Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

Numéro hors-thème / Open Issue

VOL 6 (2)
27/06/2023

Illustration de couverture / Cover Art
Han Han Li

Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

Can J Bioeth / Rev Can Bioeth. 2023

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ISSN 2561-4665

Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

The Ethics of Humanitarian Innovation: Mapping Values Statements and Engaging with Value-Sensitive Design

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Résumé
Les réponses humanitaires auprès des populations victimes de conflits armés, de migration forcée ou d'urgences sanitaires font souvent face à des défis organisationnels et opérationnels importants. En réponse à ces défis, l'innovation en aide humanitaire cherche à identifier ces problèmes, tester et développer de nouvelles technologies et imaginer de nouveaux systèmes afin de pallier ces défaillances. Le processus d'innovation en aide humanitaire amène son lot de questionnements éthiques. Ceux-ci incluent le degré d'inclusion des populations affectées lors de la prise en charge des problèmes, le développement des solutions, l'identification et l'atténuation des risques ainsi que la distribution des bénéfices. Cet article enrichit l'ensemble des connaissances sur les implications éthiques des pratiques en innovation humanitaire de deux façons. Premièrement, nous dressons un portrait des concepts éthiques évoqués à travers les déclarations de valeurs et de principes éthiques publiés par des acteurs actifs dans le domaine de l'innovation humanitaire. L'analyse de ces documents nous permet d'identifier six valeurs fondamentales (les principes de bienveillance, autonomie, justice, responsabilité, durabilité et inclusion) auxquelles se joignent 12 valeurs secondaires et 10 concepts et pratiques connexes. Deuxièmement, nous proposons deux activités auxquelles les organisateurs d'innovation peuvent recourir afin de placer leurs valeurs au cœur du développement de leurs projets, et d'anticiper et de planifier une stratégie en cas de conflits de valeur. Favoriser une approche délibérée aux systèmes de valeurs et de principes éthiques en innovation humanitaire permet de centrer ces activités sur des engagements concrets. Les approches que nous présentons permettent de faciliter la diffusion des connaissances entre les différents agents, de promouvoir une attention particulière aux valeurs à travers les étapes d'innovation et de bâtir une résilience et une capacité à répondre aux situations présentant des dilemmes éthiques.

Mots-clés
conflit armé, catastrophe, éthique, humanitaire, innovation, conception basée sur les valeurs, éthique technologique

Abstract
The humanitarian sector continually faces organizational and operational challenges to respond to the needs of populations affected by war, disaster, displacement, and health emergencies. With the goal of improving the effectiveness and efficiency of response efforts, humanitarian innovation initiatives seek to develop, test, and scale a variety of novel and adapted practices, products, and systems. The innovation process raises important ethical considerations, such as appropriately engaging crisis-affected populations in defining problems and identifying potential solutions, mitigating risks, ensuring accountability, sharing benefits fairly, and managing expectations. This paper aims to contribute to knowledge and practice regarding humanitarian innovation ethics and presents two components related to a value-sensitive approach to humanitarian innovation. First is a mapping of how ethical concepts are mobilized in values statements that have been produced by a diverse set of organizations involved in humanitarian innovation. Analyzing these documents, we identified six primary values (do-no-harm, autonomy, justice, accountability, sustainability, and inclusivity) around which we grouped 12 secondary values and 10 associated concepts. Second are two proposed activities that teams engaged in humanitarian innovation can employ to foreground values as they develop and refine their project's design, and to anticipate and plan for challenges in enacting these values across the phases of their project. A deliberate and tangible approach to engaging with values within humanitarian innovation design can help to ground humanitarian innovation in ethical commitments by increasing shared understanding amongst team members, promoting attentiveness to values across the stages of innovation, and fostering capacities to anticipate and respond to ethically challenging situations.

Keywords
armed conflict, disaster, ethics, humanitarian, innovation, values-based design, technology ethics

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INTRODUCTION

Structured approaches to innovation in the humanitarian sector have become increasingly prominent over the past decade. This development is linked to discussions of accelerating learning, accountability and improvement of system-wide performance amongst humanitarian organizations, funders, practitioners, and other stakeholders (1). There has been a corresponding global proliferation of innovation labs, accelerators, and hubs that seek to reimagine solutions and processes to address emergent and long-standing humanitarian challenges. Since 2009, the humanitarian innovation sector has itself

ISSN 2561-4665

evolved “in nature and substance…” enabling the innovation agenda “to better match the complexity of the problems it seeks to address” (2).

Distinctive features of this innovation-driven humanitarian learning include adopting a structured approach to innovation and its evaluation, considering reactive changes to structured and evidence-driven approaches, and promoting changes at structural and system levels. However, discussions of the ethical dimensions of humanitarian innovation have not kept pace with the rapid technical and managerial developments associated with humanitarian innovation, though they have been garnering increased attention (see, for example the 2019 special issue on ethics and innovation in the *Journal of Humanitarian Affairs*) (3). As the reach and boundaries of the humanitarian innovation field are drawn and redrawn in response to a rapidly evolving humanitarian landscape, the need to deepen ethical analyses of humanitarian innovation is pressing. Simultaneously, developing ethical guidance through frameworks and methods to support innovation teams is key to harnessing such analyses for practical impact on the ground.

In this paper, we seek to contribute to ethics in humanitarian innovation, and the ways that a values-sensitive approach can be enacted. We begin with an introduction to humanitarian innovation and ethics, and then present an analysis of values that are included in normative statements of organizations involved in humanitarian innovation. Finally, we introduce and describe two activities that humanitarian innovation teams can use while developing and refining their projects to foreground values and attend to them across their innovation activities. These activities are rooted in value-sensitive design that focuses purposeful attention on values in design processes and has been proposed as a promising approach for humanitarian innovation ethics (4-7).

ETHICS AND HUMANITARIAN INNOVATION

Discussing the humanitarian sector, Betts and Bloom define innovation as “a means of adaptation and improvement through finding and scaling solutions to problems, in the form of products, processes or wider business models” (8, p.5). Reflecting this breadth, humanitarian innovation initiatives are conducted in diverse settings and address varied topics and problems across the sector. The solutions developed by humanitarian innovators, in the form of product or process innovations, also show considerable diversity. Cutting edge technological innovations garner the most attention and discussion, but non-technological innovations – for example, ones focused on improving organizational processes and coordination between actors – are also a key sector of innovation (2). The World Food Program’s Innovation Accelerator presents an illustrative example of a humanitarian innovation initiative. Established in 2019, the Scale-Up Enablement Programme supported the following projects in resource-constrained settings: a digital marketplace for farmers in Kenya to sell their crops online (Farm to Market Alliance), a global smartphone application allowing people to donate meals across the world (ShareTheMeal), and low-tech hydroponic systems in desert geographies to support food-insecure families (H_2Grow) (9). Many innovative practices and products in the global food supply sector, such as those listed above, are implemented under the charge of “disrupting hunger”, a phrase which echoes the technology industry’s rhetoric of disruptive change. This influence reflects broader patterns in humanitarian innovation that include the establishment of cross-sector public-private partnerships, as well as the involvement of a broader set of actors in the humanitarian space.

While global and transnational networks such as the Global Partnerships for Humanitarian Impact and Innovation (GPHI2) of the International Committee of the Red Cross (ICRC) shape the innovation ecosystem considerably, efforts to localize humanitarian innovation exist. Such initiatives include the work of several networks supporting small-scale, grassroots innovators in countries affected by humanitarian crises, such as Response Innovation Lab (RIL) or the Start Network. Breaking with the traditional top-down processes of humanitarian relief between aid donors and recipients, some innovation efforts have been spearheaded by communities and organizations based in conflict-affected regions such as the Northeast Humanitarian Innovation Lab.

As with humanitarian actions more generally, innovation activities have ethical implications that warrant careful attention (10). For example, ethical considerations related to the use of emergent information and communication technologies (ICTs) include accuracy of information, protecting the privacy and security of users, responding to inequalities, demonstrating respect for communities, protecting relationships, and managing expectations (11). Since innovation projects often go beyond ideation into phases of prototyping and testing to determine whether a new approach is an improvement over existing practices; it is emphasized that innovators have a responsibility to ensure “that any increased risk remains isolated to the innovating organization rather than passed to an affected community” (1). In a similar spirit, the ICRC warns that innovating in the absence of ethical standards “will undoubtedly cause confusion and inconvenience, waste resources and create additional risk and vulnerability” (12, p.27). These assessments highlight the importance of attending to the ways that innovation processes intersect with situations of vulnerability experienced by populations affected by crises. Examining structural features of humanitarian innovation initiatives, multiple authors have also expressed concern regarding the roles of private for-profit actors, neoliberal and neocolonial global dynamics, and market-driven innovation models drawn from the technology industry, directing attention to potential misalignment with ethical commitments of humanitarians (13,14). While research activities in humanitarian contexts typically require review and approval from one or several research ethics committees, depending on the participating institutions and locations in which the project is undertaken, many innovation activities do not undergo such scrutiny.

Ethics guidance for humanitarian innovators has been developed within both the humanitarian and social innovation ecosystems (3,15). Other initiatives have focused on specific domains of innovation, such as guidance related to innovations in ICTs (16). Multiple organizations, initiatives and individuals have also emphasized the need to articulate ethical values or guiding principles to orient responsible innovation activities more generally (7). Taken together, these contributions present a portrait of diverse values that humanitarian innovation stakeholders consider to be important for guiding innovation activities. However, formal statements of values may appear abstract and remain disconnected from the actual processes of developing, implementing, evaluating and scaling innovations. In the next section, we map statements of values and identify patterns and linkages across them, before considering ways that attention to values can be further integrated in innovation processes.

MAPPING CONCEPTS IN NORMATIVE STATEMENTS OF VALUES

We drew on McDougall and colleagues' Critical Interpretive Review approach to map and analyze normative values statements for humanitarian innovation that have been developed by or for organizations involved in humanitarian innovation (17). The question orienting this exercise was, "How are ethical values expressed in normative statements that aim to guide organizations involved in humanitarian innovation activities?" We defined a normative statement as an explicit *articulation of a set of concepts presented as guiding values or ethical principles for orienting humanitarian innovation*. To identify normative statements, we used multiple approaches. Between September 2019 and February 2020, open searches were conducted using Google, as well as focused databases for academic and grey literature, i.e., Google Scholar, Scopus, ProQuest, and OpenGrey. Clusters of key terms linked to the concepts of "humanitarian", "innovation", "ethics" and "values" were tailored to specific databases, with no restriction on publication date. Targeted searches were also conducted of official websites associated with intergovernmental agencies, non-governmental organizations, interagency initiatives, funding agencies, private organizations, research groups, and foundations (e.g., ICRC, Humanitarian Innovation Fund, and ALNAP's Humanitarian Evaluation, Learning, and Monitoring [HELP] Library). Finally, we hand-searched reference lists of relevant documents.

Normative statements were assessed based on scope, source and content. They were included if they articulated specific normative values (or ethical principles) for humanitarian innovation (though these could be intermixed with technical or operational principles). Ethical guidelines or frameworks that were not based around specific values were not included, nor were statements that focused only on technical or operational aspects of innovation. Further, statements were included if they addressed humanitarian innovation generally and were not specific to a particular innovation domain or emergent technology. Thus, those that focused exclusively on technologies such as artificial intelligence, drones, or big data management in humanitarian action were excluded. Statements also had to be endorsed or put forward by a specific organization, be included in a report issued by an organization engaged in humanitarian innovation or be the result of a collective process that involved representatives of organizations involved in humanitarian innovation.

Following these steps, eight sources were retained for the mapping exercise (Table 1), meeting our goal of surveying a wide array of normative statements, i.e., statements linked to non-governmental organizations, networks, an intergovernmental organization, a private foundation and funding programs. We acknowledge that we may have missed some normative values statements pertaining to humanitarian innovation, such as ones not available in English or framed differently than our search terms. Nonetheless, this targeted approach is in line with a Critical Interpretive Review that aims at capturing and critically reviewing key sources in a structured and thorough manner, rather than exhaustively assembling every possible source related to the research question (17).

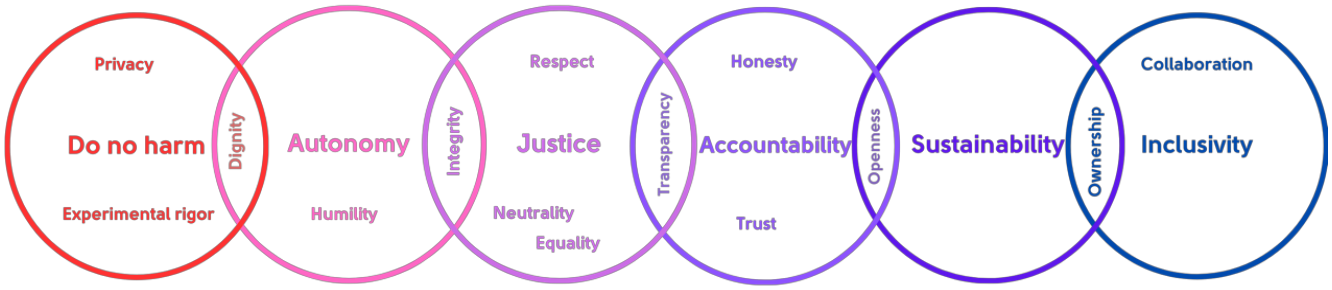
Table 1: Characteristics of included statements of ethical values and principles

	Linked organization or entity	Role of organization or entity	Name of document	Type of document	Date
1	Medécins sans Frontières' Transformational Investment Capacity (TIC) (18)	Invests funds, intellectual capital, and human resources to support humanitarian innovation projects	Guiding practices	Set of practices that projects supported by the TIC are to follow	2018
2	United Nations Office for the Coordination for Humanitarian Affairs (OCHA); Betts and Bloom (8)	Coordination of humanitarian response	Humanitarian Innovation: State of the Art	Ethical Framework for Humanitarian Innovation included within OCHA policy paper (such papers are "produced primarily for internal purposes and serve as a basis for promoting further discussion and policy analysis in their respective areas. They do not necessarily represent the official views of OCHA.")	2014
3	Oxford Refugee Studies Centre (15)	Workshop in preparation for World Humanitarian Summit with participation from academia and humanitarian sector	Principles for Ethical Humanitarian Innovation	Set of innovation principles drafted in preparation for 2016 World Humanitarian Summit. Workshop was convened at Oxford University and included participation of NGOs, intergovernmental agencies, funders and academics.	2015
4	Red Cross and Red Crescent Movement; Binger, Lynch, Weaver, American Red Cross (12)	Humanitarian agency	Principled Approach to Innovation	Official submission to the World Humanitarian Summit, drafted with support from the American Red Cross, International Committee of the Red Cross, International Federation of Red Cross and Red Crescent Societies, Korean Red Cross, Netherlands Red Cross, Red Cross Red Crescent Climate Centre, and Swedish Red Cross.	n.d.
5	IKEA Foundation (19)	Private foundation, funder of innovation projects with UNHCR	Ethical Framework	Framework to guide private foundation's activities, including for emergency relief and refugee-focused initiatives	n.d.
6	Global Alliance for Humanitarian Innovation (GAHI), managed by Elrha* (20)	Network aiming to connect, mobilize and amplify innovation	Values	GAHI was launched at the World Humanitarian Summit (WHS) with the overall goal to address the innovation needs in the sector that could not be effectively tackled by individual actors and organizations working on their own	2016-2019
7	Response Innovation Lab (RIL) (21)	Network aiming to convene, matchmake and support humanitarian innovation	Response Innovation Lab	Guidance document providing guiding principles for RIL staff, members and partners.	2018
8	Humanitarian Innovation Fund (HIF) (22)	Funding program under the management of Elrha	Humanitarian Innovation Guide Principles and Ethics	Includes 1) principles for humanitarian innovation management; and 2) set of ethical guidelines "to help mitigate the risks associated with the practice of experimentation in humanitarian environments."	2018

*GAHI was launched in 2016 but was closed down in 2019 (after the initial search was conducted). We retained the document in our analysis for the purpose of illustrating the values it foregrounded as a unique network of humanitarian innovators.

After repeated close reading of the sources, using QDA Software Atlas.ti (Version 8.4.4), the texts were coded and labels assigned to related value concepts. This process identified 28 distinct codes. Data display tables and concept maps were then developed to further clarify and refine an analytic structure, clustering related values and establishing linkages across concepts and between statements. Through this process, several codes we merged, and others added or refined, resulting in a total of 30 codes. We identified six primary values that represent more prominent and overarching conceptual categories and classified 14 concepts as secondary values that we interpreted as being closely related to one or several of the primary values, often functioning as actionable principles. Figure 1 illustrates the relationship between primary and secondary values.

Figure 1: Venn diagram of primary and secondary values



An additional ten codes were categorized as 'associated concepts,' concepts that were included in the normative statements but are not normative values in their own right. They are nonetheless concepts or design principles with ethical implications that present as enablers or challenges to the primary values (e.g., consent is often considered as an important way to operationalize the value of autonomy). The primary values, secondary values and associated concepts are presented in Table 2. In the following section, we briefly describe the six primary values and how they were defined, contextualized, and/or justified in the normative statements.

Table 2: Primary and secondary values, and associated concepts, identified in normative statements

Primary values	Secondary values	Associated concepts	Illustrative excerpts linked to the primary value
Do-no-harm	Experimental rigor Dignity* Privacy	Data security Consent	"Under no circumstances should humanitarian innovation lead to intentional harm. Risk analysis and mitigation must be used to prevent unintentional harm, including from primary and secondary effects relating to privacy and data security, impacts on local economies, and inter-communal relationships." (15) "We apply ethical standards to ensure the innovation process and outcomes do not create additional vulnerability, dependencies, risks or other harms." (12)
Autonomy	Dignity* Humility Integrity*	Consent	"All humanitarian innovation must be conducted with the aim of promoting the rights, dignity and capabilities of the recipient population. Innovation must be based on representative consultation and informed consent." (15,21)
Justice	Integrity* Equality Neutrality Respect Transparency*		"Equity and fairness should underpin the distribution of benefits, costs, and risks resulting from innovation." (15,21,22) "We are a trusted, neutral convener with the ability to lead an equitable and fair innovation process." (12) "Equity and fairness should underpin the distribution of benefits, costs, and risks resulting from innovation. Innovation should be sensitive to, and useful for, the most marginalized populations, including sensitivity to age, gender, and disability." (22)
Accountability	Transparency* Trust Honesty Openness*	Conflict of interest User-Centeredness*	"Engagement in humanitarian innovation constitutes an obligation to ensure accountability to recipient populations, including establishing processes for complaints and recourse relating to unforeseen consequences and maleficence." (15) "Improve mechanisms for sustained dialogue and communication during all stages of the innovation process." (7,8) "Projects should be visible across the MSF movement and have a high degree of accountability." (18)
Sustainability	Openness* Ownership*	Timeliness Quality Proven Impact	"Ensure that the local market and local systems are well understood before implementation, and that measures are in place for long-term impact and sustainability." (8) "[a resilience strengthening solution] has the required financial resources to support its current use and growth, but does not compromise natural resources or the interests of future generations." (8) "We actively work towards sustainability and making the best possible use of resources." (19)
Inclusivity	Collaboration Ownership*	Communication Representation Partnership User-centredness*	"As a central component of innovation, partnership is […] a means to draw in ideas, good practices, and resources from private technology developers, military R&D agencies, universities and affected people themselves." (8) "Affected populations have the right to inclusion during the process as well as to benefits from the outcomes of such a process." (22)

* indicates secondary values or associate concepts that relate to two of the primary values

SUMMARIES OF PRIMARY VALUES

Do-no-harm: A central concept in many of the normative statements is the commitment to avoid causing harm through humanitarian innovation. In multiple normative statements, innovation stakeholders are guided to enact the 'do no harm' principle, a central concept in the broader domain of humanitarian ethics (23,24). Innovation involves uncertainty and includes cycles of experimentation, piloting, testing, and evaluating. Efforts to improve practices and processes, or test products, may give rise to risks distinct from those occurring in regular humanitarian activities, and possibly worsen existing power struggles (8). As the HIF ethical guidelines indicate, "Applying 'Do No Harm' necessitates an anticipatory approach toward identifying, describing, and analysing intended and unintended impacts that might arise because of research and experimentation." This quotation from the HIF's Humanitarian Innovation Guide reflects a common emphasis in other normative statements on issues related to particularities of experimentation. To mitigate the risks of harms linked to this step of the process, several values statements point to rigorous evaluations of an innovation's impacts, upholding standards of research ethics, and undergoing external review of experimentation activities where relevant – including assessing how these processes could harm populations affected by crisis, especially marginalized groups or individuals (12).

***Autonomy*:** Respect for autonomy in the context of innovation encompasses designing and implementing innovations in ways that acknowledge and promote the rights, dignity and capabilities of crisis affected populations, and especially persons who will engage with the innovation process and its products. This is supported by responsiveness to "change the shape or direction of a project in response to stakeholder perspectives, social values, and changing circumstances." (22) Respect for autonomy is operationalized by engaging communities in the identification of problems to be addressed through innovation, the design of innovation projects, and by recurrently seeking their informed consent as the circumstances and conditions of the innovations evolve, and especially during trials, pilots or experimental activities (15,22).

***Justice*:** The principle of justice is often conceived of as "fairness" and linked to concepts of distributive, social and procedural justice. Addressing justice requires attention to how risks and benefits are apportioned within and across populations, and amongst innovation stakeholders (22), and dedicated effort to attend to the needs of marginalized or especially vulnerable groups (15,21). Justice is a relational concern in partnerships, requiring integrity and honest dealing, including attention to conflicts of interest (19). Also important for innovation is procedural fairness in the way that decisions are made, including transparency of processes (18,20).

***Accountability*:** Those involved in humanitarian innovation activities should accept responsibility for their actions and be accountable to both the crisis-affected populations they assist and to the partners and donors involved in their project (15). Strong mechanisms of accountability rooted in openness and transparency about the successes and failures of the innovation processes foster trust between partners and help maintain the legitimacy and reputation of the system and its actors (20). A further aspect of accountability relates to respecting the rights of affected populations to rectify and redress harms that may result from an innovation process (22).

***Sustainability*:** Sustainability is featured in multiple normative statements but is defined in at least two ways: first, fostering innovations that promote longevity of the innovation and its long-term impact, and second, innovating in ways that are ecologically responsible. The first emphasizes concern for the continuity of positive impacts of practices, processes and products that are developed through innovation (8,22). The design principle of openness and the local ownership of the innovation project are related concepts fostering sustainable practices. Fair and sustainable innovation practices are linked to commitments to avoid displacement of local businesses; provide crisis-affected communities with needed information, training and infrastructure; and sharing resources between all participating actors (e.g., community, funders, and aid workers), even beyond the termination of the project (8,12). Ecological sustainability reflects a concern for the legacy of the innovation activity, its resilience to environmental shocks, and potential unintended harmful impacts on the environment, especially for future generations (12).

***Inclusiveness*:** Innovation projects should be demand-driven, responding to needs within crisis-affected communities as identified by end-users (8). Considering the inherent uncertainties and uneven distribution of risks in the contexts in which humanitarian innovations are deployed, special care must be taken to avoid exacerbating the vulnerability of particularly at-risk or marginalized groups by excluding them from an innovation project (22). A non-tokenistic, user-centred approach can promote inclusion by integrating crisis-affected communities in all stages of the innovation process; collaboration and meaningful engagement of stakeholders across disciplines and industries was also identified as a form of inclusiveness (8,21). A feature of the Red Cross and Red Crescent Movement's approach is described as "advocating for equitable access so as not to exclude important stakeholders in the innovation process." (12) Further, ethical innovation practices foreground meaningful collaboration and consultations with end-users and promote fair representation in their partnerships.

DISCUSSION OF VALUES MAPPING

This mapping exercise provides a portrait of what values are included in normative statements as of May 2020. Considerable variability exists across the values statements in terms of purpose, framing, and substantive content. Organizations frame and disseminate these statements in different ways, referring to them as summations of guiding principles, guiding practices, ethical standards, or values. They include concepts ranging from broad ethical principles (e.g., justice), to operationalized practices (e.g., obtaining informed consent), and design strategies (e.g., user-centredness). In drawing upon these statements, innovators will need to be attentive to the fit and focus of the included content in relation to their own needs and purposes.

A second consideration relates to whether values statements were tailored to organizations or developed for a broader humanitarian audience. For example, the Red Cross and Red Crescent's Principled Approach to Innovation articulates how innovation activities can be aligned with the seven humanitarian principles, the key normative reference points for the Red Cross movement. In other instances, statements draw from principles formulated for the practice of innovation in the development field. The UNICEF Principles for Innovation and Technology in Development have been particularly influential to other organisations, with aspects included in the normative statements of the UNHCR and the RIL. These trends raise interesting questions about the specificity of the value set that might be most relevant to humanitarian innovation or humanitarian innovation organizations, and the transferability of value sets from neighbouring domains.

We also note that some values statements appear to be more focused on specific phases or aspects of innovation (e.g., problem recognition or experimentation phases). Generally, little guidance is provided alongside the normative statements about how innovators ought to apply them in their work, nor how to adjudicate between principles in situations when they might conflict. One challenge with principle-based approaches to ethics in any practice domain is the possibility of conflicts arising between two or more principles. The Humanitarian Innovation Guide notes this possibility in terms of the application of the fundamental humanitarian principles for innovation, stating that "efforts should be made to articulate all potential tensions, conflicts, and challenges to such principles and the strategies that innovators will use to resolve such tensions." Moreover, challenges may arise when partners from different organizations, with different sets of values (whether or not articulated in normative statements) seek to collaborate. Such challenges may be especially likely when collaborations span the humanitarian and private sectors, or if there is involvement of military actors. The diversification of stakeholders and funding sources in the humanitarian innovation ecosystem can complicate the delineation of coherent values and create tensions between stakeholders. As innovators seek to integrate an ethics framework in their projects, potential value conflicts should be identified and strategies to mitigate them developed, along with guidance on practical ways to integrate values into innovation processes.

Based on this review, several questions can be asked: how do these values map onto the actual practices of innovators and innovations teams? How can values be integrated across different innovation stages from problem recognition to scaling? How can innovators address potential trade-offs or conflicts between values? How can these values and associated concepts draw attention to power imbalances in the innovation process, amongst partners, and between innovators and crisis-affected

populations? And importantly, how can one best attend to these considerations and ensure that injustices are not reinforced by the innovation project? In the following section, we present two activities that can support teams in making values more concrete in their project design process.

Foregrounding Values in Innovation Projects: Two Activities to Support Value-Sensitive Humanitarian Innovation

As described above, organizations involved in humanitarian innovation have identified a wide range of values to guide their innovation activities. A challenge for innovators and innovation teams is the question of how to integrate these values into their projects in a deliberate and tangible manner. A range of frameworks and approaches exist that could provide methods and structure for engaging values in humanitarian innovation (25-29). Among these, value-sensitive design (VSD) is particularly salient (30). VSD was developed as an iterative approach for developing technology applications and incorporating close attention to human values across all phases of the design process (4,31). A wide range of VSD methods have been developed (32), and VSD has been proposed as a useful approach for guiding humanitarian innovation (6,7).

With the goal of illustrating practical approaches for enacting a value-sensitive humanitarian innovation approach, we highlight two activities that innovation teams could undertake as practical means of foregrounding values within their innovation process. These activities were developed as part of an initiative that our research group undertook to develop an ethics toolkit for humanitarian innovation for the Humanitarian Innovation Fund. This development was inspired and informed by the above review of the literature on humanitarian innovation ethics; interviews with humanitarian innovators, donors, funders, and researchers; and a series of iterative workshops with innovators and innovation teams.

The first activity provides a process for teams to identify the values that they deem most important to attend to within a particular project and guides them to articulate how and why the values are particularly salient. The second activity builds on the first by having the team consider how the identified values are relevant to each of the different components of their project work plan, and how these values might be hindered or even threatened. Innovators can then reflect on how the project design might be adjusted to avoid, minimize or mitigate these potential issues, effectively establishing a values-driven strategy for their innovation process. Both exercises can be conducted in-person or online, and they should have a facilitator, who can be a member of the team or someone outside the group.

Activity 1: Values Clarification

As demonstrated through the mapping review, some organizations have identified values to guide humanitarian innovation. Due to the nature of innovation projects, teams will continuously benefit from engaging in discussion to clarify organizational and project-specific values. These conversations may be especially important for collaborative innovation projects that involve partners from multiple sectors (e.g., humanitarian organizations, academia, industry). This process can help team members develop a shared understanding of and commitment to a core set of concerns. In doing so, it can help clarify expectations and priorities, and may help prevent misunderstandings.

In preparation for the activity, the facilitator should prepare a set of values for the team to consider. These can be drawn from the organization's values statement (or a number of values statements within a partnership), from guidance documents specific to the domain of innovation, or other relevant source. The results of the mapping exercise presented above could also be the basis for this values list or be used to supplement other sources. For an in-person session, the facilitator writes each of these values on a card and places them on a table. Online, the values could be organized as a list or word cloud that is visible to all participants. When the group is convened, the facilitator explains the purpose of the exercise, and responds to any questions. Participants are then invited to look over the list of values. Before discussing with others, they are asked to write down three to five values that strike them as especially relevant to their project. If they think other values are important but missing from the cards/list, they are encouraged to take note of them. The facilitator then asks each member of the team to share which values they identified as particularly important to their project, and why. The team then discusses which values were frequently included and which were included by a minority. The facilitator should encourage the team to think about the values in the context of the particular project, rather than for innovation in general or for other innovation projects. The team should also be attentive to situations when the same value is understood differently by members of the team, and these differences should be discussed. For example, team members might have chosen 'sustainability' as the value, but some could be thinking about environmental impacts of the project, while others could be considering the likelihood of durable benefits for end users. Any newly proposed values that were not on the original list should be considered by the group. Through discussion, the team should aim to arrive by consensus at a set of four to six values that they agree are especially important to attend to in their project. Importantly, this selection does not mean that other values are not relevant to the project, but rather that the team has chosen to prioritize these 4-6 values, at least for the time being.

The second part of the exercise involves group work to write a short summative description of what the team thinks it will mean to be attentive to each of the selected values in their project. For example, if the team identified 'inclusion' as a key value, they might have written the following description of how they planned to enact that value: "We will be attentive to power structures that exist within the project and strive to listen to diverse voices, especially those of people who have been marginalized within the population affected by the crisis." By doing so, the team has the opportunity to concretize their commitment to inclusion and to 'make it their own' for the purposes of their project.

We piloted this activity in workshops in the Philippines and Germany, and online with multinational groups, and observed that innovation teams often drew upon the values identified in the mapping review when selecting project-specific values, rather than starting with a pre-established set of organizational values. This process also provides an opportunity for all team members to bring their perspectives, commitments, and priorities to the table. Discussing the wider set of values in relation to their own project can thus support teams to establish common ground when people are drawn from different organizations or have different familiarity with value-related vocabulary. Where team members have different perspectives on which values to highlight for their project, discussion can help clarify how people understand these terms and their application to the specific project. It also provides an opportunity to consider differences across organizational values statements, and how to align the value set for a particular project. The second part of the exercise aims to support participants to go beyond the creation of a list (which may feel like an abstract exercise) and express the value as a project-specific commitment in order to make its application more tangible and tailored.

Activity 2: Foresighting

The second activity presents a further opportunity to consider how values relate to planning and implementing a humanitarian innovation project. The values used in this exercise may be generated through the Values Clarification activity, or could draw on another source, such as a set of organizational values. The intent is for teams to consider potential challenges to enacting the prioritized values within their planned project. This can be considered an act of foresighting, by which we mean to "identify possible outcomes, anticipate contingencies, and be diligent in planning" (33) while aiming to "understand and anticipate how choices and actions made today shape or create the future". (34)

If done in person, this activity works well with a poster-sized paper that team members can group themselves around. Online, some form of shared work board (such as Miro, StormBoard or similar tools) can be used. Prior to the session, the facilitator should ensure that the team has a copy of their project work plan. This work plan can be pre-populated across the centre of the poster or work board. In many instances, it may help to organize this material visually as a set of boxes or circles arranged linearly according to the timeline of the project (e.g., a box or circle could be created for a community consultation workshop or a pilot trial of the innovation in a particular locale).

In beginning the discussion, the facilitator should review the goals and steps of the exercise. Participants can then be invited to review the project components and timeline, and small corrections made. Depending on the complexity of the project and the stage of development, practical decisions may need to be made about which components to focus on or the degree of granularity that will be introduced. Next, the set of key values that the team has identified as particularly important for their project are listed across the top of the page. The facilitator then invites participants to consider how each project component relates to the values, asking themselves: "what might hinder the enactment of these values at this step of our project?" For example, a team which identified 'inclusion' as a key value might be prompted to reflect on whether challenges could arise for incorporating marginalized groups into a community consultation workshop, or whether accessibility barriers could exist for the inclusion of people with mobility impairments (for further examples, see the EHI case studies).

The final step in the foresighting exercise is to discuss ways to avoid, respond to, or mitigate potential harms that could arise from the identified challenges. The product of the Foresighting Activity can thus be seen as an actionable, values-driven strategy to anticipate ethical challenges and to increase the alignment of the innovation project's components with the stated values of the team members. This activity gives the team an opportunity to assess and adjust project plans according to a value-sensitive approach and encourages teams to establish patterns of reflection and discussion around the ethics of their work, a process that fosters learning, mutual support, and accountability.

During piloting workshops that we conducted, the foresighting exercise led to many rich discussions centred around how values connect with project activities. Depending on where an innovation team was situated in their process (ranging from early-stage problem recognition to late-stage implementation), different decisions were made about the degree of granularity in which project components were separated out for discussion. Some teams focused on an area of challenge about which they were already loosely aware, but had not yet addressed in detail, while other teams discussed potential issues that they had not yet considered. Both types of discussions can be fruitful outcomes of the foresighting exercise and provide opportunities to adjust project plans. The exercise was noted as being most effective when teams have a high degree of shared buy-in to the key values guiding the activity.

CONCLUSION

As the field of humanitarian innovation continues to evolve in the years to come, it will benefit from the adoption of proactive approaches to integrate and address values and that promote alignment between innovation projects and the needs and priorities of populations affected by crisis. Clarifying values and ethical commitments is more important as innovation integrates multi-sectoral partnerships and as diverse actors engage in this space. Within humanitarian innovation, increasing emphasis has been placed on fostering local, grassroots innovations, a development that promotes direct engagement by populations affected by crisis, and greater attention to local needs and contextual realities. These initiatives may involve collaboration among partners with different goals, expectations, and commitments. In other instances, innovation projects involve partnership between humanitarian organizations and private industry. Burns cautions that "private-sector logics, languages and rationalities" are increasingly prominent in digital humanitarian innovation and are influencing the humanitarian sector more broadly. (14) The values motivating private-sector organizations are likely to differ from those motivating humanitarian

organizations, which could lead to challenges within partnerships and innovation initiatives. Activities like those described in this paper may bring differences to the surface and allow fruitful discussion and articulation of a common vision for the values that will guide an innovation project. Regardless of the configuration of partners and stakeholders who are involved, engaging in values-sensitive design will promote attention to how ethical commitments can animate and guide design decisions and the implementation of a humanitarian innovation project. While the development of organizational values statements is an important contribution, tangible strategies are also needed to support innovation teams to foreground values in their practices and across their innovation projects.

Reçu/Received: 10/05/2021

Publié/Published: 27/06/2023

Remerciements

Nous remercions Ian McClelland, Anna Skeels et Bjorn Rust du Fonds d'innovation humanitaire pour leur contribution très utile aux idées et activités présentées dans cet article. Nous remercions également les autres membres de notre équipe de recherche, Rachel Yantzi, Ali Okhowat et Lydia Kapiriri, ainsi que tous les innovateurs qui se sont engagés dans différentes itérations des outils de clarification des valeurs et de prospective lors d'une série d'ateliers en 2019 et 2020. La cartographie des déclarations de valeurs et le développement des deux activités ont été entrepris dans le contexte du projet Éthique pour l'innovation humanitaire qui a été initié par Elrha et entrepris par les membres du Groupe de recherche sur l'éthique de la santé humanitaire. Ce travail a été rendu possible grâce au financement du Foreign, Commonwealth and Development Office (FCDO) du Royaume-Uni et du ministère néerlandais des Affaires étrangères. Lisa Schwartz bénéficie du soutien de la chaire Arnold L Johnson d'éthique des soins de santé.

Acknowledgements

We are grateful to Ian McClelland, Anna Skeels and Bjorn Rust from the Humanitarian Innovation Fund for their very helpful input related to the ideas and activities presented in this article. We also thank the other members of our research team, Rachel Yantzi, Ali Okhowat and Lydia Kapiriri, and all the innovators who engaged with different iterations of the values clarification and foresighting tools at a series of workshops in 2019 and 2020. The values statement mapping and development of the two activities were undertaken within the context of the Ethics for Humanitarian Innovation project that was initiated by Elrha and undertaken by members of the Humanitarian Health Ethics Research Group. This work was made possible by funding from the UK Foreign, Commonwealth and Development Office (FCDO), and the Netherlands Ministry of Foreign Affairs. Lisa Schwartz is supported by the Arnold L Johnson Chair in Health Care Ethics.

Conflits d'intérêts

Aucun à déclarer

Conflicts of Interest

None to declare

Édition/Editors: Aliya Affdal

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

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Can J Bioeth / Rev Can Bioeth. 2023;6(2):11-19

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Operationalizing Equity in Surgical Prioritization

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Résumé

L'allocation des ressources en soins intensifs et le triage des patients ont fait l'objet d'une grande attention pendant la pandémie de COVID-19, mais il y a peu de conseils concernant les aspects éthiques de l'allocation des ressources et de la priorisation des patients dans des circonstances "normales" pour les systèmes de soins de santé canadiens. Les listes d'attente chirurgicales, qui ont été globalement exacerbées par la pandémie de COVID-19, sont l'un des contextes dans lesquels des décisions d'allocation et de priorisation sont nécessaires. Dans cet article, nous détaillons le processus utilisé pour développer un cadre éthique afin de soutenir la priorisation des opérations chirurgicales non urgentes à l'Hôpital pour enfants malades de Toronto, un hôpital pédiatrique tertiaire. Notre objectif était de fournir des conseils pour les aspects les plus valorisants de l'établissement des priorités, en particulier lorsque l'urgence clinique n'est pas suffisante pour dicter la priorité à elle seule. Dans cette optique, nous nous sommes efforcés de prendre en compte les aspects familiaux, relationnels et d'équité. Dans le cadre des efforts concertés de notre institution pour traiter de manière éthique et efficace notre retard en matière de chirurgie, un groupe de travail sur l'éthique a été formé, composé de cliniciens de la chirurgie, de l'anesthésie, des soins intensifs, d'un bioéthicien de l'hôpital, d'un conseiller parental et d'un chercheur en bioéthique de l'université. Un processus d'équilibre réflexif a été utilisé pour développer un cadre éthique. À cette fin, la même méthodologie a été utilisée pour créer un support pour la priorisation des patients qui identifie les facteurs cliniquement et moralement pertinents pour la priorisation parmi les cas chirurgicaux médicalement similaires, avec un objectif substantiel étant d'identifier et de corriger les inégalités en matière de santé dans la priorisation chirurgicale, dans la mesure où cela est possible. Bien que d'autres étapes soient nécessaires pour valider plusieurs aspects du cadre, notre recherche suggère qu'un cadre éthique fondé sur les réalités pratiques des opérations hospitalières apporte la cohérence, la transparence et le soutien nécessaire aux décisions qui sont souvent laissées aux cliniciens individuels, ainsi qu'une occasion de réfléchir à la présence d'inégalités en matière de santé dans tous les domaines de la prestation de soins de santé.

Mots-clés

priorisation, équité de santé, allocation des ressources, rationnement, justice distributive, éthique organisationnelle

Abstract

The allocation of critical care resources and triaging patients garnered a great deal of attention during the COVID-19 pandemic, but there is a paucity of guidance regarding the ethical aspects of resource allocation and patient prioritization in 'normal' circumstances for Canadian healthcare systems. One context where allocation and prioritization decisions are required are surgical waitlists, which have been globally exacerbated due to the COVID-19 pandemic. In this paper, we detail the process used to develop an ethics framework to support prioritization for elective surgery at The Hospital for Sick Children, Toronto, a tertiary pediatric hospital. Our goal was to provide guidance for the more value-laden aspects of prioritization, particularly when clinical urgency alone is insufficient to dictate priority. With this goal in mind, we worked to capture familial, relational, and equity considerations. As part of our institution's concerted efforts to ethically and effectively address our surgical backlog, an ethics working group was formed comprising clinicians from surgery, anesthesiology, intensive care, a hospital bioethicist, a parent advisor, and an academic bioethics researcher. A reflective equilibrium process was used to develop an ethics framework. To this end, the same methodology was used to create a support for patient prioritization that identifies clinically and morally relevant factors for prioritization among medically similar surgical cases, with a substantive goal being to identify and redress health inequities in surgical prioritization, inasmuch as this is possible. While further steps are needed to validate several aspects of the framework, our research suggests that an ethics framework grounded in the practical realities of hospital operations provides consistency, transparency, and needed support for decisions that are often left to individual clinicians, as well as an opportunity to reflect upon the presence of health inequities in all domains of healthcare delivery.

Keywords

prioritization, health equity, resource allocation, rationing, distributive justice, organizational ethics

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ISSN 2561-4665

INTRODUCTION

The initial shutdown of nonemergent or 'elective' surgery during the early months of the COVID-19 pandemic created a global backlog of postponed procedures, as well as a hidden waitlist of patients who are delayed in referral for surgery due to ongoing diminished surgical, screening, and diagnostic capacity. Surgical backlogs are compounded by backlogs in other domains, such as screening and cancer diagnosis. While the term 'elective' has been widely used to capture any procedure that is categorically neither emergent nor urgent – that is, not immediately threatening to life or limb – it is colloquially misleading (1). The term 'elective' encompasses a range of vital procedures, many of which are time-sensitive and carry significant consequences for patients when delayed. These include, but are not limited to, interventions directly connected to surgery: e.g., diagnostic screening, hernia repairs, biopsies, valve replacements, spinal fusions and joint replacements. When delayed, risks of morbidity and mortality escalate (2).

A survey of twenty-five major hospitals in the US showed an initial 35% decrease in surgical activity from March to June 2021 (3). One study found that even with optimistic modeling, backlogs of > 1 million cases will remain two years after the initial shutdown, which means that even with pre-pandemic capacity, it will be impossible to get ahead of the accumulating waitlist (4). As of 2021, in the UK, NHS surgical waitlists were at a record high of 4.6 million (4), and if the estimated hidden waitlist is included, it will be 9.7 million by 2023-2024 (5). Canada's overall surgical capacity was down 47% from March to June 2020 (6), and the proportion of Canadian pediatric patients waiting past their clinically indicated window of time for surgery (7) ballooned from one third to two thirds during the pandemic (8). As of March 2023, these problems have not resolved. The Canadian Institute for Health Information found that over the past 31 months of the pandemic, 14% less surgeries have been performed, backlogs continue to grow, and patient need continues to outstrip available resources (9). Thus, the logistical, clinical, and ethical issues posed by surgical backlogs continue to require consideration, even after the immediate crisis posed by the initial stages of the COVID-19 pandemic had subsided.

Acknowledgment that the backlogs are unwieldy has been accompanied by various proposals to reduce them: increasing use of innovative procedures, developing infrastructure to maintain surgical operations during future pandemic surges (5), integrating 'prehabilitative' measures prior to surgery (10), increasing funding (5), centralizing waitlists, surgical smoothing, and making active efforts to prioritize elective cases in recognition that while they are not life-threatening, they are still necessary surgeries (11). However, even where sufficient increases in funds are available, there is recognition that would be ill-advised to race through the current backlog without oversight, transparency, and ethically informed guidance (1). Determining how to transparently and fairly work through surgical backlogs constitutes a growing problem; and there is a gap in the literature regarding the ethics of resource allocation and prioritization among 'normal' healthcare resources (12).

Working through the surgical backlogs requires many prioritization decisions, the burden of which often, though not always, fall to individual surgeons (1,13). While surgeons are certainly best positioned to evaluate the clinical urgency of a given case compared to others on their waitlists, most decisions regarding priority are not cleanly settled only by an examination of urgency. These decisions also require the weighing and balancing of seemingly incommensurate factors such as pain and quality of life, and these, along with the question of which factors ought to be considered when prioritizing, are all value laden. Further, with limitations on operative time, surgeons are left understandably vying for that time in order to serve the best interests of patients within their waitlist or division, which does not always amount to what is in the best interests of the population of surgical patients, taken as a whole (1).

Given the ethically challenging nature of prioritization decisions and the potential conflict of interests they pose for individual surgeons tasked with making these decisions, developing ethics support is necessary. In what follows, we outline the development process of one such ethics framework. The framework described here includes specific supports for prioritization based on and justified by the ethics principles identified included in the framework and is specific to one such crucial context: paediatric surgical prioritization.

FRAMEWORK DEVELOPMENT

In response to the plan to reinstate surgical services in the summer of 2020, The Hospital for Sick Children Toronto created what is now called the Surgical Backlog Initiative; it consists of multiple branches, including data modeling, communication, and an ethics working group. The ethics working group is comprised of surgeons from two different surgical subspecialties, an anesthesiologist, an intensive care physician and a bioethics associate who serves as the team lead, a hospital bioethicist, an academic bioethics researcher and a parent advisor, all of whom contributed to the development of the ethics framework, and each of whom collaborated in the authorship of this manuscript. The purpose of the ethics framework was to provide clinically and ethically informed recommendations for surgical prioritization, both in the context of individual waitlist management, and for interdivisional and systems level resource allocation. This framework was developed in response to early pandemic restrictions but is intended to function within ongoing and fluctuating levels of resource scarcity.

REFLECTIVE EQUILIBRIUM

The framework was developed in the following way. To start, the bioethics researcher completed a literature review, focusing on various provincial resource allocation guidelines within Canada, ethics frameworks for rationing critical care resources (14-16) and established bioethical literature on the ethics of resource allocation and rationing of scarce resources in general (17-

20). All members of the working group met virtually three times a week from May to July 2021, and the team lead and bioethics researcher met daily during this time. Following a widely accepted methodology in biomedical research (21), our group used a process of reflective equilibrium to develop the framework (22,23). Reflective equilibrium, as initially described by philosopher John Rawls (24), is a process by which we develop moral theories that involves working towards harmony – or equilibrium – between our considered judgments, principles, and intuitions. Because our purpose was not the development of a full-fledged moral theory, but rather to identify ways to implement already existing, justified, and accepted moral insights into a particular practical context, we included not just considered judgments and moral intuitions, but also the relevant contextual and logistical facts of the matter. These included prioritization practices already used by surgeons, family choice in surgical timing, the stated goals of our institution as we emerged from the pandemic (reduction of health inequities and promotion of health justice), and likely barriers to change (taking smaller, achievable steps, rather than proposing overhauls of long-standing systems of healthcare delivery). As the goal was for our framework be operationalizable, it was imperative to take seriously what was *possible* within our hospital.

There are two conceptual pieces of the ethics framework. The general piece is the collation of guiding ethics principles, and the more specific piece is a support for patient prioritization (SPP) that identifies factors for prioritization. The ethics principles were identified first in the process, following which the factors for prioritization were identified. The same material process was used to identify both the ethics principles and the factors for prioritization. First, multiple rounds of questionnaires were sent to each member of the working group to help isolate the key ethical issues involved in surgical prioritization and the most appropriate ethical principles relevant to the context of surgical prioritization. The responses to these questionnaires were returned to the project lead, anonymized, collated, and presented to the working group, where roundtable discussions followed. The same process was undertaken to identify the factors for prioritization, after the ethics principles had been decided upon. To ensure further stakeholder engagement throughout the framework development process, members of the Family Advisory Network (FAN) at our institution were consulted to provide additional perspectives and feedback to aspects of the framework. Those consulted were parents of children who received surgery at the hospital and who self-identified as members of marginalized groups. The conceptual ethics expertise within the working group, in conjunction with the clinical and personal expertise of the physicians and parent advisors, ensured a robust and inclusive process of reflective equilibrium. While we consider the framework complete, we also consider it a living document with a revision process built into the framework (e.g., in light of new evidence, different directives from the hospital).

ETHICS FRAMEWORK

Principles for Surgical Prioritization

The ethics principles identified by the working group can be distinguished into two types: procedural ethics principles, and substantive ethics principles. Procedural principles ensure that the processes used for priority setting are fair. Here, we draw on Norman Daniels and James Sabin's Accountability for Reasonableness (A4R) Framework (25) (Table 1).

Table 1: Procedural Ethics Principles

Principles	Definitions
Relevance	All pieces of the framework, and decisions made based on the framework, require substantial justification that reasonable people can agree to under similar circumstances.
Transparency	Prioritization decisions and justifications for those decisions ought to be made accessible and available to stakeholders.
Inclusivity	Stakeholders have been included in the development of the framework itself and continually involved in its implementation, in order that decisions supported by the framework will work better to effectively serve stakeholders.
Appeals	Decisions that are thought to be unfair can be appealed to either seek further justification, verification, or to change the decision.
Accountability	There should be a mechanism to ensure that principles are followed consistently and that all relevant actors are responsible throughout the framework's development and implementation.

Resource allocation and prioritization processes are inherently value laden endeavors, and while procedural principles are necessary, they are insufficient for determining direction of prioritization and resource allocation, or for achieving substantive justice in these processes, even if they are procedurally fair (20). To this end, the working group identified equity, nonmaleficence, beneficence, respect for autonomy, and utility as the substantive ethics principles appropriate to surgical prioritization (Table 2). Details regarding justification for why these principles were included, as well as explanation regarding how they are understood in the context of prioritization, are described in the next section.

Table 2: Substantive Ethics Principles

Principles	Definitions
Nonmaleficence	The prioritization of cases should result in the least amount of total avoidable harm. Nonmaleficence also specifies a clinical baseline below which each individual patient *must not* fall: once patients are booked for surgery, that surgery must be provided before the patient deteriorates to a point where the originally scheduled surgery is no longer beneficial.
Equity	Like cases should be treated alike unless relevant differences exist. Those differences should be identified and considered in prioritization wherever possible.
Autonomy	Although respect for autonomy will be limited in conditions where resources are limited, the prioritization should be consistent with and not violate respect for autonomy. Any justifiable limits to autonomy should be proportional to the limits on resources available, and patient autonomy ought to be respected wherever possible.
Beneficence	Prioritization should promote the best interests of each individual patient, inasmuch as this is possible given the extent of resource constraints.
Utility	Prioritization should efficiently use available resources. This maximizes benefit at a population level, where 'benefit' to the patient population is understood as achieving an appropriate balance of the above four principles: nonmaleficence, equity, beneficence, and respect for autonomy.

Support for Patient Prioritization

The ethics principles described above were then operationalized into a Support for Patient Prioritization (SPP), which identifies factors that are relevant in all surgical prioritization decisions (Table 3). Again, it was imperative that physicians who might use this part of the framework themselves were actively involved in its construction, as patient prioritization tools have less uptake and are generally less effective when they are not informed by clinical expertise (26). While these kinds of documents are called 'tools' or 'scores' in the literature, we do not use these label as they imply a validated quantifiable process that is fit for use in all cases. We call ours a 'support' because this is what it is meant to be: it identifies factors that were found to be medically and morally relevant and offers practical considerations for operationalizing them when prioritizing patients. By 'medically and morally relevant,' we mean that these are the factors that *should* be considered when making priority setting decisions. The support is designed to be complementary to how many surgeons already approach their waitlists, provide ethical justification for these practices, and to establish fairness insofar as patients are being evaluated on equivalent bases insofar as this is possible.

Table 3: Support for Patient Prioritization (SPP)

Factors for Consideration	Ethical Justification	Decreasing Priority				Increasing Priority
Risk of Disease Progression with Delay	Nonmaleficence	Can wait 16 weeks	12 weeks	8 weeks	6 weeks	4 weeks
Sequential and Time Sensitive Surgery	Nonmaleficence	Not Started	Not started, time sensitive	Started	At completion stage	Started and very time sensitive
Pain	Nonmaleficence	Intermittent, Mild	Constant, Mild	Moderate	Intermittent, Severe	Constant, Severe
Percentage out of Window	Nonmaleficence	0-25%	26-50%	51-100%	100-200%	201% +
Quality of Life Improvements	Nonmaleficence	Mild	Mild	Moderate Impact, any improvement	Significant impact, limited improvement	Significant impact, significant improvement
Relational Impacts	Nonmaleficence, Equity		Some impact, improved with support	Moderate impact, recurrent	Moderate impact, persistent	Significant impact
Health Inequity	Equity	Yes	AND can be ameliorated with social support	AND delayed presentation	AND delayed presentation with higher disease progression	AND significantly delayed presentation, with complications

USING THE SPP IN RELATION TO P-CATS

Importantly, the SPP is meant to be used once a patient's clinical urgency has been decided. Our framework recommends using the clinical tool appropriate to the institution to assess urgency. At our institution, the tool used to assess the degree of urgency and set baseline wait times for patients is the Paediatric Canadian Access Targets for Surgery (P-CATS; 7) (Table 4).

Table 4: Paediatric Canadian Access Targets for Surgery (P-CATS)

Priority Classification Level	Target Time for Surgery
Priority 1	Within 24 Hours
Priority 2a	Within 1 Week
Priority 2b	Within 3 Weeks
Priority 3	Within 6 Months
Priority 4	Within 3 Months
Priority 5	Within 6 Months
Priority 6	Within 12 Months

While the P-CATS is an excellent tool for assessments of diagnosis-specific urgency, it leaves several questions unanswered. For example, while two patients with the same condition can share the same P-CATS score, they might have radically different pain profiles. The P-CATS score alone will not differentiate between them based on their pain profile. Comparing different surgical conditions, a perianal fistula (General Surgery), craniosynostosis (Neurosurgery), strabismus (Ophthalmology), and laryngomalacia (ENT) all share the same P-CATS classification, but the consequences of delay for each condition vary widely. The P-CATS score alone does not dictate how to allocate resources between surgical divisions. P-CATS also does not account for surgeries that are part of a time-sensitive sequence, where the optimal timing for a surgical procedure depends not on the P-CATS score, but on the timing of a previous or upcoming surgery. Factors like pain, time-sensitive procedures, and risks of delay are included in the SPP for this reason: they are factors that are currently used by many practitioners to differentiate cases in the ways described above, and so they should be systematically factored into surgical prioritization practices.

The SPP is not intended to function as a rigid algorithm or score, nor to displace surgeons as decision-makers regarding their own waitlists. Our research suggested that supports such as the one we propose are less effective when they are designed for use without involvement from clinical stakeholders and practitioners. Further, when these supports are even *perceived* as overly rigid and inflexible, there is lower uptake, specifically among surgeons (26). Surgeons are best placed to know their capacity to operate and balance their caseloads, as well as the logistical parameters in which to exercise their operating time. However, research suggests that supports for prioritization are likely to provide higher levels of transparency and equity for patients, increase consistency regarding clinical conceptions of patient need, and they have the potential to alleviate moral distress (26). With these considerations in mind, we involved and engaged surgical stakeholders in developing the SPP and designed it to be flexible.

EXPLORING THE SUBSTANTIVE ETHICS PRINCIPLES

Equity

Early in the deliberative process, equity emerged as a substantive ethics principle, the inclusion of which maintained support throughout the framework development process. Equity was one of the stated goals of our institution and achieving equity has long been recognized as a key objective in resource allocation and prioritization ethics. There is growing support for the idea that healthcare systems have positive obligations to not just deliver healthcare equally, but to actively promote health *equity,* both domestically (27-30) and globally (31,32). The responsibility to work towards equity by identifying, addressing, and actively combating health inequities now within the healthcare system became undeniably clear over the course of 2020 and 2021 (32-36).

Functionally, promoting health equity entails identifying and reducing health *in*equities, which are inequalities, discrepancies, or differences in individual and population health that are avoidable, unnecessary, and unjust (37,38). Leaders in global health have gone as far as to define health equity in terms of health *in*equity. That is, health *equity* is understood as the "the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically." (39) Health inequities matter medically because of their impact on patient health, and they matter ethically insofar as the discrepancy in health state is caused in significant part by systemic injustices such as, but not limited to, racism (40), poverty, colonialism, and sexism (41).

In the context of prioritization, we analysed achieving equity as a matter of following two procedural maxims. First, patients who are alike in relevant categories of need ought to be treated alike (42). Second, differences between patients and across patient populations that we have widely agreed should *not* impact a patient's access to healthcare – such as geographic location, income, race and ethnicity – should not factor into prioritization decisions, either explicitly or implicitly.

The working group thus endeavoured to identify medically and morally relevant categories of patient need: that is, factors that should be included when making prioritization decisions. Clinical urgency was identified as the first relevant factor in surgical prioritization. Not only is this supported by the principle of nonmaleficence, but it is also uncontroversial; the consequences of not granting *prima facie* priority to urgent medical need over those who can wait without the risk of losing life and limb are widely considered to be ethically inexcusable.

At this point, the next step is determining which factors should be considered when prioritizing among cases that are equivalent with respect to clinical urgency. Again, at our institution, this occurs when patients in the same disease category have the same P-CATS score. It is worth noting that we considered and rejected two common approaches that are often used at this step of prioritization: *randomization* and *first-come / first-served* approaches. Both approaches are embraced for being practically straightforward and are acclaimed for achieving equality insofar as they treat all people the same. Our working group rejected both approaches because they fail when held to a standard of equity. People should not be treated as though they were the 'same'. With respect to their health status, they are not the same, and a commitment to equity requires that relevant differences, such as systemic disadvantage in the form of health inequities, are identified and addressed. Not only does neither approach contain a mechanism for doing this, but first-come / first-served is widely known to functionally reinforce existing socioeconomic and health inequities (20). This fails the second procedural maxim of equity, insofar as first-come / first-served approaches have been shown to allow factors such as wealth, status, and connection – which are often proxies for race – to influence the order of priority (20).

Instead, we developed the Support for Patient Prioritization (detailed above). The SPP identifies factors that should be considered once clinical urgency has been determined and surgeons are prioritizing patients who have comparable medical need and could all safely wait the same amount of time for surgical intervention. Again, these factors are the risk of disease progression with delay, whether an intervention is part of time-sensitive or sequential procedures, pain, time spent on waitlist, quality of life, relational consequences for family, and whether there is health inequity. The overarching argument in including normative factors such as relational consequences and health inequities is to operationalize the idea that disadvantaged populations should be given priority to offset, to whatever degree possible, the effects of that disadvantage on their health state. The entirety of the SPP is jointly justified by the principles of equity, nonmaleficence, beneficence, respect for autonomy, and utility, although several of the factors included in the SPP are further and specifically justified by particular ethics principles, as shown on the second column in Table 3.

Nonmaleficence & Beneficence

Proceeding with an equity lens, considerations of nonmaleficence and beneficence are structured in relation to the degree of resource constraint. For the purposes of surgical prioritization, nonmaleficence means ensuring that resource allocation and patient prioritization does the least amount of avoidable harm across the surgical waitlist. Beneficence, on the other hand, means allocating resources and prioritizing according to the best interests of patients over and above the threshold of avoiding harm. When resource constraint is high, nonmaleficence takes priority as the dominant ethical principle. On the other hand, when resource constraint is lower, allocating resources and priority decisions that are grounded by appeal to beneficence (such as allocated time to pursue surgical innovation), are justifiable.

Respect for Autonomy & Utility

Respect for autonomy is reflected primarily in the patient-centric focus of our ethics framework. Though stipulating that care must be patient-centred may seem obvious, healthcare delivery is often influenced by institutional, administrative, and logistical factors that can conflict with allocating resources in a way that maximizes patient wellbeing. There are many aspects of healthcare delivery in which the extent to which care is patient-centred can be improved (11,12,43).

Finally, utility, which in principle requires that we maximize benefit and minimize costs or harm, was found to be important for prioritization. Of course, asserting this principle requires further specification about which type of benefit we are seeking to maximize, and which type of costs or harms we are seeking to minimize. For example, according to the QALY system, 'benefit' and 'harm' are understood in terms of a unit of measurement: the quality adjusted life year (QALY) (44). However, research suggests that using QALYs as the *sole* metric for evaluating benefit and harm, and in absence of other balancing principles (such as equity), carries the consequence of exacerbating and creating health inequities (45), as is the case with adopting first-come / first-served approaches. This is true particularly when the QALY cost-effectiveness analysis is used to select against allocating resources for patients that have more complex needs, and who would therefore require a higher cost-per-QALY saved (45,46). Proceeding with a health equity lens shows us that a person's quality of life, likelihood of benefit, and life expectancy are not neutral factors – they are proxies for social inequity. Therefore, while the working group found that utility was important, it is best understood as an instrumental principle in conjunction with other substantive principles, rather than functioning as the sole normative objective. That is, maximizing the 'good' or 'benefit' is interpreted in the ethics framework to mean prioritizing and allocating resources so that they achieve the other four substantive principles: minimizing avoidable harm, remaining patient-centred, acting with the best interests of patients in mind, and with the aim to achieve equity in prioritization.

The approach in our framework to operationalizing these ethics principles is fundamentally outcome oriented. By this we mean both physiological outcomes (e.g., we meet the principle of nonmaleficence if our prioritization results in the least avoidable harm to the patient population) *and* ethical outcomes (e.g., we meet the principle of equity if our prioritization does not exacerbate health inequities further). The goals of this framework are also meant to be realistic and modest. We do not assume that having an ethics framework alone will be enough to solve the surgical backlog problem. In light of protracted resource constraints and the current lack of sufficient material resources, such as funding and personnel, it will not be possible to clear the backlog at a more rapid pace. However, an ethics framework can help to improve consistency, transparency, identify areas for improvement of prioritization processes, and ideally reduce harm to patients in the process. Several examples of how the principles and the SPP in our framework function are given below.

- *Impact to Family that Impacts the Child Factor*: A surgeon has a case where two patients can each wait six months for a surgery. Family A is a single-parent household, they live fourteen hours away from Toronto, need to rent or borrow a car, and will need to pay for accommodations while staying in the city, and have difficulty taking time off work multiple times throughout the year. Family B is a two-parent household, they live downtown and are financially secure, one parent works part-time and has little to no difficulty taking time off. When scheduling, the framework supports prioritizing additional effort in collaborating with Family A in timing of the surgery. This is a consideration that cannot be given to everybody but is less necessary for families who are financially, geographically, and logistically able to be more flexible.

- *Time Out of Window Factor*: A surgeon has a case where there are two patients, the first is P-CATS 5: they could wait for six months and have only waited for five. The second patient is P-CATS 6: they should be waiting for only one year but have waited for two and a half. Our framework recommends prioritizing the second case, *even though* their P-CATS score indicates lower urgency, therefore reflecting lower priority.

- *Health Inequity & Quality of Life (QOL) Factors*: There are two patients, both of whom suffer from the same condition, and are P-CATS 6. Patient 2 has been living with the condition for longer and was diagnosed late due to an inability to access healthcare services. Late diagnosis often means patients present with higher urgency, but this is not the case for this patient. Patient 2, however, suffers significant QOL costs as reported by them, which are compounded by their socioeconomic disadvantage. Our framework recommends that, other things being equal, the presence of health inequities and quality of life costs (both of which affect each other), priority in timing be given to Patient 2.

Importantly, the framework does *not* stipulate that an elective patient with, for example, extreme QOL costs and health inequities, be prioritized over a more urgent patient in such a way that the urgent patient does not receive needed surgery. This would fail the principle of nonmaleficence and is why clinical urgency is the first factor for consideration that our framework recommends. These recommendations for approaching prioritization are meant to direct attention to details about patient experience that are relevant but might be overlooked with a 'strictly medical' focus or a attention only to clinical urgency. In so doing, the framework aims to address several of what we earlier called the 'normative' dimensions of prioritization. What these examples should also show is that there are and will be overlaps between many factors listed on the SPP. Disease progression is likely to correlate with either increased pain or decreased quality of life (sometimes both), families who suffer health inequities are more likely to be those who experience higher relational consequences in terms of stress or financial loss, and are likely to reside in geographic locations that make travel difficult, etc., in the event of a health crisis. Given the fact that the negative effects and burdens of these factors for families are themselves cumulative, we consider this overlap appropriate.

LIMITATIONS

There are aspects of the framework and the support for patient prioritization tool (SPP) that need further validation, notably how to assess quality of life from the patient's or family's perspective so as not to perpetuate systemic bias. And although we take the inclusion of health inequity to be the strongest conceptual insight and practical goal of our framework, the logistical matter of sorting out how to identify and address health inequities so that we do not further perpetuate harm when determining priority requires further study, collaboration, and implementation. Clearly, setting out to address health inequity at the point of surgical prioritization is a small step to addressing a much larger problem. Improvements in prioritization cannot retroactively solve systemic propagation of health inequities that patients might have experienced up until the point of surgical intervention. There are limits when attempting to address health inequity at such a late stage of a patient's treatment trajectory. That being said, we think that attention to health equity in any domain provides a starting point to redressing health inequities in general, and a potential nidus for this kind of work in contexts beyond surgical prioritization.

Another limitation is that, at an institutional level, more work is needed to understand how to balance and arbitrate between seemingly incommensurate claims to medical need between different surgical divisions, all contending for limited operative time. Finally, the framework was designed for implementation at The Hospital for Sick Children, Toronto, which is a tertiary referral children's hospital, that functions within a single tier public health care system that provides access to medically necessary treatment. Like all supports for patient prioritization, the one presented here is tailored for use in a particular context. Nonetheless, we expect the ethical insights of the framework, particularly the focus on operationalizing the principle of equity, to be generalizable to non-paediatric centres and adaptable in similar referral centres that are likewise encumbered with waitlists in need of management.

CONCLUSION

While there is widespread consensus that when allocating critical care resources, these decisions should be ethics-driven, formal ethics guidance for prioritization decisions in moderate scarcity is rarely provided – this is a mistake. Individuals tasked with surgical prioritization decisions are being functionally charged with the determining a distribution of 'normal' health care services. The backlog of these services in the wake of the pandemic has brought into sharp focus that these decisions are not just determinations of urgency, they are rationing decisions. As a response, in this paper, we presented the process we undertook to develop an ethics framework that provides recommendations for prioritization of paediatric surgeries, and which is grounded in the practical realities of our hospital operations. The goal was to provide consistency, ethical justification, and

much needed support for decisions that would otherwise fall on the shoulders of individuals. With institutional and bioethics support, the burden for those choices can be shared, and moral distress mitigated. While questions about resource allocation and patient prioritization were incited by pandemic scarcity, how to allocate resources and prioritize patients in varying conditions of scarcity have persisted past the surgical shutdowns of 2020 and 2021. The longstanding pattern of failing to engage with these questions past the point of acute crisis and allowing prioritization processes to get lost in the impenetrability of bureaucracy, must change (11,12).

Reçu/Received: 17/12/2021
Publié/Published: 27/06/2023

Remerciements
Nous souhaitons remercier les conseillers familiaux de Sick Kids qui ont contribué à ce travail au-delà de l'équipe de référence qui a développé le cadre, ainsi que les directeurs Karen Kinnear et James Drake pour le soutien qu'ils ont apporté à ce projet.

Acknowledgements
We wish to acknowledge the additional family advisors from Sick Kids who contributed to this work beyond the core team developing the framework, as well as acknowledge executives Karen Kinnear and James Drake for their support of this project.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Renata Iskander & Aliya Affdal

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

C Bommier, L Simon. *Can J Bioeth / Rev Can Bioeth.* 2023;6(2):20-35

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Typologie et fonctionnement des espaces de discussion éthique en France dans le domaine de la Santé

Côme Bommier[a,b,c], Laura Simon[a,d]

Résumé

Introduction : L'éthique médicale pose la question du sens des pratiques médicales à la lumière des sciences humaines. En France, les espaces de discussion éthique (EDE) sont multiples et hétérogènes. L'objectif de ce travail était d'étudier la typologie et le fonctionnement des EDE dans le domaine de la santé. **Méthodes :** Vingt-et-un entretiens semi-dirigés ont été menés auprès de membres de onze EDE différents en France. Les données ont été analysées selon les étapes de base d'une recherche qualitative : codage, catégorisation, mise en relation et présentation des résultats. **Résultats :** Les cinq catégories d'EDE (Comité consultatif national d'éthique, Espaces de réflexion éthique régionaux, Commission éthique des sociétés savantes médicales, Comités éthiques d'institut de recherche, Comités éthiques hospitaliers) diffèrent toutes de par leurs liens avec les institutions, leurs compositions, leurs choix de thèmes discutés et la restitution de leur travail. Cependant, toutes concordent sur les points suivants : l'importance de la pluridisciplinarité, la fréquence des réunions de travail, le sens de l'engagement éthique, l'absence de reconnaissance professionnelle, la difficile valorisation des travaux et le manque de reconnaissance par les pairs. Les répondants regrettent une insuffisante articulation entre les différents EDE, bien que leurs travaux puissent être complémentaires. **Conclusion :** Décloisonner les EDE et favoriser leur articulation, sans les éloigner de la pratique de soin, pourrait favoriser la visibilité de leur démarche éthique dans le quotidien des soignants. Enfin, si la réflexion éthique est encouragée par l'ensemble de la communauté scientifique, une plus grande valorisation est souhaitée par les professionnels qui participent à des recherches en éthique appliquée.

Mots-clés

éthique, comité, commission, discussion, typologie, recherche qualitative, France

Abstract

Introduction: Medical ethics raises the question of the meaning of medical practices in light of the humanities. In France, the spaces for ethical discussion (SED) are multiple and heterogeneous. The objective of this study was to investigate the typology and functioning of SEDs in the health field. **Methods:** Twenty-one semi-structured interviews were conducted with members of eleven different SEDs in France. The data were analyzed according to the basic steps of qualitative research: coding, categorization, linking and presentation of results. **Results:** The five categories of SEDs (National Consultative Ethics Committee, Regional Ethical Reflection Spaces, Ethics Commissions of Medical Learned Societies, Research Institute Ethics Committees, Hospital Ethics Committees) all differ in their links with institutions, their composition, their choice of themes discussed and the presentation of their work. However, they all agree on the following points: the importance of multi-disciplinarity, the frequency of working meetings, the sense of ethical commitment, the absence of professional recognition, the difficulty of valorizing work and the lack of recognition by peers. The respondents regret that there is insufficient coordination between the different SEDs, although their work may be complementary. **Conclusion:** Opening up the SEDs and encouraging their articulation, without distancing them from the practice of care, could promote the visibility of their ethical approach in the daily lives of caregivers. Finally, if ethical reflection is encouraged by the scientific community as a whole, greater recognition is desired by professionals who participate in applied ethics research.

Keywords

ethics, committee, commission, discussion, typology, qualitative research, France

Affiliations

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INTRODUCTION

Le questionnement éthique naît des pratiques, qu'elle interroge et met en perspective grâce à l'apport des sciences humaines (1). Selon l'Agence Nationale pour l'Amélioration des Conditions de Travail (ANACT), « les espaces de discussion sont des espaces collectifs qui permettent une discussion centrée sur l'expérience de travail et ses enjeux, les règles de métier, le sens de l'activité, les ressources, les contraintes » (2). Un espace de discussion éthique (EDE) dans le monde du soin est donc un espace où l'on identifie et discute des tensions éthiques en rapport à la relation de soin ; cette définition exclut les comités d'éthique de la recherche. Des désignations diverses sont couramment utilisées en France pour désigner un EDE, qu'il soit local, régional ou national : « comité hospitalier du centre hospitalier d'Avignon », « Groupe de réflexion éthique de l'hôpital Foch », « espace éthique régional », « comité éthique de la société française d'anesthésie-réanimation (SFAR) », « commission éthique de la société française d'hématologie (SFH) », « comité consultatif national d'éthique (CCNE) ».

Historiquement, bien qu'elle naquît dès l'écriture du Serment d'Hippocrate (4ème siècle avant notre ère), l'éthique médicale s'est formalisée en France au XX° siècle avec l'arrêt Mercier (1936) puis au décours des expérimentations nazies sanctionnées par le procès de Nuremberg (1946). Éthique clinique (3) et éthique en recherche se sont construites tout en s'interpellant.

ISSN 2561-4665

Dans le cadre de la recherche, il fallut plus de deux décennies après la déclaration d'Helsinski (4) pour que naissent les comités consultatifs de protection des personnes dans la recherche biomédicale (CCPPRB, loi Huriet-Sérusclat, 1988) (5), qui furent ensuite remplacés par les Comités de Protection des Personnes (CPP) (6). Les organismes de recherche, tels le CNRS (1994) et l'INSERM (2000), créent aussi leur propre EDE où il s'agit de conduire et développer la réflexion sur les aspects éthiques associés aux pratiques de la recherche. Au niveau universitaire, la Société française et francophone d'éthique médicale (SFFEM) et l'Institut international de recherche en éthique biomédicale (IIREB) sont fondés en 2000, associant éthique des pratiques et éthique en recherche. Au niveau hospitalier, des comités locaux se créent progressivement, servant à la fois de comité d'éthique de la recherche (*Institutional Review Board* aux États-Unis) et d'espace de réflexion autour du soin, mais il faut attendre 2002 pour que le législateur impose désormais l'organisation d'une réflexion éthique au sein de chaque établissement de santé (6). Par exemple, en s'inspirant du modèle états-unien, des soignants créent un centre d'éthique clinique (Hôpital Cochin, Paris) dont la vocation est de « fournir une aide à la décision médicale dans des cas de situations éthiquement difficiles » (7). Dans le même temps, certaines sociétés savantes (ex. : réanimation médicale et anesthésie, hématologie, gynécologie-obstétrique) cherchent à traiter des problématiques qui leur sont spécifiques.

À partir de 1983, date de la création du CCNE, les questions bioéthiques deviennent des enjeux nationaux. Le CCNE est chargé de donner des avis sur les « problèmes moraux soulevés par la recherche dans les domaines de la biologie, de la médecine et de la santé » (8). En 2004, la loi instaurant les Espaces de Réflexion Éthique Régionaux (ERER) est votée (un espace francilien existait déjà depuis 1995) (9); ils constituent, en lien direct avec des centres hospitaliers universitaires (CHU), des lieux de formation, de documentation, de rencontre et d'échanges pluridisciplinaires sur les questions d'éthique dans le domaine de la santé. Ils font également fonction d'observatoires régionaux ou interrégionaux des pratiques au regard de l'éthique. Ces espaces participent à l'organisation de débats publics afin de « promouvoir l'information et la consultation des citoyens sur les questions de bioéthique » (10).

À l'international, il a été démontré une hétérogénéité significative de la taille des comités d'éthique, des exigences en matière d'adhésion et de formation, de la durée du mandat de leurs membres, de leurs rôles cliniques et politiques, du soutien institutionnel reçu, ainsi qu'une hétérogénéité dans les avis qui sont donnés (11-14). Ainsi, au fil du temps, une plus grande diversité professionnelle a été observée (15,16). Quant à la question du type de recours faits aux EDE hospitaliers françaises, il est davantage associé au profil des personnes qui effectuent les saisines, plutôt qu'à celui des membres qui les composent (17-19). À titre d'illustration, lorsque des EDE mettent en place des consultations spécialisées en réanimation, les tensions éthiques concernent très souvent la question du juste traitement – notamment lorsqu'il s'agit des thérapeutiques invasives (19). Plus récemment, les EDE se sont aussi saisis des problèmes d'éthique organisationnelle, dans le but de promouvoir la qualité de vie au travail et de limiter le nombre de syndromes d'épuisement professionnel (20-23).

L'objectif de notre travail qualitatif était d'étudier la typologie et le fonctionnement des EDE dans le domaine de la santé en France.

MÉTHODES

Entre novembre 2020 et juin 2021, un échantillonnage de convenance ayant la diversité pour objectif permit d'identifier dix-huit espaces de discussion éthique qui ont été contactés par courriel, en leur explicitant l'objectif de l'enquête. Nous avons arrêté les sollicitations en l'absence de réponse après trois invitations. Onze d'entre eux ont accepté de participer à l'étude, à savoir :

- le Conseil consultatif national d'éthique (CCNE) ;
- quatre sociétés savantes de spécialités – Société Française d'Hématologie (SFH), Société de Réanimation en Langue Française (SRLF), Société Française d'Anesthésie-Réanimation (SFAR), Collège National des Gynécologues et Obstétriciens Français (CNGOF) ;
- deux espaces de réflexion éthique régionaux – Île-de-France et Nord ;
- deux comités d'éthique hospitaliers – Hôpital Foch (Suresnes) et CH d'Avignon ;
- un centre d'éthique clinique – Hôpital Cochin (Paris) ;
- une commission d'éthique d'un institut de recherche – Institut national du Cancer (INCA).

Nous nous sommes entretenus avec deux membres de chaque EDE. Lorsque plus de deux membres d'un même EDE s'étaient portés volontaires, la priorité était donnée à une paire de répondants pluridisciplinaire : médecin et non-médecin (ex. : philosophe, sociologue, aumônier, ethnologue, infirmier). Vingt-et-un entretiens semi-dirigés ont été menés. Les réponses ont été pseudonymisées. Les entretiens ont été réalisés par visioconférence ou par téléphone en raison des confinements liés à la COVID-19. Chaque entretien a duré entre 45 minutes et 1h15.

Au préalable, une grille d'entretien avait été élaborée à partir de la littérature sur les espaces de discussion (2) afin d'orienter les échanges sur la typologie et le fonctionnement de chaque EDE. Les propos des répondants étaient retranscrits en temps réel par l'interrogateur (CB) au sein de la grille, qui était accompagnée d'un mémo pour mémoriser les thèmes soulevés. Après les deux premiers entretiens, la grille d'analyse a été ajustée de manière à ce que les échanges soient les plus adaptés aux EDE. Les entretiens n'ont pas été enregistrés (voir ***Discussion***).

Les auteurs (CB et LS) ont commencé l'analyse par une étape de codage (transformation des données brutes de transcription en termes concis et aisément repérables), avant de poursuivre par une étape de catégorisation (définition des catégories permettant de regrouper les codes identiques sous un titre générique). Lorsque les catégories obtenues différaient, une

discussion commune permettait de trouver un consensus sur le choix des catégories identifiées – cette étape a permis de développer des thèmes et sous-thèmes. Enfin, un travail de reconstruction a permis la hiérarchisation des concepts soulevés, associé à des allers-retours avec des éléments de bibliographie (24). Pour favoriser le contexte d'énonciation de chacun des intervenants et la compréhension du discours par le lecteur, nous citerons des extraits d'entretiens afin d'illustrer les thématiques abordées, auxquels nous associerons une catégorie professionnelle ne levant pas le pseudonymat (médecin, non-médecin).

L'étude a reçu un avis favorable du comité éthique de la recherche de l'Hôpital Foch, Suresnes, France (IRB00012437, numéro : 20-10-28).

RÉSULTATS

Parmi les 21 entretiens, celui réalisé avec le membre de la commission éthique du CNGOF a été exclu avant exploitation des résultats, car ce dernier a signalé que leur commission n'a pour mission que d'évaluer les protocoles de recherche sur des données et non de traiter de questions éthiques.

Comparatif des différents EDE

La première partie de chaque entretien abordait les questions d'ordre organisationnel et n'était donc pas sujet à interprétation. Les principales caractéristiques en rapport sont synthétisées dans le Tableau 1.

Tableau 1 : Grandes caractéristiques des espaces de discussion éthique étudiés

	CCNE	**Espaces régionaux**	**Sociétés savantes**	**Institut de recherche**	**Comités hospitaliers**
Création	Décret 1983	Loi 2004 ; Décret 2012	À partir de 1980	CNRS 1994 Inserm 2011 INCA 2018	Loi 2002
Institutions impliquées	Instituts de recherche, Président de la République, ministères	Hôpital, Université, Instituts de recherche, ARS, établissements médico-sociaux	Société savante	Institut de recherche	Hôpital
Nombre et statut des membres	3 indemnisés + 39 bénévoles	5-8 salariés + 30 bénévoles	12-15 bénévoles	7 bénévoles	2-6 salariés + 30 bénévoles
Recrutement	Personnalités reconnues dans leur discipline	Personnalités reconnues dans leur discipline	Candidatures spontanées (tout âge)	Aura dans le domaine de l'éthique	Candidatures spontanées (tout âge)
Pluridisciplinarité	Grande	Grande	Moyenne	Moyenne	Grande
Présence de patients	Oui	Oui	Non	Oui	Oui
Durée des mandats	4 ans, renouvelable	3 ans, renouvelable	3-4 ans, renouvelable	Indéterminée	3-5 ans, renouvelable
Matérialité des réunions					
Fréquence	1/mois (plénière)	1/sem à 1/mois	1/1-2 mois	1/3mois (plénière)	1/2mois, sauf CEC: 1/sem
Durée	4h	2h	3-6h	6h	2h
Absentéisme	<20%	50% (bénévoles)	<20%	Non	50% (bénévoles)
Choix des thèmes abordés					
Saisine	Président de la République, de l'Assemblée Nationale ou du Sénat	Conseil d'orientation	Conseil d'administration (rare)	Conseil d'administration	Soignants de l'hôpital
Autosaisine	Oui	Variable	Oui	Oui	Oui
Spectre	Technologie et Santé	Politique et Santé	Thématique de spécialité	Recherche et Information du public	Tout ce qui se vit à l'hôpital
Articulation avec d'autres espaces éthique	Espaces régionaux	Autres espaces régionaux, CCNE	Autres sociétés savantes (proximité thématique)	Rare	Rare (avec espace régional)
Restitution des travaux					
Écrite	Rapport + Avis	Rapport annuel	Articles scientifiques	Avis biannuels	Rapport, Journal hospitalier, Articles scientifiques
Orale	Presse généraliste	Colloques, webinaires	Congrès	Non	Colloques

Tous les EDE sont mandatés pour entretenir une réflexion éthique, que ce soit au sein d'un établissement ou d'une région. Certains d'entre eux ont même le devoir de rendre des rapports ou avis dans un temps donné (CCNE, Espaces régionaux, INCA, comités locaux). Dans le cadre des sociétés savantes, les objectifs de travaux correspondent à des restitutions en congrès et à la publication d'articles à intervalles réguliers.

> « Avoir des objectifs de publication permet de justifier la fréquence de nos réunions et de nous engager à produire une réflexion sans trop tourner en rond. » [médecin]

Bien que tous les répondants affirment entretenir une liberté de ton vis-à-vis des institutions qui les mandatent, les liens ténus qu'ils entretiennent avec elles sont déterminants. Dans les comités hospitaliers, il existe des places statutaires pour des membres de la direction. Dans le cas de l'institut de recherche, le directeur de l'institution participe régulièrement aux réunions. Certains EDE des sociétés savantes ont parmi leurs membres des élus du conseil d'administration, alors que d'autres ne solliciteront qu'occasionnellement leur participation. Au sein des espaces régionaux, les institutions (universités, centres hospitalo-universitaires) participent activement au conseil d'orientation et certains membres de l'EDE peuvent avoir une position universitaire. De manière intéressante, alors que le CCNE est l'EDE le plus sujet aux controverses politiques (ex. : mandat national sur la question de l'aide active à mourir, exposition médiatique lors de la publication de l'avis n°139 « Questions éthiques relatives aux situations de fin de vie », sur la base duquel s'est lancé un débat national (25)), il est le seul EDE dont les statuts garantissent une réelle indépendance vis-à-vis des institutions (Président de la République, ministères, Instituts de recherche).

Dans les faits, les Espaces de Réflexion Éthique Régionaux (ERER) se réunissent une fois par an lors de la Conférence nationale des ERER et travaillent conjointement avec le CCNE. Ils lui remettent un rapport annuel et ont servi de « caisse de résonnance » citoyenne lors des États Généraux de la Bioéthique en 2017. À l'inverse, sauf en de rares exceptions, les EDE des sociétés savantes, de l'institut de recherche ou des hôpitaux n'articulent pas leurs travaux avec d'autres EDE.

Tous les EDE bénéficient de locaux dans lesquels ils peuvent se réunir à titre gracieux et d'un espace de restitution de leurs travaux (congrès, colloques, revues locales ou nationales). Cela dit, les sociétés savantes et l'institut de recherche ne prévoyaient aucun financement pour le développement d'une recherche universitaire dédiée. Malgré ces limitations, tous les interviewés mentionnent l'intérêt de ces réunions de par la pluridisciplinarité qui existe au sein des EDE.

> « La pluridisciplinarité permet d'ouvrir les horizons sur des situations particulières. » [non-médecin]

> « La pluridisciplinarité interne s'enrichit grâce aux avis extérieurs lors des groupes de travail » [non-médecin]

> « La constitution du groupe est plurielle, avec à la fois des gens qui interviennent au nom d'une association ou d'une institution, et à la fois des professionnels indépendants » [non-médecin]

Celle-ci peut être contrainte par le nombre de membres (7 membres dans le plus petit EDE), par la difficulté à trouver des collègues universitaires non-soignants au sein des sociétés savantes, ou par l'absentéisme. En effet, bien que les réunions soient programmées, la présence des membres n'est pas garantie.

> « Les médecins doivent prendre sur leur temps soignant et les paramédicaux sur leurs journées de repos ». [médecin]

> « L'enrichissement n'est pas reconnu par la hiérarchie administrative : les paramédicaux doivent poser des congés pour venir en commission! » [médecin]

Enfin, elle peut être aussi contrainte par l'absence de représentants de patients, qui sont recherchés par la majorité des EDE sauf au niveau des sociétés savantes.

> « C'est un choix politique que de ne pas inclure de patient, car il s'agit d'une commission de société savante » [médecin]

> « Les médecins présents sont des gens sensibilisés à l'avis des patients, et les profils non-médecins apportent un regard « patient et famille » : ce regard est en fait le premier item débattu, car c'est le plus important! » [non-médecin]

Quant au spectre des sujets traités, ceux-ci sont de natures différentes selon les EDE : un comité local traite de situations cliniques ou de problèmes intrahospitalières, un institut de recherche soulève les enjeux éthiques liés à la recherche fondamentale, une société savante ceux liés à la recherche clinique et à la relation médecin-patient dans une spécialité donnée, un espace régional aborde des enjeux politiques qui font se rencontrer le monde de la santé et les citoyens (avec parfois des expérimentations de terrain et des projets citoyens), et enfin le CCNE traite des enjeux éthiques liés à une innovation technique dans la pratique médicale.

Analyse des thèmes abordés

La deuxième partie des entretiens s'intéressait au regard subjectif de chaque répondant sur son espace de discussion éthique dont il est membre. En reprenant leurs propos, nous avons dégagé plusieurs thématiques : la place des espaces de discussion éthique, la portée des travaux et réflexions, la question du temps, et la solitude académique.

Concernant **la place des EDE** dans leur environnement institutionnel, cela dépend de leur fondement académique ou hospitalier. L'ensemble des répondants a souligné la nécessité de ces EDE, leur raison d'être.

> « On ne peut plus ne pas s'interroger! Verbaliser stimule la réflexion. » [médecin]

D'après nos entretiens, ces EDE sont des lieux de discussion délibérative (non de négociation ou de décision), où des propositions peuvent être élaborées dans le but d'améliorer les pratiques quotidiennes.

> « Les sujets du quotidien sont les sujets de fond. » [médecin]

> « Ce n'est pas un conseil d'administration ni un comité paritaire : les positions minoritaires sont aussi respectées et mises en avant. » [non-médecin]

Les répondants soulignent l'importance d'un dynamisme dans la composition de ces espaces, ceci pour faire discuter les générations autant que les spécialités. Cette pensée se développe en grande partie grâce à la pluridisciplinarité, celle alliant le regard du professionnel de terrain et le regard extérieur amené par des collaborateurs de différents horizons (philosophie, ethnologie, anthropologie, théologie, etc.) permettant un éclairage des situations problématiques traitées selon divers prismes. Cette pluridisciplinarité nécessite une vigilance afin que chacun se sente libre d'exprimer ses idées et qu'elles soient entendues, quelle que soit sa fonction ou sa position hiérarchique.

> « Le débat est très libre! » [non-médecin]

> « L'animateur doit veiller à faire parler en premier les personnes qui seraient gênées de donner un avis contradictoire après la prise de parole d'un supérieur. » [médecin]

En France, le soin étant soutenu par la solidarité nationale, ces EDE ont à la fois une place au sein de l'institution qui les fait exister, mais aussi au sein de la société en général. Les participants de notre étude ont souligné le manque de visibilité donnée à ces EDE par leur institution ou par les pairs n'y siégeant pas. La méconnaissance de ces EDE est en lien avec le flou qui peut exister autour de la notion d'éthique dans la population générale. Dans un but pédagogique, certains membres de ces EDE (siégeant parfois au sein de plusieurs EDE) ont recours aux prises de parole publiques (publications de livres, d'articles de presse, de tribunes, etc.).

> « Il y a toujours un travail de clarification à faire, car le terme « éthique » est utilisé trop largement dans le débat public. » [médecin]

> « On apporte du grain à moudre pour ceux qui sont déjà intéressés, mais on n'arrive pas à toucher ceux qui en auraient le plus besoin » [médecin]

> « Notre image n'est pas faite auprès des autres praticiens (d'où l'intérêt des articles) » [médecin]

Concernant **la portée des travaux et réflexions** menées en EDE, elle est généralement bien en deçà des attentes des participants. Il existe deux manières de reporter ces réflexions, soit par le biais d'avis auprès de professionnels ou d'institutions, soit par le biais de publications scientifiques. Dans le cas des avis, les répondants s'estiment trop peu sollicités par les cliniciens, malgré le caractère seulement consultatif de leur mission.

> « Les gens ne nous interpellent pas assez et quand ils viennent à des formations, d'un coup tout change. On a un esprit bottom-up. » [médecin]

Cependant, au niveau local, la proximité avec le terrain favorise le recours à l'espace de discussion éthique et l'implémentation d'outils d'aide à la décision. La restitution des travaux au niveau académique passe plus largement par des publications scientifiques qui valorisent le travail mené. Cependant, celles-ci touchent un public restreint et ne sont généralement pas lues par les cliniciens qui ne participent pas à l'espace de discussion éthique. Or, c'est justement cette population que les membres des EDE espèrent sensibiliser. Ainsi, pour tenter de donner un plus grand rayonnement à l'EDE, une figure d'autorité peut être privilégiée à la présidence et des formations mises en place par les espaces régionaux et comités locaux, destinés aux professionnels comme au grand public (séminaires, diplômes universitaires, etc.).

> « La restitution de l'échange devient l'objet de formation. » [médecin]

Enfin, les espaces éthiques régionaux et le CCNE bénéficient d'une large médiatisation qui participe à la diffusion de leurs travaux.

Concernant **la question du temps**, les répondants soulignent la nécessité d'un temps long pour élaborer une pensée éthique, ce qui est parfois incompatible avec l'impératif de rendre des avis ou de produire des réflexions dans un délai limité, surtout lorsqu'il est question d'actualité (ex. : gestion de la campagne vaccinale pendant la pandémie de COVID-19). Le CCNE a la particularité de devoir répondre dans un délai qui lui est prescrit, les espaces éthiques régionaux se voient fixer des délais par leur conseil d'orientation alors que les commissions de spécialités n'ont pour seule limite celle qu'elles se proposent. Quoi qu'il en soit, tous les répondants décrivent une distorsion de la perception du temps : la réactivité attendue par les solliciteurs se confronte au nécessaire temps d'une production de pensée éthique pluridisciplinaire face à des sujets complexes.

> « L'avis oblige au compromis et celui-ci est parfois frustrant quand le temps manque au dissensus vrai. » [non-médecin]

Enfin, la **notion de solitude académique** est décrite par l'ensemble des répondants comme l'inadéquation de leur engagement avec la reconnaissance limitée qu'ils en obtiennent sur le plan académique ou hospitalier. En effet, tous les académiques soulignent le manque de reconnaissance universitaire vis-à-vis de leur engagement, voire la défiance de leurs pairs.

> « Les praticiens non-universitaires sont plus sensibles à nos travaux que nos confrères universitaires. » [médecin]

> « On est presque des missionnaires! » [non-médecin]

Cependant, la motivation des répondants reste intacte chez ces personnes impliquées depuis de nombreuses années dans la réflexion éthique, que ce soit au niveau local comme au niveau académique ou institutionnel.

> « L'exercice de l'éthique n'est pas valorisé chez les médecins, car c'est le poil à gratter de la médecine. Mais moi je me sens plus médecin ici qu'ailleurs! » [médecin]

> « Pas de reconnaissance académique, mais une satisfaction du point de vue de l'utilité sociale. » [non-médecin]

Cette motivation se constate aussi dans la volonté de se réunir régulièrement malgré les contraintes organisationnelles et de publier leurs travaux.

> « Maintenir un rythme minimal est nécessaire pour faire avancer les travaux. » [médecin]

L'engagement dans le processus délibératif pluridisciplinaire que représentent ces EDE donne du sens aux pratiques cliniques, surtout quand il y a un véritable souci d'ancrage dans le réel. D'après les répondants, ne pas s'astreindre à ce processus délibératif reviendrait à recopier des idées préconçues et serait un leurre intellectuel.

> « La réflexion n'a de sens que si elle a le souci pratique. » [médecin]

> « Le rôle de l'animateur est justement de se méfier du consensus hâtif et de confronter la pluralité des perspectives pour travailler sur leurs frontières. » [non-médecin]

L'ensemble des réponses argumentées données par les répondants sont rapportées dans l'annexe 1.

DISCUSSION

L'étude qualitative que nous avons réalisée est à notre connaissance la première à décrire les EDE en France. Elle décrit un paysage des EDE, leurs modalités de fonctionnement, leurs méthodes de travail et les objectifs qu'ils se fixent. Nous considérons qu'une meilleure connaissance des objectifs et modalités organisationnelles de ces EDE peut contribuer à la reconnaissance de leur apport, favorisant ainsi l'investissement nécessaire à leur pérennisation et à leur dissémination.

Tout d'abord, les EDE fondent leur légitimité sur une méthodologie de discussion délibérative, non décisionnaire, qui questionne les normes lorsque celles-ci entrent en conflit avec le réel. Ce positionnement pourrait paraître paradoxal en ce sens que la délibération se fait à la recherche d'un consensus alors que les EDE n'ont pas de pouvoir décisionnel ; au contraire, l'EDE est un lieu où se questionnent les antagonismes et où se déploient les différentes visions des questions fondamentales du champ de la santé. Pour le dire autrement, les membres des EDE fournissent à ceux qui les saisissent une réflexion indépendante qui permettra à ces derniers de répondre eux-mêmes aux questions qu'ils se posent en pratique. Dans notre étude, la délibération est considérée comme l'outil le plus bénéfique pour les participants aux EDE, ce qui confirme l'observation faite par Ledesma et collègues au sein d'un EDE argentin (26). Cela montre combien la participation à ces espaces est porteuse de sens pour les praticiens, tout autant que pour les patients dont les dossiers sont discutés.

L'ancrage dans le réel qui est revendiqué par les répondants corrobore l'idée d'un travail utile aux praticiens. Au sein des comités locaux, les motifs de consultation de l'EDE sont récurrents bien qu'ils s'appliquent toujours à un cas particulier. En Allemagne, Kaps et collègues rapportent que ce sont les services de médecine qui sollicitent le plus les EDE et que leurs demandes concernent principalement : la discussion sur l'arrêt des traitements actifs, l'intérêt du patient, la futilité de telle ou telle intervention, et la limitation de soins potentielle dans une hypothèse d'aggravation clinique (27). Au niveau du CCNE, les experts traitent de problèmes si importantes que leurs avis ont un impact considérable sur la rédaction des textes législatifs. Enfin, au niveau des spécialités, les problématiques abordées traiteront des manières de soigner, de gérer l'incertitude, d'anticiper des situations de crises, pour ainsi outiller les praticiens concernés.

En France, le concept de démocratie sanitaire a été consacré par la loi du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé (6). Médecins et patients cherchent un mode relationnel permettant un échange d'informations sur le diagnostic, les possibilités thérapeutiques, le contexte socio-familial, les aspects relatifs à la qualité de vie, susceptible de favoriser le dialogue et la décision partagée. Les patients sont aussi de plus en plus associés à l'élaboration des protocoles d'essais cliniques (1,28). Présents dès la fondation au sein des comités de protection des personnes (1988 en France), leur participation est bien perçue au sein des comités d'éthique de la recherche (29) et semble avoir une réelle incidence sur les soins apportés aux patients en ce qui concerne des aspects difficilement identifiables pour les soignants (ex. : préparation de la consultation, connaissance des procédures administratives, gestion de la stigmatisation due à la maladie) (30). Cette participation est plus inégale dans les EDE rattachés à une spécialité, dont les membres s'interrogent d'une part sur l'intérêt qu'en auraient les patients et d'autre part sur leur légitimité à représenter l'ensemble des autres patients atteints de maladies qu'ils n'ont pas connues. Dans notre enquête, les répondants rapportaient tous que la présence d'universitaires non-soignants (philosophe, ethnologue, anthropologue, etc.) permettait de recueillir un avis extérieur, qu'ils considèrent comme équivalent à celui d'un patient. La participation des non-soignants ne saurait être limitée par leur manque de connaissance du terrain, puisque d'autres auteurs ont déjà montré que la participation des non-experts pouvait être promue lorsqu'ils prennent le temps de questionner les soignants sur les pratiques courantes (31). Au décours de notre travail de recherche, il est important de noter que les statuts du CCNE ont évolué, incluant désormais des représentants d'association de patients au sein de leur EDE (32).

Enfin, nous soulignons l'utilité de tels EDE en dépit de leur caractère consultatif. Les temps de la réflexion et de la décision étant différents, l'utilité des EDE réside dans la réflexion permettant de mieux anticiper les situations de crise. C'est cette raison qui légitime la transmission de ces savoirs sous forme d'enseignements, dont la nécessité est soulignée dans plusieurs pays (33-36).

Les résultats de notre travail sont limités par l'absence d'enregistrement des entretiens – la prise de notes en direct pouvant limiter la fidélité des propos retenus – et l'absence d'évaluation de l'expérience des répondants (les années passées au sein de l'EDE pouvant influencer les réponses données). Nous avons décidé de nous contenter du carnet d'entretiens, car de nombreuses questions avaient une résonnance politique et les répondants se seraient autocensurés en présence d'un enregistrement vidéo. Enfin, bien que notre échantillon se voulait divers, l'échantillonnage de convenance peut avoir limité notre accès à d'autres EDE.

À l'issue de ce travail, nous en venons à l'idée qu'une complémentarité existe entre les différents espaces de discussion éthique et qu'il serait réducteur de penser que l'éthique en France serait uniquement représenté par le CCNE et les espaces éthiques régionaux, puisque des réflexions sont menées au quotidien, de façon plus informelle, en pratique clinique. C'est dans cet esprit que les comités hospitaliers ouvrent leurs portes aux patients et accompagnants. Alors que la mise en place des parcours de santé – faisant l'aller-retour entre médecine hospitalière et médecine de ville – modifie les prises en charge et relations soignant-soigné traditionnelles, décloisonner les EDE et favoriser leur articulation apparaît comme un chemin à prendre pour penser les questions d'éthique clinique. Qu'il s'agisse de la clinique ou de l'activité académique, réfléchir sur ses pratiques est un devoir d'intégrité – d'où la pertinence d'encourager et valoriser la participation des professionnels aux EDE au sein des sociétés savantes, établissements hospitaliers ou instituts de recherche.

Reçu/Received: 18/06/2022
Publié/Published: 27/06/2023

Remerciements
Nous remercions chaleureusement Pr. Dominique Bordessoule (CHU Limoges), Alice Poloméni (Hôpital Saint-Antoine, Paris, France) et Dr. Dominique Jaulmes (Paris, France) pour leur relecture attentive, ainsi que Charles Sarraute (Lyon, France) et Dr. Éléonore de Chergé (Toulouse, France) pour leurs conseils méthodologiques.

Acknowledgements
We warmly thank Pr. Dominique Bordessoule (CHU Limoges), Alice Poloméni (Hôpital Saint-Antoine, Paris, France) and Dr. Dominique Jaulmes (Paris, France) for their careful review, as well as Charles Sarraute (Lyon, France) and Dr. Éléonore de Chergé (Toulouse, France) for their methodological advice.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Abdou Simon Senghor & Aliya Affdal

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ANNEXE 1: PRINCIPAUX ARGUMENTS RAPPORTÉS PAR LES RÉPONDANTS AU COURS DES ENTRETIENS (LES RÉPONSES BRÈVES ONT ÉTÉ MASQUÉES)

	Arguments
Formez-vous un comité ad hoc?	Les réunions ne sont pas opérationnelles, mais elles donnent matière à réflexion [médecin]
	Nous ne sommes pas là pour répondre à des problématiques cliniques, mais pour élaborer une réflexion autour de sujets difficiles rencontrés dans toutes nos équipes respectives [médecin]
	En comité hospitalier, nous faisons du cas par cas et régulièrement du suivi des dossiers si le cas est complexe [non-médecin]
	On parle de cas particuliers et on soulève des questions mais on ne résout pas vraiment l'affaire sur place : on propose des voies de résolution (y compris en étant un médiateur indépendant avec la direction) [médecin]
	Nous nous réunissons parfois de manière ad hoc, pour certains cas cliniques et pour traiter le sujet de pénurie des vaccins (début 2021) [non-médecin]
	Au niveau régional, nous ne pouvons pas faire du cas par cas mais nous pouvons orienter les demandeurs, avec des contacts et de la documentation. [non-médecin]
	Lorsque nous sommes saisis sur un sujet précis, nous sommes obligés de nous y atteler [non-médecin]
Formez-vous une réunion de concertation entre représentants?	Par la délibération, nous nous concertons sans défendre des intérêts personnels [médecin]
	La pertinence de ces réunions est le partage d'expériences personnelles et la confrontation de son propre regard à la pluridisciplinarité [médecin]
	Nous n'avons pas de mandat représentatif, nous faisons tous une démarche individuelle de responsabilité collective [non-médecin]
	La pluridisciplinarité engendre un travail de délibération [non-médecin]
	On en arrive à la concertation lorsque les gens ne quittent pas leur rôle de représentants de patients [médecin]
	Les personnes qui sont là sont impliquées dans l'éthique depuis des années, ils ne représentent personne en particulier [médecin]
	Ce n'est pas un conseil d'administration, ni un comité paritaire, et il y a d'ailleurs la possibilité d'émettre les positions minoritaires [non-médecin]
	Il y a une grande liberté de parole dans les groupes de travail [non-médecin]
	C'est à la fois une réunion entre professionnels de la santé et une ouverture à la société [médecin]
	Différents modes de pratiques se confrontent et s'instruisent [médecin]
	La constitution du groupe est plurielle, avec à la fois des gens qui interviennent au nom d'une association ou d'une institution, et à la fois des professionnels indépendants [non-médecin]
	Je crains que le mouvement d'essentialisation des personnes nous mène à ce que chacun représente telle ou telle identité, mais on n'y est pas encore! [médecin]
Formez-vous un espace d'échange et de formation entre pairs?	Quand il y a désaccord, il y a échange et donc échanges de pratiques. Le côté formation intervient lors de la restitution des travaux lors de notre congrès annuel. [médecin]
	Nos réunions sont une expérience commune, vécue et partagée, aboutissant à une délibération qui ne prétend pas être une expertise éthique théorique [médecin]
	La formation intervient au travers de l'interdisciplinarité [médecin]
	Il ne s'agit pas à proprement parler d'une formation, mais d'un enrichissement grâce à l'échange (pluriprofessionnel) [médecin]
	Au sein du comité local on invite les équipes médicales à participer, avec aussi une certaine visée pédagogique (apprendre une façon de discuter) [médecin]
	La meilleure formation survient lors de notre staff de débriefing [non-médecin]
	Les échanges entre pairs ne sont pas à proprement parler de la formation [médecin]
	J'y trouve une sorte de formation personnelle et je m'enrichis de tous ces échanges sans tabou [non-médecin]
	Si nous ne rencontrons nos collègues que par visioconférence, l'intelligence collective s'en trouve un peu bridée, déjà qu'elle l'est par le délai du rendu d'avis [non-médecin]
	Les cliniciens ou chirurgiens ne viennent pas assez en dehors des cas qu'ils présentent, et c'est regrettable [médecin]
	Au sein des espaces régionaux, il y a un réseau de professionnels qui participent beaucoup aux échanges, qui sont alors pluriprofessionnels. [non-médecin]
	La formation intervient dans notre rôle de médiation avec le grand public, que ce soit au travers des débats autour des questions bioéthiques ou en construisant des liens avec éducation nationale pour diffuser des savoir-faire propres à l'éthique médicale [non-médecin]
	Nous faisons de la formation avec les étudiants qui sont avec nous [médecin]
	Il y a une sorte de formation réciproque entre des gens qui réfléchissent sur l'éthique dans l'esprit d'interdisciplinarité [médecin]

	Pour qu'il y ait échange, il y aurait besoin de lien entre les comités locaux et la commission de spécialité [non-médecin]
	Il faudrait que les internes viennent! [médecin]
	À travers les diplômes que nous proposons, nous développons de nouveaux savoirs et savoir-faire [non-médecin]
	Grâce aux groupes de travail, nous nous formons mutuellement. [non-médecin]
Avez-vous l'impression de vous réunir à titre systématique?	Il y a un rythme minimal à avoir pour faire avancer les travaux [médecin]
	Avec les autres salariés, on a des réunions de service hebdomadaires, assez longues, qui font partie de la vie du groupe. [non-médecin]
	Sans tomber dans la routine, il faut se voir régulièrement et, compte tenu de nos agendas, c'est lourd : « il faut tirer un train » [médecin]
	Ce n'est pas une contrainte. En tant que secrétaire générale, je suis très contente d'y aller [non-médecin]
	Le systématisme est le garant de notre productivité [médecin]
	La fréquence des réunions est souvent appelée par la nécessité et même l'urgence dans la mesure où des avis réguliers doivent être produits (à partir d'un premier document martyr, puis par des discussions rapides pour ajuster) [non-médecin]
	Les salariés ont des réunions de bureau hebdomadaires, mais les autres réunions, si elles sont fréquentes, n'ont rien d'automatique. [non-médecin]
	Il existe une autonomie quant à l'avancement des sujets par les groupes, et ce rythme change en fonction des dossiers et des capacités de réunion [non-médecin]
	Les statuts de note espace régional nous imposent un certain nombre de réunions [médecin]
	Au CCNE, les comités pléniers sont obligatoires et donc systématiques. [non-médecin]
Est-ce un espace de réflexion collective?	Nous élaborons une réflexion collective, d'alerte d'autres instances et de partenaires sur des questions qui posent problème aux soignants. Puis au-delà de la réflexion, nous apportons des outils (fiches pour le terrain) [non-médecin]
	La réflexion collective pourrait être améliorée [médecin]
	Nous sommes à la fois une caisse de résonance et un dynamiseur, en menant une réflexion collective depuis des années sur ce qu'est une « société accueillante » [non-médecin]
Est-ce un espace de résolution des problèmes?	Nous sommes plutôt là pour soulever des problèmes et proposer des pistes que pour donner des solutions [médecin]
	Émettre un avis rapidement permet d'ouvrir des pistes pour les cliniciens [non-médecin]
	Nous avons plus vocation à accompagner qu'à résoudre [non-médecin]
	Nous élaborons des pistes mais pas d'action [non-médecin]
	On fait émerger les problèmes et on les réfléchit [médecin]
Cet espace permet-il la mise en place d'actions préventives?	On a émis un texte sur les situations de conflits avec les familles, pour donner aux équipes des clés pour limiter les conflits et la judiciarisation [médecin]
	On ne veut pas éliminer les questions éthiques, inhérentes à la pratique [non-médecin]
	J'ai l'impression que la réflexion est une sorte d'action préventive [non-médecin]
	Dans le cadre des questions éthiques de priorisation des vaccins du COVID19, nous avons permis une action préventive de médiation entre les services [médecin]
	Les chartes émises constituent un socle de repères préventifs [non-médecin]
Comment jugez-vous la transversalité des analyses faites au sein du groupe?	L'analyse est transversale alors que nous partons de cas concrets et ce grâce à un échange constructif [médecin]
	La transversalité est aidée par la variété de la constitution, elle lui donne du sens! [médecin]
	Je rappelle parfois les intérêts des patients et des proches. J'apporte un regard extérieur. [non-médecin]
	La transversalité permet de voir des éléments et des pistes qu'on aurait pas exploré autrement [non-médecin]
	On pourrait enrichir les horizons pour avoir une vraie transdisciplinarité (socio, paramédicaux, etc.), mais on compense cela avec les auditions [médecin]
	La transversalité s'appuie sur la complémentarité entre l'espace éthique (recherche appliquée) et la recherche universitaire (plus conceptuelle) [non-médecin]
	J'ai la modestie de considérer qu'on n'a pas tous les points de vue : raison pour laquelle on monte des cycles sur un sujet, avec un groupe de travail puis ensuite un colloque pluriprofessionnel [non-médecin]
	La transversalité se reflète dans notre grand nombre de participants : on n'est pas des représentants, mais on est des personnes de la société qui essayent de faire émerger de la pensée [médecin]
	La pluridisciplinarité interne s'enrichit grâce aux avis extérieurs lors des groupes de travail [non-médecin]
Cet espace permet-il la mise en place de chantiers d'expérimentation?	Nous aimerions expérimenter des choses si seulement nous avions plus de place dans l'enseignement de DES [médecin]
	Nous avons participé à la mise en place de recherche clinique sur la mise en place du dispositif législatif lié à la sédation profonde, nous offrons une journée de formation annuelle et communiquons pendant une session au congrès de la SRLF [médecin]

	Notre principale expérimentation a été d'élaborer une fiche de LATA pouvant être intégrée dans les dossiers électroniques [médecin]
	Nous faisons des protocoles de recherche, avec le reproche assumé de ne pas avoir d'hypothèse de recherche! [médecin]
	Les protocoles de recherche sont nos chantiers d'expérimentation [non-médecin]
	Concernant les tensions éthiques liées à l'IA, domaine peu défriché, notre expérimentation consiste à importer des méthodologies de SHS. [médecin]
	Trouver une méthode qui nous permette d'avoir un consensus autour de la gestion des pénuries de vaccins : en voilà une expérimentation! [non-médecin]
	Toute médiation est une expérimentation (qui évolue d'année en année) [non-médecin]
	Nous avons expérimenté un projet étudiant citoyen (cas cliniques travaillés par des M1/M2 de 10 masters différents + jury étudiant + publication = expérience pédagogique) ainsi qu'une scène-éthique (projection film autour d'un thème + table ronde) [médecin]
	Les expérimentations font partie du quotidien, mais aussi via le DU éthique et santé, les journées de formations etc. (15-20 jours par an) ainsi qu'avec le débat public. Sans maîtrise sur les résultats, on espère seulement que les gens tiendront compte de la notion de complexité (≠ individualisme). On est littéralement des accoucheurs (maïeutique) [médecin]
	Dans des enjeux de bioéthique si complexes, toutes les propositions peuvent être perçues comme des chantiers d'expérimentation. [non-médecin]
Cet espace permet-il l'élaboration de compromis collectifs?	Il s'agit d'un apprentissage à la réflexion et au respect des valeurs de l'autre [médecin]
	Par le biais de la délibération, nous aboutissons à des recommandations/pistes de réflexions ponctuant les articles écrits en commun [médecin]
	C'est une éthique de la discussion (Habermas) : la recherche de consensus par les arguments plutôt que des délibérations qui chercheraient à prendre des décisions. En cas de désaccord franc dans notre société savante, nous pouvons saisir le CCNE. [médecin]
	On se méfie du consensus : l'animateur doit chercher la petite bête [médecin]
	Le compromis collectif n'est pas un but en soi, car il évite d'analyser la situation : nous cherchons plutôt un compromis intégratif [non-médecin]
	L'avis oblige au compromis : le consensus aurait plus de valeur si on s'était vu en vrai (épreuve de dissensus vrai) [non-médecin]
	On ne pense pas qu'il existe un unique modèle de décision en éthique ou encore un unique modèle de faire de l'éthique. Au mieux nous pouvons fournir une aide réflexive en amont de type check-list, mais ceci n'est certainement pas décisionnel [non-médecin]
	Certains points de vue peuvent être différents mais cela ne pose pas de problème au niveau éthique (débat pluraliste) [non-médecin]
	Les désaccords ne sont pas si importants lors des réunions et sont discutés au préalable : on n'est pas un conseil consultatif, ni une structure d'appel [médecin]
Cet espace permet-il un enrichissement par le dialogue?	Cet enrichissement n'est pas reconnu par la hiérarchie administrative : les paramédicaux doivent poser des congés pour venir en commission! [médecin]
	J'ai l'impression d'un impact sur les personnes qui participent à la commission (elles ne peuvent plus se permettre de ne plus s'interroger), et il y a la présence dans les colloques et la publication d'articles. Ensuite, les soignants sont très nuancés, et le temps de l'incertitude ralentit l'impact sur les pratiques : il y a nécessité d'un temps long car ce sont des questions complexes qui demandent du compromis et du tact [non-médecin]
	C'est l'occasion de lever les cloisons entre les différents métiers [non-médecin]
	Cela créé des ponts (IDE, médecins, chirurgiens) [médecin]
	Il y a un enrichissement par le dialogue. C'est une plateforme de discussion qui fait le pont entre les gens [non-médecin]
Cet espace permet-il la mise en place d'innovations organisationnelles?	Il existe des thèmes pour lesquels la commission a fait des propositions pour infléchir les pratiques de terrain, bien que les changements concrets ne soient pas bien observables. [médecin]
	Nous favorisons l'émergence d'outils servant à éviter la reproduction de situations conflictuelles [médecin]
	Il s'agit d'une source d'innovation dans la réflexion et dans l'abord des questions, mais pas vraiment dans l'organisation [médecin]
	Nous sommes source d'innovation, surtout lorsque les équipes viennent assister aux staffs [non-médecin]
	On a essayé d'apporter des innovations, y compris dans le dossier patient [médecin]
	Il y a un véritable souci pratique de l'organisation, on n'est pas seulement là pour réfléchir [non-médecin]
	Les publications, lorsqu'elles sont beaucoup lues, permettent des innovations. [médecin]
	Cela peut créer certains liens entre les praticiens mais c'est pas nous qui mettons en place ces innovations [non-médecin]
	Malheureusement, on ne voit pas les effets de ce qu'on fait. [non-médecin]

	Il n'y a d'innovations que dans le cadre de réunions avec les acteurs de terrain (gestion des situations de handicap au cours de la pandémie) par le biais des chartes [non-médecin]
	Nous avons le souhait de l'innovation : on a des chercheurs (thésards, Sciences Politiques, Droit de la Santé, etc.) pour cela. Nous créons des dynamiques, pour trouver des réponses politiques innovantes. [médecin]
Cet espace vous permet-il d'enrichir vos pratiques de recherche?	Cette participation enrichit significativement mes pratiques de recherche, car j'aborde mon sujet sous les deux facettes : familles et soignants. La présence de chercheurs en SHS et de psychologues apporte un décalage de point de vue qui nourrit les discussions. Les priorités ne sont pas toujours là où les médecins les mettent [non-médecin]
Votre participation vous offre-t-elle une reconnaissance par vos pairs?	Même si l'effet est difficile à mesurer et qu'il est modeste, nous bénéficions d'une certaine reconnaissance par le biais des publications [médecin]
	Il y a une reconnaissance de ce travail par mes pairs d'ethnologie. Car ils voient bien qu'on travaille pour l'intérêt collectif! [non-médecin]
	Le comité d'éthique est respecté (sagesse, bienveillance : compatible avec la gestion de tant d'incertitudes) mais il n'offre pas de valorisation universitaire [médecin]
	L'exercice de l'éthique n'est pas valorisé chez les médecins car c'est le poil à gratter de la médecine. Mais moi je me sens plus médecin ici qu'ailleurs! [médecin]
	Il n'y a pas de reconnaissance de cette participation au sein de la communauté des philosophes [non-médecin]
	Localement, nous sommes reconnus (surtout avec l'ancienneté) [médecin]
	L'évêque est content que je participe (incitation hiérarchique à participer, dans toute la région), ce qui est valorisant [non-médecin]
	Le CNU (section 17) ne s'intéresse pas à ce genre de choses, il préfère l'Histoire de la philosophie [non-médecin]
	En tant que juriste, je peux ajouter cette ligne à mon CV [non-médecin]
	Pas de reconnaissance académique, mais une satisfaction du point de vue de l'utilité sociale [non-médecin]
	Ce qui est bénéfique, c'est notre liberté d'action et notre capacité de mobilisation. Nous on met les gens en valeur en participant à une réflexion que leur lieu de pratique n'offre pas. [non-médecin]
	La reconnaissance n'est pas toujours positive [médecin]
	Nous ne bénéficions d'aucune reconnaissance pour cela, et prenons plutôt le risque de perdre une place [médecin]
La tenue de ces réunions permet-elle de soulever de nouvelles tensions éthiques?	Chercheuse sur les enjeux de communication entre familles et soignants, être dans la commission me permet de voir, du côté des médecins, les problématiques de pratiques soignantes, que je peux confronter aux problématiques des familles que je perçois dans mes études qualitatives. Je n'ai pas usage dans ma pratique des compromis qui sont trouvés mais je trouve cela passionnant. [non-médecin]
	Le grand intérêt? Décentrer, reformuler, élargir la réflexion. [médecin]
	Les praticiens soulèvent des tensions éthiques : moi, je découvre de nouvelles situations cliniques inédites en fonction d'un contexte original [non-médecin]
	Les tensions éthiques ne sont pas nouvelles mais leur discussion approfondie permet une renouveler dans nos pratiques médicales [médecin]
	Certaines personnes sont super enrichissantes et je prends des notes! [non-médecin]
	Les problèmes ne sont pas forcément où on les pense, les choses sont toujours grises [non-médecin]
	Les tensions éthiques s'identifient à la fois en amont et pendant les réunions. [non-médecin]
	Quand on travaille sur les programmes (partage d'expériences, ressentis, compétences), les tensions émergent de manière très claire [non-médecin]
	On se réunit parce qu'il y a des tensions éthiques : sur le handicap, le numérique, les personnes âgées, les tensions sont évidentes [médecin]
L'absence de patients est-elle une limite à vos discussions?	C'est un choix politique que de ne pas inclure de patient car il s'agit d'une commission de société savante [médecin]
	Les personnes présentes sont des gens sensibilisés à l'avis des patients, et les profils non-médecins apportent un avis patient et famille. C'est en fait le premier item débattu car le plus important [non-médecin]
	Les invités non médecins demeurent des patients [médecin]
	Les patients représentés par les membres de la société civile (on réfléchit à intégrer des associations) [médecin]
	Les patients sont entendus puisque c'est justement pour eux qu'on fait des cas cliniques [non-médecin]
	Nous avons un représentant de patients, mais il n'est forcément pas représentatif de l'ensemble des patients [médecin]
	Les médecins font très attention aux patients (par le biais des vignettes cliniques), mais l'ouverture évite l'entre-soi [philosophe]
	Le meilleur retour de l'expérience patient ne s'obtient pas forcément en commission, mais plutôt dans un lieu d'accueil au sein de l'hôpital, qui nous en retranscrit les grandes lignes. [non-médecin]
	On travaille avec des associations (surtout concernant les maladies neurodégénératives). [non-médecin]

	La parole des patients est toujours présente dans nos groupes de travail ainsi qu'au conseil d'administration. [non-médecin]
	Le débat avec le public devrait plutôt se faire avec les espaces éthiques régionaux et les états généraux. Et auditionner certains patients ou associations serait pertinent. Avoir un représentant fixe n'est pas toujours l'idée la plus pertinente. [non-médecin]
Trouvez-vous que le rôle de l'espace de discussion est assez clair pour les collègues qui ne le fréquentent pas?	On apporte du grain à moudre pour ceux qui sont déjà intéressés mais on n'arrive pas à toucher ceux qui en auraient le plus besoin [médecin]
	Notre image n'est pas faite auprès des autres praticiens (d'où l'intérêt des articles) [médecin]
	Je me pose toujours la question du rôle de la commission en termes de communication non-universitaire envers les soignants et la société civile. Je n'ai toujours pas de réponse. Qui doit prendre la parole pendant l'épisode Covid? Cela pose aussi la question du rôle public d'une spécialité. [non-médecin]
	Notre rôle est clair au sein de notre société savante, mais cela s'arrête là. [médecin]
	Notre rôle n'est pas assez clair, le lien est difficile avec les services (peur de la dégradation de l'autorité médicale) [médecin]
	Beaucoup ne nous connaissent pas. Mais les gens sont contents quand ils repartent [non-médecin]
	On a peur d'être incompris mais on publie dans le journal de l'hôpital pour se faire comprendre [non-médecin]
	Il existe un besoin de clarification de la place et du champ de cette commission au sein de l'institution [non-médecin]
	Quand on parle de déontologie, cela rajoute de la valeur à l'avis éthique. Étonnamment, ça facilite la compréhension. [non-médecin]
	Notre rôle est de plus en plus clair : il aura fallu du temps pour passer de la nébulosité à la clarté, grâce à l'action. [non-médecin]
	La structure est hybride et complexe en soi. [non-médecin]
	Il y a toujours un travail de clarification à faire car le terme éthique est trop utilisé dans le débat public : nous souhaitons diffuser la culture de la réflexion éthique dans notre région. On est presque des « missionnaires ». Pour avoir un rôle clair, il faut bien se définir et connaître son périmètre. [non-médecin]
	Les gens ne nous interpellent pas assez ; et quand ils viennent à des formations, d'un coup tout change! On a un vrai esprit bottom-up! [médecin]
	Le CCNE n'est pas forcément connu par tout le monde, bien que les états généraux de 2018 aient permis de faire connaître la commission. Les médias reprennent certains avis. [non-médecin]
Quelles sont pour vous les principales circonstances limitantes à vos discussions éthiques?	Le temps manque mais les mails permettent d'avancer tout de même [médecin]
	Il y a peu de temps pour avancer sur tous les sujets car chacun fait cela en plus de sa vie professionnelle, mais cela ne limite pas le débat. [non-médecin]
	Les enjeux politiques internes peuvent être une limite quand elle s'insère dans le débat [médecin]
	La manque de temps nous incite parfois à la priorisation de certains sujets [médecin]
	Les circonstances de discussion sont très changeantes d'une semaine à l'autre : on en tire toujours quelque chose, surtout si la réunion est bien préparée [médecin]
	Les sujets de fond sont abordés et travaillés, en dépit du manque de temps. [non-médecin]
	On manque de temps pour réfléchir : peut-être faudrait-il donner la biblio avant..? [non-médecin]
	Le temps, les visioconférences, l'urgence des avis : tout cela mène à la frustration [non-médecin]
	Chez nous, il n'y a pas d'heure de fin, le débat très libre [non-médecin]
	Le débat de fond n'est souvent pas assez abordé par manque de temps, du fait que les intervenants ne sont pas forcément les plus compétents, du fait de la mauvaise préparation de l'évènement, de la formulation des tensions, ou encore de la difficulté d'organiser des vrais débats contradictoires. [non-médecin]
	L'urgence peut toujours limiter un débat de fond, ainsi que la polémique (surtout lors des états généraux de la bioéthique) [non-médecin]
	Les personnes qui ne parlent pas se taisent simplement parce qu'elles ne se sentent pas au niveau [médecin]
	Les facteurs limitants sont multiples : le temps, la culture de l'effacement, le politiquement correct ou encore la perte de liberté de pensée. Mais c'est notre mission de poser les questions qui fâchent! [médecin]
	Nous aurions toujours la possibilité de repousser les dates limites de rendu d'avis, mais il a aussi un principe de réalité à respecter. [non-médecin]
L'articulation entre réflexion et mise en pratique est-elle difficile en éthique?	Les questions éthiques sont difficiles à généraliser, à inférer dans un autre contexte. [médecin]
	Tous les chantiers lancés vont à leur terme mais tout passe dans les mains du CA qui en fait ce qu'il désire. [médecin]
	Il existe une nécessité de temps long inhérent à la complexité des questions. Le manque de temps est une frustration acceptée. [non-médecin]
	Au local, le comité est assez pertinent qui fait avancer les choses. La formalisation des pensées prend, elle, plus de temps et passe par la publication d'articles. [médecin]
	C'est l'enjeu de notre fonctionnement que de trouver l'équilibre entre pratique et éthique [médecin]

	L'articulation avec la pratique est difficile car la décision pratique met un terme, elle ferme l'horizon de tant de questions posées [non-médecin]
	On ne peut pas induire de nouvelles pratiques tant qu'on reste si peu représentatif [médecin]
	Le passage à la pratique est compliqué car les gens ont le nez dans le guidon [non-médecin]
	On a une certaine efficacité pratique en raison du rendement lié aux avis : il y a une sorte de pression. [non-médecin]
	L'articulation avec la clinique s'opère grâce au réseautage interne, à la patience et notre pugnacité : aujourd'hui on a une place dans la réunion des chefs de service. [médecin]
	On contribue à faire bouger les lignes qui bougent forcément lentement [non-médecin]
	Au-delà de l'écriture d'une charte, il y a tout un travail de proximité pour la diffuser et la faire accepter. [non-médecin]
	On sait bien qu'on pose les questions qui fâchent et qu'on devient donc politiquement incorrect : ce qui peut fâcher les hiérarchies et empêcher la diffusion de nos idées. [médecin]
Regrettez-vous le faible impact de vos travaux auprès des soignants que vous ciblez?	Nous n'avons aucun critère d'évaluation pour juger de notre impact chez les soignants [médecin]
	Le faible impact de notre travail n'infléchit pas l'investissement des membres [médecin]
	L'impact est souhaité mais trop difficile à évaluer à court terme. Cependant, certains sujets sont tellement présents au quotidien que la contribution est certaine (ex : Léonetti) [médecin]
	Notre impact est probablement faible, mais nous avons beaucoup de retours positifs des CH non universitaires, ce qui nous raffermit. [médecin]
	L'impact est corrélé à la qualité de la communication, et à l'applicabilité de ce qu'on propose. [médecin]
	Le manque d'impact sur les pratiques s'explique aussi par le fait que nous réfléchissons sur des pratiques et habitudes d'équipes qui sont ancrées depuis des années. Qu'importe, l'objectif demeure le patient [médecin]
	Notre influence sur les projets de loi est très liée aux capacités de réseautage, mais nous n'avons aucune preuve que nos recherches influencent les équipes. C'est à elles de s'approprier ces questions dans leurs pratiques! [non-médecin]
	L'impact est limité car on est trop peu en termes de nombre [médecin]
	Les publications nous garantissent un certain impact [médecin]
	L'impact sur les pratiques soignantes doit se voir sur le long terme, dans un temps long : il se fait petit à petit [non-médecin]
	Pour mesurer notre impact, on doit se contenter de mesurer le nombre de soignants qui viennent faire des formations et qui donnent des retours positifs [non-médecin]
	On voit tout de même notre impact sur les pratiques au long terme : retours de questions, invitations à des conférences, résonance sur les réseaux sociaux [non-médecin]
	L'impact est forcément limité puisque les comités éthiques sont toujours taxés soit d'ingérence soit d'inutilité [médecin]
Existe-t-il un risque que certains membres souhaitent toujours imposer leurs idées au groupe?	Imposer ses idées est un piège dans lequel il ne faudrait pas tomber [médecin]
	Même si on garde une liberté de parole, il peut y avoir une hiérarchie implicite (le praticien hospitalier non-universitaire se sent parfois dévalué par rapport au chercheur universitaire). Quand on se libère de cette contrainte, tous cheminent dans l'intérêt de la recherche (même les non-universitaires). D'où importance du tutoiement dans cet espace de recherche. Par le passé, il y a eu des fois où il y avait de la frustration car pas assez de temps ou parole monopolisée avec les plus hauts hiérarchiques (rares). [médecin]
	Le risque d'une hiérarchie implicite existe mais le côté pluridisciplinaire retire le rapport hiérarchique entre les discutants [médecin]
	Il n'y a pas d'idée imposée, mais comme dans la société, des rapports de pouvoir s'établissent dans la prise de parole, même si chacun fait attention à l'autre [non-médecin]
	Le risque hiérarchique existe mais est maîtrisé : d'une part le comité est plutôt bienveillant, d'autre part cela rappelle l'importance dans le choix des membres [médecin]
	Il existe toujours le risque que certains veuillent imposer des idées, mais notre fonctionnement travaille la méthode et moins l'idée [médecin]
	Il y a des gens qui parlent plus que d'autres : de fait, ce sont les gens qui ont les idées plus fortes ainsi que les consultants qui parlent en dernier [non-médecin]
	Personne n'impose ses idées en dépit des différentes personnalités [médecin]
	Parfois, les convictions sont fortes, et confondues avec des certitudes [médecin]
	Il y a quelqu'un qui joue les vieux sages, certainement un reliquat du mandarinat pour ce qui est des médecins [non-médecin]
	Les membres sont humbles, au point qu'on ressente de l'autocensure de la part des non-praticiens [non-médecin]
	Il faut du temps et de la volonté pour dépasser son ressenti personnel [médecin]
	Pour éviter chacun impose ses idées, je demande aux gens de faire semblant de se mettre à la place des gens qu'ils ne sont pas (c'est ma manière de mener le débat) [médecin]

Certains membres sont-ils parfois remis en cause pour ce qu'ils pensent?	Il y a toujours un risque de timidité des nouveaux membres mais pas de remise en cause des personnes [médecin]
	Il y a parfois de grosses engueulades, d'où la nécessité du staff de debriefing. [non-médecin]
	Les critiques peuvent arriver dans le groupe, c'est le rôle des permanents de bien gérer les membres [non-médecin]
	Quand je vois que certaines personnes ne sont venues qu'une fois, je me demande si elles ont eu peur de prendre la parole. [non-médecin]
	Il peut y avoir cette peur d'être mal regardé, et donc une autocensure, d'autant plus quand c'est un débat public avec les postures peut prendre à l'occasion [non-médecin]
	Il y a des spécialistes de la bien-pensance [médecin]
	Les gens sont attentionnés, tant qu'on n'a pas trop d'importance politique. D'où l'importance d'une certaine indépendance du groupe. [médecin]
Avez-vous le sentiment parfois de trop se restreindre à des sujets d'actualité?	En dehors de la situation exceptionnelle du triage lors de la COVID, nous abordons rarement des sujets d'actualité. [médecin]
	Nous n'avons que des sujets de fond (x12-14 en même temps) [non-médecin]
	Quand on se saisit de sujets d'actualité, on a un devoir de se prononcer en tant que société savante. Quand on se saisit de sujets du quotidien, on aborde enfin les vrais sujets de fond. [médecin]
	Durant la période Vincent Lambert, on ne parlait que de ça et c'était lassant [non-médecin]
	Depuis le COVID, on parle énormément de l'actualité mais pas du tout sur le même angle que les médias : les réalités du quotidien, les vrais soucis. On a une longueur d'avance. [non-médecin]
	Finalement, le fond se rattache toujours à l'actualité. [médecin]
	Il y avait beaucoup d'actualités lors des états généraux et lors de la loi de bioéthique. Quand il y a une attente citoyenne il faut aller vite, mais sur les autres thèmes on a notre propre rythme [médecin]
	Quand nous sommes saisis sur questions d'actualité, il y a souvent trop peu de temps pour réfléchir en profondeur. [non-médecin]

Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

B Murdoch, DN Wagner, S Sandal, K Sherwood
Can J Bioeth / Rev Can Bioeth. 2023;6(2):36-42

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

The Rule of Rescue in the Era of Precision Medicine, HLA Eplet Matching, and Organ Allocation

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Résumé

La médecine de précision peut placer les cliniciens dans une position où ils doivent agir davantage comme des répartiteurs de ressources que dans leur rôle traditionnel de défenseurs des patients. Dans l'attribution d'organes et de tissus transplantables, l'utilisation de l'appariement eplet renforcera la médecine de précision mais, ce faisant, créera une tension avec la dépendance actuelle au devoir d'assistance et des facteurs fondés sur la justice pour l'attribution des ressources. L'appariement des antigènes leucocytaires humains (HLA) du donneur et du receveur est bénéfique pour pratiquement tous les types de greffes d'organes solides. Pourtant, jusqu'à récemment, l'appariement HLA n'était pas pratique et il a été démontré qu'il contribuait aux disparités ethniques/raciales dans l'attribution des organes. Des avancées récentes utilisant des eplets de la molécule HLA ont renouvelé la promesse d'un tel appariement pour prédire les résultats pour les patients. Le devoir d'assistance dans l'attribution d'organes reflète une combinaison d'impératifs éthiques, politiques et juridiques. Cependant, le devoir d'assistance peut entraver les stratégies d'attribution adoptées par les associations médicales professionnelles et l'utilisation optimale des ressources limitées en matière de transplantation. Alors que l'appariement d'eplet cherche à améliorer les résultats, il peut potentiellement contrecarrer les initiatives actuelles motivées par l'éthique, les relations établies entre patients et praticiens et les conventions fonctionnelles dans l'attribution des ressources médicales telles que les transplantations d'organes et de tissus. Les systèmes d'attribution de l'eplet doivent être conçus avec soin et en collaboration, avec des lignes directrices claires, justes et équitables qui complètent les conventions fonctionnelles et maintiennent la confiance du public.

Mots-clés

don et transplantation d'organes et de tissus, allocation des ressources, devoir d'assistance, appariement HLA, médecine personnalisée

Abstract

Precision medicine can put clinicians in a position where they must act more as resource allocators than their traditional role as patient advocates. In the allocation of transplantable organs and tissues, the use of eplet matching will enhance precision medicine but, in doing so, generate a tension with the present reliance on rule of rescue and justice-based factors for allocations. Matching donor and recipient human leukocyte antigens (HLA) is shown to benefit virtually all types of solid organ transplants yet, until recently, HLA-matching has not been practical and was shown to contribute to ethnic/racial disparities in organ allocation. Recent advances using eplets from the HLA molecule has renewed the promise of such matching for predicting patient outcomes. The rule of rescue in organ allocation reflects a combination of ethical, policy, and legal imperatives. However, the rule of rescue can impede the allocation strategies adopted by professional medical associations and the optimal use of scarce transplant resources. While eplet-matching seeks to improve outcomes, it may potentially frustrate current ethics-motivated initiatives, established patient-practitioner relationships, and functional conventions in the allocation of medical resources such as organ and tissue transplants. Eplet-matching allocation schemes need to be carefully and collaboratively designed with clear, fair and equitable guidelines that complement functional conventions and maintain public trust.

Keywords

organ and tissue donation and transplantation, resource allocation, rule of rescue, HLA eplet-matching, personalized medicine

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INTRODUCTION

During the COVID-19 pandemic, triaging decisions with limited medical resources and life-and-death outcomes prompted closer scrutiny of the ethical, practical, and legal issues surrounding the rule of rescue (1-3). Described as "the imperative people feel to rescue identifiable individuals facing avoidable death" (4), the rule of rescue is an important phenomenon in the context of medical care. In healthcare systems with limited resources, this bias towards saving identifiable patients in distress can come at the expense of other "faceless" patients and can potentially cause significant net harm on a population-wide scale. The rule of rescue is borne out of ethical and legal obligations, and possibly psychosocial impulses (4,5). The ethical obligations derive from both social values about the importance of human life and ethical training provided to healthcare professionals. The legal obligations, which we explore here, stem from fiduciary duties, common law torts, and regulatory standards imposed on healthcare professionals. In pressing situations of resource scarcity, the ethical and legal grounds of the rule of rescue can quickly erode. The justification for the rule of rescue is further cast into question by emerging technologies associated with precision medicine.

ISSN 2561-4665

Recent advancements in eplet matching research promise to generate new and more precise allocation methods in organ and tissue donation and transplantation (OTDT). The growing influence of such precision medicine, which includes eplet matching for transplant allocation, creates tensions with the rule of rescue and justice-based reasoning that are conventionally important in healthcare settings with resource scarcity and critically ill patients, such as those needing OTDT. Here we explain eplet matching and its importance, discuss the legal and ethical foundations of the rule of rescue, and examine the emerging challenge that eplet-matching potentially poses to the rule of rescue in allocation.

PRECISION MEDICINE AND ALLOCATION

Precision medicine focuses on interventions based on individual characteristics of each patient, often by targeting an individual's specific genetics and biochemistry (6). Precision medicine methods hold significant promise in several areas of medicine, including improving OTDT outcomes through epitope matching (5), and developing drug treatments for certain gene-related forms of cancer (7). The potential of precision medicine to affect the allocation of healthcare resources is theoretically immense. Some commentators have predicted a future medical provision that allocates healthcare resources through a complex algorithmic process that tailors' treatments "to the characteristics of the specific individual in the spirit of precision medicine" (8). This development could take informed decision-making mostly out of clinicians' hands, as the data and logic used could become incredibly complex. There is also the possibility or even likelihood of allocation systems advancing beyond mere algorithms and incorporating artificial intelligence (AI) that engages in machine learning, i.e., independent iterative self-modification that could make the logic and underlying data utilization opaque to physicians. Whether these systems are allowed to develop and function as described is the source of ongoing debate. While this is not the focus of our manuscript, such AI raises many ethical issues, which are engaged by key AI ethics policies such as the 2018 *Montreal Declaration on Responsible Development of Artificial Intelligence* (9). Regarding interpretability, some AI researchers are focusing on developing interpretable AI platforms to help healthcare professionals understand the logic underlying algorithmic decision-making (10).

While some argue that precision medicine enhances the traditional patient-centred ethos of healthcare provision (11), certain implications of precision medicine may complicate such aims. For example, in the context of allocating scarce medical resources, strictly data-driven allocations of precision medicine can diminish a decision-maker's ability to duly consider such value-based factors as principles of equity and justice. This could then restrict clinicians to acting more as objective resource allocators than their traditional role as patient advocates – precision medicine is thus potentially at odds with the rule of rescue.

Precision medicine in the context of scarce resource allocation already exists to a limited extent. In the field of rare disease, there are a growing number of costly therapies with precision targeted approaches. In these scenarios, physicians must often implement allocation policy at point of care (12). In the context of organ allocation, precision epitope-matching systems are being developed, presenting both potential benefits and challenges to conceptions of fairness in allocation and waitlist policy. These systems could put the codified medico-legal primacy of the patient into question. Some current allocation models, such as the model for end-stage liver disease (MELD), are designed for patient-centred allocations based on highest mortality risk (13,14). This model has already "mostly eliminated the transplant clinician's abilities to exaggerate a patient's disease severity in order to move 'up' the patient's place on the transplant list," something many would consider an improvement in ethical allocation (14). The United Network for Organ Sharing (UNOS) is exploring newer precision allocation systems (15). However, the push towards precision allocation tools can obscure the patient-physician role. As one article about this issue warns, the increased complexity of allocation tools such as innovative biomarkers may "limit the enthusiasm of transplant physicians" (16).

EPLET MATCHING – A PRIMER

In solid organ transplantation, which involves a donor's organ engrafted into a recipient, the donor's human leukocyte antigens (HLA) are the primary alloantigens recognized by the recipient's immune system. HLA mismatches between the donor's and recipient's antigens are therefore associated with a higher risk of sensitization, graft failure and rejection (17,18). The benefits of HLA matching have been demonstrated in virtually all types of solid organ transplants and HLA matching provides numerous benefits, including better and longer graft survival (19). As such, matching donors and recipients for these molecules has been a central tenet of organ allocation. However, HLA matching is particularly rare due to the overwhelming number of HLA variants – HLA genes are the most polymorphic in the human genome (20). HLA matching is thus currently not a priority in allocating critical organs such as hearts, livers, and lungs, and has also been devalued in a stepwise manner in kidney allocation algorithms (21-23). One reason for the devaluing of HLA matching in these allocation schemes is the introduction of modern immunosuppression, which decreased the risk of acute rejection (24). HLA matching, especially HLA-B, was also shown to be contributing to ethnic and racial disparities in access to transplantation (25,26).

Recent developments in structural immunology and precision medicine have, however, allowed researchers to evaluate an alternative approach. There is growing recognition that molecular differences at the antibody-accessible (surface) region of the HLA molecule determine antigenicity and can cause organ rejection. Epitopes are large surface areas where anti-donor antibodies can bind and are commonly referred as to Structural Epitopes. Within each structural epitope is a short sequence of one or more polymorphic amino acids that are directly implicated in the immune response to the allograft. This short sequence of amino acids is called a Functional Epitope, or Eplet. By breaking down each donor HLA molecule into a series of mismatched eplets, the degree of match between donor and recipient can be examined more granularity. Evolving work from several groups around the world is demonstrating that eplet matching (especially at HLA-DR and -DQ) can decrease the risk

of rejection and has an impact in graft survival (27-32). Knowledge of the level of eplet mismatch at the time of transplant can not only serve as a useful predictor of post-transplant risk of alloreactivity but also inform adjustments of immunosuppression when patients develop other complications, such as infectious or malignant complications. More importantly, because immunosuppression complications are some of the leading causes of patient death post-transplantation, precise identification of the eplet mismatch level is potentially of critical importance, both in the pre-transplant accessibility of offers and in the post-transplant risk stratification of alloreactivity to the graft.

THE RULE OF RESCUE AND ORGAN ALLOCATION

The rule of rescue is more than a concept – it is an observed reality. One study about allocation of intensive care unit beds found that the rule of rescue was often relied upon because clinicians perceived strong ethical obligations to “identifiable living patients” (33). A 2020 survey of emergency physicians found that “emergency department triage decisions are more informed by the patient’s acute presentation” than “by factors associated with the perceived risks and benefits of ICU care” (34). In that survey, emergency physicians highlighted that “established institutional triage criteria and protocols are infrequently applied” (34). In other words, the rule of rescue can undermine carefully calculated and considered polices on allocating medical resources.

Rationing and allocating scarce medical resources such as solid organs has recently sparked new bioethical debates and political controversies (35,36). Allocation policies and the application of the rule of rescue are prevalent and contentious issues, even among transplant recipients and candidates (37). For medical professionals, such life-and-death resource allocations are fraught with moral and pragmatic tensions that include equitable treatment, efficient outcomes, and assisting those most in need (38). Some bioethicists have criticized allocation based on the rule of rescue as “worst-off prioritarianism” (35), which undercuts other allocation principles such as utilitarian ideas of greatest benefit (based on cost-benefit analyses) and egalitarianism, which aims to provide “fair chances” to all patients (39). In 2006, The UK’s National Institute for Health and Care Excellence (NICE) published their deliberations on whether the rule of rescue should be rejected as a basis for medical provision (40). At that time, a majority of NICE believed “it should be applied in certain exceptional cases” that met a series of criteria (40). Despite their concerted deliberations and careful policies on this issue, NICE has been criticized for inconsistencies in their approach to the rule of rescue (41). To provide much-needed guidance and consistency for organ allocation in the United States, UNOS developed rationing policies based on organ-specific criteria, including waitlist times, illness severity, prognostic indicators, and human leukocyte antigen compatibility (38). Nevertheless, transplantation specialists sometimes allocate organs according to the rule of rescue (42).

RULE OF RESCUE IN LAW AND PROFESSIONAL ETHICS

The rule of rescue derives largely from a combination of ethics, policy, and law (5). The ethical precepts undergirding the rule of rescue include core medical traditions, such as the Hippocratic Oath. However, it is the legal obligations that form binding requirements, and which substantiate the ethical and policy pressures that reinforce the rule of rescue. In most Commonwealth countries (including Canada), in the US, and many other jurisdictions, physicians have fiduciary obligations to act in the best interests of their patients. The obligation partly reflects the physician-patient power balance, in which the patient is “peculiarly vulnerable” to their physician’s behaviours and decisions (43,44). This strong obligation can include a requirement for physicians to prioritize the interests of identifiable patients above broader concerns such as cost containment (45,46).

Another obligation is the duty of care, which derives from tort law. Physicians must adhere to a standard of care that includes reasonable skill, care, and judgment or they risk tortious liability through negligence. However, so-called defensive medicine can arise, particularly in more litigious jurisdictions like the United States, when practitioners make decisions to avoid legal liability rather than in accordance with best practice, professional guidelines, or patient outcomes. While a patient’s physician owes a duty of care, so too can their healthcare institutions, which are potentially liable for damages sustained due to improper protocols (47). Defensive medicine can also encourage more extreme forms of patient advocacy, such as exaggerating the condition of a transplant candidate in hopes of securing scarce organs or tissues (48,49). This kind of zealous advocacy for a patient can impede the equitable and effective allocation of organs and tissues.

Self-regulating colleges of physicians and surgeons have largely internalized the legal obligations imposed on physicians by transcribing them into codes of ethics, policy guidelines, and standards of practice. The American Medical Association (AMA) asserts that physicians are responsible for contributing to fair allocation policies that are explainable to patients and the public, and that respond to such criteria as medical need and benefit; lifesaving and quality of life enhancing; and objective, flexible, and transparent decision making (50). For allocating any limited medical resource, the AMA’s Code of Medical Ethics highlights five criteria: “likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and the amount of resources required for successful treatment” (51). The Organ Procurement and Transplantation Network, which oversees OTDT in the US, issued a white paper that identified three core principles for allocating organs, including utility, justice, and respect for persons and their autonomy (52). Similarly, the Canadian Medical Association (CMA) requires that physicians participating in transplantations allocate organs in an ethically sound fashion (53). To assist physicians, the CMA has instituted a set of guiding principles for OTDT that centre on justice, equal opportunity, and utility (54). However, the CMA admits that for OTDT allocations “these principles are often in conflict” (55). For instance, a utilitarian goal such as saving the most lives or maximizing quality-adjusted life years can be at odds with aims such as equality or justice that attempt to address medical comorbidities resulting from social inequities (56). Yet, highly detailed guidance for how to resolve complex problems of

conflicting principles can be lacking, which can leave crucial decisions to physician discretion. While professional discretion is a necessary reality for many aspects of medical practice, gaps or uncertainties in allocation protocols could heighten physicians' fear of liability and a tendency towards defensive medicine, consequently bolstering the influence of the rule of rescue in these critical allocations.

EFFECTS OF EPLET MATCHING & SHIFTING AWAY FROM RULE OF RESCUE

The clinical situation might dictate which rule will prevail. In a situation where patient death is imminent in the absence of a transplantation, the rule of rescue will likely prevail over eplet matching. This kind of situation includes most critical organs, such as liver, lung, heart, and, in some circumstances, kidney. Nevertheless, eplet matching may take precedence in other situations and in patients, such as the highly sensitized, for whom it is difficult to allocate offers under the current allocation system. For instance, eplet matching may take priority in most kidney transplantations and when a living donor is involved. Most cases of kidney transplantation are not emergencies, as patients can survive on dialysis for months. Likewise, some heart and lung transplantations may also become less urgent as new supportive devices are introduced. These less-urgent transplantations are opportunities for exploring eplet matching in allocation schemes and for implementing allocation rules based on utilitarianism and egalitarianism, rather than the rule of rescue. Living donation, meaning donation by a living individual who can survive without the donated tissue (e.g., kidney, liver lobe), is another field of transplantation where maximizing the expected survival of the organ may take precedence. Several new programs for living donation are already exploring allocation schemes that rely less on the rule of rescue. For example, inviting compatible donors to participate in the paired kidney donor exchange program increases the opportunity for pairing with a better HLA matched offer (57), or in the advance kidney donation program, a living donor donates their organ well in advance to the intended recipient's moment of need for that organ (58).

The implementation of eplet matching in organ allocation may limit opportunities for practitioners to exercise professional discretion. The specific manner of implementation will determine the extent of remaining professional discretion. Relying on information and criteria derived from eplet matching may result in more efficient organ allocations with better overall outcomes, with the side effect of significantly curtailing practitioner advocacy for patients. It is possible that this side effect could diminish human-centred patient care and affect both outcomes and the psychological experiences of recipients; a diminished ability for practitioners to exercise discretion to espouse ethical principles; and less understanding of organ allocation reasoning for both patients and practitioners (59).

Beneficial outcomes from precision medicine have been constrained because many technologies are still in the early stages of development (60). Placing too much importance on eplet matching without fully considering the effects on fairness might undercut current organ allocation systems and ethical norms (59). What constitutes the best possible care continues to be debated, especially as ethical consideration about quality of life continues to evolve. Eplet matching represents one of several variables that can be used in developing allocation algorithms.

Using precision medicine to inform allocation models will potentially reduce the opportunity for individual practitioners motivated by the rule of rescue to unduly influence who receives an organ first (61), especially since some practitioners stray from set policies and guidelines (62). OTDT organizations have stressed the need for consistency in allocation systems and their application (63). However, many medical resource allocation systems inconsistently apply cost-utility analyses (64). Carefully implemented eplet matching systems could introduce another objective metric for allocations, thereby helping improve consistency and fairness.

The ethical principles that guide organ allocation policies – such as justice, equal opportunity, respect for personal autonomy, and utility – might best be served by carefully designed models based on precision medicine that continue to weigh other factors as well. Ideally, these models should not increase wait times for any candidate. As precision medicine gains influence in organ allocation, practitioners and policymakers should particularly scrutinize issues about equity in access, including whether certain groups have poorer candidacy chances due to social determinants of health, racial background, or ethnic group (65). Several metrics show that wealthy individuals who are not visible minorities have better outcomes in OTDT than racialized and/or economically marginalized individuals (66-68). Crucially, there remains uncertainty about whether eplet matching will level or, like HLA matching, exacerbate allocation disparities along racial lines. Implementation of eplet matching in clinical practice requires a thorough analysis of the implications, particularly with respect to equity, the input of a wide range of stakeholders, and a pilot/transition period. A recent online public deliberation conducted with members of the Canadian public underscored several thematic concerns in implementing eplet compatibility in kidney transplantation: health maximization, mitigation of negative impacts, principles of fairness, evidence-based healthcare, and responsibility to maintain trust (69). Participants mentioned the need for flexibility, accountability, transparent communication, and a transition plan. It behooves policymakers and practitioners to ensure the implementation of algorithm-driven systems that prioritize utility do not exacerbate treatment inequities.

CONCLUSION

Eplet matching seeks to improve OTDT outcomes by tailoring interventions to the specific biological characteristics of individual patients. However, if implemented without due ethics and policy consideration, eplet matching may potentially frustrate current ethics-motivated initiatives, impair established patient-practitioner relationships, and impede functional aspects of resource

allocation. Therefore, the introduction of eplet-based allocation schemes needs to be careful, intentional, and collaborative (47). Special care should be given to the legality of new allocation systems, which may require changes to regulation, ethical guidance, and/or professional practice standards. Having clear, fair, and equitable guidelines is essential to maintaining public trust, organ supply, and the proper operation of allocation systems (70,71).

In keeping with the ethical tenets set out in professional guidelines, eplet-based allocation regimes should use a well-defined framework that pursues such guiding principles as justice, equal opportunity, personal autonomy, transparency and utility. While making continued efforts to address the shortage of donations, professional medical bodies should embrace the potential of eplet matching to predict better patient outcomes and resource allocation. In the ongoing effort to use health care resources prudently and effectively (71), any further shift towards algorithmic decision-making should be tempered by ethical principles within the health care profession, social values respecting basic human rights, and the highest ethical standards (56,72,73). Such considerations will be key to retaining patient-centred care and some degree of physician advocacy for transplant candidates and recipients. While physicians championing their patients' wellbeing can disrupt allocation systems, such physician advocacy is also emblematic of the highest virtues in modern medicine – care and compassion. Fortunately, these virtuous ends are not necessarily antithetical to more effective and precise allocation schemes, which can be designed to complement the patient-physician relationship and improve population-level outcomes.

Reçu/Received: 16/01/2023
Publié/Published: 27/06/2023

Remerciements
Dr Sandal a reçu une subvention d'Amgen Canada pour améliorer la transplantation rénale à partir de donneurs vivants et les résultats des patients souffrant d'une défaillance du greffon.

Acknowledgements
Dr. Sandal received a grant from Amgen Canada to improve living donor kidney transplantation and the outcomes of patients with graft failure.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Lise Levesque

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Évaluation/Peer-Review: Massimo Mangiola & Yann Joly

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

NJ Abernethy. *Can J Bioeth / Rev Can Bioeth.* 2023;6(2):43-52

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Institutional Conscientious Objection to Medical Assistance in Dying in Canada: A Critical Analysis of the Personnel-Based Arguments

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Résumé

Le débat fait rage sur la question de savoir si les gouvernements provinciaux et territoriaux du Canada doivent autoriser les établissements de santé à s'opposer en conscience à la fourniture d'une aide médicale à mourir (AMM). Il est probable que cette question se retrouvera bientôt devant les tribunaux à la suite de contestations de la part de patients, de cliniciens ou de groupes de défense des droits tels que Mourir dans la dignité Canada. Dans ce cas, l'une des questions clés pour les tribunaux sera de savoir si le fait d'autoriser l'objection de conscience institutionnelle (OCI) à l'AMM respecte (c'est-à-dire prend dûment en compte) les consciences des établissements de santé qui s'y opposent, considérés comme des entités unitaires. Toutefois, cette question a été étudiée en profondeur dans d'autres publications scientifiques. Une autre question clé n'a pas été suffisamment explorée. En particulier, le précédent établi par la décision de la Cour suprême du Canada dans l'affaire *Loyola High School c. Québec (Procureur général)* suggère que les tribunaux examineront si le fait d'autoriser l'OCI à l'AMM respecte les consciences du *personnel* des établissements de santé qui s'y opposent. Ma réponse à cette question est non, c'est-à-dire que le fait de permettre l'OCI à l'AMM témoigne d'un mépris excessif pour certaines consciences et d'une considération excessive pour d'autres. Pour justifier cette réponse, j'analyse les arguments qui soutiennent que l'autorisation d'OCI dans les soins de santé respecte les consciences du personnel des établissements de santé qui s'y opposent. Ma conclusion est qu'aucun de ces arguments fondés sur le personnel n'aboutit dans le cas de l'OCI à l'AMM au Canada. Certains échouent parce qu'ils se trompent sur la nature de la conscience et de la complicité. D'autres échouent parce qu'ils contredisent les positions des partisans des arguments sur l'objection de conscience des prestataires de soins de santé individuels. D'autres encore échouent parce qu'elles sont incohérentes sur le plan interne.

Mots-clés

objection de conscience institutionnelle, aide médicale à mourir, soins de santé financés par des fonds publics, liberté de conscience, personnel de santé

Abstract

Debate rages over whether Canadian provincial and territorial governments should allow healthcare institutions to conscientiously object to providing medical assistance in dying (MAiD). This issue is likely to end up in court soon through challenges from patients, clinicians, or advocacy groups such as Dying With Dignity Canada. When it does, one key question for the courts will be whether allowing institutional conscientious objection (ICO) to MAiD respects (i.e., shows due regard for) the consciences of the objecting healthcare institutions, understood as unitary entities. This question has been thoroughly explored elsewhere in the academic literature. However, another key question has been underexplored. Specifically, precedent set by the Supreme Court of Canada's decision in *Loyola High School v. Quebec (Attorney General)* suggests that the courts will consider whether allowing ICO to MAiD respects the consciences of the *personnel* within objecting healthcare institutions. My answer to this question is no, by which I mean that allowing ICO to MAiD shows undue disregard for some consciences and undue regard for others. To justify this answer, I analyze the arguments that hold that allowing ICO in healthcare respects the consciences of the personnel within objecting healthcare institutions. My conclusion is that none of these personnel-based arguments succeed in the case of ICO to MAiD. Some fail because they are wrong about the nature of conscience and complicity. Others fail because they contradict the arguments' proponents' positions on conscientious objection by individual healthcare providers. Still others fail because they are internally inconsistent.

Keywords

institutional conscientious objection, medical assistance in dying, publicly funded healthcare, freedom of conscience, healthcare personnel

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INTRODUCTION

Since the 2016 legalization of medical assistance in dying (MAiD) in Canada, many publicly funded[1] healthcare institutions have been conscientiously objecting (i.e., conscientiously refusing)[2] to provide MAiD. For example, between June 2016 and the end of 2019, in Alberta alone 125 patients were transferred out of conscientiously objecting healthcare institutions in order to get MAiD (1). However, some provincial governments – namely, Nova Scotia (2) and Prince Edward Island (3) – prevent

[1] In this paper, I focus on *publicly funded* healthcare institutions (by which I mean healthcare institutions that receive any amount of government funding, in any form) because I agree with commentators like Wayne Sumner who argue that public funding is what gives governments the pro tanto right to tell healthcare institutions which services to provide (1). In short, the case for allowing ICO by fully privately funded healthcare institutions is too prima facie strong to spend much time on. Besides, such institutions are vanishingly rare in Canada (1).

[2] Throughout this paper, whenever I say "conscientious objection" (by institutions or people), I mean "conscientious refusal." I use the former phrase because it is more popular than the latter in the academic literature, although I acknowledge that the latter is more accurate.

ISSN 2561-4665

publicly funded healthcare institutions from conscientiously objecting to MAiD, and Quebec does the same but excludes palliative care hospices for the time being (4). There is an ongoing debate about this issue, i.e., whether governments should allow institutional conscientious objection (ICO) in healthcare. This debate's two main themes are 1) patient access to healthcare services and 2) the consciences *of* objecting healthcare institutions, understood as unitary entities. Regarding the first theme, supporters argue that preventing ICO indirectly decreases patient access to healthcare services in general by causing objecting healthcare institutions to close (5-7). By contrast, opponents argue that allowing ICO to a healthcare service directly decreases patient access to the healthcare service (1,8-14). Regarding the second theme, supporters of ICO argue that healthcare institutions are agents that have consciences and thus deserve to be allowed to engage in conscientious objection (15-18). By contrast, opponents of ICO argue that healthcare institutions lack consciences (19-26). I do not discuss these issues in this paper because they have been thoroughly explored in the academic literature.

Instead, I discuss an underexplored third theme: the individual consciences of the individual personnel within objecting healthcare institutions. Specifically, I seek to answer the following question: does allowing ICO to MAiD respect (i.e., show due regard for) the consciences of the personnel within objecting healthcare institutions? Unfortunately, there is no authoritative definition of what constitutes a healthcare institution's "personnel." Indeed, not all commentators even use this term. However, most who do use this term focus on leaders (e.g., administrators, trustees, and directors) and individual healthcare providers (e.g., physicians, pharmacists, and nurses), so I follow suit and thus do not discuss non-medical staff (e.g., hospital janitors). In particular, for reasons that will become apparent later, I focus on three types of personnel within anti-MAiD healthcare institutions: 1) anti-MAiD leaders who want their institution to conscientiously object to MAiD, 2) pro-MAiD[3] individual healthcare providers who want to provide MAiD to eligible requesters but who would be prevented from doing so if their institution conscientiously objects to MAiD, and 3) anti-MAiD individual healthcare providers who want their institution to conscientiously object to MAiD. One might object that small morally cohesive anti-MAiD healthcare institutions (e.g., a private practice group consisting of several anti-MAiD doctors) have no type 2 personnel. However, like some other commentators (27), I exclude these institutions from this paper's scope, for two reasons. First, these institutions are a minor part of the contemporary Canadian healthcare system, which is characterized by morally non-cohesive institutions like hospitals (25). Second, Elizabeth Sepper has already sufficiently analyzed when to allow conscientious objection by morally cohesive institutions (25).

The relationship between ICO and personnel's consciences has been underexplored both in general and especially in the context of MAiD in Canada. For example, the only journal article that specifically analyzes whether to allow ICO to MAiD in Canada devotes just one paragraph to this topic, and the author considers only the main anti-ICO personnel-based argument, ignoring the many pro-ICO personnel-based arguments (27). This matter merits much more attention for two reasons. First, personnel's consciences are morally important; our society values conscience (particularly in healthcare), so these consciences should be front and centre in our discussion about ICO to MAiD. Second, in addition to moral importance, personnel's consciences will likely soon be *legally* important. As I show in the next section, this is because the relationship between ICO to MAiD and the consciences of the personnel within objecting healthcare institutions is likely to be central to how the Canadian courts determine the constitutionality of allowing ICO to MAiD. However, before moving on to this discussion, I offer the following outline that summarizes the themes of this paper, so far:

Figure 1: Visual representation of this paper's relationship with ICO discourse

- ICO discourse's themes:
  - Patient access *(setting aside because sufficiently analyzed elsewhere)*
  - Institutions' consciences *(setting aside because sufficiently analyzed elsewhere)*
  - Personnel's consciences
    - Types of objecting institutions:
      - Morally cohesive *(setting aside because rare and sufficiently analyzed elsewhere)*
      - Morally incohesive
        - Types of personnel:
          - Anti-MAiD leaders
          - Pro-MAiD individual healthcare providers
          - Anti-MAiD individual healthcare providers
    - Importance:
      - Moral
      - Legal *(below)*

THE IMPORTANCE OF THE RELATIONSHIP BETWEEN ICO TO MAID AND PERSONNEL'S CONSCIENCES IN THE CANADIAN LEGAL CONTEXT

To begin with, ICO to MAiD is likely soon to be judicially scrutinized. The debate could end up in court in many ways, such as 1) a private interest standing case against a forced transfer, 2) an appeal board challenge to a denial of privileges for a MAiD provider, and 3) a public interest standing case (e.g., *Carter v. Canada*) against forced transfers. However, the most likely situation will be anti-ICO advocates convincing governments to require healthcare institutions (via legislation, directives, etc.)

[3] Throughout this paper, whenever I say "pro-MAiD," I mean supporting providing MAiD to eligible requesters. Furthermore, all hypothetical cases that I discuss are assumed to involve eligible requesters.

to provide MAiD. This way has a proven track record. For example, both public and private pressure (including media attention and the threat of a legal challenge) convinced the Nova Scotia Health Authority to disallow St. Martha's Hospital from conscientiously objecting to MAiD (28). Recently, this advocacy has been proliferating. For example, Dying With Dignity Canada is encouraging the public to tell the British Columbian government to require all publicly funded healthcare institutions to provide MAiD (29). If such efforts are successful, some objecting healthcare institutions would likely legally challenge the government's anti-ICO actions. This can be extrapolated from how the Delta Hospice Society (a formerly publicly-funded British Columbian palliative care organization) fought all the way to the Supreme Court of Canada in a failed attempt to avoid being required to provide MAiD (30). However, to be clear, this court case was ultimately about the Delta Hospice Society's membership bylaws, not about ICO per se (31).

If ICO to MAiD does end up in court through a challenge to a requirement to provide MAiD, objecting healthcare institutions would probably base their main legal arguments on section 2(a) of the *Canadian Charter of Rights and Freedoms*, which entitles everyone to "freedom of conscience and religion" (32). This can be inferred from how supporters of conscientious objection by religious physicians based their main legal arguments on section 2(a)[4] in the leading Canadian court case about conscientious objection by individual healthcare providers: *Christian Medical and Dental Society of Canada v. College of Physicians and Surgeons of Ontario* (33). For context, this case was about whether the College of Physicians and Surgeons of Ontario breached the *Charter* when it required objecting physicians to provide effective referrals (33).

What would section 2(a)-based arguments for allowing ICO to MAiD look like? There are two main arguments that an objecting healthcare institution could make. First, it could argue that it itself is entitled to protection under section 2(a). In other words, an objecting healthcare institution could argue that it – as a unitary entity – deserves freedom of conscience and/or religion. Second, the institution could argue that allowing ICO to MAiD respects the freedom of conscience and/or religion of its personnel. While an objecting healthcare institution would probably make both arguments, the courts would likely look first to the second. To see why, we must turn to the leading Canadian court case about the communal aspect of religious freedom: *Loyola High School v. Quebec (Attorney General)*.

In this case, the majority of a seven-judge panel of the Supreme Court of Canada concluded that the Quebec Minister of Education, Recreation and Sport was wrong to require that Loyola High School – a Catholic institution – teach about Catholicism from a neutral perspective (34). Of note, the key finding for the majority was that the Minister's requirement unnecessarily limited the religious freedom of Loyola's *personnel*. Unlike the three judges who concurred partially in the result, the four-judge majority explicitly avoided the question of whether Loyola – as a unitary entity – has section 2(a) rights. Furthermore, even the three judges who argued that Loyola *does* have section 2(a) rights reasoned that it has these rights by virtue of how protecting its section 2(a) rights protects the rights of its personnel (34). In short, all seven judges agreed that the personnel's section 2(a) rights underlie why Loyola should be allowed to teach about Catholicism from a Catholic perspective. Therefore, it is legally important to consider whether allowing ICO to MAiD respects the freedom of conscience and/or religion of the personnel within objecting healthcare institutions.

Given this importance, one may ask why this paper focuses on conscience rather than religion. There are two reasons. The first is that, unsurprisingly, commentators on institutional *conscientious* objection tend to focus on conscience, so, given that this paper analyzes existing arguments, I follow suit. The second reason is that conscience-related analysis applies to both secular and religious healthcare institutions, not only religious ones. While most objecting healthcare institutions are religious, some are secular. For example, secular healthcare institutions were responsible for 16 of the previously mentioned 125 ICO-to-MAiD-induced transfers in Alberta (1). These institutions would have no choice but to appeal to freedom of conscience, so analyzing ICO only in terms of religious freedom would exclude these institutions.

METHODOLOGY

Having explained *why* this paper seeks to answer whether allowing ICO to MAiD respects the consciences of the personnel within objecting healthcare institutions, I will now describe *how* this paper will do so. To begin with, I present the arguments that allowing ICO in healthcare *in general* (i.e., not only for MAiD) respects the consciences of the personnel within objecting healthcare institutions. I consider general ICO arguments rather than those specific to MAiD because few if any commentators frame their arguments as exclusive to MAiD. Next, I sort the pro-ICO personnel-based arguments into three groups, as defined below. Groups 1 and 2 hold that allowing ICO respects the consciences of 1) leaders who want to engage in ICO and 2) personnel who want ICO to be engaged in, respectively. Group 3 holds that allowing ICO respects personnel's consciences because institutional conscience is a manifestation of personal conscience. Group 1 and Group 3 are less popular than Group 2 (and thus less fleshed out in the academic literature), but I nonetheless consider them because I want to consider *all* relevant pro-ICO arguments. Drawing on the anti-ICO personnel-based arguments, I then show that none of these groups succeed in justifying the case for ICO to MAiD. Ultimately, I conclude that allowing ICO to MAiD does not respect the consciences of the personnel within objecting healthcare institutions. That is, allowing ICO to MAiD shows undue disregard for the consciences of pro-MAiD individual healthcare providers and undue regard for the consciences of anti-MAiD leaders and anti-MAiD individual healthcare providers. Therefore, the ICO discourse related to personnel does not justify allowing ICO to MAiD.

[4] The appellants also argued that the effective referral requirement infringed physicians' section 15(1) equality rights, but the courts dismissed this argument (33).

DISCUSSION

Group 1: Allowing ICO Respects the Consciences of Leaders Who Want to Engage in ICO

The first group of pro-ICO personnel-based arguments, which I call Group 1, holds that allowing ICO respects the consciences of the anti-MAiD leaders of objecting healthcare institutions. In the academic literature, two main arguments fit into this group. The first is from Nikolas T. Nikas, who supports allowing ICO by arguing that "[a]ny health-care institution… should also be protected from coercion and discrimination. As institutions, they reflect the conscience of their guiding boards…" (35, p.46). In other words, prohibiting ICO prevents boards from exercising their consciences by prohibiting the provision of particular services.[5] The second argument is made by William L. Allen and David B. Brushwood, who support allowing ICO (albeit in the case of privately owned pharmacies) by arguing that the employer's conscience takes priority over the employee's conscience (36).

Drawing on a committee opinion by the American College of Obstetricians and Gynecologists (ACOG) (37), my response to the Group 1 arguments is that a leader cannot conscientiously object to a subordinate providing a service. Someone's freedom of conscience concerns what they do, not what others do, as the ACOG clearly explains: "the logic of conscience, as a form of self-reflection on and judgment about whether one's own acts are obligatory or prohibited, means that it would be odd or absurd to say "I would have a guilty conscience if she did 'x.'"" (37, p.1204) In other words, one can conscientiously object to doing something, but one cannot *conscientiously* object to someone else doing something.

Repurposing Christopher Kaczor's argument that the leaders of healthcare institutions are complicit in facilitating the actions of their subordinates (38), I believe that Nikas, Allen, and Brushwood would probably respond to the above counterargument by rejecting its assumption that objecting leaders want to conscientiously object to their subordinates providing particular services. Specifically, the Group 1 proponents would probably argue that objecting leaders actually want to conscientiously object to *doing things that make them complicit in* their subordinates providing particular services. For example, one might argue that preventing ICO forces leaders to enable the provision of particular services by giving their subordinates functional support (e.g., the use of medical supplies and staff).

Although the above response might be applicable in cases like ICO to surgical abortion, it is not applicable in the case of MAiD. To show why, I turn to a Group 2 proponent and the main supporter of ICO to MAiD in Canada: Sean T. Murphy. He describes how – unlike for services such as surgical abortion – "it is possible for non-institutional practitioners to provide euthanasia or assisted suicide to patients in a facility without requiring facility resources or the assistance or direct participation of facility staff" (39, p.1). I would extend this observation by noting that it is also possible for *institutional* practitioners to provide MAiD in a facility without requiring facility resources or the assistance or direct participation of other facility staff. Thus, with or without ICO, leaders can avoid *directly* enabling the provision of MAiD. To be fair, without ICO, leaders cannot avoid *indirectly* enabling the provision of MAiD – e.g., by giving physicians privileges and hiring nurse practitioners – but I contend that this enablement is too indirect to engender meaningful complicity (i.e., enough involvement to entitle leaders to conscientiously object to doing these actions). This line between meaningful and non-meaningful complicity must be drawn because most actions are *somewhat* interconnected, so most people are *somewhat* complicit in most actions, but people are not entitled to conscientiously object to doing most actions. For example, an anti-MAiD miner is not entitled to conscientiously object to mining metals that they know will end up in a needle that will be used to provide MAiD because the enablement is too indirect.[6] Some may disagree with me here and argue that actions like giving physicians privileges and hiring nurse practitioners are in fact direct enough to engender meaningful complicity. However, even if this were true, it would not justify allowing ICO to MAiD. To show why, I offer the following argument.

If the actions were direct enough, this would entail that leaders have a pro tanto conscientious right to decide whether their subordinates provide MAiD, but this right would have to be weighed against their subordinates' pro tanto conscientious right to decide whether to provide MAiD. The Group 1 proponents give no reasons to favour leaders' consciences, and there are three reasons to favour subordinates' consciences. The first is that, as Eva and Hugh LaFollette argue, consciences that are disrespectful of other consciences deserve less protection, all else being equal (40). As Daniel P. Sulmasy explains, "[t]o have a conscience is to commit oneself, no matter what one's self-identifying moral commitments, to respect for the conscience of others" (16, p.145). So, the leaders' consciences deserve less protection if they are disrespectful of their subordinates' consciences by preventing them from being able to decide whether to provide MAiD. The second reason is that, as Spencer L. Durland implicitly argues, consciences that are more directly involved in a decision deserve more protection regarding the decision, all else being equal (24). As Elizabeth Sepper explains, moral-integrity-related interests tend to scale to the directness of involvement (21), and this matters because protecting moral integrity is the main reason to respect conscience (41). So, the leaders' consciences deserve less protection regarding whether the subordinates provide MAiD because the leaders are less directly involved in the decision (21). The third reason is that there are more subordinates than leaders at most (if not all) healthcare institutions, so taking the choice away from the many and giving it to the few is disrespectful of personnel's consciences, in aggregate. In conclusion, the Group 1 arguments fail to justify allowing ICO to MAiD.

[5] In fairness to Nikas, I cut his quotation off early; he adds "or faith traditions" (35, p.46). However, I do not discuss the consciences of faith traditions because these are not personnel within healthcare institutions, so their consciences – if traditions can be said to have them – are beyond the scope of this paper.
[6] For more on this topic, see Murphy's discussion of morally significant causal contribution to wrongdoing (39).

Group 2: Allowing ICO Respects the Consciences of Personnel Who Want ICO to be Engaged in

The second group of pro-ICO personnel-based arguments, which I call Group 2, holds that allowing ICO respects the consciences of anti-MAiD personnel in objecting healthcare institutions who want to exercise their consciences by working in a community that follows their values (i.e., core moral beliefs).[7] In the academic literature, we can find proponents of five main arguments that fit into this group.[8] First, Mark R. Wicclair supports allowing ICO (in some cases) by arguing that, for conscientious reasons, "it can be important to physicians, nurses, pharmacists, and other personnel to be able to practice and work in a community that shares a commitment to a core set of goals, values, and principles" (5, p.131). Second, Lynn D. Wardle supports allowing ICO by arguing that "to deny [conscience clause] protection to health care institutions contradicts the central purpose of conscience clauses, which is to protect the moral sensibilities and deeply-held beliefs of the individuals who make up the institution" (45, p.186). According to Wardle, healthcare institutions effectuate their personnel's collective wills and purposes. Third, building on Wardle, Michael J. DeBoer supports allowing ICO by arguing that "[i]nstitutions are created… to [pursue] a particular mission or purpose (such as carrying out the healing ministry of the church), and the values and moral perspectives of the individuals who associate through an organization are reflected in the organization's identity and conscience" (7, p.1275). Fourth, Murphy supports allowing ICO by arguing that "it makes no sense to hold that a person is entitled to exercise freedom of conscience individually, but loses that freedom the moment he joins with someone else in a collective enterprise, especially one meant to put into practice beliefs informing the exercise of that freedom" (39, p.4). Fifth, Steven H. Miles, Peter A. Singer, and Mark Siegler support allowing ICO by arguing that people have a conscientious right to "affiliate in distinct moral communities – voluntary associations of people who share a common view of the moral good," in this case, a common healthcare philosophy (46, p.49).

My response to the Group 2 arguments is that they are inconsistent with the positions of Group 2 proponents on some cases of *personal* conscientious objection (i.e., conscientious objection by individual healthcare providers).[9] To understand why, consider the following two cases. First, imagine an anti-MAiD healthcare institution with a pro-MAiD physician whose conscience tells them that they must provide MAiD. If they do so, this would be what I call personal conscientious *provision*. The Group 2 arguments entail that this institution should be allowed to engage in ICO by preventing this physician from conscientiously providing MAiD. Thus, the Group 2 arguments subordinate this physician's conscience to the consciences of however many of this institution's personnel want to work in a community where everyone follows anti-MAiD values. Now imagine the inverse case, that of a pro-MAiD healthcare institution with some pro-MAiD personnel who want to work in a community where everyone follows pro-MAiD values. At this institution, there is an anti-MAiD physician whose conscience tells them that they must not provide MAiD. Because the Group 2 proponents support protecting personal conscientious objection regardless of what other personnel want (7,45,47,48), the Group 2 proponents would support requiring the institution to allow personal conscientious objection in this case. Thus, the Group 2 proponents would prioritize the anti-MAiD physician's conscience over the consciences of however many of the institution's personnel want to work in a community where everyone follows pro-MAiD values. As the above two cases show, the Group 2 proponents want to have it both ways. In the case of personal conscientious *provision*, they prioritize the consciences of other personnel over the conscience of the physician in question, whereas, in the case of personal conscientious *objection*, they prioritize the conscience of the physician in question over the consciences of other personnel.[10] This priority reversal is arbitrary. Interestingly, some ICO supporters agree with me here. For example, Group 1 proponents Allen and Brushwood concede that personal conscientious provision matters as much as personal conscientious objection (36).

Repurposing an argument by Murphy et al., I believe that the Group 2 proponents would probably respond to the above counterargument by arguing that this priority reversal is non-arbitrary because personal conscientious objection matters a lot (and thus cannot be outweighed by the consciences of other personnel), whereas personal conscientious provision matters less (and thus *can* be outweighed by other personnel's consciences). Specifically, Murphy et al. give two main reasons[11] why the bar for preventing personal conscientious objection is much higher than the bar for preventing personal conscientious provision (50). First, they argue that personal conscientious provision requires more of society (e.g., social resources) than does personal conscientious objection. Second, Murphy (and Genuis) claim that preventing personal conscientious objection seriously harms the would-be objector, whereas preventing personal conscientious provision does not harm the would-be provider much, if at all (49).

Murphy et al.'s reasons are inapplicable in the case of ICO to MAiD. The first is inapplicable because personal conscientious provision of MAiD requires less of society than personal conscientious objection to MAiD, both in terms of reducing referral

[7] Interestingly, the Group 2 arguments have an analog in *Loyola*; the majority of the judges concluded that allowing Loyola High School to control how it teaches about Catholicism respects its personnel's religious freedom because they became members of the institution to collectively manifest and transmit their religious beliefs, and the other judges echoed this sentiment (34).

[8] Robert K. Vischer advances an argument somewhat similar to the Group 2 arguments (42), so one might ask why I do not include him in this group. My answer is that Vischer's approach to conscience is fundamentally different because he opposes government protection of conscientious objection by individual healthcare providers (43). Furthermore, this is why I do not discuss his approach elsewhere in this paper; Group 2 proponent Murphy has already shown that this position entails that Vischer's approach violates the consciences of the personnel within healthcare institutions (44).

[9] This counterargument is heavily inspired by the anti-ICO argument of Spencer L. Durland (24).

[10] The Group 2 proponents might try to circumvent this counterargument by arguing that anti-MAiD healthcare institutions should engage in ICO differently – specifically, by only accepting anti-MAiD personnel – which would admittedly avoid the problem of having to prevent personnel from providing MAiD. However, this circumvention attempt would fail because it falls victim to a similar counterargument, given that the Group 2 proponents oppose pro-MAiD healthcare institutions only accepting pro-MAiD personnel (45).

[11] In another article, Murphy and Genuis give more reasons, specifically, reasons regarding moral integrity and moral responsibility (49). However, Group 2 proponent Wicclair disproves such reasons (41). For more of the debate on positive and negative conscience claims, see Volume 21, Issue 8 of The American Journal of Bioethics as well as Volume 31, Number 2 of The Journal of Clinical Ethics.

costs (administrative and often transportive) and in terms of expediting MAiD and thus reducing end-of-life (societal) healthcare costs (51). The second reason is inapplicable because preventing personal conscientious provision of MAiD often seriously harms the physician. As Jennifer D. Dorman and Shelley Raffin Bouchal outline, "[a]ttributes of moral distress in the context of MAiD focus on knowing the right course of action but being unable to act, especially when conflict or suffering occurs" (52, p.320). Examples of moral distress associated with wanting to provide MAiD can be found in Stefanie Green's book, *This Is Assisted Dying: A Doctor's Story of Empowering Patients at the End of Life*, in which she discusses cases where she has been constrained from providing MAiD to patients who were suffering intolerably (53). Importantly, preventing personal conscientious provision of MAiD often morally injures the physician as much as preventing personal conscientious objection to MAiD. To show why, I again turn to Group 1 proponents Allen and Brushwood, who concede that many individual healthcare providers "feel a sense of obligation to enable a terminally ill patient to end her suffering humanely that is no less profoundly felt than the objector's sense that the same act is morally reprehensible" (36, p.16). Therefore, the Group 2 proponents must either give up on supporting allowing ICO to MAiD or give up on supporting protecting personal conscientious objection regardless of the wishes of other personnel.

Some may disagree with the above analysis, so I offer a further independent counterargument: the Group 2 arguments cherry-pick which personnel's consciences to consider. Specifically, these arguments ignore the consciences of however many of an anti-MAiD healthcare institution's personnel want to work in a community where those who are eligible to provide MAiD are allowed to choose whether to do so. After all, often not all personnel working in an anti-MAiD healthcare institution are anti-MAiD, and often not all personnel who are anti-MAiD want all other personnel to be anti-MAiD. In fact, sometimes *most* personnel within an anti-MAiD healthcare institution disagree with the institution's anti-MAiD values, in which case allowing ICO to MAiD is *definitely* disrespectful of personnel's consciences, in aggregate. For example, as Ben A. Rich explains in the context of ICO by Catholic hospitals, "because of the expansion of Catholic healthcare through acquisition of previously secular or community-operated hospitals, it is less likely than ever before that the typical hospital in a Catholic system is one in which all or even a majority of the healthcare professionals on the staff… are practicing Catholics" (8, p.218). Studies lend credence to this observation. For example, a 2011 study of obstetrician-gynecologists found that "[p]hysicians who identify as Roman Catholic are no more likely (when the data are controlled for other characteristics) to work in a Catholic hospital… compared with those who report no religious affiliation" (54, p.72.e4). Extending this observation beyond Catholic hospitals, Elizabeth Sepper explains that most modern healthcare institutions are morally diverse because they "do not represent associations based on moral convictions" (25, p.1545). Instead, they represent associations based on a wide range of factors – including pay, convenience, and working conditions – all of which factor into employees' and affiliates' decisions about the healthcare institutions in which they choose to work (25). In many cases, then, allowing ICO to MAiD arbitrarily privileges the consciences of a minority of the personnel within an objecting healthcare institution. In conclusion, the Group 2 arguments fail to justify allowing ICO to MAiD.

Group 3: Allowing ICO Respects the Consciences of Personnel Because Institutional Conscience is a Manifestation of Personal Conscience

The third and final group of pro-ICO personnel-based arguments, which I call Group 3, holds that allowing ICO respects the consciences of the personnel within objecting healthcare institutions because institutional conscience is an *action* (specifically, a manifestation of personal conscience), rather than something that institutions *have*. By analogy, one can conceptualize school spirit not as something that a school possesses but rather as a set of practices in which its students participate (sometimes willingly and sometimes unwillingly). In the academic literature, one main commentator fits into Group 3: Elliot Louis Bedford.[12] He defines institutional conscience as "a judgment of practical reason made by an individual on behalf of an institution, applying institutional norms to a particular situation" (56, p.265). By "norms," he means "normative criteria," which can be established by things like policies (56). Based on these definitions, Bedford argues that "doing" institutional conscience is a manifestation of personal conscience, in the same way that personal conscientious objection is a manifestation of personal conscience (56). For Bedford, the main difference is just that "doing" institutional conscience applies institutional norms to a situation (even if one disagrees with those norms), whereas personal conscientious objection applies one's own norms to a situation (56). Therefore, the obvious implication is that protecting institutional conscience – by which Bedford seems to mean allowing ICO – respects the personal consciences of the personnel within objecting healthcare institutions. For the sake of argument, the rest of this section grants Bedford's conception of institutional conscience, although I will make the case that it does not entail what he claims it does.

My response to the Group 3 arguments is that Bedford's conception of institutional conscience entails the existence of a type of institutional conscience that goes against allowing ICO by healthcare institutions. To see why, consider the following. Bedford argues that "the activity of institutional conscience is a pervasive, ineradicable element of all human institutions, not just Catholic hospitals" (56, p.258). This entails the existence of not only healthcare-institution-specific institutional conscience but also professional-organization-specific institutional conscience. For the sake of simplicity, when I refer to "healthcare institutions" I am excluding professional organizations, even though they are institutions relating to healthcare. By "professional organization," Bedford and I mean bodies like the Canadian Medical Association (CMA), the Canadian Nurses Association, and regulatory colleges for physicians and nurses. By "professional-organization-specific institutional conscience," I mean – using Bedford's language – a judgment of practical reason made by an individual, applying a professional organization's norms

[12] Grattan T. Brown also advances a Group 3 argument (55), but this argument is unclear, as noted by Bedford (56) – so I focus on Bedford's argument, which is clearer.

to a particular situation. What does this look like? For example, most Canadian physicians[13] are bound to follow the norms (specifically, "virtues, values, and principles") in the CMA Code of Ethics and Professionalism (68, p.1). Of note for the ICO discourse, these physicians must obey the fundamental commitment of respecting patient autonomy and the professional responsibility of acting according to one's conscience, by which the CMA means following one's moral/religious beliefs (68,69). With these norms in mind, consider again the case of an anti-MAiD healthcare institution with a physician who wants to conscientiously provide MAiD, and this time assume that they are a CMA member. These norms entail that they should provide MAiD (and thereby both follow their pro-MAiD moral beliefs and respect the eligible requester's autonomy), and there are no CMA norms that contradict this entailment.[14] Indeed, the CMA explicitly supports physicians who conscientiously provide MAiD when legal (50). Thus, in the case in question, "doing" healthcare-institution-specific institutional conscience (i.e., following the institution's anti-MAiD norms) would go against "doing" professional-organization-specific institutional conscience (i.e., following the CMA's pro-MAiD norms). Therefore, allowing ICO to MAiD prevents physicians from "doing" professional-organization-specific institutional conscience. This matters because, if we grant Bedford's claim that preventing physicians from "doing" institutional conscience violates personal conscience, then we arrive at the conclusion that allowing ICO to MAiD violates personal conscience.

Interestingly, Bedford basically concedes all the above analysis (except the very last part). In response to anti-ICO arguments from medical professionalism, he concedes that what I call professional-organization-specific institutional conscience is indeed a type of institutional conscience according to his framework (70). Granted, Bedford says this about the American Medical Association and the ACOG (56), but there are no reasons to treat the CMA differently. Furthermore, he concedes that professional-organization-specific institutional conscience often goes against healthcare-institution-specific institutional conscience: "arguments from professionalism presuppose the validity of the concept of institutional conscience. Hence, the debate is… a matter of *which* institutional conscience" (70, p.420). With all this in mind, it is clear that Bedford's response to the above counterargument would simply be that healthcare-institution-specific institutional conscience takes priority over professional-organization-specific institutional conscience.

However, Bedford gives no reasons for this prioritization, and there are good reasons to flip it in the previously discussed case of an anti-MAiD healthcare institution with a physician who is a CMA member and who wants to conscientiously provide MAiD. Recall that the question here is as follows: *which of the two previously discussed institutional consciences is a more protection-worthy manifestation of the physician's personal conscience?* To answer this question, we must determine which of the two associated sets of norms is more important for the physician's personal conscience, and I propose two ways to determine this (both of which yield the same result). The first way is prioritizing the set of norms that the physician wants to follow. In the case in question, the physician wants to provide MAiD, so they want to follow the CMA's pro-MAiD norms. Inspired by Stefan Sciaraffa's argument that identifying with a role yields moral reasons to obey its obligations (71), the second way is prioritizing the set of norms with which the physician more strongly identifies.[15] In the case in question, this is probably the CMA's norms because these are closer to the physician's pro-MAiD values, and because the CMA's norms guide a physician's actions throughout their whole career (and wherever they work), whereas a particular healthcare institution's norms guide their actions only when working at that institution. This latter point matters because many physicians work at multiple healthcare institutions during their careers, and some work at multiple healthcare institutions at once. From the above analysis, it follows that the CMA's norms are probably more important and thus CMA-specific institutional conscience is a more protection-worthy manifestation of the physician's conscience. Therefore, respecting their conscience requires empowering them to "do" CMA-specific institutional conscience, i.e., empowering them to conscientiously provide MAiD. Allowing ICO to MAiD disrespects the consciences of physicians (and other personnel), so the Group 3 arguments fail to justify allowing ICO to MAiD.

CONCLUSION

None of the three groups of pro-ICO personnel-based arguments show that allowing ICO to MAiD respects the consciences of the personnel within objecting healthcare institutions. In fact, as shown throughout this paper, the main impact that allowing ICO to MAiD has on personnel's consciences is a negative one: disrespect for the consciences of personnel who want to conscientiously provide MAiD to eligible requesters.

[13] For context, there are two main ways that Canadian physicians can be obligated to follow these norms. The first is by becoming one of the tens of thousands of CMA members. The second is by working in a province or territory whose college of physicians and surgeons (or territorial equivalent) requires physicians to follow the CMA Code of Ethics and Professionalism. The vast majority of these colleges (57-64) – and Yukon's Medical Council (65) – do so. Furthermore, the colleges that do not do so require physicians to follow similar norms, at least insofar as patient autonomy is concerned (66,67).

[14] Moreover, one could argue that this entailment is buttressed by other CMA norms, such as the fundamental commitment to benefit patients (68). However, this argument is beyond the scope of this paper as it gets into the separate discussion about whether MAiD benefits eligible requesters.

[15] One may object that this second way is the same as the first because people always want to follow the set of norms with which they more strongly identify. However, this objection is wrong because someone can strongly identify with a set of norms as a whole (call it set X) despite strongly disagreeing with one of its members (call it norm X_1), and they can weakly identify with another set as a whole (call it set Y) despite strongly agreeing with one of its members (call it norm Y_1). In cases that mainly concern norms X_1 and Y_1, they may want to follow set Y rather than set X, even though they more strongly identify with set X.

Reçu/Received: 28/02/2023
Publié/Published: 27/06/2023

Remerciements
L'auteur remercie Udo Schüklenk, Françoise Baylis, Brad Abernethy, Ian D. Wolfe et Guido Calderini pour leurs commentaires utiles sur les versions préliminaires.

Acknowledgements
The author thanks Udo Schüklenk, Françoise Baylis, Brad Abernethy, Ian D. Wolfe, and Guido Calderini for providing useful comments on drafts.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Renata Iskander & Aliya Affdal

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

DN Wagner. *Can J Bioeth / Rev Can Bioeth.* 2023;6(2):53-65

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

For Women Only? Reconsidering Gender Requirements for Uterine Transplantation Recipients

Darren N. Wagner[a]

Résumé
La transplantation d'utérus est une procédure expérimentale qui n'est actuellement disponible que pour les femmes cisgenres souffrant d'une infertilité utérine absolue. Les cliniciens, les chercheurs et les défenseurs ont avancé la possibilité de fournir ces transplantations de qualité de vie aux femmes transgenres. Cet article examine les implications éthiques et pratiques de la suppression totale des exigences liées au sexe et au genre pour les receveuses de greffe d'utérus. Compte tenu des coûts et des risques importants, et des avantages modestes en termes de qualité de vie, les arguments éthiques qui s'opposent à ce que des transplantations d'utérus soient proposées à des personnes qui ne s'identifient pas comme des femmes, mais qui sont par ailleurs des receveuses appropriées, sont douteux et préjudiciables. Des transplantations d'utérus réussies avec des receveuses qui ne sont pas des femmes pourraient potentiellement diminuer le lien socioculturel entre la fonctionnalité de l'utérus et la féminité, qui est une motivation clé pour les femmes qui recherchent aujourd'hui cette procédure à haut risque.

Abstract
Uterine transplantation is an experimental procedure currently available only to cisgender women recipients suffering from absolute uterine factor infertility. Clinicians, researchers, and advocates have advanced the possibility of providing these quality-of-life transplantations to transgender women. This article examines the ethical and practical implications of removing sex- and gender-based requirements entirely for uterine transplantation recipients. Given the significant costs and risks, and the modest quality-of-life benefits, ethical arguments against offering uterine transplantations to people who do not identify as women but are otherwise suitable recipients are dubious and prejudicial. Successful uterine transplantations with non-women recipients could potentially diminish the socio-cultural connection between uterine functionality and womanhood, which is a key motivation for women now seeking this high-risk procedure.

Mots-clés
transplantation d'utérus, éligibilité du receveur, exigences de genre, cisgenre, transgenre

Keywords
uterine transplantation, recipient eligibility, gender requirements, cisgender, transgender

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INTRODUCTION

Nearly a decade since the first successful attempt, and after more than 70 reported procedures and 23 live births (1), there remain many unresolved ethical issues in human uterine transplantation (UTx). One of the more contentious issues is the criteria for eligible UTx recipients. In 2012, a group of clinician-researchers based at McGill University published "The Montreal Criteria for Uterine Transplantation," – referred to here as "Montreal Criteria" – outlining requirements for the procedure's proper conditions and patients (2). Eligible UTx recipients are genetic females[1] of reproductive age who suffer from absolute uterine factor infertility (AUFI), a condition estimated to affect about 1 in 500 women of childbearing age (1). In 2019, a UK-based research group published an argument that the procedure could clinically and ethically be offered to male-to-female transgender women (3). In 2021, researchers offered a proof-of-concept paper about the possibility of transgender women UTx recipients (4). In the same year, one of the authors of the Montreal Criteria co-wrote a revised ethical framework – referred to here as "Revised Criteria" – for UTx that expanded the category of eligible recipients to include transgender women (5). This change in the ethical framework for UTx purports to reflect shifting gender norms in sexual and reproductive medicine, which the authors of the Revised Criteria refer to as "advancing social circumstances" (5).

However, the justification for UTx is already tenuous, given the significant risks and costs, and the relatively modest quality-of-life benefits that correspond to patients' desires, expectations, and perspectives. Considering this context, UTx eligibility criteria that exclude a particular sex or gender would need a substantial technical justification or risk criticism for such discriminatory policy. Here, I explore whether these gender requirements can be justified with sound reasoning and evidence, and, if not, whether they should be discarded. In other words, I am asking: *should individuals who are neither cisgender women nor transgender women, but who otherwise meet all other clinical criteria, be eligible UTx recipients?* I argue that cisgender men, intersex people, nonbinary people, and transgender men – all of whom I collectively and inclusively refer to here as "non-women" (i.e., anyone who is neither a genetic female nor a self-identifying transgender woman) – should not be categorically deemed ineligible for UTx without absolute technical obstacles. Rather, given the modest, subjective benefits and considerable

[1] I note that "genetic female" is a technical term commonly used in scholarship on UTx eligibility. Here, when discussing transgender women, I adopt the terminology of cisgender women for parity's sake.

ISSN 2561-4665

risks and costs associated with UTx, non-women recipients should be welcomed as possibly decoupling the problematic association of uterine functionality with womanhood.

My analysis suggests that gender-based restrictions have little ethical foundation and undermine a potentially valuable contribution to the "advancing social circumstances" surrounding infertility and gender identity. Much of the justification for the therapeutic effects of UTx depends on socio-cultural norms and expectations. Without substantial technical obstacles or significantly more negative outcomes for non-women recipients, UTx procedures should not be made wholly inaccessible to that group. Indeed, part of the significance of UTx is its potential to separate reproductive capability from womanhood. Put differently, expanding UTx eligibility to include any sex or gender could effectively queer gestation (6-8).[2] This queering could alleviate the very socio-cultural expectations about uterine fertility that inspire much of the motivational desires, identity issues, and psychological harms in patients now seeking UTx.

This paper first details the context of UTx with a brief history and the current state of the field. I then outline some of the major ethical and policy issues special to UTx before examining how researchers have addressed gender criteria for UTx recipients. I explain the medical risks and therapeutic benefits of UTx to highlight the fraught ethical argument against widening the eligibility requirements to include non-women recipients. As stated, my thesis – that gender requirements for UTx recipients should be removed because they are ethically unjustifiable and socially undesirable – is framed by the specific social and medical contexts of UTx. For this purpose, I thoroughly discuss the risks and benefits of UTx. Any ethical analysis about the provision of a healthcare intervention like UTx must address the remarkable cost-benefit equation. I also presume that readers have varied background knowledge of UTx; therefore, I describe how the experimental procedure works and flag contextual details for the readers' benefit. I conclude by arguing against any strict gender- or sex-based criteria and suggest that the broader social value of UTx is the promise of decoupling gender statuses from reproductive functions.

A BRIEF HISTORY

Most scientific and philosophical articles published on UTx begin with a brief twenty-first-century history of the operation; rarely do they mention that the first such operation was performed on Lili Elbe, a Danish transgender woman who received a UTx in 1931 and tragically died shortly after from complications (9). Rarer still is a cultural history of the procedure, which predates modern medicine by many centuries. Indeed, the notion of a surgical operation to enable gestation can be traced back at least to the Greek myth of Zeus birthing Athena (10), through ideas of male-births in the Enlightenment (11), and into today's research on extracorporeal gestation (12). These omissions in the current medical narrative surrounding UTx highlight two salient points: the desire to gestate is deeply cultural and is not specific to one sex, gender, or vision.

Elbe's catastrophic procedure appears to have been followed by a decades-long pause in recorded UTx trials and experiments (9). Despite Elbe's significant place in the history of UTx, ethicists, scientists, and clinicians commonly recite a story that begins in Saudi Arabia in 2002 with the first *recent* attempted human UTx (13).[3] That graft had to be removed after necrosis set in. A Turkish team ventured the second recent attempt, which had a successful graft that led to three subsequent but unsuccessful pregnancies. In 2008, the ethics committee of the International Federation of Gynecology and Obstetrics (FIGO) classified UTx as an unethical procedure due to a lack of safety and effectiveness data (13). Then, in 2014, a Swedish team achieved a UTx breakthrough in a trial that included nine recipients with living relative donors (14), resulting in the first live birth and eight subsequent successful deliveries (15). Preceding this first successful attempt, researchers had conducted UTx experiments since at least the 1950s on several animal models (13), including mouse (16), rat (17), hamster (18), rabbit (19), dog (20), sheep (21,22), pig (23), and baboon (24). Even today, would-be UTx surgeons typically train on test animals for years before attempting a human operation (25). Despite costliness, riskiness, and ethical complications, many teams in diverse contexts have attempted the procedure, including national settings like China, US, Czech Republic, Brazil, Serbia, Germany, and India (25).[4] A cursory review of news media coverage of UTx shows distinct positivist and pronatalist themes, similar to those appearing in the scientific literature on UTx (26,27). For example, a headline from *USA Today* reads "Woman Born Without a Uterus Births 'Miracle Baby' after Transplant. Now She Offers Hope" (28). Notwithstanding these glowing headlines, ethical objections to UTx persist (13).

CURRENT STATUS AND PROMISE

UTx remains an experimental treatment but promises to soon become clinically available. While the indications for UTx recipients vary slightly between countries (25), all twenty-first-century clinical trials have required the recipient to be a genetic female with no medical contraindications to transplantation (29). The patient group is further defined as women without a uterus or with a non-functional uterus, which is estimated to represent 1.5 million women globally (30). This recipient group includes those with uterine agenesis, peripartum hysterectomy, hysterectomy for cancer, Mayer-Rokitansky-Kuster-Hauser (MRKH) syndrome, hysterectomy for benign pathologies, acquired uterine factor infertility, complete androgen insensitivity syndrome, and diethylstilbestrol exposure (25). One review study found that the median age of UTx recipients is 28 years (25); by contrast, a US survey revealed that 64 percent of women actively seeking UTx had acquired uterine factor infertility and a mean age of 33 years (25). Notably, there is a significant psychosocial component to meeting UTx eligibility requirements, as all recipients

[2] Wary of overburdening this article with feminist and queer scholarship, I am limiting my references on this point to useful entries into that robust field of criticism.
[3] Unique among all papers I reviewed, Zaami et al. note that the first attempt for a human female recipient occurred over 40 years ago, which happened "in the same Cape Town hospital where Cristian Barnard performed the first heart transplant," with the notable difference that the UTx "outcome was disastrous" (13).
[4] Many UTx programs and procedures were paused during the COVID-19 pandemic. I know of no active UTx program in Canada.

were deemed to be “emotionally stable” and have “durable relationships” (25). The primary motivation for women with AUFI seeking UTx is “the experience of pregnancy” (1).

UTx is a distinctive medical treatment that combines assisted reproductive technology (ART) with a quality-of-life (QoL) transplantation.[5] The procedure consequently engages two complex fields of medical ethics and regulation. Generally, ARTs are designed to treat difficulties in conception rather than gestation, which UTx provides (31). However, the UTx procedure also involves other ARTs such as *in vitro* fertilization (IVF) and embryonic implantation, which are integral to producing a post-transplant pregnancy. Typically, a single embryo transfer is performed six months after the UTx, which allows for surgical healing and a stabilized immunosuppression regime;[6] either vitrified or fresh embryos can now be used for implantation (1). For those who successfully gestate, delivery is by Caesarean section.

The transplantation procedure involves relatively lengthy and risky operations for donors and recipients. While currently not considered optimal, the use of dead donors resolves many risks and might represent a better option in the future. Live donors, who are typically family members or friends (25), undergo comparatively longer surgeries that average over eleven hours (31) but can be completed in as little as six hours (25). As some researchers highlight, UTx donors could potentially benefit from minimally invasive surgery by means of robotic-assisted laparoscopy (32). The operative time for recipients ranges from four to eight hours (22), and averages slightly above four hours. The recipient surgery involves a sub-umbilical midline incision. The vaginal vault is opened, and the graft is anastomosed to the vagina. The graft is then fixed and immobilized by attaching uterine ligaments to pelvic counterparts (32). A key component of successful transplantation is the vascular anastomosis for the graft’s blood supply (33).[7] The recipient is given long-term monitoring and kept on a regimen of immunosuppressives and antibiotics to maintain the graft, including before and during implantation and gestation. Unique to UTx, the graft is ephemeral as it is intended to be removed following completion of the desired number of gestations and deliveries. Discussions among researchers have recently emphasized the potential of UTx as part of the surgical interventions for gender affirmation in transgender women (3).

OVERVIEW OF ETHICAL ISSUES

UTx raises several ethical issues and engages many policy frameworks. The primary ethical issues include: 1) UTx’s status as a QoL transplantation (versus lifesaving transplantation); 2) the viability of alternatives for attaining parenthood such as adoption and surrogacy; 3) the risks for donors, recipients, and potential future children; 4) the costs and benefits for public healthcare and allocation of scarce health resources; and, the ultimate focus of this analysis that is specifically addressed in the subsequent section, access to the procedure. This purpose of overview is to acquaint the reader with the ethical landscape of UTx before advancing my argument that sex and gender requirements for UTx patients are ethically unjustifiable and socially undesirable. The argument here is that, given the tenuous ethical footing for UTx and the arbitrariness of sex/gender requirements for recipients, it is extremely difficult to justify making this procedure available to one class of recipient and not another.

If the procedure becomes clinically available, UTx will engage multiple medical guidelines and frameworks. In the UK, for example, it will be subject to such regulatory frameworks as the *Human Fertilisation and Embryology Act 1990*, the *Human Tissue Act 2004*, and the *Human Organ (Deemed Consent) Act 2019* (30). By comparison, clinical UTx in the US will engage the *National Organ Transplant Act*, the *Fertility Clinic Success Rate and Certification Act*, and several state-level regulations (34). If UTx were to be adopted in the Canadian context, regulatory frameworks that will be engaged include the *Safety of Human Cells*, the *Tissues and Organs for Transplantation Regulations*, the *Assisted Human Reproduction Act*, and provincial regulations for organ donation and transplantation.

1) Non-Lifesaving

Most organ and tissue donation and transplantation programs focus on critical or lifesaving procedures like heart, lung, and liver transplantations. Other transplant organs, such as kidneys, can be variously described as lifesaving, life-extending, or QoL enhancing. Others still are purely QoL interventions, including face, hand, corneal, larynx, penile, and uterine transplants. These kinds of transplants are ethically justified as enriching, rather than lifesaving (35). Of course, not all QoL transplantations offer the same therapeutic value. The impact of any type of procedure, on any given patient can, and should, be scored relative to costs and risks (36). Understanding what UTx achieves for different patients is crucial to determining the procedure’s ethical grounding and designing appropriate eligibility and resource allocation guidelines.

As described above, the primary motivation for those seeking UTx as opposed to other potential routes to parenthood is the experience of pregnancy (1). A secondary motivation is biological parenthood; however, there can be alternatives to attaining such an end depending on the socio-legal setting. A tertiary motivation, which applies differently to cisgender and transgender women, is gender identity affirmation (37). These QoL outcomes for UTx – the experience of pregnancy, biological parenthood, and gender identity affirmation – inform who is indicated as an appropriate UTx recipient. Crucially, non-women may readily share the first two goals. However, the inclusion of non-women as recipients could complicate how others perceive the third

[5] Procedures with similar combinations might include gonadal and penile transplants.
[6] Potentially teratogenic immunosuppression is stopped well before embryo transfer.
[7] Due to the amount of vasculature and ligamentous material excised and grafted, there is some debate about whether UTx is properly categorized and regulated as a vascular composite allograft or a solid organ transplant.

goal – gender identity affirmation. Successful UTx in non-women would challenge the conventional understanding of the uterus as a reproductive organ exclusive to women (38). This effect could be valuable in a broader social context, as the normalization of non-women as gestational carriers could alleviate the oppressive connotations that some people identify with uterine functionality and female identity (39).

The therapeutic rationale used to justify UTx is a subjective QoL improvement derived from social perspectives about pregnancy, parenthood, womanhood, and female reproductive bodies. For an individual, infertility is only harmful when certain desires and expectations exist. For those who do not want to have children, infertility can be a positive or neutral characteristic (40). However, in most medical and public contexts, infertility is regarded as a medical condition, which ascribes negative connotations to that relatively common characteristic.

The psychosocial parameters of UTx are clearly evidenced by the design and significance of recipient evaluations. Interviews of potential recipients are routinely multidisciplinary and focus on six domains: psychological well-being, relationships, managing childlessness, knowledge about UTx, relationship with the donor, and risk (25). Selected couples are deemed psychologically stable and experienced in handling difficulties together (25). Key areas of evaluation are the patient's history of compliance to medical regimens, body image, past adaptation to trauma, reasonable expectations, and adaptive coping skills (25). These requirements are designed to ensure the recipient will gain QoL benefits that supersede the procedure's inherent risks, including the risk of failing to achieve a viable pregnancy.

2) Alternatives

Much of the QoL improvements represented by UTx are the result of social, cultural, religious, political, and legal contexts. There is no discrete somatic condition being treated by UTx: no physical pain, no morbific origin, and no measurable impact on life expectancy. Rather, UTx is likely to negatively affect patients' disability-adjusted life years; and mental health conditions related to infertility are highly dependent on socio-cultural contexts.

UTx responds to a perceived missed opportunity that arises from the absence of a functional uterus. Part of that missed opportunity relates to biological parenthood and its associated experiences, meanings, and customs. Tellingly, those national contexts that first championed UTx experimentation in the twenty-first century have either predominant religions that emphasize biological parenthood (e.g., Saudi Arabia and Turkey) or legislation that prohibits surrogacy (e.g., Sweden). In many other nations, less-invasive, less-expensive, and lower-risk routes to parenthood like surrogacy and adoption have been stymied by legal and regulatory barriers (40). Canada, for example, prohibits commercial surrogacy, offers little legal framework to support altruistic surrogacy, and has a negligible amount of healthcare guidelines dedicated to surrogacy (41). Such restrictions on attaining parenthood experiences exacerbate the motivations for those pursuing UTx.

In counselling potential recipients, the leading British UTx team notes that consideration must be given to adoption and surrogacy (1). Yet, some academic literature on UTx exaggerates the limitations faced by women with AUFI and inaccurately suggests that, in the absence of motherhood through surrogacy, "uterine transplantation is the only way to parenthood" (25). Others laud UTx for potentially diminishing "the phenomena of 'wombs for rent'" associated with surrogacy (37). These arguments reveal something disingenuous about the described need for UTx as a therapeutic option. UTx is a medical intervention representing one of several possible solutions to achieving a parenthood status. Given the significant risks to recipients and donors (and potentially the child), the steep costs in terms of health resources, and the modest subjective benefits, UTx is an ethically questionable procedure. My analysis demonstrates some of the overpromise and misrepresentation in how researchers and exponents have described UTx as the only route to motherhood or parenthood for some people. Here, I offer a brief discussion about adoption and surrogacy merely to show the existence of alternatives to UTx for the purpose of realizing parenthood. There are notable problems associated with adoption and surrogacy. However, I maintain that – given the relative risks, costs, and benefits – UTx is difficult to justify as a route to parenthood.

Justifications for UTx often reflect socio-cultural factors that should rightly be scrutinized as with any other medical intervention using limited resources. Nonetheless, the motivation of some patients to achieve a type of parenthood within certain parameters and through surgical means remains valid and deserving of medical and ethical consideration. Participating in a UTx trial, which is ostensibly free for patients, may represent the only financial, legal, practical, and desirable option to realize biological parenthood for some patients, despite the risks.

3) Risks to Donors, Recipients, and Children

Until there are more viable and available artificial grafts or xenotransplantations,[8] a perennial issue in transplantation will remain how best to secure reliable donations from appropriate, informed, and consenting donors. In the context of UTx, researchers, ethicists, and clinicians continue to debate who is an eligible and preferred donor (35). Both living and deceased donors have been used for UTx procedures (25).[9] To date, there have been more successful UTx procedures and subsequent deliveries using transplants from living donors. As of 2018, only three deceased donor uterus transplantations were reported and only one led to successful delivery (25). While it is known that better outcomes are achieved with living donors of other

[8] Notably, artificial uteruses for extracorporeal gestation or "exowombs" are a nearing advancement, which would also provide another route to biological parenthood.
[9] Favre-Inhofer et al. also detail inclusion and exclusion criteria for deceased donors. Deceased donors for UTx must exhibit brain death but not cardiac death.

solid organ transplants, it is still unclear whether that correlation applies to UTx, or whether nulliparous or parous donors are preferrable (1,31).

The availability of eligible deceased organs is more limited and time sensitive. A further complication is that uterine retrieval could adversely influence the multiorgan retrieval process in deceased donors. Some aspects of the retrieval process are easier with deceased donors; however, the ischaemic times and brain-dead-related inflammation could affect the graft's functionality (1).

The organ retrieval process in living donors presents significant surgical challenges and risks. Such risks include urinary tract and bowel injuries, bleedings, vaginal cuff dehiscence, and many others (25). For QoL transplantations, only UTx and ovary transplants have been approved for living donors (35). This exception for UTx and ovary transplants likely reflects the relative commonness of hysterectomies and the related perception of these organs as a readily excisable (42). Currently, prospective living donors undergo extensive assessments, including ultrasonographic scans, human leukocyte antigen compatibility tests, blood tests, and examinations by specialists (25). Of the small cohort of UTx living donors, several sequelae and injuries have been reported. After the retrieval operation, living donors typically remain in hospital for post-operative recovery and observation for five to seven days (25).

The significant risks incurred by UTx recipients and their potential future offspring necessitate ongoing vigilance and care on the part of healthcare providers (43). For transgender women patients, there are added risks due to additional uncertainties related to gestating in a genetically-male body (4). One potential source of donor organs could be transgender men undergoing hysterectomies (4). For all potential recipients, fully informed consent and extensive patient counselling is needed to minimize harm and ensure the best results.

4) Costs and Benefits

UTx is a resource-intensive procedure, involving a series of evaluations, surgical operations, a combination of ARTs, and long-term post-operative treatment. To date, UTx procedures have been conducted within experimental programs exempt from usual health resource analyses. As a clinical option, UTx might remain outside the purview of many public healthcare systems due to its relatively high costs, high risks, and limited QoL outcomes.

Nevertheless, some surveys suggest that UTx will receive public support as a clinical therapy. One such survey found that the US public generally favours UTx as a treatment for AUFI. Of the 1247 respondents included in the results, 70% believed pregnancy was a human right, 66% believed UTx to be an acceptable alternative to "gestational carriers," and 67% believed UTx to be ethical (44). Notably, 45% of respondents thought UTx should be covered by insurance (44). Another study, which surveyed members of the social media group Beautiful You MRKH Foundation (n=281), found that 78% of respondents who considered pursuing UTx believed that health insurance should cover the procedure (41). The survey study concluded that there is a demand for available and affordable UTx in the MRKH community and emphasized that patients considering UTx have special vulnerabilities requiring extra attention to informed consent and evaluation (37,43,45).

Despite the inherent weaknesses of these survey studies, they show that expectations about the availability of UTx differ between survey groups. Again, the social context of infertility is critically important. Recall that the parenthood experience provided by UTx only differs from safer, more readily justified forms of assisted routes to parenthood – such as the less-resource-intensive procedure of surrogacy and the more-ethical option of adoption – in the gestational capacity and genetic properties. Adoption provides stable, caring, and permanent families for children who might otherwise be deprived of such crucial benefits and advantages (46). Surrogacy represents a relatively less-resource intensive option for would-be parents to make a family and provides financial benefits for surrogates (47,48).[10] While keeping this discussion necessarily brief, I contend that adoption and surrogacy represent potentially favourable alternatives to UTx, ethically speaking.

Aside from situations where alternative routes to parenthood are unavailable, Utx is responding to a narrow category of patient motivation: a desire for gestational parenthood. I know of no research suggesting that the desire for this kind of parenthood is an inherent trait rather than a psychosocial phenomenon. For those desiring Utx as a route to parenthood, the harms of infertility can be described as encultured. To what degree, then, should scarce health resources be dedicated to meeting socio-culturally derived desires and ameliorating subjective harms from infertility? Are there alternatives or ancillary options that are less resource-intensive and less risky, such as psychological therapy and educational programs? This line of criticism also applies to other ARTs, such as IVF, which represent significant costs for personal finances, health resources, and psychological wellbeing.[11] For these reasons, counselling prior to IVF treatments, for example, is required in many jurisdictions. The emergence of UTx might prompt those nations that prohibit or restrict surrogacy and adoption opportunities to reconsider their rules and regulations and, ultimately, explore crafting more supportive and protective frameworks (46,49,50).

Even where Utx treatments would not worsen already scarce public healthcare resources, it remains uncertain whether such an invasive and risky procedure should be promoted. The risks assumed by the recipient are compounded by the additional risks posed to the donor and prospective children (29). All these cost-benefit analyses lead to a central question advanced by political philosopher Emily McTernan: "what is the value of gestation and how should we respond to that value?" (51). It seems

[10] For a discussion of the social benefits and problems involved with commercial surrogacy, see van Niekerk and van Zyl's debate with McLacklan (47,48).
[11] Whether other infertility problems might be better culturally understood and addressed through non-medical interventions is beyond the scope of this paper.

unlikely, even with operative advances, that UTx will be justifiable as a publicly funded treatment given the obligations to nonmaleficence and the modest[12] therapeutic value of experiencing gestation (51). Considering the relative risks, costs, and benefits, UTx invites ethical criticisms and prohibitive guidelines that will limit access. Such limits will hopefully prevent UTx from becoming a consumer-driven medical trend. However, as McTernan concedes, UTx will not likely be banned outright (51). Conversely, medical ethicist Timothy Murphy contends that there is no reason to exclude UTx research from public expenditure, including UTx applications for transgender women and non-women recipients (40).

UTx and related pregnancies pose known and unknown risks to recipients and their potential children (37). As an experimental procedure, there is limited data on the long-term outcomes of UTx for donors, recipients, and offspring (1). In the context of UTx, such data limitations relate to things like the safety of immunosuppressant drugs taken during pregnancy and lactation (13). For recipients of other solid organ transplants, particularly kidney transplants, immunosuppressants have been shown to represent distinct risks for the success of the pregnancy, fetal development, maternal health, and some childhood outcomes (52). Notably, some jurisdictions have legal protections for the future child's welfare – e.g., the UK's *Human Fertilisation and Embryology Act* (1990) requires assessments for the welfare of the future child – although the application of such protections in clinical scenarios is debated (29). Bioethicists argue that "therapeutic misconceptions" might exist as the research participant fails to fully appreciate the expected outcomes from clinical research, overestimating the benefits and underestimating the risks despite comprehensive counselling (53). However, proponents of UTx counter these concerns by highlighting the central importance of fully informed consent (1) and the benefits of expanding reproductive autonomy offered by this procedure (54). This same argument for greater reproductive autonomy is just as applicable to non-women who desire to carry pregnancies and deliver their offspring.

Given the narrow benefits and significant risks and costs of UTx, is it appropriate to categorically exclude non-women from pursuing similar desires to gestate and deliver their own children? Or, rather, is this exclusion perpetuating the same limited perspective on gender and reproduction that fuels the demand for UTx in the first place?

SEX AND GENDER CRITERIA

I have detailed the ethical landscape – the costs, risks, benefits – defining UTx and the position of recipients, donors, and children within that landscape. To clarify, I am not arguing against the trials and potential acceptance of UTx as a therapeutic option. Rather, I am arguing that the socio-cultural perspective now used to justify UTx are neither ethically nor logically sound, and ought to be questioned and reconsidered, including (as this article focuses on) the gender requirements for recipients.

Even though UTx was first pioneered as a gender-affirming procedure for transgender women, the contemporary guidelines, narratives, and intentions of UTx research have, until recently, focused exclusively on genetic females as potential recipients. However, the merits of these exclusory criteria have since been challenged by scholars, practitioners, and would-be patients advocating for the inclusion of transgender women. Here, I critique some of the leading discussions and conclusions about sex and gender requirements for UTx eligibility.

In considering UTx for non-women, the foremost concerns that are distinct from those also faced by cisgender women include the specific technical obstacles of the procedure and the potentially unique adverse outcomes. There are several relevant anatomical and physiological differences between genetic males and females, including the availability of space within the abdomen to accommodate the graft and potential pregnancy; the availability of suitable vascularization, ligamentous support, and vaginal structure; and the variance in the hormonal environment of the recipient during pregnancy (3). However, an examination of these key differences by Jones et al. has concluded that "there is no overwhelming clinical argument against performing UTx as part of gender reassignment surgery" (3). There is thought to be sufficient homology in vascularization between genetic males and females, including the external iliac arteries used for the anastomoses in UTx. For those patients undertaking UTx as a gender-affirmation procedure, the hormonal environment is likely already feminized, although further modification may be needed, and a vaginal anastomosis will be possible from prior vaginoplasty.

There is also a legal argument for including transgender women as UTx recipients. Some non-discrimination legislation, such as the UK's *Equality Act* (2010), explicitly protects transgender people from both direct and indirect forms of discrimination to the extent that gender affirmation falls under legal provisions for protected characteristics (3). If UTx becomes an established treatment for women with AUFI, this statutory protection could prohibit discriminating against transgender women seeking UTx as a fertility treatment. A similar principle of non-discrimination could logically be extended to non-women seeking UTx as confirming a parenthood status as part of an innate, unchangeable identity. As with many cisgender people, parenthood is fundamental to many transgender individuals (55). How parenthood is legally recognized and defined has many important consequences, notably for children and especially in the context of ARTs (56).

Montreal Criteria

The motivation for twenty-first-century experimental UTx trials was to provide therapeutic treatment for women with AUFI. This purpose was consolidated by the 2012 "Montreal Criteria" which outlined an ethical framework for patient eligibility to undergo the procedure. That framework's first provision reads: "The recipient is a genetic female of reproductive age with no medical

[12] Again, "modest" given the costs, risks and benefits of UTx as a non-life-saving intervention.

contraindications to transplantation" (2). The "Revised Criteria" explained that the original gender requirement derived from Francis D. Moore's criteria for surgical innovation (5), which indicates that the laboratory background must be congruent to the clinical application of the procedure (57). Of course, if the clinical applications are imagined more broadly and the laboratory background expands to include genetic males, then there is no basis for the gender requirement. Meeting Moore's criteria would require successfully performing UTx procedures on experimental animal models that are not genetically female (non-XX). Since publication, the Montreal Criteria has been frequently cited in UTx ethics literature (25). Researchers argue that Moore's criteria have been met for offering UTx to transgender women (4). If UTx is successful in transgender women recipients, much of the surgical precedent for offering UTx to non-women will be met. The genetic basis will also be met with transgender women recipients. Indeed, people with Swyer syndrome, who may have female reproductive organs but a typically 46, XY karyotype, have achieved successful pregnancies with medical interventions (58). Current requirements for UTx recipients include being a genetic female who can provide their own oocytes and/or embryos, can demonstrate child-rearing capacity, and is seeking treatment for appropriate reasons (29).

Revised Criteria

Following a series of discussions, investigations, and publications suggesting that UTx is a viable option for transgender women recipients, Balayla et al. published a revised version of the Montreal Criteria. The Revised Criteria reversed the original stance that limited UTx eligibility to genetic females. Balayla et al. now argue that the time and research background is right for attempting UTx with transgender women recipients (5). Their justification for widening the criteria is twofold: offering treatment for gender dysphoria and responding to current social values (5). The former justification aims to enable transgender patients to attain so-called "body completeness"[13] and psychological benefits. The difficulty with such a goal is that UTx involves an ephemeral graft intended to be removed after successful and sufficient gestational use. The aim of therapeutic beneficence through body completeness is troubled by the risk of the recipient maintaining a harmful immunosuppressant regime and refusing to have a hysterectomy, as is their right once the graft is *in situ* (33). While UTx can be reimagined as a permanent QoL transplant to achieve body completeness, this is adding to risks and harms while potentially diminishing the importance of gestation in the justification of UTx.

To explain their latter justification about current social values, Balayla et al. argue that "it is not the business of medicine to decide what is unreasonable to request for a person of sound mind, except as it relates to medical and surgical risk, as well as to distribution of resources" (5). In other words, if a person of sound mind requests an operation, then who is the medical practitioner to refuse unless that request poses an undue risk or excessive medical resource consumption? This reasoning allows for any person with a risk and cost profile similar to a genetic or transgender woman to request and receive a UTx procedure. In other words, Balayla et al.'s justification should allow for non-women to be deemed as eligible UTx recipients.

Throughout their analysis, Balayla et al. also rely on biological reductionist arguments that affirm the notion that womanhood is dependent on a functional and productive uterus. Such arguments are antithetical to numerous rights-based perspectives, including those commonly advanced by critical disability and critical feminist theorists. Indeed, Balayla et al. suggest that "[i]t is normative for a person who wishes to reproduce to do so, either as part of a couple or, technological circumstances permitting, as an individual" (5). This assumption about the realization of desires to reproduce as a normative experience uncritically promotes surgical intervention towards "body completeness." The authors continue this pronatalist reasoning to absurd conclusions: "It then follows that it is normative for a person with a uterus of reproductive age who wishes to become pregnant to do so" (5). This notion, that fertile people who desire to reproduce will, is divorced from the reality that many such people do not reproduce for innumerable reasons, including conflicting desires, improper circumstances, and beliefs to the contrary. In short, not everybody who wants to become pregnant becomes pregnant, and for myriad reasons. Further, the principle of reproductive autonomy includes the idea that a person can choose their reproductive behaviours, even if non-normative. Clearly, experimental medical programs, such as UTx trials, do not passively reflect social norms. Such forays into new medical treatments actively change the landscape of how people imagine and embody reproduction, sex, and gender. Therefore, those involved in experimental programs should carefully ground their work in sound ethical principles. If redressing discriminatory guidelines is a principled goal, then it behoves policy makers to remove all possible discriminatory guidelines, not just those that are of moment.

In the end, a critical question left unasked by the Revised Criteria is: *can womanhood be achieved by possessing a functional uterus?* The Revised Criteria effectively reiterates gender binaries through new exclusionary criteria and broader medical interventions based on normative reasoning that still does not accord with core principles in reproductive and sexual medicine such as empowerment and autonomy.

QUEERING UTX

To this point, I have attempted to show that – given the ethically fraught nature of UTx – the exclusion of non-women as recipients is largely unjustified and incongruous with deeply held healthcare ethical principles such as egalitarianism and equal access. According to the very arguments made by those advancing the inclusion of transgender women, UTx should also be made available to non-women who desire gestating their offspring and who meet all other non-gender requirements for recipients. In basic egalitarian terms, if the costs, risks, and benefits are not significantly different, access to a medical treatment

[13] "Body completeness" is not an established medical or scientific concept but is used by Balayla et al. to justify UTx for transgender women on QoL terms.

should not significantly differ between groups. One may argue that the outcome of gender identity affirmation is missing for non-women. However, while gender identity affirmation is often noted as a benefit of UTx, it is not a required goal for cisgender women recipients, nor is body completeness an unproblematic goal for transgender women recipients, who will be advised that the graft should ultimately be removed to ameliorate risks associated with immunosuppression. The remaining arguments against including non-women are 1) technical issues with anatomy and physiology and 2) that such procedures would be non-normative.

Technical Issues

Many of the anatomical and physiological issues presented by non-women recipients are shared with transgender women recipients. However, as concluded for transgender women recipients, there are no foreseeable clinical issues representing insurmountable obstacles (3,59). Two key differences between non-women recipients and transgender woman recipients are the hormonal environment and the neovagina. Towards the first difference, Balayla et al. argue that an orchiectomy is needed to ensure the success of the UTx operation and to carry a pregnancy (5). This requirement supposedly excludes non-women (5), although many have testicular failure (60). For those with functional testicles, an appropriate hormonal environment could theoretically be achieved by antiandrogens and feminizing hormone therapy similar to the treatments undertaken by many transgender women (61,62). This possibility of inducing a hormonal milieu for a functioning uterus while maintaining testicles requires experimental proof.

The major anatomical difference for non-women is the absence of a vaginal structure. For UTx, the vaginal structure functions as an important attachment for fixing the graft in place, an outflow for menstrual blood, and access for embryo transfer (31). Also, a recent study highlighted the role of the vaginal microbiome in protecting the uterine graft from harmful infections (63). However, many cisgender women with MRKH have varying degrees of vaginal shortening and receive surgical treatments (63). A study of UTx recipients who had such surgical procedures revealed a wide range of vaginoplasty, including skin and sigmoid neovaginas, and an acellular porcine small intestine submucosa graft (63). For transgender women recipients, a neovagina is a likely prerequisite for UTx. Some transgender women have sigmoidal neovaginas that host microbiota more consistent with that found in the bowel (63). The data on sigmoidal neovaginas in UTx is limited to a single instance, which resulted in multiple miscarriages and no live births, although the uterine graft was successfully maintained for several years (63). Data from women who had vaginoplasty because of cervico-vaginal atresia confirmed higher rates of infections and worse reproductive outcomes. However, successful deliveries have been reported for women with skin neovaginas, amniotic membrane neovaginas, and, in a single instance, an intestinal neovagina (63). Successful UTx trials with transgender women will be a key indicator of the possibility of UTx for non-women recipients. Potential alternatives to sexually functioning neovaginas will need to be explored for non-women who seek UTx. Potentially, the transplanted uterus could have the cervix exposed in the lower abdomen, making a vaginal canal unnecessary. A modified vaginoplasty for non-women might not be as radical a procedure as it sounds. It might also be asked, if a genetic male has a neovagina, feminizing hormone therapy, and a UTx, are they a transgender woman? I think the answer is – not necessarily.[14] The answer to this question is also largely irrelevant to a clinician's analysis of a potential UTx recipient, given the procedure's subjective QoL benefits and its significantly high costs and risks.

Reproductive Norms

Medicine is often instrumental in facilitating social changes relating to sexuality and reproduction. Take, for instance, the provision of new oral contraception in an era of relative sexual liberalism (66) or the gradual acceptance of artificial insemination that paralleled a dissociation between male virility and manhood (67). But how intentional should professional medicine be in actively facilitating such changes? In setting out the eligibility requirements for UTx recipients, the authors of the Revised Criteria suggest that researchers and clinicians should merely reflect social norms. While a passive approach might seem less ethically fraught, it is a fallacy. Not only is scientifically measuring sexual norms and reproductive desires a notoriously difficult undertaking, but the role of medicine is often as a catalyst, or at least a gatekeeper, for social changes in sexuality and reproduction. Even clinical studies of sexual and reproductive issues will inevitably influence the participants' perceptions of those very issues. Medical researchers and clinicians hold positions of responsibility and influence for such socio-cultural changes. The very nature of gender affirmation and, consequently, the manifestation of gendered identities, is fixed to medical discussions, perspectives, policies, and procedures. Therefore, those involved with UTx research need to reflect seriously on how they propagate and reinforce certain cultural perspectives and social norms about sex, gender, and reproduction.

UTx might exacerbate the harms of infertility and anatomical difference. As O'Donovan et al. observe, UTx operates much like other ARTs in propagating the "motherhood mandate" in which a growing medical industry facilitates women achieving motherhood as part of a gender-fulfilling expectation (29). For example, some specialist physicians suggest that UTx "offers women anatomically or functionally unable to bear children the possibility of becoming mothers and giving birth to healthy infants" (16). This description reiterates the notion that motherhood follows from uterine functionality and gestation. While the experience of motherhood through UTx or any other ART is not intrinsically diminished because of medical intervention, such descriptions do promote surgically intensive procedures as relatively unproblematic routes to attaining "natural" experiences

[14] A recent study of transmasculine individuals who became pregnant found that some experienced pregnancy as congruent with their masculine gender identity (64). For the institutional barriers faced by pregnant, delivering, and parenting trans men, see (65).

of motherhood. This kind of maternal ideal underlies the demand for UTx and boosts the perceived[15] QoL benefits to offset the substantial costs and risks.

UTx may also diminish the desirability and availability of alternate parenthood options with more societal benefits, like adoption and surrogacy when performed under ethically sound regulatory frameworks (29). Indeed, UTx aligns with other ARTs, including IVF and gestational surrogacy, by advancing pronatalism and a specific form of geneticism that prioritizes close biological ties over other kinds of familial connection (29). Ethical justifications for UTx depend upon geneticist perspectives (68). Pronatalism and geneticism are less altruistic and utilitarian in principle, especially when costly ARTs are involved. For instance, the Middle East, where some of the earliest attempts at UTx happened, is described as a region that is "decisively pronatalistic" (69). In such cultural contexts, opting for a UTx procedure has been criticized as "more of a social decision than a medical one" (69). As an elective QoL procedure, UTx can also be understood as part of a growing socio-medical trend in body modification (70). These parameters again raise questions about the value of gestational experience and genetic similarity versus the potential harms caused by medical interventions, and they promote potentially deleterious views like pronatalism and geneticism.

For some transgender women, UTx may offer a route to address body dysphoria (3). However, even this benefit has a questionable justification. As Balayla et al. explain, "[t]he clinical scenario whereby a transgender woman seeks to undergo a UTx would be consistent with the natural premise that women carry pregnancies, and that such individuals identify as females" (5). This justification from a "natural premise" effectively enshrines a narrow and denigratory view that women are defined by carrying pregnancies. While transgender patients are entitled to pursue this motivation of embodiment and self-fulfillment (71), researchers and clinicians must exercise caution and reflection about how UTx is framed as a medical intervention. UTx should not be advertised as "womanhood for sale." Historical and social studies have shown just how mutable gender identities are as a construct in medicine at different times and places (72,73). UTx is justified as a treatment for the harms of infertility, parenthood desires, and body dysphoria; yet, as critics emphasize, UTx reinforces a restrictive narrative that binds womanhood to gestation, pregnancy, and genetically related children (29). While other ARTs can also reinforce problematic gender norms, which similarly deserves of scrutiny and criticism, UTx differs in the reasoning commonly used by those seeking treatment, the fact that it is an invasive surgical intervention, and in the kinds of associated costs and risks. Donovan et al. observe that "a society in which biological ties are less valorized may be beneficial and ameliorate some of the harms caused by infertility" (29). If so, does UTx represent a productive and beneficial response to gender identity issues related to perceptions of womanhood or does it actually create harms and propagate disparities?

Offering UTx to non-women might ease the restrictive association between womanhood and gestation, uterine function, and pregnancy. By complicating the association between womanhood and gestation, non-women who undergo UTx might alleviate some of the psychological burden placed on infertile women by social expectations about reproduction. Opening UTx to non-women also represents a potential infertility treatment for single men or in couples where a male partner is the only possible candidate to carry the pregnancy, including homosexual male couples and heterosexual couples in which the female partner is unable or unwilling to carry the pregnancy. In light of the complexities, risks, and costs of providing UTx to cisgender women and transgender women, it seems needlessly discriminatory to categorically exclude non-women as potential recipients.

IMPLICATIONS FOR DONATION SCHEMES

Like any transplantation scheme, donors are fundamentally important to UTx. As a novel QoL procedure, UTx might negatively affect the willingness of would-be donors. However, like other QoL transplants, such as face or limb, UTx would be excluded from general deceased donation schemes and require explicit consent from the next-of-kin (1,33). It has been demonstrated that next-of-kin are less likely to consent to donate if the specific organ was not previously considered (33). UTx for transgender women or non-women recipients might compound this reluctance on the part of donors. Depending on the demand for UTx, these hurdles might not be significant, especially as UTx is not as time sensitive as critical transplantations or those relying more on deceased donors. One report on UTx donation indicates that about 75% of procedures have used live donors, 70% of whom are close to the recipient (29). If this trend of direct donation from live donors continues, it will mitigate potential problems with deceased donor schemes. As with other donations, UTx requires fully informed consent, even more so because of the procedure's novelty and uncertain ethical grounding (37). Non-direct donations will raise allocation issues, which some researchers argue should be resolved according to principles of equity, reproductive opportunity, and the likelihood of success (29). These same principles could be readily extended to transgender women and non-women recipients. Indeed, the introduction of non-women as recipients might offset some hypothesized objections to public funding for UTx, including those critical of the current rhetoric surrounding UTx as wrongly associating "the ability to experience gestation and womanhood or femininity" (74). Eventually, these donor issues will become less consequential as UTx researchers are already pursuing bioengineered uterine grafts (75).

ADDED RISKS FOR DONORS, RECIPIENTS, AND CHILDREN

A final consideration for removing the gender requirement for UTx is whether having non-women recipients represents added risks for donors, recipients, and children. Safety is known to be a crucial factor for public support of UTx (44). For donors, there are likely no added risks or harms, given that the operation would be the same as for transgender women recipients. UTx trials

[15] My use of "perceived" is to highlight this subjective goal shared or advanced by certain groups of patients and practitioners.

have already been justified on the basis that the harms, risks, and consent issues for donors are comparable to those in existing organ donation and research programs (34). The same justification would apply to trials involving non-women recipients. However, extra care and safeguards should be used in obtaining fully informed donor consent, given the added novelty of the procedure.

Non-women recipients would require special clinical considerations, although these would be comparable to those needed for transgender women recipients. As discussed above, hormone therapy would be necessary as would creating a structure analogous to a neovagina. Physical health risks would include post-operative complications, including infections, thrombosis, uretic injuries, and consequences of immunosuppression. Psychological risks would relate to gender identity, sexual dysfunction, and trauma related to undergoing transplant surgery (26), all of which are broadly shared with genetic and transgender women UTx recipients.

Legal uncertainties will also arise with expanding UTx to transgender women and non-women, as some legal definitions of a child's mother are determined as the person who gestates and births (33). Some aspects of biological and legal parenthood following UTx are unknown, such as whether offspring contain genetic traces of the uterus donor and how that could affect legal parenthood (30). To be fair, many legal issues about parenthood are connected to embryo creation, rather than UTx specifically. With expert advice, lawmakers can resolve many issues with these legal definitions by enacting common-sense amendments that properly recognize parental intentions, consent, and responsibilities. In most if not all jurisdictions, better-crafted legal frameworks surrounding these continued innovations in ARTs are needed to provide certainty and clarity for children, parents, donors, and recipients.

CONCLUDING RECOMMENDATIONS

UTx trials are ethically fraught, yet they have been deemed justifiable based on the promise of clinical application, therapeutic value, and reproductive autonomy. It seems likely that UTx will soon be offered to transgender women. Given the substantial ethical problems with UTx and the likely inclusion of transgender women, the perpetuation of gender criteria is more socially harmful and needlessly discriminatory than clinically useful or ethically sound. Not only will including non-women as eligible recipients extend the same reproductive autonomy as that being granted to genetic and transgender women through this procedure, but including such recipients promises to counteract some of the potentially harmful gender constraints and reproductive norms reinforced by ARTs.

To further explore the possibility of expanding UTx eligibility to non-women or, rather, any sex and gender, researchers will need to survey potential interested patients, test the procedure on animal models, and review all data on long-term risks and harms from past and current UTx trials. A publicly available registry for UTx procedures with appropriate privacy protections would permit better data sharing and the optimization of safety and efficiency (29). Even a very small proportion of non-women interested in UTx could represent a significant number of potential recipients.

Removing the UTx gender criteria offers important social benefit. UTx is intended to improve quality of life, and that quality is largely determined by psychosocial factors and socio-cultural determinants relating to pregnancy and identity. Including non-women as possible UTx recipients will not diminish the positive meanings of gestation; rather, such an inclusion would demonstrate that uterine function is not part and parcel of womanhood.

Reçu/Received: 21/08/2022

Publié/Published: 27/06/2023

Remerciements
Je suis reconnaissant au professeur Timothy Caulfield pour sa perspicacité et ses sages conseils concernant cet article. Les évaluateurs ont formulé des commentaires et des critiques excellents et constructifs, qui ont permis d'améliorer considérablement cet article.

Acknowledgements
I am grateful to Professor Timothy Caulfield for his discerning insights and sage advice regarding this article. The peer reviewers offered excellent and challenging commentary and criticism, which has greatly improved this article.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Aliya Affdal

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

M Lang, MH Zawati. *Can J Bioeth / Rev Can Bioeth.* 2023;6(2):66-75

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Online Therapeutic Portals for Sharing Health Research: Comparative Guidance amid Regulatory Uncertainty

Michael Lang[a], Ma'n H. Zawati[a]

Résumé

Les ressources en ligne offrent un moyen particulièrement efficace de partager la recherche en santé avec les scientifiques et le public. L'utilisation de portails web pour mettre les résultats et les informations sur les études à la disposition de divers publics pourrait accélérer l'application des résultats de la recherche et permettre aux patients de jouer un rôle plus actif dans leurs soins. Cependant, l'utilisation d'outils en ligne pour partager largement des informations sur la santé soulève plusieurs questions éthiques et réglementaires délicates. Des questions telles que l'équité, la protection de la vie privée et l'autonomisation des patients peuvent poser des problèmes aux organismes de réglementation, aux concepteurs de portails et aux chercheurs. En outre, il n'est pas certain que les portails web conçus pour faciliter l'accès aux résultats de la recherche et aux informations générales sur la santé soient réglementés en tant que dispositifs médicaux dans le cadre des régimes émergents qui contrôlent les logiciels à des fins médicales. Le présent document a pour but d'examiner de manière comparative si les portails thérapeutiques en ligne destinés au partage de la recherche en matière de santé sont susceptibles d'être réglementés au Canada, aux États-Unis, au Royaume-Uni et en France. Nous constatons que, bien que ces juridictions aient toutes pris des mesures récentes pour réglementer les logiciels en tant que dispositifs médicaux, les régimes applicables n'englobent généralement pas les portails en ligne destinés au partage de la recherche en matière de santé. Bien que les portails en ligne pour le partage de la recherche en santé ne soient probablement pas réglementés dans de nombreuses juridictions (si ce n'est la plupart), les agences ont néanmoins fait part de leurs préoccupations concernant plusieurs considérations éthiques importantes (telles que l'équité, la transparence et la sécurité), auxquelles les développeurs de portails et les chercheurs doivent être attentifs et répondre. Nous décrivons ici un ensemble de questions soulignées par les régulateurs – à savoir l'efficacité, l'équité, la transparence, la confidentialité, la communication, la responsabilisation, la formation, la sécurité et l'efficacité – et examinons comment guider au mieux la conception des portails en ligne dans un contexte d'incertitude réglementaire.

Mots-clés

réglementation, éthique, portails web, information sur la santé

Abstract

Online resources offer a uniquely efficient way of sharing health research with scientists and the public. Using web portals to make results and study information available to diverse audiences could work to accelerate research translation and empower patients to play a more active role in their care. But using online tools to broadly share health information raises several challenging ethical and regulatory questions. Issues such as equity, privacy, and patient empowerment may create challenges for regulators, portal developers, as well as researchers. It is additionally unclear whether web portals designed to facilitate access to research results and general health information will be regulated as medical devices under emerging regimes that control software with medical purposes. This paper aims to comparatively address whether online therapeutic portals for sharing health research are likely to be regulated in Canada, the United States, the United Kingdom, and France. We find that though these jurisdictions have each taken recent steps to regulate software as medical devices, the applicable regimes will generally not capture online portals for sharing health research. Though online portals for sharing health research are probably unregulated in many (if not most) jurisdictions, agencies have nevertheless signalled their concerns regarding several important ethical considerations (such as equity, transparency, and safety), to which portal developers and researchers should be attentive and respond. We describe here one set of issues highlighted by regulators – that is, efficiency, equity, transparency, confidentiality, communication, empowerment, training, and safety & efficacy – and consider how to best guide the design of online portals in a context of regulatory uncertainty.

Keywords

regulation, ethics, web portals, health information

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INTRODUCTION

Tremendous developments in medicine and health research have been prompted by the rise and proliferation of the Internet (1). Medicine is being increasingly digitized, with new technologies ranging from wearable devices to AI-powered decision models greatly affecting how healthcare is delivered. Wearable devices, for example, give patients unprecedented capacity to measure and record personal health data, some of which might have clinical utility. Artificial intelligence may revolutionize how medical care is delivered, promising more efficient and accurate diagnosis, more directly tailored treatment, and more effective resource allocation.

Online portals are one example of a potentially helpful innovation that can facilitate patient access to personal medical information and to new ways of managing care. While scholars have commented extensively on ethical and policy issues

ISSN 2561-4665

related to patient portals – online tools designed primarily for improving hospital administration, tracking prescriptions, and engaging with clinical care staff (2) – the effects of online tools that translate health research into clinical practice have been a more minor focus. This paper contributes to an emerging dialogue on *therapeutic portals*, a class of online portal intended to facilitate access on the part of clinicians and patients to information and research results related to a specific disease or family of diseases and which promote the uptake of novel research findings in clinical care. We argue in this paper that emerging Internet-enabled medical tools raise numerous ethical challenges, from confidentiality to patient empowerment, from equity to safety. Such tools also fall into an apparent regulatory lacuna. While online portals might have significant clinical utility, they are not obviously subsumed under the ambit of software that has a medical purpose as it is conceived in regulation and guidance. At the same time, regulatory materials either do not define medical software or provide definitions broad enough to capture online portals. This could suggest that such portals *are* or *may soon be* subject to regulatory oversight. This paper examines the contours of this lacuna and highlights that, even in the absence of explicit regulation, portal developers may find ethical guidance in emerging regulatory documents.

In a recent contribution, we defined therapeutic portals as "web portals designed to aggregate health research findings and make them available to a diverse array of researchers, clinicians, and the general public." (3) The language of *therapeutic* portals, as contrasted with *patient* portals, was intended to capture the idea that the sharing of research findings via online resources in the context of complex disease may have therapeutic application in the sense that clinicians might use such tools to inform patient care and patients might use them to better understand a course of therapy to which they are subject. In this sense, the possible adoption of therapeutic portals is situated within a larger move toward learning healthcare systems, in which health research and therapy are mutually supportive. We approached this prior work in the context of a therapeutic portal within the ambit of "a biobank-based study to identify prognostic markers and therapeutic targets for Acute Myeloid Leukemia." (4) Cancer genomics research is fertile ground for thinking about the ways online tools might contribute to information sharing among diverse stakeholders (3). While researchers and clinicians likely have an obviously significant interest in easily accessing research findings (5), patients and the public at large could also draw considerable benefit from engaging with online resources that communicate emerging scientific consensus and that document relevant novel results.

Though therapeutic portals as we describe them may not appear to be medical devices or medical software in any *colloquial* sense, we suggest that regulators define these concepts quite broadly, potentially admitting these new tools into the ambit of existing regulation. We specifically engage with the normative frameworks of Canada, the United States, the United Kingdom, and France as a way of sketching out significant issues for the development and adoption of therapeutic portals. We do this by assessing guidance documents and government reports intended to guide software developers and regulatory agents. In each of the jurisdictions we review, medical devices are regulated by national agencies applying a risk-based classification model in which devices most likely to cause harm are subject to the most stringent premarket oversight and reporting requirements (6-9). These risk-based regulatory models are responsive to a range of potential harms and ethical challenges. In one vein, medical software presents the clear risk of physical harm to patients: erroneous or misleading information can lead directly to misdiagnosis, unsuitable intervention, or overtreatment. In a related vein, ethical challenges around the way internet-mediated clinical tools manage patient confidentiality, promote empowerment, and implicate health equity, demand particular attention.

Regulatory agencies in Canada, the United States, the United Kingdom, and France have in recent years contemplated whether software, including perhaps Internet-based tools, might be subject to existing regulatory regimes for medical devices, a development often referred to as "software as medical devices" or SaMD (10). Regulators have generally not implemented specific interpretive frameworks for the review and approval of medical software applications and Internet-powered tools; instead, faced with these emerging technological developments, they have outlined in non-binding guidance documents broad principles for the exercise of regulatory authority. To be more precise, in the case of therapeutic online portals, we know of no regulatory or legislative instrument that explicitly and directly contemplates these technologies. Formal law, in other words, leaves unanswered the question of how medical software will be regulated – from standalone computer programs to integrated applications and online platforms that may be used for clinical function. This is left to regulatory guidance and government reports, which to varying degrees clarify how agencies have been thinking about the regulation of medical software. Though not properly binding, these instruments help to structure and constrain medical software and online platform development and implementation. Until more targeted guidance or regulation is developed, this kind of agency commentary effectively operates as the most authoritative indication of the manner in which recently developed medical technologies will be regulated.

METHODS & MATERIALS

We set out to understand in broad terms how therapeutic portals might be influenced by the regulation of software as medical devices in Canada, the United States, the United Kingdom, and France. Our research question was the following: *what are the principal regulatory issues and considerations likely to be generated by the development and use of therapeutic web portals as expressed in regulatory agency guidance?* In addressing this question, we reviewed 20 documents prepared by regulatory agencies and related government entities on the oversight of software as medical devices. We first consulted the websites of each of the principal regulators responsible for the enforcement of medical device regulations in Canada (Health Canada: HC), the United States (Food & Drug Administration: FDA), the United Kingdom (Medicines and Healthcare products Regulatory Agency: MHRA), and France (Haute Autorité de Santé: HAS) to identify guidance documents related to the regulation of software as medical devices.

From there, we identified additional sources by consulting the websites of related government agencies for commentary on digital health. Finally, we used PubMed and WestLaw to identify academic sources discussing the regulation of software as

medical devices. We consulted references to regulatory guidance in these sources to identify additional government materials. A preliminary review included 41 documents that appeared to be responsive to the question of how online portals for the sharing of health research data may be regulated. Applying broadly flexible inclusion criteria, we selected 20 documents for review that 1) are issued by or on behalf of state agencies engaged in the regulation of medical devices and 2) that apply to the clinical use of Internet or software-based technologies. In interpreting these inclusion criteria, agency documents were understood to include reports and stakeholder consultation documents that may be instructive in understanding how therapeutic portals could ultimately be regulated. We found that regulators have not *directly* addressed the kinds of therapeutic portals we described above. But because these documents define medical software quite expansively, as we will describe in greater detail below, there may nevertheless be important lessons for the developers of Internet-powered resources for sharing medical information. Our present methodology is intended only to provide a preliminary overview of the regulatory landscape into which portal developers are likely to find themselves as they develop new kinds of approaches to data sharing.

We selected four Canadian documents, five documents from the United States, five documents from the United Kingdom, and four documents from France. Two of the documents included in our analysis are multilateral guidance documents, one of which is jointly agreed to by HC, FDA, and the MHRA. Though this particular document applies to the development of medical devices applying machine learning techniques, likely somewhat beyond our present focus on therapeutic portals, we have included this guidance for review due to the significance of multijurisdictional coordination on best practices for medical device development. Another is a definitional document issued by the International Medical Device Regulators Forum (IMDRF), a voluntary association of medical device regulators that includes HC, FDA, and the European Union's Directorate-General for Internal Market, Industry, Entrepreneurship, and SMEs (11). The IMDRF definitional guidance represents a major source of influence on the regulatory approaches taken in Europe, Canada, and the United States. The FDA, in fact, has adopted the IMDRF's clinical evaluation guidance in its entirety (12). Understanding how the IMDRF conceives of SaMD regulation is thus critical for understanding how therapeutic portals might be regulated in at least three of the jurisdictions under review. We excluded documents that were not responsive to both of the above criteria, namely that apply only to a specific set of medical practices, that are prepared by non-government entities, or that apply only to a specific set of medical professionals. We made this decision because such documents are unlikely to give an immediate sense of how therapeutic portals, as a broad category of Internet-based tools, may be regulated in the short-to-medium term. Documents prepared by thinktanks or non-profit organizations, for example, did not respond to our primary aim to understand whether and how therapeutic portals would be subject to direct regulatory oversight (sources are outlined in Table 1).

Table 1: Surveyed regulatory documents

Country	Document title	Issuing body	Document classification	Year
Canada	*Guidance Document: Software as a Medical Device (SaMD): Definition and Classification*	Health Canada	Regulatory guidance	2019
	What we heard: A summary of scanning and consultations on what's next for health product regulation	Health Canada	Consultation summary	2019
	Report from Canada's Economic Strategy Tables: The Innovation and Competitiveness Imperative: Health & Science	Innovation, Science and Economic Development Canada	Government report	2018
	Notice: Health Canada's Approach to Digital Health Technologies	Health Canada	Regulatory guidance	2018
United States	*Multiple Function Device Products: Policy and Considerations*	Food & Drug Administration	Regulatory guidance	2020
	Digital Health Innovation Plan	Food & Drug Administration	Government report	2020
	Clinical Decision Support Software	Food & Drug Administration	Draft regulatory guidance	2019
	Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics	Food & Drug Administration	Regulatory guidance	2018
	Software as a Medical Device (SaMD), Guidance for Industry and Food and Drug Administration Staff	Food & Drug Administration	Regulatory guidance	2017
United Kingdom	*A guide to good practice for digital and data-driven health technologies*	Department of Health & Social Care	Regulatory guidance	2021
	Consultation on the future regulation of medical devices in the United Kingdom	Medicines & Healthcare products Regulatory Agency	Government report	2021
	Guidance: Medical device stand-alone software including apps (including IVDMDs)	Medicines & Healthcare products Regulatory Agency	Regulatory guidance	2014, rev. 2021
	The future of healthcare: our vision for digital, data and technology in health and care	Department of Health & Social Care	Government report	2018
	What will new technology mean for the NHS and its patients?	Health Foundation, Institute for Fiscal Studies	Government report	2018
France	*Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care*	Haute Autorité de Santé	Regulatory guidance	2021
	Numérique: Quelle (R)évolution	Haute Autorité de Santé	Government report	2019
	National Health Strategy 2018–2022	Ministère des Solidarités et de la Santé	Government report	2018
	Stratégie nationale e-santé 2020	Ministère des Solidarités et de la Santé	Government report	2016
	Good Machine Learning Practice for Medical Device Development: Guiding Principles	Food & Drug Administration, Health Canada, and Medicines & Healthcare products Regulatory Agency	Multilateral guidance document	2021
	Software as a Medical Device (SaMD): Key Definitions	International Medical Device Regulators Forum	Multilateral guidance document	2013

In consideration of the research question posed above, our aim was not to fully define rules surrounding the regulation of software as medical devices, but rather to provide a preliminary snapshot of the ways regulators might be thinking of the issues this kind of regulation raises and to apply that snapshot to the case of therapeutic portals.

FINDINGS

Our principal findings revolve around the notion that regulators and agencies have enumerated a number of ethical considerations and issues to which the attention of software developers, patients, and the regulators themselves is drawn. We found eight issues that might have particular resonance for therapeutic portals (outlined in Table 2).

Table 2: Considerations for therapeutic portal regulation

Issue	Example treatment	Documents featuring discussion
Efficiency	"The regulatory system must be modernized, with the objective of ensuring that it serves as a catalyst for new products. A high-performing regulatory system should be predictable, efficient, consistent and transparent, so as not to present barriers to business investment, innovation and ultimately, economic growth and improved patient outcomes" (ISEDC, *Economic Tables*).	Canada (n=1): ISEDC, *Economic Tables*.
		United States (n=2): FDA, *Digital Health Innovation*; FDA, *Clinical Decision Support Software*.
		United Kingdom (n=3): DHSC, *Guide to good practice for digital and data-driven health technologies*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Numérique*; MSS, *National Health Strategy*; MSS, *Stratégie nationale e-santé*.
Equity	"[Digital health] technologies can improve access to health care information, facilitate more timely diagnoses and treatments, and improve access to care for patients at home, at health care facilities, as well as in rural and remote communities" (HC, *Notice*).	Canada (n=2): HC, *SaMD Guidance*; HC, *Notice*.
		United States (n=1): FDA, *Digital Health Innovation*.
		United Kingdom (n=2): DHSC, *guide to good practice for digital and data-driven health technologies*; DHSC, *Future of healthcare*.
Transparency	"Consultations revealed the importance of providing transparency around how classification decisions are made" (HC, *What we Heard*).	Canada (n=3): HC, *What we Heard*; ISEDC, *Economic Tables*; DHSC, *guide to good practice for digital and data-driven health technologies*.
		United States (n=2): FDA, *Multiple Function Device Products*; FDA, *Digital Health Innovation*.
		United Kingdom (n=2): DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Numérique*; MSS, *National Health Strategy*; MSS, *Stratégie nationale e-santé*.
Confidentiality	"We need to maintain a safe and secure data infrastructure that protects health and care services, patients and the public. The digital architecture of the health and care system needs to be underpinned by clear and commonly understood data and cyber security standards, mandated across the NHS, to ensure we are secure by default and that the penalties for data breaches are effective in protecting patients' privacy" (DHSC, *Future of healthcare*).	Canada (n=1): HC, *What we Heard*.
		United States (n=1): FDA, *Use of Public Human Genetic Variant Databases*.
		United Kingdom (n=4): ISEDC, *Economic Tables*; DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=2): HAS, *Functional classification*; HAS, *Numérique*.
Communication	"If a technology needs to communicate with clinical systems to share data, it must comply with the relevant clinical, professional and technical standards. There are standards that create a common 'language' in the recording of healthcare data and digital health technologies must use these" (DHSC, *guide to good practice for digital and data-driven health technologies*).	United Kingdom (n=3): DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Functional classification*; HAS, *Numérique*; MSS, *Stratégie nationale e-santé*.
Empowerment	"Digital health technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life- threatening diseases, and management of chronic conditions outside of traditional care settings" (FDA, *Digital Health Innovation*).	Canada (n=2): ISEDC, *Economic Tables*; HC, *Notice*.
		United States (n=1): FDA, *Digital Health Innovation*.
		United Kingdom (n=1): DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=2): HAS, *Numérique*; MSS, *Stratégie nationale e-santé*.
		Multilateral (n=1): *Good Machine Learning Practice*.
Training	"FDA recognizes that many different types of genetics professionals may be involved in the curation and processes for evaluation as part of a team (e.g., genetic counselors, Ph.D.-level scientists, physicians). Adequate training and expertise of individuals evaluating variants plays an important role in the quality of variant review and evaluation" (FDA, *Use of Public Human Genetic Variant Databases*).	Canada (n=3): HC, *SaMD Guidance*; HC, *What we Heard*; ISEDC, *Economic Tables*.
		United States (n=2): FDA, *Use of Public Human Genetic Variant Databases*; FDA, *Guidance for Industry and Food and Drug Administration Staff*.
		United Kingdom (n=3): DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Functional classification*; HAS, *Numérique*; MSS, *National Health Strategy*.
Safety & efficacy	"While stakeholders supported the need for oversight of these technologies, underscoring the importance of ensuring product safety and efficacy, they emphasized the need for it to be proportional with potential risks, benefits, uncertainties, and with consideration for the realities of providing frontline care. Stakeholders called for a flexible, risk-based approach that permits early or conditional market authorization while simultaneously ensuring robust ongoing product oversight, research, and surveillance" (HC, *What we Heard*).	Canada (n=4): HC, *SaMD Guidance*; HC, *What we Heard*; ISEDC, *Economic Tables*; HC, *Notice*.
		United States (n=4): FDA, *Multiple Function Device Products*; FDA, *Digital Health Innovation*; FDA, *Use of Public Human Genetic Variant Databases*; FDA, *Guidance for Industry and Food and Drug Administration Staff*.
		United Kingdom (n=4): DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Consultation on the future regulation of medical devices*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Numérique*; MSS, *National Health Strategy*; MSS, *Stratégie nationale e-santé*.
		Multilateral (n=2): *Good Machine Learning Practice*; IMDRF, *SaMD*.

The eight issues briefly outlined here provide a good overview of the kinds of considerations about which regulators are concerned. Nine sources discuss concerns surrounding the capacity of digital tools to increase efficiency or the importance of efficiency of regulation of the same. Five documents describe concerns about the equity-relevant effects of digital health. Ten documents discuss transparency, 8 discuss confidentiality, and 6 include discussions about communications with patients and the public. Seven of the surveyed sources focus broadly on the capacity of digital tools to enhance patient and public empowerment; eleven involve discussions about user training. By far the most widely considered issue in the sources we reviewed, perhaps unsurprisingly, was safety and efficacy. Fully 17 of the 20 sources under review specifically addressed this theme. As the primary orienting purpose of medical devices regulation, we expected that most surveyed documents would in some measure consider how regulation and guidance can work to assure the safety and efficacy of digital health tools, including web portals. These points naturally do not reflect the entire scope of topics raised in the surveyed sources. Other observations, rules, and principles are considered in varying degrees throughout these documents. But the eight elements we describe here, and as we outline in further detail in the discussion below, reflect important consensus considerations for the developers and users of therapeutic portals.

While regulators appear sensitive to the ethical considerations that confront therapeutic portals, we also found that online portals for the sharing of health data are unlikely to be formally regulated under the existing regime. Regulatory agencies in each of the surveyed jurisdictions have signalled similar intentions to regulate software as medical devices when a manufacturer's intended function for a software system aligns with existing statutory definitions of the concept of a medical device. In Canada, for example, HC specifies that "when the intended or represented use of software is for one or more of the medical purposes set out in the definition of a device as stated in the [*Food & Drugs Act*], that software qualifies as a medical device." (6) The FDA takes a nearly identical approach, stating in its SaMD guidance that regulation is premised on whether a software system "meets one or more of the purposes described in the definition of a medical device." (7) MHRA guidance on standalone software likewise notes that systems with medical purposes are likely captured by the legal definition of a medical device (8). Following the European Union's Directive 93/42 (13), France similarly determines whether software is a medical device according to its manufacturer's intended purpose (9). Importantly, software intended to perform one or more medical purpose will generally not be treated under medical devices regimes if it merely operates as part of an independent hardware device, such as a medical imaging system (10). What constitutes a medical purpose is generally established in formal regulation and varies in small measure from jurisdiction to jurisdiction. Though we did not review these regulatory instruments directly, the subsidiary documents considered in this review give some idea of how regulators might assess medical purposes for software. SaMD must, in other words, function independently if it is to be regulated. In the language of several reviewed documents, it must be standalone (6). We outline how SaMD is defined in each of the reviewed jurisdictions in Table 3 below.

Table 3: Definitions of SaMD

Country	Definition of SaMD	Document title
Canada	The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.	HC, *Guidance Document: Software as a Medical Device (SaMD): Definition and Classification*
United States	The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.	IMDRF, *Software as a Medical Device (SaMD): Key Definitions*; referenced by FDA on public webpage
United Kingdom	Software as a medical device (SaMD, being standalone software and software included in wider hardware) (including AI as a medical device (AIaMD)) has grown in market share and complexity. Increasingly it has applications in health and social care that could not have been envisioned when existing regulations around medical devices were developed.	MHRA, *Consultation on the future regulation of medical devices in the United Kingdom*
France	Indeed, not all the software and applications used in the field of health have [medical device] or IVDMD status. The qualification of a digital solution requires a case-by-case assessment based on the intended purpose and its specific features to characterise the medical intended use of the product.	HAS, *Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care*

This relatively cohesive approach signifies that online portals are likely to be regulated as medical devices only if they are intended by their manufacturer to perform *medical purposes* and are not otherwise functionally part of conventional device hardware.

In Canada, for example, HC notes that two factors influence assessments of medical purpose. A system is likely to be determined to have a medical purpose if it is used (a) to acquire, process, or analyze medical images or (b) to support or provide "recommendations to health care professionals, patients or non-healthcare professional caregivers about prevention, diagnosis, treatment, or mitigation of a disease or condition." (6) MHRA's guidance likewise sets out a list of factors that would militate for designation of a medical purpose. Software has a medical purpose in the United Kingdom if it functions, for example, to prevent, diagnose, monitor or treat a disease (8). Similar approaches are taken in France and the United States. The IMDRF notably includes in its definition of medical purpose – in addition to the points raised in Canada and the United Kingdom – functions related to supporting or sustaining life and the investigation, replacement, modification, or support of physiological processes (11). As above, we found that there is relatively widely distributed agreement that medical purposes relevant for the regulation of medical devices in the surveyed countries. Below, we explain in greater detail how these conceptions of medical purpose are likely to apply in the context of therapeutic portals for sharing health research findings with scientific communities and the public. From the outset, it is highly unlikely that therapeutic portals intended merely to function as a platform for facilitating access to non-specific experimental results would be interpreted by regulators to have a medical purpose. Table 4 outlines how regulators conceive of medical purpose in the surveyed countries.

Table 4: Definitions of medical purpose

Country	Definition of medical purpose	Document title
Canada	Health Canada generally interprets medical purposes as follows: • Intended to acquire, process, or analyze a medical image, or a signal from an in vitro diagnostic device or a pattern/signal from a signal acquisition system2 or imaging device, OR • Intended for the purpose of supporting or providing recommendations to health care professionals, patients or non-healthcare professional caregivers about prevention, diagnosis, treatment, or mitigation of a disease or condition.	HC, *Guidance Document: Software as a Medical Device (SaMD): Definition and Classification*
United States	The following [terms] as defined in GHTF/SG1/N71:2012 (*italics removed in this reproduction*) identify medical purpose applicable to SaMD: 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar *or* related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: • Diagnosis, prevention, monitoring, treatment or alleviation of disease, • Diagnosis, monitoring, treatment, alleviation of or compensation for an injury, • Investigation, replacement, modification, or support of the anatomy or of a physiological process, • Supporting or sustaining life, • Control of conception, disinfection of medical devices, • Providing information by means of in vitro examination of specimens derived from the human body.	IMDRF, *Software as a Medical Device (SaMD): Key Definitions*; definition cited by FDA in *Software as a Medical Device (SaMD), Guidance for Industry and Food and Drug Administration Staff*
United Kingdom	A medical purpose is determined by what the manufacturer states in the device's labelling, instructions for use and any promotional materials. Has one or more of the following functions: • Prevention of disease, • Diagnosis of disease, an injury, or handicap, • Monitoring of disease, an injury, or handicap, • Treatment or alleviation of disease, an injury, or handicap, • Compensation for an injury or handicap, • Investigation, replacement, or modification of the anatomy or of a physiological process; control of conception.	MHRA, *Guidance: Medical device stand-alone software including apps (including IVDMDs)*
France	In order to be awarded MD or IVDMD status, the digital solution must have the following cumulative criteria: • Be intended for use for medical purposes in accordance with the MD or IVDMD definition. For example, it should enable diagnosis, diagnostic assistance, treatment, or treatment assistance, • Provide a specific result for the benefit of a single patient, • Carry out an action on input data, such as an analysis with a view to providing new medical information. For example, a data analysis application in respect of a patient's specific physiological signals and equipped with alert functions for medical intended use will be deemed to have MD status. This action must be different from storage, communication, or merely a search such as a database or a digital library incorporating data solely for the purposes of archival, without processing the data.	HAS, *Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care*

In considering the potential regulation of therapeutic portals, it is illuminating to note that many of the documents we surveyed communicate significant internal limits on the scope of the definition of medical purpose and, as a consequence, on the likely application of the regulations themselves. We found that France, for example, excludes from the ambit of medical purpose functions related to the communication of medical information (14). We likewise noted that HC's SaMD guidance describes sweeping exclusion criteria, according to which software may be specifically exempt from regulatory oversight, even if it performs a medical purpose (6). Software "that does not have a direct impact on the diagnosis, treatment, or management of an individual's disease, disorder, abnormal physical state or symptoms" will generally not be subject to regulation (6). HC's guidance lists four exclusion criteria, all of which must be satisfied for software that otherwise has a medical purpose to be excluded from formal oversight: 1) the software is not intended to acquire, process, or analyze a medical image or a signal from an IVDD, 2) the software is "intended to display, analyze, or print medical information about a patient or other medical information (such as demographic information, drug labelling, clinical guidelines, studies, or recommendations)," 3) the software is only intended to support decision-making about prevention, diagnosis, or treatment of a disease or condition, and 4) the software is not intended to replace the clinical judgment of a health professional (6). There is some lack of clarity in the way these exclusion criteria are formulated, particularly regarding the requirement that each of the four exclusion criteria must be met. In an annex to its guidance, HC addresses some of this confusion by providing examples of software excluded from regulatory oversight on this rubric. Notable for our purposes here, HC explicitly indicates that it plans not to regulate software enabling patients to track health information and software for collecting and storing health information as part of an electronic health record (15). These criteria might suggest that, even in the unlikely event that therapeutic portals perform medical purposes, they may be specifically excluded from regulatory oversight under emerging SaMD regimes.

Our principal finding here is that regulatory guidance applicable to SaMD in Canada, the United States, the United Kingdom, and France would likely exclude therapeutic portals from formal oversight as medical devices. This finding, as Tables 2 and 3 above suggest, is drawn from a small number of primary regulatory guidance on the regulation of SaMD. Supplementary sources provide additional context on the intentions of regulators with respect to SaMD oversight.

DISCUSSION

In reviewing the regulatory guidance documents outlined above, we noted that therapeutic portals are not likely to be regulated as medical devices under existing SaMD frameworks in Canada, the United States, the United Kingdom, and France. On one hand, therapeutic portals as we describe them above and in previous scholarship, will not generally have medical purposes. On the other hand, even for therapeutic portals with medical purposes, it may be that these are excluded from formal regulatory oversight insofar as they primarily operate to display or distribute health research information and are not intended to replace professional clinical judgment or to directly diagnose, treat, or manage illness. Just as medical software will have a wide range of purposes and functions, therapeutic portals will conceivably take numerous forms. Some of them will, in some jurisdictions,

likely have medical purposes as defined in regulation and guidance. But for the most part, the documents we survey here take the position that SaMD regulation does not apply to therapeutic portals. These sources nevertheless offer significant guidance about the kinds of issues and principles portal developers and users should address. Below, we examine briefly how each of these themes might be facultative for the development of therapeutic portals and other digital health technologies. We offer brief comments on how these considerations could be accounted for by portal developers and users.

Efficiency

Many of the documents we reviewed highlight the likely significant role Internet-enabled health tools will play in increasing the efficiency with which patients access health services and information about their care. The FDA's *Digital Health Innovation Plan*, for example, notes that software capable of assisting in diagnosis, treatment, and data management can "enable more efficient clinical practice." (16) In the UK, DHSC's *Guide to good practice for digital and data-driven health technologies* makes a similar point, suggesting that software developers should have a clear understanding of the role their technology is likely to play in accomplishing the broader social goal of achieving better healthcare, including in the achievement of greater system efficiency (17). Apart from the capacity of digital tools to make healthcare more efficient, several of the documents we reviewed also underscore the importance for regulators to build efficient regulatory responses to innovation, mechanisms that are transparent, predictable, and consistent (18). France's HAS makes a similar point, noting that governments have an interest in making investments in the development of health technologies that would create greater efficiencies in care delivery (19). In a related vein, Canada has signalled an intention to develop, by 2025, a digital health strategy that works to ensure efficient and interoperable digital health platforms (18).

Efficiency, then, is a complex and multilayered notion in the context of digital health, referring both to the capacity of digital tools to improve healthcare and the importance of regulation that does not impede efficient technological development. For our purposes, the former of these interpretations is likely the more significant, indicating that the developers of therapeutic portals should consider carefully how the technologies they implement may affect access to the healthcare system. While facilitating sweeping access to health information might generally be perceived to be in the public interest (20), for example, the details surrounding how such access is managed matter a great deal. Especially as public health systems become increasingly resource-strained, public access to personalized health information could have unpredicted effects. If such information is not presented accessibly and in sufficient context, it could have the effect of pushing portal users to seek unnecessary care to clarify or confirm information accessed online. Thus, while therapeutic portals have great potential to increase the efficiency of healthcare delivery, so too might poor design lead to a misuse of limited health system resources.

Equity

Equity is naturally a dominant consideration associated with how the sharing of information through a therapeutic portal might be managed. As above, this is a concern that can broadly be approached in two distinct ways. First, certain documents outline the potential for online tools to address existing health inequality. Health Canada's notice on its regulatory *Approach to Digital Health Technologies*, for example, suggests that digital health can help to address inequality of care access between rural and urban Canadians (21). In this mould, the availability of health information on a therapeutic portal might have the effect of promoting equality of care access, particularly in the case of rare or difficult to treat disease. Highly complex pathologies are often treated by highly trained specialist clinicians, many of whom may be located in urban centres, effectively unavailable to rural or Indigenous populations. An online therapeutic portal making diagnostic and treatment information widely available could work toward lessening the outcome effects of such disparity. Second, some of the documents we reviewed, rather than discussing the equity-advancing potential of digital health, focus on fair application of novel health tools. In the UK, DHSC's *Guide to good practice for digital and data-driven health technologies* stresses, for example, that technology developers should be "fair, transparent, and accountable about what data is being used." (17) In creating new SaMD, developers ought to be attentive to notion that everyone should be able to benefit more or less equally from the use of a publicly available digital system. It is, to be sure, one thing to state this as a principle, and quite another to put it into practice. Professional and regulatory guidance specific to publicly accessible therapeutic portals could begin to provide concrete direction in assuring equity in this context.

Transparency

Following the theme illustrated above, discussions surrounding transparency consist of two countervailing interpretations: one at the level of the implementation of digital health tools and another at the level of their regulation. First, some of the documents we surveyed refer to the importance of transparency in the communication of health information, especially when a digital system is empowered to make decisions that affect a clinical process. This is likely to become especially relevant as artificial intelligence plays a more focussed role in the management of health information. Following this perspective, the FDA recommends that database curators "make publicly available sufficient information regarding data sources and standard operating procedures." (22) Second, certain sources emphasize the value of transparent regulatory processes. This is a view taken by HC in its 2019 consultations, in which the agency notes a demand from stakeholders to provide transparency surrounding the classification of SaMD and other digital technologies (23). The UK's *Guide to good practice for digital and data-driven health technologies* ties transparency together with confidentiality and privacy, noting that "transparency will help to ensure that the rights of data subjects under the *Data Protection Act 2018* are maintained." (17) Insofar as therapeutic portals are designed for the benefit of clinicians, researchers, and patients alike, there may be particular pressures on their developers to ensure openness about how data is sourced and organized. Researchers, for example, will have a dominant interest in ensuring that information posted on a therapeutic portal is reliable and useful. Developers could work to promote

transparency by publishing raw data and relevant source code such that external observers could scrutinize a portal's functionality. To be sure, doing this will often be infeasible for intellectual property reasons. At minimum, portal developers should reference published research results where appropriate on the portal interface.

Confidentiality

We were not surprised to find significant discussion in the sources we reviewed on issues of confidentiality, privacy, and data protection. Much of the discussion straightforwardly revolved around the role of privacy regulation as a compliment to medical device regulations. Even in the absence of regulation under a SaMD regime, therapeutic portals and other digital technologies will generally be expected to comply with privacy legislation. The UK's DHSC, in its report on the future of healthcare, emphasizes this point by noting that "safe and secure data infrastructure that protects health and care services, patients and the public" is vital for the effective implantation of digital health (24). The FDA takes a similar view, underscoring that databases are unsurprisingly required to comply with "all applicable privacy laws and regulations." (22) In the case of therapeutic portals, and apart from the requirements of formal regulation, there may be strong ethical reasons to implement strong confidentiality practices. Considering the proposed public-facing nature of these kinds of portals, risks of data breach may be especially high. By a similar measure, maintaining public trust may be especially important. Strong privacy-protecting policies in compliance with applicable law and best practices may help on both measures.

Communication

We found limited, though important, discussion surrounding communication for emerging digital health technologies in the sources we reviewed. Discussion on this topic focussed largely on the ways digital tools can be used to increase and improve communication with a range of stakeholders. France's e-health strategy, for example, makes a point of mentioning that portals may be helpful in facilitating interactions between health systems and the public (25). The FDA signalled plans in its digital health strategy to develop additional regulatory guidance for researchers using online systems for patient communication (16). This kind of guidance, in the agency's view, would encourage "digital health innovation by redesigning our policies and processes and modernizing our tools so that they match the needs of digital health technology, and providing clarity on those policies and processes so that manufacturers and developers know what they need to do." (16) Though discussion surrounding the communication of health information was only a secondary theme in the sources we reviewed, it is in our view an important consideration in the context of the design and use of therapeutic portals. These kinds of portals, at least in our description of them, are after all fundamentally tools for the communication of research findings to a broad and diverse audience.

Empowerment

The documents we review here attended to the theme of empowerment in a relatively narrow frame. Much of the discussion focussed on empowerment as it relates to patients and users of digital health technologies. France's e-health strategy takes a fairly directive position on patient empowerment, stressing that citizens should be at the centre of any advancement in digital health. This means, in particular, that patient empowerment should be a central objective of any strategy that incorporates digital technologies into the healthcare system (25). The FDA, taking a similar tack, writes that "digital health technologies can *empower consumers* to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings." (16) Empowerment is presented as an opportunity for patients, though one that needs to be subject to certain restrictions, most notably that such opportunities need to be optional. Against this backdrop, it is important to note that therapeutic portals raise the possibility that both patients and physicians may be empowered to engage differently with the course of diagnosis and treatment. To the extent that patients have access to therapeutic portals, for example, they might be empowered to engage more fully in their care in virtue of having access to data about their condition, prognosis, and available treatment options. For physicians, therapeutic portals may be empowering insofar as they provide new methods for diagnosing and treating patients. Portal developers should consider the empowering effects on both patients and clinicians that the design and implementation of their online systems for health data sharing could have. As with other themes raised in this paper, information that is accessibly drafted and is contextualized with respect to relevant scientific evidence will tend to be more empowering than information that is presented less thoughtfully.

Training

With the development of novel health technologies, it may be justified to worry whether end-users will have an acceptable degree of technical background and training in applying the system. Untrained operators of sophisticated medical tools, after all, may become sources of significant error or misuse. The UK government's report on the future of healthcare makes precisely this point, noting that "health system staff should be trained in digital services skills. An open culture should be fostered, and relationships constructed with innovators, academics, industry staff, and patients." (24) While appropriate training might be straightforwardly valuable, HC's consultation summary problematizes the potential application of pre-implementation training regimes, suggesting that "innovators do not always have the resources…to train employees." (23) With the advent of therapeutic portals, training for proper use may be a distinctly important requirement for ensuring patient safety. Researchers or clinicians unfamiliar with platform data organization may overgeneralize or otherwise rely inappropriately on a therapeutic portal. These risks may be especially pronounced for patients accessing online resources, some of whom will misunderstand technical data relevant to their care. Therapeutic portal developers may consider introducing mechanisms to introduce users to a portal's functionality, including by posting mandatory training modules or introductory explanatory notes on the portal interface.

Safety & efficacy

As outlined above, nearly all the documents reviewed discuss the dominant role that safety and efficacy play in SaMD regulation. Considering that the primary purpose of medical devices regulation is to ensure that systems used in patient care are safe and effective, this nearly universal treatment is not surprising. Even insofar as therapeutic portals are not likely to be formally subject to regulation under existing SaMD regimes, this does not mean that safety and efficacy considerations are irrelevant in this context. While therapeutic portal developers may not have a legally enforceable obligation to demonstrate the safety and efficacy of the software they produce, they arguably have a significant ethical obligation to do so. Ensuring that therapeutic portals work and that they can be safely relied on by their intended end-users ought to be the dominant concern of any software developer operating in this space.

RECOMMENDATIONS

Against this backdrop, it is in our view essential that portal developers familiarize themselves with the evolving regulatory regime applicable to SaMD. Though this paper suggests that regulation as it is presently constituted likely does not apply to therapeutic portals as we have described them, it is conceivable that this may – and perhaps *should* – change. As medical practice increasingly implements elements of the "learning healthcare system" model by integrating research findings more directly in patient care, we imagine that therapeutic portals will become vital tools for physicians and patients alike. Physicians may use these Internet-enabled platforms to stay apprised of rapidly emerging biomedical knowledge while patients may use them to become better informed about their course of treatment, empowering them to become more active partners in their care. As this happens, these tools may end up being subject to greater regulatory scrutiny. If widely adopted in the clinic, therapeutic portals could entail significant risks of misdiagnosis, misuse, breaches of confidentiality, and others. Such risks may draw the attention of regulatory agencies in the interest of securing patient safety and public trust. We recommend, then, that regulators clarify how SaMD guidance should be interpreted to apply to web portals and other Internet-enabled programs. As we suggested above, the generally agreed definition of SaMD appears broad enough to include web portals that have medical purposes. It would provide significant certainty for developers, physicians, and the public to explicitly include web systems in future guidance iterations of SaMD guidance documents. This is not to say that therapeutic portals *ought* to be regulated as medical devices, but rather that we would encourage regulators to take a clear position one way or the other. At present, the situation is ambiguous and only likely to become more so as this space evolves.

CONCLUSION

This paper gives an overview of some of the ways regulatory guidance is likely to control the development and implementation of therapeutic portals. We reviewed 20 guidance documents prepared by regulatory authorities in Canada, the United States, the United Kingdom, and France. These documents tell us that therapeutic portals are not likely to be formally subject to regulatory oversight under existing medical device regimes. The reviewed documents also point to a number of normative and logistical considerations that ought to be top of mind in the creation of novel technologies for sharing health data with diverse audiences.

In our view, portal developers should be attentive to each of the eight ethical and regulatory concerns outlined above, even if they are not formally required by regulation to do so. We give brief and preliminary recommendations for portal developers engaged in this space. In broad strokes, portal developers should be thoughtful about the way their information is presented. While accessible and contextualized health information can promote patient empowerment and equity, also making care delivery more efficient, data that is presented in ways inattentive to these elements might actually harm portal objectives. There are also good scientific reasons to attend to the ethical and regulatory concerns raised by therapeutic web portals – more carefully designed medical software is likely to be more clinically useful. But there are good social and ethical reasons to do so as well. Public trust in health systems and institutions is, as several authors have argued, a critical element in the success of medical governance (26). One way to foster public trust in the development of health technologies is to ensure compliance not just with formal regulatory requirements, but with the principled spirit of the regulation that applies in this context. Insofar as the public might tend toward increased distrust when medical technologies are supported by or use the Internet, it will be especially important for the developers of therapeutic portals to be cognizant of the regulatory infrastructure intended to support patient protection.

Reçu/Received: 04/11/2022
Publié/Published: 27/06/2023

Remerciements
Ce travail a été soutenu par la subvention de Génome Québec "Interroger et mettre en œuvre les Omics pour la médecine de précision dans la leucémie myéloïde aiguë". MHZ remercie le Fonds de recherche du Québec-Santé pour son généreux soutien, dans le cadre du programme de bourses de recherche Junior 1.

Acknowledgements
This work was supported by the Genome Quebec grant "Interrogating and implementing Omics for precision medicine in acute myeloid leukemia." MHZ acknowledges the generous support of the Fonds de recherche du Québec–Santé, Junior 1 Research Scholar program.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Aliya Affdal

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

K Dercon, M Domaradzki, HT Elisenberg, A Głos, R Handeland, A Popowicz, J Piasecki
Can J Bioeth / Rev Can Bioeth. 2023;6(2):76-89

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

COVID-19: Falling Apart and Bouncing Back. A Collective Autoethnography Focused on Bioethics Education

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Note: All authors made a similar contribution to the manuscript so are listed in alphabetical order, except for JP, who is the corresponding author.

Résumé

La pandémie de COVID-19 a perturbé la vie universitaire dans le monde entier, tant pour les étudiants que pour les éducateurs. L'objectif de cette étude est de mettre en lumière l'adversité collective vécue par les étudiants internationaux en médecine et les éducateurs en bioéthique, causée par la pandémie de COVID-19, tant sur le plan personnel que sur le plan académique. Les auteurs ont rédigé leurs mémoires subjectives et les ont ensuite analysées à l'aide d'une méthode d'auto-ethnographie collective afin de trouver les similitudes et les différences entre leurs expériences. Les résultats révèlent des schémas cohérents dans l'expérience qui se traduisent par deux métaphores : *s'effondrer* et *rebondir*. « S'effondrer » désigne l'effondrement de la vie quotidienne au cours des premières phases de la pandémie, illustré par des citations subjectives mises en contexte par les commentaires des auteurs. Le consensus est que le retour au pays et la transition vers l'enseignement à distance ont été les deux principales raisons de l'effondrement. Le terme « rebondir » englobe le rétablissement des auteurs après la rupture initiale, grâce à l'acquisition de nouvelles informations sur le virus, à la découverte de moyens de poursuivre leurs passe-temps à la maison, tels que l'entraînement ou la danse, et à l'apprentissage de l'adaptation des attentes en matière d'examens. Au niveau éducatif, le cours de bioéthique, qui a guidé les étudiants à travers les dilemmes éthiques de la pandémie, a joué un rôle important dans le processus de récupération et de rebond. C'est pourquoi nous expliquons comment il a fallu apprendre et enseigner cette matière pendant la pandémie, et comment les connaissances en bioéthique ont été appliquées pour mieux comprendre et faire face à certains des dilemmes moraux liés à la pandémie. L'étude témoigne de l'importance de l'éducation à la bioéthique pendant une pandémie et explique comment elle peut contribuer à former la résilience morale des futurs praticiens médicaux.

Mots-clés

autoethnographie, bioéthique, COVID-19, infodémie, enseignement médical, enseignement en ligne, santé publique, résilience morale

Abstract

The COVID-19 pandemic disrupted academic life worldwide for students as well as educators. The purpose of this study is to shed light on the collective adversity experienced by international medical students and bioethics educators caused by the COVID-19 pandemic in relation to both personal and academic life. The authors wrote their subjective memoirs and then analyzed them using a collective autoethnography method in order to find the similarities and differences between their experiences. The results reveal some consistent patterns in experience that are captured in two metaphors: *Falling apart* and *Bouncing back*. "Falling apart" involves the breakdown of daily lives during the initial stages of the pandemic, shown through subjective quotes contextualized through the authors' commentary. The consensus is that returning home and the transition to remote education were the two main reasons for the breakdown. "Bouncing back" encompasses the authors' recovery after the initial breakdown, achieved by acquiring new information about the virus, discovering how to continue their hobbies at home, such as working out or dancing, and learning to adjust exam expectations. At the educational level, the bioethics course, which guided students through the ethical dilemmas of the pandemic, played an important role in the recovery/bouncing back process. For that reason, we report on how it was to learn about and teach this subject during the pandemic, and how bioethics knowledge was applied for better understanding and coping with some of the moral dilemmas related to the pandemic. The study testifies to the importance of bioethics education during a pandemic and explains how this can contribute to shaping the moral resilience of future medical practitioners.

Keywords

autoethnography, bioethics, COVID-19, infodemic, medical education, online education, public health, moral resilience

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ISSN 2561-4665

INTRODUCTION[1]

During the COVID-19 pandemic, we witnessed global waves of infections: initially, the number of infections were rising, but effective public health interventions led to a reduction in the numbers, and eventually restrictions were loosened. These waves of cases and restrictions caused changes in students' and educators' attitudes toward the pandemic and public health interventions. In this collective autoethnographic study, a research team comprising two bioethics educators and five medical students describe and analyze how the public health interventions targeting the spread of the SARS-CoV-2 virus affected the education of first-year medicinal students, and what role online classes in bioethics played in their understanding of the social and cultural circumstances of the pandemic. The sudden change of the educational situation can, we argue, reveal the hidden aspects of the biomedical curriculum (5) that are not otherwise visible. Moreover, it can also help in understanding the role of bioethics in the socialization of first-year medical students.

The Medical College of the Jagiellonian University in Krakow arranges its medical program to last six years in accordance with Poland's legal requirements. The first year tackles "Ethics in medicine" in a 30-hour seminar together with courses in anatomy, physiology, biochemistry, histology, history of medicine, and genetics (6). According to the formal curriculum, the aim of bioethics training ("Ethics in medicine") is threefold: first, to give students the ability to perceive the ethical dimension of medical practice; second, to familiarize students with fundamental schools of moral thought and typical methods of ethical reasoning and argumentation; and third, to prepare students for future ethical problem-solving in their medical practice based on rational argumentation. The main topics in the training are patient rights, communication with patients and their families in an atmosphere of trust, clinical research ethics, and focus on patient well-being. Due to the pandemic, bioethics educators emphasised topics associated with public health ethics, scarce resources allocation, and epidemiology ethics. In the existing literature, the main objectives of bioethics classes for medical students can be grouped into three categories: cognition, behaviour, and attitude (7,8). Cognitive goals encompass the ability to discern and resolve ethical dilemmas using concepts and arguments that are grounded in ethical theories. Behavioural goals are met when knowledge about ethical theories and ethical standards, coupled with the skills of ethical reasoning, results in ethical behaviour such as obtaining valid informed consent or determining whether it is justified to withhold some information from a patient. Finally, attitude may refer to the concept of virtue, which can be broadly defined as a habitual disposition to fulfill one's professional duties (9). However, measuring both behavioural and attitudinal goals during formal assignments in class is challenging, leading to a debate on whether the bioethics class should prioritize these goals (7).

COVID-19 is a new human transmissible coronavirus. At the early stage of the pandemic, fever, cough, sore throat, and headaches were reported as the only symptoms (10). As the virus spread globally, lockdowns became a standard response in many countries to control transmission and halt its unknown effects. To achieve this, social interaction was limited, and movement was restricted to only essential purposes, such as food shopping and exercise. However, although lockdowns were effective at reducing transmission rates, they did not come without a burden. Pain and sacrifice endured include, but are not limited to, an increased number of deaths from other diseases (11), the ongoing effects on mental health and suicide (12), and the tragedy of many loved ones dying alone (13).

The outbreak of the COVID-19 pandemic was a challenge to educational systems around the world, forcing most universities to move their classes online in a very short period of time. This rapid digital transition was accompanied by numerous technological, organizational, and socioeconomic challenges. A lack of technological infrastructure and digital competence was widespread among both professors and students (14,15). Many studies report that online education during the pandemic

[1] **Glossary**

Autoethnography	a type of research where a researcher and their experiences are the subject of study
Collective autoethnography	a type of research where the researchers and their (shared) experience comprise the subjects of study
Moral distress	"the psychological distress of being in a situation in which one is constrained from acting on what one knows to be right due to the presence of institutional or external constraint" (1)
Moral injury	"moral suffering characterized by exposure to circumstances that violate one's moral values and beliefs in ways that erode integrity, moral capability, perception of basic goodness, and create distress on a psychological, behavioral, social, or spiritual level" (2)
Moral resilience	"the capacity of an individual to preserve or restore integrity in response to moral adversity, including situations that include moral complexity, confusion, distress or setbacks" (2,3)
Moral efficacy	the capacity to stand up for what one believes to be correct, even when faced with resistance
Self-regulation	"awareness of one's psychological and somatic states" (1)
Self-stewardship	"paying attention to one's well-being while being aware of one's limits; and moral efficacy requires advocating for what one believes is correct, even when there is resistance" (1)
Idiosyncrasies	certain behaviors, behavioral patterns, or beliefs sustained by an individual
GAD score	a numerical score based on a self-report two-item anxiety scale that was used to track the progress of generalized anxiety disorder in a set of medical students
Remote education	a type of education referring to the distance between the learner and the educator or the learner and the institution/educational resources
Distance education	a type of education referring to the distance between viewpoints and perspectives, where interaction takes place between different parties with varying understanding or values regarding the topic of discussion
Infodemic	"too much information including false or misleading information in digital and physical environments during a disease outbreak. It causes confusion and risk-taking behaviors that can harm health" (4)

exposed and further deepened existing socioeconomic inequalities, since students from poorer socioeconomic backgrounds often had no access to the necessary technical equipment and decent working conditions (16-18). Other obstacles included heavy workload, difficulties in conducting exams online, and the incompatibility of some subjects (e.g., clinical medicine) with the online mode (14,15). Therefore, as Hodges et al. rightly clarify (19), the accelerated digital transition should be understood as an instance of “MacGyvered” (improvised) experiment of “emergency remote teaching” rather than proper online courses. Preparation of such online courses usually takes many months and is evaluated accordingly. Nevertheless, this “emergency remote teaching” experiment brought some developments. A series of survey-based studies report some advantages, such as boosted confidence in the effectiveness of online medical education (20), research and technological innovations and socioeconomic interventions (14), as well as expressing educators’ readiness to transition to online teaching and the necessity to incorporate such training into professional education (21). A majority of existing studies, however, analyze educators’ perspectives with limited reference to medical subjects and bioethics. Moreover, Byron Good argues that studying medicine goes beyond acquiring certain knowledge and skills but should be seen as a process of acculturation to a specific (medical) worldview (22). In this context, bioethics serves an important role in connecting the biomedical worldview with common morality. The relevant studies that were available at the time of writing our paper (2021-2022) were limited in number and scope, primarily concentrating on the organizational and technical difficulties of online medical education (e.g., the question of how such a practice-oriented profession as medicine can be taught in an online setting). The literature did not go into great detail on issues relating to the unique nature of bioethics education, such as how to develop sensitivity for particular values and virtues, how to spark meaningful conversation, how to encourage ethical decision-making, or how to offer role models in an online environment. Neither were the students’ voices sufficiently sought. More research is needed in this area to better understand the challenges and opportunities of online bioethics education. In this regard, our study contributes to the field because it qualitatively captures the dynamics of both teaching and learning experiences.

Our research endeavour was a form of collaborative autoethnography, focusing on the experiences of educators and students in online bioethics classes during the COVID-19 pandemic. In a collective autoethnography, a group of researchers gives voice to their individual, personal perspectives and then summarize and analyze their shared experience in a more systematic manner (23,24). Due diligence to make the process of research and writing inclusive, multivocal, and collaborative was achieved through consensus decision making, which is part of the norms for collective autoethnographic research (24).

Autoethnography has already been successfully used for dealing with the professional and personal experience of educators (25), as well as several different areas where the boundaries between research and individual experience matter (26). However, to our knowledge, there is no similar study describing the shared experience of students and educators, while, most importantly, focusing on the subject of bioethics education. Considering that the COVID-19 pandemic has given rise to poignant ethical dilemmas and moral distress among medical practitioners, our focus on the role of bioethics education in understanding and addressing these challenges opens avenues for future research on the relationship between bioethics education and moral resilience during times of crisis (27). Ethical reflection allows us to analyze and understand the roots of moral distress, helping to comprehend human behaviour and, as a result, enabling individuals to cope with moral distress. According to Delgado et al., moral distress arises when a healthcare professional is unable to act in accordance with their moral beliefs and values due to external constraints or limitations (1). The pandemic provoked many situations where healthcare professionals had to adhere to institutional or public health regulations that went against what they saw as the best interests of their patients. An example would be when they had to adopt strict triage and resource allocation criteria or deny access of family members to the hospitalized (or even dying) patients due to public health restrictions, which produced moral distress or even moral injury. The bioethics class – which offers specific criteria to make informed moral judgments, discusses various ethical frameworks and explains their applications to different situations, trains students in resolving moral conflicts – can, we suggest, help to mitigate the moral and mental burden of such decisions in the future.

In the following sections, we describe our individual and group experience of studying and teaching bioethics as a part of medical curriculum. Our analysis will go beyond the description of individual perspectives, and we discern some common motifs in our individual experiences. We also think that our experience can be a point of departure for future research that may deepen understanding of how individuals become better medical students, and in consequence, better physicians.

METHODS

Research team (students + teachers) = participants

In a collective autoethnography, the researchers are also the research participants. Our team comprised two bioethics educators with backgrounds in philosophy, bioethics, and law, and five second-year medical students (at the time of data collection) of the School of Medicine in English at the Jagiellonian University Medical College (Kraków, Poland) (Table 1).

Table 1. Demographic of the research team

Research sample	7
Educators	2
Students	5
Male	3
Female	4

Home country	
Poland	3
Norway	2
UK	1
Austria/Ecuador	1

A further nuance is that our study was also an online ethnography, because it covered our online experience with remote learning to a certain extent, and the research project itself had a purely online character: since the inception of the idea for the research project, the members of the research team have never met in person, relying only on online communication.

Collective autoethnography as a methodological choice

We applied a collective autoethnographic method that captures individual experiences in certain circumstances and juxtaposes these with others' individual perspectives through a common deliberation. This approach was well suited to addressing the main research question: "How did the COVID-19 pandemic and public health measures countering the spread of the virus affect the bioethical education of medical students?"

Sara Delamont (28) has criticized the autoethnographic method, contrasting it with the autobiographical reflexivity of an ethnographer. She defines autoethnography in a narrow sense as ethnography whose "topic or focus is the author herself or himself". However, our research deviates in two respects from this very strict conception: 1) we focus on our experiences as students and as educators during the COVID-19 pandemic; and 2) as a collective autoethnography, we combine our individual experiences to look for possible patterns. Moreover, in the first phase, our research had an *in statu nascendi* character, insofar as it was in the writing process itself that we were able to realize the exact nature of our experiences. In the second phase, we collected the seven memoirs, and we reflected not only on our individual experiences but also on the experience of our co-researchers. Therefore, in that sense, our method meets Delamont's requirement of understanding ethnography: initially, we made the strange pandemic experience more familiar, and in the second phase, our already familiar experiences, internalized through the writing process, were seen in a new (unfamiliar) context, revealing patterns that became visible only when individual memoirs were juxtaposed with others' memoirs.

Data collection

On Sept. 19, 2020, JP – a bioethics educator – gathered together a research team composed of his former students and a fellow educator to collectively work on a paper on the COVID-19 pandemic and bioethical education. Due to public health measures, the research team worked remotely, using MS Teams for meetings and sharing documents. The research team was diverse, and its members had different levels of knowledge and skills regarding research and academic writing. Five members of the team were second-year medical students, who had not had any previous training in social science research. Therefore, to provide all the research team members with the necessary knowledge and skills, JP held online meetings to discuss the methodology of qualitative research, ethical problems, and practical aspects of scientific publications.

During the first team meetings, it was decided that all issues concerning the project would be solved through consensus. First, the team formulated a research question: "What is the impact of the COVID-19 pandemic and public health measures on the experience of studying and teaching bioethics?" Next, the team decided on a methodological approach and data collection methods. A collective autoethnography was the method of choice, as it allowed the team to focus both on personal and collective experiences.

The research team decided that every member would write a personal memoir of the previous spring semester (Feb.-June 2020), which was when the COVID-19 pandemic began, and the public health measures drastically transformed academic life. That period was still fresh in the research team members' memory and the main goal of writing a memoir was to gain perspective on one's own individual experience. Initial discussions of experiences during the first period of the COVID-19 pandemic revealed a broad scope of different topics that could be described and discussed in the memoirs. Therefore, the team decided that the memoirs should be three to ten pages long and focus on three broad topics: 1) "Studying/teaching bioethics during the COVID-19 pandemic", which covered important experiences from the pandemic as seen through the lens of bioethics; 2) The "existential experience of the COVID-19 pandemic", which focused on the personal experiences of the authors during the pandemic; and 3) "Understanding the COVID-19 pandemic", which covered the underlying infodemic concerning COVID-19 from a social, cultural, political, and scientific point of view (see Glossary, footnote 1). The list of broad topics was agreed upon after online discussions and a round of voting. The team decided that at the later stage of research, all the memoirs would serve as a resource for analysis. This approach allowed us to combine the subjective experiences of each team member with the more objective analysis by the whole research team.

After six weeks, seven memoirs were ready and became the subject of collective analysis – our aim was to identify common motifs in the texts. The team worked in two pairs and one trio of coders to ensure the objectivity of the process. Each team read all the memoirs and created a provisional list of common motifs. The results of coding were then compared in open forum online discussions: the team consulted the original texts of memoirs with provisional lists of motifs. After agreeing on general motifs that emerged from our memoirs, each sub-team (two pairs and one trio of coders) was assigned to code the memoirs and then to write a section of the paper.

Ethics of collective autoethnography

While the initial idea of this paper was prompted by JP, the research team adopted a consensus strategy for making further decisions concerning the research project. Reaching the consensus made the process more deliberative; sometimes difficulties arose in resolving problems or dilemmas that occurred during the process, because while the JP and AG – the bioethics educators of the medical students – did not want to impose their perspectives, the students (AP, HE, KD, MD, & RH)

were also cautious about putting their opinions forward. This strategy, along with the adopted methodology of collective autoethnography, resulted in a shift in research focus from the impact of COVID-19 pandemic on bioethics education to the impact on our personal lives of students and educators. Without a strong leader directing the research process, the researchers/participants focused their attention on the problems that interested them the most, treating the initial research question as a pretext for self-exploration.

Before the whole process started, we openly discussed ethical dilemmas that had to be addressed. We did not apply for ethical approval to a research ethics committee at our university. We came to the conclusion that all human participants were also researchers, and that we focused on issues, albeit sensitive ones, that we had already shared in different public fora. Nonetheless, having in mind privacy and confidentiality issues, we discussed how much information should be disclosed in the memoirs and then reported in the paper. We discussed the option of anonymity and decided that it should be an individual choice whether to anonymize our quotes or to not be quoted at all. Ultimately, we invariably chose to share our experience and struggles openly. For some members of our research team, sharing their experience under their own name was the main motivation to participate in the research project. We were cautious not to disclose any information that could be damaging for any third parties who played roles in our personal stories (23,24,28).

We resolved the issue of authorship and management of the research tasks in advance. JP was tasked with dividing work into packages and managing the overall process. The work packages were allocated in a consensus-reaching discussion to pairs (KD & RH, MD & HE) and a trio (AG, AP, JP), and those sub-teams worked on their own. We reached a consensus that everyone made a similar contribution to the manuscript, which is reflected in the alphabetical order of authors, except for JP, who is the last corresponding author. This strategy ensured equal positions for all researchers in the team, and we have also decided to clearly describe the rationale for the authors' order in the paper itself. The final version of the manuscript was commented on and edited by all the authors, who all accepted the final version of the manuscript. Each author contributed equally to the research project and to the production of the final manuscript.

RESULTS

Our autoethnographic efforts resulted in seven memoirs written in English, varying in length (ranging from 1979 to 3850 words), writing style, and perspective. Some of us tried to keep a chronological order of events (KD, MD, HE, AG, JP), while others divided their texts into three parts that covered the pre-established topic areas (RH, AP). All the memoirs presented personal experiences of studying or teaching bioethics during the COVID-19 pandemic, however, we varied in the way we described our lives: some descriptions were focused chiefly on professional identity, describing private aspects of life merely as a background (AG, JP, AP), while others gave a more comprehensive picture of life, where private experiences were intertwined with studying. Moreover, some of us treated our memoirs as an opportunity to share more general reflections about studying and teaching bioethics (JP), the British response to the pandemic and public life (AP), political and personal responsibility of the world leaders (HE, KD), the social and humanitarian situation in Ecuador (KD), as well as the role of social media and misinformation (KD). Others shared their private ethical doubts and dilemmas associated with the pandemic (MD, RH). We devoted one section solely to the experience of studying or teaching bioethics. Although our initial intention was to study the impact of COVID-19 on studying bioethics, the memoirs put more emphasis on the process of studying and other everyday experiences of disruptions that were associated with the public health measures. It turned out that the bioethics classes played an important role in helping to understanding the pandemic and the process of "meaning-making." Considering the issue of individual experience of the pandemic, despite many differences, there were also common motifs and themes that are best expressed through two metaphors: *falling apart* and *bouncing back*. The metaphor of falling apart captures the manifold changes the outbreak of the pandemic brought into our personal, professional, and social lives, which, for most of us, felt like a breakdown of normal life routines and a challenge to common patterns of understanding the world. The metaphor of bouncing back sums up our efforts to continue our lives in the changed circumstances and our attempts to construct our personal and professional identity anew.

Studying bioethics

The transition to online learning, including bioethics, was challenging for all the participants. There is a difference in dynamics between online and offline learning. In JP's online tutorial approach, which primarily involved providing students with reading materials, cases, and video instructions through an online platform, the major element that was missing was discussion. As MD mentioned, discussion is "fuel for thinking", while RH claimed that "…discussions are much better when you can look everyone face to face and the threshold for asking questions and sorting out misunderstanding is much lower". JP adopted this strategy for two reasons. First, some of his students had returned to their home countries, and the time differences made it difficult for them to participate in live online classes. Second, due to the lockdown, JP did not have access to an office space where he could hold online meetings. Additionally, AG found it more challenging to encourage discussion in the synchronic Zoom class mode. In a traditional classroom, students are more comfortable speaking up, and educators have more tools at their disposal to engage with students (e.g., grouping students into pairs or teams, setting up debates), whereas in an online format these options are more limited (e.g., moving to break-out rooms typically takes time and slows down the natural flow of thought-exchange), technological issues and Internet disruptions recur, and camera shyness lowers engagement.

Although the pandemic was challenging, we felt that it also opened opportunities to explore and apply bioethical learning. Through a bioethics lens, students were able to examine the dilemmas introduced by COVID-19. This led to critical questioning

of institutions and the public's response, such as the postponement of lockdown imposition in the UK and the general public's compliance with the mask mandate and social distancing. Additionally, students navigated these issues on their own, trying to balance public and individual interests.

A flood of misinformation, especially in social media, was one of the most commonly shared challenges we faced. As a result, many of us were uncertain regarding the crucial aspects of the new virus – its transmission, consequences, and the ethics behind public health measures that not only curtailed the freedom of individuals who seemed not to be exposed to serious health risk, but also deprived them of benefits of social life and education. This confusion resulted in conflicts between different groups of society. AP noted that anti-maskers believed that wearing a mask "infringes on their freedom," a conviction that stemmed from "not believing in the dangers of COVID-19, disregarding scientific evidence and sharing misinformation via social media platforms". Due to their medical and bioethics education, the students stressed the importance of wearing face masks. The ethical reason played an important role in accepting public health policy requirements; HE expressed it clearly with the following words "studying bioethics helped me understand that I was right, and that it is not okay to put your opinions before others' well-being". By learning to weigh his own interests against the welfare of others and accepting the boundaries of his own liberty, he also attested to the potential of bioethics to fosters the growth of moral and civic virtues.

The students felt that it was their duty to adhere to the recommendations and recognized that because it was a public health dilemma, the elimination of virus transmission was dependent on the collective efforts and behaviours of all.

The opposition to face mask use resulted not only from personal opinions but also the lack of guidance from governments. During the bioethics classes, the students learned that, as AP put it, "in order to effectively manage public health, the duties of healthcare leaders is to plan, safeguard and guide". However, most of the students experienced a lack of this kind of political leadership that pursued the public good during this tumultuous period, and eschewed petty power struggles and individual privileges. They realized and experienced the ethical dimension of political decisions. For example, there was a delay in the governments' mandate to wearing face masks: as A noted, "Even with the knowledge that transmission is airborne, face masks only became compulsory in shops… in the United Kingdom – four months after the lockdown." In Norway, as HE put it, the "unwillingness of the government to add stricter mask rules created an unsafe environment outside".

In addition to the lack of guidance, some students' experiences highlighted the lack of government preparation and response to the pandemic, and certain towns experienced devastating outcomes as a result. KD wrote in her memoir:

> The health system budget was cut by 20 percent in the last year. In my hometown, Cuenca, there are only 40 artificial respirators supposed to supply this emergency and the 331,000 people living in it. All of these aspects make Ecuador doomed to fail in protecting their inhabitants.

As practicing medical students, they personally experienced many of the bioethical dilemmas raised by the pandemic. RH felt this during her clerkship:

> When working at the nursing home I had to experience this inner conflict in person. (…) Feeling guilty every time we had to lock the door on people who just did not want to accept the fact that they could not visit their loved ones.

The management of public health differs from individualized care, which is more natural to our inner moral core and nascent professional ethics. However, studying bioethics helped students to come to terms with these conflicting situations, as this quote from RH indicates:

> I do think the fact that I studied bioethics simultaneously gave me an advantage. In a way I think I coped with these "lesser evil" situations.

In addition to the restrictions, the problem of healthcare prioritization was discussed by the team members in their memoirs. Decision-making factors affecting prioritization included "maximizing benefits, treating people equally, promoting and rewarding instrumental value, and giving priority to the worst off" (AP). The students learned that "an intervention is justifiable if the goal is to lessen mortality and morbidity, and the benefits and burdens are fairly balanced" (AP). Therefore, they perceived that the intended result of prioritization was to maximize the number of lives saved. However, as students who had taken the Hippocratic Oath, and sworn to do no harm, they found it difficult to comprehend, with the reality being that if "[in Ecuador] a senior is plugged to a ventilator and [if] a younger person comes, they are given priority and the elder is unplugged" (KD).

Teaching bioethics

The experiences of teaching bioethics online differed. JP found there to be a change in communication styles online compared with face-to-face interactions:

> Tone of my voice, body language (I can even act a little bit, make gestures). All of this is gone during an online class. [as a result, teaching online felt cold] The course and the whole experience of studying becomes non-personal. I can say almost the same about teaching.

Although at first AG felt “a strange feeling of detachment and disembodiment”, she found a positive outcome in the shift from the offline to the online learning experience. “Don’t we immerse in the discussion deeper in the hermetic headphones-bubble over our heads?” AG said, as “In the virtual class our only bond is the pursuit of knowledge and the exchange of information”. Instead of feeling non-personal, which was JP’s experience, AG felt online learning enabled her to still retain personal relationships with her students:

> I didn’t lose personal contact with my students. It shifted, changed, took new routes – as everything during the pandemic – but remained good, personal and often very rewarding.

AG and JP applied different online teaching techniques. While AG held online seminars mostly using Zoom, JP relied on self-tutoring quizzes and other materials uploaded on the Jagiellonian University platform, or using Microsoft Forms, and only rarely communicated with students using online video communication (MS Teams). These two forms of online teaching also raised different challenges in teaching bioethics to medical students. Live online seminars address the potential issue of low motivation when studying seemingly non-essential subjects. These classes can be emotionally engaging, and an educator can use their personal charisma and teaching style to direct students’ attention towards ethical problems in medicine. However, the second challenge in teaching bioethics is to convey to students that there are certain ethical standards in clinical practice that must be met. Therefore, bioethics taught to medical students is not merely an art of finding new arguments in abstract discussions, such as about the concept of personhood, but rather requires a specific understanding of these procedures and standards. For example, it encompasses knowledge of how to handle situations where a physician interacts with an incompetent patient (29). Self-tutoring quizzes and online materials allow students to learn these standards. In-person teaching can easily combine these two elements, also giving the educator more control over the process.

Despite the challenges of transitioning from in-person to online teaching, the COVID-19 pandemic also created some advantages for teaching bioethics. Case studies that were previously merely historical, theoretical, or seemingly hypothetical, reminiscent of scenarios from catastrophic movies, became actual, current ethical issues. The once abstract questions of “How to fairly distribute scarce resources? Who should make decisions regarding allocation? And what criteria should be used?” became everyone’s concern. The educators believed that real-life situations retained the attention of students; as JP said, they are “much more interesting than abstract principles and reasoning, they involve student’s imagination and provoke them to think, what I would do in this or that situation”.

This existential dimension revealed itself clearly during the pandemic, as JP summed up:

> Bioethics is about norms that regulate our behaviours in regard to very basic human needs, the need of being taken care of the need of being respected, and the need of being part of a community. These needs are especially important when one experiences one’s vulnerability and existential limitations.

Falling apart

Initially, we intended to focus this paper on teaching and studying bioethics during the first months of the COVID-19 pandemic. However, our diaries were dominated by personal experiences and struggles to adapt to the crisis situation. These experiences, as we now know, appear to be universal and not specific to medical students or bioethics educators. Nonetheless, two things are important in this context. First, the students themselves felt the need to share these experiences. Second, these experiences revealed personal vulnerabilities and highlighted the fact that medical students, and probably also medical professionals, were not immune to crisis and stressful situations. This observation aligns with the latest version of the Declaration of Geneva, which emphasizes the importance of physicians attending to their own health, well-being, and abilities (30). Moreover, as we discuss further below, bioethics education may have an impact on the moral resilience of medical students and professionals.

The pandemic started for us when the Jagiellonian University and the Polish government introduced restrictions and then a full lockdown (March 11-20, 2020) (31). Until then, the COVID-19 pandemic had seemed to be an abstract and faraway event, but the restrictions made it suddenly very real. When the restrictions were imposed, we experienced disbelief and confusion, but finally, we all accepted the reality of the new normal. As AG recalled:

> For me the COVID-19 pandemic began during bioethics class. (…) I noticed some unusual agitation in the room. “The suspended university from today on” – one of students read from his smartphone. “That sounds apocalyptic” – another commented. *Does it*? – I asked myself. For a moment I hesitated, still in a deep disbelief that it can ever affect us here, but the atmosphere was thickening by the second, and soon sucked me in. (…) I went home, confused and de-realized, as in the dream.

The shutdown of the university was not accompanied by a clear roadmap of further restrictions and instruction for students. Therefore, students’ plans and expectations were shaken, as KD noted:

> Thoughts, fears, rushing my mind. What should we expect now… As international students and as young people in a world where information is overwhelming? What does a lockdown mean for me residing in Poland, for my dad and brother living in Austria and for my mom back in Ecuador?

All the students decided to go back to their homes. For international students (AP, KD, HE, RH), this transition meant a journey from Poland to their countries of origin. KD poignantly depicted the atmosphere of this journey:

> The airport is filled with angst, everyone walking defensively, waiting for anyone to screw up. What does "screw up" mean, I am not entirely sure myself, but I believe it has to do with sneezing too loud or forgetting to wear your mask the right way: over your nose and mouth. We are defending ourselves from what exactly? No one knows and yet we are so panicked.

The whole process was stressful to the point of leading to somatic symptoms, as HE confessed:

> I was holding in obscene amounts of stress, and it was bound to overflow. My body ended up releasing all my stress the moment I got into my dad's car at the Norwegian airport and felt safe, which led to me puking in the car. I do not get stressed very easily, and rarely does it affect me physically. However, I ended up being very sick for a week.

Some of us also shared that we were "terrified of [our] physical and mental health on top of being scared for the world and a virus without a cure". For those who recovered from mental health challenges, the pandemic alongside the stress it caused was not only another challenge, but also a reminder of past struggles and a threat that they might come back if additional precautions were not undertaken:

> Thankfully me and my parents do have a good relationship and generally communicate well. So, I told them how it was. I was struggling, I felt like shit, and I was aware of it but wanted them to know. I told them to intervene if the situation escalated. (RH)

All first-year medical students had just moved out from their parents' homes and had begun to spread their wings. They were then, in a way, forced to move back to their homes. Living with parents felt as a breach to their newly begun adulthood, as RH noticed:

> Not only how scared I felt about the pandemic, but also the fact that I would have to move back in with my parents (…) We were living on top of each other, having loud calls at all times of the day and few out of house outings. I felt like I was a child again, with the turmoil of teenage years. And when you're in your mid-20s, that is not exactly a dream scenario.

Studying at "home-university" was very challenging, especially in such a demanding faculty as medicine. Most of the students felt no motivation. It was difficult for them to find balance between free time and studying. One of the main reasons for this was, as they reported, the fact that they were expected to spend both their free time and their study time within the same physical space, often limited to one room. The home environment, as one student reported, was full of various distractions and temptations that made it difficult to focus. HE recalled:

> The biggest factor for me was not having my friends from my class around me. I get a lot of motivation from being around my class and working together to break down the difficult topics we are studying. Being alone makes this very hard. (…) This made some of the more difficult topics harder than they could have been, something that is not appreciated before and during exams.

The transition to learning and teaching entirely online was also difficult at first. The students felt that the first year of medical school abroad was exhausting and they perceived switching to online learning as yet another challenge. Students felt that they had to keep track of everything that was happening online. In addition, they felt stressed because of the uncertainty of being unable to plan more than a week ahead. The online infrastructure was especially challenging during the time of exams, as KD reported:

> The exam page lagging whenever moving on to the next question. Every test happening in a different format and a new platform. While taking the test, we need to turn our microphones; having to concentrate with the noise of 130 people is terrible.

The educators also perceived switching to online teaching as a challenge, at first. AG reported that the pandemic occurred in her first year of work at a new faculty. She noted that:

> The first class (which still took place at university in February) I was so stressed that I barely slept, and my voice almost broke down during the class. But it was good. (…) So, during the first month I was gaining some confidence, but then the pandemic broke out, and everything was new again.

We expressed our fears and worries for our families and close friends. We did not want them to get sick. The severity of COVID-19 for elderly people was the first and foremost concern, especially if the family lived in a distant country. KD decided to visit her grandparents in Ecuador as soon as the major restrictions were lifted, after taking all the precautions to avoid infecting her grandparents (quarantine and testing):

> I haven't seen my grandma in two years now, and the possibility of never doing it again is disheartening. I need to make sure I see her and hug her before anything bad happens to her.

Bouncing back

We went through a process of adaptation by using a variety of coping strategies. Some of us started to avoid factors that could, in our opinion, affect our personal wellbeing and mental health. For instance, some of us decided to cut off the news and social media. As RH noticed, "When reading the news, the first weeks of lockdown it became so overwhelming that I eventually stopped reading it".

As KD reported, the pandemic gave her a lesson in critical thinking:

> We are dealing with a health crisis ruled in its entirety by information. (…) Information is at our fingertips, 24/7, but how we acquire it can be key in a situation like the one we are facing. Twitter, Facebook, Instagram vs Johns Hopkins University, the World Health Organization, National Institutes of Health. We need to be mindful of the power that we give to misinformation, a small click can make a difference.

Close relations with family and friends, when and where permitted, and replacing sport activities by their temporary substitutes – for instance, gym with home workouts or swing dancing with running – could also be considered coping strategies. Some students reported that the key element that allowed them to cope with stress caused by studying and exams was letting go of personal ambitions and (too) high self-expectations. RH described this experience of letting go in the following way:

> I had my final exams of first year of medical school. I only failed one. Which I was very proud of myself for. Not for failing, but for the fact that it was only one. (…) . I think not being so strict on myself to perform 100% in a troubling time was a smart move.

Resilience was also experienced at the institutional and community levels. Some countries reacted quickly and achieved impressive outcomes, as KD observed:

> Austria applies a contingency plan almost immediately and the compliance is impressive. Everyone but frontline workers have to stay at home. To avoid high rates of unemployment, the ones who can work from home are given paychecks.

The Jagiellonian University also managed to resume its activities, as HE reported: "online classes were getting better and we actually had a semi-consistent schedule". RH agreed, albeit admitting that she had to lower her expectations:

> The university tried to communicate as good as possible with us students. They did well, at least in some cases. Since everything was changed to an online platform in a short time, I was not expecting much really, as long as clear messages were to be given.

DISCUSSION

Bioethics education

The starting point of our project was the question concerning the impact of the COVID-19 pandemic on bioethics classes. However, it turns out that our memoirs were strongly focused on the effects of the pandemic on our individual lives. The main reason for this attention shift was probably the strength of these events on our personal lives; the other reasons for this shift are discussed below. The COVID-19 pandemic changed our individual and social lives so immensely that it was almost impossible to neglect this impact in any memoir, even one that was intended to focus mainly on bioethics education. This shift of focus and change of the initial question is not unusual in ethnographic research (23). In our case, it brought interesting and unexpected results: specifically, our research showed how bioethics classes and knowledge helped both students and educators better cope with the pandemic. It also revealed the individual and social ethical dilemmas that we faced in the crisis.

This result corresponds to the discussions on the concept of moral resilience, which arises frequently in bioethics literature (32). Moral resilience is not a new concept (2,3), but the outbreak of the pandemic put it in a new light and spread the concept to wider contexts than for which it ordinarily would have been used. During the pandemic, medical practitioners were confronted with moral dilemmas and moral distress that far exceeded the typical stressors of medical practice. Moral distress differs from moral dilemmas in the following way: in the latter, an agent does not know what is the morally right thing to do, while in the case of moral distress, an agent knows how to act but is frustrated by some internal or external barriers to action, e.g., the lack of resources, public health constraints, intuitional limitations (1). Moral resilience is a capacity to deal with such situations of

moral distress in a way that preserves or restores the integrity of an individual (3). Many authors argue that this capacity includes moral components such as personal and relational integrity or moral efficacy (capacity to stand up for what one believes is correct, even if confronted with resistance) (1,33). Moral resilience is shaped by ethical education, training, and discussion, which is why, for example, the Johns Hopkins Berman Institute of Bioethics organized *The Moral Resilience Rounds*, which allowed distressed physicians and other professionals to meet on Zoom to discuss morally complex situations they met in practice (34). Interestingly, it is argued that moral resilience is strengthened also by psychological components, such as being aware of one's psychological and somatic states (self-regulation) and paying attention to one's well-being while being aware of one's limits (self-stewardship) (1,3,33). Spilg et al.'s study demonstrated that the factors related to stronger moral resilience included sleeping more, being in good mental health, and receiving support from one's employer and colleagues (32).

Our study testifies to the importance of the dimension of moral resilience in medical education, in a bottom-up way. It can be argued that in our case, bioethics classes indeed contributed to shaping the moral resilience of students. Both educators reported having involved students in discussions of real-life pandemic ethical dilemmas. The students' memoirs show that these discussions helped them not only to understand complex challenges of the pandemic but also to make more informed and more resilient moral choices during their summer clerkship. For example, the situation described by RH involves a classic case of moral distress. RH knew what the right thing to do would be (enabling families to visit their loved ones in nursing homes); however, her decision was constrained by public health regulations. At the same time, RH clearly indicated that the bioethics class helped to "*cope with* these lesser evil situations", which, as such, can be interpreted as an indication of greater moral resilience.

A contribution of our study, in this respect, is also its unexpected shift of focus from solely bioethical subjects to those referring to personal situations, and, in particular, to the dimension of coping mechanisms and mental health. The students reported having experienced huge stress, which helped them understand the importance of self-care and tending to one's psychological needs to be able to sustain academic and future professional performance. As argued above, this dimension also contributes to the moral resilience of (future) medical professionals. Considering that the medical profession involves situations of moral distress also in the absence of the pandemic, these results point to the significance of shaping moral resilience as an integral part of ethics education. The need for shaping moral resilience emerged from students' memoirs, where they described the value of bioethics in terms of preparing them to solve complex moral issues in their future practice in an ethically informed and mentally resilient way. Additionally, AG noted that moral resilience-related topics, such as difficult moral conundrums (like allocating ventilators) or the boundaries of medical responsibility (like attending patients without personal protective equipment), were of particular interest to students and sparked engaging discussions during online classes. Our results also indicate that elements of ethical reasoning can also play an important part both in the continuing education of healthcare professionals, as well as routine interventions that are intended to enhance healthcare professionals' and medical students' psychological well-being, such as Balint groups (35). This conclusion corresponds with other voices in bioethical literature, which argue that the COVID-19 pandemic emphasized the importance of preparing students for situations of moral distress and shaping their moral resilience also in the classroom setting (27,36). This provides some evidence to support the position that a resilient posture in the face of adversity is a feasible goal of bioethics education. However, due to a lack of robust empirical research on this topic, it remains unclear to what extent bioethics education actually influences people or how it can help them become virtuous healthcare professionals (37).

Moreover, it seems that moral resilience may be mediated, for some students, through learning about moral theories and developing ethical knowledge and even competencies. Students testified that the moral principles and theories of bioethics helped them to understand the reasoning behind lockdowns, which were implemented with a devastating impact on societies. Initially, students were left shocked and did not have any conceptual framework for the health, social, and political situation in Poland and around the world. The bioethics classes – in particular, those on the topics of public health ethics, the just distribution of health resources, and the role of bioethics in pluralistic democratic societies – provided students with concepts and skills that they could use in their critical approach to the social crises triggered by the COVID-19 pandemic.

For JP, it was striking to see that one memoir contained explanations of public health and public health ethics taken almost directly from the reading material (AP: "intervention is justifiable…"). However, it did not seem to be a lesson learned by rote but a manifestation of how seriously these bioethics readings were taken by the student, who understood and internalized the concepts and principles of public health ethics. These bioethical principles became an important element of the student's professional medical identity. In that sense, bioethics seems to provide a safe theoretical ground where medical challenges, moral dilemmas, and conflicts of values experienced by doctors can be boldly faced and tackled. The students felt that they were also better prepared for their practical clerkships when they had to adopt some restrictive safety measures toward patients and experienced the pandemic dilemmas in person (HE: "studying bioethics helped me understand that I was right").

Therefore, it seems that bioethics classes (teaching, knowledge and competency development) played two important roles during the COVID-19 crisis. On the one hand, it was a cognitive coping mechanism that shaped moral resilience and helped us to deal with a complex, stressful, and challenging situation. On the other hand, bioethics was a part of the medical socialization process (5,22,38). According to Bryon Good, medicine creates its own object by focusing only on the human body. It is understood as a preparation and does not have proper instruments to capture human life experience and ethical values (22). Medicine explains living experience and existential fears in medical terms. Good's observations seem to support this claim; however, our experiences of pandemic revealed another dimension of medical identity, also described and analyzed

in the literature, which is associated with a set of certain ethical and cognitive values: beneficence, justice, and rationality. The aim of bioethics education is to inoculate these principles in students rather than just discussing them theoretically, so that they become integral to their professional identities and thus a foundation for their daily practice.

Perception of the past, the present, and the future

Our experience of the COVID-19 pandemic changed over time, and there are some discrepancies between our memories and how we felt later when we analyze our memoirs. The perception of the past became blurred by the present experience. This fact became clear during the discussions on the collected material (seven memoirs), and it was a cause of the differences in the final interpretation of the results.

Despite the fact that we discerned common patterns in our experience (*falling apart* and *bouncing back*), some of us (RH) pointed out that the experience went beyond bouncing back to how things (or oneself) had been before. The experience was described with the metaphor of rebirth, a notion that implies undergoing a transformation and emerging from adversity, having gained something new. However, because the metaphor of rebirth did not appear clearly across all the text of memoirs, we decided to choose the more general metaphor of *bouncing back,* which captures the process of gaining psychological and moral resilience vis-à-vis the complex situation of the pandemic. As Lin et al. put it, “Resilience refers to the ability of people to ‘bounce back’ when they encounter difficulties” (39). The backbone of resilience was coping mechanisms, ranging from exercise to a support network, and which were proven effective for other medical students.

We faced difficulties such as personal and family problems and witnessed tragedies and traumas on a societal and global scale. And we discovered in ourselves the resilience to handle pressure and the ability to adapt to and cope with the situation in a flexible manner (40). Several sources indicate that close relations to individuals with a positive COVID-19 diagnosis increased General Anxiety Disorder scores (41-43). In our case, the pandemic turned out to be a lesson of resilience for both students and educators. As discussed above, the students managed to deal with the stress of studying at “home-university” and the educators had to adapt to new ways of teaching. Both groups were learning how to deal with the personal and public challenges of the pandemic and some of the same coping strategies were adopted by other medical students, including exercise and avoiding media sources (44). However, the situation remains challenging and unpredictable, resulting in an unstable *bounce back*. An unstable *bounce back* is the same as a *bounce back*, although it is not definite, and it is an ongoing process of gaining resilience and finding new solutions to the complex challenges of the pandemic. Bioethics education added a moral dimension to the process of gaining resilience.

People who had previously experienced mental health struggles tended to foresee the worst-case scenario. In comparison to other undergraduates, medical students exhibit 8% to 15% higher rate of positively screening for depression. The numbers support the fear of a mental health decline among these students, as they have shown to be more vulnerable (41). A further study noted that 61% of medical students exhibited signs of a depressive disorder, indicating a higher prevalence of mental health hurdles than formerly recorded throughout the COVID-19 pandemic (42,43). KD thought that the world was going to end, and RH thought she might need therapy again. Although none of this came to pass, it indicates that having a mental health problem can exacerbate the negative effect of an already stressful situation. The experience of the pandemic and a breakdown in our everyday life routines made us more mindful of what we were giving our attention to; we realized the harm it was doing to our mental health and thus redirected our attention to something else. It seems that this was a kind of coping mechanism that we collectively adopted to get through the uncertainty of the time.

Personal growth through adversity

Some of us felt that the experience of mindfulness activated personal growth and heightened self-awareness in this regard. Some of the students shared that having to start all over again after finally making it into medical school was particularly troubling and hard to accept. They had to change their outlook on life and adapt to a new lifestyle of constant change, sacrificing many aspects of their social lives to reach their goals. Considering this, one would believe that this curveball would be just another minor inconvenience in the road to becoming a physician. The challenges faced in the new environment started as a disruption, but with time, they were experienced as containing unexpected benefits. Meeting these setbacks allowed us to develop into more organized and adaptive beings.

Adaptation was the main key to *bouncing back*: as the months of the pandemic passed, the new regulations and policies became increasingly familiar; we learned about our own capacity to adapt. Findings from a research article about US-based medical students’ mental health during the COVID-19 pandemic supports our claim that medical students, regardless of study year, place of residency, or method of teaching, struggled at the beginning of the pandemic (41). These data further corroborated that, later in the course of the pandemic, the students adapted and bounced back (45). Discovering substitutes for pre-pandemic activities was one form of adaptation. Medical students are no strangers to hard work, but they are also very ambitious. Any form of personal development was desired as an opportunity to be one’s best self. Also, the lack of routine at the beginning of the pandemic was disorienting and made the students feel lost in the sense of not having a plan. The students felt that it was in their nature to have a plan of action, but at that moment nothing was certain enough to have one. Fortunately, over time, as they found those substitutes and the online classes began to take on a more solid structure, they also found the routine that they desperately needed. Pinpointing the breakdown in each memory is easy, but it is rather difficult to do the same for the *bounce back* phase. Medical students are very diligent and follow their educational plan down to the last detail, but during the pandemic, that was no longer an option. Suddenly, their goals seemed unreachable and uncertain. This could

have been the start of every medical student's nightmare: the fact that all their hard work could be for nothing. In contrast to the breakdown, the *bounce back* was more of a continuous adaption where everyone tried to conquer the pandemic individually.

Limitations of the study

This study has its limitations, in large part due of the collective autoethnographic method deployed. The results of our research cannot be generalized and evidently require further, systematic investigation to draw more wide-ranging conclusions. Nor are the authors a representative sample of medical students and educators, either in general or with respect to the Jagiellonian University Medical College. However, the group of students is very diverse in terms of gender, country of origin, and mother tongue, which probably accounted for a wide spectrum of individual experience. As such, this study has the merit of pointing to key issues and adding nuance that merit further study regarding the bioethical education of medical students.

CONCLUSION

In the paper, we have shown that there were some common patterns in the experiences of the public health, social, and political consequences of the COVID-19 pandemic. As individuals, we experienced shock: we had an impression that our lives – as well as the institutions around us – were falling apart. After this initial phase of falling apart, we managed to bounce back and adjust our ways of studying and teaching in the changed pandemic circumstances. Our analysis suggests that the key factor of adjustment to the altered situation was taking personal responsibility not only for the studying process, but also for self-care and one's psychological and social needs.

Based on our experience, the most urgent recommendation for future emergency situations is to include systematic incorporation of online teaching tools into the academic curriculum and the relevant training of educators in that respect. Our findings also suggest that bioethics classes can and should be an important forum for shaping the moral resilience of future medical professionals. Moral resilience can not only protect practitioners of medicine from moral injury and professional burnout, but also lead to more integrated and better patient care. Moreover, our shift of focus from bioethics to the dimension of coping and maintaining mental health draws attention to the importance of self-regulation, self-stewardship, and care for the mental condition of medical students (especially during the situations of public health emergencies and other emergencies). These findings compels us to suggest expanding students' opportunities for obtaining professional psychological guidance and support within their institution, so that they can become more mindful and ethical health professionals.

Reçu/Received: 04/03/2022
Publié/Published: 27/06/2023

Remerciements
Nous remercions nos réviseurs et l'éditeur en chef de la revue pour leurs commentaires qui nous ont permis d'améliorer ce document. Nous remercions Mary Graham pour la révision de cet article.

Acknowledgements
We thank our reviewers and the journal Editor-in-Chief for their comments that helped us to improve this paper. We thank Mary Graham for editing this paper.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Abdou Simon Senghor & Aliya Affdal

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

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Can J Bioeth / Rev Can Bioeth. 2023;6(2):90-106

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

La collégialité dans la mise en place d'une sédation profonde et continue dans un centre de cancérologie en France

Bettina Couderc[a,b], Alfonsina Faya Robles[a], Nathalie Caunes-Hilary[b], Laurie Galiby[a], Emmanuelle Rial Sebbag[a]

Résumé
Une procédure collégiale désigne le fait de recueillir, avant de prendre une décision médicale délicate, l'avis de l'ensemble de l'équipe de soins responsable du patient, incluant le personnel infirmier et aide-soignant, entre autres. La loi Claeys-Leonetti relative à la fin de vie (2016) l'inscrit dans le droit français comme étant obligatoire lors de la mise en place d'une sédation profonde et continue maintenue jusqu'au décès (SPCMD). L'objectif de l'étude est de faire un état des lieux de la connaissance de cet aspect de loi par le personnel soignant d'un institut de cancérologie et d'identifier comment la collégialité se met en place pour une décision de SPCMD selon les services. Nous avons proposé un questionnaire en ligne et anonyme à l'ensemble des acteurs du soin (connaissance de la loi Claeys-Leonetti) puis nous avons rencontré les soignants des différents services en groupes de discussion (cadres, personnel infirmier et aides-soignants) ou en entretiens individuels (médecins). Les résultats montrent que la loi est mieux connue, toutes professions confondues, des jeunes soignants (moins de 5 ans d'expérience) et surtout mieux revendiquée par les infirmières et aides-soignantes que par les médecins. Nous rapportons la diversité de la mise en œuvre de la collégialité pour une décision de sédation, en termes de formalisation, de standardisation et d'inter professionnalisation. Nous concluons que la mise en place de la collégialité de façon anticipée pour une décision élargit les modes de communication pluri/inter professionnelle et permet d'apaiser la souffrance des patients, des médecins et des soignants.

Mots-clés
fin de vie, collégialité, cancérologie, soins palliatifs

Abstract
A collegial procedure refers to the fact that, before making a delicate medical decision, the opinion of the entire care team responsible for the patient is sought, including nurses and orderlies, among others. The Claeys-Leonetti end-of-life law (2016) enshrines this in French law as mandatory when implementing deep and continuous sedation until death (DCSD). The aim of the study was to take stock of the awareness of this aspect of the law among all the healthcare staff of a cancer institute and to identify how collegiality was established for a DCSD decision, depending on the department. We administered an anonymous online questionnaire to all those involved in healthcare (knowledge of the Claeys-Leonetti Act), and then met healthcare workers from the various departments in discussion groups (managers, nursing staff and orderlies) or in individual interviews (doctors). The results show that young healthcare staff (with less than 5 years' experience) are more familiar with the law, across all professions, and that nurses and orderlies are more likely to assert their rights than doctors. We report on the diversity of the implementation of collegiality for sedation decisions, in terms of formalisation, standardisation and inter-professionalisation. We conclude that the implementation of collegiality in advance of a decision broadens the methods of multi/inter-professional communication and helps to alleviate the suffering of patients, doctors and care givers.

Keywords
end of life, collegiality, oncology, palliative care

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INTRODUCTION

Pendant de très nombreuses années, le diagnostic d'un cancer signifiait pour les patients une maladie incurable et un décès à court terme. Les progrès de la recherche ont favorisé la mise en place de nouveaux traitements qui permettent à 50 % des cancers de pouvoir être guéris (1). Pourtant, on meurt encore de cancer au 21e siècle à l'hôpital et la question de la gestion de la fin de vie inquiète souvent les patients et interroge les professionnels. En effet, à l'inverse des siècles précédents, en France, près de 70 % des décès ont lieu dans un établissement de soins, et ceci indépendamment du statut social des personnes (2). Ce pourcentage est supérieur encore dans les grandes villes où une très grande proportion de patients décède seuls ou seulement entourés de soignants (3). Il y a un réel enjeu pour les structures hospitalières françaises à assurer « une bonne mort » aux patients. Or, il n'y a pas de définition universelle de la « bonne mort ». La très grande majorité des patients demandent à être accompagnés, et à « ne pas souffrir ». Certains espèrent « ne pas se voir mourir » alors que d'autres veulent vivre en conscience ce départ (4-7). Avec l'émergence des soins palliatifs et sa progressive – même difficile – reconnaissance au sein des organisations hospitalières, nous assistons à une redéfinition des critères de la bonne mort. Celle-ci se configure actuellement autour de trois principes phares : le soulagement de la douleur physique et mentale (5), l'accompagnement du mourant dans l'acceptation (7,9) et la pacification de la mort (7). Cette recherche de la bonne mort s'accompagne d'une volonté de promotion de l'autonomie des patients concernant les décisions autour de leur fin de vie.

Ainsi, la loi Leonetti du 22 avril 2005 relative aux droits des malades et à la fin de vie puis la loi n°2016-87 (Claeys-Leonetti) du 2 février 2016 (10) créant de nouveaux droits en faveur des malades et des personnes en fin de vie – ils ont promu l'autonomie des patients en les plaçant au cœur du processus décisionnel, qu'ils soient ou non en capacité d'exprimer leurs

ISSN 2561-4665

volontés (rédaction de directives anticipées). Elle donne accès à une « sédation profonde et continue maintenue jusqu'au décès » (SPCMD) (appelée également *sédation palliative* en dehors de nos frontières) aux personnes dont le pronostic vital est engagé à court terme (soit du fait de l'évolution de la pathologie, soit du fait d'une décision d'arrêt de traitement) et qui présentent une souffrance réfractaire aux traitements. Les professionnels de santé sont tenus de mettre en œuvre tous les moyens à leur disposition pour que toute personne ait le droit d'avoir une fin de vie digne et soit accompagnée du meilleur apaisement possible de la souffrance (article 1 de la loi; voir annexe 1) (11).

Chez le patient conscient, hospitalisé en oncologie ou pas, une SPCMD peut être mise en place à sa demande ou sur proposition médicale après recueil de son consentement. Chez le patient hors d'état d'exprimer sa volonté et qui ne s'y est pas opposé dans ses directives anticipées, la SPCMD pourra être mise en place en cas d'arrêt d'un traitement de maintien en vie (pas d'obstination) si cet arrêt peut entraîner une souffrance insupportable. Enfin, dans les cas d'urgence, par exemple, lors d'hématémèse ou d'hémoptysie, une SPCMD peut être mise en place sans consentement du patient ou de ses proches afin de calmer immédiatement ses souffrances et ainsi lui éviter une fin de vie douloureuse.

La mise en place de la SPCMD ne peut pas être assimilée à une euthanasie, car son intention n'est pas d'abréger le temps de la fin de vie, mais de soulager des douleurs physiques ou psychiques intenses et d'assurer une fin de vie paisible (12). Toutefois, que ce soit pour le cancer ou d'autres pathologies, elle est généralement associée à la toute fin de vie, car elle induit une altération profonde de la conscience du patient jusqu'à la mort (13). La SPCMD se différencie donc bien des autres modalités de sédation, car une fois initiée, elle va perdurer jusqu'au décès (sa mise en place implique qu'il n'y aura pas de réversibilité, elle n'est pas transitoire), elle est profonde (le patient sera inconscient, sans communication verbale ou non verbale possible) et elle nécessite le recueil du consentement du patient sauf en condition d'urgence. La SPCMD est donc différente des autres sédations par son intentionnalité et également par les médicaments utilisés (14-18). Par conséquent, hors situation d'urgence, la mise en place d'une sédation profonde et continue n'est pas un geste anodin et sans conséquence sur l'état psychique des soignants. Ces derniers peuvent ressentir des sentiments complexes devant la nécessité d'initier une SPCMD. Ils peuvent, par exemple, se sentir instrumentalisés par les demandes de leurs patients qui peuvent aller contre leur propre perception de la fin de vie (11,19). À l'opposé, ils peuvent assimiler la SPCMD à une procédure à privilégier afin de raccourcir la phase agonique et épargner au patient et à ses proches une attente douloureuse (20).

De fait, la loi Claeys-Leonetti prévoit que la décision médicale concernant la mise en place d'une sédation fasse l'objet d'une procédure collégiale préliminaire. Cette dernière doit inclure l'avis motivé d'un autre médecin (appartenant à un autre service et sans lien hiérarchique avec le médecin référent) devenant « consultant », ainsi que l'avis des membres de l'équipe soignante responsable des soins du patient. Elle relève donc, après examen de sa situation médicale, d'une concertation interprofessionnelle avec les membres de l'équipe dans la recherche d'un consensus, s'il est possible. Au final, et après la prise de décision, la prescription de la sédation sera exclusivement réalisée par un médecin.

Dans l'intérêt du patient, de ses proches et de l'équipe médicale, il est important que la décision de mise en place de la SPCMD se fasse selon une procédure collégiale. Cela permet d'assurer l'équité d'accès à la SPCMD pour tous les patients (pas de décision dépendant d'un seul soignant) et permet de s'assurer que toutes les alternatives antalgiques autres ont été discutées avant la proposition de SPCMD (discussion collégiale) (21,22). Tous les patients doivent avoir le même spectre de possibilités de solutions et traitements.

Nous nous sommes intéressés, dans cette étude, à la phase décisionnelle de la mise en place de la sédation profonde et continue jusqu'au décès. Elle est pertinente non seulement parce que les certitudes et incertitudes médicales (23) prennent un poids particulier lorsque la décision concerne la fin de vie du patient, mais également parce que la loi prévoit une procédure décisionnelle collégiale impliquant la participation de l'ensemble des soignants engagés dans la pratique de la sédation et donc dans la fin de vie d'un patient sous sédation (médecins, infirmières, aide soignantes, agents des services hospitaliers, etc.). Basée sur des méthodes quantitatives et qualitatives, l'étude s'intéresse à plusieurs questions : quelle est la place de la sédation profonde et continue dans les différents services d'un centre de cancérologie (ex. : chirurgie, oncologie médicale, hématologie, soins palliatifs)? La pratique de la sédation a-t-elle été modifiée depuis la loi de 2016? Quel est le degré de connaissance de la loi par les soignants? Quand et comment la SPCMD est-elle mise en place? Est-elle systématiquement précédée d'une démarche collégiale? Comment ce dispositif se construit-il selon les services? Tous les « soignants » participent-ils au processus? Le souhaitent-ils et pourquoi? Peuvent-ils être à l'origine d'une demande de procédure collégiale?

L'objectif de notre étude est de répondre à ces questions en réalisant tout d'abord un état des lieux de la connaissance de cet aspect de loi par tous les soignants d'un institut de cancérologie – c.-à-d. l'Institut Claudius Regaud, IUCT Oncopole à Toulouse – en leur proposant de remplir un questionnaire en ligne et anonyme (connaissance de la loi Claeys-Leonetti). Puis, nous avons étudié comment la collégialité se met en place pour une décision de SPCMD selon les services en rencontrant les soignants des différents services en groupes de discussion (cadres, personnel infirmier et aides-soignants) ou en entretiens individuels (médecins). Nous avons pu identifier ainsi l'importance de la collégialité dans la mise en place d'une SPCMD dans les différents services d'un centre de lutte contre le cancer.

MÉTHODOLOGIE

Sondage

Recrutement et collecte des données

Nous avons réalisé tout d'abord un sondage par questionnaire anonyme (« Connaissez-vous la loi Claeys-Leonetti? ») sous la forme de Question à Choix Multiples (QCM) afin d'évaluer la connaissance de la loi de 2016 par l'ensemble des professionnels (médecins, cadres, personnel infirmier et aides-soignantes) d'un grand institut de cancérologie français (annexe 2). Le lien correspondant au questionnaire a été envoyé par l'intranet de l'institution entre janvier et mars 2019 aux 900 soignants statutaires de l'institut (adresse courriel professionnelle). Deux relances ont été effectuées à 3 semaines d'intervalle. Les personnes intéressées à participer au sondage (présentation du sondage incluse) ouvraient le lien dans le corps du courriel et pouvaient répondre aux questions. Une mention indiquait que le fait de cliquer sur le lien équivalait à une acceptation de participer. Les participants pouvaient interrompre leur questionnaire quand ils le souhaitaient. Le questionnaire ne comportait pas de données identifiantes. Il était anonyme et les adresses IP des participants ne pouvaient pas être recueillies (annexe 2).

Analyse des données

Le but du sondage était de saisir le niveau de connaissance et de compréhension de la loi Claeys-Leonetti des soignants. Nous avons comparé le taux de réponses exactes aux QCMs des participants selon l'appartenance des soignants (services), leur segment professionnel (médecins, infirmier(e)s (IDE), Aide-soignant(e)s (AS) …) et leur ancienneté. Nous avons comparé également le taux de réponses exactes selon les thèmes abordés : légalité de la sédation, interdiction de l'euthanasie, directives anticipées, personne de confiance et collégialité dans la prise de décision d'arrêt de traitement curatif ou de mise en place de la sédation profonde et continue. Les données ont fait l'objet d'une analyse statistique simple (fréquence et moyenne) et croisée. Le questionnaire comprenait une section d'expression libre qui n'a pas été exploitée ici. Ces analyses nous ont permis de mettre en évidence des différences de taux de bonnes réponses entre les services et entre les segments professionnels.

Groupes de discussion et entretiens individuels

Recrutement et collecte des données

Dans le cadre d'une démarche qualitative de recherche, nous avons organisé des entretiens collectifs de type « groupe de discussion », janvier à mai 2020, auprès du personnel infirmier, des aides-soignantes et des cadres de santé dans les 11 services d'un centre de cancérologie – Oncologie 1, 2 ou 3 ; Chirurgie 1 ou 2, Hématologie et hématologie secteur greffe, Oncologie long séjour, Hôpital de jour, service Soins de support, Réanimation (entre 5 et 23 personnes/réunion) – et auprès des 37 membres du comité de réflexion éthique de l'institution. Les participants ont été recrutés par le biais d'une affiche placée dans le service indiquant le jour et l'heure de la proposition de l'entretien en groupe. L'affiche mentionnait que les résultats du sondage seraient présentés et que les chercheuses (noms et courriel mentionnés si nécessité de contact en amont) voulaient recueillir le ressenti des participants sur la mise en place de la collégialité dans leur service pour la prise de décision d'une SPCMD. Les soignants étaient libres de venir ou non à ces réunions. Ils pouvaient interrompre leur participation à tout moment. Les entretiens collectifs démarraient avec la correction des QCMs et un compte-rendu des résultats du sondage quantitatif, sous forme de présentations *PowerPoint*. Ces présentations nous ont servi d'introduction pour ensuite interroger les soignants sur leurs pratiques et représentations de la SDPMD.

En parallèle, nous avons réalisé 14 entretiens individuels approfondis avec les médecins des différents services : 9 oncologues, 4 chirurgiens et 1 des soins de support ; 8 femmes et 6 hommes ; 6 avec moins de 5 ans d'expérience et 8 avec plus. Les soignants ont été contactés par courriel (adresse professionnelle) et en cas d'acceptation de participer, un rendez-vous a été pris avec les deux chercheuses. Tous les entretiens d'une durée de 45 à 80 minutes selon les cas ainsi que les discussions en groupe ont été enregistrées sur bande audio. Ils ont été retranscrits puis analysés.

Analyse des données

Le corpus des données comprenant tous les entretiens a été analysé de deux façons. D'une part, nous avons utilisé le logiciel IRAMUTEQ qui permet une analyse statistique distributionnelle pour fournir les occurrences significatives d'un corpus de 97 511 mots. D'autre part, nous avons réalisé une analyse thématique sociologique (24).

Concernant l'analyse par IRAMUTEQ, le corpus a été analysé par la méthode Reinert utilisant le logiciel d'analyse lexicale IRAMUTEQ R 3.1.2 (version gratuite d'ALCESTE) (25). Le programme permet l'obtention de groupes de mots en plusieurs classes sémantiques en fonction de leur similitude (méthode de Reinert). En effet, il identifie les cooccurrences et les relations entre les différents discours, soit les mots et les segments de texte qui identifient le mieux chaque classe ou idée que les participants ont mentionnée à plusieurs reprises (méthode factorielle). Une fois que ces « classes » ont été identifiées, elles sont associées à des variables « passives » (variables indépendantes) qui sont ici le métier (médecins, IDE ou AS) ou les services (oncologie, chirurgie, hématologie …). L'analyste attribue une étiquette à chaque ensemble de vocabulaire spécifique que le logiciel avait identifié comme un monde lexical sur la base des cooccurrences et des modèles de distribution. Le corpus de texte a donc été codé en notant pour chaque retranscription : le service (oncologie médicale, soins de support, chirurgie, réanimation …), le type de soignants (personnel infirmier / aides-soignantes ou internes/médecins), le genre (pour les entretiens individuels), les années d'expériences. Deux groupes de textes ont été identifiés en fonction de la fréquence des

mots utilisés et de leur sens. Un groupe correspond à une vision très « curative » (cure) de la pratique de soin (ex. : chirurgie) et un groupe correspond clairement à une vision orientée vers le « care » (prendre soin de …).

Nous avons comparé cette classification IRAMUTEQ des différents entretiens (groupes de discussion ou individuels) avec la classification issue des analyses sociologiques des entretiens (ex. : présence ou pas de procédures collégiales, bien-être au travail). En effet, le corpus a été travaillé par l'équipe de recherche qui comprend deux sociologues (AFR et LG), une éthicienne (BC), la chef de service des soins palliatifs de l'institut (NCH) et une juriste (ERS). L'analyse sociologique thématique a été produite par les regards croisés des membres de l'équipe. L'analyse thématique sur l'importance de la collégialité a donc été construite en combinant les résultats de l'analyse par IRAMUTEQ et l'analyse du sens dégagé dans les réponses. Aucun logiciel supplémentaire n'a été utilisé.

Considérations éthiques

Ce projet de recherche a été initié par le groupe de réflexion éthique de l'Institut Claudius Regaud où s'est déroulée la recherche qui l'a approuvé. Chaque participant a consenti oralement à participer à l'étude de façon libre et éclairée. Toutes les données ont été traitées dans le respect de la confidentialité et de la vie privée des participants.

RESULTATS DE LA RECHERCHE

Analyses du sondage réalisée sous forme de QCMs

Présentations des participants

Nous avons eu 118 questionnaires remplis, dont 108 exploitables pour toutes les questions posées, correspondent à 12 % de l'ensemble du personnel statutaire de l'institut. Des 108 questionnaires, 34 % ont été complétées par des hommes et 66 % par des femmes. Cette différence est corrélée à une représentation supérieure des femmes parmi les professionnels de l'institution. En effet, dans tous les services nous retrouvons une relative parité entre hommes et femmes médecins, reflétant une féminisation de la profession (26) et une présence plus nombreuse des femmes dans les métiers des « soins » (infirmières et aides-soignantes). De plus, 72 % des personnes ayant répondu avaient plus de 5 ans d'expérience en cancérologie, ce qui est représentatif de la démographie des soignants du centre de cancérologie où le personnel est majoritairement expérimenté. Le sondage a donc été réalisée avec un échantillon représentatif des soignants et n'a pas ciblé une classe d'expérience particulière.

Tous les services de cancérologie sont représentés suggérant que l'ensemble des soignants du centre se sentent concernés par les questions de fin de vie et ont entendu parler de la loi Claeys-Leonetti (Figure 1). Concernant la répartition par corps de métiers, nous constatons que celui qui est le plus représenté est celle des prescripteurs (médecins et internes : plus de 54 % des questionnaires) (Figure 2).

Figure 1 : Répartition des soignants ayant répondu au questionnaire suivant les services

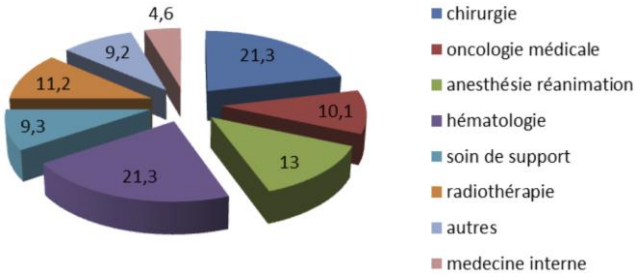
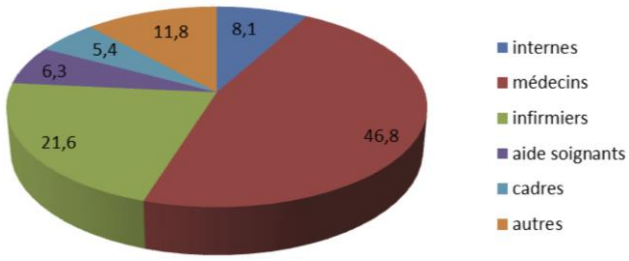


Figure 2 : Répartition des soignants ayant répondu au questionnaire par cors de métiers



Connaissance générale de la possibilité de mettre en place une sédation profonde et continue maintenue jusqu'au décès

Les questionnaires d'évaluation des connaissances de la loi de 2016 étaient organisés sous forme de questions à choix multiples (QCM). Les items reliant la loi Claeys Leonetti et la SPCMD étaient les suivants :

Parmi les propositions suivantes, lesquelles sont énoncées ou reprises dans la loi Claeys-Leonetti :

- QCM2 item a : L'interdiction de l'euthanasie en France.
- QCM 2 item d : La légitimité du double effet, c'est-à-dire que l'administration d'un médicament destiné à soulager une douleur peut également accélérer la fin de vie.
- QCM 8 item d : Elle autorise la sédation profonde et continue jusqu'au décès « en cas de souffrance vécue comme insupportable et où le pronostic vital est engagé à court terme ».

À la question sur l'interdiction de l'euthanasie en France, 56 participants sur 118 ont répondu oui (47,6 %). Cela montre que, même dans un centre de cancérologie, plus de la moitié des soignants ne savent pas que la Loi Claeys Leonetti a réaffirmé la volonté du gouvernement de ne pas légaliser l'euthanasie en France.

Il y avait également un QCM sur la SPCMD proposant les items suivants :

9) La sédation profonde et continue d'un patient...
   a. ne peut pas être refusée par le médecin.
   b. est responsable du décès du patient.
   c. peut être demandée par la personne de confiance.
   d. peut être indiquée en cas de symptômes réfractaires.
   e. peut être demandée par le patient.

À la question sur le fait que la mise en place de la SPCMD pouvait avoir comme effet secondaire une légère accélération du moment du décès alors que son intention n'est que de soulager le patient, 82/108 personnes ont répondu correctement (76 %). Lors des groupes de discussion, il nous a été rapporté que ceux qui n'avaient pas coché oui à l'item n'avaient en fait pas compris la question (double effet) ce qui laisse penser que le pourcentage de bonnes réponses est en fait supérieur. Nous appuyons cette conclusion par le fait qu'à la question 9b : *La SPCMD est responsable du décès du patient*, seules 4 personnes (3,6 %) ont répondu oui, et elles n'étaient ni médecins, ni infirmières ni aides-soignants.

À la question de l'indication de la mise en place de la sédation QCM 8 item d et QCM 9 item d, respectivement 98 (90,9 %) et 69/108 participants (64,1 %) y ont répondu correctement. On retrouve une grande majorité de médecins dans ces personnes (plus de 95 %).

Connaissance de la procédure collégiale

Nous nous intéressons ici aux trois items dans le questionnaire qui concernent la procédure collégiale.

Premier item : La loi Claeys-Leonetti encourage-t-elle la réflexion et la décision purement médicale?
La réponse à la question est « non ». En vertu de l'Article L.1110-5-2, « La sédation profonde et continue associée à une analgésie prévue au présent article est mise en œuvre selon la procédure collégiale définie par voie réglementaire qui permet à l'équipe soignante de vérifier préalablement que les conditions d'application prévues aux alinéas précédents sont remplies. » Effectivement, 88 % des répondants (95/108) ont répondu correctement.

Deuxième item : Concernant la limitation ou l'arrêt des traitements, la procédure collégiale menant à la décision de limitation de soins inclut l'équipe soignante (Aides-soignantes (AD), infirmières (IDE), médecins, psychologues …)?
La décision est collégiale, mais la collégialité ne concerne pas que des médecins, elle inclut d'autres professionnels de la santé participant aux soins d'un patient. La réponse à la question est donc oui à cet item et 85 % (n=92) des répondants ont répondu correctement. Cet item vient appuyer le précédent, quoique de manière détournée. La totalité des infirmières (100 %) des infirmières et aides-soignantes y ont correctement répondu.

Troisième item : Concernant la limitation ou l'arrêt des traitements : Si le patient est inconscient et en l'absence de directives anticipées (DA), la décision d'arrêt de traitements est médicale, et prise après procédure collégiale?
Pour cet item, la réponse correcte est oui et 81.7 % (n=89/107) des répondants ont répondu correctement. Nous nous sommes intéressés aux services (chirurgie, oncologie médicale, soins palliatifs, hématologie, etc.) et aux corps de métiers (médecins, internes, cadres, IDE, AS) qui n'avaient pas répondu correctement à ces 3 items afin de déterminer si un corps de métier ou service particulier ne connaissait pas la loi. Concernant les comparaisons du taux de bonnes réponses des différents participants entre les services, il n'y a pas de différence frappante. Concernant les corps de métier, nous constatons que 96 % du personnel infirmier et la totalité des aides-soignantes (100 %) savent que la procédure collégiale inclut le personnel soignant non-médecin (bonne réponse aux trois items). Parmi les médecins, 12 % se sont trompés à au moins un item ; ils représentent le segment professionnel qui connaît le moins bien les changements apportés par la loi de 2016 en matière de « collégialité ».

La collégialité vue par ses acteurs : Analyse des entretiens

La deuxième partie des résultats provient de l'analyse thématique des entretiens. Comme mentionné plus haut, nous avons effectué 12 groupes de discussion avec plus d'une centaine de soignants (hors médecins) appartenant à différents services et 14 entretiens individuels avec des médecins. Nous leur avons à chaque fois demandé de nous raconter un ou plusieurs cas de mise en place de sédation profonde et continue dans le service, et de nous rapporter comment la décision avait été prise.

De manière générale, et lorsqu'il est question de « procédure collégiale », la plupart des soignants rencontrés se disent très favorables à sa mise en place lors d'une prise de décision de sédation. La plupart disent qu'il est important de parler régulièrement et de manière collective des cas des patients en fin de vie et s'accordent pour dire qu'une fin de vie paisible n'est possible que si tous les gestes ont été bien anticipés, dont celui d'une sédation, évoquée bien avant sa mise en place effective.

Tous revendiquent la possibilité de provoquer cette réunion en cas de besoin urgent et souhaitent être entendus. En cas de souffrances intenses (psychologiques ou physiques), de manière générale une sédation profonde et continue est soit demandée par le patient, soit proposée par le médecin. Il existe toutefois des cas où la sédation est demandée par l'équipe soignante.

Par l'analyse du corpus des entretiens collectifs ou individuels (97 511 mots, 26 entretiens par groupe de discussion ou individuels) avec le logiciel IRAMUTEQ, nous avons pu diviser les services en deux groupes distincts, suivant les classes d'énoncés significatives (méthode Reinert) (25). Dans le tableau 1 ci-dessous, nous présentons les caractéristiques les plus significatives de chacun des groupes. Nous indiquons le nombre de services ou de médecins qui se positionnent sans aucune ambiguïté dans la classification en deux groupes (8 services/12 et 10 médecins/14) en mentionnant les spécialités des groupes de discussions ou médecins.

Tableau 1 : Occurrence de mots significatifs pour notre étude en fonction des services

Services	Oncologie médicale, soins de support	Chirurgie, hématologie
Caractéristiques	n=10 Majoritairement des membres de services ou des médecins habitués à « gérer » la fin de vie	n=8 Majoritairement des membres de services ou des soignants non confrontés à la fin de vie de manière quotidienne
Mots-clés par ordre de fréquence	sédation (n=223) moment (n=161) dose (n=55) profond (n=54) soulager (n=46) endormir (n=44)	prendre (n=243) décision (n=126) maladie (n=93) euthanasie (n=82) anesthésiste (n=69) traiter (n=24)

Les chiffres entre parenthèses correspondent à l'occurrence des mots dans les différents entretiens associées aux deux groupes.

Par l'analyse des entretiens (individuels ou collectifs) qui sont associés à ces deux groupes, nous avons identifié que le groupe 1 correspondait à des services ou des médecins habitués à gérer la fin de vie alors que le groupe 2 correspondait à des services ou des soignants non confrontés à la fin de vie de façon quotidienne.

Groupe 1 : Services habitués à gérer « la fin de vie » à l'hôpital (soins de support oncologie médicale)

En cas de demande de sédation par le patient, nous avons interrogé les soignants sur l'identité de celui auprès de qui le patient réalisait sa démarche. Il nous a été rapporté que très peu de patients demandent une sédation profonde et continue maintenue jusqu'au décès, qui reste très associée, pour eux, à l'idée de la mort imminente. Il est rare également que la SPCMD, en tant que telle, soit demandée par les proches d'un patient (pour rappel, la demande de SPCMD par la famille ou les proches n'est pas recevable légalement). Ces derniers demandent généralement uniquement à être rassurés sur le fait que tout sera mis en place pour que le patient ne souffre pas. Dans le cas où la sédation est envisagée par le patient, la décision du patient est le plus souvent (8 cas/10, chiffre donné par les soignants interrogés) recueillie par le médecin référent lors des discussions avec le patient. Il faut noter que les soignants (tous services confondus) rapportent qu'ils savent bien avant le médecin l'intention du patient du fait de nombreuses conversations informelles lors des soins quotidiens, comme à travers des réflexions et l'élaboration de la décision par le patient pendant les jours qui ont précédé une dégradation de son état général.

Devant la dégradation de l'état général d'un patient, et à la suite d'un constat d'impuissance à calmer ses souffrances, le médecin peut proposer la mise en place d'une sédation profonde et continue. Dans ce cas, la possibilité a été évoquée bien en amont de la dégradation de l'état général par le médecin et son patient, la plupart du temps.

Pour ces deux cas – c'est-à-dire, demande réalisée par le patient ou proposée par le médecin référent –, nous constatons que la situation est gérée sans heurt du fait de son anticipation, par des discussions préalables avec le(s) médecin(s) et l'équipe soignante. Une fois la proposition faite, une réunion du service est organisée afin de recueillir l'avis de l'ensemble des soignants (procédure collégiale). Généralement, le médecin référent s'assure que les proches et la personne de confiance aient été informés, qu'ils aient compris le sens du geste et qu'ils aient pu passer du temps avec leur proche. Il est par ailleurs très courant que l'annonce de la mise en place d'une sédation profonde et continue soit relayée auprès des proches une deuxième fois par l'équipe soignante. La prescription est faite et la sédation mise en place. En cas de souffrances intenses, il faut noter toutefois qu'il peut ne s'écouler que quelques heures entre la décision et la sédation. Ce type de situations de mise en sédation se passe généralement sans grandes tensions entre les professionnels. Lors des discussions dans les services, les infirmiers et aides-soignants décrivent ces sédations comme étant celles où « *tout s'est bien passé* », « *dans le calme* », etc. Nous pouvons citer cette parole :

> « Vraiment, je pense qu'on a plutôt tendance à être plus délicat, avoir des gestes plus tendres, plus doux. Des paroles plus...Plus calmes, plus apaisantes. Apaiser, aménager un peu, faire sortir les choses qui sont inutiles, enfin, faire quelque chose qui soit plus… plus agréable quoi. Et puis, il y a des patients chez qui aussi on avait organisé la chambre avec des petites décorations, des choses comme ça. La famille organise un petit peu son petit espace et... et sait comment est la personne de façon habituelle donc amène des choses. » (Aide-soignante)

> « La famille, elle nous dit « voilà, elle est calme, elle est apaisée ». Et puis après c'est plus pour la famille… Je pense que si la sédation se passe au moment le plus opportun, même si je ne sais pas s'il y a un moment opportun, mais le plus opportun… et qui sont en accord avec… ça se passe bien. » (Infirmière de deux des services d'oncologie)

Groupe 2 : Services moins habitués à gérer « la fin de vie » à l'hôpital

Dans le paragraphe précédent, nous décrivons le cas où la mise en place de la sédation est anticipée. Les médecins de soins palliatifs ou ceux d'oncologie médicale, par exemple, sont habitués à déceler les cas où la sédation peut (doit) être engagée rapidement sans toutefois correspondre à une situation d'urgence. En revanche dans les services qui ne sont pas dédiés à la fin de vie, il peut être observé une situation délicate où ce sont les soignants qui vont constater une dégradation de l'état général du patient ou recueillir des confidences du patient avant le médecin référent et demander (parfois de façon insistante) la mise en place rapide d'une sédation pour un patient. Une soignante nous dit :

> « La plupart des réunions de service concernant la sédation sont faites à la demande des soignants. Parce que...c'est quand même compliqué de faire une toilette à quelqu'un qu'on ne peut pas tourner dans le lit parce que, dès qu'on lui pose la main dessus, on lui fait mal. Et ça interroge la pratique du soignant de faire un soin et d'être agressif. Donc, si l'équipe a pris la décision, si on a recueilli les souhaits du patient et que ça va vers une sédation, c'est quand même pour moins de douleur, moins de souffrance ». (Aide-soignante d'un des services de chirurgie)

Cela peut provenir d'une dégradation rapide et non attendue de l'état d'un patient post chirurgie lourde. Ces cas peuvent engendrer des tensions dans l'équipe. En effet, les demandes viennent du fait que l'équipe soignante constate une dégradation accélérée de l'état du patient qui génère beaucoup d'émotions chez les proches et des difficultés à bien accomplir le travail pour les soignants. Les soignants vont donc réclamer une décision rapide du médecin pour la mise en place de la sédation. Ce dernier ne répond pas forcément immédiatement à leur demande. Il se retrouve à devoir gérer une situation qui n'a pas été anticipée, car inattendue sous la pression des soignants et des proches qui expriment une souffrance.

Tous les praticiens s'accordent pour dire que la souffrance des soignants doit bien sûr être entendue. Toutefois, selon le code de la déontologie et le code de la santé publique, le médecin doit être sûr d'avoir épuisé toutes les alternatives thérapeutiques ou antalgiques avant d'engager une SPCMD. En effet, une dégradation rapide post chirurgie ou post ligne de chimiothérapie (hématologie) peut être critique sans toutefois être irréversible. L'équipe soignante nous rapporte alors qu'elle estime trop long le délai entre leur demande et la prise de décision et plaide pour l'organisation d'une procédure collégiale ou pour la prise en urgence de l'avis de l'équipe mobile de soins palliatifs. Pour les médecins de chirurgie ou d'hématologie, l'habitude est plutôt de recueillir l'avis de l'anesthésiste qui est identifié, dans ces services, comme la seule habilité à pouvoir prescrire une sédation. Ce dernier n'est pas forcément disponible rapidement (dans la demi-journée).

Une fois au chevet du patient, une discussion va s'engager entre le médecin (chirurgien ou hématologue le plus souvent) et l'anesthésiste afin de déterminer si un traitement peut être engagé (reprise chirurgicale ou chimiothérapie) et si la mise en place d'une SPCMD est vraiment adaptée. Cette situation d'attente est souvent mal vécue. Il peut même arriver que les soignants saisissent en urgence le comité de réflexion éthique afin d'évoquer ce type de cas. Lors d'une réunion, une soignante nous rapporte le caractère tardif de la sollicitation de l'équipe mobile de soins palliatifs de l'institution :

> « Le hiatus est justement sur le fait que les infirmières et les aides-soignants, qui sont quand même plus à proximité des patients, perçoivent des éléments de souffrance en fin de vie pour laquelle ils ne vont pas trouver de réponse médicale (...) et effectivement, dans ces situations-là, le comité d'éthique peut être sollicité, l'équipe mobile peut être sollicitée aussi, mais parfois tardivement selon les services de soins… ». (Cadre de santé d'un des services de chirurgie)

Nous évoquons ici des cas très particuliers qui sont le reflet d'un manque de communication (ponctuel ou pérenne) entre l'équipe médicale et l'équipe soignante, ce qui est probablement à l'origine de la souffrance des équipes. Il n'est pas anodin que le champ lexical de la décision prédomine dans les propos au sein de ces services, car c'est là le point névralgique de l'expérience de la SPCMD chez ces professionnels. En effet, il est constaté dans ce cas une rupture des échanges entre l'équipe de soignants et les médecins. Cette rupture ne peut et ne doit pas être réglée lors d'une procédure collégiale autour d'un cas d'un patient, mais lors de réunion interdisciplinaire de service. En effet, nous rappelons que la collégialité ne peut, ni ne doit, se limiter aux procédures collégiales formelles. Elle doit être un mode d'exercice et de prise en soins dans les situations de fin de vie, même en dehors des questions de demandes de sédation profonde et continue et des réunions formalisées.

Ainsi, dans la temporalité qui se dessine lors de la prise en charge professionnelle de la fin de vie, le contraire de l'urgence est moins le temps prolongé que l'anticipation. En effet, des décisions importantes peuvent être prises dans l'urgence sans tension, dès lors que ces situations ont été « anticipées ». Autrement dit, que plusieurs scénarios décisionnels ont été projetés et concertés collectivement autour du devenir d'un patient.

Nous avons pu observer plusieurs cas concernant l'application de la procédure collégiale dans les services. Ceux-ci varient en fonction du degré de formalité de la réunion, de la présence ou pas de traces de celle-ci, de la quantité de participants, du

degré d'interdisciplinarité et des modalités de mise en œuvre, entre autres. Dans certains services, par exemple, on suit strictement « *la définition de l'HAS et donc c'est tout le personnel soignant qui participe* », tel que nous rapporte une femme médecin en oncologie : « *C'est au minimum l'aide-soignant, l'infirmier, le médecin : On peut rajouter un deuxième médecin appelé en qualité de consultant, et ensuite le reste de l'équipe qui est "intéressée", entre guillemets. Et plus le séjour est long, par expérience, plus le collège est important* ». Dans le service de ce médecin, on fait la traçabilité des décisions dans un progiciel accessible à tous les soignants, et ensuite « *ça apparaît dans le courrier de sortie* ».

Les propos de cette médecin s'accordent avec les retranscriptions des entretiens par groupe de discussion du service auquel elle appartient. Ce service a parfaitement intégré dans sa pratique quotidienne la mise en place de procédure collégiale formalisée. Il est même courant que l'équipe mobile de soins palliatifs soit présente.

Dans d'autres services, les configurations qui prennent la décision de la sédation s'éloignent relativement de l'esprit de la loi. La décision peut se prendre :

- En comité restreint – médecin référent, un autre médecin n'appartenant pas au service (ami du médecin, médecin des soins palliatifs, anesthésiste...), l'infirmière et l'aide-soignant présent ;
- Lors de la transmission (matin ou 14h ou soir) en présence du personnel soignant présent ;
- Dans les cas délicats et rarissimes (consentement du patient difficile à obtenir, différences de vues entre les soignants…) le comité de réflexion éthique de la structure peut être sollicité ;
- Finalement, nous avons aussi rencontré des cas où la procédure collégiale se résume à une demande du médecin référant à un de ses collègues médecins (généralement l'anesthésiste) – le reste du service se voit exclu de la décision.

Non seulement ces situations sont contraires aux définitions de la collégialité selon les réglementations récentes, mais ce dernier cas engendre aussi toujours des tensions entre les médecins et les soignants. Cela laisse supposer un ancrage fort, chez ces médecins, de l'idée d'une collégialité qui se résumerait à un « entre collègues » médecins.

DISCUSSION DES RÉSULTATS

La prise de décision de la mise en place d'une SPCMD en cas de souffrances réfractaires est délicate et peut affecter le bien-être mental des soignants. Il est nécessaire de bien différencier la situation urgente, qui ne donne pas lieu à l'organisation d'une procédure collégiale qui serait délétère, des sédations pour symptômes réfractaires et/ou sédation profonde et continue maintenue jusqu'au décès qui doivent donner leur place à cette collégialité afin de partager cette potentielle souffrance. De manière générale, et suivant nos données, nous pouvons ici reprendre les mots de Kentish-Barnes : « *La manière de gérer l'incertitude varie d'un service à un autre, entraînant des manières différentes de gérer le processus décisionnel de fin de vie*. » (30). Ainsi, l'adoption partielle, relative, plus ou moins complète, informelle ou formelle, de la procédure collégiale telle qu'elle se désigne dans les textes officiels, semble dépendre de l'organisation, de la « culture » et des possibilités de négociation interprofessionnelle des services (27).

La mention d'obligation de collégialité impliquant l'équipe des soignants (infirmièr(e)s et aide-soignant(e)s) dans la loi française est originale (29). En effet, nous ne la retrouvons pas dans d'autres pays comme le Canada (Québec), la Belgique, les Pays-Bas, le Royaume-Uni ou l'Italie, qui pourtant sont politiquement et socialement très impliqués dans la volonté de promotion des soins de fin de vie. À titre d'illustration, dans la loi (S-32.0001) concernant les soins de fin de vie du Québec (28), il est indiqué au chapitre IV section I article 24 que lorsqu'une personne demande la mise en place d'une sédation palliative continue (équivalent de la SPCMD française) lorsqu'elle est en fin de vie, son consentement doit être consigné par écrit. Il n'est pas mentionné de procédure collégiale des soignants concernant l'acceptation de cette demande. Le patient conscient et éclairé peut décider seul des soins de sa fin de vie. Concernant l'aide médicale à mourir (section II), il est stipulé article 29 que le médecin recevant cette demande doit, entre autres, « obtenir l'avis d'un second médecin confirmant le respect des conditions prévues à l'article 26 » et peut s'entretenir « de sa demande avec des membres de l'équipe de soins en contact régulier avec elle, le cas échéant ». On constate une absence de procédure collégiale obligatoire même pour un geste dont l'objectif n'est pas exclusivement de soulager les souffrances d'une personne mais d'abréger sa fin de vie (30,31). De la même façon on ne retrouve pas de procédure collégiale obligatoire en Belgique ou aux Pays Bas (32) ainsi qu'au Royaume-Uni (33) ou en Italie (34), que ce soit pour la mise en place d'une sédation palliative ou d'une assistance à mourir. Il est envisageable que cette absence d'obligation de la procédure collégiale incluant les soignants soit une volonté du législateur car ces pays ont une très forte implication juridique dans les soins de fin de vie, dont les soins palliatifs. Il convient de noter toutefois une volonté d'information de l'équipe médicale et une traçabilité notamment aux Pays-Bas du processus de décision et des considérations (35).

Pourtant, il est admis qu'accompagner un patient en fin de vie est source de détresse psychologique non seulement pour les médecins, mais également et même surtout pour les infirmières et les aides-soignantes travaillant en oncologie (36). En effet, il n'est pas rare que les patients soient connus depuis de nombreuses années par le service qui s'occupe des patients en récidive de cancer. Des liens affectifs se sont donc tissés entre patients et soignants. La décision de mise en place d'une SPCMD n'est pas facile. Elle ne peut être bien vécue que si l'ensemble des personnes du service pense qu'elle est adoptée dans l'intérêt du patient. Nous avons réalisé une revue de la littérature sur les effets psychologiques de la mise en place d'une SPCMD sur les infirmières dans d'autres pays où la procédure collégiale n'est pas inscrite dans la loi. Nous constatons que ces dernières souffrent de ne pas être concertées avant la mise en place d'une SPCMD. Ces détresses psychologiques sont

mises en évidence quand les infirmières pensent que tout n'a pas été réalisé dans l'intérêt du patient. Par exemple, outre les cas présentés ci-dessus où elles estiment que la décision de SPCMD est prise trop tardivement, elles souffrent si elles estiment que la SPCMD a été initiée alors qu'il y avait d'autres recours thérapeutiques pour calmer les douleurs physiques ou morales des patients ou lorsqu'elles pensent que la mise en place de la sédation vient de la demande des proches du patient à laquelle le médecin aurait cédé pour accélérer la fin de vie du patient. Il y a d'autres cas où les infirmières ne comprennent pas la mise ne place d'une SPCMD alors que le patient réclamait une euthanasie pour les pays où elle est légale (37,38).

Dans les articles présentant le ressenti des infirmières dans les pays où la procédure collégiale n'est pas obligatoire, il est régulièrement rapporté qu'elles souffrent aussi de ne pas être socialement et professionnellement reconnues par les médecins et que leur avis ne soit pas entendu. En effet, elles rapportent que ce sont elles qui connaissent le mieux les patients et leurs désirs et ce sont aussi elles qui savent le mieux gérer la fin de vie lorsqu'elles appartiennent au service de soins palliatifs depuis de nombreuses année (à la différence du jeune médecin nouvellement arrivé) (39).

Cette souffrance sociale existe aussi chez certains jeunes médecins qui expriment des détresses psychologiques dans la gestion de la fin de vie. Ils rapportent avoir des difficultés à gérer la pression des proches dans la prise de décision d'une SPCMD et dans sa titration (39) mais également la pression de leurs aînés (40,41). Pour eux aussi, la procédure collégiale peut être source d'aide à gérer le stress psychologique d'une décision médicale importante. Ainsi, un médecin soutenu par son service se sentira conforté dans sa gestion de la fin de vie d'un patient (assentiment à une « bonne » décision). De même, les situations où la mise en place de la sédation est anticipée et actée par une procédure collégiale permettent aux « jeunes médecins » (les internes en France) de rédiger une prescription de sédation sans difficulté morale majeure. En effet, il n'est pas rare dans un centre de cancérologie que ce soit le jeune interne de garde qui doive gérer une dégradation brutale de l'état du patient et donc la mise en place d'une SPCMD pendant la nuit ou le week-end. Il sera plus confortable pour lui et les soignants présents que la décision puisse être prise sereinement, car anticipée et actée par une réunion collégiale. La famille et les proches seront aussi rassurés devant l'assurance qu'une décision sage et consensuelle peut être prise quel que soit le moment (nuit ou week-end). Ainsi nos données qualitatives par entretien s'accordent avec l'analyse lexicographique où nous observons des discours qui n'hésitent pas à parler de sédation en mettant en valeur la question du soulagement et des temporalités dans l'accompagnement (dose, moment).

La procédure collégiale incluant tous les membres du service semble donc à privilégier non seulement pour l'intérêt du patient qui sera sûr d'être accompagné jusqu'à la fin de sa vie par toute une équipe, mais également pour les soignants eux-mêmes qui seront assurés d'être épaulés dans toutes leurs actions. Nos conclusions appuient les recommandations écrites entre autres par Epstein et Hamric (42). La procédure collégiale de décision permet de prendre une décision comprise et acceptée par tous.

La France est donc particulière dans son désir d'éviter des décisions solitaires arbitraires pouvant engendrer un rapport de force entre médecin et patients ou entre soignants et tient à des procédures solidaires. Nous pouvons rajouter que la procédure collégiale est aussi présente dans la législation française pour les décisions de limitations de traitements si le patient est hors d'état d'exprimer sa volonté et pour la décision de refus d'application des directives anticipées, jugées par le médecin comme inappropriées ou non conformes à la situation médicale du patient. Par l'obligation de procédures collégiales, la loi Claeys-Leonetti revendique une éthique de vulnérabilité et de solidarité collective (43).

Pourtant, notre sondage révèle que cet état d'esprit (solidarité) n'est pas parfaitement acquis par les médecins. En effet, concernant l'acceptabilité de la procédure collégiale, notre étude montre que de nombreux médecins-prescripteurs n'ont pas intégré ou accepté que la sédation dût être précédée d'une décision collective, incluant l'ensemble de professionnels qui s'occupent du patient. Certains médecins ont verbalisé le fait que compte tenu qu'ils étaient seuls décisionnaires et responsables, ils ne comprenaient pas que « *Chaque soignant, quelle que soit sa profession, pèse à poids égal – ou devrait peser – dans la discussion* » (22). Cependant, une inflexion apparaît dès lors que l'on détaille les différents médecins puisque parmi ces 12 % de répondants à notre étude, nous ne trouvons aucun interne et ce ne sont que des praticiens ayant fini leur formation depuis plus de 5 ans qui assimilent le moins la collégialité. On ne saurait ici rapporter ce fait à une cause certaine. Plusieurs phénomènes peuvent y jouer : nous supposons que les médecins plus récemment formés (à la loi de 2016, entre autres) et, plus largement, socialisés à des nouveaux modèles de partage de la décision construits contre le modèle paternaliste (44) intègrent mieux l'intérêt pour le patient et le service de la procédure collégiale. Proches des valeurs de la démocratie sanitaire, il s'agit de professionnels plus enclins à l'ouverture à d'autres formes de savoir et à des pratiques plus humanisées de la médecine, etc.

Concernant le moment de prise de décision, nous voulons insister sur le fait que tous les soignants (médecins, IDE, AS, etc.) s'accordent pour dire qu'une fin de vie anticipée et préparée est gage de sérénité à la fois pour le patient et l'équipe. Cela passe par la nécessité de mettre en place – malgré le manque de temps, de disponibilité, de personnels, etc. –, des réunions de service très régulières avec l'ensemble des membres du service. La SPCMD ne peut être proposée, en France, qu'en fin de vie. Elle est donc appliquée dans les heures ou des quelques jours précédant le décès du patient. Elle a pour but d'assurer une fin de vie paisible et sans souffrance. Elle n'est pas mise en place afin d'abréger la fin de vie et donc d'abréger les souffrances, qu'elles soient physiques ou psychiques. C'est pourquoi il est nécessaire de pouvoir anticiper le moment afin d'agir rapidement, mais sereinement, le moment venu. Dans ce contexte, la collégialité assure au patient qu'à tout instant il peut bénéficier d'une décision prise dans son intérêt. Celle-ci ne doit dépendre ni d'une seule personne (ex. : le médecin) ni d'un groupe détaché du médecin qui ne dispose peut-être pas de tous les éléments du dossier du patient et peut confondre

une fin de vie avec une étape douloureuse de la mise en place d'un traitement. Une décision prise à l'issue d'une procédure collégiale assure au patient une décision plus juste (la meilleure décision pour lui à un moment donné) et équitable. La décision ne dépendant pas d'une seule personne, on peut supposer que la même décision serait prise quel que soit le service ou l'équipe médicale en même temps que prenant en compte, dans la décision, plusieurs paramètres. Le fait d'anticiper la fin de vie évite la possibilité que, devant mettre en place une SPCMD, le médecin ne puisse matériellement réunir les membres du service et que le patient meurt en souffrant par manque de coordination entre soignants. C'est pourquoi en cas d'urgence la loi prévoit que le médecin puisse prendre seul une décision de sédation.

Concernant les soignants (médecins et équipe traitante), la collégialité a pour fonction de délibérer, ce qui amène le collège en position de décision. Par conséquent, même si la prescription est médicale, le pouvoir décisionnel est partagé et cela attenue les différences entre corps de métiers en répartissant les responsabilités (22). En effet, un soignant ayant donné son avis en réunion est responsable de la position prise. Il est donc partie prenante de la décision du médecin en cas de convergence de vues. Ainsi, aucun professionnel ne doit se sentir en dépossession d'un pouvoir d'emprise sur ses propres actes, surtout quand ces actes sont liés à la vie et la mort d'autrui. C'est le sentiment, néanmoins, de plusieurs soignants devant s'occuper de l'acte de sédation ou des patients sous sédation alors qu'ils n'ont pas participé aux décisions. Ainsi, il faut que certains médecins comprennent que « *la collégialité n'annihile pas le pouvoir, elle le partage* » (22) et qu'elle permet un rééquilibrage (au moins décisionnel, même si toujours imparfait par rapport à la « théorie ») des relations de pouvoir entre les métiers, les types de savoirs, et les disciplines.

Cette question de la collégialité va se poser de façon plus prégnante dans les années à venir. En effet, la France est un des pays d'Europe ou l'on meurt le plus à l'hôpital (45). Afin de ramener la mort à la sphère familiale, des efforts sont réalisés afin de proposer un suivi en soins palliatifs à domicile. Comment se mettra alors en place la décision collégiale d'opter pour une SPCMD ? Il semble envisageable que le médecin prendra seul la décision (avec bien sur l'accord de son patient ou la lecture de ses directives anticipées) ou consultera seulement l'infirmière suivant le patient à domicile. À la suite de nos voisins européens, il est probable également que la législation française change en faveur de la légalisation du suicide assisté ou de l'aide médicale à mourir. Ceci se ferait après une consultation citoyenne de la population française. La place de la collégialité dans la prise de décision sera débattue. Au vu des discussions rapportées ici, elle parait la manière la plus adaptée de faire comprendre au patient et à ses proches que ces pratiques ne sont pas un abandon du patient, seul maître de son destin, mais bien un accompagnement en collégialité d'une fin de vie personnalisée pour la personne placée au centre des préoccupations d'une équipe bienveillante.

CONCLUSION

La loi Claeys-Leonetti relative à la fin de vie de 2016 a pour but la diffusion de la culture palliative. Et si elle se fait par des procédures formalisées, telles que la procédure collégiale, l'objectif de la loi est surtout d'insister sur la nécessité de l'approche pluridisciplinaires dans toutes les situations de fin de vie pour permettre une prise en charge apaisée des patients et éviter la souffrance des équipes. Donc, élargir les modes de communication pluri/inter professionnelle est la piste permettant d'apaiser la souffrance des patients, des médecins et des soignants. Elle permet aussi de se mettre en accord avec le guide européen pour l'éthique médicale qui, dans son quatrième article, indique que « le médecin ne peut substituer sa propre conception de la qualité de vie à celle de son patient ». La procédure collégiale permet d'éclairer le médecin sur les souhaits souvent partagés avec l'équipe soignante du patient. Elle sera également une réponse à l'isolement du médecin généraliste dans le futur.

L'analyse de l'ensemble des réponses des soignants à notre sondage et lors des discussions en groupe de discussion ou individuelles a montré une connaissance partielle de la loi. Notre étude confirme ainsi les résultats d'études précédentes (46). Cela a conduit le comité de réflexion éthique de l'Institut Claudius Regaud où a été réalisée cette étude à proposer des formations destinées à l'ensemble des soignants sur la loi Claeys-Leonetti. Ces formations concernent d'abord l'application de la loi Claeys-Leonetti qui est encore trop peu respectée en France. Elles insistent sur le caractère solidaire de la loi et l'implication de tous les soignants dans les décisions de mise en place de traitements impactant la qualité de vie des patients (et leur fin de vie). Elles visent également à former les médecins à mettre en place des discussions approfondies avec leurs patients sur la fin de vie afin de mieux connaître le patient, de recueillir des directives anticipées et ainsi de faire rupture de la réticence de certains patients à évoquer les décisions futures concernant leur fin de vie. Cela favorisera la promotion du respect de l'autonomie des patients afin de les placer au cœur du processus décisionnel concernant les décisions de traitements ou de soins de fin de vie.

Concernant l'action des pouvoirs publics, notre étude a montré qu'il ne suffit pas de changer la loi, mais qu'il est nécessaire de l'accompagner par des politiques adéquates de formation des professionnels de santé et de diffusion plus large auprès des citoyens pour que celle-ci soit véritablement appropriée par les divers acteurs.

Reçu/Received: 22/07/2020

Publié/Published: 27/06/2023

Remerciements

Les auteurs souhaitent remercier la fondation ARC pour la recherche contre le cancer qui a financé ce projet. Ils remercient également le personnel de l'Institut Claudius Regaud (IUCT-Oncopole) pour leur participation.

Acknowledgements

The authors would like to thank the ARC Foundation for Cancer Research for funding this project. They would also like to thank the staff of the Claudius Regaud Institute (IUCT-Oncopole) for their participation.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Brigitte Desrosiers & Aliya Affdal
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ANNEXE 1 : ARTICLE R. 4127-37 EN VIGUEUR DEPUIS LE 6 AOUT 2016 EN FRANCE

« Art. R. 4127-37.-En toutes circonstances, le médecin doit s'efforcer de soulager les souffrances du malade par des moyens appropriés à son état et l'assister moralement. Il doit s'abstenir de toute obstination déraisonnable et peut renoncer à entreprendre ou poursuivre des traitements qui apparaissent inutiles, disproportionnés ou qui n'ont d'autre effet que le seul maintien artificiel de la vie. »

« Art. R. 4127-37-1.-I.-Lorsque le patient est hors d'état d'exprimer sa volonté, le médecin en charge du patient est tenu de respecter la volonté exprimée par celui-ci dans des directives anticipées, excepté dans les cas prévus aux II et III du présent article.

« II.- En cas d'urgence vitale, l'application des directives anticipées ne s'impose pas pendant le temps nécessaire à l'évaluation complète de la situation médicale.

« III.- Si le médecin en charge du patient juge les directives anticipées manifestement inappropriées ou non conformes à la situation médicale, le refus de les appliquer ne peut être décidé qu'à l'issue de la procédure collégiale prévue à l'article L. 1111-11. Pour ce faire, le médecin recueille l'avis des membres présents de l'équipe de soins, si elle existe, et celui d'au moins un médecin, appelé en qualité de consultant, avec lequel il n'existe aucun lien de nature hiérarchique. Il peut recueillir auprès de la personne de confiance ou, à défaut, de la famille ou de l'un des proches le témoignage de la volonté exprimée par le patient.

« IV.- En cas de refus d'application des directives anticipées, la décision est motivée. Les témoignages et avis recueillis ainsi que les motifs de la décision sont inscrits dans le dossier du patient.

« La personne de confiance, ou, à défaut, la famille ou l'un des proches du patient est informé de la décision de refus d'application des directives anticipées.

« Art. R. 4127-37-2.-I.-La décision de limitation ou d'arrêt de traitement respecte la volonté du patient antérieurement exprimée dans des directives anticipées. Lorsque le patient est hors d'état d'exprimer sa volonté et en l'absence de directives anticipées, la décision de limiter ou d'arrêter les traitements dispensés, au titre du refus d'une obstination déraisonnable, ne peut être prise qu'à l'issue de la procédure collégiale prévue à l'article L.1110-5-1 et après qu'a été recueilli auprès de la personne de confiance ou, à défaut, auprès de la famille ou de l'un des proches le témoignage de la volonté exprimée par le patient.

« II.- Le médecin en charge du patient peut engager la procédure collégiale de sa propre initiative. Il est tenu de le faire à la demande de la personne de confiance, ou, à défaut, de la famille ou de l'un des proches. La personne de confiance ou, à défaut, la famille ou l'un des proches est informé, dès qu'elle a été prise, de la décision de mettre en œuvre la procédure collégiale.

« III.- La décision de limitation ou d'arrêt de traitement est prise par le médecin en charge du patient à l'issue de la procédure collégiale. Cette procédure collégiale prend la forme d'une concertation avec les membres présents de l'équipe de soins, si elle existe, et de l'avis motivé d'au moins un médecin, appelé en qualité de consultant. Il ne doit exister aucun lien de nature hiérarchique entre le médecin en charge du patient et le consultant. L'avis motivé d'un deuxième consultant est recueilli par ces médecins si l'un d'eux l'estime utile.

« Lorsque la décision de limitation ou d'arrêt de traitement concerne un mineur ou un majeur protégé, le médecin recueille en outre l'avis des titulaires de l'autorité parentale ou du tuteur, selon les cas, hormis les situations où l'urgence rend impossible cette consultation.

« IV.- La décision de limitation ou d'arrêt de traitement est motivée. La personne de confiance, ou, à défaut, la famille, ou l'un des proches du patient est informé de la nature et des motifs de la décision de limitation ou d'arrêt de traitement. La volonté de limitation ou d'arrêt de traitement exprimée dans les directives anticipées ou, à défaut, le témoignage de la personne de confiance, ou de la famille ou de l'un des proches de la volonté exprimée par le patient, les avis recueillis et les motifs de la décision sont inscrits dans le dossier du patient.

« Art. R. 4127-37-3.-I.-A la demande du patient, dans les situations prévues aux 1° et 2° de l'article L. 1110-5-2, il est recouru à une sédation profonde et continue provoquant une altération de la conscience maintenue jusqu'au décès, associée à une analgésie et à l'arrêt de l'ensemble des traitements de maintien en vie, à l'issue d'une procédure collégiale, telle que définie au III de l'article R. 4127-37-2, dont l'objet est de vérifier que les conditions prévues par la loi sont remplies.

« Le recours, à la demande du patient, à une sédation profonde et continue telle que définie au premier alinéa, ou son refus, est motivé. Les motifs du recours ou non à cette sédation sont inscrits dans le dossier du patient, qui en est informé.

« II.- Lorsque le patient est hors d'état d'exprimer sa volonté et qu'un arrêt de traitement de maintien en vie a été décidé au titre du refus de l'obstination déraisonnable, en application des articles L. 1110-5-1, L. 1110-5-2 et L. 1111-4 et dans les

conditions prévues au présent article, le médecin en charge du patient, même si la souffrance de celui-ci ne peut pas être évaluée du fait de son état cérébral, met en œuvre une sédation profonde et continue provoquant une altération de la conscience maintenue jusqu'au décès, associée à une analgésie, excepté si le patient s'y était opposé dans ses directives anticipées.

« Le recours à une sédation profonde et continue, ainsi définie, doit, en l'absence de volonté contraire exprimée par le patient dans ses directives anticipées, être décidé dans le cadre de la procédure collégiale prévue à l'article R. 4127-37-2.

« En l'absence de directives anticipées, le médecin en charge du patient recueille auprès de la personne de confiance ou, à défaut, auprès de la famille ou de l'un des proches, le témoignage de la volonté exprimée par le patient.

« Le recours à une sédation profonde et continue est motivé. La volonté du patient exprimée dans les directives anticipées ou, en l'absence de celles-ci, le témoignage de la personne de confiance, ou, à défaut, de la famille ou de l'un des proches de la volonté exprimée par le patient, les avis recueillis et les motifs de la décision sont inscrits dans le dossier du patient.

« La personne de confiance, ou, à défaut, la famille, ou l'un des proches du patient est informé des motifs du recours à la sédation profonde et continue.

« Art. R. 4127-37-4.-Le médecin accompagne la personne selon les principes et dans les conditions énoncées à l'article R. 4127-38. Il veille également à ce que l'entourage du patient soit informé de la situation et reçoive le soutien nécessaire. »

ANNEXE 2 : QUESTIONNAIRE PROPOSÉ À L'ENSEMBLE DU PERSONNEL SOIGNANTS D'UN CENTRE DE CANCÉROLOGIE FRANÇAIS

Bonjour,

Dans le cadre d'un travail du comité de réflexion éthique de l'IUCT-O et les débats actuels concernant les révisions des lois de bioéthique, nous désirons faire un état des lieux sur la connaissance de la loi de 2016 Claeys-Leonetti par les soignants de notre structure par l'intermédiaire du questionnaire ci-dessous.

En effet, la connaissance de cette loi a une incidence sur la prise en charge des patients et la satisfaction des soignants.
Votre participation à l'enquête est entièrement libre. En cas d'acceptation, vous pouvez cliquer sur le lien suivant et commencer l'enquête. Vous pouvez interrompre votre participation à tout moment ;

Vous avez jusqu'au 30 novembre pour répondre en ligne. Les résultats nous permettront de proposer une conférence sur ce sujet et/ou une conférence sur la sédation.

N'hésitez pas à tester vos connaissances. Cela ne vous prendra que 10 minutes et c'est entièrement anonyme. Ni votre nom, ni l'adresse IP de votre ordinateur ne seront collectés.

Il peut y avoir plusieurs réponses justes par item.

Nous vous remercions par avance de votre participation.

Le comité de réflexion éthique IUCT-O

Partie 1 : la loi

1) La loi Claeys-Léonetti
   a) Est relative aux droits des malades et à la fin de vie.
   b) Repose sur des principes éthiques.
   c) Est la 1ere loi à permettre au patient de refuser un traitement.
   d) Est la première loi à introduire la notion de personne de confiance.
   e) Est la première loi à introduire la notion de directives anticipées.
   f) Je ne la connais pas.

2) Parmi les propositions suivantes, lesquelles sont énoncées ou reprises dans la loi Claeys-Leonetti :
   a) L'interdiction de l'euthanasie en France.
   b) La condamnation de l'obstination déraisonnable.
   c) Le respect du refus de tout traitement par le patient.
   d) La légitimité du double effet, c'est-à-dire que l'administration d'un médicament destiné à soulager une douleur peut également accélérer la fin de vie.
   e) Les directives anticipées.
   f) Je ne sais pas

3) La loi Claeys-Leonetti...
   a) Encourage l'information et le recueil de consentement du patient.
   b) Consacre l'irresponsabilité pénale du médecin en cas de limitation ou d'arrêt argumenté des thérapeutiques.
   c) Encourage la réflexion et la décision strictement médicale.
   d) Encourage la rédaction de directives anticipées pour inclure les volontés du patient en cas d'incapacité à communiquer dans la procédure collégiale au patient.
   e) Autorise le suicide médicalement assisté.
   f) Je ne sais pas.

Partie 2 : Les directives anticipées - la personne de confiance

4) Les directives anticipées...
   a) Doivent être rédigées par tous les patients d'un établissement de cancérologie.
   b) Ont une durée illimitée en absence d'une révocation par le patient.
   c) Sont rédigées par le patient pour le cas où il ne pourrait plus s'exprimer.
   d) Lorsqu'un médecin souhaite les outrepasser, il le fait après procédure collégiale.
   e) Prévalent sur l'avis de la personne de confiance.
   f) Je ne sais pas.

5) Concernant les directives anticipées :
   a) Il appartient aux soignants de tracer la présence ou l'absence des directives anticipées dans le dossier.
   b) Un patient privé de liberté (prison) a le droit de formuler des directives anticipées.
   c) Un patient sous tutelle n'a pas le droit de formuler des directives anticipées.
   d) L'expression orale antérieure d'une volonté non circonstanciée ne saurait constituer une directive anticipée.
   e) Les directives anticipées sont fixées durant tout le processus de fin de vie du patient, pour éviter tout changement d'avis.
   f) Je ne sais pas

6) En absence de directives anticipées...
   a) Le médecin prend seul les décisions concernant le patient qui n'est pas en état de communiquer.
   b) Seule la personne de confiance pourra exprimer la volonté du patient pour un patient inconscient (seuls les propos rapportés par la personne de confiance ont valeur de témoignage).
   c) Le patient conscient (apte à rendre des décisions en connaissance de cause) exprime ce qu'il souhaite pour son traitement et il est entendu.
   d) Une sédation sera automatiquement effectuée.
   e) Une sédation ne pourra pas être mise en place.
   f) Je ne sais pas

7) La personne de confiance :
   a) Sa désignation par le patient est obligatoire
   b) Peut être le médecin traitant du patient
   c) Est toujours la personne à prévenir en priorité en cas de décès du patient
   d) Peut refuser ce rôle
   e) Est l'interlocuteur privilégié pour l'équipe médicale pour les décisions de soins
   f) Je ne sais pas

Fin de Vie : Sédation

8) Concernant la fin de vie :
   a) Selon la loi Claeys-Leonetti, les directives anticipées s'imposent au médecin « sauf en cas d'urgence ou de teneur manifestement inapproprié
   b) Les directives anticipées sont révocables à tout moment.
   c) L'avis de la personne de confiance prévaut sur les directives anticipées
   d) La loi Claeys Leonetti autorise la sédation profonde et continue jusqu'au décès « en cas de souffrances vécues comme insupportables » et lorsque le pronostic vital est engagé à court terme.
   e) La loi Claeys Leonetti permet au patient conscient de prendre, sans l'accord du médecin, des décisions sur l'arrêt de ses traitements.
   f) Je ne sais pas

9) La sédation profonde et continue maintenue jusqu'au décès
   a) Ne peut pas être refusée par le médecin
   b) Est responsable du décès du patient
   c) Peut être demandée par la personne de confiance
   d) Peut être indiquée en cas de symptômes réfractaires
   e) Peut être demandée par le patient
   f) Je ne sais pas

10) Concernant la limitation ou l'arrêt des traitements :
   a) Grace aux progrès des techniques médicales, le médecin peut et doit tout faire pour maintenir le patient en vie
   b) Éviter l'obstination déraisonnable signifie arrêter tous les traitements pour le patient
   c) L'arrêt des traitements constitue une forme d'euthanasie
   d) La procédure collégiale menant à la décision de limitations de soins inclut l'équipe soignante (Aide soignantes, infirmières etc.)
   e) Si le médecin limite les traitements, les soignants sont obligés de limiter les soins de base et de confort
   f) Je ne sais pas

11) Concernant la limitation ou l'arrêt des traitements :
   a) Une incertitude avérée sur la qualité de vie future autorise l'arrêt des thérapeutiques
   b) Toutes les religions sont opposées à l'arrêt des thérapeutiques
   c) Son objectif est la préservation de la dignité du patient en fin de vie
   d) L'arrêt des traitements entraine des poursuites pénales pour le médecin
   e) Si le patient est inconscient, et en absence de directives anticipées, la décision d'arrêt de traitement est prise après procédure collégiale
   f) Je ne sais pas

12) Concernant les soins de pathologies chroniques (soins palliatifs) /soins de support :
    a) Lors d'un arrêt de traitement, l'accompagnement de fin de vie et le soulagement des douleurs physiques et morales restent du domaine du soin.
    b) Avec la mis en place des soins palliatifs (pallium) dans les services de réanimation notamment, les médecins peuvent se permettent d'être moins bon techniquement.
    c) Dans le cadre du continuum de soins, les soignants doivent prévoir l'après traitement
    d) La limitation de traitement s'effectue obligatoirement quand on n'a plus d'espoir de guérir le patient
    e) « Arrêt de traitements » et « arrêt des soins » veulent dire la même chose.
    f) Je ne sais pas.

Vous

Est-ce que la loi Claeys-Leonetti est adaptée à votre pratique des soins ?
    a) Oui
    b) Non

Si non, pourquoi ?
    a) Elle de respecte pas l'auto-détermination et la volonté du patient
    b) Elle ne va pas jusqu'à l'encadrement légal d'une pratique existante clandestine et inégalitaire.
    c) Elle ne prend pas en compte la gestion de la souffrance
    d) Elle ignore nos pratiques
    e) Elle donne trop de droits aux patients
    f) Seul le patient peut juger de sa propre dignité
    g) Elle ne fait pas de distinction entre une limitation ou un arrêt de traitement, suivi de la mort du patient et une injection d'un produit entrainant la mort du patient.

Vous êtes :
    a) Un homme
    b) Une femme

Vous êtes :
    a) Interne
    b) Assistant
    c) PH
    d) PU
    e) Infirmiers
    f) Aides-soignantes
    a) autre

Vous avez :
    a) moins de 5 ans d'expérience
    b) plus de 5 ans d'expérience.

Votre spécialité :
    a) chirurgie
    b) anesthésie réanimation
    c) médecine interne
    d) oncologie médicale
    e) radiothérapie
    f) radiodiagnostic
    g) hématologie
    h) soins de support (dont équipe mobile)
    i) autre

Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

A Filleul, M-J Drolet, A Hudon
Can J Bioeth / Rev Can Bioeth. 2023;6(2):107-119

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Démasquer le paternalisme latent en santé : apports du philosophe Ruwen Ogien

Arthur Filleul[a,b], Marie-Josée Drolet[c,e], Anne Hudon[b,d,e]

Résumé
Le but de notre article est d'identifier ce qui, dans la pensée du philosophe libertaire et égalitaire Ruwen Ogien, permet de démasquer et de réinterroger le paternalisme latent qui perdure encore dans les pratiques des professionnels de la santé. Car bien que les avancées récentes des modèles de soins laissent plus de place à la voix des personnes accompagnées ainsi qu'à leur libre autodétermination, celles-ci n'ont pas mis fin au paternalisme en santé. Nous présentons ici les différents points clés de l'argumentaire d'Ogien visant à critiquer le paternalisme en santé, pour prendre conscience du paternalisme latent et constater que de celui-ci découle des injustices épistémiques et sociales qu'il importe de renverser.

Mots-clés
autonomie, bioéthique, éthique clinique, injustice épistémique, paternalisme, soins de santé, Ruwen Ogien

Abstract
The aim of our article is to identify what, in the thinking of the libertarian and egalitarian philosopher Ruwen Ogien, enables us to unmask and interrogate the latent paternalism that still persists in the practices of healthcare professionals. Although recent advances in models of care have made more room for the voice of those being cared for and for their free self-determination, they have not put an end to paternalism in healthcare. We present here the various key points of Ogien's argument aimed at criticising paternalism in healthcare, in order to be aware of the latent paternalism and recognize that it gives rise to epistemic and social injustices that must be reversed.

Keywords
autonomy, bioethics, clinical ethics, epistemic injustice, paternalism, healthcare, Ruwen Ogien

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> *J'ai toujours senti qu'au fond de la pensée de Ruwen, il y avait une hantise et comme un secret, liés à la conscience que le pire est encore possible, que la liberté est fragile, que la démocratie et l'esprit qui la gouverne, c'est-à-dire le respect de l'autre et la confiance en l'individu, étaient attaqués. Cette conscience du fait que la liberté est un bien précieux confère aux livres de Ruwen une grande profondeur. Il y a comme un reste dans cette philosophie, quelque chose qui n'est pas dit, mais qui donne à sa pensée une humanité et une universalité bouleversantes. Cette œuvre, y compris dans ce qui, en elle, est suggéré, peut inspirer des générations de philosophes. J'ai la chance d'en faire partie.*
>
> Corinne Pelluchon (1).

INTRODUCTION

Le paternalisme médical, qu'il soit épistémique, moral ou éthique[1], est cette idée suivant laquelle il importe de protéger les individus d'eux-mêmes, ou d'interférer pour que ceux-ci prennent de bonnes décisions, notamment celles qui sont censées contribuer à leur santé et leur bien-être (3). Dans sa posture la plus forte ou radicale, le paternalisme retire toute capacité décisionnelle à une personne, car celle-ci est estimée incapable de reconnaitre ce qui est bien pour elle (4). Le modèle de soins passé, empreint d'un fort paternalisme, où le médecin prenait la décision unilatéralement, a été progressivement remis en question depuis la fin de la Seconde Guerre mondiale (5,6). Les luttes internationales pour la reconnaissance des droits des personnes ayant une expérience du handicap durant les années 1970 ont été des années charnières pour ce changement de modèle (7-9). Les modèles actuels donnent plus de place à la voix des personnes soignées, à leur autonomie décisionnelle ainsi qu'à leur libre autodétermination, faisant par la même occasion reculer la présence et l'influence du paternalisme (10). En pratique, ces changements dans les modèles de soins se manifestent sous différents angles. Par exemple, certaines responsabilités sont remises entre les mains des personnes qui reçoivent des soins, notamment en soutenant l'éducation à la santé et l'autogestion de leur condition (11). Les professionnels de la santé se tournent également davantage vers des approches conjuguant à la fois la prise en compte des aspects biologiques, psychologiques et sociaux de la personne (12-

[1] Dans ce texte, nous reprenons la distinction entre l'éthique et la morale proposée par M-J Drolet et M Ruest (2). Ainsi, la morale se réfère à un ensemble de valeurs et de règles de conduite prescrites et généralement basées sur une religion, des dogmes, des traditions ou encore des us et coutumes. L'éthique, quant à elle, en tant que discipline philosophique propose des valeurs, des principes ou des vertus et se base sur des arguments et des prémisses rationnelles pour formuler les théories qu'elle articule. À noter qu'Ogien, comme la plupart des philosophes, ne fait pas de distinction entre l'éthique et la morale dans ses œuvres ; il emprunte alors indifféremment les mots « éthique » et « morale ».

ISSN 2561-4665

15). Bien que ces changements dans les pratiques se veulent anti-paternalistes, le respect de l'autonomie décisionnelle ainsi que de la libre autodétermination des personnes est encore actuellement marqué d'un paternalisme latent (16).

Ce paternalisme latent contribue à perpétuer d'importantes injustices épistémiques. Le concept d'injustice épistémique, développé par la philosophe Miranda Fricker (17), désigne des injustices ayant trait aux connaissances et aux savoirs. Il y a présence d'une telle injustice lorsqu'une personne voit sa parole indûment remise en question ou dévaluée par un groupe dominant qui ne reconnait pas la légitimité du savoir de la personne (18), ce que Fricker (17) désigne comme une injustice épistémique de nature testimoniale. Il y aussi présence d'une telle injustice, de nature herméneutique cette fois-ci, lorsque les ressources interprétatives collectives ne permettent pas à une personne de rendre compte de son expérience (19). En somme, un individu est confronté à une injustice épistémique lorsque sa parole n'est pas jugée crédible, alors qu'elle devrait l'être (injustice testimoniale) ou lorsque les connaissances existantes ne lui permettent pas de décrire son vécu expérientiel, car celles-ci représentent les expériences des groupes dominants (injustice herméneutique).

Dans ces descriptions, on perçoit que le paternalisme en santé recule, mais persiste au sein de certaines pratiques ou cultures de soin. Les justifications qui soutiennent ce paternalisme par les professionnels de santé ou les institutions sont notamment reliées à l'idée qu'ils font « ce qu'il y a de mieux » pour les personnes ou qu'ils empêchent ces personnes de « se faire du mal ». Malgré ces justifications qui peuvent sembler attirantes, ce paternalisme latent soulève de nombreux enjeux éthiques. Tout d'abord, un acte paternaliste est par essence une violation de l'autonomie individuelle d'une personne, généralement d'une personne en situation de vulnérabilité. Bien qu'une finalité soi-disant « bienveillante » soit en général à l'origine de cette violation, le droit d'une personne se voit tout de même bafoué. Considérant qu'il importe que les professionnels de la santé contribuent à redonner du pouvoir d'agir aux personnes en situation de vulnérabilité, cette violation est préoccupante, voire incohérente avec leur mission sociale.

Ensuite, pour qu'il advienne, le paternalisme implique une vision infériorisée de la personne accompagnée, laquelle est entretenue par le professionnel de la santé. Suivant cette vision, la personne accompagnée n'est pas capable de bien réfléchir parce qu'elle ne comprend pas tout à fait ce qu'il se passe, ne prend pas en considération certains éléments cruciaux ou parce qu'il lui manque certaines capacités ou aptitudes pour parvenir à la bonne décision. Le fait que des professionnels de la santé aient une telle vision des personnes accompagnées est problématique d'un point de vue éthique. Elle ouvre toute grande la porte aux abus de pouvoir.

De plus, le paternalisme en santé a le potentiel de contribuer à une perte de confiance des personnes accompagnées envers les professionnels de santé et les institutions. En ne cherchant pas à partager en toute transparence les informations nécessaires à une prise de décision libre et éclairée, à mieux communiquer les savoirs existants et à jour avec les personnes accompagnées et en refusant de soutenir leur autonomie décisionnelle, c'est le respect des personnes et de leurs droits qui se retrouvent outrepassés. Enfin le paternalisme maintient et aggrave de nombreuses injustices en maintenant les privilèges sociaux et épistémiques des professionnels de santé. En ce sens, il se présente comme un autre visage oppressif, voire une forme de capacitisme (20). Le paternalisme est d'autant plus préoccupant puisque les personnes âgées, de même que celles issues de minorités sociales, culturelles ou économiques risquent d'être touchées davantage par cette oppression, car elles sont souvent sujettes aux stéréotypes et préjugés des professionnels et institutions de santé (21). C'est donc pour remédier à ces enjeux inquiétants qu'il nous importe d'en finir avec le paternalisme en santé.

Pour ce faire, la lecture du philosophe Ruwen Ogien nous est apparue pertinente, notamment parce qu'elle permet de cerner où se cache encore le paternalisme en santé ainsi que de recueillir des arguments contre certaines pratiques ou cultures de soin actuelles pouvant être jugées comme paternalistes. En somme, la lecture de l'œuvre de Ruwen Ogien nous a amenés à des réflexions critiques et éthiques sur la persistance d'un paternalisme latent en santé. La réflexion éthique, à la fois critique et rationnelle (22), nous permet de nous intéresser à l'argumentation sur laquelle reposent certaines pratiques paternalistes et d'évaluer la résistance de ces arguments. Nous verrons ainsi que le paternalisme prend de nouvelles formes en lien avec les évolutions récentes des modèles de soins et qu'il conduit à de nombreuses injustices épistémiques, de même qu'à des injustices sociales. Cet article vise donc à présenter et à approfondir les apports critiques de la pensée de Ruwen Ogien à notre objet de réflexion.

CORPUS DES DOCUMENTS A L'ETUDE ET ELEMENTS METHODOLOGIQUES

Pour mettre en lumière les réflexions du philosophe Ruwen Ogien sur le paternalisme et ses apports à une réflexion éthique sur le sujet, il nous est paru important d'explorer plusieurs de ses ouvrages, mais également la réception de ses pensées par la communauté philosophique. Suivant une posture herméneutique (23), nous avons donc étudié 8 de ses ouvrages, 5 vidéos ou baladodiffusions où on peut l'entendre parler de ses idées, 4 textes rédigés par des commentateurs de ses ouvrages ainsi que 5 hommages qui lui ont été rendus. Au total, 22 documents ont guidé la rédaction de cet article (Annexe 1 : Corpus des documents étudiés). Considérant qu'Ogien se démarque par une philosophie vivante, qui se nourrit de la discussion, l'entendre lui-même exprimer ses réflexions par l'entremise de vidéos ou de baladodiffusions a permis de mieux comprendre sa pensée. De même, lire des commentateurs de ses œuvres assure une prise en compte de la réceptivité critique de sa philosophie. Enfin, lors de son décès, en 2017, différents milieux philosophiques lui ont rendu hommage, revenant ainsi sur son œuvre, sa vie et sa personne. Ces témoignages sont une autre manière d'explorer les contributions d'Ogien à diverses réflexions philosophiques contemporaines.

Cet article est rédigé à la lumière de la lecture d'un ensemble de sources variées qui traitent de la philosophie et du philosophe original qu'était Ruwen Ogien aussi bien par son parcours existentiel que par sa pensée. Au-delà de l'argumentaire construit dans ce texte visant à démasquer le paternalisme latent en santé, nous souhaitions faire découvrir (ou redécouvrir) aux lecteurs le philosophe Ogien certes, mais également l'éclairage que ses ouvrages et sa philosophie peuvent apporter aux nombreuses réflexions qui émergent dans le domaine de la santé. Ainsi, une brève description de son parcours de vie est présentée à l'Annexe 2 pour mieux situer les lecteurs face à l'œuvre singulière d'Ogien.

APPORTS DE LA PENSEE DE RUWEN OGIEN AUX PRATIQUES CLINIQUES EN SANTE

Les réflexions d'Ogien nous permettent de réinterroger la place du paternalisme dans notre société, le tout sous couvert d'une défense de l'égalité des droits et libertés de chacun et chacune. Dans cette conception radicalement anti-paternaliste, l'essence de la médecine ne s'arrête pas à l'idée d'un mal ou d'une souffrance à retirer, elle deviendrait une « médecine des désirs » comme la nomme Durand (24). Ainsi lorsque l'on évoque le devoir des professionnels de la santé, ce n'est pas que le devoir passif de respecter la volonté, mais également le devoir positif de favoriser l'émancipation. Nous tâcherons d'illustrer dans cette section comment ces réflexions peuvent servir à la critique du paternalisme latent en santé, tant dans les pratiques de soins au quotidien, qu'à un niveau sociétal.

Critique du paternalisme libéral

Comme nous l'avons évoqué, le paternalisme autoritaire s'essouffle, mais en reculant, il laisse place à un paternalisme dit « libéral ». Celui-ci prend appui sur la théorie du *nudge*, qui permettrait, selon ses promoteurs, de maintenir l'autonomie et la liberté décisionnelles des personnes tout en les amenant à faire des choix plus utiles et plus bénéfiques pour elles (25). De manière simpliste, par l'entremise de diverses techniques discursives propres au marketing, la théorie du *nudge* influence, sans coercition, les choix individuels, un peu comme le font les publicités qui nous incitent à consommer divers objets, produits ou services dont nous n'avons pas véritablement besoin. Cette théorie exploite non plus la force ou la loi pour nous contraindre à choisir certaines options parmi un ensemble d'options, mais use de nos biais psychologiques, de nos difficultés à raisonner statistiquement (biais cognitifs) et de notre préférence pour le présent, le tout pour nous faire acquiescer à différentes propositions. Cette théorie, qui oriente les choix offerts aux personnes de sorte qu'une seule option semble finalement valable, séduit autant qu'elle ne déplaît dans le monde de la santé, créant ainsi un débat entourant les enjeux éthiques qui découlent du recours aux *nudges* en clinique (26-31).

Un exemple de *nudge* pourrait être le suivant : estimant à la suite d'une blessure qu'une opération chirurgicale semble nécessaire, le professionnel de santé recommande cette intervention. La personne blessée refuse et s'oppose à l'intervention, car cette procédure implique pour la personne un parcours considéré comme éprouvant et qu'elle a dans son entourage quelqu'un pour qui cette procédure a été décevante. Un conflit émerge donc entre le respect de l'autonomie décisionnelle de la personne et le principe de bienfaisance (32). Le professionnel de la santé, lors de la discussion, pourra *nudger* la personne en axant la conversation sur les risques de ne pas recourir à l'intervention : « Vous pouvez ne pas vous faire opérer, mais vous passez à côté d'importantes chances de guérison », plutôt que de miser sur les gains potentiels liés à ce choix, tels que l'absence de risques liés à l'anesthésie, les coûts plus faibles, etc. En usant d'un biais cognitif, celui d'une plus grande sensibilité à la perte qu'au gain, le professionnel laisse la possibilité de ne pas se faire opérer ouverte, mais oriente intentionnellement son discours vers les avantages de l'intervention pour contraindre, sans coercition, la personne dans son choix (33). Les défenseurs du *nudge* estiment que, dans cette situation, le recours au *nudge* est non seulement possible, mais justifié et que ce dernier ne viole pas l'autonomie et la liberté décisionnelles de la personne (34).

Selon les défenseurs du *nudge* en situation clinique, l'utilisation de ces techniques discursives par le professionnel de santé permettrait à la personne de prendre « la meilleure décision » pour elle-même (28). Certaines justifications s'appuient sur l'idée que les personnes qui sont confrontées à la maladie sont en situation de vulnérabilité et qu'elles ne peuvent pas raisonner efficacement, de sorte qu'il convient alors de les protéger en utilisant des *nudges*, ces choix présentés d'une manière telle qu'une seule option semble être « la bonne » finalement (30). Ainsi, selon certains promoteurs du *nudge* en clinique, on amène les personnes à faire ce qui est bien pour elles, sans qu'elles ne soient conscientes du dispositif discursif caché qui oriente leur décision, maintenant ainsi leur « autonomie décisionnelle » et favorisant par le fait même les « meilleures décisions cliniques », du point de vue des professionnels de la santé.

L'œuvre de Ruwen Ogien est dédiée en grande part à la critique du paternalisme. En effet, Ogien refuse l'idée suivant laquelle un tiers comme l'État puisse nous limiter dans nos choix personnels si ces choix ne nuisent pas directement à autrui. Il critique le recours à des moyens coercitifs étatiques pour imposer à des concitoyens une conception particulière du bien (35), ce qu'il qualifie de « paternalisme dur », lequel a été vivement critiqué au 19^{e} siècle par le philosophe anglais John Stuart Mill (36). Mais Ogien s'attaque également à ces nouvelles formes contemporaines de paternalisme, particulièrement à ce nouveau paternalisme dit « libéral » (3).

Certains défenseurs du *nudge* en situation clinique se basent sur l'idée suivant laquelle seules les personnes en situation de vulnérabilité (comme les enfants ou certains aînés, les personnes malades ou marginalisées ou encore celles ayant une expérience du handicap) seraient caractérisées par une certaine « incompétence cognitive » et que les interventions paternalistes seraient censées y remédier (3). Ainsi, certains professionnels de santé ne défendent pas l'idée de généraliser l'utilisation des *nudges*, mais simplement de les utiliser à l'encontre des personnes qu'ils jugent « trop vulnérables » ou ayant

une autonomie décisionnelle qu'ils considèrent comme « trop faible ». Cela revient à axer l'utilisation de *nudges* préférentiellement auprès des individus ayant des comportements estimés « à risque » ou « différents » afin qu'ils adoptent des comportements soi-disant plus sains.

Distinguer ce qui devrait être *nudgé* de ce qui ne devrait pas l'être constitue une discrimination épistémique claire selon Ogien, laquelle se voit totalement injustifiée d'un point de vue éthique. Pour Ogien, ces personnes ne sont certainement pas moins compétentes cognitivement que d'autres adultes soi-disant sains d'esprit et bien portants. Les prises de décisions pour sa propre santé sont difficiles, elles demandent une compréhension d'informations complexes, remplies d'incertitudes. De plus elles s'inscrivent au sein d'habitudes de vie préexistantes qui favorisent les biais cognitifs, par exemple, le fait de ne retenir que les informations confirmant les croyances ou pratiques habituelles. En se basant sur différents travaux du domaine de la science cognitive (37), montrant l'incohérence entre les choix et les préférences des personnes adultes ou encore leur incapacité à raisonner logiquement ou statistiquement, Ogien en arrive à affirmer qu'il n'y a aucune raison de ne pas traiter les adultes comme des enfants. Et donc, par extension, les personnes soi-disant bien portantes comme des personnes malades.

Au-delà d'être assez arrogante et naïve sur le plan épistémique, cette idée de *nudger* certaines personnes spécifiquement est intrinsèquement paradoxale à l'idée même du *nudge* qui repose sur l'idée d'universalité humaine dans les difficultés de raisonnement. C'est le fondement même de la réflexion de Thaler et Sunstein, les créateurs de la théorie des *nudges* (25). En effet, pour eux, puisque nous sommes tous vulnérables aux biais cognitifs, nous devrions tous être *nudgés*. Si les personnes en situation de vulnérabilité ne sont pas plus « défaillantes épistémiquement » que les adultes en bonne santé, il n'y a alors pas de raison de leur imposer à elles, plus qu'aux autres, des *nudges* (3). Mais est-ce pour autant une raison valable de *nudger* tout le monde comme le pensent Thaler et Sunstein?

Au-delà de dénoncer l'injustice épistémique qui découle de ces *nudges* effectués auprès des personnes en situation de vulnérabilité, Ogien s'oppose également à son application généralisée. Pour lui, le paternalisme libéral ne se distingue en rien, ni politiquement, ni moralement, ni éthiquement, du paternalisme dur et autoritaire (3). Il s'agit en fait d'un autre visage de ce même paternalisme. Comme ce dernier, le paternalisme libéral promeut une vision soi-disant objective du bien, sans tenir compte des préférences individuelles et subjectives des personnes. Par exemple, le professionnel de santé peut penser que la personne devrait choisir le traitement qui a, à son avis, les meilleures chances de guérison potentielle quel que soit les conséquences de ce traitement (ex. : fatigue, douleur, coût, risques associés) et donc *nudger* la personne pour qu'elle choisisse ce traitement. En réalité, la personne peut avoir une préférence ou effectuer un refus de traitement pour des raisons qui lui sont propres (ex. : refus de subir plus de soins ou plus de souffrances, soins en inadéquation avec ses croyances religieuses ou culturelles, estimation différente des risques et bénéfices, interprétation différente des données probantes). Pour Ogien, les seules différences entre le paternalisme dur et autoritaire ainsi que le paternalisme libéral résident dans le degré et la forme des contraintes imposées aux libertés individuelles qui sont moins frontales, moins brusques ou violentes. Dit autrement, la finalité de ces paternalismes est la même, mais ce sont les moyens de l'exercer qui diffèrent en quelque sorte. Ainsi, bien que le paternalisme libéral semble plus acceptable, voire séduisant, il est en réalité tout aussi injustifiable éthiquement. Ce paternalisme est même plus insidieux, car il manipule des personnes de manière malhonnête, notamment celles se trouvant en situation de vulnérabilité. En présentant les choix qui s'offrent aux personnes d'une manière orientée, l'intention reste de les restreindre et de les contraindre dans leurs choix, en les orientant par l'entremise de stratégies discursives cachées, à prendre une décision qui a déjà été décidée en amont par un tiers. Il s'agit donc d'un refus de reconnaitre la capacité qu'ont les personnes à déterminer leurs préférences et leur propre conception « du bien ». C'est une contrainte importante à l'autodétermination, un refus du respect de l'autonomie individuelle qui se fonde sur l'infantilisation et la dévalorisation radicale des personnes en situation de vulnérabilité à réfléchir par elles-mêmes et à prendre des décisions qui les concernent en premier lieu.

Le *nudge*, c'est en quelque sorte « mettre du vieux vin dans de nouvelles bouteilles » (27). Pourtant, cette théorie fondamentalement antidémocratique et paternaliste semble se développer à grande vitesse et avoir créé un engouement certain à en juger par la création « d'unités de *nudges* » au sein même des gouvernements britannique et états-unien notamment (38).

Séduire pour être soigné

L'un des enjeux importants du paternalisme médical contemporain est qu'il contraint, plus ou moins implicitement, les personnes dites malades à maintenir l'attention des équipes soignantes. Sans cette attention, elles se verraient abandonnées ou moins bien traitées. Or, cela est injuste pour les personnes faisant face à la barrière de la langue, à des troubles de la santé mentale, à des difficultés communicationnelles ou encore à des différences culturelles. Cette nécessité, bien que problématique, est difficilement perceptible par les équipes ou les institutions de soins, mais demeure une réalité. C'est pourquoi il nous semble pertinent de faire appel à Ruwen Ogien lorsqu'il examine les devoirs et les efforts qui lui sont demandés en tant que personne vivant avec une maladie chronique et dégénérative dans son livre intitulé *Mes mille et une nuits* (39).

À travers ses réflexions, Ogien en arrive à comparer sa situation à celle de la célèbre Shéhérazade. Rappelons que, dans ce conte perse, le roi, pour se venger de l'adultère de sa femme, décide de passer chaque nuit avec une jeune femme différente et de l'assassiner au matin. Pour mettre un terme à ces féminicides, notamment à l'assassinat de sa jeune sœur, Shéhérazade

décide de se porter volontaire. Elle met alors en place une stratégie pour le moins originale, soit celle de raconter tous les soirs une histoire palpitante au sultan, sans cependant la terminer, le rendant ainsi captif de sa narration. Elle espère ainsi que, captivé par son récit sans fin apparente, le roi en vienne à s'attacher à elle et ne l'assassine pas. Cette stratégie se révèle finalement efficace, car au fil des nuits, le roi finit par tomber amoureux d'elle. Elle se voit dès lors sauvée et le massacre s'arrête. Pour Ogien, sa situation de malade chronique est comparable à celle de la princesse perse, car comme il l'indique dans ce passage : il est contraint comme malade à « faire durer le suspense comme Shéhérazade, en évitant de [se] mettre à dos les soignants, c'est le mieux [qu'il] puisse espérer [s'il a] bien compris la nature de [sa] maladie » (39, p.42).

Cette comparaison peut sembler étrange, inusitée, choquante, incongrue ou même paranoïaque, mais elle invite à une réflexion importante sur le paternalisme latent dans les pratiques cliniques. Pour un professionnel de santé, lorsqu'il est bienveillant, attentif et empreint de compassion pour une personne, c'est bien parce qu'il estime que cette personne mérite que l'on investisse autant d'efforts pour elle. Or, si la personne malade déçoit, si elle ne répond plus à ce que le professionnel attend d'elle, si elle n'en fait qu'à sa tête, il peut être tentant pour un professionnel de ne plus mettre autant d'efforts et d'énergie dans les soins et les services prodigués, malgré l'idée de la soi-disant « neutralité affective » du professionnel de la santé (40). Cette possibilité plonge donc la personne malade dans une tentative de séduction permanente à l'endroit des professionnels de la santé. Ainsi, il arrive que celle-ci ne puisse plus mettre en avant ses propres attentes, envies et conceptions pratiques vis-à-vis du soin, mais qu'elle doive au contraire se conformer à celles des professionnels de la santé par peur de perdre cette empathie qui lui permet de survivre et qui lui assure l'accès aux soins et aux services dont elle a besoin et dépend. Il en résulte alors une relation paternaliste, car ce sont les attentes, envies et conceptions des professionnels qui vont primer sur les siennes, par peur du côté de la personne soignée, de ne plus être suffisamment « séduisante » (39).

Ogien exprime ainsi l'idée suivant laquelle la relation thérapeutique puisse être clairement de nature paternaliste, sans même avoir recours à des actions ouvertement brutales ou paternalistes. En effet, pour lui, il suffit qu'une action paternaliste soit possible (ex. : décision médicale unilatérale, refus de prise en compte du témoignage de la personne malade) pour que les effets soient les mêmes. Les personnes s'en remettent alors à un conformisme dans le but de séduire les professionnels, plutôt que d'exprimer véritablement leurs attentes, envies et conceptions personnelles. Les réflexions d'Ogien peuvent se retrouver dans ce que Balint appelle la « fonction apostolique » du professionnel de la santé (41), l'idée que c'est lui ou elle qui impose ses propres valeurs, « sa Foi et sa Loi » et que la personne soignée doit s'y conformer, ou sinon trouver un professionnel dont la « Foi et la Loi » lui conviennent mieux. Ogien et Balint s'accordent donc sur l'idée que les conceptions qu'imposent les professionnels de santé aux personnes soignées ne sont pas simplement liées à des questions techniques, mais également à des conceptions morales et éthiques. Cela occasionne de nombreuses injustices sociales, puisqu'en fonction du professionnel que l'on rencontre et de nos propres attentes, envies et conceptions personnelles, nous ne pourrons possiblement pas obtenir un soin ou un service conforme à nos préférences. L'analogie que propose Ogien avec le célèbre conte perse aide à percevoir l'asymétrie de pouvoir qui se présente de fait entre une personne malade et tout professionnel de la santé (42). Cette situation peut être qualifiée d'asymétrie épistémique. En effet, dans cette relation, le professionnel est d'emblée estimé comme celui qui détient les connaissances valables ainsi que les bonnes valeurs, alors que le malade est considéré comme celui qui dépend de celles-ci et doit donc les respecter et s'y conformer.

Il s'ensuit que les savoirs expérientiels du malade, ses valeurs et préférences ont dans cette relation peu de poids, voire un poids négligeable. Elles se voient contraintes de réaliser un véritable travail pour ne pas briser la relation thérapeutique, laquelle est requise pour obtenir les soins et les services dont elles dépendent. Jouant avec cette image du malade-travailleur, Ogien va jusqu'à se décrire comme un patient en « contrat à durée indéterminée » avec les hôpitaux de santé de Paris (39, p.110). Ogien décrit son « rôle de malade » dans la perspective de la « bouffonnerie sociale » qu'est la maladie, inscrivant de la sorte ses réflexions sur la théâtralisation de la vie dans la lignée des travaux de Goffman (43).

Finalement, si les personnes s'assurent de toujours suivre les conseils donnés par les professionnels, ce n'est pas nécessairement pour leur propre santé, mais surtout pour montrer qu'elles sont des personnes qui cherchent véritablement à « résister à la maladie », à guérir et combattre comme il se doit le mal qui les habite. Elles doivent également prouver qu'elles ont encore un rôle social à jouer, qu'elles peuvent être utiles à la société. Tous ces devoirs décrits par Ogien s'inscrivent dans ce que Parsons (44) nomme « le rôle social du malade ». À défaut de bien jouer leur rôle, ces personnes pourraient se retrouver dans la case des « déchets », soit tous ceux et celles qui ne méritent pas que l'on dépense de l'argent public pour leur bénéfice (39). Les personnes malades font dès lors grande attention aux apparences : il importe de ne pas montrer qu'elles sont trop fatiguées ou trop douloureuses, mais au contraire d'arborer un visage de combattants, sans toutefois se montrer trop en forme pour que la situation ne se retourne pas contre elles. Si l'on est trop bien portant, on peut alors être jugé suffisamment en forme pour travailler ou pas assez épuisé pour avoir le droit à un traitement spécifique ou une thérapie particulière. Toutes ces stratégies, tous ces rôles, tous ces efforts que font les personnes malades pour susciter l'empathie des professionnels, ne sont finalement qu'une tentative de survie – à l'instar de Shéhérazade et de sa façon d'amadouer le sultan. Mais ces efforts masquent alors les véritables attentes et préférences des personnes malades quant aux traitements ou aux rôles qu'elles souhaiteraient, contribuant de ce fait à maintenir des relations paternalistes, sans même avoir le besoin d'user de décisions ouvertement paternalistes.

Paternalisme et *advocacy*

Le terme « *advocacy* » peut se définir par le fait pour un professionnel de la santé de défendre les droits éthiques et universels des patients (et non pas leurs droits juridiques) (22). L'idée que les actes *d'advocacy* puissent être de nature paternaliste n'est

pas nouvelle (45) et cet argument est toujours utilisé dans les débats contemporains relatifs au soi-disant devoir *d'advocacy* (46). Cet argument repose sur l'idée que le paternalisme peut se concrétiser par une action du professionnel (la défense de certains droits) qui rendrait la personne passive, lui retirant finalement sa capacité à s'autodéterminer (47). *L'advocacy* manifesterait alors une attitude de surprotection qui ne serait qu'un autre visage du paternalisme exercé par des professionnels de la santé.

Dans sa quête anti-paternaliste, Ogien défend une éthique minimale, c'est-à-dire une éthique excluant du champ moral le rapport à soi-même et les devoirs positifs, c'est-à-dire ceux relatifs à la bientraitance (48). Il n'en reste que le rapport à l'autre et pour seul devoir, le devoir négatif de ne pas nuire à autrui. On peut alors penser que défendre cette éthique minimale dans le monde de la santé permettrait de réduire drastiquement le paternalisme médical, moral et éthique, mais empêcherait des actes d'*advocacy*. Promouvoir cette éthique minimale crée également de fortes inquiétudes, comme celle de renoncer à la protection des malades contre eux-mêmes ou à l'idée d'excellence et de perfectionnement pour les professionnels de santé. Pour Hurst (49), ces inquiétudes sont infondées ; au contraire, l'éthique minimale pourrait contenir des aspects représentant une exigence forte, notamment celle d'une considération égale de la voix de chacun et chacune.

Ogien, pourtant toujours sensible aux actes et attitudes paternalistes, pourrait estimer que *l'advocacy* ne cache pas nécessairement une forme de paternalisme. Il explique que rien n'empêche l'aide aux personnes, qui doivent user de leurs droits et prendre des décisions difficiles lorsque celles-ci la demandent, ainsi que la solidarité à l'égard de ces personnes une fois leur décision prise (50), même si cela peut aller contre les attentes ou préférences de la famille ou de l'équipe médicale ou professionnelle. Au contraire, soutenir la personne et ses droits lui permettrait de prendre ses décisions avec le moins d'ingérence de la part d'un tiers (ex. : État, famille, équipe médicale/professionnelle ou autre) favorisant ainsi la libre autodétermination. Autrement dit, lorsque l'*advocacy* est réalisée à la demande de la personne malade et que les stratégies advocatiques sont planifiées avec elle (51), celle-ci est justifiée selon Ogien.

Prenons l'exemple d'une personne malade, qui, après avoir entendu l'ensemble des professionnels lui parler des bénéfices et des risques attendus d'un traitement, souhaite néanmoins y mettre un terme. Cette décision est pourtant contraire à l'avis de l'équipe professionnelle et à celui de sa famille. Ainsi, la personne ressent alors une lourde pression morale et sent bien qu'on la blâme pour sa décision : « tu devrais te battre plus », « tu renonces trop vite », « tu as oublié de considérer certains aspects ». Dans cette situation difficile, cette personne fait donc appel à un professionnel avec lequel elle entretient une bonne relation, une relation de confiance, pour défendre ses droits auprès de sa famille et de l'équipe professionnelle. Sans cette aide, la personne malade aurait peut-être finalement cédé sous cette pression morale, prenant finalement une décision contraire à sa vision des choses, à son point de vue, à ses attentes, envies et conceptions. On voit bien avec ce type d'exemple que *l'advocacy* peut apporter une aide cruciale pour la libre autodétermination des personnes soignées, tout en rentrant dans le cadre de l'éthique minimale défendue par Ogien.

Mais cette défense de la non-ingérence pose la question de la charge décisionnelle, celle-ci revient alors systématiquement dans les mains d'une personne en situation de vulnérabilité. À ce titre, Ogien rappelle que c'est simplement un droit et que la personne n'est pas obligée de l'exercer (50). Celle-ci peut également souhaiter s'en remettre à la décision du corps médical, de l'équipe professionnelle ou de sa famille, si elle n'en a pas la force ou la volonté. Ce qui pose un problème, selon Ogien, c'est l'exclusion systématique des personnes soignées des décisions qui les concernent en premier lieu du fait que les responsabilités délibératives seraient « trop lourdes », trop complexes pour elles. Suivant le philosophe, ce type d'argument ne tient pas la route puisqu'il est ouvertement paternaliste et infantilisant, contribuant ainsi à augmenter la vulnérabilité chez la personne malade, cette dernière se voyant départie de ses pouvoirs et capacités.

On voit ici que de réaliser des actes *d'advocacy* pour la personne qui le demande n'est pas contradictoire avec une défense d'une éthique moins paternaliste, voire minimale, au contraire, prendre la défense d'une personne malade qui subit des actes ouvertement paternalistes serait une action concrètement anti-paternaliste. Comme le rappelle Durand et Dabouis (52), le principe de non-nuisance, dans la conception d'Ogien, recouvre des dimensions sociales et politiques, ce qui signifie que « ne pas nuire à autrui » n'est pas un appel à l'aveuglement ou à un désengagement vis-à-vis des situations où il pourrait exister des injustices. Au contraire, pour Ogien, le respect des libertés de chacun et chacune est lié à une recherche d'une société plus juste, plus solidaire, qui passe par une défense des droits et libertés de l'autre, ce qui autorise donc les actes *d'advocacy*. Il est crucial de noter qu'ici c'est seulement la demande de la personne qui marque « le droit » pour un professionnel de santé de réaliser des actes *d'advocacy*. Toute action en dehors de ce cadre serait alors vue comme une ingérence et un acte paternaliste, même s'il était réalisé avec des intentions altruistes ou bienfaisantes. Comme le dit le dicton populaire : « l'enfer est pavé de bonnes intentions ».

Acharnement herméneutique

Les pratiques ou les relations paternalistes dans le monde de la santé causent des injustices épistémiques. En effet, étant donné leur avantage social, les professionnels de la santé ont la capacité d'ignorer ou de dévaluer le témoignage de la personne ou du moins de ne pas le prendre en compte. Parfois, le témoignage peut également être écouté et pris en compte, mais jugé irrecevable et donc être exclu de la conversation épistémique (17,19). Ces injustices sont d'autant plus grandes qu'elles sont liées aux préjugés des professionnels de santé, ainsi la voix de la personne malade est susceptible d'être jugée différemment en fonction de son genre (53), de son âge (54) et de sa couleur de peau (55). Ces discriminations dans la prise en compte du discours existent donc entre les personnes sur des critères sexistes, âgistes et racistes, mais également

dépendamment de la nature du discours porté par la personne, selon qu'il s'arrime ou non avec les valeurs et mœurs sociales dominantes.

Pour illustrer ce propos, Ogien dans *La vie, la mort, l'état* (50) prend l'exemple d'une personne atteinte d'une maladie incurable, ayant conservé ses capacités intellectuelles, souhaitant maintenir un traitement complexe, malgré des conditions difficilement supportables pour elle et ses proches ainsi qu'un coût important pour la société. Si cette personne fait la demande de continuer à vivre, personne ne remettra sa parole en question et ses décisions seront prises à la lettre malgré des conditions de vie plus que difficiles. Cependant, si cette même personne formule une demande d'aide à mourir, alors le raisonnement change : il ne faudrait plus prendre cette décision littéralement, mais interpréter celle-ci comme « un appel à décoder » (50, p.123). Ogien juge que cet exemple consiste en un « acharnement herméneutique »[2] (50, p.125), c'est-à-dire une surinterprétation des paroles de la personne, comme s'il y avait un sens plus profond à donner à son propos, un sens psychologique caché, ce qui n'était pourtant pas le cas pour l'exemple pro-vie précédent.

On comprend bien que l'on puisse se questionner longuement sur le choix d'une fin de vie puisque c'est un acte irréversible. Il est finalement logique que l'on cherche à comprendre de manière plus approfondie les intentions de la personne afin de s'assurer qu'elle ait bien toutes les informations nécessaires à sa prise de décision éclairée et possiblement le temps de changer d'avis. Néanmoins, la critique d'Ogien reste encore plus pertinente dans des exemples plus quotidiens. Lorsqu'une personne souffrant de douleurs chroniques décide de suivre un traitement de réadaptation qu'un professionnel de la santé lui propose, malgré le fait qu'il puisse parfois n'avoir que peu de bénéfices attendus ou alors dans des conditions difficiles, peu de gens remettront la décision de la personne en question, suivant l'idée qu'elle souhaite se remettre sur pied et suivre un traitement. Peu de gens encore se permettront d'interpréter cette décision comme une demande d'aide, une erreur de jugement ou soutiendront qu'il s'agit d'une incompréhension de la situation. Pourtant, si la personne refuse la réadaptation, alors le raisonnement change, son choix ne sera pas perçu comme une décision raisonnée, raisonnable et intelligible. Des professionnels ou encore des membres de la famille chercheront à comprendre ce que la personne souhaite communiquer par ce refus, lequel ne peut pas être la conséquence d'une « bonne » réflexion. Ces situations d'acharnement herméneutique sont donc paternalistes puisque c'est bien une tierce personne (ex. : professionnel de santé, famille) qui fera le choix de ce qui est acceptable ou non et qui déterminera si on doit ou non prendre en considération la voix de la personne. Autrement dit, tous ces cas de figure où une personne malade prend une décision différente de l'équipe médicale ou professionnelle ou d'un autre tiers sont fréquemment jugés comme irrationnels.

Pour Ogien « [s]avoir si le mourant a l'intention de continuer à vivre aussi longtemps que possible ou non est une chose. Connaitre les motifs exacts de cette intention en est une autre. La première question a une valeur morale et légale évidente […]. La seconde question n'est pas toujours pertinente du point de vue politique ou moral » (50, p.126). Dans l'exemple précédent, savoir si la personne à l'intention de suivre le traitement ou non est important puisque la personne pourrait très bien vouloir suivre le traitement, mais il est possible que les conditions de ce traitement ne lui conviennent pas. Mais chercher à connaitre en détail les motifs de l'intention de la personne, si le refus est un choix personnel, n'est pas pertinent sur le plan éthique et politique selon Ogien. Il s'agit en quelque sorte d'une atteinte à la vie privée, à la vie intime de la personne.

L'acharnement herméneutique consiste donc en cette surinterprétation des paroles et des décisions de la personne malade, en cette recherche de sens caché ou du moindre détail pour expliquer une décision et possiblement tenter de la renverser. Il contribue à des injustices épistémiques de nature testimoniale puisque l'évaluation de la voix de la personne, c'est-à-dire la reconnaissance à sa capacité à produire de la connaissance, diffère en fonction de la nature de la décision finale prise par la personne. Cet acharnement est soutenu par cette conception paternaliste suivant laquelle c'est une tierce personne (ex. : professionnels de santé, famille, État) qui va généralement décider des arguments qui sont recevables ou non pour un choix qui n'est pourtant que du ressort de la personne soignée.

Dolorisme et résilience

« Ce qui ne me tue pas me fortifie » (55), c'est cet aphorisme nietzschéen qui pourrait résumer le concept du dolorisme. Le dolorisme peut malgré tout prendre des formes très variées, comme en atteste la riche littérature à son sujet (57-59). Le dolorisme se retrouve aussi bien dans la morale chrétienne que chez des auteurs ouvertement anticléricaux. Selon les défenseurs du dolorisme, la personne souffrante développerait un avantage épistémique, c'est-à-dire qu'elle serait plus lucide sur elle-même, sur le monde qui l'entoure, voire sur la condition humaine en général. La personne aurait également un avantage moral, en ceci que sa souffrance accentuerait sa capacité d'empathie et sa sensibilité envers son prochain. Ce dolorisme semble s'ancrer parfois assez profondément dans la culture de santé, notamment lorsque l'on accepte un peu trop facilement que certaines douleurs ou souffrances, physiques, psychologiques ou sociales sont inhérentes à la vie humaine. Ces idées sont dangereuses puisqu'elles laissent à un tiers le choix des douleurs et souffrances qui seraient acceptables et celles qu'il faudrait combattre, laissant parfois l'individu face à son propre sort. Dans son livre *Mes mille et une nuits* (39), Ogien mène une charge critique contre ce dolorisme et l'idée de résilience qui en découle.

Commençons par reconnaître qu'il est possible que dans certains cas, la maladie ait pu rendre plus lucides certains individus sur leur propre vie et leur corps. Cette maladie leur a même peut-être permis de se rendre compte de la fragilité et de la vulnérabilité humaine et de développer dans une certaine mesure leurs compétences morales. Mais Ogien, en accord avec

[2] Expression qu'Ogien doit à Mauron (56).

les écrits de Hitchens (60), estime que ces cas de figure ne sauraient être généralisés à l'ensemble des personnes malades. Ces cas ne permettent pas de rendre compte de l'expérience des personnes que la maladie a laissées considérablement affaiblies, meurtries ou même, anéanties. Cet affaiblissement n'est pas seulement de nature physique, mais également de nature psychologique ou sociale, en coupant certaines personnes de leur vie sociale active ou encore de la possibilité d'expérimenter des expériences humaines positives. Pour Ogien, le dolorisme présenté dans sa forme factuelle et objectivable, c'est-à-dire lorsqu'il promeut l'idée que la souffrance ou la douleur nous fait réellement grandir, ne supporte pas le poids de l'étude critique et de la démonstration. Ogien soutient l'idée que ce que Nietzsche décrit dans son aphorisme « ce qui ne me tue pas me fortifie » (55) n'est pas une vérité littérale, mais plutôt une « illusion utile, un slogan efficace » (39, p.52) permettant aux malades de se consoler dans leur malheur, de limiter dans une certaine mesure l'étendue et la profondeur de leur souffrance. On peut également penser que le dolorisme permet aux professionnels de la santé d'accepter l'idée suivant laquelle les personnes qu'ils soignent ne souffrent pas inutilement et sans raison, qu'il y a un aspect positif à tout cela, quelque chose à en tirer.

Pour Ogien, l'acceptation du dolorisme dans le monde de la santé est dangereuse puisque celui-ci est lié à des idées politiques et sociales qui « empêchent de prendre tout à fait au sérieux les souffrances physiques des malades, même les plus intolérables, et qu'elles contribuent ainsi à conforter ce qui reste du paternalisme médical » (39, p.22). En effet, si les professionnels de la santé ont intériorisé l'idée que l'amélioration de la condition de la personne passe forcément par de la souffrance, il se peut qu'ils ou elles restent indifférents aux revendications de personnes pourtant confrontées à des situations de souffrances inacceptables. De cette culture doloriste, ancrée dans le monde de la santé (61), émane un concept plus récent, mais tout aussi inquiétant, selon Ogien, soit le concept de résilience. La résilience qui peut se définir comme « le processus par lequel un individu va intégrer et transformer les expériences traumatiques et continuer à se construire sans développer de psychopathologies » (62). Cette notion prend racine dans des idées issues de la psychologie positive (63). Elle prétend que le fait de s'appuyer sur un évènement malheureux (ici la maladie) pour se reconstruire, voire atteindre le bonheur ou la réussite est non seulement possible, mais estimable. Ces idées sont très à la mode actuellement à en croire les rayons entiers d'ouvrages dédiés à ce type de développement personnel dans certaines librairies.

Cependant, cette idée de résilience est d'abord très confuse conceptuellement, car elle ne s'interroge pas sur sa raison d'être ; elle serait comme une évidence, il faudrait par essence être résilient ou ce serait un idéal de l'être. On ne s'interroge pas à savoir si c'est parce que la résilience est une vertu, un devoir envers soi-même ou contribue positivement au bien-être. De plus, pour Ogien, la résilience repose sur un optimisme naïf, qui se révèle très culpabilisant pour les personnes qui n'arrivent pas à se reconstruire. L'idée que tout le monde peut surmonter ses échecs, que les défaitistes sont simplement des personnes qui ne se donnent pas assez les moyens, peut contenir, comme le dolorisme, un aveuglement aux injustices que rencontrent les personnes. Cette « cruauté sociale » qui découle de l'obligation à faire preuve de résilience (39, p.57) peut très bien s'illustrer lorsqu'un professionnel de la santé, en souhaitant aider la personne malade à faire preuve de résilience, lui explique comment elle devrait se servir de ses souffrances et de sa situation pour se reconstruire, pour rebondir dans la vie comme l'ont fait tant d'autres personnes avant elle qui avaient une situation similaire à la sienne. En plus d'adopter une telle attitude dévalorisante et paternaliste, le professionnel ne prend ainsi plus le temps d'écouter et de constater avec empathie les souffrances des personnes malades.

Cette critique fait écho à celle de Butler (64), pour qui, le mot de résilience émerge d'un vocabulaire d'origine néo-libéral qui ignore que des individus peuvent être brisés définitivement. Pour Butler comme pour Ogien, cela peut conduire à ne plus reconnaître que certaines personnes ont simplement une vie réellement dévastée et que rien ne justifie qu'on leur impose ce devoir moral de résilience qui est une pratique non seulement paternaliste, mais profondément violente (64). Le dolorisme et la résilience seraient donc les deux faces d'une même pièce, celles de devoirs moraux et éthiques forts envers soi-même, d'un volontarisme à toute épreuve, quelle que soit la souffrance ou la difficulté rencontrée. Ces idées imposent même qu'il faille se servir de cela pour devenir une meilleure personne, une « meilleure version de soi-même ». Or imposer ces idées aux personnes soignées, au-delà de l'aspect paternaliste, contribue à masquer les injustices auxquels elles sont confrontées, et face auxquelles les professionnels de la santé devraient s'indigner.

CONCLUSION

Les mutations récentes des modèles de soins ont bien fait reculer le paternalisme médical, moral ou éthique dans le monde de la santé. Ce sont des avancées majeures pour le respect des libertés et des droits des personnes soignées, mais cela ne rime pas pour autant avec la fin du paternalisme. Ainsi le paternalisme continue aujourd'hui encore à remettre en question l'autodétermination de certaines personnes et à favoriser des injustices épistémiques et sociales. Cela contribue au capacitisme en santé, ce système de croyances et d'oppressions suivant lequel les personnes qui ont un corps (incluant un cerveau) et un fonctionnement physique, mental, psychique ou social différents seraient inférieures aux personnes ayant un corps et un fonctionnement considérés normaux ou dans la moyenne (20). De fait, d'après le modèle capacitiste, cette « infériorité » serait une justification pour leur retirer ou minimiser leur capacité à prendre des décisions qui les concernent pourtant en premier lieu. Dans ce contexte, nous avons montré que la lecture d'Ogien permet de maintenir une véritable vigilance quant à cette problématique. Les ouvrages d'Ogien, qui détaillent sa philosophie, peuvent permettre aux professionnels de la santé de prendre un recul critique et éthique face à leurs réflexions et pratiques cliniques afin d'identifier au mieux les situations où un paternalisme médical, moral ou éthique latent perdure dans leur travail quotidien, au sein de leur équipe soignante, de leur organisation en santé ou plus largement de la société. La philosophie d'Ogien peut également amener à comprendre comment ce paternalisme latent entretient des injustices épistémiques et sociales dans le domaine de

la santé et en société. Ogien nous aide également à rester en éveil face aux formes nouvelles de paternalisme qui apparaissent et pourront apparaitre, qui sont parfois plus insidieuses et donc plus difficilement observables. Loin d'être un abandon thérapeutique, le refus du paternalisme est au contraire une exigence forte envers les professionnels de santé dans l'idée d'une considération véritable, respectueuse et égale, quelles que soient les décisions prises par les personnes vis-à-vis de leur propre santé. Comme l'évoque Morsa (16), malgré les fondements déflationnistes de cette éthique, elle requiert au contraire, un maximalisme des stratégies et des moyens visant à l'autonomisation des personnes. L'œuvre philosophique rigoureuse d'Ogien permet de soulever et de soutenir ces réflexions, tout en demeurant accessible grâce à l'approche pédagogique et l'humour qui caractérisent son écriture. La pensée de ce philosophe et son application aux débats éthiques en santé ont été jusqu'à aujourd'hui peu explorées. Pourtant, Ogien fait partie de ceux qui, dans nos sociétés contemporaines, laïques et pluralistes, ont le potentiel d'inspirer de nombreuses réflexions éthiques dans le respect de l'égalité radicale des individus, de leurs libertés et de leurs droits, et ce, par-delà leurs différences et singularités.

Reçu/Received: 14/11/2022

Publié/Published: 27/06/2023

Remerciements
Arthur Filleul a reçu des fonds de la part de MITACS Globalink, Société Française de Physiothérapie ainsi que la CBH Graduate School. Anne Hudon souhaite remercier les Fonds de recherche du Québec - Santé (FRQ-S) Chercheur Boursier Junior 1 et le Centre de recherche interdisciplinaire sur la réadaptation du Montréal métropolitain (CRIR-IURDPM, CIUSSS Centre-Sud-de-Montréal) pour leur soutien financier. Marie-Josée Drolet remercie les Fonds de recherche du Québec - Santé (FRQ-S) Chercheur Boursier Junior 2.

Acknowledgements
Arthur Filleul received funding from MITACS Globalink, Société Française de Physiothérapie and CBH Graduate School. Anne Hudon would like to thank the Fonds de recherche du Québec - Santé (FRQ-S) Chercheur Boursier Junior 1 and the Centre de recherche interdisciplinaire sur la réadaptation du Montréal métropolitain (CRIR-IURDPM, CIUSSS Centre-Sud-de-Montréal) for their financial support. Marie-Josée Drolet thanks the Fonds de recherche du Québec - Santé (FRQ-S) Chercheur Boursier Junior 2.

Conflits d'intérêts
Marie-Josée Drolet collabore avec Bryn Williams-Jones, éditeur en chef de la *Revue canadienne de bioéthique* dans un projet de recherche financé par le Conseil de recherches en sciences humaines (CRSH) du Canada visant à développer une typologie des enjeux éthiques soulevés par la pratique de la recherche. Anne Hudon est éditrice pour la revue ; ni elle ni M. Williams-Jones n'ont participé au processus éditorial.

Conflicts of Interest
Marie-Josée Drolet is collaborating with Bryn Williams-Jones, Editor-in-Chief of the *Canadian Journal of Bioethics*, on a research project funded by the Social Sciences and Humanities Research Council of Canada (SSHRC) to develop a typology of ethical issues raised by research practice. Anne Hudon is editor for the journal; neither she nor Williams-Jones participated in the editorial process.

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ANNEXE 1 : CORPUS DES DOCUMENTS ETUDIES

Types de documents	Références	Nombre
Ouvrages	• Ogien R. Mes mille et une nuits - La maladie comme drame et comme comédie, Albin Michel (39) • Ogien R. Mon dîner chez les cannibales – et autres chroniques sur le monde d'aujourd'hui, Grasset (3) • Ogien R. L'État nous rend-il meilleurs ? Editions Gallimard (35) • Ogien R. La guerre aux pauvres commence à l'école : sur la morale laïque, Grasset (65) • Ogien R. L'influence de l'odeur des croissants chauds sur la bonté humaine et autres questions de philosophie morale expérimentale, Grasset (66) • Ogien R. La vie, la mort, l'État. Le débat bioéthique, Grasset (50) • Ogien R. L'éthique aujourd'hui. Maximalistes et minimalistes, Editions Gallimard (48) • Ogien R, Canto-Sperber M. La Philosophie morale, Que sais-je ? Presse universitaire de France (67)	n=8
Vidéos ou baladodiffusions	• La grande librairie, France 5 (68) • La conversation scientifique, France Culture (69) • Si tu écoutes j'annule tout, France Inter (70) • Ce soir (ou jamais), France 2 (71) • Le tête à tête, France Culture (72)	n=5
Textes de commentateurs	• Savidan P, Merrill R. Du minimalisme moral. Essais pour Ruwen Ogien. Raison publique (73) • Abel O et al. L'éthique minimale : Dialogues philosophiques et théologiques avec Ruwen O. Revue de Théologie et de Philosophie (74) • Jouan M. La morale et ses limites, La philosophie de Ruwen Ogien, La vie des idées (75) • Tavaglione N. Le cimeterre d'Ogien : justification publique et déflationnisme éthique, Philosophiques (76)	n=4
Hommages	• France Culture. Ruwen Ogien, Toute une vie contre le paternalisme (77) • Nadeau C, Turmel P. In memoriam Ruwen Ogien. Philosophiques (78) • Nadeau C, Giroux V, Weinstock D. Penser et agir : réflexions en hommage à Ruwen Ogien (79) • Besnier J-M, Gateau V. Remise du Prix Éthique et réflexion à Ruwen Ogien (80) • Joignot F. Ruwen Ogien, Disparition d'un philosophe de la liberté, Le Monde (81)	n=5

ANNEXE 2 : BREVE DESCRIPTION DU PARCOURS DE RUWEN OGIEN

Pour mieux comprendre les réflexions d'Ogien, il importe de porter un regard sur le parcours singulier qu'est le sien, car à l'instar de tout humain, celui-ci se présente comme le lieu à partir duquel il a élaboré sa pensée (Figure 1).

Figure 1 : Parcours existentiel et philosophique de Ruwen Ogien

Ruwen Ogien est né à la fin des années 1940[3], dans un camp de réfugiés, en Allemagne, à la suite de la Seconde guerre mondiale, d'une famille polonaise juive parlant le Yiddish. Ses parents, originaires d'un milieu ouvrier, alors sur le chemin de l'Amérique, arrivent en France, où ils finiront par s'installer définitivement. Le jeune Ogien y apprend donc le français. Il grandit sous le statut d'apatride qu'il conservera jusqu'à ses 18 ans, lequel contribue à son identité cosmopolite.

À la fin des années 1970, il devient docteur en anthropologie sociale. S'inscrivant dans le courant ethnographique, il produit durant les années 1980 des ouvrages et des recherches sur divers sujets, dont ceux de la pauvreté et de l'immigration (82,83). Il est alors un chercheur de terrain attaché à comprendre la réalité vécue de personnes en situation de marginalité. Au début des années 1990, il réalise une thèse en philosophie morale sous la direction de Jacques Bouveresse (84). S'attachant à la philosophie analytique, qu'il apprécie pour sa rigueur et sa sobriété argumentative, son œuvre philosophique qui traite évidemment de sujets sérieux, donne une place importante à l'humour et à la pédagogie. Ses premiers travaux philosophiques sont dédiés à la méta-éthique et il traite alors de sujets comme la volonté (85) ou la haine (86).

Au début des années 2000, à la suite de ces travaux à diffusion restreinte, il prend position sur des questions alors controversées dans le débat public français. Il publie ainsi des ouvrages sur le travail du sexe (87), la pornographie (88) et la sexualité (89). Dans ces livres, il défend les libertés de préférences sexuelles ainsi que les droits des travailleurs et travailleuses du sexe, dénonçant avec ardeur la moralisation du débat public par des éthiques qu'il qualifie de « maximalistes ». En opposition à ces éthiques, il développe ainsi une « éthique minimale » (48), laquelle se fonde sur un seul principe éthique, celui de ne pas nuire à autrui ou le principe de la « non-nuisance » (*harm principle)* issu du philosophe John-Stuart Mill. Ogien étend ce principe de la sphère politique à la sphère morale (35). Cette éthique anti-paternaliste en vient alors à exclure du champ de la morale et de l'éthique tous les « crimes sans victimes » (90), autorisant ainsi la consommation de stupéfiants, la prostitution et toute autre sorte de pratiques entre adultes consentants. Cette éthique « minimale » le met alors dans une position de penseur radical, étiquette qu'il accepte si on entend par-là qu'il pousse son argumentation jusqu'au bout (670), à ses racines, sans nullement s'arrêter à ce qui peut être choquant socialement.

Dans les années 2010, il rédige plusieurs ouvrages qui mettent de l'avant son point de vue égalitaire sur les thématiques économiques et sociales (35,65), tout en maintenant sa thèse minimale relative aux libertés du cercle privé. On peut ainsi percevoir que la défense des libertés mise de l'avant par Ogien se fonde en fait sur une défense de l'égalité fondamentale des libertés et droits humains (79). Chez Ogien, la notion de droits est large car elle comprend les « droits sociaux » (et non pas simplement les droits individuels), c'est-à-dire ceux en rapport avec l'éducation, la santé, le travail ou le logement (35). Il estime que le rôle de l'État est de prodiguer les ressources minimales requises à chacun pour que toute personne puisse réaliser sa propre conception du bien, ce qui requiert la neutralité éthique de l'État.

En 2017, Ogien décède d'un cancer du pancréas. Durant sa maladie, il rédige un livre dans lequel il partage son expérience de la maladie et des soins, récusant avec vigueur le dolorisme médical, cette idée suivant laquelle la maladie aurait nécessairement des vertus positives (39). À la suite de sa mort, nombreux sont les hommages qui lui sont rendus (77-81), lesquels mettent en avant l'humilité qu'impose sa pensée : une pensée exigeante et d'un grand sérieux philosophique, en dépit de son usage de l'humour qui traverse ses écrits. Pour Ogien, le recours à la morale ou à l'éthique est trop souvent utilisé dans le but de blâmer les victimes d'injustices – migrants, pauvres, malades – afin de leur faire porter la culpabilité de leur situation et ainsi les priver de leurs libertés et de leurs droits, le tout au nom de leur soi-disant propre bien. À travers ses idées anti-paternalistes à l'égard des personnes en situation de vulnérabilité, voire de grande vulnérabilité, Ogien nous invite à demeurer prudents et attentifs aux injustices qui découlent trop souvent de nos jugements et de notre moralisme, voire de nos éthiques « maximalistes ». Il nous rappelle que la justice sociale passe avant tout par un partage des richesses issues de la coopération économique, sans empiéter sur les libertés individuelles. Cette lutte contre les injustices sociales passe notamment par le renversement des injustices épistémiques.

[3] Ogien a toujours conservé privée son année de naissance exacte. Il estime que cela lui permet de garder une part de sa vie privée, même s'il reconnait que c'est également quelque peu par coquetterie qu'il n'a pas voulu divulguer cette information personnelle.

Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

A Nair, CM Berryessa, V Dubljević
Can J Bioeth / Rev Can Bioeth. 2023;6(2):120-132

ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

A Scoping Review of Ethical and Legal Issues in Behavioural Variant Frontotemporal Dementia

Anirudh Nair[a], Colleen M. Berryessa[b], Veljko Dubljević[c]

Résumé
La variante comportementale de la démence frontotemporale (vcDFT) est un sous-type de démence frontotemporale caractérisé par des changements de la personnalité, du comportement social et de la cognition. Bien que les anomalies neurales fassent que les patients atteints de vcDFT aient du mal à inhiber les comportements problématiques, ils sont généralement considérés comme des individus totalement autonomes. Par la suite, les patients atteints de vcDFT démontrent une compréhension du bien et du mal, mais sont incapables d'agir conformément aux normes morales. Afin d'étudier les questions éthiques, juridiques et sociales associées au vcDFT, nous avons procédé à une revue de la littérature académique avec des critères d'inclusion et d'exclusion et des codes dérivés de nos travaux antérieurs. Parmi notre échantillon final de cinquante-six articles, quatre mentionnent les patients atteints de vcDFT comme inaptes à être jugés pour cause de folie, et seize mentionnent l'utilisation de preuves de démence dans un tribunal pour mieux comprendre l'autonomie des patients atteints de vcDFT. D'autres questions émergentes ont été découvertes, notamment la formation des policiers aux situations impliquant des patients atteints de vcDFT et l'éducation des prestataires de soins de santé sur la manière d'aider les soignants à faire face à la vcDFT. La littérature actuelle met en évidence l'inadéquation des applications traditionnelles des catégories médico-légales telles que l'autonomie, la capacité et la compétence, pour informer les évaluations de la capacité cognitive dans les contextes cliniques et juridiques, et mérite d'être prise en compte par les neuroéthiciens.

Mots-clés
prise de décision, démence frontotemporale, maladie neurodégénérative, neuroéthique, questions réglementaires

Abstract
Behavioural variant frontotemporal dementia (bvFTD) is a subtype of frontotemporal dementia characterized by changes in personality, social behaviour, and cognition. Although neural abnormalities cause bvFTD patients to struggle with inhibiting problematic behaviour, they are generally considered fully autonomous individuals. Subsequently, bvFTD patients demonstrate understanding of right and wrong but are unable to act in accordance with moral norms. To investigate the ethical, legal, and social issues associated with bvFTD, we conducted a scoping review of academic literature with inclusion & exclusion criteria and codes derived from our prior work. Among our final sample of fifty-six articles, four mentioned bvFTD patient-offenders as unfit to stand trial by insanity, and sixteen mentioned the use of dementia evidence in a court of law to better understand the autonomy of bvFTD patients. Additional emergent issues that were discovered include: training police officers to handle situations involving bvFTD patients and educating healthcare providers on how to help caregivers navigate bvFTD. The current literature highlights the inadequacy of traditional applications of medico-legal categories such as autonomy, capacity and competence, in informing cognitive capacity assessments in clinical and legal settings and deserves consideration by neuroethicists.

Keywords
decision-making, frontotemporal dementia, neurodegenerative disease, neuroethics, regulatory issues

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INTRODUCTION

Behavioural variant frontotemporal dementia (bvFTD) is a subtype of frontotemporal dementia characterized by changes in personality, social behaviour, and cognition (1). Patients with bvFTD often behave in inappropriate or illegal ways, engaging in impulsive behaviour or committing crimes, as seen in 37-56% of reported cases (2). Despite the fact that they may lack the neural circuitry to inhibit wrong actions, patients with bvFTD are generally considered fully autonomous individuals (3). This confusion about autonomy may stem from the seemingly paradoxical ability of bvFTD patients to know the difference from right and wrong yet not be able to act in accordance with their understanding of moral norms (4). Unsurprisingly, the condition is linked with a range of ethical and legal issues.

Ethical Issues in bvFTD

Dementia, and especially bvFTD, reverses the hard-won freedoms and rights that are enjoyed by most adult human beings (5). Social exclusion and stigmatization of both persons living with dementia and their family members contribute to significant mental health burdens. Additional crucial ethical concerns raised by ethicists are deception, objectification, social isolation, and marginalization (6). However, the range of concerns may seem daunting unless a form of classification is adopted. A common way that academic debates approach ethical issues (in any type of condition) is to apply principlism. Principlism is

ISSN 2561-4665

an established approach in biomedical ethics, based on a set of values that medical professionals can refer to in the case of confusion or conflict, which include 1) respect for autonomy, 2) beneficence, 3) non-maleficence, and 4) justice (7).

Respect for *autonomy* refers to the right of the competent individual to make personal decisions regarding their medical care, including the right to refuse unwanted treatment. The principles of *beneficence* (do good) and *non-maleficence* (do no harm) originate from the earliest versions of the Hippocratic Oath. Today, these elements guide healthcare professionals in their administration of medical interventions: all other things being equal, the morally right medical intervention will be the one that is most beneficial to the patient and least harmful. While beneficence and nonmaleficence are presented in foundational bioethics texts as separate principles, they jointly operate as a dyad in clinical practice and research. Finally, the principle of *justice* – usually pertaining to the degree to which healthcare resources are fairly distributed in society – is to some extent dictated by the economic environment in which a medical system operates. Notions and theories of justice vary widely across academic and political fields, and we will limit our discussion to the specific cases of injustice as they pertain to living with dementia, while at the same time noting that, at least in the US, socioeconomic status often determines the degree to which, if at all, healthcare resources are accessible (8).

The principlist answer to questions of autonomy in bvFTD suffers from a kind of dichotomy, as noted above: morally, the patients seem to be lacking autonomy, whereas legally, they are considered fully autonomous. This dichotomy mirrors the debate on autonomy in dementia more generally. Two well-established positions about autonomy in dementia, developed by Ronald Dworkin and Agnieszka Jaworska respectively, offer guidance in the pressing ethical dilemmas.

Ronald Dworkin (9) argues that there are two types of interests: *critical* and *experiential*. Critical interests are those relating to what an individual considers good or bad and are fundamental to a person. Experiential interests are those relating to one's immediate experiences: one's interest in experiencing pleasure, avoiding pain, etc. According to Dworkin, persons in the late stages of dementia are capable of holding on to their experiential interests but lack the agency to express their critical interests.

By contrast, Agnieszka Jaworska (10) defends the view that the immediate interests of an individual, even in cases of dementia, should not be overridden as long as this individual has the ability to value them. She adds that experiential interests are time-specific, for one can only care for them if the person has them currently. Dworkin and Jaworska both agree that dementia patients can experience feelings, and therefore have experiential interests, but disagree on the capacity to hold critical interests. Unlike Dworkin, who believes dementia patients have no critical interests, Jaworska argues that they do, and are just not in a state to communicate them. Dworkin argues that dementia patients have no concept of a whole life, which in turn prevents them from generating critical interests. Jaworska responds by saying one does not need to have the concept of a whole life to generate critical interests; one merely needs to have a concept of what one wants and does not want in one's life. From this she links the ability to generate critical interests to the ability to value things, since the things a person values as good are also the things they want in their life. Further, someone can still have the capacity to value things that are good for them even if they do not remember their history.

The principlist approach to the ethics of FTD considers the issue of justice, particularly the fair distribution of resources. Dementia care is expensive, and most families living with dementia struggle financially. In the US, up to 75% of the care is provided directly by family (11), and in 2013, the value of unpaid caregiving for dementia – approximately $470 billion – exceeded the value of paid home care and total Medicaid spending in that same year (12). Partly due to effects of stigma, care provided by the family comes at substantial personal cost and risk to their own wellbeing (13).

In addition to economic justice issues, FTD also presents potential social justice issues, especially regarding feminization of care and unfair discrimination. Namely, some feminist literature has addressed the economic and political context of "feminized jobs" such as caregiving (14): these jobs tend to be the least respected and paid in any given society. Additionally, caregiving in the family is usually provided by women. Moreover, the medical community and the media sometimes speak about the impact of dementia in catastrophic terms, such as the "dementia tsunami" which is "worse than death" (15). This "panic-blame framework" (16) conceptualization of dementia is driving dominant representations, contributing to social isolation, stigmatization, and ultimately constraining access to adequate healthcare and support.

Legal Issues in bvFTD

In recent years, there has also been both recognition and concern about the complex relationship between FTD, particularly bvFTD, and criminal behaviour. In contrast to other forms of dementia, as mentioned above, bvFTD spares memory and learning in its early stages, and instead, its most striking symptoms are impairments to moral decision-making, empathy, punishment and reward processing, and impulse control (2-3,17). As such, this nexus of symptoms leads individuals with bvFTD, specifically in the early stages of the disease, to be at a higher risk of violating moral and legal norms; many such transgressions committed by individuals with bvFTD are criminal, with their likelihood of criminality being significantly more like than those with other forms of dementia (18). Crimes associated with bvFTD are most often reactive rather than instrumental in nature and are the result of the disinhibition, punishment insensitivity, and lack of empathy associated with the disease (19). This, unfortunately, often leads people with bvFTD to increased involvement with the criminal justice system; although the prevalence of bvFTD specifically in the criminal justice system is not known, the prevalence of dementia in US prisoners has been estimated to range from 1% to 30% (20).

Individuals with bvFTD have been considered a significant challenge for the justice system and correctional facilities, raising as they do a range of complex legal issues for the competency or fitness to stand trial, legal insanity, responsibility determination, appropriate sentencing, and how evidence on bvFTD is used in trial proceedings (21). Scholars argue that the current legal framework in the US is oriented more towards stable psychiatric disorders that can be treated, and with symptoms that can improve; conversely, bvFTD, like other forms of dementia, is neurodegenerative and marked by progressive cognitive decline (21). In some cases, by the time an offense is tried, the individual's bvFTD will have progressed significantly from its earlier stages in which the criminal behaviour was committed, which can cause intense complications (22).

Further, scholars have argued that different types of evidence on bvFTD – including neuroimaging data, psychiatric or neuropsychological reports, and genetic testing – may be potentially useful for decision-makers in determinations of competency, responsibility, and degree and type of punishment (19). Indeed, the severe neurological influences of the disease on the risk for criminal behaviour can be hard – for defense attorneys, prosecutors, and judges, who are likely not familiar with the complex effects the disease's symptomatology has on individual decision-making and processing – to both understand and know how to potentially integrate it in legal decision-making (22). Unsurprisingly, there have been widely disparate outcomes in trials in which underlying bvFTD has been either missed, disregarded, or minimized (21). Given the likelihood of increasing cases of this kind, understanding the range of immense legal issues and implications that bvFTD can have for the trial process, and the overall criminal justice system, is necessary in order to efficiently and fairly address and manage criminal behaviour stemming from the disease (19).

The discussion above shows that the ethical and legal issues associated with bvFTD are complex and multifaceted. To map the emerging trends in normative issues of bvFTD, we conducted a scoping review of academic literature found in Web of Science, PubMed, and PhilPapers databases, as these best capture the general sentiment of the larger academic community towards the normative issues facing to bvFTD.

METHODS

Data Collection

This project builds upon our prior research regarding the public representation of legal and ethical issues faced by persons with Frontotemporal Dementia (FTD) and their caregivers (23). Thus, our aim in the current study was to ascertain the extent of any similarly relevant discussions in the academic literature. To this end we first searched common, widely accessible databases for any articles relevant to frontotemporal dementia in the aforementioned capacities, and subsequently coded the retrieved articles qualitatively with themes identified by Nair and Dubljević (23).

We first constructed a comprehensive search query that comprised of the following terms: *"theft" or "violations" or "violent" or "violence" or "moral" or "immoral" or "morality" or "immorality" or "criminal" or "illegal" or "wrong" or "ethics" or "justice" or "ethical" or "crime") and "frontotemporal dementia".*

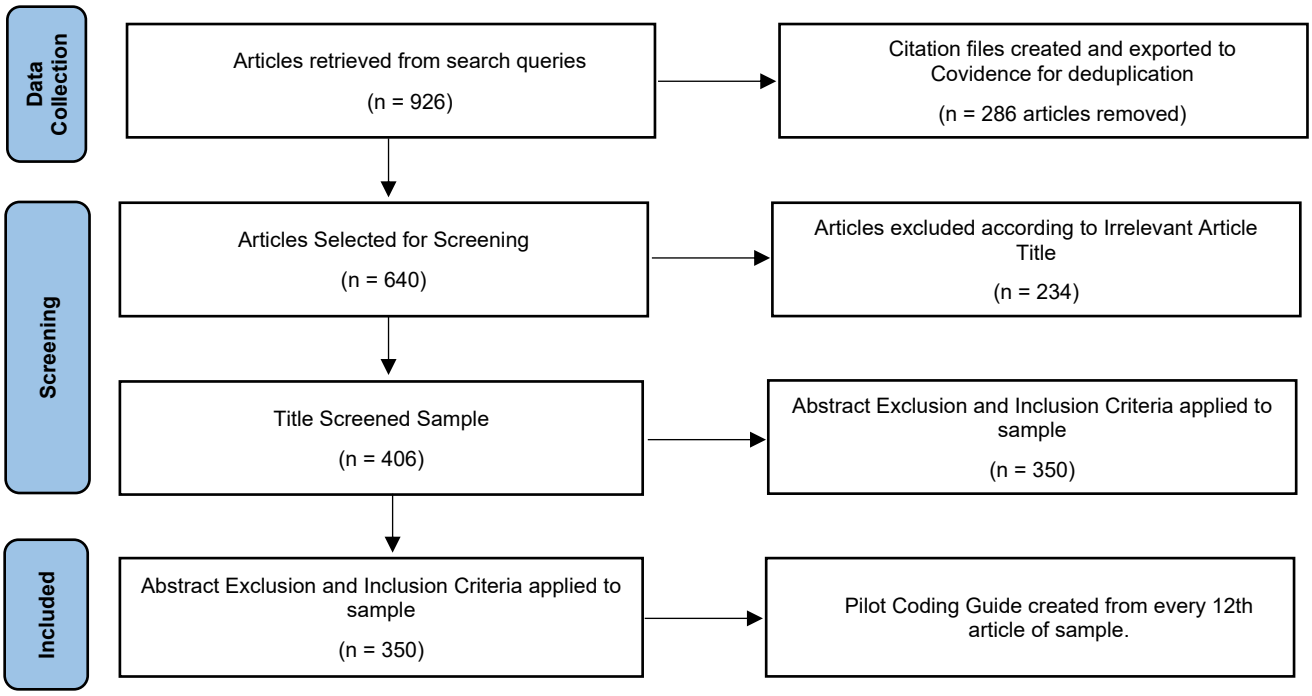
This search query was then submitted to the PubMed and Web of Science databases. We selected these databases in order to retrieve a sample of articles that were wide-ranging in their themes, but also easily accessible, to better reflect how the public domain might be informed. Two coders (AN and a research assistant under the supervision of VD) performed the same search procedure independently. The search was first done using PubMed, with the "full-text" criteria selected and no limits on the date range for the articles, and yielded 194 articles. Next, the same search was conducted in Web of Science, with the "Topics" criteria selected, within the date range of 1950 and 2021 to ensure both coders retrieved the same search results; this search yielded 191 articles.

A similar search was also performed on the PhilPapers database to integrate further articles into our sample that examined FTD from ethical or legal perspectives. This search was performed with the "Professional authors" criteria selected, using the "basic" filter and no limits on the date range. Due to constraints on maximum terms permitted per search, we split the aforementioned search query into individual search terms: *"theft & frontotemporal dementia", "violations & frontotemporal dementia", "violent & frontotemporal dementia, "violence & frontotemporal dementia", "moral & frontotemporal dementia", "immoral & frontotemporal dementia", "morality & frontotemporal dementia", "immorality & frontotemporal dementia", "criminal & frontotemporal dementia", "illegal & frontotemporal dementia", "wrong & frontotemporal dementia", "ethics & frontotemporal dementia", "justice & frontotemporal dementia", "ethical & frontotemporal dementia", "crime & frontotemporal dementia".*

The individual searches collectively yielded 521 articles. The articles in each search were compiled as citation files and exported into Covidence, an online coding platform for literature reviews. Each coder submitted their own searches to Covidence, and duplicates were automatically removed, yielding 640 total articles to be screened.

Data Screening

Figure 1: Adapted PRISMA flowchart



After duplicates were removed by the program, the two independent coders (AN and the research assistant) screened the sample by title to remove any immediately irrelevant articles. A third coder, VD, resolved any disputes that arose. 234 articles were excluded as irrelevant during the title screening phase.

The sample was then further screened by abstracts according to the criteria in Table 1.

Table 1: Inclusion and exclusion criteria used to screen articles

Inclusion	Exclusion
Ethical Dilemmas	Irrelevant
Crime	Tangential
Decision Making	Duplicates
Ethical and Legal Implications in Relation to FTD	Articles that discuss FTD but not Ethical or Legal Issues
(Peer Reviewed) Articles in English	Articles not in English

Finally, articles were further screened using the above criteria based on their abstracts, which resulted in the removal of a further 350 articles from our total sample, leaving a final sample of 56 articles.

Data Coding

Next, a smaller pilot sample was constructed from the full sample to assess intercoder reliability and resolve any discrepancies between the coders with regards to the classification of the data, while also revealing any emergent codes that were not already included in the coding scheme. To accomplish this, the articles in the final sample were sorted alphabetically and every 5th article selected for review. This yielded a pilot sample of 12 articles, which were subsequently coded by two independent coders (AN and the research assistant). After conducting the pilot sample review, the exclusion criteria from Table 1 were applied to each individual article in the full sample. The remaining articles were subsequently fully coded.

Each of the codes were grouped into three thematically similar domains, and each code was then further categorized into sub-codes to capture the range of incidence of each. The domains, codes and subsequent sub-codes are listed below along with the basis used for their classification.

1. Pathology and Quality of Life

This domain aimed to capture the incidence of dementia in the literature, along with any discussions on quality of life for both patients with FTD as well as their caregivers. The codes in this domain are as follows.

Type of Pathology
All of the studies in our sample were included based on their discussion of frontotemporal dementia. Although a majority of the literature explicitly tested for this behaviour, many studies also categorized any behaviour that was a consequence of frontal lobe deterioration as *frontotemporal dementia* (FTD). We were also interested in identifying the number of instances where FTD was further classified as *behavioural variant frontotemporal dementia* (bvFTD).

Recommendations
For this code we identify any recommendations on how best to deal with the disease, suggested lifestyle choices for preventing or lessening the risk of disease, or strategies for managing the disease and its symptoms that were recommended for both *persons with dementia,* as well as their *caregivers*. We also included any recommendations mentioned in the literature for *healthcare providers*. This included personnel that were involved in any capacity in the diagnosis or treatment of the disease.

Stigma
Here we identified any mention of sources of stigma or feelings of shame that were associated with the disease and its behaviour. These included:

- ***Self-stigma:*** Stigma that the persons with dementia themselves experienced as a result of feelings of fear, shame, or apprehension towards behaviour that was associated with the disease.
- ***Social stigma:*** Misinformed social perceptions and beliefs of dementia that are inaccurate and detrimental to the public portrayal of the disease and those affected.
- ***Structural Stigma:*** Societal norms or institutional practices that were detrimental to the public perception of the disease and those affected.

Discussions of Caregiver Distress and Difficulty in Accessing Healthcare
Here we identified any mention of *caregiver distress* with care, that is, distress that was brought about from caring for persons with dementia. Additionally, we identified any mention in the literature of persons with FTD experiencing *difficulties in accessing healthcare.*

Discussions of Capacity or Autonomy
This code sought to identify reports of persons with dementia suffering a loss of autonomy in their daily lives. To identify this, we coded any instances of a *loss of occupation* or a *loss of driving license*. We also coded for any mentions of a lapse in *intellectual faculties*, which were usually depicted as changes in emotional processing or a lack of empathy.

Use of Metaphors
This code identified any metaphors that were used to characterize or describe FTD. Our study coded for the following types of metaphors:

- ***Personhood:*** These were metaphors that either observed a radical shift in the personality of individuals with FTD or used an analogy to the onset of the disease as an entirely different mental state or, in many cases, a loss of personhood altogether.
- ***Moralizing:*** These phrases reflected language used to describe the disease in value laden terms.

2. Criminal and Socially Inappropriate Behaviour

Criminal Behaviour Associated with the Disease
For this code we identify any reported criminal behaviour associated with the disease, according to the following sub-codes:

- ***Theft:*** Reports of theft that were related to acts of shoplifting or robbery.
- ***Violence:*** Reports of violent behaviour committed by persons with dementia, such as physically attacking roommates in care facilities, caregivers, or loved ones.
- ***Sexual Crimes***: Reports of sexual crimes associated with FTD ranging from uncharacteristic sexual assault to persons with dementia possessing child pornography.
- ***Trespassing:*** Reports of persons with dementia trespassing on private property.
- ***Traffic Violations:*** Reports of persons with dementia committing traffic violations or being involved in motor vehicle accidents.

Socially Inappropriate Behaviour Associated with the Disease
Frontotemporal dementia can also be associated with frequent socially inappropriate behaviour in persons with the disease that usually is not serious enough to bring legal charges yet is still alarming. Here we sought to identify the following:

- ***Mismanagement of Personal Finances:*** Reports of persons committing uncharacteristic or extravagant purchases.
- ***Sexually Inappropriate Behaviour:*** Reports of persons with dementia using adult pornographic material or making inappropriate sexual advances.
- ***Social Misconduct:*** Reports of any behaviour that was awkward, inappropriate for the situation, or off-putting, including disinhibited or profane speech and approaching strangers.
- ***Public Indecency:*** Reports of persons with dementia occupying a public space with indecent gestures or while being nude.
- ***Public Urination:*** Reports of persons with dementia urinating in a public setting.

3. Effect of Fitness to Stand Trial or Legal Responsibility

Our study sought to survey the extent to which the academic literature has addressed the moral gray area of persons with FTD in the legal realm. This domain endeavoured to capture any ethical or legal discussions surrounding the fitness or capability of persons with dementia to stand trial, as well as the different types of evidence that are admissible and how a person's fitness to stand trial in the context of a dementia diagnosis is ascertained.

Effect of Fitness to Stand Trial

This code identified any mentions of persons with dementia being granted special considerations or deemed incapable of being held legally responsible for their actions due to their diagnosis. Sub-codes included:

- ***Inability to Appreciate Morality/Legal Insanity Defense:*** Any mentions of a legal entity recognizing a person with FTD as being incapable of appreciating the morality of their criminal actions, or a person with FTD using an insanity defense.
- ***Mental Competence/Decision-Making Defect:*** Any instance of a healthcare professional testifying that the person with FTD may have compromised decision-making or mental competence.
- ***M'Naghten Test:*** Any discussions regarding the M'Naghten, or the legal test for insanity in the US legal system.

Different Types of Dementia Evidence

Here, we coded the different types of evidence used in a legal defense or otherwise used to arrive at a diagnosis of frontotemporal dementia.

- ***Neuroimaging:*** Any mentions of neuroimaging technology used to indicate signs of frontal lobe atrophy in patients. The majority of literature in our sample referenced MRI, PET and/or SPECT scans.
- ***Genetic Testing:*** Use of genetic testing to determine a propensity to inherit FTD. Also included was literature that discussed counselling for those with a genetic predisposition for the disease.
- ***Psychiatric Testing:*** The use of expert witnesses or psychiatric scales/measures to verify a diagnosis of FTD.

RESULTS

We encountered a variety of different themes, topics and issues discussed that need to be represented qualitatively and quantitatively in order to fully capture and represent the richness of the data. Presented below are several different excerpts from each code that better represent the diversity of topics encountered.

Table 2: Codes, Quotes, and Sources

Code	Excerpt
Criminal Behaviour Associated with FTD	She enjoyed visiting this private property daily despite being told that she would be prosecuted if she continued to visit. Also, she enjoyed emptying bags of trash from a moving car on the open road and watching each piece bounce on the ground (2).
Socially Inappropriate Behaviour Associated with FTD	As examples, one of our patients began placing her head into the car window of strangers to strike up a conversation, another began making open remarks in public about strangers' obesity, and yet another lost his job after commenting inappropriately on the breast size of women working with him (24).
Stigma	Family members often experience guilt and shame because of the behaviour of the patient when taken care of at home, and various behavioural problems cause great challenges to family caregivers and to staff after admission to different types of institutionalized care (25).
Metaphors	Spouses commonly complained that the patient seemed foreign or 'alien', with a remote, blunted affect (24). Had to distinguish between the demented patient and "the person he/she used to be," as though they were two different people (26).
Legal Responsibility	Under the current legal system, in many jurisdictions, individuals affected by bvFTD who still exhibit preserved cognitive function might be considered to bear full moral and legal responsibility in the absence of strong evidence of neurocognitive dysfunction (5).
Types of Evidence: Neuroimaging	Neuroimages of individuals with bvFTD may show neural abnormalities, but those images alone cannot be used to diagnose the disorder. Neuroimages of individuals with bvFTD also often show distinctive types and variable degrees of atrophy to affected brain regions that differ from individual to individual. Thus, it is likely possible that a judge, due to the range of variability in neuroimages of bvFTD individuals and the fact that the neuroimages alone cannot be used to diagnose the disorder, could rule this evidence inadmissible in court (19).
Types of Evidence: Behavioural	Deficits in processing reward and punishment relating to future outcomes have been found in bvFTD patients using the Iowa Gambling Task (27).
Types of Evidence: Neurological	Evaluation for neurologic disorders and possibly neuropsychological testing, coupled with neuroimaging, is helpful in ruling out a neurodegenerative disease (18).
Capacity or Autonomy	In the vast majority of patients, the course of bvFTD is characterized by a progressive disability. Patients lose the ability of self-care, most patients become unable to carry out even the basal activities of daily living and ultimately become dependent on long-term care (28).
Recommendations	Specifically, when older adults start displaying behaviours that are criminal and a change from their baseline behaviour, an evaluation for neurologic disorders and possibly neuropsychological testing, coupled with neuroimaging, is helpful in ruling out a neurodegenerative disease. If identified, these individuals can then be appropriately channeled to available social resources (18).

Pathology and Quality of Life

We found that the prominence of the FTD classification is higher when compared to the more specific bvFTD diagnosis. Although FTD (n=18) was the more prevalent characterization, bvFTD (n=15) was still a considerably common characterization of the disease. This result might suggest a growing acknowledgement of the specialization of the disease but could also denote the fact that ethical and legal issues are more frequently encountered in bvFTD (as opposed to, say semantic variant FTD). Many definitions included Frontotemporal Lobar Degeneration as simply 'FTD'.

Criminal and Socially Inappropriate Behaviour

The most common criminal incidences are theft, traffic violations and violence (see Table 3), which may suggest a predisposition of people living with bvFTD towards such behaviour. However, it should be noted that the severity of these crimes might increase the likelihood of such crimes being reported. As such, less egregious crimes such as trespassing, and public urination might be underreported and not as frequently observed in the literature or the media, and so different behaviours may have been under-reported (23).

Table 3: Criminal Behaviour in bvFTD

Criminal Behaviour	
Theft (13)	Violence (10)
Sexual Misconduct (4)	Public Indecency (2)
Public Urination (3)	Trespassing (6)
Traffic Violations (9)	

At the same time, socially inappropriate behaviour was less prominently discussed than criminal behaviour. Social misconduct (e.g., rude behaviour) is the most commonly discussed, followed by sexually inappropriate behaviour (e.g., lewd comments). Even though mismanagement of personal finances is mentioned, this issue has not received much attention.

Table 4: Socially Inappropriate Behaviour in bvFTD

Socially Inappropriate Behaviour	
Mismanagement of Personal Finances (2)	Sexually Inappropriate Behaviour (7)
Social Misconduct (9)	

Stigma

In our sample, we found only three reported accounts of stigma suffered as a result of possessing FTD or an FTD diagnosis: each subcode reported only a single incidence of stigma. These results are promising in comparison to the larger incidence of stigma that was observed in a recent review of print media coverage of FTD. In fact, Nair & Dubljević (23) reported twenty incidences of social stigma, seven for self-stigma, and two for structural stigma. A smaller incidence of reported stigma in the literature might suggest a more balanced, non-stigmatizing portrayal in the scientific literature, including portrayals of the experience of living with dementia, as well as the social and structural stigma suffered as a result.

One such notable perspective offered with regard to mitigating stigma surrounding FTD was made by Trachtenberg & Trojanowski (29). They choose to draw attention to the stigma associated with the term 'dementia', especially in contributing to stigmatic perceptions, and describing the term as "A generalization that is pejorative and harmful based on historical and current patient, caregiver, and physician perspectives." According to their recommendations, 'dementia' in the abbreviation FTD should be changed to 'disease' in order to "speak about frontotemporal disease to our patients and their families without stigmatizing this disorder or those facing the daunting challenge of living with it."

Conversely, an FTD diagnosis might also elicit pro-social reactions, such as sympathy or pity for the person with the disease (19). This might provide benefit in criminal sentencing scenarios, so long as such reactions are informed by knowledge of the potential to regulate and monitor FTD tendencies. However, the sparse mention of self-stigma may be related to the lack of insight that is relevant to bvFTD; more empirical research needs to be conducted to confirm this association.

Discussions of Burdens in Healthcare Access and Caregiver Distress

Our study observed 4 instances of discussions in the literature regarding burdens faced either by persons with FTD or their caregivers in accessing healthcare. Some articles cite the substantial burden that FTD patients present to both society and their caregivers, describing persons with FTD as causing "substantial financial loss and caregiver distress." (19)

We also found five reports of caregivers mentioning distress regarding caring for someone with FTD or coping with life after FTD. Diehl-Schmid and colleagues (28) report that "patients with bvFTD are less likely to be cared for at home until death than patients with Late Onset Dementia (LOD). BvFTD caregivers are often faced with the double burden of providing care while

performing other roles, such as parenting, working, and managing the household." Although there is a discussion regarding these issues in the literature, these topics merit further focus. In contrast to the four instances of discussion of this code, the study reporting on the print media sample encountered forty-three instances of discussions of both financial burdens and access to healthcare (23).

The need to focus more attention on accessible healthcare and guidance for persons with FTD and caregivers is compounded by the disparity in the availability of information regarding the nature of FTD and additional information in coping with FTD as well as counselling and support for caregivers. According to Sagbakken and colleagues (25), "caregivers of patients with FTD were significantly less satisfied with the provision of information about the disease, counseling, and follow-up concerning how to manage the situation compared with caregivers of patients with early-onset Alzheimer's disease". Finally, they point to findings "that caregivers, in general, need extensive support in coping with the situation of their family member with FTD."

Metaphors

Our study found a comparatively limited usage of both personhood (n=5) related and moralizing (n=3) metaphors. These results suggest a balanced, less stigmatizing portrayal of the experience of FTD and its depiction in the literature. In contrast, our public media sample found a much larger (n=63) incidence of both types of metaphors. This discrepancy suggests a need for better public communication regarding the onset, and changes in behaviour that are observed alongside FTD progression.

Legal Responsibility

The legal dimension of FTD was of prime importance in our review, particular with regard to how the literature reported on the autonomy and agency of those with FTD. We found three instances of a legal insanity defense being used in criminal cases pertaining to FTD. In the context of the American legal system, one of the most common standards for determining legal insanity in half of US states is the M'Naghten test. Unfortunately, the criteria for legal insanity, that a person is "unable to appreciate the nature and quality of the wrongfulness of his acts" (30), do not accommodate the circumstances commonly found in cases of FTD, notably, that the person with FTD can, to an extent, appreciate the immorality of their action. By contrast, the Lund-Manchester criteria for legal insanity seem more applicable to circumstances in FTD, as highlighted by Diehl Schmidt and colleagues (2). The authors draw attention to the "German legal concept of 'incapability of acting in accordance with the appreciation of the unlawfulness of an offense'" as a much more fitting test in the context of persons with FTD.

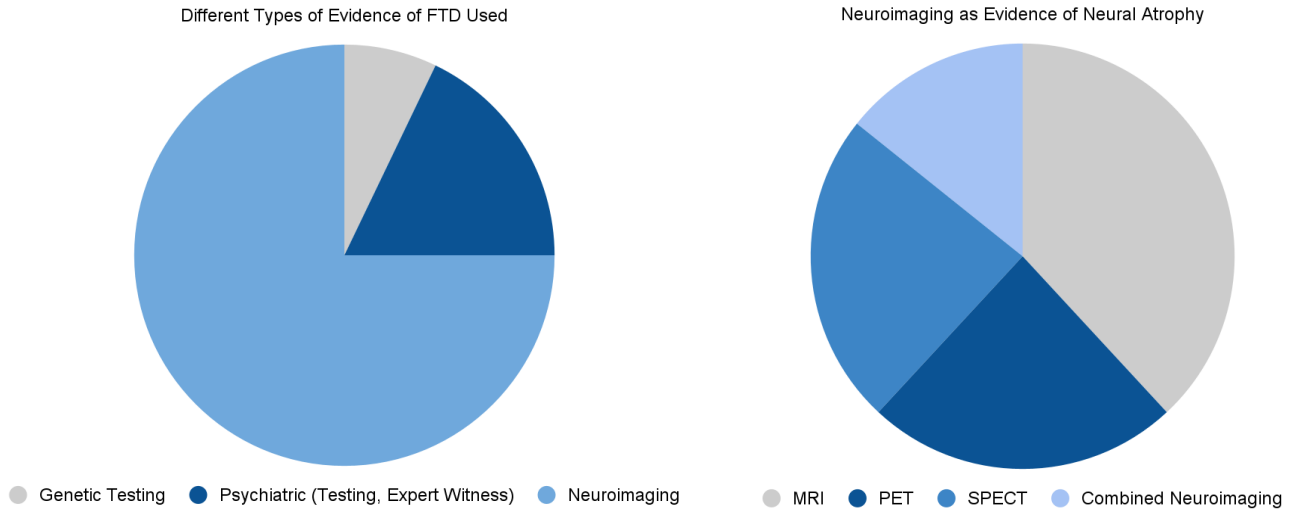
It is also important to highlight the many dimensions of cognition and mental ability that deteriorate or, in some cases, are lost entirely in FTD. Our study recorded mentions of lapses in memory, driving, and speech. As such, a new standard for mental disability in legal contexts should be developed, to incorporate these facets into determination of mental faculty and responsibility.

Effect of Fitness to Stand Trial

The most common incidences of mentions of specific effects of fitness to stand trial are *Inability to Appreciate Morality/Unfit by Reason of Insanity* (n=4), followed by *Establishing Appropriate Legal Test* (n=3) and *Mental Competence/Decision-Making Defect* (n=2), which may suggest that these issues are not common. However, it should be noted that this may have been under-reported, and that future studies should access court records in order to ascertain actual prevalence.

Types of Evidence

Figure 2: Evidence for verification of FTD



The neuroimaging code in our study returned some of our highest results. A prominent theme in the literature is the need for accurate and efficient methods of diagnosis that involve neuroimaging techniques. Baird, Kennett & Schier (21) mention that the characteristic "frontal executive dysfunction, identified by cognitive assessment or frontal lobe pathology on neuroimaging investigations, was common and reported in 10/30 cases." We found that MRI was the most mentioned neuroimaging method used to corroborate FTD (n=8). However, other methods were also prevalent, as shown in Figure 2. Our sample also suggests that the most effective method is a combination neuroimaging techniques. Since there is no clear physiological marker for FTD, neuroimaging becomes even more important as a method for detection (31).

It is important, however, to recognize that neuroimaging is not the only method to rely in either detection of FTD, or the submission of evidence that confirms an FTD diagnosis. Berryessa (19) states,

> Although neuroimages of individuals with FTD can be used to demonstrate neural abnormalities or the presence of FTD, these abnormalities can vary widely from person to person. As a result of this variability, a judge may rule this evidence inadmissible. These pieces of evidence might also work against the person in question, suggesting to a judge or jury that specific brain regions associated with moral faculties have deteriorated and as a result, the consequential immoral behaviours that may have led them to criminal circumstances are out of their control.

The observed variability in brain scan evidence can also prove difficult in the case of expert testimonies. Baird, Kennett & Schier (21) highlight several cases where expert witnesses reported conflicting interpretations of MRI brain scans of FTD, describing them as "inconsistent with a diagnosis of FTD."

Despite neuroimaging being the most common form of admitted dementia evidence (n=21), psychiatric measures, which include psychiatric tests or expert witnesses, were reported in our sample in five separate instances. In fact, Baird, Kennett & Schier (21) also report that in their investigations, 58% of expert witnesses were psychiatrists, and 21% were psychologists.

Capacity or Autonomy

Discussions of capacity and/or autonomy and their subsequent loss due to FTD were much less prevalent as compared with the study of the print media sample (4). There seems to be a shift in focus towards intellectual deficits (n=6) rather than the effects of FTD on social markers of capacity such as driving (n=1) and occupation (n=2).

Recommendations

We encountered several different recommendations for dealing with FTD. Although some of these recommendations were intended for persons with FTD (n=2), the vast majority were directed toward caregivers (n=9) or healthcare providers (n=6).

> When previously law-abiding middle aged or older patients suddenly start committing minor crimes, particularly theft or shoplifting, a neurodegenerative brain disorder should be considered, and a thorough psychiatric and neurologic examination arranged. If the patient has a diagnosis of FTLD, the patient's family needs to be informed that the crimes are a symptom of the disease rather than the patient's fault (2).

Other recommendations suggest effective strategies for fostering trusting and informed relationships between caregivers and their healthcare providers.

> Non-pharmacological interventions should be also directed to the patient's caregiver, in order to help them to develop strategies for managing behavioral disturbance, modifying the living environment and reducing burnout. We think that there is the need of a multidisciplinary team with specific disciplines, such as neurologists, psychiatrists, neuropsychologists, social worker, occupational therapist, neurorehabilitation professionals, and nurses, that can identify a multimodal rehabilitation program for the patient and an educational program for caregivers (32).

Additional Issues

Several emergent issues that could not be accurately captured as *themes* (since they were single instances) still merit being mentioned. These include: 1) the effect of Tau pathology on incidence of crime (18); 2) brain donation for FTD patients (33); 3) the fact that police officers are increasingly becoming first responders for elderly FTD patients (34); and 4) the need for reconsidering the punishment of individuals with dementia (19).

DISCUSSION

***Specific ethical issues*:** There seems to be a growing acknowledgment of bvFTD as deserving separate attention from broader FTD, notably with a shift in focus toward intellectual deficits, rather than the effects of FTD on social markers of capacity, such as the ability to drive or continue working. That said, this does not translate into a fine-grain analysis of specific issues pertaining to the disease. For instance, with intellectual deficits (n=6), the present results are much less specific than

the results of the print media analysis, which noted higher instances of “loss of speech” (n=28) and “loss of memory” (n=24) reported by the media (23). This may be due to the fact that the academic audience is already better informed about specific deficits, unlike the general public, which needs to be provided with adequate background in order to grasp the ethical issues.

Portrayal of stigma in the academic literature (n=3) seems significantly reduced in comparison to the public media representation of FTD (n=29). A smaller incidence of reported stigma suggests a balanced and non-stigmatizing portrayal in the scientific literature of the experience of living with dementia (23). Similar to the observed disparity between academic and public media samples, this diminishment might be a result of a more informed discussion in the academic literature as opposed to public media environments, especially regarding the social and structural elements surrounding FTD.

The fact that FTD patients consider themselves to be fully autonomous – whereas their family members need to manage their behaviour to avoid financial, reputational, and even criminal-justice repercussions – can cause significant strain and caregiver distress. Furthermore, most dementia care is geared toward Alzheimer’s, which decreases the legitimate options and resources these family caregivers have at their disposal, and that is arguably unfair. Although there is some discussion regarding the burden FTD patients may place on caregivers and society, the low incidence of these discussions (n=4) in contrast with the weight of their potential answers highlights that more focus should be placed on these topics. Solutions to these dilemmas can potentially provide the most effective methods of improvements in the quality of life of not only persons with FTD, but their caregivers as well. Although there are recommendations for caregivers in dealing with the stress and burden of caring for a loved one with FTD, these recommendations vary widely and may not be universally applicable. Thus, more concrete and consistent suggestions are needed for the healthcare or academic communities.

Specific Legal Issues: Results here show broad recognition of the relationships between bvFTD and particular types of criminal behaviour, particularly theft, traffic violations, types of reactive violence, and sexual crimes. As crimes associated with bvFTD are thought to be influenced by the disinhibition, punishment insensitivity, and lack of empathy associated with the disease (18,19), it is unsurprising that offenses widely discussed in existing literature appear to stem from impairments to moral decision-making and impulse control (4,19). However, it should be noted that some of these crimes, especially theft, violence, and sexual crimes, may be more likely to be reported than quality-of-life crimes, such as public indecency; thus, some criminal or property offenses may be under-reported or less likely to lead to criminal justice system involvement (23).

Our review also suggests existing interest and concern about the involvement of individuals with bvFTD. Although bvFTD has been thought to raise a range of complex legal issues (17,19,21,35), results indicate that to date this literature’s primary focus has been on how evidence of bvFTD is used in trial proceedings, and, to a lesser extent, issues related to determining and standards of legal insanity in cases involving bvFTD (i.e., the M’Naghten Rule). A range of different types of evidence on bvFTD, including neuroimaging data, psychiatric or neuropsychological reports, and genetic testing, have been discussed to support diagnoses of bvFTD in legal proceedings (19). Yet, neuroimaging data appears to be by far the most prevalent way of supporting diagnoses of bvFTD in legal proceedings, with a combination of MRI, SPECT, and PET methods used to accurately and efficiently provide evidence of a diagnosis, with oftentimes little reference to other diagnostic criteria (21,35).

This is surprising, given that neuroimages alone cannot be used to diagnose the disorder, with both short- and longer-term clinical tracking and third-party corroboration of behavioural changes considered imperative to an accurate diagnosis (17). Indeed, there is no clear neurological or physiological marker for FTD, with neuroimages of individuals with bvFTD often showing distinctive types and variable degrees of atrophy to affected brain regions that can differ from individual to individual (19). Unsurprisingly, the fact that evidence of and areas of atrophy can range for those with bvFTD likely contributes to why expert opinion in legal proceedings can often conflict on whether neuroimaging findings in particular cases ‘prove’ or show a defendant’s bvFTD diagnosis (32).

Given the prevalence and role that neuroimaging evidence appears to hold in legal proceedings as tests or proof of bvFTD, those involved in the legal process, who are unlikely to be familiar with its complex methodology, should be more educated about neuroimaging in general, as well how neuroimaging evidence on bvFTD should be used to support a bvFTD diagnosis. Particularly, as neuroimaging only represents one of three criteria needed for diagnosis (17), legal decision-makers, including defense attorneys, prosecutors, and judges, should be aware of the limitations of and potential errors in using neuroimages as the sole or chief proof of bvFTD without other clinical and behavioural evidence.

Further, although broadly noting how neuroimaging evidence can be used to substantiate a bvFTD diagnosis, existing literature still appears quite limited in examining how such evidence can also be used to show how the disease’s symptomatology affected an individual’s decision-making, potentially contributed to offending, and if and how such evidence may influence legal decision-making at different legal stages. Broader literature on the use of neuroimaging evidence at different legal stages in criminal trials shows that it is most often presented when and may be most relevant to 1) determining a defendant’s competency, and 2) determining a defendant’s punishment at the sentencing stage (36). However, discussions on the use of such evidence during these two legal stages in cases involving bvFTD appeared in only a small fraction of the literature included in this review. Particularly, Berryessa was one of the few authors to discuss how neuroimaging evidence may lead to questions on the potential moral blameworthiness of offenders with bvFTD, as well as the court’s potential hesitance regarding the use and utility of deterrent or retributive punishments for such defendants (19). This suggests the need for a broader examination of the use and potential influence of neuroimaging evidence on bvFTD during these other legal stages, particularly punishment.

Moreover, bvFTD is diagnosed by formal clinical criteria that are accepted as the standard, at least in the US. Many different conditions can be mistaken for bvFTD, especially psychiatric disorders; hence, focusing on neuroimaging or other measures, or relying on cases where patients were diagnosed by clinicians with insufficient expertise (as opposed to trained neurologists) may further complicate the issue.

Finally, to date, the literature has focused almost exclusively on the legal relevance of bvFTD in court settings; however, emerging issues noted in this review suggest that a wider examination and discussion of how bvFTD may intersect with the legal process is warranted. Particularly, police officers are those most likely to be first responders to events involving patients with FTD that are exhibiting criminal behaviour (34). Future studies should thus consider police officers' knowledge of bvFTD, how the impairments associated with the disease may cause complications in interactions between individuals with bvFTD and law enforcement, and whether and what types of training for these situations is needed.

CONCLUSION

Our study began as an attempt to expand upon work from our prior print media literature review that cataloged the experiences of both persons with FTD as well as their caregivers. In this regard, it is reassuring to note that the academic discussion of bvFTD seems more balanced than the print media, with an increased emphasis on criminal behaviours rather than socially inappropriate acts and language that characterize the disease in ways that are less stigmatizing. Nonetheless, the present review revealed several emerging themes that require further attention from the scientific community. To begin with, the relatively little discussion on matters of caregiver distress and burden is concerning, since, according to our print media sample, caregivers tend to feel overlooked and overburdened following a bvFTD diagnosis. Although strategies for coping with the burden of caring for a person with bvFTD and managing the disease are beginning to emerge in public discussion, these topics need equal if not greater attention from the academic community, as researchers and clinicians are better equipped than journalists to comment on coping strategies and techniques for disease management, as well as providing further resources. Finally, this paper highlights some of the specific legal issues that still merit attention from jurisprudence experts. One such matter is the range of legal criteria that could be used to classify legal insanity for a person with FTD. The criteria that determine this classification are of utmost importance, as they have tremendous bearing on the fates and legal responsibilities of bvFTD offenders and often determine whether they receive help, medical intervention, or legal punishment. The apparent obsolescence, at least for bvFTD, of one of the most common current legal tests for insanity in the US (the M'Naghten Test), as well as the existence of more contemporary legal insanity tests in countries such as Germany (the Lund-Manchester criteria), reaffirms the importance of implementing more robust legal insanity criteria to effectively approach the complicated disease of bvFTD and its consequential changes in behaviour. Future work should also consider the relevance and impact of bvFTD for other commonly used tests of legal insanity in the US, such as the standard under the American Law Institute Model Penal Code, which has not been sufficiently discussed in the literature. Finally, another similar issue of legal importance is the role of expert witnesses in cases involving bvFTD and the different types of evidence plaintiffs and defendants may be allowed to submit for testimony in court. Thus, more careful academic discussion on these legal issues, as informed by knowledge of the medical nature of bvFTD, will help to mitigate the demonization and misunderstandings of persons with bvFTD and their related offending.

Reçu/Received: 07/02/2023
Publié/Published: 27/06/2023

Remerciements
Les auteurs remercient Brian Lee pour son aide à la recherche et au codage pilote. Nous remercions tout particulièrement les membres du groupe de recherche en éthique neuro-informatique pour leurs commentaires sur une version antérieure du document.

Acknowledgements
The authors thank Brian Lee for research assistance and assisting with pilot coding. Special thanks to the members of the Neuro-Computational Ethics research group for their feedback on an earlier version of the paper.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

B Murdoch. *Can J Bioeth / Rev Can Bioeth.* 2023;6(2):133-135

COMMENTAIRE CRITIQUE / CRITICAL COMMENTARY (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Recent Canadian Negligence Decisions Relating to Prenatal Care: Implications for Physicians' Screening Practices

Blake Murdoch[a]

Résumé

Cet article résume plusieurs décisions rendues par des tribunaux canadiens depuis 2015 dans le cadre de litiges portant sur des naissances et des vies injustifiées. Le succès du demandeur dépend souvent de la question de savoir si le lien de causalité est établi, selon la prépondérance des probabilités, entre le manquement d'un médecin à la norme de diligence et le préjudice subi par les parents ou l'enfant né ultérieurement. Le fait que les médecins ne proposent pas ou ne prescrivent pas de tests de dépistage ou de diagnostic a été une source de responsabilité en cas de naissance injustifiée, et le fait de ne pas s'assurer que les patients comprennent les résultats peut l'être également. Les médecins doivent veiller à recommander des tests de diagnostic lorsqu'ils sont en présence d'indications cliniques préoccupantes, conformément aux lignes directrices de la pratique professionnelle. Compte tenu des avantages du dépistage prénatal non invasif (DPNI) et de la menace d'une responsabilité pour naissance injustifiée en cas d'omission d'en parler, il est probable qu'il soit propulsé dans une position de plus en plus importante en tant qu'offre de premier choix pour le dépistage des aneuploïdies. Le comportement prudent des médecins consiste à discuter et à proposer un DPNI et à s'assurer que les résultats sont compris. Cela peut réduire la responsabilité du médecin, améliorer l'autonomie reproductive de la patiente et parfois être bénéfique pour la santé de la patiente en prévenant ou en atténuant le traumatisme que des femmes bien informées peuvent choisir d'atténuer lorsqu'elles en ont l'occasion.

Mots-clés

droit, bioéthique, soins prénataux, obstétrique, dépistage prénatal non invasif

Abstract

This article summarizes several Canadian court decisions from 2015 onward stemming from wrongful birth and wrongful life litigation. Plaintiff success often turns on whether causation is established, on a balance of probabilities, between a physician's breach of standard of care and the harm to the parents and/or the child later born. Physicians' failure to offer or order screening or diagnostic tests has been a source of wrongful birth liability, as too can be failure to ensure patient understanding of results. Physicians should ensure that they recommend diagnostic testing when presented with concerning clinical indications in accordance with professional practice guidance. Given non-invasive prenatal screening's (NIPS) advantages and the threat of wrongful birth liability for failure to discuss this procedure, it is likely to be propelled into an ever more prominent position as a first-choice offering for aneuploidy screening. Appropriately cautious physician behaviour involves discussing and offering NIPS, and also involves ensuring that results are understood. This can reduce physician liability, improve patient reproductive autonomy, and sometimes benefit patient health by preventing or lessening trauma that informed women may opt to mitigate when granted the opportunity.

Keywords

law, bioethics, prenatal care, obstetrics, non-invasive prenatal screening

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INTRODUCTION

Medical negligence litigation relating to pregnancy and prenatal care exists in several forms. Wrongful life claims, where a (disabled) child sues a healthcare provider for prenatal negligence but for which the child would never have been born, are not prohibited in Canada but are usually rejected on public policy grounds due to concerns about valuing life vs non-existence (1). Wrongful birth claims are more commonly successful. They consist of one or more parents suing a health care provider for negligence, such as for a failure to disclose material risks but for which the pregnancy would have been terminated. Wrongful birth claims are predicated on a failure to provide material information or appropriate care that results in "being deprived of the opportunity to make an informed choice, post conception to terminate." (2,3)

Several forms of prenatal screening exist in Canada. Ultrasound is commonly used, as is related nuchal translucency analysis, and invasive measures such as amniocentesis are generally reserved for secondary diagnostic confirmation. For clarity, fetal ultrasound can be either a screening or a diagnostic test, but for aneuploidy it is only used for screening. Notably, maternal blood-based non-invasive prenatal screening (NIPS) is an evolving technology that is becoming an established mainstream screening option in Canada, though funding varies by province. Current practice guidance from the Society of Obstetricians and Gynaecologists of Canada (SOGC) recommends that the various aneuploidy screening options be discussed with patients, as well as the option of foregoing screening, including the risks, benefits and alternatives (4). A 2020 SOGC statement, which was reaffirmed in 2021, says that during the COVID-19 pandemic, NIPS, where funded and available, can be offered as a first-choice screen (5).

ISSN 2561-4665

It is important for physicians involved in prenatal care to understand the common law landscape, and particularly recent court decisions on negligence torts relating to prenatal screening, diagnostic testing and decision-making. Below are summaries of several Canadian decisions from 2015 onward stemming from prenatal negligence litigation. Following these summaries, I present concluding thoughts on the law's impacts on physicians' practices surrounding prenatal testing. *Nota bene*, our institute summarized and discussed earlier key Canadian decisions in 2014 (1).

CASE SUMMARIES

***KS v. Willox,* Alberta Court of Queen's Bench in 2016 (6), affirmed by Alberta Court of Appeal in 2018 (7)**
A child born prematurely with resulting severe disabilities sued two doctors for negligence for failure to recommend either ultrasound-indicated or emergency cervical cerclage for the mother's incompetent cervix that caused premature labour. The trial judge found that the general practitioner breached standard of care for not consulting specialists and failing to schedule ultrasounds after findings including unusual discharge and spotting. Despite these breaches, the claim was dismissed as the plaintiff was found not to have established causation. Ultrasound-indicated cerclage was not recommended for first pregnancies during the time period in which the pregnancy occurred. In addition, it was not established that the mother would have undergone emergency cerclage in the narrow, approximately two-day window of time in which it would have been available. Also, the mother had contracted chorioamnionitis prior to delivery, which could have quickly necessitated removal of the cerclage stitch and would have resulted in a similar premature birth. The appeal court held that the trial judge was correct in concluding causation was not established. The Supreme Court of Canada dismissed leave to appeal.

***TS v Adey*, Ontario Supreme Court in 2017 (8)**
The parents of a child born disabled due to SALL4 gene mutation sued a radiologist and an obstetrician for negligence. They claimed the radiologist did not communicate ultrasound findings in an appropriate way and the obstetrician did not review its results or advise the parents of the concerns raised in a timely manner, to allow them the opportunity to act via further testing and elective termination. The judge found that but for the negligent actions of the doctors, the parents would have been referred to a fetal development clinic or at least a follow-up ultrasound would have been ordered. Causation was established as the court held that but for this negligence, a reasonable person in the mother's circumstances would have terminated the pregnancy.

***Beauchamp v. Gervais,* Ontario Supreme Court in 2015 (2)**
A child born with spina bifida and her parents sued a radiologist, and others who were later dismissed from the claim, for failing to read obstetrical ultrasounds and diagnose the condition. The case history does not include a trial decision, and the published court decision rejected the defendant's motion for dismissal on the basis of time limitations. The judge also struck the child off as a plaintiff, leaving only the parents. It is likely the claim was settled.

***Florence v. Benzaquen,* Ontario Supreme Court in 2020 (9), affirmed by Ontario Court of Appeal in 2021(10)**
A mother and her triplets born premature with resulting disability sued the mother's gynaecologist for prescribing the fertility medication Clomiphene without advising of the associated risks including multiple pregnancy, and despite it allegedly being contraindicated in the circumstances. The motion judge struck the claim as it is not recognized by law that doctors owe a duty of care to a future child for negligence that occurred pre-conception. The appeal court upheld this conclusion in a split decision. The application for leave to appeal to the Supreme Court of Canada was dismissed with costs.

DISCUSSION

As the above summaries elucidate, court determinations relating to prenatal care and wrongful birth/life can often turn on whether causation was established, on a balance of probabilities, between a physician's breach of standard of care and the harm to the parents and/or the child later born. A significant portion of the jurisprudence concerns failure to order or interpret and appropriately communicate ultrasound results, some of which were screening and others more diagnostic in nature. This relates in part to the fact that complex or rare ultrasound results can require a significant degree of interpretation by specialists.

Regarding failure to order ultrasounds, physicians should ensure that they order testing when presented with concerning indications in accordance with professional practice guidance. The interests of patients and the desire for a defensive medical practice may contribute to greater use of ultrasound and other screening resources, but Canadian law generally does not allow physicians to prioritize health system concerns over the interests of individual patients to whom they are fiduciaries (11).

NIPS will likely play a large role in the future of prenatal screening for aneuploidy, so it is forward-looking to consider it in relation to this jurisprudence. NIPS and related forms of prenatal genetic sequencing exist to identify very specific genetic conditions and provide clear, "Yes or No" results that are bounded with high confidence and little to no specialist interpretation. Physicians can be responsible not only for discussing and offering NIPS, but also for ensuring that patients understand the various probabilities of false positive or negative results, as well as for upholding the practice standard of recommending a positive NIPS result indicating aneuploidy be confirmed with a secondary invasive diagnostic test (4). Genetic counsellors can be helpful but do not necessarily negate physicians' fiduciary obligations in relation to patient comprehension.

NIPS is advantageous as, though it may still pose psychological and/or social risks like all prenatal screening does, it does not present a significant medical risk to pregnant women or fetuses. As such, the law covered here and previously (1) suggest that

a finding of causation is likely, and liability to physicians is therefore likely to result, in cases where they are held to have breached standard of care for failing to raise and discuss NIPS as an effective aneuploidy screening option and harm from a detectable genetic anomaly results. Liability could also derive from failing to recommend NIPS over an invasive equivalent test once a patient shows interest in undertaking aneuploidy screening, if the latter subsequently causes harm. Finally, if NIPS reveals any anomalies, a physician could face liability for failing to ensure that the results are confirmed using invasive diagnostic testing and understood by the patient. While these topics are not entirely settled in the law, the threat of wrongful birth and other liability is likely to propel NIPS into an ever more prominent position as a first-choice screening test.

Overly defensive medicine can harm patients and by extension public trust in the medical system, so it should be avoided. However, appropriately cautious physician behaviour involves discussing and offering prenatal screening, as well as diagnostic testing when indicated. It also involves ensuring results are interpreted completely and patients understand them. These behaviours can reduce physician liability and benefit patient reproductive autonomy, and in some cases can also benefit patient health by preventing or lessening serious psychological and/or physical trauma that informed patients choose to mitigate when granted the opportunity.

Reçu/Received: 08/02/2023
Publié/Published: 27/06/2023

Remerciements
Ce travail a été financé par le projet PÉGASE-2 de Génome Canada, *PErsonnalisation par la Génomique du dépistage prénatal d'Anomalies chromosomiques dans le Sang matErnel : vers un dépistage de premier niveau* (RES0038244). Les bailleurs de fonds spécifiques qui ont soutenu cette recherche comprennent Génome Canada et Génome Alberta.

Acknowledgements
This work was funded the Genome Canada project PEGASUS-2, *Personalized Genomics for prenatal Abnormalities Screening USing maternal blood: Towards First Tier Screening and Beyond* (RES0038244). Specific funders that supported this research include Genome Canada and Genome Alberta.

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Julien Brisson & Aliya Affdal

Les éditeurs suivent les recommandations et les procédures décrites dans le Code of Conduct and Best Practice Guidelines for Journal Editors de COPE. Plus précisément, ils travaillent pour s'assurer des plus hautes normes éthiques de la publication, y compris l'identification et la gestion des conflits d'intérêts (pour les éditeurs et pour les auteurs), la juste évaluation des manuscrits et la publication de manuscrits qui répondent aux normes d'excellence de la revue.

The editors follow the recommendations and procedures outlined in the COPE Code of Conduct and Best Practice Guidelines for Journal Editors. Specifically, the editors will work to ensure the highest ethical standards of publication, including: the identification and management of conflicts of interest (for editors and for authors), the fair evaluation of manuscripts, and the publication of manuscripts that meet the journal's standards of excellence.

Évaluation/Peer-Review: Eline M. Bunnik

Les recommandations des évaluateurs externes sont prises en considération de façon sérieuse par les éditeurs et les auteurs dans la préparation des manuscrits pour publication. Toutefois, être nommé comme évaluateurs n'indique pas nécessairement l'approbation de ce manuscrit. Les éditeurs de la *Revue canadienne de bioéthique* assument la responsabilité entière de l'acceptation finale et de la publication d'un article.

Reviewer evaluations are given serious consideration by the editors and authors in the preparation of manuscripts for publication. Nonetheless, being named as a reviewer does not necessarily denote approval of a manuscript; the editors of *Canadian Journal of Bioethics* take full responsibility for final acceptance and publication of an article.

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

C Landry. *Can J Bioeth / Rev Can Bioeth.* 2023;6(2):136-139

COMMENTAIRE CRITIQUE / CRITICAL COMMENTARY (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

"Home to Fail" Discharges: A Question of Motivation

Christinia Landry[a]

Résumé
Renvoyer des patients "chez eux pour échouer" tout en anticipant leur réadmission rapide est, à première vue, troublant d'un point de vue éthique, comme le sont toutes les sorties non sécurisées. Toutefois, les cas de retour "chez eux pour échouer" peuvent également être discrètement troublants sur le plan éthique dans la mesure où ils soulèvent des questions de paternalisme médical en raison d'une composante motivationnelle qui conduit à ce type de cas : en renvoyant un patient "chez elle pour échouer", elle en viendra à comprendre que vivre chez elle n'est pas sûr et donc pas judicieux, ce qui l'incitera à choisir différemment à l'avenir.

Mots-clés
planification de décharge, sécurité, prise de décision, paternalisme, autonomie

Abstract
Sending patients "home to fail" while anticipating their speedy readmittance is, prima facie, ethically troubling as are all unsafe discharges. However, "home to fail" cases may also be covertly ethically troubling insofar as they raise questions of medical paternalism due to a motivational component which drives these types of cases: by discharging a patient "home to fail" she will come to appreciate that living at home is unsafe and thus unwise, prompting her to choose differently in the future.

Keywords
discharge planning, safety, decision making, paternalism, autonomy

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INTRODUCTION

During my tenure as a clinical ethics fellow in acute care, "home to fail" was often voiced during discharge planning but remains unstudied. In fact, a quick search of PubMed in Winter 2023 did not yield any mention, unlike its parent term "unsafe discharge", which returned over two hundred and seventy hits. In my experience, "home to fail" cases presented in a number of different shapes and sizes, but they were all characterized by a fully-informed, decisionally-capable, and medically-stable patient requesting to be discharged home despite the medical team's warning against it. The medical team predicted that the patient would not be able to care for herself properly (or receive the care she needed) and would quickly return to acute care. "Home to fail" was then part of an individual's larger patient narrative insofar as her decision to return home did not conclude this chapter of her medical story.

This phenomenon is not to be confused with signing oneself out Against Medical Advice (AMA). Although, both phenomena fall under the umbrella of unsafe discharge, what is key to the "home to fail" case is that the patient is medically stable unlike the AMA case. After discharging "home to fail", the patient often returned to hospital after a brief stay at home, generally sicker and more decompensated than before her initial admission – perhaps she did not take her medication properly, clean her wound adequately, avoid the stairs, or abide by her diet. Conversations with the patient regarding appropriate aftercare continued upon her readmission with the hope on the part of the medical team that after a (few) failed discharge(s) and numerous attempts to be clinically persuasive, that the patient would realize that returning home was unsafe; and she would agree to move into supportive housing or a more supportive living environment.

Sending patients "home to fail" while anticipating their speedy readmittance – because they are predicted to fail to thrive – is *prima facie* ethically troubling as are all unsafe discharges. However, it is my contention that "home to fail" cases may also be covertly ethically troubling. Unlike other types of unsafe discharges, "home to fail" cases raise questions of medical paternalism due to a motivational component that drives these types of cases: by discharging a patient "home to fail", she will come to appreciate that living at home is unsafe and thus unwise. In my brief investigation of this phenomenon, I will use a vignette to frame and unpack my experience of "home to fail" cases, explore the principles and values at work, and finally conclude that "home to fail" discharges warrant further normative and empirical exploration.

"HOME TO FAIL:" A VIGNETTE

Ms. Smith is a 75-year-old widow without any living relatives who was hospitalized after a neighbour found her unconscious in her own entryway. The house itself was in a state of extreme neglect, providing some evidence that Ms. Smith was failing to look after her basic needs for food and hygiene in addition to failing to control her insulin levels. She presented at the hospital as confused and was discovered to be suffering from diabetic shock. After a few days of treatment and monitoring, Ms. Smith was deemed medically stable and demanded to go home. The medical team was reluctant to discharge her home because they suspected that she would quickly decompensate and return to the hospital, or worse, that she would die. She has no

ISSN 2561-4665

family and home care cannot provide her with the level of care that she requires to safely remain at home. The medical social worker compiled a number of long-term care facilities that were accepting new residents which he discussed with Ms. Smith over a number of bedside visits, but each time she adamantly refused, finally stating: “All of my best memories are in that house. You can’t make me go to a nursing home! If I die, at least I’ll die at home!”

LAYING THE GROUNDWORK: “HOME TO FAIL” CASES

The first question that comes to mind in a case like this is whether or not Ms. Smith is in fact capable of deciding where to live upon discharge. Although evaluating and/or assessing capacity entails negotiating legal criteria and navigating situational nuances, for the sake of this vignette we can look to Allen Buchanan’s and Dan W. Brock’s famous work on competence. In “Deciding for others,” they detail three interconnected components of competence or decisional-capacity necessary for directing one’s own health care (1). One may argue that these criteria are used to determine capacity for treatment decision-making and not capacity for where and how to live once one is medically stable. Indeed, choosing where and how to live requires a different sort of capacity than, for instance, refusing life-saving medical treatment or commencing chemotherapy. However, we may think of Buchanan’s and Brock’s criteria as the gold standard of decisional-capacity which can be applied not only to treatment decisions, but also to risky discharge decisions. Indeed, capable people may freely choose to live at risk, provided that they are not harming others, but we must first confirm their decisional-capacity to do so.

Buchanan’s and Brock’s first criterion is the *capacity for communication and understanding*. We always want to ensure the patient is able to express an understanding of her diagnosis and prognosis and how her illness will be helped or hindered based on where and how she lives. In the case of Ms. Smith, as in other cases of this nature, patients are found to have a capacity for communication and understanding. They can verbally work this part of their story into a larger narrative. However, they may not yet fully appreciate that this is not the end of their patient experience.

Buchanan’s and Brock’s second criterion is the *capacity for reasoning and deliberation*. According to Buchanan and Brock, Ms. Smith needs only to demonstrate a capacity for reasoning and deliberation and not necessarily a well-reasoned and well-deliberated decision on where to live. She does not yet comprehend the larger narrative involved in “home to fail” cases like her own. There is a desire on the part of some bioethicists to claim that poor reasoning is a marker of a lack of decisional-capacity and that life and death decisions should not be permitted to be made on weakly-reasoned choices (2-3). While it is true that medical teams are not keen to see patients make poorly-reasoned decisions that put their safety at risk, many of us would be deemed incapable of directing our own care or post-treatment care if our choices needed to be free of fallacious reasoning and biases.

One of the most common pitfalls of reasoning and deliberation that may yield irrational choices in “home to fail” cases is the cognitive bias toward the present and near future at the cost of the distant future. Dan W. Brock and Steven A. Wartman explain that patients may fail to give adequate consideration to how their present decision-making will harm them in the future (4). This bias may be at work in Ms. Smith’s decision to return home. Perhaps she fails to truly appreciate how quickly she will be readmitted to acute care despite the medical team’s prognosis should she return home. But does her dismissal of their warnings render her decision irrational or just imprudent?

Buchanan’s and Brock’s third criterion is patient *capacity for a concept of the good and reasonably consistent and stable values*. Namely, can the patient tell you what is important to her; is her explanation coherent and consistent over time? What is clear in this case is that Ms. Smith values living independently; perhaps she even values this more than living longer in supportive care as per her claim, “If I die, at least I’ll die at home.” Certainly, we can appreciate her decision given the state of many long-term care facilities and the loss of self-determination that many people experience when they move into care (5-7).

TWO POSSIBLE ANSWERS TO THE ETHICAL DIFFICULTY OF “HOME TO FAIL”

The short answer to the problem of unsafe discharges accepted by most clinical ethicists is that in all but extreme cases the principle of respect for patient autonomy trumps beneficence and justice (8). Principlism is the most often-used normative theoretical perspective in biomedical ethical decision-making (9-11). The famous principlists, Tom L. Beauchamp and James F. Childress explain, “Respect involves acknowledging the value and decision-making rights of autonomous persons and enabling them to act autonomously.” (11, p.104) In health care, this means patients need to be free from coercion or influence and they must be fully informed of their diagnosis, prognosis, and treatment options so they can reasonably choose what is in their own best interest. For Ms. Smith this choice is to live at home. And certainly, we are welcome to dislike our patients’ choice to live at risk but we are not welcome to derail it – this would constitute overt paternalism. Indeed, “the dignity of risk is smothered by paternalistic concerns” with failure (12, p.10). The action of discharging patients “home to fail” as with other unsafe discharges honours patient autonomy and their right to self-determination by releasing control over their well-being and allowing them to fail (or succeed) on their own terms (13).

A different and more difficult answer to the problem of “home to fail” is that acute care facilities are legally and ethically obligated to ensure a safe discharge and sending someone “home to fail” suggests risking a significant magnitude and probability of harm (14,15). Therefore, in these cases respect for patient autonomy meets a competing moral consideration calling into question autonomy’s place as the decisive principle. Any unsafe discharge compromises the medical teams’ adherence to the principle of beneficence and nonmaleficence which requires that medical practitioners ensure patients’ well-being (11,16-19).

Although one may argue that prohibiting Ms. Smith from returning home does just that; it inflicts further suffering through the loss of self-determination – paramount to which is the ability to take risks and the right to return home to fail – but is this sort of suffering undue given the stakes?

Now, we would be remiss if we skipped over the strong paternalism in this different and more difficult response to the problem. Strong paternalism has been ethically and legally troubling since the advent of the 1970's patient-centred model of care which encourages patients to determine their own conception of the good and choose accordingly (20-21). Hints at exercising one's own will over that of a patient may lead to a rupture in the health care relationship and could result in legal trouble. If we take Ms. Smith's values and interests seriously, it is clear that she would rather die at home than live in a long-term care facility. Indeed, the patient-centred model entails that there may be times when respecting patient autonomy may make patients physically worse off because they privilege their mental well-being over their physical well-being, if we can separate the two.

Interestingly, there may be a more subtle form of paternalism at play in the first answer to the problem. It may be the case that one of the key motivations for medical teams' decisions to send patients "home to fail" is not merely an honouring of patients' autonomy or freedom over safety, but also the hope that their failure garners. Medical teams hope that patients will make a different decision the next time they are discharged from acute care, a decision that aligns with the values and interests of the medical team – the decision to be discharged into a safe living environment. This hope champions beneficence and nonmaleficence rather than autonomy and is also what makes "home to fail" cases different from your run-of-the-mill unsafe discharge. The case, in some sense, remains open insofar as it is merely part of the individual's larger patient narrative: she will return home; she will take risks; she will fail; she will be brought back into care; she will choose to be discharged to a safer living environment. And her autonomy will be preserved at every stage.

Further "home to fail" not only compromises the principle of beneficence and nonmaleficence, it also undercuts the principle of justice as responsible resource stewardship which is the fair, equitable, and appropriate distribution of scarce medical resources (11). Discharging Ms. Smith home with the anticipation that she will be readmitted sicker and more decompensated entails that more public funds are spent than if she were discharged into some form of supportive living. Of course, she may be entitled to public funds to (help) cover her care costs, but this type of care is in no way financially comparable to the cost of acute care, particularly if it is intensive. However, privileging distributive justice concerns in discharge planning would be, for all but the steadfast (act) utilitarian, highly troubling; health care practitioners are generally discouraged from bedside rationing and encouraged to advocate for the patient to whom they are attending (22,23). Nevertheless it bears noting, we as a society pay a very steep price in honoring patient autonomy given that they may make poor health care decisions that result in more acute care admissions, but alas this is the cost of the patient-centred model of care – a cost some may be willing to bear if they favour patient autonomy and the right to take risks and fail.

CONCLUSION: DISCHARGING PATIENTS "HOME TO FAIL"

Discharge often raises complex clinical, legal, financial, organizational, and ethical issues (15). In terms of the ethical, we often find that the principles, values and duties they represent come into conflict with one another. In all cases of unsafe discharges, we must weigh the patient's right to self-determination and the duty to protect them from harm or failure (24,25). However, in unsafe discharges where the patient is medically stable, decisionally-capable, fully informed, and choosing an unsafe living environment, the principle of autonomy is paramount. I argue that "home to fail" cases are ethically troubling in the way that any unsafe discharge is ethically troubling. Nevertheless, "home to fail" presents its own challenges insofar as these cases are framed by a problematic motivational component that is unaccounted for if one is focusing on the ethicality of the action alone, i.e., honoring patient autonomy. However, integral to the full ethical assessment of any action are the agents' intentions. One of the medical team's intentions is that by discharging a patient "home to fail" that she will eventually appreciate that living at home is unsafe and makes her worse off. Is "home to fail" then not problematically motivated and potentially paternalistic? Certainly, discharging a decisionally-capable patient "home to fail" is a morally appropriate action from a patient-centred perspective. Giving patients the freedom to take risks, fail, and try again (and often again) preserves their dignity even though they may pay for it with their health and we as a society pay for it with our health care resources. Nevertheless, we are left wondering, might one of the central motivations informing the action of discharging patients "home to fail" not in fact be morally wrong, and might this influence our ethical assessment of the practice? If so, to what extent does this particular motivation matter if the action is *prima facie* ethically right?

Reçu/Received: 22/10/2022
Publié/Published: 27/06/2023
Conflits d'intérêts
Aucun à déclarer
Conflicts of Interest
None to declare

Édition/Editors: Ann M Heesters & Aliya Affdal

Les éditeurs suivent les recommandations et les procédures décrites dans le Code of Conduct and Best Practice Guidelines for Journal Editors de COPE. Plus précisément, ils travaillent pour s'assurer des plus hautes normes éthiques de la publication, y compris l'identification et la gestion des conflits d'intérêts (pour les éditeurs et pour les auteurs), la juste évaluation des manuscrits et la publication de manuscrits qui répondent aux normes d'excellence de la revue.

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Évaluation/Peer-Review: Kevin Reel & Kevin Rodrigues

Les recommandations des évaluateurs externes sont prises en considération de façon sérieuse par les éditeurs et les auteurs dans la préparation des manuscrits pour publication. Toutefois, être nommé comme évaluateurs n'indique pas nécessairement l'approbation de ce manuscrit. Les éditeurs de la *Revue canadienne de bioéthique* assument la responsabilité entière de l'acceptation finale et de la publication d'un article.

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

ART, CULTURE ET OEUVRE DE CRÉATION / ART, CULTURE & CREATIVE WORKS

Chronique du cinéma 2 : *De son vivant* – apprivoiser le mourir

Nathalie Plaat-Goasdoue[a], Jacques Quintin[a]

Résumé
Apprivoiser et penser le mourir par le biais du cinéma, c'est peut-être une des possibilités offertes par ce long métrage d'Emmanuelle Bercot mettant en vedette Benoît Magimel et Catherine Deneuve. Le film *De son vivant* aborde de manière frontale la question de la fatalité, au travers du récit de vie, et de mort, d'un jeune quadragénaire atteint d'une maladie dont le sombre pronostic ne fait aucun doute. Nous y suivons Benjamin, dans la dernière année de sa vie, alors que ce dernier affronte, l'inéluctable de sa finitude annoncée dans ce délai posé clairement : de six mois à un an. Se faisant, il se trouve plongé, ainsi que ses proches, de manière radicale, au cœur de ses questions existentielles, placé devant une série de choix qui se posent à lui, malgré – ou grâce à – la réalité de sa mort. Les nombreux enjeux éthiques rencontrés tout au long de son parcours sont exposés pour toutes les personnes impliquées : soignants, patient et proches.

Mots-clés
soins palliatifs, cancer, mort, soignants, vérité, oncologie, sens

Abstract
To control and think about death through cinema is perhaps one of the possibilities offered by Emmanuelle Bercot's feature film starring Benoît Magimel and Catherine Deneuve. *De son vivant* tackles head-on the question of fate, through the life-and-death story of a young man in his forties suffering from a disease whose prognosis is grim. We follow Benjamin, in the last year of his life, as he faces the inevitability of his finitude announced in this clearly stated time frame: from six months to one year. In so doing, he finds himself and his family plunged radically into the heart of his existential questions, faced with a series of choices that he must make, despite – or thanks to – the reality of his death. The many ethical issues encountered throughout his journey are exposed for all those involved: caregivers, patients and relatives.

Keywords
palliative care, cancer, death, caregivers, truth, oncology, meaning

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Apprivoiser et penser le mourir par le biais du cinéma, c'est peut-être une des possibilités offertes par ce long métrage d'Emmanuelle Bercot mettant en vedette Benoit Magimel et Catherine Deneuve. Paru sur nos écrans en 2020, sur fond de pandémie mondiale, le film *De son vivant* (1) aborde de manière frontale la question de la fatalité, au travers du récit de vie, et de mort, d'un jeune quadragénaire atteint d'une maladie dont le sombre pronostic ne fait aucun doute. Nous y suivons Benjamin, interprété de manière magistrale par Benoît Magimel, dans la dernière année de sa vie, alors que ce dernier affronte, non sans une certaine terreur, l'inéluctable de sa finitude annoncée dans ce délai posé clairement : de six mois à un an. Se faisant, il se trouve plongé, ainsi que ses proches, de manière radicale, au cœur de ses questions existentielles, placé devant une série de choix qui se posent à lui, malgré – ou grâce à – la réalité de sa mort. Le récit nous donne accès aux nombreux enjeux éthiques qui traversent les soins de médecine palliative, et ce, autant du point de vue des soignants, que celui des proches et des malades dans leur relation aux soins de fin de vie.

Professeur de théâtre, Benjamin pousse ses élèves à oser vivre pleinement leurs émotions, à s'abandonner à leur passion, à oser une vraie présence qui accepte la vulnérabilité, à avoir, donc, le courage d'embrasser tout de leur vivant. Mais, *de son vivant* à lui, nous découvrons peu à peu un homme qui a le sentiment de n'avoir rien engendré de personnel, de n'avoir « laissé aucune trace », de n'avoir été « essentiel pour personne », même, on pourrait le formuler ainsi : d'avoir vécu dans une forme de mensonge ou d'inauthenticité.

Ce dilemme entre vérité et mensonge traverse d'ailleurs tout le film, que ce soit dans la tension entre réel et imaginaire que dans ses points d'articulation au cœur de la relation médecin-patient.

Toutefois, c'est possiblement le rapport au langage, ses limites, ses dimensions multiples et son aspect ontologique qui pourrait constituer la trame la plus profonde du film. Tout au long du film, nous suivons les personnages dans leur recherche « des mots pour le dire », sans qu'ils n'y arrivent complètement. Que ce soit dans la recherche du bon mot, dans l'impuissance de « ne pas trouver les mots » ou dans les échanges qui font la part belle aux silences, regards et autres gestes, le film permet de rendre compte du déficit de langage pour rendre compte d'expériences parfois indicibles. Le film s'ouvre d'ailleurs sur le témoignage d'une infirmière, pleurant de n'avoir su « trouver les mots » pour consoler une femme ayant perdu son mari dans les quelques minutes où elle était absente de la chambre, alors qu'elle le veillait depuis des semaines. La quête du dire, du dire vrai, de la révélation jalonne tout le film jusqu'à cette idée des « mots qu'il faut dire avant de quitter ». Les mots les plus difficiles à dire, mais les plus importants toucheraient ainsi au pardon et à l'amour.

L'art, lui aussi mis au service du « dire qui ne se dit pas avec des mots », tient une place prépondérante dans la vie des personnages, qu'ils soient patients, médecins ou proches. Des scènes où des soignants chantent ensemble ou celles des danseurs de tango dans la salle commune devant médecins et patients, s'entrecoupent avec celles des échanges strictement

ISSN 2561-4665

verbaux entre les personnages. Même son fils, qui hésitent à rencontrer son père qu'il n'a pas connu, parviendra à lui dire quelque chose à travers la chanson et la guitare.

Il y a aussi, par le prisme de la question du langage, cette recherche, pour ne pas dire « obsession » de la vérité. Elle s'incarne dans ce qui pourrait presque être perçu comme un impératif moral reposant sur une conceptualisation de la fin de vie en tant que moment de révélation, de vérité. Cette posture, largement répandue dans la croyance collective contemporaine pourrait néanmoins ici être vue comme potentiellement totalisante menant à un risque de normalisation de ce que serait le *bien mourir* pour tous et toutes.

Par ailleurs, nous savons que la « situation-limite », telle que théorisée par Karl Jaspers (2) est susceptible de se présenter, pour plusieurs, comme une occasion d'accéder à une plus grande authenticité, ce qui semble réellement s'incarner pour Benjamin et ses proches. La mère de Benjamin livrera d'ailleurs un texte aux étudiants de son fils, rempli de *leçons de vie*, un peu comme si la mort venait révéler quelque chose du sel de l'existence qui fait dire : « si je recommençais, je ferais autrement ».

Le personnage de la mère, incarné par une Catherine Deneuve tout en retenue, nous permet de visiter le désir d'acharnement, le refus de la perte, le lent apprivoisement de la mort d'un fils qui, on le devine, a été au cœur de son existence. Avec l'aide du médecin, elle aussi cheminera. Les scènes où elle est représentée dans une forme d'attente passive, couchée, assise, ou marchant seule dans les corridors de l'hôpital, viennent appuyer ce passage de mère qui « est en contrôle » à « mère qui accepte graduellement de laisser aller ».

JOUER LE RÔLE DE SA VIE

À la réception du diagnostic, on observe d'abord l'acteur *jouer* avec les informations qu'il vient de recevoir, sans nécessairement les intégrer, en demeurant caché derrière ce que nous pourrions qualifier de ***faux self***, selon la formule issue de la théorisation psychanalytique des relations d'objet. Au départ, la performance théâtrale maintient le personnage dans une forme d'existence caractérisée par l'inauthenticité. Mais, peu à peu, c'est aussi le théâtre qui permet à Benjamin de jouer sa propre mort à venir, d'exprimer ce qu'il n'arrive pas à exprimer. C'est en passant par l'altérité portée par les personnages des grandes tragédies, par leurs voix, qu'il découvre peu à peu sa propre voix. Les déchirements seront ainsi déclinés, sur scène, puis dans la vraie vie de Benjamin, où la question de « faire le ménage de la table de sa vie », selon la formule de son oncologue, lui sera proposée afin de partir en paix. Tous les personnages, fictifs comme réels, se poseront les grandes questions inhérentes aux contingences de nos existences finies : Qu'est-ce que vivre? Qu'est-ce que la présence? Qu'est-ce que le courage? Qu'est-ce que mourir? Qu'est-ce que l'amour?

Ne trouvant aucun acteur à la hauteur de ce qu'elle voulait voir s'incarner à l'écran dans le rôle de l'oncologue, Emmanuelle Bercot a fait appel à un oncologue pratiquant à New York, le Dr Gabriel Sara qui, pour la première fois, a joué son propre rôle dans un film. La juxtaposition des identités fictives et réelles fait ici un clin d'œil supplémentaire à la tension entre l'espace imaginaire et l'espace que nous désignons en tant que réalité. L'oncologue-acteur habite toute la gamme des états humains convoqués dans cet espace de la relation médecin-patients, lorsque la médecine ne peut plus guérir, mais, peut-être, prendre encore soin. Pour le Dr. Sara, il s'agit de « marcher un chemin, avec son patient », en plaçant la relation au centre. Il ponctuera les échanges avec son patient de moments où il oscillera entre des postures où il révèle des informations (explications sur la maladie, interprétations sur les vécus en jeu, etc.) et d'autres où il s'ajustera au rythme et aux événements relationnels qui surgissent avec son patient. Par exemple, s'il choisit d'être très direct sur l'inéluctable de la mort qui attend son patient, il ne lui dévoilera pas certaines informations qui lui ont été révélées par des proches, préférant remettre aux protagonistes la responsabilité de faire les choix qu'ils auront à assumer.

Les postures éthiques de l'oncologue sont révélées tout au long du film au travers des dialogues avec ses patients ou ses collègues. Il insiste notamment sur le fait que ce sont les personnes qui choisissent quand, avec qui et comment elles vont mourir et sur la posture héroïque qu'il faut reconnaître au patient et non au soignant. Il rappelle l'importance de ne pas faire de tort « *primum non nocere* » du serment d'Hippocrate lorsque la mère tente de prendre le contrôle sur la suite des événements. Il identifie la « permission de partir » donnée au malade par les proches, comme un « cadeau d'amour ». Il fournit aussi de nombreuses explications sur le vécu de la maladie, d'une manière qui pourrait parfois nous paraître se substituer à la parole subjective non-née, pas encore mentalisée, à naître. Nous pouvons nous demander ce qui constitue la qualité de la vie : l'action, le dire, la relation et si c'est au médecin de le décider, au patient ou encore aux proches? Les sentiments d'injustice, la relation au corps, au toucher, les limites de l'implication du soignant, la souffrance des soignants et la prise en soin par l'institution, de cette souffrance sont aussi explorées d'une manière qui parait jusqu'ici inédite dans le cinéma occidental.

Finalement, c'est peut-être la question de la sensualité, de l'éternelle tension entre Éros et Thanatos qui sera la plus audacieusement abordée dans le film. Les gros plans sur les visages, les bouts de peau, les plans longs sur un ciel vu de la fenêtre de la chambre de l'hôpital ou même sur une fraise, nous font visiter, d'une manière qui donne à penser, ce qu'il peut être, de s'avancer vers sa propre mort à travers son corps. Le tabou du corps, celui du désir vivant jusqu'à la fin, est présenté d'une manière qui pourra même en choquer certains, ou en conforter d'autres, selon nos propres positionnements éthiques. Si la mort est au centre du film, c'est aussi la vie, l'éros et même une certaine quotidienneté qui reprend néanmoins le dessus, qui sont célébrés. Alors que le patient va mourir, on se dit « à lundi » entre collègues et nous reprenons ainsi le chemin de notre vie. *De son vivant,* une ode à la vie, lorsqu'elle est vécue en tension directe avec la mort.

Reçu/Received: 17/05/2023

Publié/Published: 27/06/2023

Conflits d'intérêts

Jacques Quintin est l'éditeur de la section Arts, culture et œuvres créatives. Il n'a pas participé à l'évaluation ou à l'acceptation du manuscrit.

Conflicts of Interest

Jacques Quintin is the section editor of the section Arts, Culture and Creative Works section. He was not involved in the evaluation or acceptance of the manuscript.

Édition/Editors: Aliya Affdal

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

M Gordon. *Can J Bioeth / Rev Can Bioeth.* 2023;6(2):143-148

TÉMOIGNAGE / PERSPECTIVE

Kevorkian's Legacy

Michael Gordon[a,b]

Résumé
L'histoire de l'introduction moderne du suicide assisté en Amérique du Nord suit un parcours tortueux, depuis le rejet total de l'idée jusqu'à sa mise en œuvre dans de nombreuses juridictions. L'Amérique du Nord n'a pas été un leader dans cette approche des soins de fin de vie, les Pays-Bas et la Belgique ayant joué ce rôle. Après avoir occupé une place criminelle et éthiquement anathème dans la société nord-américaine, elle a été ressuscitée en deux décennies pour devenir une pratique juridiquement et éthiquement acceptable. L'évolution historique du suicide médicalement assisté et de l'assistance médicale à la mort a, à bien des égards, imité l'évolution d'autres changements majeurs dans la vision du monde de l'homme et, à l'instar du suicide assisté, a fait l'objet d'un rejet quasi universel, avant d'être finalement adopté par les personnes et les institutions qui avaient initialement rejeté les idées exprimées pour la première fois par des personnes réfléchies et héroïques. Galileo Galilei était l'une des icônes de la science et de la découverte : il a failli être brûlé sur le bûcher pendant l'Inquisition avant d'être « ressuscité » et de retrouver sa place au panthéon des grands penseurs – mais il lui a fallu près de quatre cents ans pour atteindre ce sommet. Nous devons faire très attention à la manière dont nous interprétons les nouvelles idées et pensées, ainsi qu'au processus et aux conséquences que nous appliquons en cas de rejet.

Mots-clés
éthique, Kevorkian, AMM, euthanasie, Galileo

Abstract
This history of the modern introduction of assisted suicide in North America follow a tortuous course, with complete rejection of the idea, to implementation in many of its jurisdictions. North America was not a leader in this approach to end-of-life care, with the Netherlands and Belgium playing that role. Tracing the path from a felonious and ethically anathematic place in North American society it was resurrected into a legally and ethically acceptable practice over a period of two decades. The historical course of PAS (Physician Assisted Suicide) and MAID (Medical Assistance in Dying) in many ways mimicked the evolution of other major changes in our view of the world, and like assisted suicide, experienced almost universal rejection and ultimately the embrace of those people and institutions that initially rejected the ideas first expressed by thoughtful and heroic persons. Galileo Galilei was one of the icons of science and discovery: he was almost burned at the stake during the Inquisition only to be "resurrected" to his place in the pantheon of great thinkers – but it took almost four hundred years to reach that pinnacle. We must be very careful how we interpret new ideas and thoughts about the process we apply and the consequences if we reject them.

Keywords
ethics, Kevorkian, MAID, euthanasia, Galileo

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I remember the news reports; I was not quite sixty-years old. I had already completed my MSc in medical ethics and was a practicing academic geriatric specialist. I had some superficial interest in PAS (Physician Assisted Suicide) from papers I had read from the Netherlands. I had seen patients both old and young who I thought in the back of my mind, "why can't we do something to help them die", acknowledging that it was illegal in North America.

As quoted by Margaret P. Battin in *Physician-assisted Dying and the Slippery Slope: The Challenge of Empirical Evidence*, in the November 2011 Willamette Law Review, quoting a statement from Canadian Medical Association, 1998 (1):

> Euthanasia and assisted suicide are opposed by almost every national medical association and prohibited by the law codes of almost all countries... If euthanasia or assisted suicide or both are permitted for competent, suffering, terminally ill patients, there may be legal challenges... to extend these practices to others who are not competent, suffering or terminally ill. Such extension is the "slippery slope" that many fear.

This was the year before I read the following 1999 summary article from the British Medical Journal, which merits sharing again (2).

> A Michigan jury last month found Dr Jack Kevorkian guilty of second degree murder in the death of Thomas Youk, a 52-year-old resident of Detroit who had amyotrophic lateral sclerosis. Dr. Kevorkian made a videotape of himself injecting Mr. Youk, who was paralysed, with lethal chemicals last September. The tape was broadcast in November by the CBS News programme *60 Minutes*. (3)

ISSN 2561-4665

At his trial, Dr. Kevorkian failed to convince the judge that his proposed witnesses, Mr. Youk's wife and brother, were relevant to the defense. Aside from the videotape, which showed how much Mr. Youk was suffering while he was alive, no testimony was presented about Mr. Youk's condition and his apparent desire to end his life.

Because Dr. Kevorkian was charged with murder, Judge Jessica Cooper instructed the jury that the issue of whether Mr. Youk consented to his death was irrelevant.

This was the fifth time in a decade that prosecutors had tried Dr. Kevorkian in the death of a seriously ill person. Three trials ended in acquittal and a fourth ended in a mistrial. In all the previous cases, Dr. Kevorkian had violated laws against assisted suicide by helping patients give themselves a fatal injection through a so-called suicide machine (Figure 1)

Figure 1: Dr. Jack Kevorkian showed reporters his "suicide machine"

Credit: Associated Press (3)

In Mr. Youk's case, Dr. Kevorkian administered the fatal injection himself. Reaction to the verdict, and to the minimum sentence of 10 to 25 years in prison that Dr Kevorkian faces, was mixed.

The Hemlock Society, chief proponent of doctor assisted suicide said, "This verdict is not about Dr Kevorkian and the videotape. This verdict is about the contempt that the government has for people like Thomas Youk and other patients who are suffering painful deaths every day."

"This verdict is about the government's refusal to give dying patients and their families' reasonable choices at the end of life." (2)

At that time, medical assistance in dying already existed in the Netherlands following the well-known Postma case in 1973. It took almost thirty years for the practice to become legalised even though euthanasia was conducted without punishment until that time as long as the guidelines were followed; it became legalized in 2002 under strict conditions (4).

According to a report in the New England Journal of Medicine (5)

> Since the notification procedure was introduced, end-of-life decision making in the Netherlands has changed only slightly, in an anticipated direction. Close monitoring of such decisions is possible, and we found no signs of an unacceptable increase in the number of decisions or of less careful decision making.

This finding was years before Kevorkian's euthanizing Mr. Youk in 1998, which provoked his first trial.

> However, nine disability rights organisations in the United States have opposed the legalisation of assisted suicide and euthanasia. Diane Coleman, president of Not Dead Yet, a leading grassroots disability rights group, said that the euthanasia movement was “very threatening to a disabled person,” and she hoped that Michigan’s ban on assisted suicide would be maintained.
>
> Dr Nancy W Dickey, president of the American Medical Association (AMA) said, “Patients in America can be relieved that the guilty verdict against Dr Jack Kevorkian helps protect them from those who would take their lives prematurely.”
>
> “The AMA remains committed to assuring patients’ dignity, adequate relief of pain, and palliation of other symptoms during their final days. The AMA has long been a proponent of compassionate, quality care for dying patients. We will continue our efforts to teach physicians everything they should know about providing proper end of life care.” (2)

Years later, after Kevorkian’s death, relevant excerpts from an article published in The American Journal of Bioethics, in 2011 (6), included the following statements:

> (He died), but not by his own hand or through physician-assisted suicide. Known as the physician who helped dozens of people end their lives and, in one case, committed active euthanasia. He was eighty-three years old and had been suffering from complications of hepatitis, cardiovascular disease, hypertension, and lung disorders. Kevorkian’s enduring fame came from a crusade he undertook with a vengeance, helping people die, people who had terminal illnesses or debilitating disorders like Alzheimer disease and Lou Gehrig’s disease. By his own count he helped more than 130 people die. The state of Michigan convicted Kevorkian of second-degree murder in 1999, for directly injecting lethal substances into Mr. Youk.
>
> Most bioethicists shunned the man who treated his ideas like certainties engraved in moral stone. Most bioethicists believe that broad discussion is necessary to introduce far-reaching changes and want deliberated choice, especially in morally fraught matters, but Kevorkian was better at monologue than dialogue. Virtually without exception, the medical profession has rejected Kevorkian’s unilateral call for the creation of the specialty of “obitiatry,” a medical discipline focused on his proposals regarding experimentation and death.
>
> Bioethics does not always get to pick the pioneers who pave the way in medical and legal change.
>
> Unpolished and confrontational, Jack Kevorkian styled himself as an outsider as he campaigned to make better medical use of bodies before people died and after they died. ‘Dr. Death’ certainly made a dent in the view that no physician anywhere should ever help a patient die. When the Supreme Court handed down two decisions regarding physician-assisted suicide in 1997, the retired pathologist in Michigan was only at the margins of the discussion (Vacco v. Quill 1997; Washington v. Glucksberg 1997). Later on, the Supreme Court also declined to review his conviction. For all his bravado, Kevorkian ended up largely irrelevant to the legalization of physician-assisted suicide where that has occurred (6).
>
> As kidney disease progressed toward the end of his life, Kevorkian indicated that he regretted his actions. The lawyer explained: “He did what he did, and it brought [physician-assisted suicide] to public awareness. … He now realizes that having performed it when it was against the law, wasn’t the, probably, appropriate way to go about it. … What he should have done was work towards its legalization verbally.(7)

Thirteen years later, in 2023, with PAS legalized in many states in the United States, MAID in Canada, and various forms of PAS and MAID in most countries in the western world, one might look at Kevorkian, whatever his motives or his flawed personality, as a tireless advocate for a humane way for those experiencing irremediable pain and suffering who no longer have to pass through the jaws of modern medical technology to die (8,9).

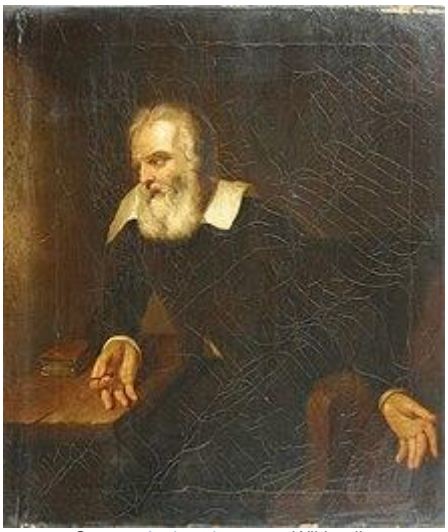
Kevorkian was obviously not the first pioneer of medicine and science, whether visionaries or stubborn egoists whose initiatives eventually became part of the fabric of the societies in which they lived. In his book *Galileo*, James Reston Jr. (10) recounts how Galileo was many centuries ahead of his time regarding his astronomical discoveries and writings, and which led him to almost be burned at the stake during the Inquisition. Extracts from Wikipedia, also documented in Reston’s book, show how Galileo defended *heliocentrism* based on his astronomical observations of 1609, i.e., placing the sun rather than the earth at the centre of the solar system (11).

> By 1615, Galileo's writings on *heliocentrism* had been submitted to the *Roman Inquisition* by Father Niccolò Lorini, who claimed that Galileo and his followers were attempting to reinterpret the Bible, which was seen as a violation of the *Council of Trent* and looked dangerously like *Protestantism*. In February 1616, an Inquisitorial commission declared *heliocentrism* to be "foolish and absurd in philosophy, and formally heretical since it explicitly contradicts in many places the sense of Holy Scripture". The Inquisition found that the idea of the Earth's movement "receives the same judgement in philosophy and ... in regard to theological truth it is at least erroneous in faith". Pope Paul V instructed Cardinal Bellarmine to deliver this finding to Galileo, and to order him to abandon *heliocentrism.*" (11)
>
> For the next decade, Galileo stayed well away from the controversy. He revived his project of writing a book on the subject… Galileo's resulting book, *Dialogue Concerning the Two Chief World Systems*, was published in 1632.

Being avant garde can dangerous, especially when it brings into question widely accepted and deeply believed norms and world views – and this led to Galileo's interrogation by the Inquisition.

> His final interrogation, in July 1633, concluded with his being threatened with torture if he did not tell the truth, but he maintained his denial despite the threat (12).
>
> The sentence of the Inquisition was delivered … in three essential parts:
>
> - Galileo was found "vehemently suspect of heresy" (though he was never formally charged with heresy, relieving him of facing corporal punishment), namely of having held the opinions that the Sun lies motionless at the centre of the universe, that the Earth is not at its centre and moves, and that one may hold and defend an opinion as probable after it has been declared contrary to Holy Scripture. He was required to "abjure, curse and detest" those opinions.
> - He was sentenced to formal imprisonment at the pleasure of the Inquisition. On the following day, this was commuted to house arrest, under which he remained for the rest of his life.
> - His offending *Dialogue* was banned; and in an action not announced at the trial, publication of any of his works was forbidden, including any he might write in the future (12).

Figure 2: Portrait of Galileo gazing at the words "E pur si muove"



Source: And yet it moves, Wikipedia

But while being forced to officially renounce his work, and then isolated, Galileo nonetheless continued to advance his studies.

> According to popular legend, after recanting his theory that the Earth moved around the Sun, Galileo allegedly muttered the rebellious phrase "And yet it moves"… Galileo was allowed to return to his villa at Arcetri near Florence in 1634, where he spent part of his life under house arrest (13).
>
> It was while Galileo was under house arrest that he dedicated his time to one of his finest works, *Two New Sciences…* this book was highly praised by Albert Einstein. As a result of this work, Galileo is often called the "father of modern physics" (14).

Figure 3: Statue outside the Uffizi, Florence

Source: Galileo Galilei, Wikipedia

Of the many lessons that can be learned from the history of Kevorkian and Galileo is that new ideas might be shunned by the authorities and "experts" in a given field of study, only to be shown to be valid years or even decades later – or as in the case of Galileo, centuries after the first reporting. Even with the rigor of so-called *Evidence-based medicine* (EBM), very strict recommendations that affect millions of lives might be proven erroneous years after the initial studies on which the recommendations are made. The case of Hormone Replacement Therapy (HRT) is a case in point. More than twenty-years after the almost total prohibition of its use, it is now evident that the results of the study resulted in substantial harm to many hundreds of thousands of women world-wide (15). The current anti-vaccination movement is an historical continuum of strong negative views about vaccines even as scientific evidence has proven their value over a number of centuries (16).

After so many years, many of those who support the concept and implementation of MAID and PAS probably don't know the name of Kevorkian. For those who are older, some may continue to think of him as "Dr. Death", rather than the pioneer that he was, with all the attendant human and social complexity that this involved (8).

Reçu/Received: 21/02/2023

Publié/Published: 27/06/2023

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Hazar Haidar & Aliya Affdal

Les éditeurs suivent les recommandations et les procédures décrites dans le Code of Conduct and Best Practice Guidelines for Journal Editors de COPE. Plus précisément, ils travaillent pour s'assurer des plus hautes normes éthiques de la publication, y compris l'identification et la gestion des conflits d'intérêts (pour les éditeurs et pour les auteurs), la juste évaluation des manuscrits et la publication de manuscrits qui répondent aux normes d'excellence de la revue.

The editors follow the recommendations and procedures outlined in the COPE Code of Conduct and Best Practice Guidelines for Journal Editors. Specifically, the editors will work to ensure the highest ethical standards of publication, including: the identification and management of conflicts of interest (for editors and for authors), the fair evaluation of manuscripts, and the publication of manuscripts that meet the journal's standards of excellence.

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

M Gordon *Can J Bioeth / Rev Can Bioeth*. 2023;6(2):149-151

TÉMOIGNAGE / PERSPECTIVE

Medicine and the Humanities

Michael Gordon[a,b]

Résumé
Dans les premiers récits écrits, les médecins et les maladies jouaient souvent un rôle important. Certains érudits renommés de la tradition juive, comme Moïse Maïmonide était un philosophe, un écrivain prolifique et un médecin. Parmi les auteurs mondialement connus, on peut citer : François Rabelais (1483-1553), Anton Tchekhov (1860-1904), Arthur Conan Doyle (1859-1930), Oliver Sacks (1933-2015) et le contemporain Abraham Verghese (1955-), pour n'en citer que quelques-uns. Le lien entre la médecine et les sciences humaines semble avoir diminué dans certains domaines, en partie à cause de l'accent mis sur les avancées scientifiques en médecine et de la diminution de l'intérêt pour les sciences humaines, en particulier dans l'enseignement supérieur. À mon avis, c'est un problème pour la médecine.

Mots-clés
sciences humaines médicales, éducation, étudiants en médecine

Abstract
In the earliest writing of stories, physicians and illnesses often played an important role. Some of the renowned scholars in the Jewish tradition, like Moses Maimonides was a philosopher, a prolific writer, and a physician. A few of the world-famous authors include: François Rabelais (1483-1553), Anton Chekhov (1860-1904), Arthur Conan Doyle (1859-1930), Oliver Sacks (1933-2015) and the contemporary Abraham Verghese (1955-), to name just a few. The connection between medicine and the humanities appears to have diminished in some domains due partially to the focus on the scientific advances in medicine and the diminished focus on the humanities, especially in higher education. This I suggest, is a problem for medicine.

Keywords
medical humanities, education, medical students

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I recall a clinical seminar in the mid-1980's with a number of medical students from the University of Toronto. I made a reference to Plato in my explanation of some historical point. I could see a look of puzzlement on the students' faces. I asked if they knew what I was referring to? One ventured, "playdough, the stuff that kids play with". The others nodded in agreement with the answer.

I enquired if they had ever heard or read anything of the works of Plato or Socrates and only one nodded yes. I explained why I referred to Plato and Socrates in my medical seminar and described how the so-called Socratic Method involves a shared dialogue between teacher and the students. I explained that the Socratic Method was in fact the basis of interactive teaching (1). Perhaps like the newly extolled evidence-based-medicine, the students might have understood that this current standard method, like the Socratic method, involves a shared dialogue between teacher and students.

Out of interest, I asked these students what they had studied in their undergraduate degrees. All had done a bachelor's degree in either health sciences or kinesiology; one had done psychology. When I asked why they had not thought of English literature, for example, they indicated that they thought that would not help them get into medical school. I thought to myself, "what a shame, the struggles and conflicts and joys, expressed in novels, is a most wonderful preparation for medicine, which after all is focused on people, with all their own conundrums, beyond their clinical concerns".

Fortunately for me, I had attended the liberal arts Brooklyn College, where without tuition, students could benefit from high quality higher education. Even though I was enrolled as a pre-med student, like all other students I had to complete the requisite introductory 101 courses: English, History, Philosophy, Classics and Social Studies. Of course, I did the science requirement for pre-med, but these courses did not inspire me as much as the liberal arts courses. I chose to do some extra humanities courses such as Art History, Shakespeare's tragedies and then as a summer course, existentialism through literature. The course was taught by a marvelous professor, who after he got to know the students better, revealed that he was about to be inducted into the Jesuit order – a "Roman Catholic order of religious men founded by St. Ignatius of Loyola, noted for its educational, missionary, and charitable works" (2) – when at the last minute he changed his mind. When asked by a student why, he said, "I realized that I would be celibate for the rest of my life, and I loved women". The final statement was, "I married a wonderful woman and have five daughters". Talk about divine justice.

Years before, while living overseas and working at an Israeli university medical centre, a discussion came up about the studying of humanities as good preparation for medical school. A very senior member of the Medicine Faculty stated unequivocally that the proper pre-medical training should focus on scientific studies. If desired, humanities should be left to students' leisure time.

ISSN 2561-4665

I was astounded. When I returned to Canada, I was happy to learn that many medical schools were incorporating humanities into the core training goals of medical school.

As reported Danielle G. Rabinowitz in her 2021 article “On the arts and humanities in medical education” (3)

> In 1971, Edmund Pellegrino, one of the founding figures of modern medical ethics, who gained international renown for his deeply reflective scholarship spoke of the role of “medical progress … in open[ing] up difficult questions about the relationships of medicine and technology to human values – [matters of the utmost concern to the humanist]. In doing so, he urged those present to consider the importance of “the application of the humanistic disciplines – like literature, history, philosophy – to the matter of medicine.” (3)

The article continues with reference to a study of the American Association of Medical Colleges (AAMC),

> In July, 2017, a conference was held to strategically “build a case to medical educators that [studying the arts and Humanities] is integral to what we do [as physicians]”. This came on the heels of results identified through an AAMC-lead curriculum inventory that highlighted that in the 2015–2016 academic year, only 119 American medical schools had a mandatory Medical Humanities course versus 103 offering electives (AAMC Curriculum Report on Medical Humanities). This underscored the lack of a “deep, sustained, foundational, across-the-board incorporation into all [American] medical schools” (4)

More than a decade later, an article from the March 6 2023 issue of the New Yorker magazine highlighted plummeting enrollment in the humanities,

> The [COVID-19] crisis, when it came, arrived so quickly that its scale was hard to recognize at first. From 2012 to the start of the pandemic, the number of English majors on campus at Arizona State University fell from nine hundred and fifty-three to five hundred and seventy-eight. Records indicate that the number of graduated language and literature majors decreased by roughly half, as did the number of history majors. Women’s studies lost eighty per cent. “It’s hard for students like me, who are pursuing an English major, to find joy in what they’re doing,” Meg Macias, a junior, said one afternoon as the edges of the sky over the campus went soft. It was late autumn, and the sunsets came in like flame on thin paper on the way to dusk. “They always know there’s someone who wishes that they were doing something else (5).

For anyone who has attended any of my teaching sessions or lectures, they will become aware very quickly that I often refer to elements of the humanities to make a certain point: it could be from literature, history (such as international, sports or scientific). I sometimes do this with patients, depending on their backgrounds. One older female patient that I was seeing, who was an avid reader, gave me a copy of *The Professor and the Madman* by Simon Winchester: as per the write up describing the book, it “is researched and eloquently written, is an extraordinary tale of madness, genius, and the incredible obsessions of two remarkable men that led to the making of the Oxford English Dictionary – and literary history.” (6)

Probably the most frequently literary work I refer to is Shakespeare’s *King Lear*. It has many of the common elements of family strife that I often see within patient dynamics that I have become witness to as a geriatrician. Greed, perfidy, foolish decisions on the part of angry parents, and expressed love rather than that which is spoken. Pain, death and grief all occur as if often the case within families – I have heard all the stories from patients and their families.

After I retired from the Baycrest Geriatric Centre in Toronto, where I had worked for forty-four years, I was asked if I would be willing to do Zoom-based seminars with family practice residents. The format would be *reflections* on their clinical experience. It was a change from my usual seminars which had traditionally focused on a combination of the wonderful history of medicine and medical ethics. Thus far I have done three sessions and the students appear to have caught on to the change of focus from clinical issues to the “story” of the patient’s life. One resident said he was amazed that when he saw an older woman, she wasn’t that interested in talking about her many medical problems, but rather the issues occurring with her grandchildren – some good, others worrisome. He recognized that in his training, no one had ever emphasized the importance of the “story” that the patient focused on, beyond their medical concerns. He admitted that her talking about her grandchildren brought smiles and laughter as well as tears as she related each one’s successes and trials.

I often recommend books that deal with a broad spectrum of human experience. The coming-of-age novels like James Joyce’s *Portrait of the Artist as a Young Man* (7), or George Elliot’s *Middlemarch* (8), an historical perspective on the development of Medicine and the complexities of love and other human relationships. It also highlights an important notion, which is the so-called *Hand from the Grave* whereby someone can wreck a surviving supposedly love-one’s dreams by doing as was done in Middlemarch: Dorothea discovers that the will of her deceased husband, Edward Casaubon, contains a provision that calls for her to be disinherited if she marries her beloved Ladislaw.

The challenge for educators in the medical sciences is to encourage rather than be neutral or disparage their students’ focus on the humanities during their undergraduate years. Also, when advising aspiring physicians what they should study during their undergraduate years, rather than suggesting health sciences of subjects like kinesiology (both majors are very popular for aspirants to medical education), the should encourage a focus on one of the humanities (my preference is literature) with

the sciences as minor subjects, sufficient to qualify for medical admission. I am aware that many counselors might not concur with my recommendations. I have yet to find a medical trainee or physician who bemoans their undergraduate studies in the humanities. But I have heard many others admit that they missed out on a robust exposure to literature, the arts, and the social sciences.

Doctors deal with stories: of their patients, their families, their colleagues, and the whole medical community. The best preparation for being able to receive and understand these stories is exposure to and internalization of the world of stories. The protagonist in A.J. Cronin's *The Citadel* decides to denounce a colleague who he witnessed practicing medicine in an unprofessional manner, and who will then face potential punishment by the licensing authority. His exoneration is a wonderful experience for any reader who plans on a medical career: medical ethics has become one of the newer frontiers to be combined with clinical practice (7).

A wide-ranging, eclectic exposure to literature, philosophy, classics, the visual arts, and history is in my opinion the best preparation to produce physicians who are not just excellent in their clinical skills, but are also understanding, empathetic and can relate to their patients and their families in humane manner.

Reçu/Received: 24/04/2023

Publié/Published: 27/06/2023

Conflits d'intérêts
Aucun à déclarer

Conflicts of Interest
None to declare

Édition/Editors: Hazar Haidar & Aliya Affdal

Les éditeurs suivent les recommandations et les procédures décrites dans le Code of Conduct and Best Practice Guidelines for Journal Editors de COPE. Plus précisément, ils travaillent pour s'assurer des plus hautes normes éthiques de la publication, y compris l'identification et la gestion des conflits d'intérêts (pour les éditeurs et pour les auteurs), la juste évaluation des manuscrits et la publication de manuscrits qui répondent aux normes d'excellence de la revue.

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Canadian Journal of Bioethics
Revue Canadienne de Bioéthique

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Can J Bioeth / Rev Can Bioeth. 2023;6(2):152-154

LETTRE À L'ÉDITEUR / LETTER TO THE EDITOR

Quand les bactéries font la loi : regards éthiques, épistémiques, juridiques, politiques, sociaux et techniques sur l'utilisation du microbiome humain à des fins judiciaires

Aliya Affdal[a], Frédéric Bouchard[b], Charles Marsan[a], Ely Mermans[b,c], Vincent Mousseau[d,e,f] Vardit Ravitsky[a], Christine Rothmayr Allison[g], Simon St-Georges[g], Pierre Trudel[h], François-Joseph Lapointe[i]

Résumé
L'utilisation du microbiome humain à des fins judiciaires comme objet d'étude implique divers enjeux allant d'une remise en question de notre conception traditionnelle de l'identité au respect de la vie privée, en passant par le type de consentement à recueillir lors du prélèvement d'un échantillon de microbiome. La particularité de cette étude nécessite le travail conjoint d'une équipe multidisciplinaire composée de spécialistes en éthique, criminalistique, droit, microbiologie, philosophie et science politique.

Mots-clés
microbiome, recherche, expertise multidisciplinaire, judiciaire

Abstract
The use of the human microbiome as a subject of study for forensic purposes raises a number of issues, ranging from a challenge to our traditional concept of identity to respect for privacy and the type of consent to be obtained when a microbiome sample is taken. The particular nature of this study requires the joint work of a multidisciplinary team made up of specialists in ethics, forensic science, law, microbiology, philosophy and political science.

Keywords
microbiome, research, multidisciplinary expertise, forensics

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The English version of this text appears below / La version anglaise de ce texte figure ci-dessous.

Les corps de police modernes et les tribunaux disposent de nombreuses ressources techniques (caméras de surveillance, écoute électronique, empreintes digitales, ADN) pour assurer la sécurité des membres de la société et leur accès à la justice. Continuellement, des investissements sont faits afin de développer des outils novateurs pouvant contribuer au travail d'enquête et judiciaire. Le microbiome humain, c'est-à-dire l'ensemble des communautés bactériennes que les humains portent sur leur corps, représente un de ces outils.

À la manière de l'analyse génétique plus « classique », qui cible les variations de certains marqueurs non-codants de l'ADN *a priori* considérés uniques à chaque individu (à l'exception des jumeaux identiques) (1), le microbiome pourrait permettre d'identifier ou d'exclure les individus impliqués dans des délits. Par contraste, l'analyse du microbiome dans une perspective forensique[1] permettrait l'analyse des fluctuations des communautés microbiennes liées à l'individualisation, l'alimentation, la santé et la géolocalisation récente (2). Bien que de nombreuses études scientifiques aient révélé le potentiel du microbiome en la matière (3,4), l'admissibilité devant les tribunaux et l'acceptabilité sociale de ce type de preuve restent, encore à ce jour, fortement discutable.

En effet, l'utilisation « d'empreintes bactériennes » en criminalistique soulève de nombreuses questions à l'interface de l'éthique, du droit, de la microbiologie, de la philosophie et des sciences politiques : quelle est la fiabilité scientifique de ce type de preuve? Comment les corps policiers et les laboratoires médico-légaux devront-ils recueillir et conserver les échantillons? Comment la preuve pourrait-elle être évaluée par les instances judiciaires? Quels risques cet outil pose-t-il aux libertés individuelles et à la vie privée? Les informations fournies par le microbiome peuvent-elles renforcer certaines discriminations policières et judiciaires? Faut-il repenser l'idée de responsabilité morale ou juridique?

Dans la recherche académique, la complexité de certains sujets nécessite parfois une collaboration multidisciplinaire. Afin d'esquisser des réponses aux questionnements susmentionnés, la présente étude « Quand les bactéries font la loi » a

[1] La science forensique, parfois appelée criminalistique, est la discipline qui réfère à l'étude des traces matérielles résultantes d'une activité criminelle par leur détection, leur reconnaissance, leur collecte, leur analyse et leur interprétation (5).

ISSN 2561-4665

précisément dû faire appel à des spécialistes en éthique, droit, microbiologie, philosophie et science politique pour réfléchir aux différentes implications liées à la possible utilisation du microbiome humain à des fins judiciaires.

Ces spécialistes ont mis en lumière des enjeux liés à la remise en question de notre conception traditionnelle de l'identité, au type de consentement à recueillir lors du prélèvement d'un échantillon de microbiome, à l'interprétation des résultats et des analyses des traces microbiennes, au stockage du microbiome dans des biobanques ou encore aux possibles atteintes au respect et à la protection de la vie privée. Afin de faciliter le transfert des connaissances de cette étude interdisciplinaire et de rendre les analyses accessibles à un large public, les résultats, sous forme de capsules vidéo, sont présentés sur le site internet : Quand les bactéries font la loi.

Cette recherche, effectuée dans le contexte académique et juridique québécois dans l'éventualité d'un usage policier et juridique du microbiome humain, a mis en lumière la force de la collaboration interdisciplinaire, en apportant des regards croisés sur une éventuelle rupture avec le modèle actuel de l'utilisation des profils génétiques à des fins judiciaires. Les divers spécialistes ont souligné le potentiel de l'utilisation du microbiome à des fins judiciaires, par exemple pour disculper un innocent dont l'ADN se trouverait sur une scène de crime. Des réserves et préoccupations éthiques ont également été émises considérant, par exemple, les risques de profilage ou encore le large éventail d'informations disponibles lié au mode de vie.

L'utilisation du microbiome à des fins judiciaires pourrait éventuellement constituer une approche complémentaire aux ressources techniques existantes, comme dans le cas d'un ADN de faible quantité ou de mauvaise qualité. Cependant, avant de pouvoir être considérée comme méthode principale dans des affaires judiciaires, l'utilisation du microbiome mériterait d'être précisée, discutée et validée par des comités inter- et transdisciplinaires.

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When Bacteria Make the Law: Ethical, Epistemic, Legal, Political, Social and Technical Perspectives on the Use of The Human Microbiome for Legal Purposes

Modern police forces and courts have many technical resources at their disposal (surveillance cameras, wiretaps, fingerprints, DNA) to ensure the safety of members of society and their access to justice. Investments are continually being made to develop innovative tools that can contribute to investigative and judicial work. One such tool is the human microbiome, i.e., the bacterial communities that humans carry on their bodies.

Like more "classical" genetic analysis, which targets variations in certain non-coding DNA markers *a priori* considered unique to each individual (with the exception of identical twins) (1), the microbiome could help identify or exclude individuals involved in crime. In contrast, analysis of the microbiome from a forensic[2] perspective would enable analysis of fluctuations in microbial communities linked to individualization, diet, health and recent geolocation (2). Although numerous scientific studies have revealed the potential of the microbiome in this field (3,4), the admissibility before the courts and the social acceptability of this type of evidence remain, to this day, highly debatable.

Indeed, the use of "bacterial fingerprints" in forensic science raises many questions at the interface of ethics, law, microbiology, philosophy and political science: how reliable is this type of evidence scientifically? How should police forces and forensic laboratories collect and store samples? How might the evidence be evaluated by the courts? What risks does this tool pose to individual freedoms and privacy? Could the information provided by the microbiome reinforce certain forms of police and judicial discrimination? Should we rethink the idea of moral or legal responsibility?

In academic research, the complexity of certain subjects sometimes calls for multidisciplinary collaboration. In order to sketch out answers to the above-mentioned questions, the present study "When Bacteria Make the Law" had to call on specialists in

[2] Forensic science, sometimes called criminalistics, is the discipline that refers to the study of material traces resulting from criminal activity, through their detection, recognition, collection, analysis and interpretation (5).

ethics, law, microbiology, philosophy and political science to reflect on the various implications linked to the possible use of the human microbiome for judicial purposes.

These specialists have highlighted issues such as the challenge to our traditional concept of identity, the type of consent to be obtained when taking a microbiome sample, the interpretation of results and analyses of microbial traces, the storage of the microbiome in biobanks and possible breaches of privacy. To facilitate knowledge transfer from this interdisciplinary study and make the analyses accessible to a wide audience, the results, in the form of video capsules, are presented on the website: Quand les bactéries font la loi.

This research, carried out in the academic and legal context of Quebec in the event of a police and legal use of the human microbiome, has highlighted the strength of interdisciplinary collaboration, providing a cross-section of views on a possible break with the current model of using genetic profiles for forensic purposes. The various specialists highlighted the potential of using the microbiome for forensic purposes, for example to exonerate an innocent person whose DNA was found at a crime scene. Reservations and ethical concerns were also voiced, however, regarding the risks of profiling and the wide range of lifestyle-related information available.

The use of the microbiome for forensic purposes could potentially represent a complementary approach to existing technical resources, as in the case of low-quantity or poor-quality DNA. However, before it can be considered as a primary method in forensic cases, the use of the microbiome would need to be clarified, discussed and validated by inter- and trans-disciplinary committees.

Reçu/Received: 14/06/2023

Publié/Published: 27/06/2023

Remerciements
Nous remercions Dominique Bernier, Martin Gibert, Catherine Girard, Yann Joly et Sarah Noël pour leur précieuse participation et les Fonds de recherche du Québec (FRQ) pour avoir financé ce projet dans le cadre du Programme intersectoriel Audace.

Acknowledgements
We would like to thank Dominique Bernier, Martin Gibert, Catherine Girard, Yann Joly et Sarah Noël for their invaluable participation and the Fonds de recherche du Québec (FRQ) for funding this project.

Conflits d'intérêts
Aliya Affdal est directrice scientifique et Vardit Ravitsky est membre du conseil consultatif de rédaction de la *Revue canadienne de bioéthique*. Elles n'ont pas participé au processus éditorial.

Conflicts of Interest
Aliya Affdal is Scientific Director and Vardit Ravitsky is a member of the Editorial Advisory Board of the *Canadian Journal of Bioethics*. They did not participate in the editorial process.

Édition/Editors: Hazar Haidar & Bryn Williams-Jones

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