with cell phones

Although I said I didn't like teaching online, I found myself doing it:

reputation for
teaching online in India
for free

POLITICAL LIFE

I didn't know whether political life was an appropriate topic for my haiku practice, but I've come to see that politics, in the best sense of that word, is inevitable (7). So, I began with climate change, where even no response is a response — usually a bad way of responding. I began by paying attention:

beautiful but …
earliest cherry blossoms
in a thousand years

August day
requiem for
a glacier

carbon offsets:
Martin Luther
would not approve

climate change
what I owe children —
a lot more

Then three haiku that reflected the American situation:

networks of
strong ambulances
weak neighbors

we live in
a world where *he*
might be elected

the supreme court
decision makes no
historical sense

Then some of the frustrations of trying to engage in:

politics with
people raised on
the Internet

I made a joke about my volunteer work, but jokes have meaning:

I'm a poll worker
prepared to die
for a fair count

And then some reflections on the nature of politics:

to live an ethical life
without political life:
impossible

political life:
how we should organize
our life together

In the end, my haiku practice didn't change my view about the inevitability of political life.

SPIRITUAL PRACTICE

I began my haiku practice because I wanted to be more present in the moment, more mindful, and more responsive. This practice did help me to become more present and mindful, but I'm not sure it helped me to become more responsive. I will return to the problem of cultivating responsiveness at the end of this essay, but I am coming to think that this problem deserves its own essay.

I begin this section about spiritual practice by making fun of myself:

a notebook to
to record my
lack of progress

birthday celebration:
extra spoonful of yogurt
on my steel cut oats

later I will
pay attention
to the moment

Then I reflected on the dispositions that I say I want to cultivate:

perseverance
cultivating that virtue
this week

humility:
knowing when to
not claim credit

But some dispositions, or at least the lessons that I extracted, seemed too saccharine:

be nice to people
especially when you
don't feel like it

And some dispositions reflected deeper problems:

when I see
my imperfection clearly
the seer feels proud

I saw my problematic relationship to lists:

although it's done
I write it on the list
to cross it off

to-do list
a guide becomes
a tyrant

But I believed deeply in forming habits:

if goodness
is like fitness —
training helps

I also reflected on what I called the cultural context of spiritual practice:

no God to call us
what's left of a vocation —
just enough

possible regret:
a condition of
meaningful choice

Slowly, I came to see that all my training in philosophy was not helping me:

philosophy
taught me to misinterpret
useful advice

Furthermore, I was critical of other people's spiritual practices:

cars exiting
the church lot —
still in a hurry

However, I also saw what counted for me as spiritual progress:

neighborhood
Korean church
bike tracks in snow

And I saw how spiritual practice was connected to a good life:

demoralized:
life without
moral ideals

Social accountability was built into my practice:

Buddhist pen pal
checks on me monthly
checks on herself

And so, I did not quit. I wanted:

to live again
but only if I can
live better

Perhaps that was the deep goal of my practice.

DEATH

There is a long tradition among haiku poets of formulating death poems (8). Although these were supposed to be poems voiced on their death beds, it seems that some of these poets cheated and formulated the poems in advance. However, most people that I am acquainted with live as if they are not going to die. But what does it mean to live as if we are going to die? Here again, it is easy to misunderstand:

I live today
as if it's my last day —
skip the laundry

One idea is that we should prepare now for God to assess our lives and pass a judgment about the rewards and punishments that we deserve. But this idea is very Christian, even punitive, and — dare I say it? — undemocratic. The idea turns life into a contest with very high stakes. Unlike the idea of vocation, I do not think that the idea of judgment day survives when we give up the theological context. So, I moved on.

Death hit hard when my older brother died. Then I noticed a lot of death in my life:

dented fence
where the spruce tree
fell to its death

October
a month of birthdays —
and deaths

When a good friend died of pancreatic cancer, I reflected:

what does a
pancreas do when it's
not ending a life

today I wanted
to telephone my friend —
long dead

I was critical of other people's attitudes:

he professed
very deep love
after she died

But I was also critical of my own attitude:

I don't fear death
because I don't love life —
enough

I say I'm not
afraid to die —
but not now

I learned that:

people die
on their schedule
not mine

When it came to my own death, I didn't think in terms of relationships, regrets, or prospects in the world. Since my mathematical training had a deep influence on me (7), I formulated my death poems in mathematical terms:

my death
poem
ϕ

In other words and symbols:

my
death
{ }

But maybe the way I was living was contributing to my thoughts about death because I noticed:

walk in the forest
banishes thoughts
of death

Slowly, my attention shifted to a different way of living.

ATTITUDE TOWARD DEATH

Over time, I began to think less about the idea of a judgment day, and more about the importance of living well. To put it philosophically, I thought less in terms of right and justice, and more in terms of goodness. I noticed this shift during my hike in the forest. My old way of being was clear:

if the prospect of
death doesn't reform me
what will

But my haiku began to reflect doubts about my old view:

thoughts of death
don't make me live better —
and you

What began as a few doubts became a shift:

I understand
we will all die but
how we live …

I summed up this shift with a haiku:

practice
living
not dying

But this shift was not easy. It involved more than new terms, lenses, and tools. It required new habits — new ways of inhabiting the world.

MY TENTATIVE CONCLUSION

My haiku practice helped in my spiritual development. As I said, I hoped it would help me to become more present in the moment, more mindful, and more responsive. But I learned that responsiveness required its own practice, training, and essay. I also learned that to become more responsive, I would have to confront some of the habitual ways of responding that are part of the unspoken background in my culture. Those are the next steps that I need to take, but moral practice is never finished, not because we are imperfect beings, but because change is a part of life.

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REFERENCES

1. Dwyer J. Haiku, spiritual exercises, and bioethics. Canadian Journal of Bioethics / Revue canadienne de bioethique. 2018;1(2):44-47.
2. Dwyer J. Frameworks and practices in bioethics. Canadian Journal of Bioethics / Revue canadienne de bioéthique. 2023;6(1):84-94.
3. Hass R. The Essential Haiku: Versions of Basho, Buson, and Issa. New York: HarperCollins; 1995.
4. Basho M. The Narrow Road to the Deep North and Other Travel Sketches, translated by Yuasa N. New York: Penguin Random House; 1967
5. Victoria B. Zen at War. 2nd edition. Lanham, MD: Roman & Littlefield; 2006.
6. Modern Haiku. Submission Guidelines and Policies.
7. Dwyer J. Why philosophers aren't better people. Canadian Journal of Bioethics / Revue canadienne de bioéthique. 2024;7(2-3):175-79.
8. Hoffmann Y. Japanese Death Poems: Written by Zen Monks and Haiku Poets on the Verge of Death. Rutland, VT: Tuttle Publishing; 2018.

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ART, CULTURE ET OEUVRE DE CRÉATION / ART, CULTURE & CREATIVE WORKS

Chronique du cinéma 11 : Paternel, Amanda et La plus précieuse des marchandises — une éthique du lien

Jacques Quintin[a]

Résumé
Nous présentons trois films, *Paternel*, *Amanda* et *La plus précieuse des marchandises*, qui mettent en scène des liens brisés par la violence et réparés en établissant de nouveaux liens. Dans chacun des films il y a une démonstration d'une éthique relationnelle jumelée à une éthique de la vertu du courage.

Mots-clés
responsabilité, violence, relation, sens, courage

Abstract
I present three films, *Paternel*, *Amanda* and *La plus précieuse des marchandises* (The Most Precious Cargoes), which depict bonds broken by violence and repaired by establishing new ones. In each film, there is a demonstration of a relational ethic coupled with a virtue ethic of courage.

Keywords
responsibility, violence, relation, meaning, courage

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S'il existe une question éthique fondamentale, c'est bien celle-ci : que faire de sa vie et celle des autres? Moïse fut abandonné sur les rives du Nil. Et d'autres l'ont recueilli. Plus près de nous, ces mêmes questions nous habitent toujours. Le cinéma est là pour nous le rappeler. Pensons au films *Paternel* (1), *Amanda* (2) et *La plus précieuse des marchandises* (3).

Paternel est un film réalisé par Roman Tronchot en 2023. L'intrigue se déroule dans une petite ville du centre de la France, Auxerre, où un prête, Simon, se dévoue tout entier à sa mission apostolique. Mais dès le début du film, durant un office, une femme, Louise, arrive avec son fils Aloé âgée de 11 ans. On apprend rapidement que Simon en est le père. Il a conçu cet enfant durant ses années de séminaire sans le savoir. Au départ, sans refuser la paternité, il refuse d'assumer son rôle de père en raison de sa vocation auprès de ses paroissiens. Plus tard, l'idée lui viendra qu'il pourrait assumer ses deux responsabilités : être un bon prêtre pour ses fidèles et un bon père pour son fils. Ce film illustre la tension au cœur de la condition humaine entre la vie spirituelle et la vie terrestre, entre une vie consacrée à Dieu et une vie consacrée à la vie ici-bas, entre un idéal qui fait rêver et le champ de l'activité composé d'imperfections.

Mais Simon sera confronté à l'inertie ou au conservatisme de l'institution catholique. Il ira même jusqu'à dénoncer le mensonge et l'hypocrisie de l'Église, ou de sa morale, qui la maintiennent à l'écart du monde contemporain. D'ailleurs, à la fin du film, lorsqu'il présentera son fils, aucune personne ne sera offusquée : Simon aura droit à des applaudissements. Le film laisse sous-entendre que la population est déjà ouverte à accorder aux prêtres la possibilité de vivre une vie de famille faite d'aléas.

On voit Simon qui tente par tous les moyens de concilier deux ordres de grandeur opposés : une vie consacrée à un idéal, à une promesse, celle du salut des âmes et une vie liée à la culture du lien entre les humains. On peut y voir une reprise de la conciliation travail-famille. Simon montre beaucoup de résistance laissant entendre que c'est un choix impossible comme si c'était tout l'un ou tout l'autre. On le voit bien lorsqu'une jeune paroissienne de 16 ans enceinte, accompagnée de sa mère, vient le consulter, probablement, pour obtenir l'accord du prêtre pour un avortement. Cette scène, de manière implicite, rejoue ce que Simon aurait pu vivre s'il avait su qu'il avait mis sa copine enceinte durant ses années de séminaire. Finalement, Simon se montre inflexible. Il laisse sous-entendre que c'est un cadeau de la Vie et que le Seigneur supportera la jeune fille. C'est le respect de la Vie au risque de nuire à la vie humaine qui se déploie dans le champ de l'activité, de la finitude. Finalement, la jeune fille se prévaudra de l'opportunité d'une interruption volontaire d'une grossesse avec le support de Louise, celle qui a accepté sur une base volontaire de garder l'enfant, Aloé, le fils de Simon.

Sans savoir pourquoi, Louise décide de quitter les lieux mais laisse Aloé entre les mains de Simon à son insu, ce qui le jette dans l'embarras. Que diront les paroissiens? Simon a une image à protéger. Il s'assurera de minimiser la présence d'Aloé autour de lui. Une manière de tenir caché un secret. Tranquillement, il apprend à apprivoiser son fils, Aloé. C'est ce lien qui va finalement avoir raison des résistances de Simon. Le sens de l'existence n'est pas logé dans un idéal, dans le respect de la Vie sacrée, mais dans le champ relationnel où chacun peut dire et s'entendre dans leur histoire. Il y a une obligation du lien et du prendre soin qui émerge de la relation elle-même, et non pas d'un ailleurs qui s'impose de l'extérieur. Il s'agit d'une éthique relationnelle, jumelée à une éthique de la vertu, celle qui promeut le courage de maintenir vivant le lien malgré les adversités. Louise l'affirme dès le début : il est injuste qu'Aloé soit sans père. Il s'agit alors de réparer une injustice. Il y a un appel au cœur de la condition humaine qui consiste à répondre aux injustices.

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Simon et Aloé démontrent que l'éthique relationnelle est déjà-là, bien avant le droit. Si elle fonde le droit, elle s'y oppose aussi très fréquemment. Elle entre en conflit avec différentes moralités, avec les diverses règles d'une société. On peut dire que Simon vit un conflit de loyauté : l'Église ou la vie humaine telle qu'incarnée dans le champ de l'activité quotidienne. On reconnaîtra le conflit entre Antigone et Créon dans la pièce de Sophocle (4).

L'éthique relationnelle ne renvoie pas à un système de valeurs qui pense à la place de l'être humain pour lui dire ce qui est bien et juste. Elle ne propose pas des devoirs ni des comportements qui auraient une dimension universelle. Elle est une forme de non-savoir laissant sous-entendre que le bien — les valeurs ou le sens — se dégage de la relation elle-même. Il n'y a pas d'injonction au respect de la Vie, sinon l'idée que la vie devient vivante à travers un engagement relationnel. C'est la rencontre de l'autre qui crée le lien. La vie n'est plus une entité qui nous dépasse, mais quelque chose qui prend forme dans un engagement profond envers les uns et les autres. Il y a une norme, mais celle-ci est spontanée. Elle émerge de la rencontre entre deux personnes. Autrement dit, un lien s'instaure entre les personnes qui engagent une responsabilité : prendre soin du lien. « L'éthique relationnelle nous oblige à penser que nous ne pouvons apprendre quelque chose de nous-mêmes, saisir notre vie dans toutes ses péripéties, sans l'appui du dialogue avec ceux qui dépendent de nous et ceux dont nous dépendons » (5). Finalement, Simon va défroquer pour se mettre au service de son fils tout en maintenant sa foi. On pourrait ajouter que sa foi prend tout son sens en s'incarnant dans une responsabilité envers l'autre. Le Christ ne s'est-il pas incarné justement pour sauver les Hommes? C'est en se faisant humain que l'on rend l'humain à son humanité.

Tout commence avec la relation. Avec celle-ci, s'établit un devoir d'assistance. Il suffit alors de l'arrivée d'un autre dans notre vie pour que celle-ci se transforme. Le film d'animation La plus précieuse des marchandises (3), réalisé par Michel Hazanavicius et adapté d'un conte créé par Jean Claude Gremberg, l'illustre parfaitement. Il s'agit d'un enfant jeté dans la neige à travers une fenêtre de train qui se dirige vers un camp d'extermination, Auschwitz. C'est un couple de bûcherons qui récupérera l'enfant. Ce sera pour eux un cadeau tombé du ciel qui va transformer leur vie. Celle-ci prendra un sens nouveau en dépit du froid, de la faim, de la misère et de la guerre. Ainsi, c'est à travers des liens faits d'humanité qui permet aux êtres humains de transcender les difficultés de l'existence, voire la méchanceté des humains qui se dévoile en temps de guerre à l'intérieur d'une lutte de pouvoir. D'ailleurs, dans Paternel, Simon accueillera Aloé lorsqu'il abandonnera le pouvoir qu'il exerçait sur les âmes. Il dira à l'adolescente qu'il n'a pas su l'écouter et la supporter dans sa réflexion sur l'avortement, étant trop soucieux de l'injonction du respect de la vie sacrée au détriment de la vie concrète d'un être humain devant soi.

Cela peut impliquer un abandon de notre pouvoir sur notre vie et y voir une critique de l'*empowerment*. Je pense au film Amanda de Mikhaël Hers sorti en 2018 (2). Un jeune homme, David Sorel, 24 ans, qui vivait jusque-là dans le présent et dans l'insouciance en profitant de la vie au maximum, se voit confier la garde de sa nièce en raison du décès de sa mère à la suite d'un attentat à Paris. Cette responsabilité qu'il accepte difficilement au début le transformera.

Devant la violence, celle de l'Église, celle de la guerre et celle des pertes, le lien devient le meilleur rempart contre le désespoir et la déshumanisation. Il faut sauver le lien car c'est le lien qui nous sauve, qui nous rend intègre et qui nous donne une santé existentielle. Il est intéressant de constater que ces trois films nous démontrent que c'est dans la simplicité de la vie concrète que prend sens une vie, et non pas dans des idéaux porteurs de violence. En ce sens, on peut dire que nous n'avons pas besoin de cours ou de s'instruire d'un discours éthique pour cultiver un lien : s'y plonger suffit. À travers le lien, on devient toujours le parent de quelqu'un d'autre.

Si ces trois films peuvent nous aider à réfléchir sur ce qu'est l'éthique et la réponse à la violence, nous pouvons aussi nous en servir, par extension, comme levier pour mieux penser à tous ces réfugiés qui sont abandonnés et rejetés par leur pays sur le rivage de nos existences. C'est d'une politique du lien dont nous avons besoin pour les accueillir, ce qui nous éloigne de nos intérêts économiques. Il convient d'abandonner un peu de soi pour donner une place à autrui. Dans chaque être humain se cache un Moïse qui vit de l'espérance d'être sauvé. Dans chacun de ces films, il y a un combat : se battre contre la mort psychique avec les armes du lien. Pour tous nos problèmes éthiques, demandons-nous où est la place de la relation et du dialogue?

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RÉFÉRENCES

1. Allociné. Paternel.
2. Allociné. Amanda.
3. Allociné. La plus précieuse des marchandises.
4. Sophocle. Antigone. Paris : Les Belles Lettres; 2013.
5. Michaud P. La thérapie contextuelle de Boszormenyi-Nagy. Louvain-la-Neuve : De Boeck; 2005.

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ART, CULTURE ET OEUVRE DE CRÉATION / ART, CULTURE & CREATIVE WORKS

Chronique du cinéma 12 : Les crimes du futur — Les aléas de l'évolution et de la déshumanisation

Raphaël Mathieu Legault-Laberge[a], Jacques Quintin[b]

Résumé
Commentaire à propos du film *Les crimes du futur* du réalisateur canadien David Cronenberg. Le film met en scène un univers dystopique dans lequel la survie de l'espèce humaine soulève de grands défis. Confrontés à un monde toxique et pollué, les humains se transforment subrepticement en une nouvelle espèce, capable de survivre dans un environnement dégradé. Cette production cinématographique questionne les rapports nature/culture et aborde les limites de la condition humaine contemporaine.

Mots-clés
mutations génétiques, corps humain, évolution, anthropocène, dystopie

Abstract
Commentary on the film *Crimes of the Future* by Canadian director David Cronenberg. The film depicts a dystopian universe in which the survival of the human species poses major challenges. Faced with a toxic and polluted world, humans are surreptitiously transforming into a new species capable of surviving in a degraded environment. This film production questions the relationship between nature and culture and addresses the limits of the contemporary human condition.

Keywords
genetic mutations, human body, evolution, Anthropocene, dystopia

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L'évolution, en tant que force motrice et transformative du réel, implique un devenir continu des espèces, l'humanité y compris. Les transformations qu'elle suppose soulèvent des enjeux bioéthiques de premier plan. Le film *Les crimes du futur* (1), du réalisateur canadien David Cronenberg, engage l'auditeur sur des chemins sombres et inquiétants, les chemins du post-humanisme, qui questionnent le futur des sociétés. Le cinéaste met en scène un monde où la toxicité des déchets qui polluent l'environnement a conduit à des transformations génétiques irréversibles. Celles-ci engendrent des mutations bio-corporelles qui redéfinissent la nature et l'essence anthropologique de l'humanité.

Ce film dystopique illustre ce à quoi pourrait ressembler l'une des retombées du transhumanisme, syndrome d'une évolution accélérée, à travers le thème du corps, de la technologie et de la vie sociale aseptisée. Quel est le devenir de l'espèce humaine? Les sociétés sont-elles prêtes à vivre, gérer et encadrer les manifestations des mutations de l'humanité? Qu'est-ce que ces manifestations impliquent du point de vue éthique?

Les premières images se présentent avec des couleurs vives, ce sera la seule séquence polychromatique de tout le film. Cette ouverture montre le naufrage d'un navire, laissant sous-entendre la fin d'un monde : il y a un avant et un après. Par la suite, tout le film se déploie dans des décors monochromatiques et défraichis, durant la vie nocturne, où s'expriment toutes les pulsions et les fantaisies enfouies dans la psyché humaine.

L'introduction met en scène un enfant qui mange des matières plastiques. Sa salive parvient à dissoudre ces matières toxiques et son organisme les digère sans peine. Il est le prototype d'une nouvelle humanité mutante, capable de survivre dans des conditions dégradées de l'environnement. Or, la mère de l'enfant, ne pouvant supporter la monstruosité de cette réalité, le tue et téléphone à son ex-conjoint pour qu'il récupère son corps. C'est ce corps qui sera autopsié plus tard, lors d'une représentation théâtrale visant à faire connaître l'existence d'un groupe d'individus dont le corps a été modifié par la technologie (dont le père de l'enfant fait partie) et qui est considéré comme criminel par le gouvernement. Dès les premières scènes, on entre dans les méandres labyrinthiques d'une humanité qui n'est plus vraiment humaine, c'est-à-dire dans les enjeux éthiques d'une post-humanité plongée dans le chaos. Dans ce monde où la nature a perdu son ascendance, l'être humain en vient à se nourrir de produits artificiels et de déchets industriels qu'il a lui-même fabriqués.

C'est dans ce contexte que l'auditeur est introduit à l'univers artistique de Saul Tenser (Viggo Mortensen), un artiste de la bio-ingénierie, et Caprice (Léa Seydoux), une chirurgienne spécialisée en traumatologie. Ensemble, ils performent un art théâtral au cours duquel Tenser se fait opérer par Caprice, grâce à un appareil technologique futuriste, pour se faire retirer des organes créés par son corps. Ces performances artistiques exposent l'intériorité du corps humain, un corps qui ressent différemment la douleur et qui devient le miroir d'une réalité qui éclipse la transcendance, celle-ci subsistant uniquement dans une matière vivante qui, tel un cancer, devient incontrôlée et incontrôlable. L'intériorité de l'humain se réduit ici à une matérialité, perdant par le fait même son aura idéale, intellectuelle ou mystique. Le corps n'est plus qu'un objet de manipulation soumis au caprice de la volonté humaine. Pas étonnant qu'apparaît rapidement à l'écran les mots suivants : « Le corps est la seule réalité ».

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Caprice est d'ailleurs le nom de la compagne de Tenser. Le couple se prend en quelque sorte pour Dieu, comme tous ces savants fous que l'on retrouve fréquemment dans l'histoire du cinéma. Tout devient possible dès que l'on considère le corps comme une matière vide de sens, comme le suggèrent Galilée (2) et Descartes (3), voire comme un organe auquel ne s'adjoint jamais la douleur, voire une âme. Cronenberg expose parfaitement ce corps qui trouve sa jouissance en se laissant pénétrer par la technologie et le scalpel.

Ainsi, il devient possible au corps de s'autonomiser dans une sorte d'autocréation fondée sur la volonté. La technologie permet de créer du sens à partir du néant, d'une création *ex nihilo*. La chirurgie ne vise plus à soigner, mais à transformer le corps selon la volonté humaine, pour ne pas dire selon ses fantasmes. L'enjeu éthique n'est plus alors de vivre en harmonie avec la nature, mais avec une technologie qui fait en sorte que le corps devient une fiction, une performance ou un concept sans ancrage dans le réel, en phase avec le nominalisme. Ce qu'est le corps en soi n'a plus aucune importance. Nous sommes aux antipodes de la pensée de Thomas d'Aquin (4), qui défendait l'idée que l'être humain doit prendre soin et respecter l'intégrité de son corps, corps prêté par Dieu. Il s'agit d'éviter le péché d'orgueil qui consiste à se prendre pour Dieu et à pervertir la dynamique originelle entre le corps et l'âme.

Les performances théâtrales, qui sont mises en scène par Tenser et Caprice, mais aussi par d'autres artistes de la bio-ingénierie, impliquent également un caractère érotique qui fait en sorte que les mutilations corporelles deviennent l'équivalent d'une nouvelle forme de sexualité. On a l'impression que Tenser et Caprice rejouent Adam et Ève. Ils sont envoutés par la curiosité de savoir tout ce que la technologie rend possible. Face à ces réalités qui dépassent la nature humaine telle qu'on la connaît aujourd'hui, les spectateurs qui assistent à ces performances théâtrales — tout comme l'auditeur du film de Cronenberg — se trouvent plongés dans un malaise profond, qui naît à la fois de l'horreur soulevée par la vue des corps mutilés, mais également de l'incompréhension des paramètres d'une condition post-humaine. Jusqu'où l'évolution peut-elle conduire le devenir de l'humanité? Anthropologiquement parlant, à quel moment l'humain cesse-t-il d'appartenir à une espèce précise et bien déterminée?

C'est dans cet ordre d'idées que les nouveaux organes produits par Tenser sont catalogués par une instance gouvernementale qui tente, tant bien que mal, de gérer l'évolution de l'espèce humaine. L'idée est que de nouveaux organes développés par certains individus pourraient avoir de nouvelles fonctions, ce qui ouvre la porte à l'inconnu, à l'incertitude. Qui sait à quoi ces « proliférations corporelles » pourraient conduire? Les autorités gouvernementales, selon une logique panoptique toute foucaldienne de la surveillance et de la punition (5), ont hautement à l'œil les mutations biologiques du corps humain. Elles tentent de conserver un certain ordre social dans ce monde chaotique. On apprend alors que Tenser est un agent double qui travaille pour les autorités gouvernementales. Il est chargé d'enquêter et d'amasser sur le terrain des informations à propos du groupe criminel composé d'individus dont les corps ont été modifiés et qui se nourrissent de déchets industriels. Plusieurs scènes montrent d'ailleurs Tenser alors qu'il rencontre son supérieur, le chef d'une police de la bioéthique, dans un lieu où sont entassées de multiples épaves de navires. La symbolisation utilisée par Cronenberg renvoie bien entendu à une interrogation à propos de l'échec et du naufrage de l'humanité elle-même. Du début à la fin du film, les épaves des navires représentent une humanité qui s'est échouée sur les rives d'un environnement devenu trop hostile pour en assurer la survie naturelle.

L'auditeur en apprend graduellement davantage à propos du groupe criminel. Celui-ci manufacture, à partir de déchets toxiques, une nourriture qui ne peut être absorbée que par les « mutants » de l'espèce humaine, c'est-à-dire ceux et celles qui possèdent les nouveaux organes nécessaires à sa digestion. Or, le nombre de membres du groupe augmente et son pouvoir grandit, ce qui le conduit à souhaiter une reconnaissance officielle de la part du gouvernement.

Le père de l'enfant tué au début du film, qui se veut en quelque sorte le chef du groupe, demande alors à Tenser et Caprice de pratiquer en public, sous la forme d'une représentation théâtrale, une autopsie du cadavre de son fils, ce qui porterait au grand jour l'existence d'une nouvelle forme d'humanité. Tenser, étant lui-même un « mutant » de l'humanité, se trouve face à un dilemme éthique. Soutient-il les autorités gouvernementales qui cherchent à contrôler et à freiner le devenir de l'humain? Ou rejoint-il les rangs d'une post-humanité qui doit assumer les conséquences irréversibles d'un environnement malsain? Lui et Caprice accepteront finalement de pratiquer l'autopsie du cadavre en public, d'en faire un spectacle qui expose la portée des mutations génétiques d'un corps dont les organes assurent de nouvelles fonctions biologiques.

Des enjeux majeurs sont soulevés par la production cinématographique de Cronenberg. Ce film propose une critique d'une vie anesthésiée, de l'art et d'une société sans émotion. La technologie nous éloigne-t-elle de notre humanité et de nos ressentis? Qu'est-ce qu'on fait à l'être humain? Quel avenir lui réserve-t-on? Qu'en sera-t-il des générations futures? Jusqu'où pouvons-nous manipuler le corps, en faire un objet de manipulation? Est-il notre propriété?

L'univers décrit par Cronenberg est glauque, sombre, et semble représenter un futur sans avenir. C'est ce sentiment que plusieurs personnes portent dans nos sociétés de la consommation, du désir éphémère, de l'artificialité plastique et de la désillusion. Face à des frontières biologiques et éthiques brouillées, l'humain se confronte à une déception de lui-même. Ce serait probablement l'un des messages fondamentaux porté par cette production cinématographique. L'avenir s'ouvre alors sur une nouvelle corporalité qui réinscrit l'évolution dans un devenir qu'aucune autorité « humaine » ne parvient à contrôler. Elle s'ouvre sur l'ère d'un post-humanisme fondé sur des caprices humains, trop humains.

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RÉFÉRENCES

1. Allociné. Les crimes du futur.
2. Galilée. Dialogue sur les deux grands systèmes du monde. Paris : Seuil; 2000.
3. Descartes R. Discours de la méthode. Paris : Garnier-Flammarion; 2016.
4. Thomas d'Aquin. Somme théologique, tome 2. Paris : Cerf; 1984.
5. Foucault M. Surveiller et punir : Naissance de la prison. Paris : Gallimard; 1975.

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TÉMOIGNAGE / PERSPECTIVE

Science en société : Le cas Idoine pour une dynamique interdisciplinaire valorisant les compétences

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Résumé

L'éthique de la recherche s'est historiquement concentrée sur le « chercheur en laboratoire », négligeant des aspects fondamentaux de la vie universitaire, tels que le transfert des connaissances, les dynamiques bibliométriques et les inégalités structurelles. Ces enjeux influencent profondément les trajectoires académiques, particulièrement dans un contexte où l'interdisciplinarité et le décloisonnement des facultés sont devenus des impératifs académiques et sociétaux. Ce texte explore une force latente présente dans les institutions universitaires, capable de transcender les cloisonnements traditionnels pour favoriser une meilleure intégration des compétences, des savoirs et des pratiques, d'abord dans son institution, mais aussi plus largement en société. Nous introduisons le collectif Idoine comme un modèle organisationnel permettant d'étudier et d'expérimenter des mécanismes qui répondent aux besoins de transfert de connaissances, tout en investiguant les structures institutionnelles qui freinent l'interdisciplinarité et la valorisation des compétences des étudiants et des chercheurs. Le collectif Idoine est envisagé comme un objet d'étude en éthique procédurale et en gouvernance, permettant d'analyser comment des cadres organisationnels alternatifs peuvent soutenir la science en action, décloisonner les disciplines et renforcer le lien entre université et société. En examinant ces dynamiques, ce texte invite à repenser la place des étudiants et des chercheurs dans la production et la diffusion des savoirs, tout en mettant en lumière les tensions structurelles qui subsistent dans le milieu académique.

Mots-clés

éthique universitaire, financement de la recherche, initiative collaborative, innovation sociale

Abstract

Research ethics has historically focused on the "laboratory researcher," neglecting fundamental aspects of academic life, such as knowledge transfer, bibliometric dynamics, and structural inequalities. These issues profoundly influence academic trajectories, particularly in a context where interdisciplinarity and the breaking down of barriers between faculties have become academic and societal imperatives. This text explores a latent force present in academic institutions capable of transcending traditional divisions to promote better integration of skills, knowledge and practices, first within its institution, but also more broadly in society. We introduce the Idoine Collective as an organisational model for studying and experimenting with mechanisms that meet the needs of knowledge transfer, while investigating the institutional structures that hinder interdisciplinarity and the promotion of students' and researchers' skills. The Idoine Collective is considered as a subject of study in procedural ethics and governance, allowing us to analyse how alternative organisational frameworks can support science in action, break down barriers between disciplines and strengthen the link between universities and society. By examining these dynamics, this text invites us to rethink the place of students and researchers in the production and dissemination of knowledge, while highlighting the structural tensions that remain in academia.

Keywords

academic ethics, research funding, collaborative initiative, social innovation

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Une demande croissante de services émerge dans le milieu académique, émanant de divers acteurs de la société civile, tels que les journalistes, les organismes à but non lucratif, les municipalités et les entreprises. Dépassant la recherche et l'enseignement, ces demandes couvrent une variété de mandats, allant de la vulgarisation scientifique à la formation, en passant par la réflexion pluridisciplinaire critique sur des enjeux sociétaux actuels. D'une part, cette demande exprime une forte attente sociétale de rapprochement entre recherches et société civile, afin de faire circuler et partager les savoirs. Actuellement, ces offres de service demeurent souvent centralisées, administrées et gérées par le corps professoral. Pourtant, ces services d'expertise pourraient être réalisés, administrés et gérés par des diplômés poursuivant une spécialisation aux cycles supérieurs (alias, les « étudiants gradués »)[1]. D'autre part, la requête de services tend à inscrire la recherche et l'enseignement dans une logique commerciale, impulsée par un régime libéral favorisant la consommation, l'innovation technologique et les compétences techniques en vue de consolider un capital matériel et humain (1) : c'est-à-dire, le « service ». À travers la preuve de concept d'Idoine (signifiant « qui convient parfaitement à une situation »), nous proposons

[1] Reconnaissons le triple caractère des études graduées : la personne est à la fois étudiante, à la fois diplômée, à la fois employée; ainsi, elle est également en formation, en position d'expertise et en offre de services. Idoine vise à formaliser ce triple statut et à clarifier ces trois rôles afin de valoriser la capacité de l'expert, actuellement latente sous le couvert de « l'étudiant à former ». Un diplômé (métier, technique, baccalauréat, maîtrise, doctorat clinique, professionnel ou PhD) peut poursuivre sa spécialisation ou bifurquer vers un autre domaine (métier, technique, baccalauréat, maîtrise, doctorat, voire une résidence clinique ou scientifique, un fellowship en médecine ou un postdoctorat de recherche). Ainsi, un « expert en formation » signifie très rarement que l'expert est « entièrement » en formation.

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une approche constructive face à cette double dynamique. Elle permet de répondre de manière urgente et décentralisée à ces besoins sociétaux tout en adoptant une posture critique vis-à-vis de l'impulsion technique, afin d'équilibrer les intérêts sociétaux et économiques, ainsi que les devoirs intellectuels et épistémiques, dans un cadre éthique et réfléchi, qu'il s'agisse de la recherche, de l'enseignement ou du service.

Faute de financement, une spécialisation aux cycles supérieurs s'apparente de plus en plus à un parcours du combattant. Entre l'implication dans des activités académiques exigeant une expérience substantielle et la nécessité d'occuper un emploi à temps plein pour subvenir à ses besoins, la conciliation d'une rémunération et d'une spécialisation (ou travail-études) devient, pour de nombreuses personnes n'ayant pas de soutien a priori, un obstacle compromettant leurs perspectives académiques et professionnelles. Cette conciliation se complexifie davantage lorsque nous la resituons dans le monde réel, alors qu'un bon nombre de personnes diplômées poursuivant une spécialisation aux cycles supérieurs s'ouvre aux défis de la parentalité, du logement, ou de la fiscalité. Les organismes subventionnaires, dans leur évaluation des candidatures, s'appuient sur divers critères, tels que les résultats académiques, l'engagement dans des initiatives étudiantes, les emplois antérieurs et les bourses déjà obtenues. Dans ce contexte où le temps constitue la ressource la plus précieuse pour développer un dossier compétitif, jongler entre études (spécialisations), travail, famille et autres réalités limite considérablement les chances de se démarquer. En conséquence, le parcours académique des « étudiants non-boursiers » se précarise : un grand nombre d'heures est consacré à des emplois souvent déconnectés de leur domaine de spécialisation, ce qui n'apporte aucune valeur ajoutée à leur dossier pour solliciter du financement ni aux cursus de leur formation, ni n'apporte à la société en termes de richesse disciplinaire, académique et épistémique. De plus, un refus de financement ne compromet pas seulement l'année en cours, mais génère également des répercussions durables sur les années suivantes, le manque de temps entravant toute possibilité de bonifier le dossier académique et de renforcer sa compétitivité. Déconnecter le financement et la spécialisation a des implications pratiques, mais aussi sociétales et épistémiques, en imputant à l'institution académique la richesse de son plus vaste corps d'expertise, c'est-à-dire ses personnes diplômées poursuivant leur spécialisation aux cycles supérieurs.

Conscients de cette réalité de la spécialisation aux cycles supérieurs et de ces préoccupations institutionnelles, les auteurs ont fait l'exercice de revisiter les missions universitaires — recherche, enseignement et service —, dont l'opération, la gestion et l'administration nous semblent articulées sous une formule de gouvernance descendante qui, soi-disant, va de soi. En adoptant une posture collaborative, constructive et critique avec et envers l'institution universitaire, le projet « Idoine » est né. Une perspective se maintient, selon laquelle les études académiques doivent s'imposer comme une servitude qui, à son terme, devrait nous élever. Effectivement, étudier est un labeur intellectuel — l'écriture d'un mémoire ou d'une thèse constitue un défi! Cependant, beaucoup de choses entrent dans cette boîte noire que représentent « les études graduées » et ainsi, plusieurs amalgames entourent le processus de la spécialisation académique. Au cours de l'année d'idéation du collectif Idoine (2023-2024), nous avons mené de nombreuses discussions avec des personnes diplômées poursuivant une spécialisation aux cycles supérieurs afin de définir et de préciser leurs besoins, rôles et missions.

Sans désir de formaliser, de délinéer ou de fermer de nouveau cette « boîte » avec une idée toute construite, nous maintiendrons ouvert et accessible le concept de la gouvernance de ce collectif. Cette philosophie d'ouverture se réalise en énonçant, réfléchissant et recadrant, au besoin, les prémisses ancrant la gouvernance avant, pendant et après la formalisation de son collectif (c'est-à-dire en considérant par défaut un mouvement d'itérations, de théorisations et d'applications). Conséquemment, Idoine ouvre la possibilité de concevoir une « boîte » faite par et pour les diplômés poursuivant une spécialisation aux cycles supérieurs (alias, les « étudiants gradués »), transcendant les affiliations universitaires (l'université, la faculté, le secteur), s'autorisant la capacité de croître, de se transformer et de réfléchir à un mieux-vivre interdisciplinaire et universitaire. En pratique, nous imaginons une sorte de firme d'experts valorisant ces personnes diplômées, ainsi déjà expertes, bien qu'en cours d'une spécialisation additionnelle (alias, ces « étudiants gradués »). Ainsi, Idoine valorise leurs diplômes et les expériences connexes déjà acquis; et la gamme de services offerts variera en fonction des membres composant cette firme de consultance académique. En adoptant une perspective ouverte et coopérative, en collaboration avec le milieu universitaire, les laboratoires de recherche et les processus déjà institués, nous croyons que, dès sa mise en action, cette plasticité de fonctionnement saura constamment élargir l'offre, la qualité et l'efficacité des services de son institution.

En prémisse, cette démarche d'ouverture, comparable à une « étude de marché » participative et exhaustive, a confirmé un sentiment partagé par l'ensemble des participants inauguraux impliqués dans l'idéation d'Idoine, qu'ils soient en processus de spécialisation aux cycles supérieurs ou chercheurs postdoctoraux, qu'ils soient affiliés aux universités de Montréal, McGill, Laval ou Sherbrooke (Québec, Canada). Cette démarche d'ouverture s'est réalisée de manière boule-de-neige, comme les approches ethnographiques et les approches de la gouvernance participative, en incluant aussi des échanges avec le corps professoral et administratif de l'institution, notamment en mobilisant les réseaux de recherche régionaux, nationaux et internationaux dans lesquels les auteurs et les collaborateurs professoraux et administratifs œuvrent activement. Ces échanges ont révélé des perspectives similaires et favorables à une reconceptualisation de la gouvernance de l'offre de service, ainsi qu'une vision plus décentralisée de l'opération, de la gestion et de l'administration sociétale et intellectuelle de ce service d'expertise. Plus encore, le démarchage auprès de partenaires externes à l'université s'est avéré positif, témoignant de besoins réels et de la crédibilité de l'expertise au sein des cycles supérieurs. Le constat fut, alors, celui d'un besoin de soutien pour améliorer l'articulation des relations entre la science et la société — incluant la valorisation et la diversification des types d'acteurs universitaires s'investissant dans le service de conseil, de diplomatie et d'encadrement des/en sciences, technologies et société. Essentiellement, nous avons constaté cette force latente, ce leadership existant et cette volonté de valoriser l'expertise, de diffuser la science, d'aider en société; et une incapacité d'effectivement réaliser cette valorisation, et ceci même à la hauteur des personnes diplômées poursuivant aux cycles supérieurs (alias, les « étudiants gradués »), ainsi

que des compétences et des expériences accréditées par l'établissement d'enseignement même les ayant octroyées. En effet, pourquoi est-ce difficile pour un ou une ingénieur, médecin, biologiste et philosophe diplômé(e)s, par exemple, d'offrir en service ses compétences déjà acquises pour la seule raison qu'il ou elle est en train d'acquérir de nouvelles cordes à son arc, en réalisant une spécialisation doctorale? Les universités devraient, à l'inverse, mettre en valeur les compétences acquises lors du premier cycle universitaire : une force d'expertise-conseil pour l'État, les entreprises et la société civile, demeurant en latence lors du processus de spécialisation, alors que ces compétences ont pourtant une valeur en société.

Cette réflexion ne prétend pas constituer une revue systématique des écrits, du paysage ethnographique ou du « marché », mais bien de poser une première prise de position collective, à l'échelle d'un petit collectif en émergence, et qui pourrait, par la force de l'itération de cette même réflexion, fonder une position plus « à propos » (idoine) de la réalité académique québécoise. Ainsi, notre intention n'est pas de mettre l'accent sur la création d'Idoine, mais de souligner l'importance — et ceci depuis la perspective des personnes diplômées poursuivant aux cycles supérieurs (alias, les « étudiants gradués ») — d'initier des projets collectifs. L'innovation que nous souhaitons mettre de l'avant en rapportant le cas d'Idoine est la valeur, dont nous soulignons l'importance, de documenter les dynamiques collectives, l'amorce de mouvements sociaux, l'étude des relations interdisciplinaires et de disposer l'offre de services universitaires à l'investigation des recherches en éthique. Pour acquérir cette capacité réflexive et apprenante, Idoine se comprend comme indissociable d'un Laboratoire Idoine s'enracinant, entre autres, dans les Programmes de bioéthique de l'École de santé publique de l'Université de Montréal, venant étudier in situ sa dynamique de création, d'organisation et de relation entre scientifiques, envers la société, et par rapport à sa propre gouvernance. Nos premiers constats indiquent que l'enjeu dépasse les frontières locales et se retrouve, sous diverses formes, à l'échelle internationale, influencé par des facteurs propres aux contextes nationaux, culturels et disciplinaires (2,3).

À titre de personnes diplômées et en spécialisation dans les Programmes de bioéthique, les auteurs ont amorcé le collectif Idoine en s'appuyant sur les principes fondamentaux des méthodologies en bioéthique, à savoir une approche réflexive, adaptative et collaborative, mobilisant, opérant et révisant le socle de principes orientant la prise de décision, la gouvernance et l'avenir d'un projet (1,4). Nous avons orienté ces efforts en misant sur l'interdisciplinarité et la traduction des connaissances de l'Université vers la société. Cette démarche ne se limite pas à une réflexion sur l'offre de services actuelle (transfert de connaissances, conseil, mentorat, capitalisation des bonnes pratiques au sein de communautés de pratique) ou future d'Idoine, mais s'étend à une analyse de sa nature même, afin d'envisager « ce que devrait faire », voire « devrait être » ce collectif pour s'améliorer et améliorer la vie académique. En introduisant à titre d'objet d'étude le réseau, la gouvernance et les productions d'Idoine, la projection de nouvelles offres de service par ses membres deviendra plus tangible, ainsi que la possibilité de découvrir des dynamiques innovantes d'organisation liant ses membres entre eux, puis en société, apportant de nouvelles manières de conduire la recherche scientifique et technologique (le Laboratoire Idoine). Ainsi, la « boîte » Idoine permet de remettre en question les approches traditionnelles renforçant les cloisons universitaires (facultés) et économiques (secteurs). La perspective classique dichotomise l'offre de son analyse, rendant formelles les directions et immuable (ou peu apprenante) l'architecture de gouvernance; les administrateurs, gestionnaires et experts sont déterminés par leur création. Idoine clarifiera et documentera les moyens rendant possible l'examen en continu du contexte stratégique (les risques), économique (le financement lors des études graduées et postdoctorales), juridique (le choix du véhicule inter-/transdisciplinaire optimal), sociologique (les impacts, dynamiques de pouvoir) et éthique (l'équité procédurale), et ses succès ainsi que ses apprentissages à l'égard d'une dynamique de gouvernance plus complexifiée, intégrant par défaut une agilité collaborative, adaptative et réflexive de type communautaire.

Dans chaque université canadienne existent des comités, des procédures et des politiques, liant notamment l'Établissement aux Fonds subventionnaires, visant à opérer l'éthique en sciences. Actuellement, ces processus s'intéressent essentiellement à l'intégrité et à la conduite responsable des chercheurs et des projets de recherche; un intérêt mis en lumière par les études en éthique de la recherche. Nous croyons que l'éthique de la recherche gagnerait à élargir son champ d'attention. L'objet, centré sur le chercheur en laboratoire, devrait englober la vie universitaire et la place des connaissances académiques dans la société. Cette vie universitaire se caractérise d'abord, selon nous, par son corps étudiant prégradué, gradué aux cycles supérieurs et ses recherches postdoctorales et associées, ou encore ses résidences et *fellowships* scientifiques ou cliniques, donnant vie à cet écosystème intellectuel. Actuellement, l'attention est rivée sur les éléments de sa structure organisationnelle — un squelette effectivement important — comprenant son corps professoral, de soutien et administratif. Retourner l'attention, transitant de la (infra)structure professorale au (éco)système « étudiant », permettrait de reconnaître des contributions souvent négligées, comme le travail (largement bénévole) des personnes diplômées poursuivant aux cycles supérieurs (alias, les « étudiants gradués »), pour soutenir les activités de laboratoire (ex. : mesures), compléter les offres de service (ex. : rapports), soutenir l'offre de formation, de supervision et d'enseignement. Cette part de tâches académiques (souvent techniques) ne tombe pourtant que rarement sous le cadre de leur formation spécialisée, mais comprend des acquis lors d'une technique passée, du baccalauréat ou d'une autre occasion. Effectivement, réaliser ces tâches relève des activités de maintenance de leur laboratoire, de leur centre, de leur institut ou de leur université d'affiliation. Ces tâches sont nécessaires à la recherche, à l'enseignement et au service. Cet argument s'applique généralement à l'infrastructure des activités de recherche et à l'écosystème des acteurs rendant la science possible (souvent invisibilisés au sein des universités : secrétaires, fiscalistes, gestionnaires, administrateurs), car leur apport direct ne va pas à l'avancement ni au maintien épistémologique de la discipline (validité). Même des activités aussi centrales à la qualité de la science que la révision par les pairs demeurent largement bénévoles et sous-évaluées par les institutions, bien qu'essentielles à l'excellence scientifique (5).

Chercheurs et étudiants, particulièrement ceux qui prennent la voie de la recherche, sont accablés par les exigences de production de connaissances, d'enseignement et de transfert des savoirs, auxquelles s'ajoutent des critères d'excellence, des

standards de production, la recherche de financement et la diffusion des travaux. Évidemment, des efforts existent au sein de l'Université pour accentuer les soutiens à la recherche et aux études, mais demeurent timides face à l'ampleur de la situation, sans la capacité effective de créer des dynamiques conséquentes avec la force des pouvoirs à l'œuvre. Prenons en exemple la place que prennent les maisons d'édition dans l'évaluation et la diffusion de la science, ainsi que les tarifs à la publication et à l'accès à la littérature scientifique. Ces impératifs à publier peuvent provoquer des conflits d'intérêts, notamment entre la production (le laboratoire X), la diffusion (maison d'édition) et l'application (un laboratoire Y) des connaissances. Ils réduisent alors le pouvoir effectif de l'université à promouvoir une science de qualité et à maintenir un contrôle sur les incitatifs à une conduite responsable ainsi qu'à une formation approfondie, valorisant davantage les prémisses (épistémologiques de la connaissance), plutôt que la capacité économique et les intérêts financiers à « faire sortir les publications ». Cette prise de conscience du contexte académique explique une motivation grandissante pour le projet Idoine et l'inscrit parmi un ensemble d'initiatives déjà à l'œuvre en vue d'étudier et de remédier à ces situations problématiques, en espérant trouver ainsi des pistes alternatives d'organisation de la vie universitaire et de collaboration entre les sciences (*Science4Sciences*) et auprès de la société (*Sciences2Society*).

Imaginons une dynamique qui ne reposerait pas exclusivement sur les épaules du corps professoral pour le transfert des connaissances expertes. Avant le transfert, le travail se conduit essentiellement en laboratoire, entre autres, par l'auxiliariat de laboratoire, l'assistanat de recherche et les recherches postdoctorales, sous la direction d'un professeur. Le fardeau, cependant, de nouer les partenariats de recherche, de solliciter du financement, de maintenir un rapport client et, en bref, de mettre en « vitrine » son laboratoire pour une *Science2Society* repose sur les épaules du corps professoral (sans négliger le soutien administratif ou facilitateur dynamisant l'infrastructure universitaire). Pourtant, il y aurait une valeur gagnant-gagnant à davantage partager cette responsabilité de « marketing » en science au sein du laboratoire qui, en réalité, ne devrait pas tendre à s'instituer comme un devoir « professoral ». Une certaine perspective tend à se consolider dans le milieu universitaire, rappelant l'organigramme des entreprises privées, entendant (réduisant) la compétence du professeur (expert, chercheur et enseignant) à la présidence d'un laboratoire. Les professeurs doivent déjà composer avec les nombreuses contraintes associées à l'enseignement : la création, l'actualisation, la progression, l'offre de cours, parfois avec l'aide et l'encadrement d'auxiliaires. À cela s'ajoutent les exigences liées à leurs activités de recherche, telles que la conception des protocoles de recherche, l'obtention de financement, la gestion de projets, le recrutement de personnel, la création de partenariats, l'implémentation de technologies et la prise en compte des réalités du terrain. Par ailleurs, les professeurs sont imputables, devant rendre des comptes aux bailleurs de fonds, aux médias, aux comités d'éthique et à d'autres instances. Enfin, leur charge comprend également des responsabilités administratives au sein de leurs départements, centres, instituts ou universités d'affiliation, ainsi que dans des fonds subventionnaires, particulièrement au Québec, où ils participent activement à la conception et à l'opération des programmations scientifiques et pédagogiques. Ce constat amène à se demander si la responsabilité de soutenir les mouvements transformatifs de nos communautés, tant à l'échelle locale qu'internationale, devrait réellement incomber uniquement au corps professoral. Bien que le rôle des professeurs soit central, nous croyons que cette charge ne devrait pas être exclusivement assumée par ceux-ci.

Dans notre modèle Idoine (ce collectif est bi-organisationnel, comprenant un réseau et un laboratoire), nous proposons de tourner l'attention vers le corps diplômé poursuivant aux cycles supérieurs (alias, les « étudiants gradués ») qui possède un potentiel sous-utilisé pour contribuer activement à ces transformations. Le collectif Idoine est désormais institué à l'office des entreprises à titre d'Organisme sans but lucratif depuis 2025, d'une part, et amorce la création d'un consortium de recherche (multi-universitaire) en éthique de la recherche, en interdisciplinarité et en relation avec la société. Ce partage vise à donner l'agilité suffisante pour réfléchir à la manière de mieux articuler un modèle de type coopératif, au regard du véhicule juridique, administratif, économique, technologique et scientifique, puis à mettre à l'essai ces idées pour améliorer le parcours académique. Il s'appuie sur une force latente présente dans nos universités qui pourrait, selon nous, renforcer les relations interdisciplinaires, décloisonner les facultés et répondre aux besoins croissants d'une expertise mieux intégrée en société. Cette force latente est celle du réseau croissant d'Idoine comprenant ses membres — diplômés poursuivant aux cycles supérieurs (alias, les « étudiants gradués ») en recherche —, puis de leur mise en relation avec des organisations partenaires, comprenant des laboratoires de recherche infra-universitaires, des instances subventionnaires et des organismes de la société bénéficiant d'un service d'expertise. Nous plaidons pour une valorisation accrue des compétences acquises à l'université, à une époque où le transfert de connaissances est central, tant pour les scientifiques que pour les citoyens. Terminant sa phase de preuve de concept (2024-2025), ses premières stratégies d'organisation et offres de service d'Idoine apportent désormais des démonstrations pratiques de cette force latente des universités et de la possibilité d'un partage des responsabilités plus cohérent, valorisant et productif entre les expertises/experts composant nos universités.

Cependant, la « vie étudiante » est loin d'être exempte de défis. Les parcours types définis par les programmes universitaires en matière de progression, de crédits et de financement ne reflètent pas toujours les réalités complexes vécues par le corps étudiant prégradué, gradué en spécialisation et en début de carrière. Le financement, souvent attribué par le biais de concours, repose sur des critères bien connus : le mérite académique, le prestige anticipé du projet de recherche, les distinctions obtenues, l'implication « étudiante » et les expériences professionnelles. Cependant, l'accès à ces programmes reste hautement contingenté, avec des taux d'attribution qui, selon les sources, se situent autour de 25 %, légèrement en deçà au niveau fédéral (6) et au-dessus au niveau provincial en 2024-2025 (7). Il est donc particulièrement difficile pour de nombreuses personnes d'obtenir ce type de financement, d'autant plus qu'il est souvent nécessaire de combiner plusieurs sources pour atteindre un revenu viable. Même en cas de succès, un emploi en parallèle à une spécialisation s'avère fréquemment indispensable. Aux cycles supérieurs, cela implique souvent d'occuper un ou plusieurs emplois qui ne mettent pas en valeur les compétences et l'expérience acquises. Ces compromis prolongent la durée d'une spécialisation et limitent l'accès à des

stages ou à des immersions prolongées, essentiels à l'acquisition de savoirs, de compétences et de réseaux professionnels nécessaires à la réalisation des aspirations de carrière. Ces réalités, bien qu'influencées par les conditions initiales et les privilèges de chacun, contribuent à creuser davantage les inégalités structurelles déjà présentes dans la société. Comme conditions et privilèges, considérons de prime abord le statut socio-économique, le pays d'origine et les études internationales (ou non), mais autorisons-nous aussi à creuser certaines généralités plus profondes — dont les prises de risque (souhaitées ou obligées) et la marginalisation. L'expertise, la recherche et les études avancées impliquent un effort créateur risqué et marginal, conduisant à des risques et à une marginalisation, ou initié par une prise de risque et une marginalité. Ainsi, la vie étudiante (dire même, la vie universitaire) est caractérisée par la diversité, crée la diversité et émerge de cette diversité. Dès lors, l'étude de ces conditions initiales — instituant, systématisant, limitant l'expression de cette diversité, de ses dialogues, de ses maillages, échanges, assemblages et rebrassages — gagnerait à s'organiser autour, depuis et avec le système y donnant vie, c'est-à-dire la vie universitaire, incluant ces diplômés poursuivant aux cycles supérieurs (alias, les « étudiants gradués »).

De nombreux défis confondants compliquent la vie quotidienne du corps professoral, postdoctoral, en spécialisation et étudiant, tels que l'émigration, l'achat d'une première propriété, la proche aidance (y compris la jeune aidance), le deuil ou la parentalité, et peuvent prolonger ou interrompre l'avancée en carrière. Dans certains cas, ces défis forcent les individus à poursuivre leur parcours en tentant de gérer les effets négatifs sur leur santé physique et mentale. Le milieu académique, déjà marqué par une forte prévalence de troubles tels que l'insomnie et la dépression (8), exacerbe cette vulnérabilité. Ces réalités compliquent également l'implication dans des activités académiques et réduisent les chances d'obtenir des distinctions ou des financements, éléments essentiels pour rester compétitif. Faute de financement, d'emploi ou d'engagements pertinents dans leur domaine de spécialisation, un cercle vicieux s'installe : les trajectoires académiques sinueuses s'éloignent des attentes des organismes subventionnaires. Si les organismes subventionnaires œuvrent à développer des stratégies pour rendre compte de ces problématiques, la situation est complexe et dépasse le cadre seul de leur compétence. Le problème est insidieux (*wicked problem*) et nécessite une approche globale, appuyant la vie universitaire depuis les hautes (macro) instances jusqu'au quotidien de l'expérience académique, sans quoi l'écart se creuse entre les dossiers compétitifs et ceux des étudiants confrontés à ces contraintes.

En favorisant l'amélioration de l'employabilité des diplômés poursuivant aux cycles supérieurs (alias, les « étudiants gradués ») dans leur domaine d'expertise pendant leur spécialisation ou leurs recherches postdoctorales, la bonification de leur parcours d'apprentissage, ainsi que la valorisation et le développement de nouvelles compétences, l'éthique de la recherche émergeant du Laboratoire Idoine pourrait devenir une force transformative positive au sein des universités. Cette force dépasserait alors le rôle administratif, parfois perçu comme « de conformité » et souvent associé aux comités d'éthique de la recherche. Le développement d'un véhicule organisationnel tel qu'Idoine, s'instituant entre Science et Société, dont le fonctionnement est lui-même soumis à des investigations éthiques, pourrait jouer un rôle déterminant dans l'intégration respectueuse et constructive de la science au sein des communautés (9). Cette approche offrirait une nouvelle perspective sur la mobilisation des connaissances, en renforçant la collaboration entre les chercheurs, les universités et la société.

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RÉFÉRENCES

1. Resnik DB. Moral distress in scientific research. The American Journal of Bioethics. 2016;16(12):13-15.
2. Low BS, Koshy S, Thein KMM, Tayeba S & Saha S. Factors associated with sleep disorders among international university students in Malaysia. Sleep and Vigilance. 2024;8:1-8.
3. Carrion LL, Bramstedt KA. Academic integrity, moral courage, and whistleblowing in student research. In: Eaton SE, editor. Second Handbook of Academic Integrity. Springer International Handbooks of Education. Springer, Cham. 2024.
4. Boudreau LeBlanc A. Global living ethics: unveiling practical and theoretical synergies through reflexive balancing. Canadian Journal of Bioethics / Revue canadienne de bioéthique. 2024;7(4):71-83.
5. Hallonsten O. Stop evaluating science: A historical-sociological argument. Social Science Information. 2021;60(1):7-26.
6. Canadian Association for Neuroscience. Science funding in Canada — Statistics.
7. Fond de recherche du Québec. Offres de financement 2024-2025.
8. Ganske KM. Moral distress in academia. Online Journal of Issues in Nursing. 2010;15(3):6.
9. Boudreau LeBlanc A, Dupras C, Williams-Jones B, et al. Safe spaces for co-operationalizing one health: building on momentum in bioethics. Ethics, Medicine and Public Health 2026;34:101233.

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LETTRE À L'ÉDITEUR / LETTER TO THE EDITOR

Ethical AI: More Than Just Responsible or Trustworthy

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intelligence artificielle, IA, bioéthique, responsable, fiable

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Critical discussions about AI governance are often obscured by the interchangeable use of terms: "ethical AI" (1), "responsible AI" (2), and "trustworthy AI" (3). While related, their distinctions are profound, and we believe the focus must be squarely on ethical AI, as it provides a foundational moral framework that extends beyond the operational scope of "responsible" or "trustworthy" practices. Responsibility and trust are subsets of the overarching ethics. Further, "responsible AI" is too often aligned with legal defensibility, corporate compliance, and accountability (2,3), while "trustworthy AI" — with frameworks like "Z-Inspection" — concentrates on technical reliability and quality control (4). These concepts are necessary but fall short of the bigger picture that is ethical AI. Reducing ethics to a checklist of compliance and functionality sidesteps the deeper and more complex engagement with moral values and societal good.

The importance of this distinction becomes clear in high-stakes fields like pharmaceuticals, device, and diagnostics research and development (1). An AI-assisted system can be fully compliant ("responsible") and technically flawless ("trustworthy") yet still lead to profoundly inequitable outcomes. Consider an AI tool for clinical trial recruitment that, in optimizing for data completeness, marginalizes underrepresented populations. This is not a technical glitch; it is an ethical failure that perpetuates health inequities. As another example, an AI-assisted system could be created and deployed as a human bioweapon, challenging the principle of ethical use. This highlights a foundational concept: legality is not a substitute for ethics, as there can be things that are legal (and compliant) but not ethical. Technology invariably outpaces regulation, creating a vast space where specific laws do not yet exist for every ethical dilemma. A framework grounded in moral principles is therefore essential to navigate this territory, moving beyond what is merely legal to what is fundamentally normatively right.

Ensuring that AI practices are sound requires a proactive approach that places ethics at the forefront of innovation. We must move the conversation beyond the comfortable but insufficient language of responsibility and trustworthiness. Prioritizing ethical AI is a commitment to rigorous moral scrutiny, especially in critical fields like drug development, where the ultimate measure of success is the advancement of human health and equity.

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REFERENCES

1. Ménard T, Bramstedt KA. Developing a set of AI ethics principles to shape ethical behavior in drug development. Ther Innov Regul Sci. 2025;59(3):399-402.
2. Goellner S, Tropmann-Frick M, Brumen B. Responsible artificial intelligence: a structured literature review. 2024;arXiv:2403.06910.
3. Bouhouita-Guermech S, Haidar H. Scoping review shows the dynamics and complexities inherent to the notion of "responsibility" in artificial intelligence within the healthcare context. Asian Bioeth Rev. 2024;16(3):315-44.
4. Zicari RV, Amann J, Bruneault F et al. How to assess trustworthy AI in practice. 2022;arXiv:2206.09887v2.

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