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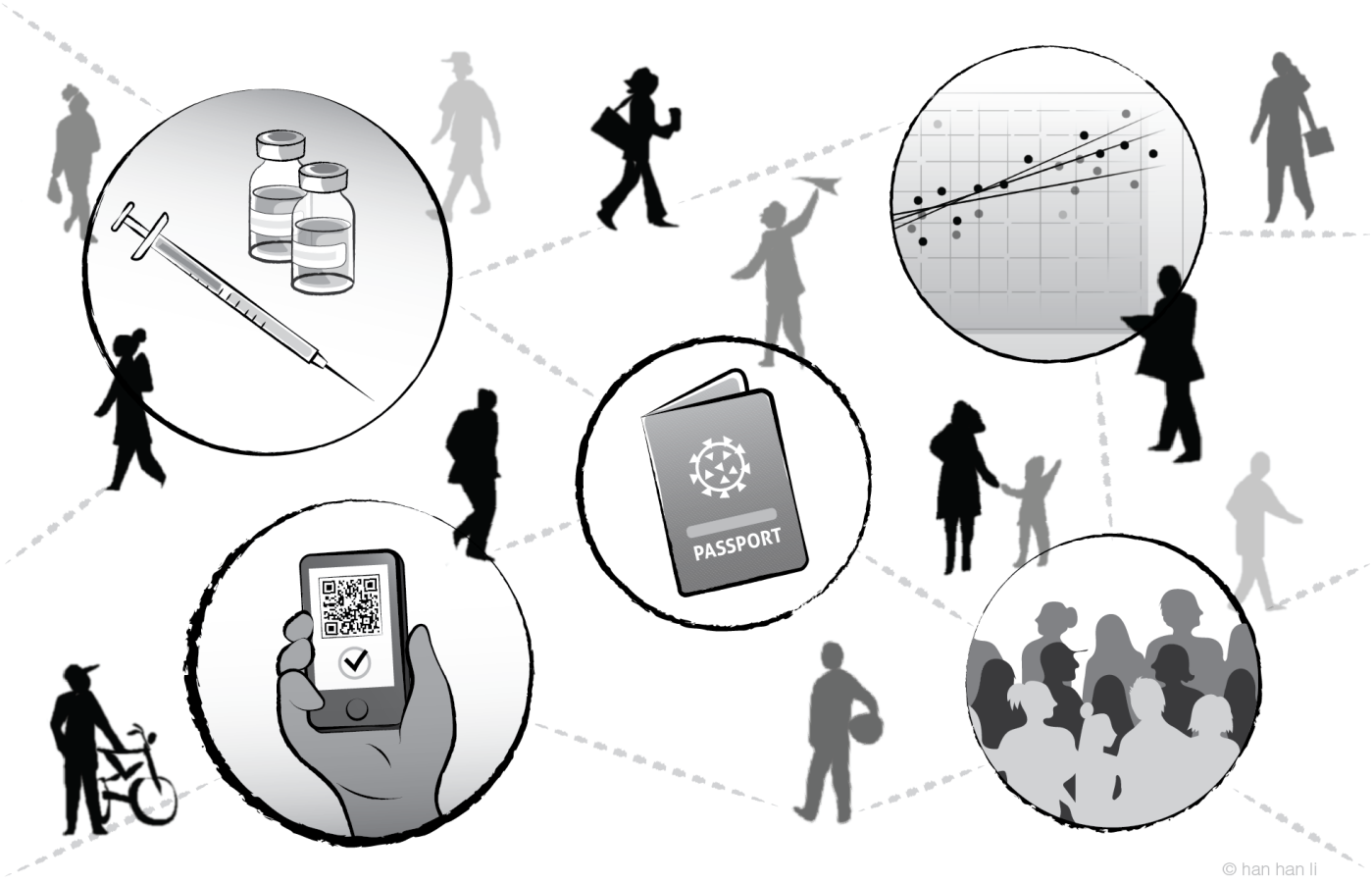

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Non-invasive Prenatal Testing for Fetal Whole Genome Sequencing: An Interpretive Critical Review of the Ethical, Legal, Social, and Policy Implications

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Résumé

Introduction: Les tests prénataux non invasifs (TPNI) permettent d'effectuer des tests génétiques sur un fœtus par l'analyse de l'ADN sans cellules provenant du plasma de la mère. Le TPNI est facile et sûr pour le fœtus, puisqu'il ne nécessite qu'une prise de sang de la mère et ne présente donc aucun risque de fausse couche. Il est considéré comme supérieur aux autres tests de dépistage prénatal et peut également être réalisé plus tôt dans la grossesse. Le TPNI a un potentiel futur pour le séquençage du génome entier du fœtus (SGEF) pour une gamme élargie de conditions, telles que les conditions génétiques à déclenchement tardif et le statut de porteur. **Objectif:** Examiner les implications éthiques, juridiques, sociales et politiques de l'utilisation potentielle des tests prénataux non invasifs pour le SGEF. **Méthodes:** Cette étude est une revue critique et interprétative de la littérature explorant et rapportant les implications éthiques, légales, sociales et politiques de la mise en œuvre potentielle du TPNI pour le séquençage du génome entier du fœtus, qui sera appelé séquençage prénatal non invasif (SPNI). Une recherche dans les bases de données et les listes de références a été effectuée entre 2010 et 2019 pour les termes liés à « test prénatal non invasif » ET « séquençage du génome entier fœtal » et dérivés. **Résultats:** Après la sélection, 32 articles ont été inclus. Les données ont été regroupées en quatre catégories thématiques : 1) implications éthiques pour le futur enfant concernant l'autonomie et les préjudices, ainsi que pour les futurs parents concernant l'autonomie, les préoccupations relatives au consentement éclairé et les préjudices ; 2) implications juridiques, y compris les préoccupations relatives à la vie privée ; 3) implications sociales, y compris les changements dans la dynamique familiale, les perceptions sociétales modifiées et les préoccupations relatives au handicap, la justice et l'équité dans l'accès au test, et la pression sociale pour utiliser le test ; et 4) implications politiques, y compris les préoccupations relatives au coût et au financement, la limitation de la portée du test, ainsi que le conseil, l'éducation et le soutien. **Discussion:** La discussion des résultats met en évidence plusieurs implications éthiques, juridiques, sociales et politiques de l'utilisation du TPNI pour le SGEF. Ces résultats ont des implications sur la mise en œuvre du TPNI pour le SGEF, y compris la manière dont l'autonomie du futur enfant devrait être équilibrée avec l'autonomie des futurs parents, la portée des conditions qui devraient ou non être testées – et couvertes ou non par le système de santé – et la réglementation de l'introduction du SGEF, entre autres. Des recherches supplémentaires doivent être menées pour répondre à ces préoccupations et ainsi orienter le débat sur la mise en œuvre clinique du SGEF par le biais du TPNI.

Mots-clés

dépistage prénatal non invasif, séquençage du génome entier du fœtus, QEJS, futur enfant, futurs parents

Abstract

Introduction: Non-invasive prenatal testing (NIPT) allows for genetic testing of a fetus through the analysis of cell-free DNA from the mother's plasma. NIPT is easy and safe for the fetus, since it only requires a blood draw from the mother and therefore holds no risk of miscarriage. It is considered superior to other prenatal screening tests and can also be performed earlier in the pregnancy. NIPT has the future potential for fetal whole genome sequencing (FWGS) for an expanded range of conditions, such as late onset genetic conditions and carrier status. **Objective:** To review ethical, legal, social, and policy implications of the potential use of non-invasive prenatal testing for FWGS. **Methods:** This study is a critical interpretive literature review exploring and reporting ethical, legal, social, and policy implications of potential future implementation of NIPT for FWGS, which will be referred to as non-invasive prenatal whole genome sequencing (NIPW). Database and reference list searching was conducted between 2010 and 2019 for terms related to "non-invasive prenatal testing" AND "fetal whole genome sequencing" and derivatives. **Results:** Following screening, 32 articles were included. Data were grouped into four thematic categories: 1) ethical implications for the future child concerning autonomy and harms, as well as for prospective parents involving autonomy, informed consent concerns, and harms; 2) legal implications including privacy concerns; 3) social implications including changes in family dynamics, altered societal perceptions and disability concerns, justice and equity in accessing the test, and social pressure to use the test; and 4) policy implications including cost and funding concerns, limiting the scope of testing, as well as counseling, education, and support. **Discussion:** The discussion of results highlights several ethical, legal, social, and policy implications of NIPT use for FWGS. These findings have implications on NIPT implementation for FWGS including how the autonomy of the future child should be balanced with the autonomy of prospective parents, the scope of conditions that should or should not be tested for – and covered or not covered by the healthcare system – and the regulation of FWGS introduction, among others. Further research needs to be performed to address these concerns and hence guide the discussion about the clinical implementation of FWGS through NIPT.

Keywords

non-invasive prenatal screening, fetal whole genome sequencing, ELSI, future child, prospective parents

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INTRODUCTION

Twenty years following the first publication of the human genome sequence, a staggering decrease in the cost of genome sequencing has been shown, from almost USD$100 million to approximately USD$1000 (1). With continued advances in science and technology, the cost of sequencing the human genome will continue to decrease. The landscape of techniques to advance the field of genome sequencing are constantly changing, making genome sequencing more accessible, common, and efficient; and a technology that will be inevitably deployed as part of individual and population-wide genetic testing.

Non-invasive prenatal testing (NIPT) allows for genetic testing of a fetus through the analysis of cell-free DNA from the mother's plasma to screen for fetal abnormalities including chromosomal aneuploidies, such as Down syndrome, sex chromosome anomalies, and microdeletion and microduplication syndromes (2). NIPT entered the market in 2011 and has been rapidly introduced into prenatal practice (3). NIPT is more accurate than the existing prenatal screening tests (e.g., maternal serum screening) and is therefore considered to be superior (4,5). Further, NIPT is easy and safe for the fetus, since it requires a blood sample from the mother (6) and therefore holds no risk of miscarriage compared to other invasive diagnostic procedures, such as amniocentesis and chorionic villus sampling. It can also be performed early in the pregnancy at about the eighth or ninth week of gestation (7).

In the near future, NIPT can potentially be used for fetal whole genome sequencing (FWGS) as shown by proof-of-principle studies (6,8). FWGS determines the complete DNA sequence of the fetus, which is not yet clinically available, but has been developed in the research setting (8,9). Non-invasive prenatal testing using FWGS – also called non-invasive prenatal whole genome sequencing (NIPW) – might offer parents a vast range of complex information related to the fetus such as: variations of unknown significance, non-medical traits (e.g., eye colour, athletic ability), carrier status, susceptibility genes, and late-onset genetic conditions (e.g., Alzheimer's disease) (10,11). The integration of this technology into prenatal care will present key challenges at the ethical, social, legal, and policy levels. For instance, concerns are raised about the psychological burden (i.e., anxiety and stress) that the quantity and complexity of information will pose for prospective parents and the threat to their future children's autonomy by infringing on the right to choose whether or not to know their genetic information.

To our knowledge, a critical interpretive review on the ethical, legal, social, and policy implications (ELSI) for the potential future use of NIPT for FWGS (i.e., NIPW) has not been conducted. Our review is thus timely, given the ongoing clinical development of NIPT for FWGS and the need to identify and address ELSI raised by this technology. Finally, this review offers general suggestions as starting points for policy considerations in this ever-growing field.

METHODS

Study design

A critical interpretive literature review (12) was conducted to identify and analyze ten years of literature concerning the ethical, legal, social, and policy implications of NIPT for FWGS. Critical interpretive literature reviews focus on capturing and analyzing "key ideas" relevant to the research question (13), i.e., by analyzing the literature as a whole, generating theory, not excluding literature based on rigid criteria, and reporting the search strategy (12,13).

Eligibility criteria

For screening literature results, we included: studies that address non-invasive prenatal testing using fetal whole genome sequencing; English or French language articles (regardless of country of origin); studies published between January 1, 2010 and December 31, 2019; peer-reviewed or published work in journals (e.g., systematic reviews, meta-analyses, case reports, theoretical literature, commentaries, as well as empirical research including qualitative, quantitative, and mixed methods research); and grey literature, if available (e.g., national and international policy reports). Excluded were clinical studies (e.g., randomized controlled trials, cohort studies, controlled trials, epidemiological studies, animal and *in vitro* studies), thesis dissertations and conference proceedings or abstracts, and public opinion articles from non-experts.

Information sources

Information sources included the following electronic databases: *Medline*, *psycINFO*, *PubMed*, *PubMed Central*, *Scopus*, and *Web of Science*. Relevant grey literature and other academic papers were also collected through individual searching (e.g., snowballing from list of references, and Google searches).

Search strategy

The following search strategy was used to identify literature in the electronic databases: (NIPT OR non-invasive prenatal testing OR NIPS OR non-invasive prenatal screening) AND (non-invasive prenatal whole genome sequencing OR non-invasive fetal genome sequencing OR NIFGS OR fetal whole genome sequencing OR *WGS OR prenatal whole genome sequencing OR cell-free fetal DNA OR cell-free DNA). Secondary search procedures included: reference list searching, forward citation searching, and searching in journals. The search strategy was evaluated by comparing search results to a subset of relevant literature previously chosen by the author (HH).

Selection process

Covidence software was used to first screen sources by removing duplicates, then by reading titles and abstracts. Two reviewers (HH and RI) independently screened titles and abstracts, as well as full-text documents for studies meeting the eligibility criteria. Both reviewers extracted data independently from the included full-text articles and then compared results to reach a consensus.

Data management, collection, and synthesis

Data results were recorded and maintained on Microsoft Excel and NVivo 12 (QSR International) and references were managed using Zotero. Both reviewers (HH and RI) extracted data from the literature by recording relevant information, including title, author, publication year, country of study, study type or design, sample population, objectives, important quotes, and comments on the ELSI of potential future uses of NIPT with FWGS. The ELSI data were extracted using NVivo 12 by coding quotations and categorizing them under themes based on a codebook developed by the authors. The codebook listed key themes and ideas present in the ELSI literature on the potential future uses of NIPT with FWGS. The codebook was refined and finalized throughout the data extraction process to reflect the different implications and common themes.

RESULTS

Screening results

Following the screening process, which initially identified 3334 articles in the search, a total of 32 articles were included in the synthesis (14) (Figure 1), and these were used for data extraction and coding of relevant themes in NVivo 12. Of the 32 articles, most articles are from 2017 (Figure 2) because of responses to a target article (15). Also, more than half of the included articles had corresponding authors from the United States, with other common countries being the Netherlands, the United Kingdom, and Canada.

Figure 1. PRISMA diagram for source selection

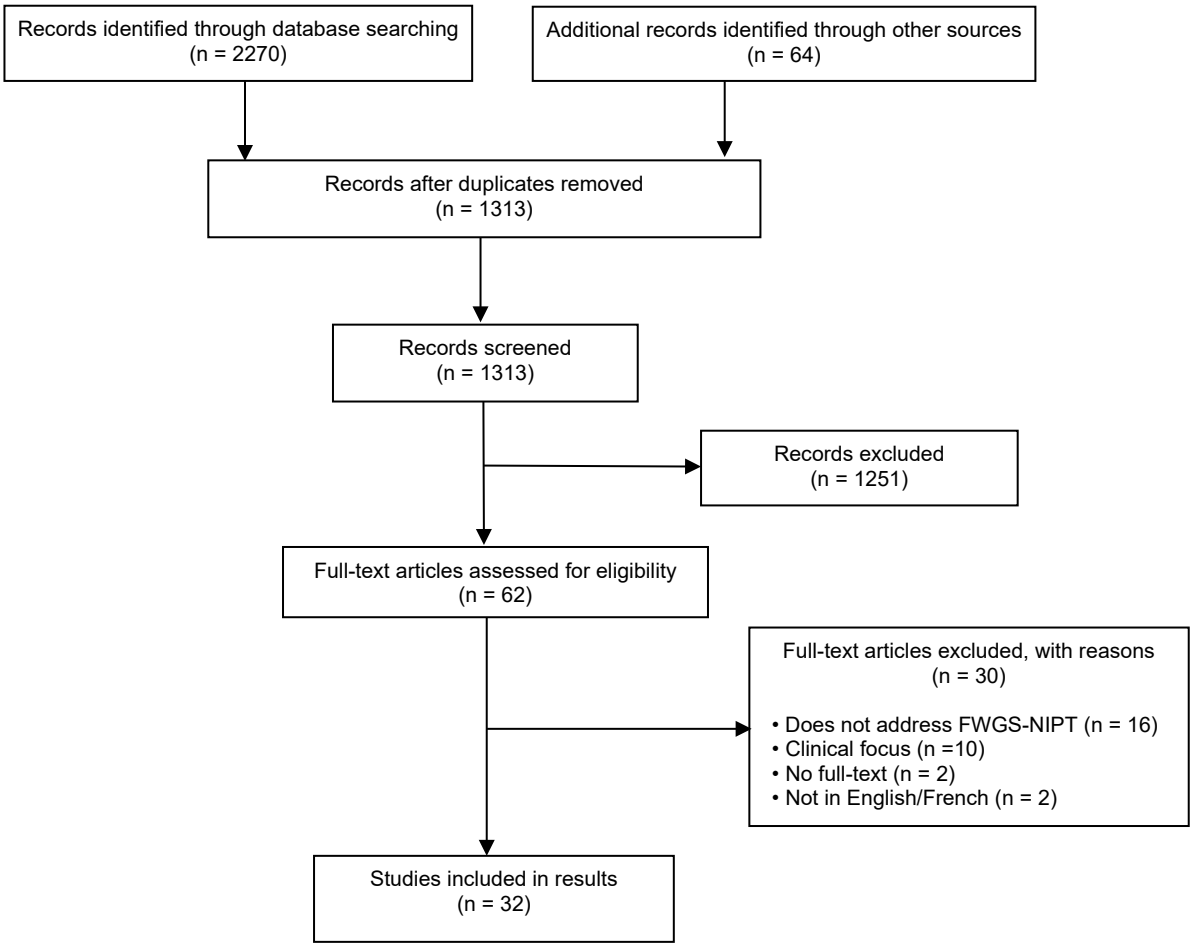
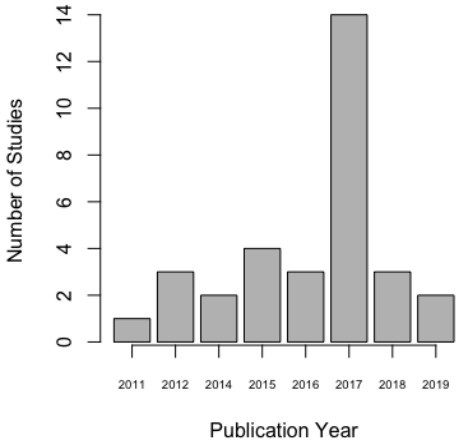


Figure 2. Year of publication for included studies



Data Extraction Results and Critical Analysis

There are various terms used to refer to FWGS through NIPT, including non-invasive prenatal whole genome sequencing (NIPW) and prenatal whole genome sequencing. For the current paper, we will use the acronym "NIPW". The following results show the categorization of themes as ethical, legal, social, and policy implications (ELSI) of implementing NIPW. Reviewers (HH and RI) organized themes independently and then consolidated and finalized through discussion. As shown in Table 1: 1) *Ethical* implications are separated into implications for the future child (1A) and implications for prospective parents (1B); 2) *Legal* implications include privacy concerns related to the future child; 3) *Social* implications explore changes in family dynamics, altered societal perceptions, equity in accessing NIPW, and societal pressure to test; and 4) *Policy* implications examine cost and funding concerns, limiting the scope of NIPW testing, as well as counselling, education, and support. Some subthemes involve overlaps and can be discussed from different perspectives (e.g., privacy concerns are discussed as an ethical implication and a legal implication).

Table 1. Themes and subthemes of ELSI of NIPW

1) Ethical	**(1A) Future child** • Future autonomy • Harms	**(1B) Prospective parents** • Parental autonomy • Harms • Informed consent
2) Legal	• Privacy concerns	
3) Social	• Changes in family dynamics • Altered societal perceptions and disability concerns • Justice and equity in accessing NIPW • Social pressure to use NIPW	
4) Policy	• Cost and funding concerns • Limiting the scope of testing • Counseling, education, and support	

1A) Ethical implications for the future child

The literature recognizes the importance of considering both future children and potential parents in decisions about NIPW, as they are both key stakeholders if the technology is to be implemented. The literature discusses future children's rights to autonomy by invoking their right to know/not to know their genetic information, their right to an open future, and future privacy. Further, it discusses potential harms to the future child such as anxiety and other psychological burdens.

Future autonomy

One of the most noted ethical implications of NIPW relates to the autonomy and right to self-determination of the future child. In the context of NIPW, authors often referred to a diversity of terms to discuss children's future autonomy, including the child's "right to know" (16) or "right not to know" (10,15-22) genetic information about themselves, "right to an open future" (15,16,18-25), and future privacy or other references to privacy (21,23,25,26). Several sources acknowledged that NIPW can raise concerns surrounding autonomous rights of future children (10,16,18-21,27). Authors explored how genetic testing can prevent

the right of future children to choose between knowing and not knowing certain information about themselves at a later age and that there would be more harm than good by not respecting this right to choose (16,19). Several other sources discuss how this technology could threaten the autonomy and interests of future children by removing their ability to decide whether they want to access this information (18,21,27,28).

While some sources expressed these concerns over autonomy, Bayefsky and colleagues found that the negative impact on the child's ability to make decisions upon reaching adulthood was of least concern to obstetricians and gynecologists who were surveyed (17). In the same vein, Rhodes believes that autonomy cannot be violated in this case "because no one can thwart a capacity that does not exist" (22, p.35) since fetuses and young children do not have decisional capacity. Rhodes compares the imposition of NIPW on children to how doctors and parents impose vaccinations and other treatments without consent (22). Further, Deans and others make a similar comparison with school attendance and healthy eating habits that parents might impose on their children, by citing this "soft paternalism" as being justifiable since it holds long-term benefits for the future adult (e.g., securing employment) (23). However, they view testing for adult-onset conditions as a form of unjustified "hard paternalism" because it impedes on the child's private sphere by limiting their (future) choices of choosing not to know such information (23).

The respect for autonomy argument ties closely to the child's "right to an open future" – a phrase coined by American philosopher Joel Feinberg – to indicate that "respect for children as future persons requires safeguarding their future autonomy" (16, p.536). For instance, several articles cite the child's right to an open future as being threatened in the context of NIPW (16,18,20,21,24,25). The Nuffield Council on Bioethics raises the argument about allowing future children to make their own choices in order to access the same opportunities as those who do not know their genetic makeup, which would leave their future open and respect their decisional autonomy (21). They describe this right as being "'in trust' that could be violated in advance by the use of NIPT to identify genetic information about them" (21, p.108). The right to an open future can be threatened by removing life options, such as options concerning education, employment, housing, lifestyle, and other aspects of one's life that may be changed because of knowledge from NIPW (21). However, given that parents inevitably shape and change the course of their children's lives, the right to an open future argument is not universal. Some question whether parents ought to leave their children's futures open. Rhodes denies this argument and does not believe the technology would jeopardize the child's open future because the results would not threaten or impede on the child's abilities (22).

This right not to know is prevalent in the NIPW literature because it relates directly to autonomy and choices future children can make about their future. NIPW can undermine the right not to know genetic information (10,18,28) and some articles cited the right not to know unless the genetic information is medically relevant during childhood (18,20). While the right not to know is advocated for in most of the articles included in our review, Rhodes denies this as a right and instead argues that there is a *prima facie* duty to be informed (22). The author explains that there is no right not to know information that is relevant for decision-making, thus testing the fetus is not violating this nonexistent right (22).

Finally, some authors raised concerns about how NIPW might invade the privacy of future children (21,23,25). According to the literature, learning of genetic information can impede on the informational privacy of the future child by sharing confidential information with parents and/or other parties that can threaten the future child's autonomy (21,23,25). There were no references in the literature we reviewed that explicitly denied the right to privacy of future children; however, the literature shows that protecting informational privacy is in the best interest of the future child. Deans and colleagues argue that not testing a born child to protect their privacy as a future adult should also be applied to not testing a fetus (23). They argue that facts about someone's future invades their private sphere and "knowledge about a person's adult-onset conditions is exclusively the business of the at-risk individual, not her parents" (23, p.7).

Harms to the future child

The ethical principles of beneficence (protecting individual welfare) and non-maleficence (ensuring no harm) are significant considerations in the NIPW literature. Few articles mention beneficence *in utero* and protection of the fetus (29,30) as justification for NIPW use. In that line, Deans and colleagues explain that arguments "against testing a foetus for information for the sake of that being […] would have to rely either on the foetus having rights and interests at the time of being a foetus, or on the claim that the future child or adult has interests that ought to be safeguarded in advance" (23, p.7). Most articles used beneficence of the future child as a guiding principle for NIPW implementation (10,28,30). Informational harms on the child may become apparent upon learning of certain genetic information, such as adult-onset conditions or other trivial information (11,16,18,19,21,23).

As part of balancing the risks and potential benefits of NIPW for future children, the literature explored the psychological effects and burdens that NIPW may have on them (16,19,21,23). For instance, learning of genetic information may result in a child experiencing anxiety or stress, including future development of a certain disorder (23,25). Psychosocial harms may include damage to self-esteem, parental over-protectiveness, discrimination, and stigmatization over knowing certain conditions (16,21,28). While these sources argue that genetic information, especially in relation to adult-onset diseases, can be psychologically damaging for future children, Rhodes opposed this view, stating that there is insufficient evidence to support psychosocial impacts (22). Rhodes argued that it is unavoidable that any decision made – whether or not to test – will affect the future child in some way by having knowledge or ignorance of their genetic information (22). Thus, it seems that while it is conceivable that genetic information can result in negative effects on mental health, further evidence is needed to solidify and justify this claim.

1B) Ethical implications for prospective parents

Some prospective parents may derive great benefit from exercising their parental autonomy and right to know the genetic make-up of their future children in order to decide about pregnancy management. However, others may experience negative consequences such as information overload that might impede their informed consent.

Parental autonomy

The most widely discussed ethical implication for prospective parents regarding NIPW is their autonomous right to test for genetic information and their freedom to choose to continue or terminate the pregnancy. In the literature, various terms are employed to discuss and refer to parental autonomy including: reproductive decision making (10,11,15-18,24,25,29,31,32), informed choice (15,16,18,19,21,24,33), procreative freedom (15), and reproductive choice (10,15,16,18,19,21,25,27-29).

Many sources argue for supporting parental autonomy and informed choice (16,25,27,28,30,33). Chen and Wasserman proposed an unrestricted policy for NIPW under which prospective parents "could obtain information on any genetic variant known to substantially raise the probability of any condition or trait relevant to their reproductive decision making or planning" (15, p.4). They believe that adopting this policy will increase procreative freedoms and inform reproductive decision-making, which respects parental autonomy (15). Rhodes concurs with the policy and states that "just as we should regard people who never want to assume any of the responsibilities of parenthood as free to avoid procreation, we should regard people who choose to avoid the exceptional obligations to a child with special needs as free to reject that parental role and abnegate any related commitments" (22, p.35). However, to further support parental autonomy under this policy, an understanding of parents' perspectives on and preferences for these decisions need to be considered (34). The literature reveals that prospective parents should make informed reproductive decisions and that their autonomy is rooted in parental responsibility (16,19,27,28). Similar to Rhodes (22), Yurkiewicz and colleagues compare autonomous decision-making regarding NIPW to the broader autonomy that society offers to parents such as freedom to raise children according to personal values, free from government interference (28). Exploring parental autonomy, Ravitsky and others argue that NIPW does not lead to enhanced autonomy but instead might hinder it, for example, by burdening prospective parents with a vast amount of information (32).

Parental autonomy is associated with the right to know information about future children because it has implications on reproductive decision-making and therefore, pregnancy management. Based on the literature, this right to know might be stretched from an unlimited right of prospective parents to access any information about the fetus (16,21,28,35) to a more limited right to know of certain information that is "meaningful" or "useful"[1] (15,18,19,25,27,30,31,35) to make an informed decision without specifying the nature of this information (i.e., whether it is medical or not). Richardson and Ormond add that while any piece of information can be valuable to parental reproductive decision-making, it should be recognized that harms could arise from this knowledge in terms of stress and anxiety (35). Deans and colleagues discuss the ethical implications of testing "purely for information", which includes learning information about the fetus either to help parents bond with their future child or to satisfy their curiosity, with no further intended action (e.g., pregnancy termination) (23). In this regard, they conclude that it is unacceptable to test the fetus for adult-onset conditions, carrier-status, and non-serious traits. Dondorp and others believe that neither claims of the right to know and the right not to know information about the future child are founded, because claiming a right not to know for actionable and beneficial information is as contested as claiming a right to know over non-actionable findings and those for late-onset conditions (16).

From a legal viewpoint, and given the current state of genetic testing, a woman who gets NIPT can access all the information this technology produces without healthcare provider interference (36), which would be translated into a vast amount of information once NIPW is clinically available. If no clear guidelines are introduced with NIPW, conflicts will be exacerbated between healthcare professionals and prospective parents over what information parents should have access to, which might lead to diminished trust in physician-patient relationships (10).

Harms for prospective parents

The impact of NIPW on prospective parents and the resulting harms are mainly discussed in terms of psychological harms including stress, anxiety, and confusion (11,15,19,21,23,25,28-30,32,35,37). For example, the right to know certain information about a future child, including variants of unknown significance (i.e., genes with uncertain functions or significance to health) can lead to negative psychological impacts on prospective parents, such as anxiety and stress, leading to concerns over information overload and adequate result management (10,24,38). The complex information included in NIPW can lead to increased stress when compared to information resulting from testing for only selected conditions. Several sources recognize the unnecessary anxiety that could result from learning of information about their future child (10,11,21,23,24,28,29,35), as well as false reassurance and decision stress (19). Not only could NIPW lead to unnecessary anxiety, but also "a loss of enthusiasm for a previously wanted child" (15, p.9) due to unwanted or unexpected genetic test results. While learning of genetic information can lead to distress, decisions about how to act on the information can also foster anxiety and confusion for prospective parents (10,19,37,39).

Nevertheless, another argument in the literature stated that learning of genetic information can lead to preparation for a child with special needs or to reproductive decision-making that can reduce psychosocial distress by avoiding suffering for the future child (25,27). On another note, harms to prospective parents have been discussed in terms of physical risk to the mother. For

[1] "Useful" is not well-defined in the literature and varies by source. Chen and Wasserman acknowledge that different people find different information to be "useful" (15). Richardson and Ormond believe that for some families, any information, even if uncertain, may be useful in making autonomous decisions (35).

instance, there is reason to believe that implementing NIPW could lead to changes in the prevalence of invasive diagnostic procedures, such as amniocentesis. If NIPT became a diagnostic test, it could lead to a decreased need for invasive diagnostic procedures, especially if women are currently being offered invasive tests (11). However, since it is currently only a screening test, the increased use of NIPT can lead to increases in invasive diagnostic procedures, which could lead to harms not only to the fetus (i.e., miscarriage risk), but also physical and psychosocial harms to the mother (19,21,27). In addition, NIPW could have high false-positive rates when initially implemented, which could lead to unnecessary invasive diagnostic procedures (31,32).

Informed consent

In addition to the previously mentioned psychosocial harms that come from learning of genetic information, there is a risk of decisional conflict, which can be understood as anxiety influencing reproductive choices that can lead to future regret (10) or general regrets over reproductive choices and decisions about genetic testing (29). This dilemma is a consequence of a lack of informed decision-making and consent for NIPW. Informed consent may not only be impeded but also may lead to decisional regrets because of information overload from the complex and expansive information resulting from NIPW. For example, while Chen and Wasserman believe that prospective parents will be overwhelmed by the quantity of results of NIPW under an unrestricted policy, they believe that a restricted policy will enhance confusion (15). However, commentators disagree about the unrestricted policy framework because it involves an overly comprehensive consent process that would lead to excessive information that could then impede decision-making (27,29,32,34,40). Another argument is that processing complex genomic data could lead to decision-making that is inconsistent with the preferences of prospective parents (25,29). Unlimited choices may threaten reproductive autonomy instead of supporting it because unlimited choice complicates decision-making and therefore undermines informed consent (10,16,18,19,24).

In addition to causing information overload, the literature shows a focus on ensuring that consent is comprehensive and that parents understand the risks and potential benefits (11,18,24,41). One concern is that parents and healthcare professionals may view NIPW as routine care and will not consider those risks and benefits carefully (36). Changes in norms of parents being expected to act on information because of test implementation may also lead to changes in pregnancy expectations that will complicate informed consent (10). Expanding the test beyond well-known conditions, such as Down syndrome, can lead to difficulties in ensuring parents receive meaningful options for reproductive decision-making and hence hinder their informed consent (19).

2) Legal implications

While the literature is not as yet focused on the legal implications of NIPW, an ethical consideration that could be equally discussed from a legal viewpoint is privacy concerns for the future child.

Privacy concerns

The informational privacy of the future child as an ethical implication has also been explored from a legal perspective, including data storage and management, i.e., how this data should be stored, analyzed, and mined, whether it should be destroyed, who should make decisions surrounding the data, and who has control over it (11,21,26). These issues are also considered to be legal concerns that might affect policies surrounding NIPW because of privacy laws that safeguard health information. Another implication related to privacy is the potential for discrimination in health insurance – based on the genetic information – against individuals who had their fetal genome sequenced, and who may experience difficulties accessing certain goods and services if insurance companies or employers had access to their personal information (21,26).

3) Social implications

Implementation of NIPW could lead to both negative and positive societal outcomes. For instance, a positive outcome could include the improvement of prenatal care as well as pregnancy and delivery management (31). Further, data obtained from testing could lead to advances in biomedical research to help treat conditions with no cure; patients could promote research and join advocacy organizations, which would lead to positive societal outcomes (28). However, there are also negative outcomes that require further discussion to determine the balance of risks to benefits, which we grouped under the following four themes: i) changes in family dynamics, ii) altered societal perceptions and disability concerns, iii) disparities in test use and access, and iv) societal pressure to test.

Changes in family dynamics

When children are born who have been tested for certain conditions, there is a risk that parents will treat these children differently based on their genetic traits. Treating children differently can lead to biases in how parents choose to raise children, can alter relationships between family members, and can ultimately affect the child's life course (10,17,21,28). Knowing this information can lead to parents either having higher expectations of their children and being less accepting of flaws (17,23,29), or having lower expectations of their children and not encouraging their success. For example, parents who learn that their child's predicted IQ is low may become more tolerant of poor academic outcomes, which leads to less parental support and negative effects on the child's success (10).

Chen and Wasserman view these changes positively, believing that parents who know that their children are susceptible to certain conditions will lead to a higher appreciation of the fact that no baby is perfect (15). It could also have a positive effect

for susceptibility genes if parents are aware of them and can influence the incitement of strong genes or suppression of poor genes. For example, if it is known that a child is susceptible to lung cancer, parents can act on this knowledge by educating their child and not smoking around the child to suppress the gene (10). While this may lead to positive outcomes, upon learning of adult-onset conditions, parents may also view their child as vulnerable despite them being healthy as children, which can lead to harmful treatment or stigmatization (23,24). There can also be further changes to expectations of children as well as an understanding of what having a normal or healthy baby means (10,21). While parents may have low expectations upon learning of poor genes, parents may also have expectations for a perfect child and value having control over their child's genes (42). Donley and colleagues also discuss the possibility of the "self-fulfilling prophecy", which is a "worry that the anxiety caused by awareness of one's susceptibility to a condition, as well as parental expectation for the disease to develop, might actually increase the likelihood of the condition manifesting in the child" (10, p.10). Learning of genetic information can lead to changes in family dynamics and how parents choose to raise their children, which includes the possibility that children will be objectified or have their worth determined by their genetics. Viewing children based on their successes or failures because of their genetic traits does not acknowledge them as persons and could lead to them being viewed as commodities (21,23,28).

NIPW may also alter family dynamics by providing prospective parents time to plan for the birth of an affected child by catering to their needs based on knowledge from testing (21,38), which could be viewed as beneficial for the future child (30). There is also discussion around how psychological preparation could lead to parents being more supportive as well as the benefits for the child to psychologically prepare for the development of their own conditions (23). In addition to emotional (19,38) and psychological preparation, "parents may also be better able to put in place social, practical and financial arrangements for care of their child" (23, p.5). Learning of test results can inform choices about plans during pregnancy, such as whether to continue the pregnancy and plan for the birth of the future child with a disability, or to choose termination (21,28). Although there is currently no evidence that preparing for the birth of a child affects their future (40), it is of interest to further elucidate whether preparation (if any) influences the life course and outcomes for children.

Altered societal perceptions and disability concerns

Beyond altering perceptions within family units, widespread use of NIPW could affect societal perceptions and social norms. Similar to how parents may view the ideas of "normal" and "healthy" differently (10,21,27), it may cause society to re-examine how we value persons, what it means to be human (36), and how we view the role of children and parents (42).

Altered societal perceptions of how to define "normal", "healthy", or even our conception of "the good life" (24) can result in discrimination against conditions that fall below newly defined thresholds (21,25,28). It is important to explore whether implementation of NIPW will lead to stigma against individuals who have conditions that are in the scope of NIPW testing. In Chen and Wasserman's unrestricted testing policy proposal, they believe that limiting tests to certain conditions would exacerbate discrimination and convey to those living with said conditions that they are a burden on society, whereas if testing included any and all conditions or traits as they propose, it would not send this discriminatory message and would put all conditions on the same level (15). They believe that the more restrictive the list of conditions, the more stigmatizing the test will be for those living with the conditions on the restricted list (15). Commentators do not wholly agree with this claim and think that it could instead lead to devaluation of individuals with conditions who were not previously included in testing programs, such as those with Alzheimer's disease (39). Shakespeare argues that Chen and Wasserman's proposal for unrestricted testing policy may lead to people being devalued as persons with strengths and weaknesses, and instead viewed as having functional faults (37). Shakespeare also claims that we should be accepting of diversity and support those with disabilities by allowing inclusivity and accessibility, especially when many conditions are not severe and do not discount the worth of individuals (37).

The concerns surrounding endorsement of disability discrimination has also led to the slippery slope concern that more testing will lead to further scrutiny of minor abnormalities (e.g., short stature) or cosmetic and non-medical traits (e.g., intelligence, hair colour) (19). There is also concern that changes in perceptions and expectations of children might lead to parents wanting the freedom to have designer babies by choosing traits based on parental values and preferences (17,21). Beyond this is the concern that NIPW will lead to eugenics, which can be understood as any attempt to improve the genetic traits in a population (21). Several sources (17,32,37,41) discuss the possibility of the increases in discrimination and the push towards testing for and acting on less severe conditions as akin to eugenics. However, Rhodes believes that this slippery slope argument is fallacious because NIPW will lead to more freedom, rather than negative consequences (22).

With an increased uptake of prenatal genetic testing and the expansion of the range of conditions that can be tested, there is a possibility for increases in the rate of pregnancy terminations (10,17,21,28). There is concern that parents might choose to terminate based on variants of unknown significance, or trivial or non-medical characteristics (43). The literature also expresses concern that with increased termination rates, there will be a trivialization of abortion and abortion decisions (18,19,25,27). Trivialization involves the concern that increased termination is because of unimportant or discriminatory reasons, instead of reasons such as avoiding suffering for the future child (27). While some argue that increased termination will exacerbate discriminatory attitudes for persons living with the tested conditions, others believe that terminating a pregnancy because of the possibility for disability is not the same as discriminating against persons living with the same disability (18). Chen and Wasserman argue that because there is limited attachment to the fetus earlier in the pregnancy when NIPW is conducted and that pregnancies are not yet disclosed, it may make termination decisions easier (15). NIPW may also lead to safer and less costly pregnancy termination because the prenatal test can be done earlier in the pregnancy (11). Increases in testing can also lead to termination of *wanted* pregnancies, which can exacerbate previously discussed psychological anxiety and distress

for prospective parents (37). Some sources (21,32) suggest that these increases in termination rates can be seen as encouraging eugenic attitudes, an ensuing result of the slippery slope.

In addition to the consequences of increased termination rates, the social implications of NIPW also include societal imbalance, such as gender imbalances (e.g., resulting from terminating pregnancies based on sex selection) or genetic imbalances and decreases in population diversity as a result of parents selectively terminating based on certain conditions. Furthering prenatal genetic testing can lead to changes in how we value diversity and tolerate differences (24,25,37). Selective terminations can lead to potential harms in society because this threatens biological benefits of genetic diversity, which are known to help with adaptation to changing environments and other survival characteristics (21). However, Berkman and Bayefsky deny that such imbalances will lead to population-level shifts, but that the true effects of selective termination resulting from widespread use of NIPW with regards to decreasing genetic diversity should be explored (29).

Justice and equity concerns in accessing NIPW

Another social implication of implementing NIPW is the disparities in test access and use. NIPW might be expensive, which could indicate that more affluent individuals of higher socioeconomic status would be able to take advantage of it, therefore raising inequalities in access to testing based on income (11,24) or what Chen and Wasserman qualify as “genetic inequality” (15). Such situations might lead to disadvantages for those who cannot afford the test because they will more likely suffer the negative effects of increased invasive testing (11). Tabor and others also believe that it is possible that children with undesirable conditions will be disproportionately born to lower income families who could not afford NIPW, therefore extending societal imbalances and loss of diversity as previously discussed (11).

On another note, the inequity in using the test might be correlated to other factors such as religion, ethnicity, and education (41). For instance, patients with higher education levels may have a better understanding of the test and its results, which might eventually lead to disparities in informed decision-making surrounding testing and reproductive decisions.

Societal pressure to test

Another social implication discussed in the literature that can arise from the future use of NIPW is the societal pressure to undergo prenatal testing. With potential widespread and routine use of NIPW, it is likely that more women will feel pressure to undergo testing to learn about fetal information (10,11,15). There is concern that this will lead to undue commercial pressure to receive test results because of the push towards categorizing testing as necessary for protecting the future child, which incites a strong commercial interest in expanding the market for NIPW (29,34). Commercial push for NIPW and a lack of genetic counsellors might lead physicians to rely on genetic testing companies for counselling, which introduces a conflict of interest due to company-affiliated genetic counsellors providing counselling, which in turn, might increase pressure on parents to accept screening for high amounts of information (29).

In addition to societal and commercial pressures to undergo NIPW, there exists a pressure to act on the test results. Once prospective parents succumb to the pressure of agreeing to testing, they may also experience pressure to act on the results (10,36), therefore threatening parental autonomy (11). Chen and Wasserman express this sentiment when they claim that women who decide to continue their pregnancies have “a moral duty to seek medical intervention for a preventable or treatable fetal condition, if the intervention does not impose too great a burden on her” (15, p.10). This reveals how societal pressure to act can manifest and influence reproductive decision-making for prospective parents who undergo NIPW, including the decision to terminate (11,25). In fact, there is a belief that pressure to terminate reverses social progress towards civil rights and social support for individuals and families with these “undesirable” traits and disabilities (11).

While there is a possibility that parents will experience pressures to use NIPW and act on test results, there are also claims that there is currently no clinical need for the test, and parents currently have no interest in undergoing the test because it does not influence decision-making (38,42). Kraft observed this stating that pregnant women were more interested in choosing a name or finding childcare than they were in talking about the child’s genome (34). However, once NIPW is clinically available, it will be important to understand the impact on demand for testing.

4) Policy implications

Policy implications relate to how policies and guidance surrounding NIPW will be implemented. Relevant policy implications we identified in the literature include: i) cost and funding concerns, ii) limiting the scope of NIPW testing, and iii) counselling and support for prospective parents.

Cost and funding concerns

NIPW will be expensive for years after it is first implemented (21). Policies need to address how funding will be organized to reduce disparities and avoid genetic discrimination of health and life insurance. Costs need to be considered for maintaining support for prospective parents (40), clinical time for patients (24), and education for clinicians (40). Also, it is crucial to consider the downstream costs of additional testing, data collection, storage, analysis, interpretation, and follow-up of test results, including abortions (24,26,32,33,40,41). Moreover, the possible surge in NIPW use might increase financial burdens on the healthcare system and society (26) because of increased requests for genetic counselling, and overtreatment and medicalization of less severe conditions or non-medical traits (11,17,24,28). Chen and Wasserman deny the objections surrounding increased costs as a justification against implementing an unrestricted testing policy because they believe the

costs are necessary for responsible testing; they believe that additional costs are justifiable for the benefits that testing will proffer, but agree that from a public health perspective, it is logical to prioritize preventing more clinically severe conditions[2] (15). Thus, the cost effectiveness of NIPW needs to be assessed before it becomes clinically available (19,24,25).

Considering costs and funding of NIPW is necessary because in order to justify funding, the priority order of the screening technology must be discussed in relation to other goods and services (24,44). Allyse and colleagues state that the only way for an unrestricted policy on NIPW to work is if we live in a "frictionless healthcare setting in which all concerns of scientific limitation and resource allocation have been removed" (40, p.2). From a similar perspective, Ravitsky and others argue that funding decisions should be contingent on whether the testing technology is clinically highly accurate and translates into an enhanced reproductive decision-making, with the belief that even if this is the case, "there is no obligation to fund access […] to all available tests that may inform a reproductive decision, especially if the clinical significance of potential results is unclear" (32, p.40). Therefore, testing and counselling should be an out-of-pocket expense to avoid taking resources away from more urgent needs if parents wish to test for a wider set of conditions that are not medically indicated (32). There are claims that funding and investing resources into NIPW, especially unrestricted testing policies, would deprioritize and devalue other important public health goals and services that are more necessary and justifiable, such as universal pregnancy and neonatal care counselling and support (40). Authors agree that there should be reflection on how important it is to spend scarce resources on NIPW compared to other supports, conditions, and areas of healthcare to uphold the principle of distributive justice (25,27,44).

Limiting the scope of NIPW testing

The decision surrounding whether to fund NIPW requires determining the types of conditions that should be permitted for testing and which of those should be publicly funded. We previously discussed Chen and Wasserman's unrestricted testing policy proposal, which would include testing for any condition or trait that prospective parents believe is useful for reproductive decision-making (15). However, most agree that testing should be limited to conditions that have clinical significance and actionability, where the condition can be treated and prevented before birth or treated following birth (10,11,16,19,21,24,25,27,30,33,43). Chen and Wasserman believe that only restricting based on medical severity simplifies reproductive decision-making because it is not the only factor in deciding about testing and termination (15). Testing for late-onset diseases or susceptibility genes that are not immediately actionable in extreme circumstances, such as when there is no treatment available and termination is an option, has also been viewed as justifiable for the scope of testing (21,28), but not by all sources (24). There is also a high degree of uncertainty regarding the utility and significance of results (10,11,15,17,28), which may or may not be useful for parents to learn (24). Testing "for information only", without intentions to act on results, can also be justified because there may be medical benefits to managing pregnancy or birth (23). With the exception of Chen and Wasserman, there was little support in the literature we reviewed for including non-medical and other minor genetic traits in the scope of testing (15). Overall, it is evident that it will be difficult to agree on a set of conditions and variants that should be permitted for testing (40); nonetheless, determining the scope of testing is essential for policymaking surrounding NIPW.

Counselling, education, and support

If NIPW is to be implemented in clinical practice, there would need to be policies surrounding the level of counselling and support required for prospective parents as well as healthcare professionals who will offer this counselling. For instance, several authors advocate for a comprehensive pretest counselling process for prospective parents prior to undergoing NIPW so they are informed of harms and potential benefits of testing (10,15,19,21,24-26,28,36) to help facilitate informed decision-making. Educating prospective parents to ensure they are offered comprehensible information about NIPW and including a decision aid tool to explain the technology might support choices to accept or decline NIPW (10,15,24,25,28,36). Nonetheless, some authors argue that even with extensive counselling[3] it may still be difficult for parents to usefully apply the information from NIPW because of the vast amounts of information involved (32). When women were asked what sort of information they wished to receive from their NIPW results, almost half wanted clear recommendations and all options presented, and more than one-quarter wanted all options presented along with a joint decision-making process (38). This reveals that women find counselling and support from healthcare professionals helpful for making decisions following NIPW testing. The literature also recognizes that although genetic counsellors are best placed to counsel patients, there may be a shortage of counsellors (15,17,26), which needs to be considered before the test becomes accessible. One idea to overcome this shortage is to implement web-based or virtual interactive genetic counselling to reach large numbers of patients and to standardize the complex information NIPW offers to enhance understanding (15,26,28).

To ensure that parents receive counselling, support, and adequate information and education, healthcare professionals require proper education and training. Currently, healthcare professionals are not trained to discuss the complex information involved in NIPW because it is not yet used in practice. In one study, most obstetrician-gynecologists reported that they were

[2] There are variations in how "severity" is defined in the literature. Chen and Wasserman acknowledge that prospective parents would define mild, moderate, and severe conditions differently, and is thus a subjective classification (15). It can be defined based on quality of life of the future child or even the level of burden the condition would have on prospective parents. While some argue for more broad definitions of "severity", Munthe believes that severe conditions are those for which "no conceivable extent of societal adaptation or support will reduce the burdens to parents sufficiently to make access to (prenatal testing) into a mere luxury product" (43, p.44).

[3] The definition of "extensive counselling" and what this includes is not well-defined or discussed in the literature. Extensive counselling in this context should, we suggest, involve guidance from qualified healthcare professionals to help parents interpret NIPW results and discuss options that are in line with the values of the parents.

uncomfortable with the idea of communicating NIPW results to patients, preferred to refer patients to genetic counsellors, and believed that they would not have the necessary resources to interpret results (17). Professional societies can contribute to education and training on NIPW (10,26,41) along with medical education programs for healthcare professionals (35). Overall, additional training for clinicians on how to present and return genetic information that correlates with patient preferences is necessary (38). Part of the policies surrounding clinicians' education should also include developing guidance on how clinicians returning results should manage incidental findings[4] such as misattributed paternity (28) or findings that have health implications for parents or close relatives (11,19). Policies should therefore elaborate on what information should be returned, to whom, by whom, and when, and should reflect patient preferences (21,24,26). Further, such policies should discuss what information clinicians are responsible for interpreting, and how and whether data should be stored or reanalyzed when knowledge about variants of unknown significance become understood in the future, and whether patients should be recontacted (24).

DISCUSSION

This review provides an overview of the ethical, legal, social, and policy implications (ELSI) for the potential future use of non-invasive prenatal whole genome sequencing (NIPW). This research is useful to further understand the main implications of NIPW's clinical introduction and to shed light on the main stakeholders affected by this technology. It can thus inform and guide policy decisions for the future implementation of NIPW, including the main factors and arguments that need to be elucidated for effective and ethically sound policies. The literature shows that there are competing interests between two principal stakeholders: the future child and the prospective parents. These competing interests often translate into tensions over the same ethical concern. For instance, when exploring ethical issues surrounding autonomy, we notice that the literature discusses this with respect to the autonomy of future children and the autonomy of prospective parents, which are in conflict with each other. Several articles (10,16,18-21,27,28) explore how NIPW affects the autonomy rights of future children, including rights to an open future – whether as future children or adults – because they will be unable to choose whether to know or not know genetic information about themselves (e.g., late-onset diseases) that can influence their life course (16,18,20,21,24,25). While most authors agree that there is a risk to undermining the autonomy of future children, others argue that NIPW enhances parental autonomy because it can inform prospective parents' reproductive decision-making (15,25,27,28,30,33,46). The literature expressed further concern related to threats over informed consent caused by information overload from NIPW (10,15,16,18,19,24).

Based on our literature review, NIPW-related policy should elucidate how the autonomy of the future child should be weighed against the autonomy of the prospective parents to resolve conflicts over testing for a certain condition, which might in turn, be a challenging and arduous task given the vast amount and complexity of information generated by NIPW. Professional guidelines on genetic testing provide insights but are sometimes ambiguous regarding how to resolve conflicts over testing for certain conditions. For example, in its position on *Prenatal Testing for Adult-Onset Conditions*, the US National Society of Genetic Counselors recommends that conflicts "between the right of prospective parents to obtain information and the right of the future child should generally be resolved in favor of the parents" (47, p.1144). However, the American Committee of Obstetrics and Gynecology states, "In pregnancies likely to be carried to term, […] the decision to test should be reserved for the child to make upon reaching adulthood" (48, p.1498), and parental preferences should also be taken into account (48). In another joint statement with the Canadian College of Medical Geneticists, the Canadian Paediatric Society argues that "children should only be tested when it is for the purpose of better medical care" (49, p.42) and "for genetic conditions that will not present until adulthood [susceptibility or predictive testing], testing should be deferred until the child is competent to decide whether they want the information" (49, p.45). While recommendations by various professional societies might offer some guidance for clinical practice, a future NIPW policy should carefully address the clinical uses of NIPW, including the information that should or should not be offered to prospective parents.

In reviewing the social implications of NIPW, an interesting implication involved the changes in family dynamics. Several articles (10,17,21,23,28,29) discussed how the way parents treat their children would undoubtedly change based on what they learn from testing, even if subconsciously. The influences of these changes are difficult to measure because they are contingent on the type of information shared with parents, how the information is presented, how parents perceive the information, and how they choose to act or not act on the information when raising the child. This implication is important to understand because it can motivate research that would determine the kinds of information that might affect childrearing, which might in turn, inform policymaking.

In addition to changes to family dynamics, NIPW can lead to altered societal perceptions, including our ideas of what is "normal" and "healthy" (21,24,36,42). The literature discussed whether and how this technology would shape our understanding of human nature, which is important to anticipate and consider before implementing NIPW. Some sources (21,25,28) acknowledged that altered perceptions can include discrimination against conditions and traits that do not meet newly defined standards of "normal" or "healthy". While it is possible that Chen and Wasserman's unrestricted policy testing for all conditions can put all traits on equal ground and does not decide that one disease is worth testing over another (15), it will not stop negative societal perceptions towards the conditions, especially if more people are born without these undesirable traits. It is important to discuss how changes in societal perceptions towards select traits will affect individuals with those traits. For these

[4] Incidental findings are findings that are discovered and are outside the primary goals of the test, which in this case, would be relevant for NIPW (45). They also include testing results that prospective parents have not inquired about and can reveal clinically significant information.

reasons – and since persons living with disabilities as well as disability group advocates are critical stakeholders – their perceptions and voices must be included in discussions surrounding clinical introduction of NIPW.

The literature also explored several policy implications for NIPW implementation. For instance, several authors (10,15,19,21,24-26,28,36) agree that there should be improvements in supporting and counselling prospective parents to inform their decision-making, although fewer articles (10,26,35,38,41) addressed the need for education and training for healthcare professionals. The challenge in providing adequate information requires, on one hand, that healthcare professionals are trained, educated, and well-prepared for NIPW implementation, and on the other hand, that prospective parents understand the information provided to enhance informed decision-making. From that perspective, decision aid tools (e.g., websites) might be developed to facilitate parental decision-making that is congruent with their own values and preferences.

As with any technology, NIPW raises questions of funding and coverage by the healthcare system. Several sources (24,26,32,33,40,41) argued that the downstream costs of additional testing, including data collection, interpretation, and follow-up can burden the healthcare system. In addition, others discussed further burdens involved with overtreatment and medicalization of less severe conditions (e.g., non-medical conditions) that could result from implementation of NIPW, which has implications for cost distribution and how costs for NIPW might deprioritize other health concerns. Whether funding NIPW is contingent on the type of condition to be tested and whether there should be a limit on the scope of conditions to be tested are important considerations for discussions on cost and accessibility. However, since the literature shows a knowledge gap surrounding how to define the limitations – if any – on testing, more studies need to be conducted on how and whether policies should limit the scope of testing. Such studies can involve consultations with policymakers, persons living with disabilities, and disability rights advocates, among others, to learn more about their perceptions on what a future policy regarding NIPW coverage and testing should involve.

At a macro level, policies and regulations required for implementing NIPW can be developed either at governmental or nongovernmental levels. Some authors believe that regulatory interventions are not required at the government level (28,29) and rather should be regulated through professional societies and nonbinding guidance to uphold parental autonomy (29). In addition, Sullivan and colleagues showed that only about 15% of pregnant women agree that governments should decide on the categories of fetal genetic information that can and cannot be returned (38). However, for those who believe that NIPW should not yet be offered to pregnant women, governments would need to be involved in implementing a moratorium on testing (21). While guidance and regulations through professional societies are critical to guide healthcare professionals and prospective parents in using and implementing NIPW, governmental regulation of NIPW are also important, especially in countries like Canada where parental autonomy and reproductive choice are highly valued. Therefore, more research should be conducted on the types of regulations that could be introduced to allow for the ethically permissible implementation and use of NIPW.

LIMITATIONS

The use of a critical interpretive approach to conduct this review allowed for a comprehensive set of data spanning ten years in the literature on this topic, which might not have been so extensive in a more rigid search strategy. Including several electronic databases in the search helped to mitigate retrieval biases while a secondary manual search procedure limited source selection and publication biases. However, there are some limitations that should be acknowledged. While only English and French language articles were included, including studies from all countries helped somewhat to mitigate the possibility of selection biases. Since this was a critical interpretive literature review, there is a possibility of interpretation bias in which it can be difficult to objectively interpret and communicate findings from the literature; involving two interpreters partially mitigated this problem. Also, it is difficult to anticipate implications as well as draw conclusions from the literature considering the paucity of research on NIPW. The lack of empirical research assessing opinions and perspectives towards NIPW from key stakeholders indicates that critical voices are not included and therefore, evidence-based policies cannot yet be made. However, the technology is still evolving and it is important to review the theoretical literature on this subject before implementation. Our understanding of this technology will improve when it is introduced into clinical practice and more healthcare professionals and patients have lived experience with NIPW testing.

CONCLUSION

The implementation of NIPW in clinical practice offers several benefits, but raises challenges at the ethical, social, legal, and policy levels. Some perceived benefits include providing parents more time to plan for a child with special needs, upholding parental autonomy and the right to know, as well as the therapeutic benefits that might be potentially offered to the future child. Potential challenges include the anxiety and stress that can manifest for both parents and children, the threatened autonomy and right to an open future for the future child, information overload that undermines parental informed consent, concerns for informational privacy of the future child, and negative effects on parenting and treatment of children. Societal concerns of implementing NIPW include the potential for eugenic attitudes in society and discrimination against people with disability, increased rates of pregnancy termination for minor traits, altered societal perceptions of “healthy” and “normal”, and a societal pressure to use NIPW. Some policy recommendations include those that minimize cost and maximize priority of health resources, education for healthcare professionals, increased counselling and support for parents, minimizing disparities in access to testing, and limiting testing to certain conditions.

Table 2. Example of questions raised by NIPW

- Should parents have access to all the information NIPW provides?
  - If yes, based on what criteria?
  - If not, what information should they have access to and why?
- Who should decide on limiting or not limiting access to the information generated through NIPW? Governmental or nongovernmental (e.g., professional societies)?
- Should NIPW be covered by the healthcare system for specific conditions?
- How should social disparities (e.g., income, education) be addressed in test access and use?
- How should results be managed?
- How should incidental findings be managed?

While this review sheds light on various factors to be considered when discussing NIPW implementation, it shows that many questions are left unanswered (see Table 2) and thus there are many avenues for research to explore. As discussion surrounding NIPW is still in its infancy, it is of great importance that these concerns be addressed to allow for safe, fair, and ethical implementation into practice.

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Launching the Newfoundland and Labrador Health Research Ethics Authority Act and Reflections on its Current Status

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Résumé
La Loi *Health Research Ethics Authority (HREA)* a été créée pour garantir que l'évaluation éthique de toutes les recherches sur la santé humaine dans la province de Terre-Neuve-et-Labrador est effectuée par un comité d'éthique de la recherche (CER) local, dans la province. La Loi HREA a été adoptée à la suite de plaintes déposées par des patients et des membres de leur famille participant à une étude de recherche clinique en génétique menée par une équipe de chercheurs de l'extérieur de la province qui n'ont pas assuré un suivi clinique approprié. Cet examen fournit un compte rendu des étapes de la rédaction de la loi et de la préparation de sa promulgation et comprend des informations sur les principaux intervenants impliqués dans le processus. Elle fournit également un bref commentaire sur la HREA et le nouveau Comité d'éthique de la recherche en santé, dans les années qui ont suivi la proclamation, et sur la façon dont la HREA s'aligne sur les intérêts nationaux d'harmonisation de l'évaluation éthique de la recherche dans plusieurs CER. Au départ, le processus a été envisagé comme un simple passage à un comité d'éthique de la recherche légiféré par la province ; cependant, la tâche réelle a consisté à établir une nouvelle entité pour superviser l'évaluation éthique de la recherche et à élargir ou améliorer le bureau nécessaire pour gérer cette supervision de l'évaluation éthique de la recherche. La tâche des comités de travail chargés d'établir la législation s'est avérée plus complexe que ne l'avaient envisagé les organisations partenaires, le gouvernement de Terre-Neuve-et-Labrador, l'Université Memorial de Terre-Neuve et l'Eastern Health Authority, et la charge de travail et le temps nécessaires pour établir et proclamer la législation ont été plus importants que prévu.

Mots-clés
intégrité, responsabilité, législation provinciale, Comité d'éthique de la recherche, Autorité d'éthique de la recherche en santé

Abstract
The *Health Research Ethics Authority (HREA) Act* was established to ensure that research ethics review of all human health research in the province of Newfoundland and Labrador is conducted by a local, in-province, Research Ethics Board (REB). The HREA Act arose as a result of complaints by patients and family members enrolled in a clinical genetics research study being conducted by a team of researchers from outside the province who failed to provide appropriate clinical follow-up. This review provides a record of the steps taken to draft the legislation and prepare for proclamation and includes information on the key stakeholders involved in the process. The review also provides a brief commentary on the HREA, and the newly formed Health Research Ethics Board, in the years following proclamation and how the HREA aligns with national interests for harmonizing research ethics review across multiple REBs. At the outset, the process was envisioned as simply moving to a provincially legislated research ethics board; however, the actual task involved establishing a new entity to oversee research ethics review and expanding or enhancing the office required to manage this research ethics review oversight. The task for the working committees involved in establishing the legislation was more complex than envisioned by the partner organizations, the government of Newfoundland and Labrador, Memorial University of Newfoundland and the Eastern Health Authority, and the workload and time to establish and proclaim the legislation was more involved than anticipated.

Keywords
integrity, accountability, provincial legislation, Research Ethics Board, Health Research Ethics Authority

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INTRODUCTION

The province of Newfoundland and Labrador (NL), Canada, is considered a valuable source of genetic information as a consequence of limited European settlement and migration over the past 200 years (1). This has led to considerable genetic research on the population by researchers within the province and from elsewhere. While this has resulted in numerous positive outcomes for the people of NL, there have also been a number of instances in which researchers have arrived in the province, engaged in research and not appropriately followed up with participants. As a result of a particularly egregious case in the 1990s involving clinical and genetics researchers from out-of-province and a lack of clinical follow-up, the NL government began a process to review genetics research policies in the province and set the stage to establish provincial legislation to oversee the research ethics review of all human health research to be conducted in the province.

In Canada the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, commonly referred to as TCPS (2)[1], established by the three major federal granting councils – the Canadian Institutes of Health Research (CIHR),

[1] There are three versions of TCPS cited in this document. The first is the original 1998 version (2). While working on the legislation and proclamation a second version became available with updates, TCPS2 (3). The current version of TCPS is TCPS2 2018 (20).

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Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC) – sets the guidelines for conducting human health research based on the three hallmarks of research ethics: a) respect for persons, b) concern for welfare and c) justice. The ethics review process serves as a mechanism of checks and balances to ensure that research participants are not exposed to undue harm and that the research is conducted ethically. For clinical research, there is an added ethical consideration with regards to the dual role that clinician-researchers play; that is, duty to care and their interests in pursuing health research (2), and with respect to genetics research, there is a further consideration of how newly discovered genetic information will be managed and shared with participants and, where applicable, family members (3).

The work to develop legislation for local research ethics review in NL owes a great deal to participants who had been enrolled in a clinically-based genetics research study, and their families. They initially complained to the provincial and academic authorities about inappropriate research practices in a study in which they or their family members were asked to participate. Over the course of 11 years a small group with affiliations to government, Memorial University, the Eastern Health Authority, the pharmaceutical industry and the private sector worked together to help draft legislation and support its implementation.

THE *HEALTH RESEARCH ETHICS AUTHORITY (HREA) ACT*

On July 1, 2011, NL became the first province in Canada to require that all human health research (publicly and privately-sponsored) to be conducted in the province be reviewed by a local (within the province) Research Ethics Board (REB) approved by the legislated oversight body, the Health Research Ethics Authority (HREA) (4). The HREA Act (4), which received assent 12 December 2006 and came into force on 1 July 2011, proclaims that the HREA (the Authority) is to ensure human health research in NL is conducted in an ethical manner and to enhance public awareness of the ethical dimensions of research. The Authority is responsible to the Minister of Health and Community Services. The legislation includes the timeframe of research ethics review and imposes penalties for individuals who do not comply with the Act. Since the legislation was passed, there have been two changes: a regulation was added to specify that, despite any other REBs approved under the authority, all clinical trials and genetics research be reviewed by the Health Research Ethics Board (HREB) established under the Authority; and in 2011, Section 2.1 (4) was added, recognizing the relationship with the Labrador Inuit Land Claims Agreement Act (5).

The purpose of this article is to describe the path from public response to unethical research practices to legislated ethics review, implementation of the Act and its aftermath. The authors participated in this endeavour from its inception in 1999 to implementation of the Act in 2011. At the time of inception, PMC served as the Chair and SB a member of the two main committees, described below (the Provincial Health Research Ethics Board Working Group and the Transition Team) involved in helping to draft the legislation and in the implementation of the Act. PMC, as the Associate Dean, Research and Graduate Studies in Memorial University's Faculty of Medicine, the office responsible for the management of Memorial's Human Investigation Committee (HIC, the REB that reviewed the majority of health research in the province), had experience with the operational issues of the research ethics review process. SB was the co-chair of the HIC and provided considerable expertise in the running of a research ethics review committee, and ethical issues relevant to both clinical and qualitative human health research. Both PMC and SB had served for many years as members of the HIC and participated in national organizations concerned with research ethics review. This report is a subjective account – based on minutes and meeting notes, presentations, email exchanges and personal notes – to describe the sequence of events leading to implementation of the HREA Act. As there was no precedent for provincially legislated ethics review in Canada, the transition to legislation required consideration of a new approach to how to seek ethics approval. A list of the milestones leading up to the legislation is provided in Table 1.

Table 1. Milestones in the development of the HREA Act

Event	Date	Outcome
Formal stakeholders committee – Provincial Advisory Committee on Human Health Research	Jan 2000	Two committees were established: • Provincial Health Research Ethics Board (PHREB) Working Group • Genetics Standards Development Working Group
Skanes' White Paper presented to House of Assembly	May 2000	Discussion began on legislation for oversight of research ethics review for the province
National Council on Ethics in Human Research (NCEHR) Site Visit	1 Mar 2001	Review of the procedures and operations of the Human Investigations Committee (HIC)
Experts Panel	Jul 2001	Review of genetics research and the proposed legislation
1st MOU signed by Minister of Health and the President of Memorial University	Apr 2002	Established the basis on which discussions would continue for province-wide research ethics review
Meeting with government Social Policy Committee	May 2003	Government gave support to proceed
Health Research Ethics Authority Act	12 Dec 2006	Assent

SETTING THE STAGE FOR LEGISLATION

In the 1990s a group of residents of central Newfoundland, who were participants in a genetics study conducted by an out-of-province American research team (from Baylor University, in Texas), complained to the provincial clinical genetics team and the local research community about lack of follow-up and clinical care associated with the research. At the time, researchers

affiliated with institutions from outside the province (out-of-province) interested in conducting research in NL were expected to have research ethics review from their home institutions; however, there was no requirement for contact with appropriate health care providers or local researchers within the province. These researchers would not necessarily have been known to the health professionals or researchers in the province. Following complaints from the research participants and family members, an investigation by both the out-of-province research team's university Institutional Review Board (IRB) and the U.S. Office of Health Research Protections of the National Institutes of Health, led the IRB to withdraw approval of the study and to suspend the research privileges of the three researchers associated with the study for a three-year period. This widely publicized situation (6-9) highlighted the vulnerability of participants in research studies where the researchers involved were not responsible to a local authority. As a result, the provincial Department of Health and Community Services (DHCS) commissioned Dr. Verna Skanes, a retired senior administrator of the Faculty of Medicine, Memorial University, to review how human genetics research was conducted in the province, in particular, with respect to patient participation, participant safety, research ethics review and commercialization of results. Dr. Skanes' White Paper concluded that the province needed "a clearly articulated policy, covering both academic and private studies, for research ethics review of all human research projects" and that the province should: "establish as soon as possible a provincial research ethics board" (10).

At the time, human health research conducted by researchers in NL received ethics review from several different REBs. Researchers affiliated with Memorial University of Newfoundland (the sole university in the province) or one of the regional health authorities were required to submit to a local (in-province) REB, following guidelines set by the TCPS (2), and Health Canada Guidelines for clinical trials. Several boards existed for this purpose throughout the province. The largest of these was the Human Investigations Committee (HIC), which served the largest group of health researchers from Memorial and the Health Care Corporation of St. John's (forerunner to the Eastern Health Authority). This was the largest teaching and tertiary care hospital system in the province. Clinical researchers in private clinics often acquired research ethics review through out-of-province, for-profit REBs. Researchers from out-of-province, who were interested in conducting research in NL, received ethics approval from their home institution. As described above, there was no requirement for these out-of-province researchers to contact appropriate health care providers, local researchers or REBs within the province.

In response to the Skanes' report, and following a meeting of provincial stakeholders (representatives from the regional health authorities, health boards, private and academic researchers, provincial government, and Memorial University), in May 2000 the Department of Health and Community Services (DHCS) established two working groups: the Provincial Health Research Ethics Board (PHREB) Working Group and the Genetics Standards Development Working Group[2]. The PHREB Working Group was tasked with making recommendations on legislation for research ethics review of human health research conducted in the province. Topics identified and discussed by the PHREB Working Group became significant components of the HREA Act. Members of the Working Group had extensive experience in conducting research, REB review and administration, and included: the co-chairs of the Human Investigations Committee (HIC); the Associate Dean of Research and Graduate Studies, Faculty of Medicine, Memorial University; the Manager of the Patient Research Centre, Eastern Health; and representation from the Western Regional Health Authority, the DHCS, the NL Health Boards Association, private clinical practice, and the social sciences. With the assent of the legislation in December 2006, the Working Group was discontinued but its members, along with other members from relevant stakeholder communities, became the Transition Team responsible for the implementation of the legislation.

Background to drafting the HREA Act

At the time that the PHREB Working Group was created, the extent of the task ahead was not fully appreciated. The Skanes' report (10) provided a framework to begin consideration of a province-wide human health REB but the practical challenges (for example, the governance oversight of the REB, including financial and human resources) of how this would be accomplished needed to be addressed. Over the six years that the Working Group met, they engaged with members of the government, the university, the regional health authorities and existing REBs, and they invited input from recognized experts in the area of ethics review from outside the province. These meetings were important to understand the unique concerns of various jurisdictions, such as concerns related to the over-study of populations, and financial and human resource issues.

In working with government, it was clear that basic terminology sometimes created a challenge. For example, in Canada, the committees that provide ethics review of research are called Research Ethics Boards (REBs). However, the use of the term "board" does not imply that the REB is a business or corporate board reviewing and approving the operational activities or the strategic direction of an organization. Once this difference in the meaning of the term "board" was understood it became necessary to define a structure to oversee the management, human resources and financial operations, tasks which had been done by the University, for a province-wide REB. The task of the PHREB Working Group to "establish as soon as possible a provincial research ethics board" (10) was thus more complicated than originally anticipated and resulted in legislation that recognized the necessity of an overarching organizational entity, the HREA. The challenges of the Working Group centred around six topics.

Stand-alone versus amendment to existing legislation

Although Skanes had recommended legislation, it was not clear if this was best accomplished through existing legislation – such as the University Act (11), for example, which regulated the HIC, or the Health and Community Services Act (12) which

[2] The Genetics Standards Development Working Group, tasked with clarifying the policy implications of commercial genetic research, provided a final report to the DHCS (Jan 2003): *Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador.*

addressed the protection of the health of the public – or if new stand-alone legislation was required. The Working Group reviewed these options and following meetings with government and Memorial University's legal counsel, it was determined that to satisfy the basic principles required for oversight of health research ethics review across the province, the most appropriate path was stand-alone legislation focused specifically on local (within the province) health research ethics review. Moreover, such legislation would need to apply to both institutional (all academic areas, including clinical) and community-based researchers. Stand-alone legislation would also provide a mechanism for an inventory of all human health research being conducted in the province. The proposal for stand-alone legislation for human health research ethics review was presented to and approved by the government's Social Policy Committee (the committee responsible for reviewing Cabinet submissions on social policy, including health and community services) in May 2003, three years after we had begun the task.

Recommendation for the Health Research Ethics Authority (HREA)

At the time that the legislation was being developed, the existing REBs in the province were managed either through the hospitals or, in the case of the HIC, Eastern Health and the university shared management through an office of Memorial University. Once it was understood that the new provincial REB would not oversee human and budgetary resources, the PHREB Working Group proposed the establishment of the HREA (the Authority), with responsibility for oversight of the office responsible for the new HREB; educating current and potential researchers in research ethics and public awareness of ethics review of health research in the province (Section 5(2) of the HREA Act); providing government an annual report of all health research being conducted in the province (Section 22 of the HREA Act); and approving any other research ethics bodies that met the standard for research ethics review (Section 8 of the HREA Act). The recommendation was that the HREA be a small board with members from the three major stakeholders – DHCS, Eastern Health and Memorial University – and a representative at-large from the community; the Chair of the HREB would sit as an *ex officio* member of HREA (Section 3 of the HREA Act) (4).

Existing Research Ethics Boards

A major issue for the PHREB Working Group was to determine how the REBs that were currently in place should be considered with respect to the legislation. For example, should the REBs of Memorial University or of the regional health authorities continue to exist with the new legislation applying only to studies conducted by out-of-province researchers? Key to this discussion was what to do with HIC, the REB which reviewed the largest number of health research studies in the province. The HIC, established in 1969, was known to the health research community and was the REB used by the major health research institutions of the province (Memorial University and Eastern Health).

The outcome of meetings with members of the three University REBs – the HIC, the Interdisciplinary Committee on Ethics in Human Research (ICEHR), and the ethics board of Grenfell College – and the hospital ethics committees of the regional health authorities was that the legislation should apply to all health research in the province (Section 9 of the HREA Act) and that all of the currently existing boards would adhere to the new legislation. A regulation subsequent to the legislation required that the provincial Health Research Ethics Board (HREB, Section 7 of the HREA Act) would review all clinical trials and genetics research. Other REBs (which are referred to as research ethics bodies in the Act, Section 8 of the HREA Act) that met national standards for research ethics review – at the time of proclamation, the TCPS2 (3) – and were not-for-profit, would be eligible to be approved under the new legislation but they would not be eligible to review clinical trials or genetics studies. By the time the legislation was enacted, the REBs affiliated with Grenfell College and three of the regional health authorities (Central, Western and Labrador-Grenfell) had all declined to be approved under the Act. The Grenfell College REB would continue to review non-health research; the three regional health authorities would continue to review research for resource-appropriateness to their institution, but no longer include research ethics review.

The Working Group determined that under the new system, researchers would be required to notify the HREA of their submission for ethics review and to name the REB (that is, HREB, ICEHR or another approved research ethics body) to which the protocol was submitted. In transitioning to the new system, it was also recognized that it would be essential to establish a "board of record" process for research that had been initially approved by a REB that ceased to exist.

Ethics review of health research in the social sciences and humanities

Considerations of the broad spectrum of research to be included under the rubric of "health" helped formulate the legislation. These discussions also confirmed the need to include, in the guiding "principles" of the PHREB Working Group and, subsequently in the legislation, a broad definition of health research that included the social determinants of health. It was this definition that was written into the HREA Act (4). A particular concern was raised with respect to health-related social sciences and humanities research. The first iteration of the TCPS (2) was based on the Medical Research Council's "*Guidelines on Research Involving Humans*" and "*Guidelines for Research on Somatic Cell Gene Therapy in Humans*" and replaced the SSHRC document "*Ethics Guidelines for Research with Human Subjects*". Social sciences and humanities researchers, particularly those using qualitative methods, were concerned that new legislation would further impose a medical model of research ethics review. In order to appropriately consider these issues, the membership of the Working Group and Transition Team always included one or more social scientist researchers.

Timing of research ethics reviews

The length of the review process was a significant issue for the PHREB Working Group and Transition Team. Time to approval was frequently criticized by researchers despite data indicating that delays were often due to delayed responses from the

researchers to REB queries (personal communication, Chairs of HIC). Community physicians were particularly apprehensive and repeatedly noted that delays in approval for clinical trials could mean losing the opportunity to participate in national and international studies. This issue was of sufficient concern to prompt several community physicians to meet with the Minister of Health. The Working Group met with clinicians within the greater St. John's area individually and in group dinner-meetings to discuss the timing of the review process, and how to improve efficiency and to encourage the involvement of private physicians as members of the HREB. As a result, the legislation specifically incorporated clauses to require a timely ethics review of all health research (Sections 9(3) and 9(4) of HREA Act).

Financial and human resources

Early on in its deliberations, the PHREB Working Group established a basic budget and work-plan for the operation of a provincial REB. The initial estimates of expenses for province-wide research ethics review modeled the operation of the HIC. At that time (1999-2000) the cost of running the HIC was borne by the two partner institutions, the Faculty of Medicine of Memorial University and the Health Care Corporation of St. John's (forerunner of the Eastern Health Authority). Expenses included hosting bi-weekly REB meetings, a single secretarial position, an honorarium for the chair of the HIC, a small travel budget to attend national meetings, funding for distribution of the review packages and office expenses for communicating with members of the HIC review board, particularly those outside the hospital and university. Expenses such as office and meeting space, insurance, phone and internet, were in-kind contributions provided primarily through the Faculty of Medicine. The earliest budgets, submitted to the DHCS, reflected the need for a senior level person, an Ethics Officer, to manage the office and additional secretarial support, and that expenses would also be required to fund monitoring, additional office space and start-up costs including upgrades to computer facilities. Budgetary information also included revenue derived from fees for review of industry-sponsored clinical trials. In May 2003 the government's Social Policy Committee, in a meeting with the Working Group, continued to acknowledge their commitment to the province-wide research ethics review. It was recognized that the DHCS, Memorial University and Eastern Health would be the primary parties involved in offsetting expenses for the HREA. However, from the outset it was acknowledged that the new HREA would be a unique entity not directly administered by any one of the participating organizations. Where possible, efficiencies would be achieved to reduce overall expenses, including in-kind contributions that would allow for savings in such areas as space and IT support. As with most organizations, budgetary considerations and human resources continued to be major points of discussion for the Transition Team, and as expected, remain as complex issues for the HREA.

Memorandum of Understanding

During the course of discussions by the PHREB Working Group, Memorial University and the DHCS signed a Memorandum of Understanding (MOU) to acknowledge their on-going commitment to province-wide research ethics review and to establish the basis on which the discussions would continue. Included in the MOU was a commitment by both organizations to protect and safeguard research participants by ensuring a comprehensive ethics review of all human health research, to promote the education of health researchers and the community and to provide recommendations on health research ethics policy. The MOU acknowledged financial support from Memorial University in partnership with the Health Care Corporation of St. John's (forerunner of the Eastern Health Authority) and the role of DHCS to provide funds to cover any additional costs associated with the operation. The MOU was signed by the Minister of Health and the President of the University in April 2002 and was used as a basis for further discussions leading up to the proclamation of the legislation.

External consultations and information sessions

As noted previously, leading up to the legislation being passed, consultations were held with research ethics experts from outside the province. These included consultations that were purposely requested to obtain feedback from national experts in the field, including an Experts Panel[3] and members of the Federal Panel on Research Ethics (PRE), which was responsible for the TCPS; consultations that took advantage of other meetings being held in the province, (e.g., National Council on Ethics in Human Research (NCEHR) site visit in 2001); and informal interactions with ethics scholars at meetings in other parts of the country, in particular, the annual meetings of the newly formed Canadian Association of Research Ethics Boards (CAREB). The consultations were useful in confirming the value of establishing a provincial REB. They were especially helpful in focusing attention on aspects of the legislation that would need to be considered if the provincial REB was to provide timely review: addressing issues around publicly and privately funded research, triaging clinical versus social science and humanities health research, and addressing the need for monitoring approved studies and their review process. These early consultations often focused on the issues related to the REB and less on the management of the research ethics office.

Members of the PHREB Working Group had several meetings to consult with the research community and research ethics or resource committees across the province to consider the legislation and how it would change the way in which research ethics would be reviewed and by whom. These sessions were meant to provide information to the community on the development of the new law as well as to gain feedback to be considered in the final legislation and how it would be administered across the breadth of the province. Not least important was softening the loss of autonomy of the smaller REBs being subsumed under the HREA. These sessions continued through the transition period and consisted of face-to-face meetings as well as teleconferences and phone conversations with departments, REBs, individual researchers and clinicians.

[3] The Experts Panel consisted of three internationally recognized experts in the field: Timothy Caulfield (Research Director of the Health Law Institute, University of Alberta), Michael McDonald (Maurice Young Chair in Applied Ethics and Director of W. Maurice Young Centre, University of British Columbia) and Douglas Kinsella (Professor of Medicine (Rheumatology), Director of Medical Bioethics and Assistant Dean of Research and Bioethics, University of Calgary).

TRANSITION TO THE HREA

Following assent of the HREA Act in December 2006, the PHREB Working Group was discontinued and the Transition Team[4] appointed. Several members of the Working Group continued as part of this Team, including the past and current chairs of the HIC, the Associate Dean Research and Graduate Studies (Faculty of Medicine, Memorial University), the Manager of the Patient Research Centre (Eastern Health) and a member from the NL Health Boards Association. In addition, the Transition Team added a representative from the DHCS, an additional member from Eastern Health (Vice President Quality, Patient Safety and Planning), the Chair of the ICEHR, and representatives from private clinical practice and Rx&D (Canada's Research-Based Pharmaceutical Companies). When appointed in 2007, the Ethics Officer for HIC also became a member of the Transition Team. As with the Working Group, the members of the Transition Team had extensive experience with research and research ethics review. Although there were slight changes in the work titles and job positions of members of the committee, over the next five years (2006-2011), only one member – who had retired – resigned from the Transition Team. Three members of the Team had been present from the outset (since 1999) and they continued to provide the historical context in which this legislation was developed. Several members of the Transition Team participated in national organizations and committees that related to the establishment of province-wide research ethics review for NL. One member of the Transition Team sat on Health Canada's REB; three members participated in CIHR committees (to provide recommendations for the National Strategy for Patient-Oriented Research, privacy best practices, and research involving Indigenous Peoples); one had been a board member of the NCEHR; one had been a board member of CAREB; and two members of the Team sat on the Canadian General Standards Board (CGSB) developing standards for REBs overseeing biomedical clinical trials. Four members regularly attended CAREB meetings.

The Transition Team developed Terms of Reference which focused on the four primary activities described in detail below: 1) communication and information sharing, 2) planning for implementation of the HREA Act, 3) implementation of concurrent legislation, i.e., the Personal Health Information (PHI) Act, and 4) developing the policy manual. The Team regularly informed its three partners – DHCS, Eastern Health and Memorial University – of activities and progress, either directly through their representatives on the Team or by formal correspondence from the chair of the Transition Team to the Minister, CEO and President of those organizations. In addition, the Rx&D received feedback through their representative member on the Team.

The development of the policy manual was done by the Policy Advisory Group (PAG), which had evolved from the Policy Advisory Committee of the HIC established in 1996. The PAG included four members of the Transition Team in addition to a representative from the School of Nursing at Memorial University and the community, all with the same breadth of ethics review experience as the Transition Team. The considerable overlap in membership between the two committees ensured that development of recommendations on policies informed discussion for the Transition Team and that, as the policy manual was drafted, it was aligned with the recommendations of the Transition Team. This was particularly important in operationalizing the activities of the HREA office and the HREB and, at proclamation, facilitated a more seamless transition. Initially, the Transition Team and PAG met on alternate weeks but moved to more frequent meetings in the year leading up to proclamation.

Communication and Information Sharing

Informing the local communities

The purpose of the Transition Team's communication strategy was to ensure that there was continuing and consistent messaging to the community, expanding the communications that had begun under the PHREB Working Group in 1999. Several tools were used, including development of a website and newsletters and presentations and messaging notes for specific groups, as well as articles in the *University Gazette* and letters to a variety of stakeholder groups. In addition, the Transition Team met, either face-to-face or by conference call, with groups from across the province to describe the transition to the new province-wide research ethics review process and discuss how the new legislation would affect their work.

In order to assist with consistency the Transition Team used a common slide template, in every presentation, which included the names of the members of the Transition Team and their affiliations; a statement from the Act indicating that all health research in the province would need to be approved by the HREB or an approved research ethics body; membership and role of the Authority; the organizational chart; distinction between the HREB and other research ethics bodies; distinction of research ethics review from resource allocation reviews; and the website and contact information for the HREA Transition Team. As necessary, additional slides were included that provided unique information for a particular audience. For example, in presentations to the clinical community, information was provided on timelines of the review process and review fees for clinical trials. In contrast, presentations to the ICEHR community focused on how existing boards, such as ICEHR, would relate to the HREA and how qualitative research studies would be reviewed. A second measure, which helped with consistency and also gathered feedback from the stakeholder communities, was to have at least two members from the Transition Team present at the information sessions, one to lead discussion and the other to take notes. The issues raised from these sessions were helpful in discussions at the regular meetings of the entire Transition Team.

[4] The Transition Team included: F Brunger, S Buehler, R Coates, L Felt, B Fisher, J Harnett, J House, M Khraishi, W Miller, P Moody-Corbett, R Neuman and L Purchase.

Sessions were conducted with a number of groups to reach as many researchers, REB members and the public as possible to describe the role of the transition team and the new legislation in relation to their work and research ethics review. Often, sessions were repeated in order to provide updates and progress. This was done, for example, with the physicians and administrators in the three regional health authorities not represented on the Transition Team (Central, Western and Labrador-Grenfell), Indigenous groups, physicians and nurses in the community, and the university community at large. In addition, upon request, sessions were held with specific groups such as the Cancer Care Program, the Health Research and Primary Healthcare Research Units, the Privacy Commissioners Office and the Newfoundland and Labrador Centre for Health Information. The information sessions were well attended and feedback from the participants was useful in aiding the Transition Team to address details necessary for proclamation, e.g., timing of review, storage of data.

Participation in national organizations and committees

Through associations with national organizations and committees, members of the Transition Team were aware of, and participated in, strategies being used in other provinces and nationally to streamline and harmonize the research ethics review process. The connections provided an opportunity to solicit information on best practices and proved useful in directing the Transition Team on common procedures. These interactions were also an opportunity to inform the community outside NL of the changes that would be occurring in research ethics review in the province. In addition, contacts with two national offices, PRE and NCEHR, were particularly important during the transition period. During these five years from assent of the HREA Act to proclamation, PRE was undertaking an update of the TCPS (2). One face-to-face meeting and correspondence with the Executive Director, responsible for the TCPS, was important to ensure conformity of the HREA Act with the 2nd edition (TCPS2 (3)) as well as to provide input to the Executive Director on points of the legislation relevant for consideration in TCPS, such as implied consent and protecting vulnerable participants. The President of NCEHR also provided advice and support for the HREA Transition Team. It was hoped that NCEHR, as an independent body, would provide the required appraisal of the HREB and any other research ethics bodies approved under the HREA Act. However, financial support for NCEHR from the national granting councils was discontinued prior to the proclamation of the HREA Act. Consequently, the Transition Team recommended that this critical assessment be provided by experienced former members of the NCEHR site visit team living outside the province.

Communicating the date of proclamation

A frequent question asked by community members, researchers and others during the many information sessions was the date when the HREA Act would come in to affect. However, throughout the time leading up to implementation of the Act, the government was unclear on the date of proclamation. Initially, the timeline for proclamation had been set for early in 2008; that date was cancelled. The DHCS was unable to commit to a suitable timeline and by 2009 the date of proclamation was indefinite. The HREA Act was eventually proclaimed in 2011, four years after the Transition Team had received their first notification to be ready. This resulted in ongoing information sessions over an extended period of time, with concern raised by both local and national groups on whether the province would be capable of implementing the Act.

Planning for implementation of the HREA Act

As described in this section the Transition Team focused on five major themes that needed to be in place in order to implement the Act.

HREA Board

The Act established the Authority as the oversight body to ensure human health research was conducted in an ethical manner and to enhance public awareness. One of the first roles of the Transition Team was to make recommendations to the Minister, DHCS, the President of Memorial University and the CEO of Eastern Health on the appointment of members to the Authority. The initial members of the HREA Board were named in December 2007 and although this group met informally by conference call and for one face-to-face meeting, the HREA Board of Directors would not be a formal entity until the time of proclamation on July 1, 2011. By this time there had been a number of changes to the status of the originally named board members, and new appointments were made close to the date of proclamation. While the HREA was still an unofficial entity, the Transition Team was given responsibility for providing the plan and procedures to implement the Act and to keep the HREA Board of Directors and the partner organizations apprised of progress in this regard.

Ethics Officer and human resources

Although the HREA was to be a stand-alone entity it was also recognized that it initially would not have the resources or expertise to hire permanent staff. A major challenge in implementing the legislation was to provide a continuation of services for research ethics review through the transition period. For instance, an application submitted to the HIC would have a response from the newly established HREB, within the legislated time period. In order to assist the Transition Team in making recommendations, the staff undertook a review of similar offices in other health research institutions (both university and academic healthcare organizations) in Canada. The review was valuable but clearly demonstrated considerable variation in both human resources and workload among institutions. Given the importance of retaining experienced staff immediately before and after proclamation, it was recommended that the HREA continue the arrangement with the partner organizations, Memorial University and Eastern Health, regarding staff assignments. However, as described below, in anticipation of the new HREB, which would replace the HIC, there were necessary changes in the office arrangement and staffing.

On recommendation of the PHREB Working Group a senior level position had been created, the Ethics Officer, financed by an arrangement between Memorial University and Eastern Health. The Ethics Officer became a member of the HIC office, the Transition Team and the PAG and worked with the HIC co-chairs to manage the application process and oversee the daily office management. In reviewing human resource needs for the HREA office and considering the projected workload it was recommended that the office have, in addition to the Ethics Officer, two ethics coordinators, one for each sub-committee and also a general secretarial position; as described in the next section, the HREB would operate with two subcommittees, one responsible for clinical trials and genetics research and the other a general health research review committee. The Transition Team also suggested that from time-to-time additional staff might be required, e.g., during vacation periods or times of particularly heavy workload.

HREB review committees

Through the transition period the HIC continued to operate as a REB for the Faculty of Medicine and Eastern Health and was used as the basis for establishing the HREB. However, it was not clear how the HREB would be structured in order to efficiently review an expanded clinical workload. Under the legislation, all health research – including research by community physicians or researchers from outside of the province not currently reviewed by the HIC – would be reviewed by the HREB. While it was not possible to get an exact account of the number of community physicians engaged in clinical research, it was clear (through meetings with physicians in the greater St. John's region and individual discussions with physicians) that, despite the overlap in trials being conducted through both institutions and private practices, there could be a substantial increase in the number of applications to the HREB. The legislation had indicated clear timelines for review of applications; in order to accommodate an expected increase in numbers, particularly of clinical trials, the breadth of research to be reviewed, and legislated timelines, the Transition Team recommended that the HREB have two research ethics review subcommittees: the Clinical Trials Committee (HREB-CT) responsible for reviewing clinical trials of drugs, devices, and genetics research, and the Non-Clinical Trials Committee (HREB-NCT) responsible for reviewing all other human health research.

In anticipation of the earlier proclamation date communicated by government (i.e., 2008), an advertisement for Expressions of Interest to serve on the HREB had been publicized in local newspapers, as well as in the Memorial *University Gazette*. A list of potential members for the HREB was established based on fulfilling the membership requirements described in the legislation (Section 7 of HREA Act), the TCPS2 guidelines for membership to REBs (3), and recommendations being made by the CGSB (Canadian General Standards Board) committee for REBs reviewing clinical trials (13). Fortunately, a number of the HIC members were interested in continuing to serve as members of the new HREB and would provide experience and continuity. From the pool of eligible applicants, HREB members were assigned to each of the two subcommittees, allowing for staggered terms of appointment from one to three years. Through the work of the PAG (Policy Advisory Group), it was proposed that the HREB have a Chair and Vice-Chair, each of whom would serve as chair of one of the subcommittees. In addition, the Chair would sit on the HREA as an *ex-officio* member. To ensure a smooth transition period, the selection of the initial Chair and Vice-Chair was from those research members of the HIC who had considerable experience in the ethics review process.

Approval of HREB and Research Ethics Bodies

The purpose of the HREA Act is to ensure that all human health research conducted in the province is approved by the HREB or a local HREA approved research ethics body (Section 9(1) HREA Act). This required the Transition Team to develop a procedure for approval of the research ethics bodies as well as putting in place a mechanism to record all the human health research being conducted in the province. The Transition Team identified NCEHR as the national body that was most suited to provide an assessment of the HREB and other research ethics bodies in the province, based on their experience in assessing Canadian REBs. However, as noted earlier, national funding for NCEHR was cancelled in 2010 prior to the proclamation of the HREA Act and the NCEHR assessment process was discontinued. As a result, the Transition Team recommended that assessment of the HREB and any other research ethics bodies applying for approval be provided by experienced members of the former NCEHR site visit team who lived outside the province.

In order to document human health research being conducted in the province the Transition Team recommended that a notification form be submitted along with the application to the HREA. The proposed notification form was a simple document that, in addition to identifying the name and contact information for the researcher and affiliated institution(s) or organization(s), identified the position of the principal investigator, the type of research being conducted, where the research was to be conducted and from which REB or research ethics body the researchers were seeking approval. This process would provide an inventory and a single point of information regarding all health research being conducted in the province. With this notification, it would be possible to provide accurate information on the number of human health research studies submitted for review, approved and being conducted in the province of NL, information that would be unique in Canada.

Financial considerations

Once legislation was in place, a major responsibility for the Transition Team was estimating the budgetary requirements of the HREA, including potential sources of revenue. As described earlier, the initial budget for the provincial HREB was proposed to DHCS in 2000 and was based on the expenses of operating the HIC in the late 1990s. At that time, the expenses were shared between the Faculty of Medicine of Memorial University and Eastern Health; in addition, the Faculty provided a number of in-kind contributions. However, by the time the legislation was drafted there had been a number of changes that made it clear that the new HREA would require more resources than those originally anticipated. For example, it became clear that in addition to a provincial health research ethics board (the HREB) to replace the HIC, the HREA would be responsible for approving additional research ethics bodies, documenting all human health research in the province, managing the operations

of the HREA office and providing public education regarding health research ethics review. As well, the legislation included a requirement for reviews to adhere to strict timelines; with the anticipated increase in the number of protocols to be reviewed, it was expected this would translate to increased workload, and thus expenses, despite increased income from industry trials. As noted earlier, the recommendation that the HREB have two subcommittees (HREB-CT and HREB-NCT) to manage the workload required additional staff. Furthermore, with the stand-alone nature of the HREA came new expenses related to meeting and office costs, insurance, and audit. It was also clear that the national and international procedures for research ethics review were changing, and it would be important for the HREA to ensure representation at national and international meetings to maintain up-to-date information. As a result, the estimates were outdated by a decade and the financial needs were considerably higher than originally envisioned. Any additional or new activities, such as an appropriate system to monitor on-going research for adherence to ethics approvals, would result in further expenses.

There were four sources of revenue for operating the HREA and HREB: the government, Memorial University, Eastern Health and review fees for industry-sponsored clinical trials. During the lead-up to proclamation there was no way to know how many community trials might need to be reviewed by the HREB and so the fourth source of revenue, review fees, was an unknown. The final budget, prepared by the Transition Team for the partner organizations (DHCS, Memorial University and Eastern Health), included estimates of revenues considering varying numbers of research protocols to be reviewed, in-kind contributions and continuation of revenue from Memorial University and Eastern Health. However, full agreement on the budget, from all parties, was never completely resolved prior to proclamation. Particularly worrying was how a shortfall would be handled, which relied upon the MOU signed in 2002 and verbal commitments through joint meetings of the parties. Despite this risk, plans for proclamation proceeded.

Concurrent legislation: Personal Health Information (PHI) Act

Two years after the HREA Act was passed, the government of NL passed legislation (June 4, 2008) for handling personal health information (PHI Act (14)). The PHI Act, which applies to both public and private data custodians, establishes rules related to the collection, use and disclosure of personal health information as well as an individual's right of access to and correction of their own health information. Because of the significance of the use and disclosure of personal health information in research, and to assist in coordinating proclamation of both HREA and PHI Acts, the Chair of the HREA Transition Team was also a member of the PHI Act Implementation Steering Committee. The Steering Committee established seven Working Groups. The HREA Transition Team Chair was the Chair of the Working Group focused on health research, the role of which was to provide advice and recommendations to the Steering Committee on the implications of the PHI Act for the health research sector.

The relationship between the HREA Act (4) with the PHI Act is found in Section 44 of the PHI Act (14). This section provides that disclosure of personal health information for research purposes can only occur if the research has been approved by a REB or research ethics body approved by the HREA. As outlined in the HREA Act, the HREB or ethics review body must be assured that the researcher will take sufficient measures to safeguard personal health information, including confidentiality, privacy and security of the information. The REB approving the research study is required to monitor the researcher's recordkeeping, adherence to the approved protocol, conduct of the study and privacy safeguards (Section 11, HREA Act); it has the authority to suspend research that it believes is not being conducted properly (Section 11(5), HREA Act).

Policy Manual for the HREB

Over the many years that the HIC provided ethics review it had established policies to facilitate consistent review and practices, and in 1996 a policy review committee was formally created to look after policies. Once the HREA legislation was passed in 2006 this committee was renamed the Policy Advisory Group (PAG) to serve a role similar to the HIC policy review committee in providing advice to the HREB and taking responsibility for developing and maintaining a Policy Manual for the new HREB. The PAG prepared a Policy Manual to document for the Transition Team the policies to guide the new HREA and HREB. The Manual continues to be available as a resource document (HREB Policy Manual) at the HREA website (www.hrea.ca). The manual includes a brief introductory section to provide the context for the HREA Act and the establishment of the HREB as well as a brief description of the historical context and the principles of research ethics review. It addresses a number of specific policy topics, including: the membership, function, operation and documentation of the HREB; the management of the ethics office, including staffing and staff responsibilities; the review process, monitoring, appeals, consent-assent, and required signatures; policies related to handling special populations including Indigenous communities, children and youth, and those with cognitive impairments; and policies protecting privacy the membership and personal health information.

REFLECTIONS ON THE PROCESS

The establishment and implementation of the HREA was a long process and along the way there were challenges and opportunities for the committees. In this section, we provide a description of five major issues that demonstrate the strengths and weaknesses of the process. The information may be useful for those involved in developing similar legislation or for those research ethics review organizations that are undergoing change. Before considering these issues, however, it is important to recall why the legislation came to exist. In the late 1990s and early 2000s members of the public had made a complaint to the NL government and provincial clinical genetics team regarding clinical genetics research being conducted by out-of-province researchers; the lack of follow-up was at the crux of the issue for families and participants in these studies. Given that the

TCPS identifies duty to care and to “act in the best interests of patients” as crucial considerations for clinical researchers conducting health research (TCPS2 Chapter 11.A (3)), it was unclear how or why the lack of clinical follow-up had occurred. The government of NL needed to understand what could be done to avoid similar circumstances from happening in the future. The Skanes’ report (10), in 2000, was the starting point for developing provincial legislation that would require local research ethics review of research involving Newfoundlanders and Labradorians. As the process to establish legislation proceeded over the years, the fundamental issue at the heart of the legislation – protection of research participants – was often lost from sight as key players from the partner organizations came and went.

Working committees and resources

There were three primary committees involved in the process of drafting legislation, shepherding the transition to proclamation and implementation: the PHREB Working Group, the Transition Team and PAG. Minimal resources were provided to these committees, and no specific secretarial staff was available for this task. The PHREB Working Group initially met monthly then biweekly, a pattern that was continued by the Transition Team; PAG and the Transition Team met on alternate weeks. In the year leading up to proclamation more frequent meetings were held. In addition, as described above, members of these committees participated in communication meetings with researchers, community members and the partners as well as national meetings dealing with research ethics review and meetings associated with the concurrent PHI legislation (14). These activities required an unanticipated major time and workload commitment over the 11 years from the initial government sponsored meeting in 2000 to proclamation in 2011.

Although the membership of the three committees varied slightly over the years there were three members who participated continuously over this time and five who were members of the PHREB Working Group and, subsequently, the Transition Team until proclamation. It is unlikely that the transition to HREA would have succeeded without the considerable commitment of these key persons to meeting attendance and participation in tasks assigned outside the formal meetings, such as community visits. The partners owe much to this group for their continued commitment to the provincial research ethics review concept. It is possible that appropriate resources from the outset, including secretarial support, may have facilitated the process and reduced the length of time required to develop and implement the legislation; but, as described below, the many changes in the senior administrations of the HREA partners, particularly government, also contributed to the delay.

Changes in senior governance – Government, Memorial University and Eastern Health

At the outset, the move to implement province-wide legislation to govern the ethics review of human health research was established by the senior levels of the government, the University and Eastern Health. However, as the years went by the commitment from government waned and similarly, there was a reduced engagement by the senior administration of the University and Eastern Health. This was likely the result of two main factors. First, the initial problem of unethical research being conducted by researchers from out-of-province, with inappropriate follow-up with patients and families in the province, was no longer an on-going, political issue. With the large amount of publicity, the subsequent withdrawal of the approval for the study and the suspension of the privileges of the investigators involved in the initial incident, the original problem was eventually resolved. As a result, the government was no longer receiving complaints from community members and therefore, no longer actively involved in the issue. For the members of the PHREB Working Group and the Transition Team, many of whom continued to be involved in research ethics review on the HIC, the very real problem of access for out-of-province researchers to Newfoundlanders and Labradorians, continued to be a concern.

Also contributing to decreased attention by the partner organizations were the changes in senior administrative positions. Because of the length of time from the initial request for legislation to implementation (over ten years) there was continuing change in the senior levels of all three organizations. This was particularly problematic in the government, where, in addition to changes in the party in power and its leadership, there were numerous changes in Ministers, Deputy Ministers and Assistant Deputy Ministers in the DHCS. The government saw five changes in premiers, ten Ministers of Health and eight changes in Deputy and Assistant Deputy Ministers. Therefore, there was a continuous challenge with corporate memory at the senior levels of government and the DHCS regarding the HREA legislation.

The healthcare delivery system was also re-structured in 2005, shifting from fourteen regional boards to four regional health authorities (Regional Integrated Health Authorities Order (15)); and the Health Care Corporation of St. John’s (one of the original partners in the legislation) became part of the Eastern Regional Health Authority. In addition, Eastern Health had four changes in the senior executive positions. The University also underwent changes, including four Presidents and two Deans of Medicine. This situation was in contrast to the stable membership on the PHREB Working Group, Transition Team and PAG. There is no question that the changes in the senior administrations of the partner organizations had an impact on the ability of the PHREB Working Group and Transition Team to engage with the people who were ultimately responsible to sign off on the legislation and the necessary budgetary and human resource arrangements for the HREA.

Relationship with PHI Act

The PHI Act (14) received assent July 2008 (14), two years after the HREA legislation was passed and although there was a section in the PHI Act that referenced the HREA, the Transition Team was not invited to discussions regarding this new legislation until after it had passed. There was a lack of understanding by the PHI Act Implementation Steering Committee of the roles of the HREA, researchers and data custodians which resulted in two issues that needed to be resolved prior to

implementation of both Acts. One issue that arose was the lack of understanding of the role of REBs in safeguarding personal health information. In adhering to TCPS, the HREA Act (4) states that research ethics approval requires researchers to specify how they propose to safeguard the privacy and confidentiality of research information (including personal health information, data collection, storage and destruction). All REBs in the province, moreover, had been applying this policy in their reviews for over 15 years. This was not well understood by the PHI Implementation Steering Committee and considerable time was spent discussing how the HREA approved REBs would handle this responsibility. An additional issue that raised concern for the HREA Transition Team was the possibility that the PHI Act would be proclaimed in the absence of the HREA Act, which could jeopardize some health research. Specifically, the wording of Section 44 (PHI Act), in which, secondary use of personal health information for research purposes was disallowed without approval of an HREA approved REB. In the end, the PHI Act was proclaimed April 1, 2011 and the HREA Act on July 1, 2011; consequently, under the law no secondary use of personal health information would have been allowed from April to July 2011.

Proclamation Date

As described above the date of proclamation was changed repeatedly. In December of 2007 the Transition Team was asked to have implementation details in place for proclamation of HREA in March of 2008. This necessitated notifying the research community; recruiting and assigning members to the HREB; appointing the HREA board; confirming human resources and budget; and having the approval process for research ethics bodies, a notification strategy, and appropriate review procedures in place. However, the lack of agreement on financial issues resulted in these dates being changed and eventually no firm date being considered for several more years. This situation not only created concern from the local research community, but it also brought into question the entire credibility of the move to a province-wide research ethics review system for researchers and industry outside the province. This concern was further heightened by the introduction of the PHI Act, which appeared to be set for proclamation without having the accompanying HREA Act proclaimed.

It had been anticipated that there would be a six-month lead-in period for proclamation; this was not the case. The date of proclamation, July 1 2011, was announced to the Transition Team approximately one month prior to its occurrence. By then, one proposed member of the new HREA Board was transitioning to a new position out of province and had resigned, as too had the Ethics Officer. Both positions were essential for the implementation of the HREA and the new HREB; thus immediate action was required to fill the HREA Board position and an expedited search for a new Ethics Officer to be in place in time for proclamation. Also, government's notification of the proclamation date occurred at a time when most of the members of the Transition Team were out of town and many service offices, such as support for information technology, were working with reduced staff. Ensuring a seamless rapid transition from the HIC to the HREB supported by the required forms and policies, a new website, two new committees and adherence to legislated timeline was a significant challenge for the few Transition Team members on site and reachable and required a number of very long days.

Budgetary issues and human resources

There was much anxiety about proclaiming the HREA without a written statement clearly outlining the financial support and human resources available from the three partners at the outset, or at least early in the process of establishing the province-wide ethics review process. Among the budgetary challenges was the change from establishing a single provincial REB, as recommended by the Skanes' report (10), to developing the HREA which would oversee all approved REBs in the province and including the HREB which would be reviewing all the clinical trials previously submitted to private REBs. The final budget, recommended by the Transition Team to the partners was considerably higher than that originally envisioned, which had been based on the cost of operating the HIC in 1999. By the time of proclamation, the estimate of expenses was nearly three times that which had been originally proposed by the PHREB Working Group ten years earlier. In addition to inflation, the expenses for the new HREA included increased staffing and expenses associated with the increased workload for the HREB. Although the revenues included the fees for the review of industry-sponsored clinical trials, it was not possible to estimate the number of additional protocols for review or confirm what might be the actual revenues. As the date of proclamation approached, there was significant concern on the part of the Transition Team as to how the expenses would be covered, particularly if the situation arose that these exceeded the revenues. The three partners – Memorial University, Eastern Health and DHCS – also recognized this concern and, although a formal written commitment from the partners was not obtained before proclamation, the original MOU (2002) signed by Memorial University and the DHCS fortunately included a clause to address any potential shortfall. Further complicating this situation was the lack of clarity on human resources. For example, the staff in the HIC office was employed by Memorial University and the Ethics Officer was an employee with Eastern Health. Establishing the HREA as a stand-alone entity was undertaken with the assumption that, at least in the short term, the arrangement with the partner organizations for human resources would be maintained. However, the lack of a formal arrangement or a MOU to address the responsibilities of each of the partners regarding human resources was a concern.

The budgetary issues and human resource concerns created considerable angst among the Transition Team members and serious apprehension regarding potential consequences if the HREA failed to meet its commitments. It was felt by the Transition Team that much of this uneasiness during the lead up to proclamation could have been relieved with appropriate consideration of the budget at the outset and a firm written commitment from the partners for financial security for the HREA.

FOLLOWING PROCLAMATION

The White Paper prepared by Dr. Skanes highlighting the issues of human genetics research (10) was presented to the NL government 20 years ago and the HREA Act was proclaimed 10 years ago. The focus of this paper was to describe the process of developing and implementing the legislation, not to provide a review of the outcome of the legislation on health research in the province. Before reflecting on five areas that have stood out since proclamation, described below, it is worth noting that the legislation has created an opportunity for positive changes that improve the ability to review and assess human health research in the province. For instance, establishing three ethics committees to focus on distinct research areas, offers more focus to the review of human health research. In particular, given the number of research studies in the area of genetics and genomics, a specific review committee dedicated to this area has the potential to strengthen the review process. In addition, the provincial legislation provides a unique opportunity for a simple tracking system to monitor the number and type of human health research studies being conducted in the province. Once the Constituency Committee is established, as outlined in the legislation, this will provide direct access to feedback from the community on the effectiveness of the HREA and the province will be in a position to ask more specific questions regarding participant protection.

Memorandum of Understanding 2012

An important milestone that occurred after the HREA Act was proclaimed, in September 2012, was the signing of a second MOU by all four parties: Eastern Health, HREA, Memorial University, and DHCS (on behalf of the Government). The MOU addressed two major issues that had been raised by the PHREB Working Group and the Transition Team and which had created challenges prior to proclamation, i.e., human resources and budget, including overbudget backup. The 2012 MOU clarified the responsibilities of each party to the financial and human resource requirements of the HREA. In addition, the MOU described the necessary transition of the HREB to serve as the Board of Record for studies which had been approved under the HIC.

Communications

Communication of the research ethics review process to the NL public is a key element of the legislation (Section 5(2), HREA Act) and as such, an important focus of the HREA. A major component of a good communication strategy is maintaining a publicly accessible website. The first HREA website was developed prior to proclamation and although there were updates and modifications it was only in 2016-2017 that the website underwent a major refresh. Procedures for submission, guidelines, forms and resource materials, including a helpful video on “The Ethics Review Process”, are now more accessible and the website itself appears more user-friendly. Some information was not retained from the original website, for example, the early HREA Annual Reports, which allowed for a retrospective of the activities over the years are no longer available. However, the update now posted is a welcome change. As such, it would be useful to survey the users and determine the ease of accessibility and to incorporate a system to receive on-going feedback on the website.

Other aspects of communication are the on-going orientation and educational sessions for members of the HREBs, ICEHR, researchers, students, and staff. The sessions include national and regional activities on streamlining and facilitating research ethics review of studies that affect specialized groups (such as oncology, pediatrics, Indigenous groups). These have been useful to ensure that in-coming REB members and the research community are familiar with the legislation, and the related offices and procedures, as well as national policies. However, the HREA has yet to identify the Constituency Committee required in legislation (Section 19, HREA Act). This Committee is necessary to bring together researchers and the public to raise awareness of research involving human participants in health research in NL and the research ethics review process. This committee is required to meet with the HREA and approved REBs, at least once a year, to discuss responsibilities in research ethics related matters.

HREA and HREB and Office Workload

HREA

As expected, since it was initiated the HREA has seen changes in membership as individuals in the partner organizations come and go in their respective home positions. There have been three Chairs of the Authority. However, there has been continuity in the membership over the years, including at least two members of the HREA who participated in the transition to the provincial legislation, therefore retaining its corporate history.

HREB and Office Workload

The work on a REB is demanding and requires a considerable commitment of time before meetings and during meetings, to complete thorough ethics reviews of research protocols, which are often detailed and highly complex. Although the membership is voluntary the review committee must include members knowledgeable in human health research, research ethics, and law, and includes representation from the general public. It has been particularly difficult to maintain an adequate roster of eligible members for the HREB, and their subcommittees. As a result, the HREB chair and co-chairs and the Ethics Office engaged in a rigorous recruitment initiative in 2018 and were able to report the membership was in good standing in the 2018-2019 Annual Report (16). This area will continue to be a challenge for the HREA and one might expect that improved communication, in particular with the establishment of the Constituency Committee, will improve their ability to seek volunteers for the HREB.

When legislation was proclaimed the HREB included two subcommittees: HREB-CT dedicated to clinical trial research and HREB-NCT dedicated to non-clinical trial research. In 2018-2019 a new HREB subcommittee was established specifically responsible for genetics and genomics research (HREB-GG). This committee began meeting in the fall of 2019 and its impact has yet to be considered in the HREB Annual Report to the HREA. In 2018 the HREA also commissioned a review of the HREB by Clinical Trials Ontario (CTO) (17). The CTO Review Team focused on the clinical trials subcommittee, HREB-CT, and compared the HREB-CT review process with that used by CTO eligible REBs and a small number of REBs from elsewhere in Canada. The report noted that the frequency of meetings for the HREB was higher than that for the other REBs: HREB-CT and HREB-NCT each meet every two weeks compared with the more typical monthly review cycle for REBs elsewhere in Canada. This means that every week the Ethics Office staff are preparing and distributing meeting materials, screening for incomplete or unclear applications, drafting minutes, and communicating committee decisions. The CTO Review Team reported that this probably places a large burden of work on the Ethics Office staff, that is not directly related to ethics review and, as a result, hinders more efficient timelines. The CTO Review Team also noted that the ethics office staff at REBs elsewhere in Canada tend to be in higher level managerial positions compared with HREB staff who work at a more administrative level. Since the CTO report was completed the HREA Ethics Office has changed the office positions to include an Ethics Director overseeing two Ethics Officers, an Administrator and a Receptionist. The meeting frequency has not been modified but it will be important to assess whether these changes in staffing improve the efficiencies of the ethics review process.

The Submission Process

At the time of proclamation, the procedure for submission of study protocols to the HREB was by paper, however, over the years the HREA Office has worked with Memorial University to now submit applications electronically through the university on-line administrative services system, ROMEO. Among the many advantages to electronic submission (reduced workload, ease of access, reduction in paper use, and ease of tracking of all research protocols) is that the ROMEO system is used by a number of REBs across Canada. One might hope that in the future this system could provide an opportunity for a more harmonized or streamlined research ethics review across the country, especially of clinical trials being conducted at multiple sites.

Research Review Turn-around Time

In establishing the HREA and the HREB, concern was raised by local clinical researchers that the turn-around time for research ethics review would be slower and create a reluctance of industry to support clinical trials research in the province. As a result, Section 9(4) of the HREA Act specifically speaks to the timeline of the review process. However, the review process and specifically, turn-around times by the HREB-CT have become a major challenge for this committee and for the HREA. Initially, it appeared that the HREB was succeeding in supporting the increased workload following proclamation. In a report presented at the annual CAREB meeting in 2013, the HREB Chair and Ethics Officer tracked the review process and timeline to approval (18). In contrast to the concerns raised by local clinician researchers prior to legislation, they found that the number of clinical trials had steadily increased, rising from 45 applications in the year prior to the legislation, to 62 in 2011 and 74 in 2012. The average turn-around time for clinical trials applications (from submission to final full approval) was 36.8 days, with an average of 14.8 days spent with the ethics review committee, HREB-CT and 22 days with the research team. They also reported that, in collaboration with the province's Indigenous communities, an innovative iterative process had been created for navigating between the initial Indigenous community approvals, health board resource reviews, and HREB review. It would appear that all was well with the research ethics review process and on a positive path moving forward.

However, in the spring of 2018 the CBC published an article reporting that a local biotech company, Sequence Bioinformatics Inc. (Sequence Bio), had filed a court order with the NL Supreme Court against the HREA and HREB (19). Sequence Bio had been waiting more than six months for the HREB-CT to make a final decision on a pilot study. They challenged that the HREB was required by law "to decide on a research application within 30 days of receiving it, as set out in provincial legislation." The Supreme Court found in favour of the biotech company that the wording of the legislation (Section 9(4) HREA Act) be interpreted such that "within 30 days of receipt of an application, the Board must approve the application, reject the application or approve the application subject to conditions" (20). This case draws attention to the importance of research ethics review timing. It is interesting to note that although the PHREB working group contributed to the legislation they were not allowed to see the final wording of the Act prior to enactment and therefore they were not aware of the flawed wording of this clause. It was at this time, that the HREA commissioned CTO to conduct a review of the HREB, in particular to review the timing of ethics reviews done by HREB-CT compared with REBs elsewhere in Canada (17). The CTO review team identified a small number of clinical trials (six) that could be compared with a small number of study sites (one to four) in other parts of Canada. The results indicated that the HREB-CT review from time of first submission to approval was longer than at most of the other study sites (four of the six studies). However, the results also showed that in NL the research studies spent much more time in revision with the research study teams than with the HREB-CT, a feature which was only seen in one of the other comparator REBs. The data also showed that HREB-CT and the other REB offices spend considerable time pre-screening applications to ensure they are complete and clear before the study is presented to the REB for ethics review. Unfortunately, the data are based on small numbers, but what is apparent from the CTO 2018 report (17) is the considerable degree of variability in the time taken to review clinical trial studies. The results raise the concern that there is little standardization to the research ethics review process, a complaint that has been voiced by many researchers across Canada over many years and discussed below.

NATIONAL CONSIDERATIONS

In the late 1990s, at the time that the NL government initiated the working groups to address concerns with clinical and genetics research in the province, clinical researchers across the country and several national organizations were reporting the challenges in conducting multicentre clinical trials in Canada. A major complaint was the time taken to receive final ethics approval to conduct any large, multi-site study. It was felt that the review process, requiring each participating institution to provide research ethics approval, unnecessarily duplicated the review process, occasionally resulting in delayed study starts and did not address, as intended, the concern of identifying local ethical issues. With no national standards and no REB accreditation system in place each board bases its decision on its own set of procedures, albeit following the national TCPS Guidelines (21) and, for clinical trials, the international *ICH - Good Clinical Practice* guidelines (22). Given the national interest in streamlining the research ethics review process, the move in NL to legislation that would result in a single oversight body, the HREA, and cover all human health research, was watched closely by research ethics organizations from across the country.

For decades, Canada has talked about implementing an oversight system for human health research ethics review, in particular clinical trials, and numerous recommendations have been made by taskforces, national committees and organizations to introduce an accreditation system or required standards for research ethics review. There have been a number of significant attempts.

1. In 1988 the Canadian Medical Research Council, Health and Welfare Canada (Health Canada) and the Royal College of Physicians and Surgeons jointly established the *National Council on Bioethics in Human Research* (NCBHR). As reviewed by Verdun-Jones and Weisstub in 1997 (23), NCBHR advised and consulted with REBs across Canada to enhance knowledge of research ethics issues through educational seminars and workshops, and through the regular *NCBHR Communique.* During NCBHR's nine years they arranged site visits of REBs and produced the *Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine* (23). Many of the same issues were of concern then as now: challenges in providing educational standards for REB members; issues of financial and administrative resources; ethics review of clinical trials conducted at multiple sites. In the mid-1990s NCBHR broadened its mandate to include the two other granting councils, NSERC and SSHRC, and became established as the *National Council on the Ethics of Human Research* (NCEHR) (24). Although both NCBHR and NCEHR recognized the importance of oversight for REBs, in Canada (for example, NCEHR had recommended in 2003 a *Taskforce for the Development of an Accreditation System for Human Research Protection Programs* (25)) there was no follow-up by the government on these recommendations and in 2010 funding was discontinued for NCEHR.

2. In 2000 McDonald (24) published a comprehensive review of the *Governance of Health Research Involving Human Subjects*. The review looked at the role played by REBs in the governance of research ethics review, noting that there is "no uniform set of standards that applies across the board to the protection of Canadian research subjects" and that "such oversight as there is of REBs is piecemeal and haphazard at both local and national levels" (24). By comparison, the oversight of research involving animals is "far more effective and independent than that for research involving humans". McDonald suggested that NCEHR might play a similar role to the Canadian Council on Animal Care in the oversight of REBs in Canada.

3. The 2004 report from the Standing Committee on Health, *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs* (26), noted "there is no single national body mandated to provide oversight for the ethical conduct of human research in either the public or private sector." One of the recommendations of this committee was to establish an accreditation system with oversight for REBs that review clinical trials.

4. From 2005 to 2008, the Sponsors Table Experts Committee met (with representation from the Royal College of Physicians and Surgeons, Association of Universities and Colleges, Health Canada, Association of Faculties of Medicine of Canada, CIHR, NSERC, SSHRC, Rx&D, and others), producing the document *Moving Ahead Final Report of the Experts Committee for Human Research Participant Protection in Canada* (27). Their fundamental recommendation was a Council that "would bring the three elements of education, policy and accreditation together in a single standalone entity".

5. In 2007, Health Canada and the CIHR tasked the *Canadian General Standards Board* (CGSB) to establish "unambiguous Research Ethics Board policies and procedures that adhere to Canadian and international norms" for clinical trials. The committee, which included representatives from REBs and user organizations (including university and healthcare organizations) from across Canada, produced the CGSB Standard, *Research Ethics Oversight of Biomedical Clinical Trials,* which was posted in 2013 as a voluntary standard. However, by 2018 it was withdrawn due to limited use (13).

6. In 2011 the CIHR, Rx&D and the Association of Canadian Academic Health Care Organizations co-hosted the Clinical Trials Summit in Ottawa (28); one of the main areas of focus was the challenges in research ethics review. Following this, the Senate Standing Committee on Social Affairs, Science and Technology published *Canada's Clinical Trial Infrastructure* 2012 highlighting the "need for standardization of research ethics review process and the accreditation of research ethics review boards" (29).

7. In 2013 CIHR's Strategy on Patient Oriented Research, commissioned yet another group to produce a report on *Streamlining of Health Research Ethics Review* (SHRER). The report listed 13 recommendations focused on harmonization and standardization of REBs (30). The recommendations highlighted the value of streamlining the review process through standard operating procedures, common forms, and a training curriculum, supported through a system of evaluation, qualification of REB members and chairs and using common benchmarks and metrics to assist REBs in their work based on developing a widely available database of Canadian REBs and a repository of resources that would be widely distributed.

8. An outcome of the Clinical Trials Summit (point 6 above) was the establishment of the *Canadian Clinical Trials Coordinating Centre* (CCTCC), which in 2015 commissioned yet another group to "identify strategies to improve efficiencies of ethics reviews and advance strategic issues like accreditation in regards to clinical trials". The CCTCC REB Accreditation Working Group relied heavily on the work of the SHRER group and in 2017 in their *Final Recommendations* report (31), listed as the first recommendation: "Distribute the SHRER Report committee recommendations widely and take action on the applicable recommendations."

9. Recently, Nicholls et al., 2018 (32), have provided a summary of the work in this area over the past several years and propose a similar national approach: "that the best solution for Canada would be to develop a national leadership body to work with provincial initiatives and develop national cooperation and support, facilitating acceptance of reviews between provinces."

Despite these numerous efforts to address accreditation of REBs and harmonization and standardization of the research ethics review process, especially clinical trials, a national system does not yet exist in Canada. It would be of interest to determine to what extent this is an issue in other countries and how it has been resolved. For example, the UK has undergone a change to coordinate research ethics committees and standardize protocols through their Research Ethics Authority (33). In exploring this topic, it would be important to consider successes and challenges to other approaches. In Canada, it appears that the two major stumbling blocks for establishing such a system appear to be 1) governance – who would be the oversight body, and 2) funding – who would pay, aside from the seemingly trivial but substantial problem of agreement on forms. These were the same challenges faced by NL in moving to a provincially legislated research ethics review process. Given the countless dollars that have been spent for committees, reports, workshops and taskforces, not to mention lost trials or research that never proceeded, it is long past overdue for Canada to move forward and provide the necessary resources and meaningful dialogue with all stakeholders (research participants, researchers, administrators, funders, and the public) to address this issue.

CONCLUSION

Two elements of the HREA Act have yet to be fully realized: the ability to document all health research involving humans being conducted in the province and the engagement of a constituency community to serve as a representative body for members of the population. A third element that continues to be a challenge for REBs across Canada is how to monitor on-going research. These three aspects of the research ethics review process are interconnected. The first step in monitoring is a clear and accurate listing of on-going and completed human health research in the province. At a minimum this would include information on where and by whom the work is being conducted. This information would provide the focus for annual meetings of the constituent committee, the HREA, the HREB, including each of its subcommittees, and approved research ethics body (ies) to discuss the issues arising in the review of human health research in the province of NL.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Consent to Research in Madagascar: Challenges, Strategies, and Priorities for Future Research

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Résumé
La conduite éthique de la recherche, quel que soit le contexte, dépend du consentement volontaire et éclairé de ses participants. Cependant, assurer un consentement volontaire et éclairé est loin d'être facile, et nécessite une compréhension des facteurs contextuels qui peuvent compliquer sa réalisation dans des contextes de recherche particuliers. Cet article est basé sur le premier atelier sur les « Complexités du consentement à la recherche en santé à Madagascar », qui s'est tenu à Antananarivo, Madagascar, en octobre 2018. Y sont présentés différents défis liés au consentement libre et éclairé auxquels font face les personnes chargées de la mise en œuvre ou de la surveillance de la recherche en santé à Madagascar. Les défis clefs identifiés lors de l'atelier comprennent : la traduction et l'adaptation des protocoles pour usage en dialectes locaux et auprès de populations peu scolarisées; l'acquiescence perçue des participants à la recherche, conformément aux normes culturelles, et qui pourrait masquer leurs préférences réelles; les contraintes de temps engendrées par des échéanciers de recherche serrés qui allouent peu de temps à la collecte de donnée, et donc aux processus de consentement; l'existence de craintes et de tabous par rapport à certaines procédures ou certains sujets de recherche; et l'incertitude quant à comment approcher et comment s'assurer de la validité du consentement individuel dans des contextes où l'avis des chefs traditionnels est communément cherché et respecté. L'article propose des stratégies pour faire face à ces défis et des questions devant faire l'objet de recherches plus poussées.

Mots-clés
éthique de la recherche, consentement, Madagascar, recherche sur la recherche, santé mondiale, Afrique subsaharienne

Abstract
The ethical conduct of research in any setting hinges on the voluntary and informed consent of research participants. Working towards consent that is truly voluntary and informed, however, is far from straightforward, and requires attention to contextual factors that may complicate achievement of this ideal in specific research settings. This paper is based on Madagascar's first "Consent complexities in health research in Madagascar" workshop, held in Antananarivo, Madagascar, in October 2018. It identifies a number of challenges encountered by individuals responsible for the conduct or oversight of health research in Madagascar related to informed and voluntary consent. Key challenges identified included: adaptation of consent tools into local dialects and for limited literacy populations; perceived acquiescence of potential participants regardless of actual preference based on cultural norms; perceived time pressures within tight project timelines to collect data as quickly as possible, limited time for consent processes; fears and taboos related to specific research procedures or topics; and, uncertainty about how best to approach and verify the validity of individual consent in contexts where traditional leaders' influence is conventionally sought out and respected. Potential strategies for responding to each of these challenges are proposed, as are key questions meriting further study.

Keywords
research ethics, consent, Madagascar, research on research, global health, Sub-Saharan Africa

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INTRODUCTION

Voluntary and informed consent to research participation constitutes a universal minimum ethical requirement of research involving human participants (1,2,3). This requirement cannot be understood outside the history of widely publicized and less widely denounced human rights abuses in the name of research. This history precedes but includes in the 20th century: Nazi scientists during World War II forcing concentration camp prisoners to take part in inhumane and often fatal experiments (4,5); intentional infection with active Hepatitis of disabled minors at the Willowbrook School in New York State in the 1950s and '60s towards developing a vaccine (6); nutritional experiments on indigenous minors in Canadian residential schools that denied already malnourished children in control and treatment groups adequate nutrition (7); and the infamous Tuskegee experiments that left African American "volunteers" to suffer and in many cases die from treatable syphilis in the name of scientific "natural"

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observation until the 1970s (8). These “scandals”, while initially framed as anomalies, are today understood to have been possible and indeed justified within deeply engrained and long-standing systems of values and discrimination that have normalized the routine neglect, abuse, exploitation, and dehumanization of racialized, indigenous, disabled, institutionalized, and other socially constructed minorities (9,10). The importance of research ethics governance in general, and commitments to voluntary and informed consent in particular, cannot be understood outside this history of abuse and unequal treatment in research of socially marginalized and less powerful groups.

While none today would deny that informed and voluntary consent are non-negotiable in scientific research, normative interpretations of this requirement and the practices and processes intended to uphold consent have become a focus of increasing discussion and critique from researchers working in global health contexts (11-14). Core to normative research ethics’ definition of valid or meaningful consent to research are a number of presumptions about how humans everywhere should and can affirm their rights to participate in research or not. The very notion of autonomous decision-making is for many at odds with how they make decisions: i.e., it is informed by their sense of connectedness and obligation to others and/or in consideration of the impact of their decision on others and their community (11-15). Power imbalances between healthcare professionals and the general population, and norms of deference linked to gender, age, class, or other differences may also affect perceptions and actual framings of what it means to voluntarily participate in research (13,16-18). Ensuring voluntariness may be further complicated in high poverty contexts, where those approached for participation in research may have high need or desire for the income, healthcare, social recognition, or other benefits that participation may bring (19-23). Lack of familiarity with the concept of health research as distinct from healthcare or limited literacy may also complicate communication of consent information, adding to the challenge of ensuring that potential participants understand a research project prior to consenting (16,17,19,24).

A growing number of scholars and organizations have stressed the importance of attending to cultural and/or community differences in expectations and standard processes for conducting ethical research in different settings (1,11,12,25-28). Doing so can better equip these stakeholders to engage in research activities in ways that account for such differences, reduce misunderstandings, and inform the tailoring of research processes to best uphold commitments to core research ethics principles. This paper identifies a number of “consent to research” complexities and challenges identified by individuals involved in the conduct or oversight of health research in Madagascar. It is the outcome of the first “Consent complexities in health research in Madagascar” workshop, held in Antanarivo October 10, 2018, co-organized by Western University, the Madagascar National Biomedical Research Ethics Committee (CERBM), and the Institut Pasteur de Madagascar (IPM). Several proposals for addressing such challenges, including ideas for further research identified by workshop attendees, are discussed. Until now, there has been no Research on Research (RoR) to identify and better understand particularities to the ethical conduct of research in the context of Madagascar. This workshop, and the discussions on consent complexities it generated, are timely, if not overdue. Health research activities are on the rise in Madagascar, as in many African countries. With such expansion comes responsibility: for those involved in research in the country, it is important to reflect on existing practices and develop adjustments, if and where needed, to better protect research participants and the ethical integrity of research in the country. While focused on the Malagasy context, it is anticipated this paper and the workshop methods it describes will be of value to research stakeholders in other national settings.

CONTEXT AND METHODS: THE “CONSENT COMPLEXITIES IN HEALTH RESEARCH IN MADAGASCAR” WORKSHOP

Several of the authors (EN, SGL, AK, LD) were funded through a Canadian Institutes of Health Research (CIHR grant #15610) grant to explore complexities of consent and compensation in global health research. EN and SGL met with the CERBM in August 2018 to learn more about identified research needs related to consent in the country. Members of the CERBM felt consent posed an important challenge, especially in the context of work with rural populations. The CERBM suggested that a workshop with other individuals with experience conducting research in the country could be a fruitful way for the CERBM and the Canadian researchers to learn more about consent complexities in the country. The workshop was not designed as a study, but as a first step towards identifying consent-related research questions for the Malagasy context. It was facilitated by EN and SGL, with the agenda approved by the President of the CERBM in advance. The request to develop an article based on workshop discussions came from attendees themselves, who regarded the exercise as valuable for its affirmation and clarification of several key challenges faced by researchers, and to further reflections on how these might be mitigated in the future.

Workshop attendees: sampling strategy

We recognize that the perspective of actual participants in research is crucial to clarifying complexities of consent in any context. For this workshop, we had a limited budget, limited capacity for participants, and could not agree on a recruitment strategy that would allow meaningful and diverse representation from this key stakeholder group. On this basis, a decision was made to focus recruitment on individuals involved in the conduct or oversight of research. Invitations to attend the workshop were sent to all contacts of the IPM and the CERBM, including healthcare centres, universities, private research institutes, non-governmental organizations (NGOs), and all members of the CERBM. These organizations were asked to identify one or two individuals with direct experience engaging in consent processes with patients or community members in the context of research in Madagascar.

Thirty-three individuals from 15 organizations attended the workshop. These included individuals with a range of research experience, i.e., junior researchers working primarily on the front lines of data collection, experienced social scientists and epidemiologists, clinician researchers, and expert members of the CERBM. Organizations represented at the workshop included: the National Institute of Public Health, the University of Madagascar, Antananarivo Hospital Centers, the Malagasy Academy (l'Académie Malgache), the Institut Mérieux, several NGOs (Action Against Hunger, Actions de Terrain, Intégration, Autonomie – ATIA, Professionals for Fair Development – GRET, Médecins du Monde, Population Services International Madagascar), and private and public scientific institutions (Centre d'Infectiologie Charles Mérieux, Institut Pasteur Madagascar).

Structure and documentation of workshop discussion

In keeping with our primary objective of learning more about challenges to meaningful consent experienced by health research-investigators and regulators, the workshop featured small group discussions followed by a synthesizing exercise.

Small group discussions

Following a brief overview of the plan and objectives for the day, workshop attendees were invited to form four groups of approximately eight individuals. To ensure a diversity of perspectives in each group and to promote cross-organization learning, attendees from the same organization were asked to join separate groups. Each group was asked to identify a volunteer to take detailed notes on the discussion, with an understanding that notes would be fed back to the larger group. Small group discussions were organized in three timed blocks (30 minutes each). The first discussion block invited attendees to share those challenges related to consent that they regarded as the most common or important to troubleshoot. In the second block, attendees were asked to identify normative expectations for consent processes that were not challenges, in their experience. The final block asked attendees to describe strategies they had used in response to challenges experienced, and to identify what further research or resources might facilitate navigation of consent complexities in the country, moving forward.

Synthesizing exercise

The final hour of the workshop involved regrouping the attendees to discuss and begin to develop consensus on key complexities and recommendations. In three rounds corresponding to the three small group discussion blocks, each group presented a summary of main points raised in their discussion. One of the workshop facilitators (EN) tracked the points raised by each group on a flip chart, asking attendees to confirm the accuracy of these notes as she proceeded. All attendees had the opportunity to add to challenges, norms, and recommendations for next steps identified by members of other groups as their colleagues presented them, and these comments were also recorded on the flip chart. A summary of the workshop was prepared in the days following the workshop, based on the large group discussion recorded on flip chart notes. This report was circulated to all workshop attendees for their review, to provide the opportunity for additional suggestions and comments, and to ensure it represented an accurate record of key points raised in the workshop. Small suggestions on wording were obtained in this process. The revised report forms the basis for the present article.

Ethics

We did not obtain ethics approval for the conduct of this workshop, as it was not conceptualized as research, but rather as an intersectoral consultation aiming to advance sharing and understanding of consent challenges in the country (see Appendix 1: Invitation to workshop letter). It was thus framed as such. Verbal consent was sought and obtained from all workshop attendees at the workshop regarding an eventual submission for publication of a summary of the workshop discussion, following a request from attendees that we pursue this avenue.

RESULTS: IDENTIFIED CHALLENGES TO INFORMED CONSENT IN MADAGASCAR

Workshop attendees had no trouble identifying several complexities of consent in the context of Malagasy health research. These fell into two main categories: 1) challenges related to consent form preparation for national review and local use; and 2) challenges of ensuring meaningful consent of research participants during data collection. Specific challenges within these broader categories are presented below, along with potential mitigation strategies and avenues for future research and dialogue (Table 1).

Table 1: Challenges to informed consent in the Malagasy context and suggested strategies and research questions for addressing these

Challenge areas	Underlying structural factors	Proposed mitigation strategies	Proposed avenues for future research and dialogue
1) Consent form preparation for national review and local use			
Language and clarity Protocols developed in French, English, or other languages must be translated into Malagasy and from Malagasy into local dialects. Technical terms may not have local-language equivalents or may be unfamiliar to participants. Attempts at explaining or paraphrasing terms adds length and complexity to documents/conversations.	• Tension between desire for concision and clarity, and for thoroughness and accuracy. • Tension between formal ethical norms and local norms and realities.	• Feasibility studies, development and dissemination of training on how to develop (clear, appropriate) consent documents. • Anthropological fieldwork by researchers and trainees, to develop clearer understanding of potential participants' day-to-day lives. • Development and dissemination of "sample" consent documents, in local languages, that demonstrate effective information sharing. • Development and dissemination of "sample" visual and audio-visual tools to support effective information sharing.	• What specific items or aspects within consent discussions and forms represent the most consistent challenges to informed consent in specific studies? Are there patterns in the challenges to the understanding of consent discussions across or within Malagasy participant populations? • What terms, analogies, or paraphrasing are being used to explain terms that have no equivalent in local dialects, if any? Are these effective in increasing Malagasy research participants' ability to provide informed consent (do these increase understanding)?
2) Optimizing meaningful consent during data collection			
Pressure to consent Politeness norms in some Malagasy communities prioritize agreement. If invited, participants may not feel comfortable declining to participate in a study.	• Tension between formal ethical norms and local norms and realities.	• Anthropological fieldwork by researchers and trainees to develop clearer understanding of communication norms in research communities. • Giving participants enough time to reflect on their decisions about participation.	• Would providing more time to participants for their decision-making result in more individuals expressing a preference not to participate? • What amount of time (hours? days?) would be sufficient to reduce the influence of norms of politeness on decisions to partake in research (assuming these do influence consent to research in at least some Malagasy communities)?
Addressing taboos Key research procedures and topics may be the subject of taboos (e.g., blood samples, discussions of sexuality). Researchers may feel uncomfortable addressing, or uncertain of how best to address, such topics.	• Tension between formal ethical norms and local norms and realities. • Lack of material, institutional, and educational support for Malagasy researchers.	• Development of pre-deployment training for frontline researchers, that focuses on making explicit expectations and fears about taboos.	• Are there respectful and sensitive ways of discussing topics that relate to taboos?
Addressing concerns about signatures Participants may feel uncomfortable signing consent documents, whether or both because they are unable to read these documents themselves, and/or in light of local histories in which rights were ceded by signing documents.	• Tension between formal ethical norms and local norms and realities. • Lack of material, institutional, and educational support for Malagasy researchers.	• Development and dissemination of training materials outlining alternative means of documenting consent. • Development and dissemination of "sample" consent documents that allow participants to choose between different means of documenting consent.	• What (various) meanings and implications does the act of signing carry in rural Madagascar? • What alternate means could be acceptable for documenting consent?
Individual consent Given norms of respect for chiefs' and families'/communities', researchers may feel uncertain that potential participants' choices genuinely reflect personal preferences.	• Tension between respect for collective/community and individual decision-making.		• How can Malagasy ideals of respect for the community, family, and for chiefs be reconciled/balanced with health research ethics norms that emphasize individual decision-making?

Time limitations Researchers may face limited time to engage in consent processes. Participants may not have time for consent forms and discussions that explore, clearly and in comprehensible terms, all categories of information normally required by REBs. Deciding what information to prioritize may be difficult.	• Tension between desire for concision and clarity, and for thoroughness and accuracy.		• What aspects and dimensions of consent documents should be prioritized? • What level of detail would best serve to inform potential participants without overwhelming them?
Ability to ask questions Participants may not feel free or comfortable asking questions of researchers. In the absence of questions, researchers may have difficulty assessing participants' understanding.	• Tension between respect for collective/community and individual decision-making. • Tension between formal ethical norms and local norms and realities.	• Anthropological fieldwork by researchers and trainees, to develop clearer understanding of communication norms in research communities. • Develop and share strategies for strengthening trust between researchers and potential participants. • Ask participants to explain key information in their own words, as a means of assessing their understanding and to elicit questions.	• Do potential or confirmed participants truly feel hesitant to ask questions of researchers? On what bases? How does hesitancy intersect with social position, gender, or other factors? • What methods can serve to gage potential or confirmed participants' understanding of research projects and terms of participation?
Concentration Consent and information conversations may include topics or occur under conditions that are distracting to researchers and/or participants.	• Lack of material, institutional, and educational support for Malagasy researchers to identify and assess the ethical significance of participants who may seem distracted during consent processes.	• Anthropological fieldwork by researchers and trainees, to develop clearer understanding of potential participants' day-to-day lives.	• Are there particular topics, research procedures, or conditions that participants would define as limiting their ability to process and participate as fully as possible in consent processes?

Challenge area 1: Consent form preparation for national review and local use

Preparation of consent forms was stressed as a challenge by a number of workshop attendees. Research in Madagascar is almost entirely funded by non-Malagasy based institutions and agencies. This implies multiple ethics approvals of the protocol and study instruments: from non-Malagasy partner institutions, as well as from the National Ethics Committee in Madagascar (the CERBM). Many international partnering institutions recommend and expect the adoption of specific language in consent forms as a condition for their approval of protocols. A first complexity of consent is related to internationally funded research in Madagascar, and the need to adapt study protocols that include non-Malagasy institutional language preferences for the Malagasy context.

Consent forms often need to go through multiple translations: into French sometimes, into Malagasy, and then, into Malagasy dialect(s). The latter occurs in the field via translators, if (as is often the case), researchers are not versed in the local dialect spoken by potential participants but also because Malagasy dialects do not have standard written forms. For limited literacy populations – a significant demographic in Madagascar research – it is expected that all consent form components will be verbally explained to potential participants. Some scientific and medical terms have no equivalent in standard Malagasy or dialects. Workshop attendees noted a tension between the desire to create forms that are as concise as possible so that these can be read to research participants in their entirety, and the need to explain concepts through a series of words or sentences because there is no equivalent term in the target language or dialect.

Echoing a recurring theme in the literature (29,30), many attendees were uncertain as to the level of detail they should include in consent forms. A few wondered if it was important, for example, to name funders, or the particular bacterium in a bacteriological study. They expressed worries that such detailed information could confuse and reduce, rather than increase, potential participants' understanding of a study. Both junior and senior researchers worried about "cut and paste" approaches to consent forms that negated the importance of ensuring the language and information in forms were adapted to specific populations, participant education level(s), particular concerns, and prior exposure to information, studies, or methods. These practical complexities and concerns are well founded, and echo those raised by researchers and ethicists interested in the quality and challenges of informed consent in African clinical research (13,31-34). In a systematic review that looked at clinical research participant understanding for consent, across 21 African studies, over 50% of participants were found to have consented without understanding key concepts relevant to the study in which they volunteered (35). Seventy percent appeared unclear that they were even involved in research (35). In contexts of limited literacy and when working in languages that do not possess equivalent terms for key research concepts, supporting informed consent necessitates careful planning and innovation to adapt consent instruments and procedures (29,35,36).

Workshop attendees identified a dearth of opportunities for formal training on the drafting of protocols and consent forms as a factor complicating efforts to deal with these issues, especially for students and early career researchers.

Challenge area 2: Optimizing meaningful consent during data collection

Workshop attendees identified five key challenges to the ideal of informed and voluntary consent arising at the "field" level, during data collection. Three were understood as stemming from Malagasy cultural beliefs, norms, and socio-economic conditions, and as being more pronounced amongst research participants living in rural regions and with limited literacy. The remaining two pertain to conditions that may be more directly in the researcher's control.

A cultural norm of the Malagasy answering 'yes' even when they are thinking 'no'

One of the cultural norms that workshop attendees identified as challenging was the observed tendency of Malagasy peoples, whether or not in the context of research, to answer 'yes' even when they may be feeling or thinking 'no'. One attendee, a research assistant experienced in obtaining consent in the country, described this practice manifesting when, for example, they presented research to individuals in rural areas and some individuals agreed before they finished explaining what the study was about or involved for those who might enroll. In the assessment of workshop participants, the Malagasy may choose to express acquiescence, whether to follow norms of politeness or perhaps, sometimes, simply to help bring a tiresome line of questioning to a quicker end. This makes it more difficult to ascertain whether or not a participant's consent actually represents their preference.

Taboos and fear

Certain studies involve the collection of biosamples. While biosample collection may involve a wide range of biological materials, the collection of blood samples was highlighted by workshop attendees as being uniquely challenging in the Malagasy context. Fear of blood drawing was common, particularly in village settings, with the occasional result that once the procedure was mentioned, potential participants seemed to stop listening to any new information, even as they assured researchers to continue, and that all was fine. Workshop attendees expressed uncertainty about whether potential research participants' distraction due to this fear could undermine their ability to absorb information and thus provide informed consent.

Certain acts, including intentional removal of blood from the body, whether through donation or for biosample purposes, as well as speaking about sexuality, were noted as being taboo to many Malagasy participants. Whether or not respecting such taboos represented best practice in populations whose health needs required engaging these topics (e.g., through studies on causes of high teen pregnancy rates), was discussed without resolution. Some proposed the best way forward in such scenarios was to respectfully avoid talking about the taboos directly, for example, by framing a study about adolescent sexuality as being about adolescent activities. Others were uncertain that this aligned with a commitment to honesty and transparency in the provision of information to potential participants. The animated and unresolved discussions around what to do in the face of taboos highlighted an apparent division amongst workshop attendees: between those who felt ethically challenged reframing research in ways that would obscure the connection of this research to taboo practices or topics, versus others who regarded such reframing as respectful and pragmatically necessary. The latter perspective merits critical consideration. It does indicate an extractive approach to research, wherein a complexity of consent is reduced to being an obstacle to the researcher's agenda.

Fear and concerns around signatures

In many remote areas of the country, the arrival of "outsiders" in villages can recall unwelcome experiences related to mining or, dating further back, colonial government missions. These historical precedents can lead to (at least initial) associations of researcher "outsiders" with dishonest intentions and risks of harm. In workshop attendees' experience, learning about such histories and ensuring villagers understand how the intentions of researchers differ from those of past outsiders may be critical to not only building trust, but also to ensuring potential participants understand that they have the right to refuse without risk of harm. Some potential participants may trust researchers and find value in research projects while still distrusting the normative requirement of sealing the consent process with a signature.

Respect for leaders (les chefs)

The respect accorded to traditional leaders poses a particularly salient challenge to the ideal of individual consent in Madagascar. Norms of respect for (usually male) heads of households, traditional leaders such as kings, and elected leaders such as village chiefs, require research teams to seek consent from these individuals before approaching any of those for whom they are assuming the role of leader. The extent to which members of communities feel able to refuse (or accept) participation in a study once their leaders have given approval (or refusal) is unclear.

Time pressures

Noted by several attendees engaged in field-based data collection was the tension between time needed to engage in meaningful consent discussions with study participants, and limited time for data collection. Budgets can be lean, and daily or weekly expectations lived as quotas for questionnaire completion or collection of bio-samples put pressure on researchers to sometimes rush the consent process. Those being recruited do not have unlimited time either. Potential study participants were observed to tire and grow distracted or annoyed if consent forms and discussion were overly long or detailed.

Creating an environment conducive to questions and discussions

Time pressures and cultural norms can conspire to create situations where potential participants are reluctant to ask questions. Researchers explained feeling uncertain of potential participants' level of understanding when, after a lengthy explanation of a study, participants had no questions for them. Currently, researchers are uncertain whether a lack of questions or discussions prior to participants providing their consent indicates an actual lack of questions and concerns, reflects participants' fatigue in the face of lengthy study and participant explanations, or represents a situation where, for reasons unclear to the researcher, a potential participant has questions or concerns but is not expressing these. Researchers were not sure how to proceed in such scenarios. One attendee noted that they felt uncomfortable at the prospect of pressuring unwilling potential participants to speak up.

Researcher engagement in consent processes

Some workshop attendees who worked on teams in the field admitted that researchers themselves sometimes lack concentration during consent processes. Reasons for this included the time pressures just described, or researchers perceiving consent as a chore that one just had to "get done", prior to starting data collection. Whatever its cause, it was noted that researchers' lack of concentration could lead to accidental omissions of consent information, and limited attentiveness to potential study participants' questions or even apparent discomfort.

Challenges and complexities not identified in workshop discussions

Notably absent in workshop discussions was the limited choice of those invited to participate in research. This struck the first author (EN), and co-facilitator of the workshop, as worth underlining. She was primed to note such an absence based on her involvement with a World Health Organization working group dedicated to advancing good participatory practices in the conduct of clinical research and based on her long-standing interest in bringing under-recognized perspectives to bear on global health research ethics (37-41). A key theme in the literature on consent to research in sub-Saharan Africa centres on the challenge of ensuring voluntariness in the context of projects or studies that provide participants with free, valued, and otherwise inaccessible options for medical consultations, treatment, diagnostic tests, or even benefits such as food supplements (20, 36). Only one participant in the workshop briefly referred to the poverty of participants and their need for healthcare as a complicating factor for consent in the Malagasy context.

Many have argued for the importance of community input and collaboration in research ethics guidance development and oversight (26-28,31-35,37-39,42-45). Collaborating with members of researched populations for research ethics development and oversight has been advocated as part of broader commitments to minimize harm, decolonize research ethics, foster respectful researcher-participant relations, and avoid the objectification of research participants. There is a global move to advance evidence-based or practical ethics by listening to and recognizing the value of research participants' experience-based insights for guidance. No attendee in the workshop raised the possibility of involving community representatives in the development or improvement of informed consent processes, forms, or research ethics training more generally. No attendee suggested that further research on decision-making or consent processes and challenges in Madagascar could or should be developed in partnership with representatives from researched communities and localities.

The absence of calls for collaboration or engagement with individuals in researched communities is worth noting. This absence arose in the context of a workshop limited to individuals involved in recruitment, enrollment, and oversight of research in Madagascar; but that does not render it less significant. This absence may reflect prevalent understandings and approaches shared amongst those responsible for the conduct of research in the country. It may indicate prevalent understandings about how and with whose input best practices for the conduct of research could be advanced – in this case, without the involvement of participants. It may also reflect a dominant and uncritical conceptualization of research as an extractive endeavour, i.e., one that is organized around participant enrollment and data collection goals, and that engages with researched populations for the exclusive purposes of fulfilling research agendas without significant input from those populations. Such an extractive approach to research reduces consent complexities to pragmatic barriers. Histories, ongoing power relationships between researchers and those approached for participation, and social-cultural ideas and norms animating participants' engagement with research are seen as barriers to research in need of troubleshooting, rather than something to explore in dialogue with those being approached for research participation.

Several strategies were proposed in relation to the challenges encountered by researchers as they seek to support potential participants' consent decision-making. These are described below and fall into two main categories: *practical strategies* to address challenges related to consent, and *recommendations* for further dialogue and empirical investigation.

Practical strategies to address consent challenges related to protocol preparation, navigating cultural norms and taboos, and time pressures

There is a need, especially pressing for Malagasy students and junior researchers, for more training in the "how to" of formulating protocols and consent forms. Workshops focused on the preparation of consent forms, in particular, could help de-mystify the process and prepare researchers to thoughtfully engage with this, in both a pragmatic and respectful manner.

Pre-field anthropological training could orient researchers to the diversity within as well as across specific Malagasy populations and encourage them to be informed about prior activities by "outsiders", and therefore be ready to explain their

own presence and purpose in relation to these historical precedents. Related to this latter point, researchers could be primed to remain intensely curious in general, and attentive to relations of power, apparent discomfort, preconceived ideas, or conditions that could influence participants' abilities to understand and freely consent or refuse participation in research. Supervisors and educators could further emphasize the importance of being present, alert, and responsive to potential misunderstandings during consent processes, so as to ensure the quality and ethics of research.

Specific open-access tools that could be created include: a reference document with suggestions for translating scientific and medical terminology into Malagasy dialects, and audio-visual tools to support research participants' (especially limited literacy participants') understanding of study goals and methodologies. Researchers need to slow down when necessary to ensure potential participants have the time to ask questions and express concerns. One attendee recommended the strategy, described in the literature over 20 years ago (46) and which they found effective, of asking a potential participant to summarize the consent information just explained to them.

The National Biomedical Research Ethics Committee in Madagascar (CERBM) currently allows researchers to adapt consent processes in response to population needs or individual preference – for instance, by allowing limited-literacy populations and communities who might be wary of providing signatures to "outsiders" to provide their consent orally. If the experience of workshop attendees is representative, this flexibility is not widely known and rarely practiced in Madagascar. The creation of a Malagasy/French open-access document outlining when and why oral consent may be used, and with what risks and advantages, could help legitimize it as an ethically acceptable alternative.

Recommendations for further discussion and research

Overarching tensions highlighted in the workshop merit further discussion and empirical exploration in and of themselves, to support the development of best practice guidelines for the ethical conduct of research in Madagascar. No consensus was reached amongst attendees with respect to the challenge of determining how minimalist can be information shared in a consent process while remaining sufficient for consent to remain informed and thus valid. This challenge was clearly entangled with time pressures lived by all attendees: pressures to "complete" the consent confirmation process, collect data, and complete research. Some attendees seemed to hope that there might be a quick fix to the "problem" of long consent forms and consent processes. Such comments raise concerns: some front line health researchers may be engaged in poor practices by rushing consent processes. A number of senior and junior researchers noted as much, calling for a change to the research culture so that more time was expected and reserved for initial consent processes. Others questioned the feasibility of such a change, especially in a context where virtually all research is funded by international partners and projects that often have strict timelines. How to bring about this change in culture and norms, as well as the impact this could have on the quality of consent processes, remains to be seen.

Ensuring that the content and wording of consent forms is accessible to potential participants in accordance with their literacy level and cultural context is a known requisite of ethical consent to research participation processes (26). While workshop attendees recognized this need, no clear strategy for meeting it was identified. Procedures, such as for blood biosamples which are the subject of common fears and taboos, may need to be explained and addressed to a degree that potentially exceeds their place in a study. Further research, conducted within distinct and diversely located projects throughout the country, is needed to determine what constitutes culturally and contextually appropriate types and levels of information to support informed consent. As one attendee noted, research is needed to understand the specific impact on participant understanding and decision-making when more or less information is included.

The relationship between collective and individual consent also merits further research. Attendees remain uncertain how researchers might best enact their ethical responsibility to respect distinct cultural values and practices, while also ensuring – in accordance with this foundational research ethics principle – that individual participants' consent to research is voluntary. A review of key research ethics guidance shows that these provide little in the way of practical advice for navigating dual responsibilities to respecting values of individual and collective consent. Thus, for example, the latest CIOMS (1) stresses the importance of "showing respect for communities" and "ensuring community acceptance" of projects (1, p.25), while maintaining that community leaders' permission may "in no case […] substitute for individual informed consent" (1, p.35). The Canadian *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (42), a key reference point for Canadian co-authors on this publication, provides a good example of the possibilities – and limitations – of efforts to explicitly address or regulate these tensions. Since 2009, this guidance document has included a Chapter on research with aboriginal Canadian groups, developed under the leadership of and in consultation with aboriginal scholars and community members. This Chapter defines collective decision-making as an important cultural practice in many aboriginal communities that researchers working in these communities are ethically bound to respect but provides no guidance on how one might operationalize "collective decision-making as a complement to individual consent" (28, Ch.9). In sum, the challenge of ensuring individual consent while remaining respectful of collective decision-making and of leaders' authority is not limited to Madagascar. It is potentially present in all contexts where relational and collective decision-making and respect for family or community leaders' evaluation of the acceptable and unacceptable are dominant cultural practices. Workshop attendees agreed that deepening understanding of how chiefs and research participants understand the relationship between individual and collective consent would represent a valuable addition to Research on Research scholarship and research ethics guidance in the Malagasy context.

No workshop attendee raised issues related to the absence of representatives from researched communities at the meeting. It is not clear whether this reflects an actual lack of recognition for the importance of working with such representatives, but it may. Discussions with members of researched communities are needed to advance understanding of the consent complexities identified by workshop attendees and their ethical significance. Indeed, all further research on consent complexities in Madagascar ideally would be developed and implemented in meaningful collaboration with former participants to research studies in the country, or with individuals positioned to speak on behalf of researched populations. Such collaboration on the design of study questions, methods, and analysis of findings would have practical and ethical benefits. Notably, it could multiply insights on consent complexities and as a result strengthen research ethics guidance and localized strategies to further support informed consent to research in the country. Just as important, such collaboration enacts recognition that participants – as stakeholders who are directly affected by research processes – are well positioned to clarify what counts as ethical, respectful, and in this way "best" practice in a particular setting (47,48). Inviting input on study objectives and questions from members of researched populations also supports a shift away from an extractive approach to research that engages with participants for agendas that are established outside the purview of researched populations' concerns and priorities. How best to achieve increased engagement with members of researched communities in ways that feel non-extractive to these stakeholders will itself require dialogue with researched community representatives (48,49). Such invitations, at this point in Madagascar as elsewhere, will not necessarily be welcome or trusted. These will occur against a backdrop of colonial and neocolonial extractive research, dominant hierarchies of knowledge, and racial, economic, and social hierarchies; as such, it can be expected that invitations to "collaborate" from researchers from "outside" may be interpreted as attempts at exploitation (38,47-49).

CONCLUSION

There is nothing simple about ensuring free and informed consent to participate in most circumstances of biomedical research. Best practices for supporting voluntariness must also be developed in ways that enable reconciliation of universal principles for the ethical conduct of research with cultural practices and values that may at times appear or actually be at odds with these principles. The 2018 "Complexities of Consent in Madagascar" research dialogue initiative brought together representatives from a range of institutions and with a range of experiences in the conduct of research in Madagascar. Together, we identified key challenges, potential strategies, and questions in need of further exploration for supporting consent in this sub-Saharan African country. One workshop is insufficient to identify and troubleshoot all the complexities of informed and voluntary consent, even for a single national context. As previously noted, this workshop included a limited number of stakeholders, and it did not include actual research participants. Consultations or research with individuals and communities that have been invited to participate in research studies is necessary, if the complexities and challenges of consent in Malagasy contexts are to be described and addressed in ways that can inform "best practices" that resonate with both research participants and those in charge of studies. Anthropological studies can play an important role in advancing understanding of the lived experiences of those conducting research amongst diverse Malagasy populations as well as individuals approached for research participation. While we recognize that the workshop generated neither comprehensive nor empirically robust findings, the discussions are worth documenting and sharing. They illuminated numerous important issues related to informed consent processes in Madagascar health research that merit attention, notably in the form of capacity building, practical tools, and further research. The workshop discussions summarized here represent a first, if not conclusive step, in developing evidence-based context-specific strategies to strengthen consent and research ethics processes in Madagascar. More events through which researchers can share and collectively troubleshoot new and old concerns and challenges related to the application of research ethics principles will be important to developing shared best practices that are tailored to Malagasy contexts.

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APPENDIX 1: INVITATION TO WORKSHOP LETTER

Antananarivo, October 1, 2018

Subject: Invitation to workshop on challenges related to the ethics of consent to health research in Madagascar

Health research in Madagascar is conducted in accordance with international ethical norms and must be approved by the Bioemdical Research Ethics Board of Madagascar (CERBM) within the Ministry of Public Health of Madagascar. Ensuring the protection of participants in the context of clinical research within unique cultural and legislative contexts requires constant reflexivity.

The CERBM, researchers from Western University (London, Canada) and local researchers have deemed it important to discuss those challenges connected to the ethics of health research, and, more specifically, related to informed and voluntary consent, pertaining to Malagasy research participants. These discussions are financed by the Institutes for Health Research of Canada (CIHR).

The organizers wish to invite you to a workshop on the challenges of consent and the ethics of health research that will take place October 10, 2018, at the Institut Pasteur of Madagascar starting at 8:30 am. Les organisateurs souhaite vous inviter l'atelier de travail et de formulation autour

You and members of your organizations are invited to this workshop. Please note that those individuals to whom we are extending this invitation are primarily field researchers and researchers who are experienced in enrolling participants in health research projects.

In order to facilitate the organization of this workshop, please do confirm your intention to attend as well as the number of participants from your institution who will attend prior to October 5, 2018 by communicating directly by email xxx@pasteur.mg or by phone at (xxx xxxxxxx).

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Re-contact Following Withdrawal of Minors from Research

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Résumé
Le re-contact des mineurs inscrits dans des recherches lorsqu'ils atteignent l'âge de la majorité ou de la maturité afin d'obtenir leur consentement autonome pour poursuivre leur participation est considéré comme une exigence éthique. Cette question a généralement été étudiée dans le contexte des mineurs qui participent activement à la recherche. Cependant, qu'en est-il lorsque le mineur s'est retiré de la recherche ou a été perdu de vue? Les chercheurs peuvent-ils, dans ces circonstances, recontacter le mineur à l'âge de la majorité ou de la maturité afin d'obtenir son consentement à participer à nouveau à la recherche? Dans cet article, nous explorons la possibilité éthique de recontacter les mineurs dont la participation à la recherche a pris fin, une fois qu'ils ont atteint l'âge de la majorité ou de la maturité. En particulier, nous identifions les scénarios dans lesquels la participation d'un mineur à un projet de recherche peut prendre fin et nous discutons des facteurs qui peuvent aider à déterminer cette licéité éthique. Enfin, nous discutons des défis pratiques et éthiques du re-contact et présentons des modèles de re-consentement qui peuvent être utilisés par les chercheurs.

Mots-clés
re-contact, re-consentement, mineurs, consentement, assentiment, recherche, éthique

Abstract
Re-contacting minors enrolled in research upon their reaching the age of majority or maturity to seek their autonomous consent to continue their participation is considered an ethical requirement. This issue has generally been studied in the context of minors who are actively involved in the research. However, what becomes of this issue when the minor has been withdrawn from the research or has been lost to follow-up? May researchers re-contact the minor at the age of majority or maturity under these circumstances to seek the consent of the minor to re-join the research? In this paper, we explore the ethical permissibility of recontacting minors whose participation in research has ended, once they have reached the age of majority or maturity. In particular, we identify scenarios in which the participation of a minor in a research project may end and discuss factors that can help determine such an ethical permissibility. Finally, we discuss the practical and ethical challenges of re-contact and present re-consent models that may be used by researchers.

Keywords
re-contact, re-consent, minors, consent, assent, research, ethics

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INTRODUCTION

The issue of re-contacting minor research participants to obtain their own consent when they reach the age of majority or maturity has been studied in the context of maturing minors who are actively involved in research (i.e., enrolled participants). However, what becomes of this issue when the participation of the minor in the research ends prior to their attaining the age of majority or maturity (i.e., the minor is no longer an enrolled participant)? May the researcher renew contact with the minor after a period of inactivity and seek their consent to re-join the research project? There have been limited discussions of this issue in the literature. However, as longitudinal and biobanking research projects involving minors become more prevalent, the need to explore this question is timely.

Illustrative of the practical relevance of this issue is the example of the Maternal Adversity, Vulnerability and Neurodevelopment (MAVAN) Study, a prospective community-based, pregnancy and birth cohort of Canadian mother-child dyads. The MAVAN Study follows mothers and their children from birth into adulthood and examines pre- and post-natal influences, and their interaction, in determining individual differences in mental health (1). As the MAVAN Study shifts from assessing children and adolescents to young adults, the researchers are now faced with the question of whether it is possible to re-contact young adults whose participation had ended by withdrawal or because the individual had been lost to follow-up. For a longitudinal developmental study that has been collecting data and biosamples from its participants, there is value in trying to retain as many participants as possible. Larger sample sizes not only have greater statistical power, which is important in answering research questions and detecting meaningful effects (2), but there is also great scientific interest in observing the development of participants over time and obtaining information from them at later life stages. In a longitudinal development study such as MAVAN, there is a strong scientific rationale for wanting to re-contact previous participants. It is therefore useful to explore the ethical permissibility of re-contacting previous participants so that prospective assessments of early life experiences can be compared with post-maturity/majority functioning. Accordingly, this paper explores the question of whether and when it is ethically permissible to re-contact previous minor participants to ask them to re-join a research project.

We begin with an introductory overview of re-contact and the capacity-based approaches that determine when a minor becomes capable of providing their own informed consent to research participation. In particular, we will outline how the

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maturity-based approach to determine capacity for re-contact cannot apply where the participation of a minor has ended by withdrawal or where they have been lost to follow-up. Next, we consider three different scenarios in which a minor's participation in a research project may end: 1) the parent (or guardian) withdraws the minor; 2) the minor asks to be withdrawn; and 3) loss to follow-up (attrition). We consider the ethical permissibility of re-contact in each scenario and identify key factors that may influence such permissibility. Finally, we discuss the practical and ethical challenges of re-contact and present re-consent models that may be used by researchers, where ethically permissible. While this article largely focuses on the Canadian ethical and legal landscape, our findings are not unique to Canada and may be generalizable across jurisdictions.

RE-CONTACT AND THE CAPACITY TO PROVIDE INFORMED CONSENT

As previously mentioned, re-contact involves contacting research participants who were enrolled as minors in the research to seek their informed consent to continue their participation in the research when they reach either the legal age of majority or the age of maturity. Paediatric research may include projects that are carried out over extended periods of time, such as longitudinal studies and studies of large population cohorts that may include biobanks (3-5). These types of studies will often collect data and biological samples from minors over time (6). In contrast, in other research, there is no ongoing interaction with the participants who donated their data and biological samples. In both cases, research participants should be given either the right to consent to continue their participation in the research (or to the continued storage of their data or biological samples) or to withdraw the consent their parent(s) or guardian(s) provided on their behalf. Alternatively, they can also simply be notified that they are enrolled in the research and will remain therein unless they opt out (3).

Re-contact is rooted in the principle that informed consent should be viewed as a continuing process (3). Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (hereafter "TCPS2"), the joint policy of Canada's federal research agencies, states that consent is an ongoing process to be maintained throughout the duration of the research (7, art. 3.3). Therefore, "if the children mature sufficiently to decide on their own behalf (subject to legal requirements), the researcher must seek the children's autonomous consent in order for their participation to continue" (7, p.33). Re-contact should therefore be seen as an extension of this principle.

Recent literature has begun to question the practicality and obligatory nature of an ethical duty to obtain an expressed, explicit re-consent in the context of paediatric biobank donors (3,4,8). Still, the majority view for paediatric research, in general, remains that minor research participants should be given the chance to provide their own informed consent at the age of majority or maturity (9). Moreover, the need for re-contact may vary depending on the type of research being conducted. For example, in the context of research focused on child development and psychopathology, the need for re-contact may be considered of even greater importance (10).

In this paper, we demonstrate that re-contact where the participation of the minor has ended by withdrawal or because of loss to follow-up differs from re-contact where the minor remains enrolled in the research. For one, we argue that the approach used to determine the capacity of the participant to provide informed consent greatly determines whether a researcher may be able to re-contact a former minor research participant. For instance, while some jurisdictions use the legally fixed age of majority as the age at which consent for research participation can be provided, others adopt a maturity-based approach (3).

Within the Canadian legal and ethical landscape, there is a mixed maturity-based and legislative approach in the context of medical treatment and research. The province of Quebec adopts a statutory approach, whereby minors 14 years of age or over may independently consent to participate in research deemed minimal risk by a competent Research Ethics Board (REB) (11, art. 21). Consent for research that is deemed greater than minimal risk must be provided at the legal age of majority (11). In contrast, Ontario adopts a mature minor rule. Overall, Canadian common law provinces adopt the mature minor rule (3), which considers the capacity of the individual minor to understand the research, rather than relying on their attaining the legally fixed age of majority (3,12,13). In short, minor research participants may acquire the maturity and, hence the capacity to consent to participate in a research project, prior to reaching the legal age of majority in their jurisdiction (14).

Other international jurisdictions have also adopted the mature minor approach. The Netherlands, for example, uses a dual consent system, whereby children 12 years of age and older can consent to participate in research, in addition to their parents' consent (3,14). While there are no precise methods of determining a minor's level of maturity (15), they should generally be able to understand the objectives of the research, the associated risks and benefits, study procedures, long-term implications and the level of commitment required (16). Nevertheless, within the biomedical research context, maturity will depend not only upon the participant, but also on the type of research and the level of risk it involves (13). Hence, in the absence of a legislated age of "medical" majority, maturity should be determined on a case-by-case basis (12).

This discussion of capacity is germane to our analysis of re-contact as the mature minor rule could not apply in cases where the participation of the minor has ended in the research. The researcher, having lost contact with the minor, would be unable to evaluate the capacity to provide an autonomous informed consent. Therefore, in the absence of a legislated age of "medical" majority, the biomedical research determination of "maturity" could not occur for re-contact withdrawn minors or those who had been lost to follow-up. Re-contact would therefore not be permitted in the absence of legislation determining the age of majority, subject to REB approval. Based on this precept, we will analyze the ethical permissibility of re-contact, while recognizing the rights of withdrawal of both parents (or guardians) and minors, as well as the right of minors to make their own choices when they become adults.

POTENTIAL RE-CONTACT SCENARIOS AND ETHICAL PERMISSIBILITY

As mentioned at the outset, the focus of this article is on considerations surrounding the issue of re-contact where the participation of a minor in a research project has ended prior to their attaining the age of majority or maturity. As previously stated, this is a novel issue that has received little attention. We therefore presume that most consent forms for research projects involving minor participants have not addressed what may happen if the research team wishes to re-contact the now mature minor or adult after a period of inactivity. Indeed, the issue of re-contact for enrolled participants has generally not been well addressed in consent forms (3). For instance, a 2013 study of Canadian paediatric research consent forms found that nearly half the consent forms reviewed did not contain any clauses addressing the re-contact of minors (3,8). It is therefore probable that researchers wishing to re-contact former minor participants at the age of majority or maturity have not provided for this possibility in their research projects' consent forms. Accordingly, should they wish to re-contact these former participants, they will need to receive guidance from their institutional REB, which will ultimately decide whether re-contact is ethically permissible in the particular situation. Our present discussion will focus on factors that can help determine this ethical permissibility.

Some have argued in the literature that re-contact of minors whose parents provided proxy consent for their participation in an earlier study is not ethically permissible if the parents did not "contemplate such contact when they initially consented to the child's participation" (17). We contend that there may still be an ethical basis for re-contacting former minor participants, even if this was not contemplated in the initial proxy consent, though this permissibility is subject to several considerations and reasonable limits. Most notably, the ability to re-contact a former research participant needs to be framed within both the fundamental right to participate in or to withdraw from research (7,18) and the right to privacy, which includes the right to be left alone. Within a research project such as MAVAN, which studies mother-child dyads, the rights of both the mothers and the children need to be considered. We therefore identify three potential scenarios in which a minor's participation in research may end and consider whether re-contact would be permissible, taking all relevant factors into consideration. In this paper, we identify key factors that may influence the ethical permissibility of re-contact in such a context.

Scenario 1: Parental (or guardian) withdrawal from the research project

Due to lack of capacity, minors are generally considered incapable of fully appreciating the risks and benefits of research participation (6). Accordingly, consent for minors to participate in research is provided by their parent(s) or legal guardian(s) (10,19). In this sense, parents (or guardians) act as the surrogate decision-makers for their children until they reach the age of majority or maturity and gain the legal capacity to make autonomous decisions (9). Nonetheless, as stated in the United Nations *Convention on the Rights of the Child* (20), any such parental decisions must be made in the best interests of the child (BIC) and consider their well-being (art. 3(1)) and their right to be heard (art.12(2)). Moreover, in the paediatric context, it is important to consider not only the immediate interests of the child, but also their future interests, given that children's interests are fluid and evolve over time with age and maturity levels (20,21). Finally, as a child exists in relation to others, familial interests and values and the parent-child relationship must also be factored into the determination of their best interests (22,23). This is especially pertinent in research projects involving both parents and children.

As an extension of their proxy decision-making role, parents (or guardians) have the authority to withdraw minors from a research project should they so choose (4). In light of this authority, we consider whether and how the decision to withdraw a minor from research influences the ethical permissibility of re-contacting the minor once they have reached the age of majority. In particular, we will consider the increasing capacity and rights of minors as they age and the concomitant decrease in the degree of parental authority (14). While it is recognized that parental decision-making can continue to affect minors well into adulthood (8), the scope of parental authority decreases in conjunction with the minor's cognitive development (14). Therefore, where a minor reaches the legal age of majority, parental authority is no longer applicable and the now-adult, having acquired legal capacity, has the right to make their own choices. We therefore argue that re-contact in this scenario can be permissible, subject to certain considerations and limitations which must be evaluated by a REB.

Firstly, when they reach the age of majority, the former research participant should be able to decide whether they wish to participate in research. The literature has long recognized the individual right to participate in research and to have access to the benefits of participating in research (25). Now fully able to provide autonomous informed consent, without parental authority or influence, the now-adult should be offered the choice to re-join the research project in which they had been enrolled as a minor. We argue that the ethical basis of re-contact in this scenario is rooted in the principle of respect for autonomy, which recognizes the former research participant's right to make their own choices and to make decisions about their actions (26). Though parents (or guardians) exercise legal authority over minors, they cannot always make the decisions that the minor would have made had they been capable of providing their own informed consent at the time the decision was made on their behalf (27). Indeed, research has demonstrated that, over time, minors may wish to make different choices than those made for them by their parents (28). The now-adult may wish to re-join the research project from which they were withdrawn and exercise their autonomy in relation to the research project. Moreover, when minors reach the age of majority, they have a right to access their personal health information (17), including information that may have been collected during a research project. One may therefore argue that the now-adult or mature minor should have the right to know about their previous participation in the research project, if they so choose (17).

Conversely, in a research project containing mother-child dyads, such as the MAVAN Study, it is possible that the minor's health information may also include health information collected from the parent (or guardian) (17). While not absolute, children generally do not have the right to access their parents' (or guardians') personal information and the parent's (or guardian's) decision to withdraw themselves from the research must be respected. Indeed, in a mother-child dyad study, it is highly likely that the parent (or guardian) withdrew themselves from the research project as well. A great deal of information about the mother, the child and their relationship would have been collected during the course of the research, inevitably intertwining the information collected from the two participants. Moreover, the parent (or guardian) may not wish for their child to know about their participation in the research. This is especially true if the research entails a certain degree of personal sensitivity (17). Parental privacy rights and the right of the parent (or guardian) to be left alone after withdrawal must be considered. This is especially relevant if researchers wish to make use of information collected from the minor's initial participation in the research project. It should be noted here that Canadian ethical guidelines do not require the destruction of participants' data or biosamples, but rather leave it to researchers to address how participants' information is handled when they withdraw from the research project (7, art. 5.3).

Scenario 2: Minor (who provided assent) asks to be withdrawn from the research project

While minors are generally incapable of providing informed consent to research participation, their capacity does evolve and develop over time (14). The maturity level of minors involved in research can vary greatly, from infants to those close to the age of majority (24), and should be considered when minors enroll in research. Although they generally lack the capacity to make autonomous decisions, minors may still be able to communicate their opinions in a meaningful way by providing their assent or dissent to participate in research (7). Assent is generally understood to be a minor's affirmative agreement to participate in research (29,30). At a minimum, it involves the ability of the minor to understand the significance of the research (7). Though it does not hold legal standing (31), a child's assent, when it can be given, is complementary to parental consent (32) and acknowledges the child's agency (33).

Minors can provide their assent if they are able to understand the purpose of the research in general (7, art. 3.10), understood as age 7 and up (34). Similarly, where the minor is incapable of providing assent (for example, they are too young to be able to understand the general purpose of the research), their assent to continue their participation should be sought once they are able (7). Assent serves as a record of the child's wishes concerning their participation in a research project (14) and, like consent, is a continuous process that, depending on the nature of the research, may need to be reconfirmed throughout the duration of the project (35).

The importance of obtaining assent from minors capable of understanding the research project is enshrined in normative documents such as the TCSP2 (7) and the *Declaration of Helsinki* (18). Obtaining assent, where applicable, may also be supported by the right of the minor "to be heard" in the United Nations *Declaration on the Rights of the Child* (3,20). Where a minor is capable of providing assent and does not agree to take part in the proposed research project, this disagreement or dissent should usually preclude their participation (7,24,36). Dissent may be overridden by the parent(s) or guardian(s) under exceptional circumstances, such as where participation in research is considered the "best medical option" for the minor (24, p.65) or where the "prospect of direct benefit" is only available through research (37). Nevertheless, the general rule remains that if a minor expresses their desire to no longer participate in the research project, their wishes should be respected and they should accordingly be withdrawn from the research project.

Accordingly, it is possible that a minor who initially provided assent to participate in a research project may, at a later point, change their mind and no longer wish to continue their participation. Under current ethical guidelines, this decision should be respected, subject to the exceptions outlined above, and the minor's parents (or guardians) should withdraw them from the research project. Due to the respect that should be accorded to the minor's decision, we argue that re-contact in this scenario should not be ethically permissible. This determination respects the child's expression of their wishes and acknowledges their developing autonomy (24), as well as supporting their right to be heard (3,20). Indeed, subject to the very specific exceptions, this lack of agreement to continue participation in the research project should be treated as definitive and the minor's wishes must be respected (38). Some authors have even suggested that re-contact where the minor has withdrawn may constitute a privacy breach if there was no permission to be contacted in the future (39). We therefore maintain that a dissenting minor's request to be withdrawn from the research should be respected and that there should be no re-contact unless a REB decides otherwise.

Scenario 3: Attrition

Attrition refers to the loss of study participants over the course of a research project (40). Within the context of longitudinal studies, attrition is a common issue and has an impact on paediatric longitudinal cohorts in particular, as these studies investigate development over time (3). Attrition may create bias in longitudinal studies where the "lost" participants differ from those who remain in the study (41,42). This attrition can be attributed to a number of factors, including withdrawal, loss to follow-up, or death of participants (43). For the purposes of this article, attrition differs from withdrawal of participants, as it focuses on the loss of participants in a research project over time due to lack of ongoing engagement. The distinction between active withdrawal by participants and attrition through non-response from participants has been previously made in the literature (44). In such circumstances, since there was no clear withdrawal of the minor from the research project, through either the minor's or the parent/guardian's initiative, re-contact at the age of majority or maturity could be sought in order to

accurately ascertain the wishes of the individual to continue their participation in the research project. Again, this is subject to REB determination and oversight.

DISCUSSION

Re-contacting a former minor research participant to re-join a research project after their participation ended may be of interest to researchers for a variety of purposes. In most cases, this will be for longitudinal studies, which may include biobanks. More specifically, this form of re-contact could only be of interest where researchers have retained (but are not using) data that was collected from the research participant's initial participation in the project and updates are required. Again, under Canadian ethical guidelines, destruction of data or biological samples is not required when participants withdraw from research.

Capacity to provide informed consent can be attained either at a legally fixed age (a majority-based approach) or at the age at which the minor has matured sufficiently to be able to make their own decisions (a maturity-based approach). Where the participation of a minor in a research project has ended due to withdrawal or where they have been lost to follow-up, evaluation of the maturity level of the minor is not possible. This means that re-contact of a former minor research participant, where ethically permissible and with REB approval, can only occur when the minor has reached the legislated age of "medical" majority in their jurisdiction.

Even where it may be ethically permissible, re-contact may still present certain challenges, which researchers must consider before seeking REB approval to re-contact former minor research participants. Indeed, re-contact may not always be a straightforward process and researchers must be cognisant of the challenges this can raise and how they may affect their research projects. Ancillary to the issue of re-contact is that of re-consent and which model researchers should use to obtain the consent of the previous participants to re-join the research project. All these considerations must be factored into researchers' plans to obtain REB approval for re-contact.

Practical and Ethical Re-contact Challenges

A key challenge in re-contacting participants is that it requires considerable time, effort, and financial expenditure on the part of researchers (27). Tracking down previous research participants can be an especially costly and difficult task, particularly if the last known address of the research participant or their contact information has changed over time (4). Moreover, one must also consider the privacy concerns raised in attempting to track down former research participants if there last known address has changed (7). This is notably a challenge in a research project such as the MAVAN Study that collects not only information from the minor, but their mothers as well, who were also participants in the project. This raises the issue of whether researchers may contact the minor's parent(s) or guardian(s) to obtain their contact information once they have reached the age of majority or maturity, as it may be the case that the minor has changed addresses. Generally, we recommend sending a letter to the minor's last known address, *addressed personally to the now-adult minor*, as the least intrusive method of re-contact. However, we argue against personally contacting the parents (or guardians). Given that they most likely were participants as well and would have also withdrawn from the research, their right to be left-alone after withdrawal *must* be respected.

While re-contact may raise many – often burdensome – challenges for researchers, it should be balanced with a number of factors, including feasibility and cost efficiency (3,9). For one, larger sample sizes have greater statistical power, which is important in answering research questions and detecting meaningful effects (2). For research projects which have "legacy" data and biosamples, that is, data and biosamples that had been collected from participants prior to withdrawal or loss due to attrition, re-consent is required for their use (45). The valuable information the retrospective use of this data can bring can also factor into researchers' decisions in seeking REB approval to re-contact and re-consent participants where there are legacy data and biosample sets. Within the paediatric longitudinal research context especially, data represent specific points in time in the course of the participant's development and are not replicable (46), making this consideration all the more important. Indeed, certain research questions can only be investigated through longitudinal research projects. There is thus scientific interest in observing the development of these participants over time and, hence, obtaining information from them at later life stages.

In short, researchers must consider several practical and ethical factors in assessing whether to submit a re-contact plan to their REB of record. This assessment will be unique to each research project and its specific needs and objectives. However, re-contact should not pose an undue burden to researchers and jeopardize the conduct of their projects. A "middle ground" between the scientific value of re-engaging former participants and resource expenditure should therefore be sought. This balancing act will ultimately decide whether permission to re-contact is worth pursuing for the research team.

Overview of Re-consent Models

Once all relevant factors have been considered and a researcher has obtained REB approval to re-contact former minor research participants, they must decide how to obtain the participant's consent to re-join the research project. The literature presents and describes three primary models of re-consent available to researchers: a) new consent; b) notification with opt-out; and c) waiver of re-consent (3,8,47). These models are generally applied to minors who have reached the age of majority or maturity while actively participating in a longitudinal study. As mentioned above, consent is ongoing throughout the research project and, in Canada, researchers have a duty to seek the minor's autonomous consent for their participation in the research

to continue when they reach the age of majority or maturity (7). Some authors have highlighted the inaccuracy of the term "re-consent" as applied to minors in research, as the minor never provided their consent to participate in the research but rather did so through the consent provided by their parent(s) or guardian(s) (27). Nonetheless, the use of "re-consent" in this context is widely accepted by the literature (48,49,50). We now consider, for the purposes of our present discussion, how these models may be used in the context of re-consenting former minor research participants.

New consent

Upon reaching the age of majority or maturity, the former research participant may be asked to formally consent to continue their participation in the research project. This approach is employed by the Norwegian Mother, Father and Child Cohort Study (MoBa), which requires explicit consent to remain in the study from children enrolled in the project when they reach 18 years old (3,51). Re-consent may be accomplished by presenting a new consent form which reiterates the initial terms of the proxy consent given by their parent(s) or guardian(s) on their behalf. The research participant would then be asked to re-consent to these terms, as well as the terms for the continuation of the research project. In some cases, these terms may differ from those initially consented to by the parent(s) or guardian(s). For instance, some research projects conduct more invasive procedures on adult participants but not minors. The participant would then be asked to consent to these new terms as part of the new consent.

Alternatively, new consent can also be accomplished through an addendum to the initial consent form signed by the parent(s) or guardian(s). This approach is used by the MUHC Centre for Applied Ethics of the McGill University Health Centre in their template consent form for investigator-initiated paediatric clinical research (52). In the addendum, participants are given the opportunity to review the consent form signed by their parent(s) or guardian(s) when they were first enrolled in the research project and are asked to either consent to their continued participation or to withdraw from the research project. The modalities of how their information will be handled if they choose to withdraw must be specified.

Notification with opt-out

A notification with opt-out model is another possible re-contact approach. Under this approach, notification letters explaining the study are sent to minor participants when they acquire the capacity to provide autonomous informed consent, reminding them of their participation in the original research project (through their parent's or guardian's consent), and informing them of their right to withdraw (3). The efficacy of this approach depends, though, upon participants' contact information remaining valid and up-to-date throughout the duration of their participation.

This approach has been adopted, for example, by Statistics Canada, first in the Canadian Health Measures Survey (CHMS) (3) and now in the Canadian COVID-19 Antibody and Health Survey (CCAHS), which collects questionnaire data and blood samples from participants to better understand how COVID-19 has affected the health of Canadians (53). When minor participants reach the age of 14, they receive a letter asking for their approval to keep their blood sample in the COVID-19 biobank (53). If, at this point, the participant wishes to have their sample removed from the biobank, they must notify the CCAHS team by letter or email (53).

Waiver of re-consent

Though not a model of re-consent *per se*, seeking a waiver of re-consent from a REB is a potential method for researchers to continue to use identifiable information from minor research participants without having to re-contact them (9). Within the American context, Institutional Review Board (IRB) practice is variable, with only some IRBs granting such waivers and others requiring that collected information be destroyed if the minor cannot be reached at the age of majority (9). Within the Canadian context, under the TCSP2, a waiver of re-consent is possible for the secondary use of identifiable information, if the applicable REB determines that certain criteria are met (7, art. 5.5A). It is of note that this is an exception to the general rule that requires re-consent of minors who reach the age of majority or maturity within the context of the research project (7, art. 3.3).

Among the criteria that a REB must evaluate for a waiver are the essential nature of the information to the research and the impossibility or impracticability of seeking the consent of individuals to whom the information relates (7). Mere inconvenience does not constitute impracticability (7). Rather, re-consent must pose an undue hardship or onerousness that could jeopardize the conduct of the research project (7). Seemingly, this would not apply to research that involves ongoing interaction with participants, but instead to research that does not entail continuous interaction, such as certain biobanking projects that make data and biosamples available for future research but that have limited contact with participants (9). Examples of impracticability given in the TCPS2 include situations where participants are likely to be deceased, are geographically dispersed, or are difficult to track (7). Impracticability may be further heightened where significant time has lapsed since the participant's initial consent or, in the case of longitudinal studies, their most recent consent. Generally, re-consenting minors upon reaching the age of majority or maturity in a longitudinal study would be considered less onerous by a REB. However, given that in certain circumstances it may be difficult to track down former research participants where their contact information has changed or is not easy to find, re-consent may be considered impracticable and pose an undue burden on researchers, to say nothing of cost. In short, the waiver remains at the discretion of the institutional REB.

Application of Re-consent Models to Re-contact Scenarios

As previously stated, current re-consent models are generally applied to minors who have reached the age of majority or maturity while enrolled in a longitudinal research project. They have yet to be tested in obtaining consent from previous

research participants to re-join a research project. Here, we discuss their applicability in research projects, such as the MAVAN Study, that wish to re-engage previous minor participants. Again, re-contact in this situation can only occur when the minor has reached the legal age of majority in their jurisdiction, as the mature minor rule cannot apply when there is no contact with the minor. Where re-contact is permitted by a REB, researchers may consider that the applicability of the re-consent models depend upon the particular circumstances of their research projects and how the participation of the minor ended.

In the circumstance where the participation of the minor ended due to withdrawal by the parent (or guardian), seeking a new consent would be the most applicable model. After a period of inactivity, a new consent outlining the terms of participation for re-joining the research project would be the most feasible approach in obtaining the informed consent of the former participant. Though beyond the scope of this paper, researchers should be conscious of any potential familial implications where the former participants consent to re-join the research project. In such a case, there may be associated privacy concerns raised for the parent, as exists in research that involves the collection of genetic or genomic information from participants (54).

A notification with opt-out approach would only appear to be applicable where the participant has been lost to follow-up. Under this model, since there was no explicit withdrawal of the participant, they can, upon reaching the age of majority, be notified of their participation via the previous proxy consent given by their parent(s) or guardian(s) (3). Consent to continue participation is implied, unless the participant chooses to explicitly withdraw. This notification approach does not have to wait for loss or withdrawal of a participant, but can also manifest itself in annual updates, birthday cards, etc. that are sent to the minor so as to maintain engagement.

A REB re-consent waiver, which constitutes an exception to the general rule that informed consent is required, could be applicable in either the withdrawal or attrition scenarios. The applicability of this model depends on whether the research project's institutional REB grants a waiver of re-consent. The researchers must be able to demonstrate the impossibility or impracticability of re-contacting the research participants, as well the other required criteria. Additionally, the researchers must still have access to the prior participant's information, which must not have been destroyed or completely anonymized upon withdrawal. Otherwise, a waiver would not be relevant. Where a waiver is sought for data collected from participants who have been lost to follow-up, researchers would not be able to collect prospective information from participants, which may limit scientific value or utility to researchers, depending on their specific projects' objectives.

CONCLUSION

As paediatric longitudinal research projects become more common, researchers may wish to re-contact and re-consent previous minor research participants for numerous reasons of scientific interest to their research project. In this specific situation, we have argued that re-contact could only be possible when the former participant has reached the legal age of majority. The maturity-based approach, applicable to re-contact for enrolled minor participants, is inapplicable where there is no contact with minor, as researchers would not be able to assess the latter's level of maturity.

Working from this premise, we considered different scenarios in which the participation of a minor in a research project may have ended and considered the ethical permissibility of re-contact in each scenario. Where re-contact is deemed ethically permissible by a REB, the former participants can be re-consented either by being asked to provide a new consent or by a notification with opt-out approach. Alternatively, a waiver of re-consent is applicable subject to the fulfillment of certain criteria and REB approval. Nonetheless, there are practical challenges to re-contacting prior research participants that researchers must consider and balance with the scientific value of re-consenting these participants. We hope this discussion serves as a practical guide for researchers when they seek REB approval to re-contact former minor research participants who have reached the age of majority. As a future best practice for research projects for which this could be a relevant issue, we suggest that researchers provide parents (or guardians) the option of consenting to the re-contact of their child at the age of majority or maturity after their participation in the research project has ended, as well as potentially re-contacting the parent(s) or guardian(s) themselves to facilitate re-contacting the minor. This has also been suggested in the literature. In this manner, obtaining consent from the outset minimizes many of the ethical challenges in determining the ethical permissibility of re-contacting the minor at the age of majority or maturity. While this does not eliminate the practical challenges of re-contact, such as change of address of the minor, it serves to streamline and clarify practices for researchers going forward.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Community-Level Vulnerabilities and Political Field Experiments

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Résumé
La plupart des documents relatifs à l'éthique de la recherche sur la vulnérabilité s'intéressent à la vulnérabilité des individus et des populations définies par la vulnérabilité potentielle de leurs membres (comme les adultes souffrant de déficiences intellectuelles ou les prisonniers). Cependant, la recherche impliquant des sujets humains ne prend pas toujours l'individu comme unité d'analyse : les expériences politiques de terrain peuvent appliquer une intervention à une communauté dans son ensemble. Cet article soutient que la vulnérabilité au niveau de la communauté n'est pas réductible à la somme des vulnérabilités des membres d'une communauté, et qu'il est donc nécessaire de considérer la vulnérabilité au niveau de l'analyse de la communauté lors de l'analyse des implications éthiques des expériences politiques sur le terrain. Je passe d'abord en revue la littérature éthique sur la recherche d'intervention communautaire et la recherche émergente sur l'éthique des expériences de terrain politiques. Je mets ensuite en évidence les principaux comptes rendus du concept de vulnérabilité au niveau individuel. En m'appuyant sur le concept de « torts collectifs » de Whitfield, je soutiens que les communautés peuvent être affectées négativement de manière distincte des torts causés aux membres individuels de la communauté, et que la variation de la susceptibilité à de tels torts au niveau de la communauté est largement conforme aux conceptualisations existantes de la vulnérabilité. Je suggère des questions que les chercheurs peuvent prendre en considération lors de la conception d'expériences politiques sur le terrain afin de s'assurer que les vulnérabilités au niveau communautaire sont prises en compte.

Mots-clés
vulnérabilité, expériences politiques, expériences de terrain, éthique de la recherche, communautés

Abstract
Most research ethics literature on vulnerability focuses on the vulnerability of individuals and populations defined by the potential vulnerability of their members (such as adults with intellectual disabilities or prisoners). However, research involving human participants does not always take the individual as the unit of analysis: political experiments may apply an intervention to a community as a whole. This paper argues that community-level vulnerability is not reducible to the sum of the vulnerabilities of community members, and that there is thus a need to consider vulnerability at the community level of analysis when analyzing the ethical implications of political field experiments. I first review ethical literature on community intervention research and the emerging scholarship on the ethics of political field experiments. I then highlight key accounts of the concept of vulnerability at an individual level. Drawing on Whitfield's concept of "collective wrongs," I argue that communities can be negatively affected in ways that are distinct from harms to individual community members, and that variation in susceptibility to such wrongs at the community level is largely consistent with existing conceptualizations of vulnerability. I suggest questions that researchers should consider when designing political field experiments to ensure that community-level vulnerabilities are taken into account.

Keywords
vulnerability, policy experiments, field experiments, research ethics, communities

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INTRODUCTION

Political field experiments test potential policy initiatives by applying experimental methods in a naturalistic and often large-scale context (1,2). Field experiments are increasing in popularity as a tool in the ascendant "evidence-based policymaking" paradigm (3) and in political science scholarship (2,4). These experiments may involve interventions at a community level. For example, a political field experiment may involve modifying the structure of unemployment benefits in an effort to increase the employment rate or changing the built environment in a neighbourhood to promote the use of active transportation. Communities may be randomly or purposively assigned an intervention and compared to "control" communities that receive no intervention or "treatment as usual." Along with community-level interventions, these experiments may have community-level effects – benefits and harms, both intended and unintended – that can affect the community as an entity.

Adopting a community level of analysis in research raises distinct ethical questions. This paper focuses on the concept of vulnerability, asking how vulnerability may be understood at a community level in political field experiments. I argue that adding a community level of analysis to discussions of vulnerability in political field experimentation is essential because community vulnerabilities are not reducible to the vulnerabilities of a community's individual members. As such, failing to consider the vulnerability of communities may result in unanticipated adverse effects. While community-level intervention research is carried out in many disciplines (including community psychology, public health, and others) and methodological traditions (including community-based participatory research), I aim to contribute specifically to the emerging literature on the ethics of political field experimentation. As such, examples will be drawn primarily from the ethical and empirical literature in this area.

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First, I highlight interdisciplinary scholarship on the ethics of community-level research. Second, I review ethical literature relating to political field experiments. Third, I provide a brief overview of definitional debates around individual-level vulnerability in research ethics. Fourth, I argue that communities can be negatively affected in ways that are not accounted for at an individual level of analysis. I will provide examples of domains in which community-level wrongs may occur and argue that susceptibility to incurring wrongs during political field experimentation can vary across communities and research situations. Fifth, I propose that this variation in susceptibility to wrongs is congruent with existing definitions of vulnerability, and therefore necessitates considering vulnerability at the community level when conducting political field experiments. Finally, I suggest considerations for researchers conducting political field experiments and call for further investigation and conceptualization of this issue.

ETHICS IN COMMUNITY-LEVEL RESEARCH

Political field experimentation is only one example of research conducted at a community level. Ethical questions in community-level research require attention to the concept of a community itself, and to the complexity and dynamism of community relations. I draw on interdisciplinary literature to highlight some of these issues below.

Defining communities

The question of what constitutes a community is critical in community-level research. Writing in the field of community psychology, Krause and Montenegro propose seven characteristics of community: social relationships, shared culture, shared identities, a sense of community, collective action and motivation, and spatial and temporal dimensions (including virtual or other spaces) (5). In an article on community engagement in biomedical research, Weijer and Emanuel suggest ten characteristics of communities, while acknowledging that not all communities will have all characteristics. Excluding health-specific domains, their list of characteristics suggests that key features of a community are shared traditions, identities, and resources, along with mechanisms for collective decision-making and representation (6). Literature on community-based participatory research (7-9) and public health (10) has defined communities in terms of social ties and shared identities.

Communities, however, are not homogenous, but rather have internal divisions, hierarchies, and conflict (7-9). Moreover, it is important to note that defining the boundaries of a community can be fraught with challenges. Demarcating the limits of a particular community necessarily requires exclusion as well as inclusion – it involves stating who is in and who is out (5). In intervention research, these boundaries may have important implications both for the distribution of resources, and for the application of safeguarding processes. As such, community-level ethical issues may arise as soon as researchers attempt to define the community with which they are engaging.

In this paper, I consider a community to be a group that includes social relationships, shares elements of identity, and engages in purposeful collaboration. In light of the above discussion, this description is not intended to imply homogeneity, nor is it suggested that this definition alone is sufficient to neatly bound any given community.

A community level of ethical analysis in research

As noted above, many fields have longstanding traditions of community-level intervention research. These fields each have distinct values such as humility in community-based participatory research (11), and frameworks for ethical intervention such as Nuffield's ladder of interventions in public health (12). Researchers conducting political field experiments can nonetheless turn to this ethical scholarship to understand some of the issues at stake in research with communities. These issues include the obligations of researchers towards communities, differential effects within the community, and difficulties identifying who can validly represent the community.

The obligations of researchers working with communities are less well-established than those pertaining to individuals, but this is not to say the former are unexplored. Four decades ago, Rappaport identified a dialectic of needs and rights that arises in relation to community intervention, noting that a needs-based view implied requirements for protection, even paternalism; a rights-based view suggested a focus on freedom and self-determination (13). Rappaport called for a synthesis of these ideas, which he termed "empowerment" and described as "enhance[ing] the possibility for people to control their own lives" (p.15). Empowerment continues to hold sway as an important concept in the ethics of community-level research (14). Meanwhile in the field of public health, ethicists have argued for an obligation to support communities' "flourishing," a condition that encompasses resilience and the enabling of individual and collective capacities (15). Like autonomy in individual-level research, empowerment and flourishing are principles that can help to orient ethical research design.

However, the internal heterogeneity of communities creates challenges for actualizing these principles. Interventions targeting a community as a whole may have differential effects within that community. That is, an intervention may benefit some subgroups but harm others; moreover, while some interventions may only target a subgroup within a community, inter-relationships within a community may lead to unexpected effects on "non-participants" or the community as a whole (16). Complicating the picture further, different value systems within a community mean that there may be disagreement about what constitutes a benefit or a harm, and for whom (16). This complexity can introduce dilemmas and tensions into the conduct of research.

Beyond benefit and harm, the concept of consent is also a thorny issue when interventions are applied at a community level. Given the complexity of communities as described above, who can speak for the community as a whole? Engaging with community governance or other forms of representation has been argued to be necessary but insufficient to safeguard communities as a whole (11). This insufficiency derives from the diversity within communities, which may not be represented in formal governance structures. Similarly, writing about cluster randomized trials, Gallo and colleagues suggest: "A gatekeeper may give permission for the cluster to participate in the study if they have legitimate authority with respect to the individuals involved and if their authority extends to the decision at hand" (17, p.9); however, they go on to describe the challenges of determining a gatekeeper's legitimacy and accounting for within-group diversity. Questions of "speaking for" a community can also arise with respect to representing or portraying that community, as may occur in the dissemination of research findings (18). Communities cannot be presumed to speak with a single voice.

In the face of these ethical challenges, scholars in fields and methodologies that focus on community-level work have suggested extensions or adaptations to transdisciplinary ethical frameworks such as the Belmont principles. For instance, Campbell and Morris suggest that community psychologists interpret and extend the Belmont principles of respect for persons and beneficence to consider the implications of research for groups, communities, and cultures (19). While adopting a community level of analysis does not resolve the tensions of differential values and effects, it can surface them. Once identified, community psychology scholar Sánchez Vidal argues for a systematic approach to weighing options in community-based research (16):

> But if there are clear incompatibilities among values or if the beneficence distribution is unbalanced, it is necessary to rank-order values (or actors) so that an option is selected that is most beneficial (or less harming) to the primary values or actors chosen. Although in many instances there will not be a perfect option, it must always be an option that is globally better than the rest in terms of values, consequences, and methods involved (p.78).

This approach enables a systematic management of differential effects and may be of interest to researchers in other fields coping with similar research challenges.

THE ETHICS OF POLITICAL FIELD EXPERIMENTS

Literature on the ethics of political field experiments has not directly confronted the issue of a community level of analysis, although related issues have been raised. The ethical relevance of a naturalistic context and the potential for widespread effects will thus be discussed below, while a more detailed discussion of the ethics of political field experimentation can be found in Phillips' recent review (4).

Political field experiments are carried out in the naturalistic context of the community, rather than in a laboratory or other contrived setting. Naturalistic contexts have implications for informed consent, as some political field experiments may be designed to be "unobtrusive" to further maximize the validity of findings (20). In these cases, participants may have partial or no awareness of the experiment taking place. Minimal risk is one requirement of justifying unobtrusive designs (20). Further, political field experiments not only intervene in natural settings but do so within the framework of an experiment, which requires comparison. Kukla (21) offers an alternate vision of equipoise for this type of research. Her argument centres the contextual appropriateness – rather than the abstract "equality" – of trial arms. Teele (22) also describes the complexity that natural contexts introduce into experimentation. Drawing on examples from international development, she points to jealousy between sites receiving and not receiving a desired intervention, as well as tensions between community and researcher values, as risks that are visible only when the context of the field is thoroughly understood. Teele argues that fulfilling the principle of beneficence in field experiments requires a deep, contextualized understanding of risks.

The benefits and harms of political field experiments may also accrue to individuals and entities beyond those directly enrolled in a study. For instance, in a political field experiment distributing election information, friends and neighbours of those receiving the information may also be affected (4,23). McDermott and Hatemi argue that the widespread impact of political field experiments – and accompanying widespread risk of harm – requires a new ethical principle to guide field experimentation: respect for societies (1). This principle would require field experiment researchers to consider the impact of their experiments not only on participants, but also on non-participants and on the broader population and society in which those participants exist. Whitfield (24), meanwhile, argues that field experimentation in policy research "is distinctively concerned with people in or as committees, associations, states, polities, nations, corporations, and other types of groups engaged in some manner of collective decision making" and "the agency and attendant rights of the relevant collection *as a group*" (24, p.530; italics in original). Whitfield goes on to argue that this focus on groups *as groups* requires attention to particular types of wrongs, namely those impinging on groups' legitimate decision-making. I will return to Whitfield's argument below to inform a provisional concept of vulnerabilities occurring at the level of a community.

DEFINING VULNERABILITY

Vulnerability is an important concept in research ethics, where it is used to flag a need for special attention or protection (25). The American Political Science Association's 2020 *Principles and Guidance for Human Subjects Research* states

“Researchers should be especially careful to respect participants’ autonomy when conducting research with low-power or vulnerable participants and communities” (26). But what does it mean for a community to be vulnerable? While the concept of vulnerability is subject to ongoing debate in the research ethics literature, this debate has centred almost entirely on the concept of vulnerability as applied to individual research participants. Even concepts of “vulnerable groups” in fact consider vulnerability at an individual level of analysis. To provide grounding for a concept of vulnerability at a community level, I review existing definitional debates around individual-level vulnerabilities below.

Guidance relating to vulnerability in research – including in major research ethics frameworks such as the Belmont Report, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the Declaration of Helsinki – focuses on individuals who are vulnerable because of personal characteristics, or interactions between personal characteristics and context. The 1979 Belmont Report called attention to issues of capacity for consent when addressing vulnerability, and listed groups whose individual members may be considered vulnerable (such as people who are poor or very ill) (27). More recently, the 2013 Declaration of Helsinki defines vulnerability as “an increased likelihood of being wronged or of incurring additional harm” (28). This definition is referenced in the 2016 CIOMS guidelines, which like earlier reports, points to specific potentially vulnerable groups – including those with reduced capacity for consent, pregnant women, and institutionalized individuals – but also calls for attention to context when determining vulnerability (29).

These shifting guidelines reflect debate and advancement in the ethics literature on vulnerable individuals. Hurst (30) and Luna (31) offer two of the most prominent scholarly conceptualizations of vulnerability. Both critique consent-based definitions, suggesting that these fail to address the full spectrum of possible risks in research, and do not justify the perceived vulnerability of some groups. For instance, pregnant women are commonly labelled as a vulnerable group, but face no particular barriers to providing consent (30,31). Meanwhile, both Hurst and Luna also argue that labelling entire groups as vulnerable runs the risk of stereotyping (30,31). While their critiques of existing work on vulnerability share similarities, Hurst and Luna put forward distinct alternatives. Hurst argues that vulnerability can be defined as an increased likelihood of incurring wrongs. She further states that applying this definition involves asking first if a potential research participant faces a greater likelihood of wrongs, and second whether the researcher or review board has a share in the obligation to minimize that likelihood. Luna argues against defining vulnerability, suggesting the concept should remain fluid. Her work shifts the focus from what vulnerability is, to how it is produced; she suggests that contextual features, individual traits, and study design can all act as dynamic “layers” of vulnerability that wrap around an individual, and as such a person who is vulnerable in one setting may not be vulnerable in another.

More than a decade after Hurst and Luna’s initial articulations of each of their positions, the precise nature of vulnerability continues to be subject to lively debate in the literature. However, this debate continues to focus on the vulnerability of individuals. An individual focus on vulnerability is explicit in Hurst’s writings (30), narrowing it to an individual’s risk of incurring wrongs. While Luna’s (31) work brings attention to context, she is interested in context insofar as it “wraps around” the individual. Even early accounts identifying vulnerable groups are, in fact, focused on individuals who belong to those groups, and not the group as a collective unit. For instance, labelling adults with profound intellectual disabilities as a vulnerable group suggests that any person from this group could face increased risks when engaging in research. However, this move from singular to group vulnerability is neither inevitable nor always appropriate. Labelling a group as vulnerable is a categorical decision based on shared traits; it does not assume ethically-relevant social relationships or interdependencies among vulnerable group members which, as discussed above, are key features of communities.

In some instances, vulnerability may be generated by hierarchical or coercive institutional contexts such as prisons, educational institutions, or the military (32). The relationship of interest in these circumstances is not among participants, but rather between individual participants and the institutional order in which they are embedded. For instance, ethical concerns relating to research with people who are incarcerated revolve around the limits to individual prisoner’s exercise of autonomy (32), and not the “community” of people in prison as a whole. Prisoners are in this case treated as a category of individuals who share specific, institutionally-imposed threats to their ability to consent.

Thus, although the phrase “vulnerable communities” appears frequently across research ethics literature, the question of what it means for a community to be vulnerable is left unanswered. As such, it is unclear whether current definitions as described above are sufficient to guide research undertaken at a community level.

COMMUNITY-LEVEL VULNERABILITIES

In seeking to address community-level vulnerabilities, I follow Hurst’s conceptualization of vulnerability as variable susceptibility to wrongs. I first draw on Whitfield to extend the concept of wrongs to a community level, then argue that communities have varying susceptibility to these wrongs; I suggest that the concept of vulnerability can be applied at a community level of analysis. I also follow Luna (31) in treating vulnerability as an emergent condition rather than an intrinsic property. Luna argues that individuals are rendered vulnerable by circumstance and that vulnerability is layered rather than dichotomous; in keeping with this approach, I will suggest ways in which community-level vulnerabilities can emerge through the process of political field experimentation, rather than seeking to label certain communities or types of communities as inherently vulnerable.

Communities and collective wrongs

If individual vulnerabilities can be understood in terms of (individual) wrongs, community vulnerabilities can be understood in terms of collective wrongs. Whitfield, in his call for ethical principles specific to empirical political science research, provides just such a concept. He distinguishes between three types of wrongs, the first and most familiar of which are individual wrongs, i.e., those perpetrated against distinct individual persons. Second are diffuse wrongs, which pertain to the shared attributes of individuals, for instance the perpetuation of stereotypes. Third, and most relevant here, are collective wrongs, which "are done to the moral status and due consideration of groups" (24, p.532). While Whitfield takes a narrow view of groups as "constituted collectives that function as intentional agents in their own right" (p.532), such as governments or other decision-making bodies, I extend the concept of collective wrongs to a broader array of communities that may be subject to political field experimentation, using the provisional definition of "community" described above.

Whitfield's taxonomy may imply that collective wrongs exist independently from individual and diffuse wrongs. In fact, this is unlikely to be the case. Individuals are embedded in communities, and communities are comprised of individuals; feedback loops among levels of analysis can shape intervention effects, harms, and vulnerabilities (33,34). However, while collective wrongs are not fully separable from individual-level effects of an intervention, nor are they reducible to a simple sum of individual effects. Rather, I posit that wrongs at a community level impinge or affect the elements that define a community, such as social relationships, shared identities, and collective functions. These effects cannot be understood without adopting a community level of analysis.

Income inequality provides a good example. If one of the functions of a city is to support the livelihood and flourishing of its inhabitants, we can say a city is "doing well" when the quality of life there is high, life expectancy is long, and people are happy to live there. Conversely, a city is "doing poorly" when the quality of life is poor, and its residents live short and unhappy lives. Research in public health has demonstrated that income inequality is associated with poorer and more unequal population health, independently of other major factors including overall wealth (35,36). Various pathways have been hypothesized to explain this effect, including increased chronic stress (36) and weaker public infrastructure and services (37). An increase in inequality may arise from various differential effects within the community, including benefits to some groups and smaller benefits, neutral effects, or losses to others. However, the problem of inequality is relative, by definition, and so may not be visible at an individual level of analysis.

Threats to social cohesion are another instance of a community-level effect. The term "social cohesion" is used to describe the extent of trust and intra-community networks within a group. Like social equality, social cohesion is independently associated with wellbeing (38-40). If benefits accrue – or are perceived to accrue – to one group and not to another, cohesion may be undermined (40). Tension may also arise when social discourses of "deservingness" are breached (41). Workers, for instance, may object to the provision of more generous benefits to the unemployed; or law-abiding citizens may object to increased supports for incarcerated people. In these hypothetical situations, benefits to a subgroup within the community may have ramifications for the cohesiveness of the community as a whole.

Veering closer to Whitfield's original argument, we can also see threats to governance as a collective wrong that can be incurred by a community. Governance reflects the ability of a community to make decisions that affect the collective. Governance requires both authority (the power to make decisions) and legitimacy (social acceptance of authority) (42). Where governance is undermined, a community loses the capacity to self-organize, support its members, and manage its resources. Political field experiments relating to voting may undermine the legitimacy of elections, a clear threat to governance (23). Meanwhile, field experiments have gained particular prominence in research on international development (43), and scholars have noted that well-intentioned international aid may have the effect of undermining governance – when essential services are provided by an entity other than the government, the government may lose legitimacy as a body capable of meeting population needs (44). This can spur a cyclical effect, as a government that has lost legitimacy will be hobbled in efforts to gather and distribute resources, leading to increased need for outside support and further reduced legitimacy. As in the above examples, this effect can occur without harming or wronging any particular member of the community. In fact, external aid may provide tangible benefits like health or social services. But despite these benefits to individuals, the community's decreased ability to self-govern represents a collective wrong.

The above descriptions are only examples of collective wrongs affecting communities and are in no way intended to represent a comprehensive or exhaustive list. In fact, such a list would be difficult to compose, as it would require a fully-articulated inventory of the ethically-relevant interests of groups. Instead, I hope to illustrate the possibility of analyzing community-level wrongs as a distinct concern, one that cannot be deduced by tallying individual-level wrongs. This is important because analyzing wrongs solely at an individual level may miss risks of the sort described above, thereby creating the potential for unintended, adverse effects.

Community vulnerabilities

If we accept that collective wrongs are those affecting a community's ability to function as a community, and that collective wrongs are not reducible to a collection of individual wrongs, we can then ask whether all communities are at equal risk of being wronged in this way. This potential for a range of levels of risk is central to many conceptualizations of vulnerability. In Hurst's work (30), and in the 2013 Declaration of Helsinki (28), this issue of risk is explicit – both describe vulnerability as an excess risk of wrongs (and, in the latter case, harms). In Luna's argument, layers of vulnerability may accrue or be peeled

back depending on context (31). The metaphor of layers therefore implies a spectrum or range of vulnerability, although risk per se is not addressed. In all these accounts, vulnerability tells us that something is more than usually susceptible to damage, or in need of greater care.

Empirical and conceptual literature provides examples of a range in risks of wrongs at a community level. Inequality may pose a greater threat in communities that do not have effective mechanisms for redistribution of resources (35,37). For instance, income inequality may be mitigated by taxation policies. At a smaller scale, neighbourhoods may redistribute resources through informal or formal networks like places of worship. However, in communities without redistributive capacities, the full force of increasing inequality will be felt. Threats to social cohesion, meanwhile, are a more prominent concern in communities with pre-existing divisions and tensions. Teele, for instance, comments on a field experiment carried out by Paluck and Green in Rwanda, where a radio program was developed in which actors voiced dissent with the aim of assessing the effect on listeners' tendencies to defer to authority. Teele argues that promoting the democratic norm of contestation could in fact pose a threat to the fragile balance of a post-genocidal society (22). Threats to governance may be most pronounced where governance structures are weak or are already undermined. This issue is reflected by Cragoe, who notes that traditional governance and other forms of leadership in some Indigenous communities may exist in tension with governance structures instituted by the state. He argues that researchers working with Indigenous communities should consult with the most appropriate community leaders to ensure that the interests of participants are legitimately represented, and to avoid replicating and reinforcing damaging, paternalistic colonial relations (45). These examples suggest that social features and processes – whether internal to a community or imposed by outside forces – can place some communities at additional risk of incurring collective wrongs during the process of political field experimentation.

However, it is critical to note here that the objective of naming community vulnerabilities is *not* to label specific communities as vulnerable. As described above, research with communities has adopted a focus on empowerment that dialectically acknowledges the risks faced by communities and seeks to actualize community rights and capacities (14). In keeping with this synthesis, I suggest that community-level vulnerabilities in political field experiments are not fixed properties of the community. Rather, community-level vulnerabilities emerge through the interaction between a study or intervention design, and features of the community receiving that intervention. Inequalities may be deepened when an experiment distributes goods to the already-advantaged; social cohesion may be weakened when a study produces benefits that accrue to a specific group, or that violate social norms of fairness; governance may be weakened by an intervention that circumvents or overrides existing, local decision-making structures. Naming these vulnerabilities is not grounds for excluding communities from research, but rather is intended to prompt responsive study designs that minimize harm while respecting community-self-determination.

Creating such designs requires researchers to ask of their political field experiments: In what ways does this study design interact with this specific community's context and makeup to affect the likelihood of wrongs – including wrongs affecting social relationships, shared identity, collective activity, and other elements that make this community a community? What wrongful effects might this study have on subgroups within the community? How might the susceptibility to these community- and subgroup-level wrongs be reduced or offset in the context of the experiment? How might differential effects be fairly and appropriately balanced? Moreover, the dynamic nature of communities mean that any changes introduced to a field experiment to offset vulnerabilities may introduce new, and newly differential, effects. Thus, managing vulnerability will be an iterative process. Sánchez Vidal's framework quoted above can provide a helpful structure for managing that complexity while aligning decisions with relevant values and minimizing overall harm (16).

These questions and processes are critical because a failure to consider community-level vulnerabilities in political field experiments risks incurring detrimental effects. This risk is present even when individual vulnerabilities have been carefully taken into account. For instance, ensuring consent processes are adapted to the needs of individual participants is critical, but will prevent none of the potential community-level wrongs described above such as increased inequalities, damaged cohesion, or undermined governance. On the other hand, tailored strategies rooted in a deep understanding of local contexts including conflicts, resources, and norms, along with collaboration with community members and community leaders, may help prevent unintended wrongs to communities, *as communities*.

A CALL FOR FURTHER EXPLORATION

This paper adds to emerging conversations on the ethics of political field experiments. While existing ethical frameworks are oriented towards protecting individuals, political field experiments often concern communities. Applying the concept of vulnerability at the community level alerts us to the possibility of increased susceptibility to collective wrongs – wrongs that impede community relationships, identity, and functioning. While not independent of individual-level effects, these wrongs may be overlooked when political field experiments are subjected to individual-level ethical analysis alone. Future scholarship can create a firm definition of community-level vulnerabilities; suggest obligations implied by these vulnerabilities; further consider vulnerabilities at a subgroup level and the interactions of vulnerabilities across levels of analysis; and identify strategies for identifying community-level vulnerabilities and mitigating the risk of associated wrongs. While I have drawn here primarily on literature relating to field experiments in political science and policy, future work can also address the relevance of community-level vulnerabilities in other disciplinary traditions.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Recognizing Racism in US Bioethics as the Subject of Bioethical Concern

Charlene Galarneau[a,b]

Résumé
L'étude du racisme et de la bioéthique américaine soulève la question de savoir si et comment le racisme a fait l'objet d'un examen bioéthique. Il est certain que la bioéthique a utilisé ses outils d'analyse pour étudier les aspects racistes des soins cliniques et de la recherche biomédicale. Mais la bioéthique a-t-elle étudié le racisme dans la bioéthique en tant que sujet? Un examen attentif des rapports, articles et livres pertinents de la littérature de bioéthique américaine publiés aux débuts de ce domaine, avant 2000, révèle des résultats mitigés. Dans les années 1970, le racisme en tant que préoccupation bioéthique était inexistant, vaguement sous-entendu, puis examiné et condamné avec force. À la fin des années 1980 et au début des années 1990, le racisme était plus fréquemment décrit et critiqué, souvent dans le contexte de discussions sur les perspectives afro-américaines de l'éthique biomédicale et des inégalités dans les soins de santé. Comprendre comment le racisme en bioéthique a été abordé comme une préoccupation éthique a des conséquences sur les récits historiques racontés sur le domaine, sur le travail de bioéthique antiraciste d'aujourd'hui et sur la vision d'un avenir bioéthique antiraciste.

Mots-clés
racisme, bioéthique, suprématie blanche, Tuskegee, rapport Belmont, perspectives afro-américaines

Abstract
Attending to racism and US bioethics raises the question of whether and how *racism in bioethics* has been the subject of bioethical scrutiny. Bioethics has certainly brought its analytical tools to bear on racist aspects of clinical care and biomedical research. But has bioethics studied racism in bioethics as its subject? A close examination of relevant reports, articles, and books in the US bioethics literature published in the early days of the field, pre-2000, shows mixed findings. In the 1970s, racism as a bioethical concern was variously nonexistent, vaguely implied, and powerfully examined and condemned. In the late 1980s/early to mid-1990s, racism was more frequently described and critiqued, often in the context of discussions about African American perspectives of biomedical ethics and inequities in health care. Understanding how racism in bioethics has been addressed as an ethical concern has consequences for the historical narratives told about the field, for antiracist bioethics work today, and for envisioning an antiracist future for bioethics.

Keywords
racism, bioethics, white supremacy, Tuskegee, *Belmont Report*, African American perspectives

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INTRODUCTION

"The system is not broken. The system was built to be this way" (1). These words of filmmaker Ava DuVernay about the racist nature of the US criminal justice system have resonance for US bioethics. Bioethics is not broken. Bioethics was built to be this way. Racist norms, assumptions, and social relations are deeply engrained in the theories, cultures, and practices of bioethics as well as in the health professions and academic disciplines that comprise this field. In this paper, racism and white supremacy are defined as follows: "Racism is an organized social system in which the dominant racial group, based on an ideology of inferiority, categorizes and ranks people into social groups called 'races' and uses its power to devalue, disempower, and differentially allocate valued societal resources and opportunities to groups defined as inferior." (2, p.106) White supremacy is "the belief or theory that white people are superior to other peoples, and should therefore have greater power, authority, or status. Also: a social system based on or perpetuating the political, economic, and cultural dominance of white people." (3)

Four starting points frame this inquiry: first, racism and white supremacy have been integral to the US since its founding and continue to permeate US society, including health care and bioethics (4). Second, racism is a moral wrong that differentially harms all persons. Third, the socially constructed nature of racism suggests that it can be socially *de*constructed; and fourth, bioethics as a field has a moral obligation to work toward the elimination of all forms of racism including in bioethics. A present-day accounting of harms done by racism in bioethics is needed for the possibility of repair (4). This raises the question of when and how bioethics has centred racism as a subject of ethical concern. To be clear, I am not asking about how bioethics has addressed racist aspects of, say, clinical care or biomedical research. Rather I am asking when and how bioethics has placed *racism in bioethics* at the centre of bioethical scrutiny. While racial injustice across all sectors of society is receiving significant attention in the 2020s, did this happen earlier in bioethics? Were there efforts to name and ethically analyze racism in bioethics before the year 2000?

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A review of late 20th century bioethics literature is revealing[1]. In this paper, I focus principally on two historical "moments" in bioethics: the late 1970s and late 1980s/early to mid-1990s. Together, these periods illustrate the wide range of bioethics scrutiny given to racism, in particular anti-Black racism. Generally speaking, in the 1970s, racism in bioethics was simultaneously ignored, vaguely recognized, and deeply critiqued in various key publications in the field. In the late 1980s and early to mid-1990s, robust discussions about the existence and/or nature of African American perspectives in bioethics included critiques of the exclusionary and imperialistic Eurocentric mainstream of bioethics. The racism of bioethics as well as bioethics' resistance to racism are not well-studied; nor are they a significant part of the historical narratives typically told about the field (5,6). "Historical truth telling" – a strategy coined by DA Washington – is needed to create a fuller narrative of the field (7). This is particularly salient for a field that has recently signaled its commitment to anti-racism (8,9). Making plain past moments when racism in bioethics has come under bioethical scrutiny as well as moments of antiracist work also serves to showcase those doing the work, largely though not exclusively African Americans.

The author Arundhati Roy observes, "We know of course there's really no such thing as the 'voiceless'. There are only the deliberately silenced, or the preferably unheard" (10, p.1). This review confirms that those who named and examined racism in bioethics decades ago were not voiceless. Their voices have often been unheard if not also deliberately silenced in bioethics. Notably, "not hearing" and silencing are classic practices of racism. The persistent resistance to the dominance of an exclusionary and marginalizing Eurocentric bioethics is an important legacy that, if known, can support and shape present day anti-racist efforts as well as to help envision an anti-racist and equitable bioethics future.

THE 1970s

Ironically, this analysis begins with a moment when racism was not made the subject of bioethical analysis but rather when racism was both "unheard" and reinforced. In 1972, the US public learned of the US Public Health Service's "Tuskegee Study of Untreated Syphilis in the Negro Male" (USPHS Tuskegee Study) involving 600 research subjects, all African American men in Alabama (11). Follow-up reports by two governmental bodies passed ethical judgment on the Study and made recommendations for improved human subjects research.

In immediate response to the moral outrage about this research, the US Department of Health, Education, and Welfare established the Tuskegee Syphilis Study Ad Hoc Advisory Panel (Ad Hoc Panel) to determine whether the Study was justified in 1932 and whether it should be continued in 1972, to assess the adequacy of existing policies to protect research subjects, and to make policy recommendations as needed. Ethical assessment was not an explicit goal of the Ad Hoc Panel though the Panel's examination and recommendations were steeped with ethical values, norms, and assumptions. In its 1973 Final Report, the Ad Hoc Panel did not name racism as an ethical matter in the USPHS Tuskegee Study. While it vaguely referenced difficult social conditions, the Report drew pointed attention to the personal characteristics of the African American research participants, highlighting traits that ostensibly made them incapable of understanding the research and thus incapable of giving consent to participate. For example, the Final Report states:

> History has shown that certain people under psychological, social or economic duress are particularly acquiescent. These are the young, the mentally impaired, the institutionalized, the poor and persons of racial minority and other disadvantaged groups. These are the people who may be selected for human experimentation and who, because of their station in life, may not have an equal chance to withhold consent (12, p.12).

And quoting Senator Hubert Humphrey: "the powerless, the poor, the least educated, and members of minority groups are the likeliest human guinea pigs.… It is those who cannot understand what is being done to them…" (12, p.34).

The Panel's focus on the supposed inability of "persons of racial minority" and others to consent supported the Panel's labeling them as vulnerable and in need of protection against unscrupulous researchers. The Panel did not address the racism of the social context that created vulnerability and made some persons "the likeliest human guinea pigs." In short, while the Ad Hoc Panel's Final Report was silent about racism in the Tuskegee Study, it employed pathologizing racial stereotypes that rendered certain persons as incapable of consent.

In rare contrast in the bioethics literature of that period, historian of medicine Allan M. Brandt discerned and articulated the racism foundational to this research Study (13). He examined the racialized scientific thought that undergirded medical attitudes of the time, for example, ideas that Black persons were excessively sexualized, essentially diseased, innately inferior, and ignorant. Brant concludes, "In retrospect the Tuskegee Study revealed more about the pathology of racism than it did about the pathology of syphilis; more about the nature of scientific inquiry than the nature of the disease process" (11, p.27). Brandt also examined the Ad Hoc Panel's work in relation to its (in)attention to racism. He argued that the Ad Hoc Panel's failure to evaluate the Study in its historical and ideological context led the Panel to miss "the essentially racist nature of the experiment" (13, p.27). Instead, the Final Report pointed to the lack of informed consent and the withholding of penicillin treatment as the Study's central ethical problems.

[1] This review entailed an examination of US bioethics publications from the field's early days for their attention to racism in bioethics. This included landmark reports, journal articles, entries in The Encyclopedia of Bioethics – the field's core reference work – and relevant books and edited volumes. This review is neither fully comprehensive nor representative of the range of multidisciplinary and multi-professional literature we today call "bioethics" but rather focused on the fledgling field's more narrow literature.

Also in 1973, the US Congress in passed the National Research Act which established the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (Commission). The Commission was charged with the creation of ethical principles for medical research. Its most well-known publication, *The Belmont Report: Principles of Ethical Research on Human Subjects* (Report) was issued in 1979 and names three ethical principles as necessary considerations for ethical medical and other scientific research: respect for persons, beneficence, and justice (14). The Commission's only reference to racism is found in the Report's description of the principle of justice and the application of justice to the selection of human research subjects. The Report noted that "injustice arises from social, racial, sexual and cultural biases institutionalized in society" and that "unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects" (14, p.9).

Echoes of the Ad Hoc Panel's Final Report reverberate in the Belmont Report in its characterization of racial minorities as "vulnerable subjects:"

> One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition (14, p.9).

In short, neither the Belmont Report (1979) nor the Ad Hoc Study Final Report (1973) attended to racism as a significant bioethical concern, despite the fact that both the investigations and Reports were motivated at least in part by the USPHS Tuskegee Syphilis Study and that contemporaneously, race relations were at the centre of significant social, political, legal, and scholarly debate.

The relative silence about racism in these official Reports contrasts strikingly with two articles in the 1978 inaugural edition of the *Encyclopedia of Bioethics* (15). Under the subject heading "Racism," two entries explicitly name and powerfully indict racism in biomedical ethics. The first, "Racism and Medicine" (16) was written by historian James H. Jones, author of the soon-to-be-published *Bad Blood: Tuskegee Syphilis Experiment: A Tragedy of Race and Medicine* (17). In the *Encyclopedia*, Jones names and condemns the biological interpretation of race: the belief in Black "constitutional inferiority" in relation to whites; the segregation of medical institutions; and the discrimination in professional medical education. He unambiguously critiques the professional ethics of medicine declaring that "At no point in time has the ethical code of physicians served to immunize them against the racial prejudices of American society" (16, p.1409). Nor does he spare individual physicians:

> The vast majority of physicians never regarded the race question as an ethical issue for medicine. Race remained a social issue for them, and if racial attitudes impinged upon the physician-patient relationship, doctors were no more likely to be troubled by the results than they were to question how racism defined other contacts between the races (16, p.1409).

Moreover, Jones maintains, "most of the progress that has been made on the racial front in medicine to date has been in response from pressure outside the profession" (16, p.1409). This damning assessment of medical ethics is sustained in the second *Encyclopedia* entry, "Racism and Mental Health" by psychologist Aaron D. Gresson (18). Herein Gresson describes the pathologizing of Black individuals in psychological theory that simultaneously ignores oppressive social forces including racism that challenge mental health and shape mental health services. Signaling an opportunity for bioethics to intervene, he noted that "the confusion and racist ambivalence characterizing current mental health practice are likely to endure unless bioethical analysis and sensitivity are intensified and result in action-oriented policy statements" (18, p.1413).

In sum, this inquiry into 1970s bioethics literature reveals that racism as a bioethical concern was variously nonexistent, vaguely implied, and powerfully examined and condemned. Calls for bioethics and professional medical ethics to address racism were also voiced.

THE LATE 1980s/EARLY TO MID-1990s

The late 1980s and early to mid-1990s brought significant attention to African American experiences in both health care and biomedical ethics and with it came a focus on racism in both realms. Central to this consideration were two multi-year academic projects engaging African American approaches to bioethics: one located primarily in the Washington, DC area and the other in Chicago.

The African-American Perspectives on Biomedical Ethics Project (Project) in the Washington D.C. area emerged from a series of conversations, the first being the 1987 "Think Tank on Black Perspectives on Death and Dying" organized by faculty from Howard and Georgetown Universities. The Project sponsored subsequent conferences in 1989 and 1990 and its work culminated in 1992 with the publication of *African-American Perspectives on Biomedical Ethics*, an edited volume of selected

conference papers and more, edited by Harley E. Flack and Edmund D. Pellegrino (19)[2]. In public recognition of what is now called white supremacy, Pellegrino anticipates dominant group reactions to these published African American perspectives, reactions steeped in the prevailing philosophical culture of the time. In the Foreword, Pellegrino notes:

> Many moral philosophers trained in the Anglo-American or Eurocentric modes of doing philosophy may find here a disturbing voice. Some will have difficulty accepting some of the papers as "proper" philosophy. Some will misinterpret them as lacking rigor or analytical bite, or as being too anecdotal. Others will miss the usual deference to prima facie principle or to standard ethical theories (21, p.*vi*).

Acknowledging the dominance of Eurocentric philosophy and its judgment of other approaches as inferior, Pellegrino ultimately asserts that "Transcultural dialogue is a necessity, even a moral requirement for any biomedical ethical enterprise committed to justice in its encounter with peoples of differing cultural values" (21, p.*ix*).

In this volume, two papers stand out in their critiques of racism in ethics and health care. Cheryl J. Sanders offers an African American perspective that explicitly names its racist societal context: "it seems absurd to speak of the unique moral context of the African-American experience of suffering without also addressing the cause of this suffering in the broader moral context of Euro-American racism" (22, p.166). She bluntly challenges the book's unstated assumption that African Americans want to be involved in contemporary bioethics:

> Further it may be that African-Americans have thoughtfully concluded that Western biomedical ethics is not useful or applicable to their dilemmas precisely because their data and input have not been taken into account. In other words, the dialogue being called for may have taken place already in other quarters, and the lack of scholarly work by African-Americans in the field may be indicative of an informed judgment that biomedical ethical discourse is an esoteric and exclusive enterprise in which African-American participation is not really welcome (22, p.166).

Furthermore, Sanders resists representing an African American perspective "as merely an interesting minority perspective or contribution, but should inform the shape and connect of the whole [biomedical ethics] discourse" (22, p.171).

In "Yes, There Are African-American Perspectives on Bioethics," Annette Dula offers a perspective rooted in experiences "of unequal power relations, of oppression, domination, subordination, and ridicule" as well as in a social justice-oriented activist philosophy engaged by many African American philosophers (23, p.194)[3]. "With few exceptions," says Dula, "Euro-American philosophers have either gingerly approached or neglected altogether to comment on social ills and injustices such as slavery, racism, sexism, poverty, and class struggles" (23, p.196). Dula recommends the further development and articulation of African American perspectives by African American bioethicists who, she suggests, should organize professionally and "join the mainstream debate so as to influence policy that affects African-Americans, poor and powerless people generally" (23, p.201).

In roughly the same years, halfway across the country at the University of Chicago's Center for Clinical Medical Ethics, a multi-year seminar led to the 1994 volume, "*It Just Ain't Fair": The Ethics of Health Care for African Americans*, edited by Annette Dula and Sara Goering (24). In twenty-two essays, each accompanied by a commentary, this book sought:

> [T]o facilitate a dialogue among African Americans, medical ethicists, and those working in African-American communities; and to shape the development of medical ethics so that it no longer reflects the dominance and arrogance of any one group. We wish to encourage the growth of a community of medical ethicists whose analyses embody an ethic of caring and respect for all groups, a responsibility to condemn unjust medical practices, and a humility and an empathy regarding human suffering, which in the end transcends all cultural and racial prejudices and differences (24, p.8).

Herein African American experiences and examinations of institutional and interpersonal racism and health care inequities are woven through the many voices representing wide-ranging professions and disciples. Akin to the 1992 volume, there was brief reference to white supremacy: an explicit recognition that "the 'gold standard' [in our health care system] is middle-class whiteness" (25, p.97).

Finally, in 1996, a sweeping article by law professor and nurse Vernellia R. Randall was published: "Slavery, Segregation and Racism: Trusting the Health Care System Ain't Always Easy! An African American Perspective on Bioethics" (26). Resonating with the work of the earlier two volumes, Randall outlined historical and contemporary expressions of racism including slavery, segregation, and the harmful health care treatment of and experimentation on African Americans. She declared that "fear and distrust of the health care system is a natural and logical response" to it though one "rarely acknowledged in traditional bioethical discourse" (26, p.192). A quarter century ago, Randall named the cultural particularity of Eurocentric bioethics including its resistance to other cultural views and "wonder[s] if this resistance is based on some attempt – unconscious or conscious – to avoid having to truly structure a multi-cultural society and keep the Eurocentric view dominant" (26, p.235).

[2] For details of the Project's development, see Flack's Introduction: The confluence of culture and bioethics, xi-xx. This volume may well constitute the first book to centre African-Americans both as authors and as subjects in US bioethics. This book and the questions it addressed were revisited in a 2007 volume (20).
[3] Oddly, Dula's paper is not described in the volume's Introduction as are all the other papers.

In sum, this capacious work on African American perspectives in bioethics that appeared in the late 1980s/early- to mid-1990s did not universally address racism, but when it did, it did not hedge in naming the exclusionary framing of Eurocentric philosophy built into bioethics, and the many health care inequities experienced by African Americans.

LESSONS LEARNED AND FURTHER CONSIDERATIONS

This brief look back at the US bioethics literature shows us that since the late 1970s, if not earlier, racism in bioethics has been the subject of at least some bioethical attention and critique. These conversations and critiques appear to be little known in the field and as such contribute to a historical silence about racism in mainstream US bioethics. More historical truth telling and bioethical analyses are needed to create a more comprehensive history. In particular, antiracist critical analysis is needed to identify how white supremacy has functioned and continues to function in the field. Accordingly, more historical truth telling and bioethical analyses are needed to create a more antiracist present and future. The final words go to Sanders whose incisive critique of bioethics three decades ago embodies the moral courage needed in contemporary bioethics:

> Moreover, what is arguably the most distinctive ethical claim that African-Americans have made against a racist America, namely, the fundamental affirmation of human dignity regardless of social condition, is clearly worthy of acquisition by biomedical ethicists who are conscientiously concerned with transcending the particularities of race and culture in pursuit of justice and human wholeness (22, p.171).

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Studying Vulnerable Populations Through an Epigenetics Lens: Proceed with Caution

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Résumé

L'épigénétique – l'étude des mécanismes qui influencent et modifient l'expression des gènes – fournit des informations uniques sur la façon dont l'environnement social et physique d'un individu a un impact sur le corps au niveau moléculaire, en particulier dans les populations victimes de stigmatisation et de traumatismes. Les chercheurs ont recours à des études épigénétiques pour comprendre comment les modifications épigénétiques entraînent des déséquilibres dans les résultats de santé des populations vulnérables. Cependant, l'étude des facteurs qui rendent une population épigénétiquement vulnérable présente des défis éthiques et méthodologiques particuliers. Nous nous attachons ici à démontrer comment, en ciblant certaines populations pour la recherche épigénétique, cette recherche peut pathologiser les pratiques socioculturelles et médicales de ces populations d'une manière qui accroît leur vulnérabilité. En utilisant une approche d'étude de cas, cet article examine trois populations vulnérables qui intéressent actuellement les chercheurs en épigénétique – les populations autochtones, autistes et transgenres – afin de mettre en évidence certains des défis à relever pour mener une recherche non stigmatisante en épigénétique.

Mots-clés

épigénétique, éthique de la recherche, confidentialité, vie privée, recherche en sciences sociales, populations vulnérables

Abstract

Epigenetics – the study of mechanisms that influence and modify gene expression – is providing unique insights into how an individual's social and physical environment impact the body at a molecular level, particularly in populations that experience stigmatization and trauma. Researchers are employing epigenetic studies to illuminate how epigenetic modifications lead to imbalances in health outcomes for vulnerable populations. However, the investigation of factors that render a population epigenetically vulnerable present particular ethical and methodological challenges. Here we are concerned with demonstrating how, in targeting certain populations for epigenetic research, this research may be pathologizing socio-cultural and medical practices in those populations in a way that *increases* their vulnerability. Using a case study approach, this article examines three vulnerable populations currently of interest to epigenetic researchers – Indigenous, autistic, and transgender populations – in order to highlight some of the challenges of conducting non-stigmatizing research in epigenetics.

Keywords

epigenetics, research ethics, confidentiality, privacy, social science research, vulnerable populations

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INTRODUCTION

The modern field of epigenetics – the study of mechanisms that influence and modify gene expression – is giving researchers unique insights into how an individual's social, cultural, and physical environment affect the body at a molecular level (1). In part because these modifications show the potential to be both heritable and reversible, this finding has raised a great deal of interest for researchers engaging with populations who are considered vulnerable by way of their environmental and social exposures. In particular, researchers are employing epigenetic studies to illuminate how epigenetic modifications may lead to imbalances in health outcomes. Framing their research around these vulnerabilities, however, carries the risk of exposing these populations to increased levels of stigmatization and harm. The ethics literature on research with vulnerable populations typically focuses on two areas: the ability to consent to research, and exacerbated power imbalances between researchers and participants, such as those experienced by groups who have historically been the targets of unethical research practices (2). While both concerns exist as well for epigenetics research, the close link between a group's status as vulnerable and the investigation of vulnerability as a *target* of research intensifies many ethical and methodological challenges. In this article, we will therefore highlight ways in which conducting research framed around epigenetic "harm" may itself harm vulnerable populations by increasing stigmatization and pathologization.

Vulnerable Populations & Epigenetics

The phrase "vulnerable population" carries multiple meanings within the research context. In research ethics policies and guidance documents, "vulnerable" often refers to individuals with limited decision-making capacity or power (3). This lack of

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power is deeply entangled with experiences of discrimination, stigmatization, and exclusionary practices within the medical and research contexts and elsewhere that in turn generate other forms of vulnerability. For example, ethnocultural minorities who have historically been the targets of unethical research practices may in turn end up further excluded from research advances, notably by self-selecting out of research due to concerns about research conduct or historical trauma, exhaustion from being over-targeted for research recruitment, paternalistic ethical and legal regulations, or due to gaps in recruitment practices. In other areas, the lack of decision-making power that is attributed to individuals with cognitive disabilities may in turn exacerbate power imbalances between researchers, caregivers, and research participants. These definitions more recently expanded to incorporate an intersectional understanding of vulnerability that unpacks the challenges of working with multiply marginalized individuals (4). Finally, current experiences during the global coronavirus pandemic are bringing new attention and perspectives to the conversation around vulnerability, reiterating vulnerability not as a fixed state, but as something that may be intensified or alleviated for different individuals and groups through changing policies and circumstances (5).

Populations of interest to epigenetic researchers may be considered vulnerable by virtue of different factors, including discrimination and stigmatization, lack of access to healthcare and healthcare information, and questions about capacity for free, full and informed consent (1). A great deal of research already exists on strategies to mitigate these harms and to encourage participation from excluded groups in new research, much of which is applicable to epigenetics research (6). Other challenges, however, may require new types of strategies and methodologies. Because epigenetics enables us to examine the social and environmental contributors to health and disease at a molecular level, populations that have experienced large-scale trauma or early-life adversity are being examined to provide evidence of the patterns already noted by researchers in other medical and social science fields. In providing a new layer of evidence for existing observations of health precarity and reduced health outcomes for populations that face discrimination, stigmatization, and trauma, researchers risk reifying stereotypes and placing contestable normative values on cultural behaviours or cognitive differences.

Here, we will examine the ways in which epigenetic research, in seeking to confirm epidemiological observations concerning behaviors and practices at the molecular level, risks contributing to stigmatization. Because epigenetics research ties together the biological and the social, the potential for increased pathologization – the presumptively inappropriate or unwarranted treatment of a physical or behavioural state as though it were a medical condition – of socio-cultural practices will be particularly high (7). There is also an increased potential for placing disproportionate personal responsibility for health on already vulnerable populations. Moreover, research that seeks epigenetic links amidst very broad groups that are considered vulnerable run the risk of homogenising those same groups and failing to undertake an intersectional analysis of the many varying factors that might influence the marginalization or vulnerability of a given member of that wider community (4). Finally, although the language of vulnerability is used here to indicate groups that have been harmed or are at risk of harm in the research context, this terminology belies the extreme resiliency that individuals and communities have shown in the face of these and other harms. The language of epigenetic “harm” in particular works to pathologize the bodies of those deemed vulnerable, frequently by researchers external to that identity, and precludes us from seeing how an individual or community might be viewed instead as having developed epigenetic *reinforcement* as a result of those experiences.

A note: we have used the term “social” throughout this paper largely to refer to the broad collection of experiences, practices, and environments through and in which people may encounter epigenetic modifiers. When the term “cultural” is used in place of or in addition to social, it is to refer more specifically to those experiences, practices and environments that are most personally relevant to the individual or the community with which they identify. Nevertheless, the delineation between these two terms is not always clear; nor is there a clear line between the socio-cultural environment and the biological factors that arise from it. This complexity should be noted as a further confounding factor in epigenetic research that looks to tie these domains together.

Materials and Methods

Using a case study approach, this article will examine three vulnerable populations currently of interest to epigenetic researchers – Indigenous, autistic, and transgender populations – and use these as examples to highlight some of the challenges of conducting non-stigmatizing research in epigenetics. The populations were selected because they represent a diversity of vulnerable populations – ethno-cultural, neurodevelopmental, and social – where epigenetics researchers have shown particular interest in understanding those vulnerabilities. Moreover, they provide us with examples of research into the relationship of the social, environmental and biological factors for health outcomes at different stages, ranging from a significant amount of existing scholarship (Indigenous populations) to research that is just emerging (transgender populations). We then examine the commonalities between these cases and propose several points to consider in conducting studies with populations whose vulnerability may be increased by their involvement in epigenetic research.

INDIGENOUS POPULATIONS

Epigenetics, Health, and Research

Indigenous communities[1] have emerged as populations of particular interest to epigenetics researchers in large part because of the clear examples of intergenerational trauma, including collective intergenerational trauma (8). Other populations that have faced large-scale trauma – notably Holocaust survivors (9), survivors of the Dutch Famine (10), and African American populations (11) – have been similarly targeted by epigenetics researchers seeking to understand both the effects of trauma on the body, and their potential heritability. Researchers with an interest in the developmental origins of health and disease (DOHaD) – a field which examines how early life (at or prior to conception, in utero, and infancy and early childhood) environments impact health and disease risk – have been particularly interested in using epigenetics, because it presents a promising new path for understanding trauma and associated health disparities. Notwithstanding the interest in this topic, thus far this work has been largely theoretical in nature; a clear epigenetic link is posited because of the increasing understanding of the impacts of trauma on the epigenome, but empirical research is still in its early stages.

Health disparities amongst Indigenous populations include cardiometabolic disease risk, type 2 diabetes, life expectancy, and vulnerability to the development of psychiatric disorders[2] (12). Indigenous women and children in particular experience profound health disparities worldwide (12). Although many aspects of these disparities are tied directly to the *current* harms of colonialism (e.g., lack of access to necessary services, stress of the lived experienced of racism, loss of cultural and traditional ways of life), the potential heritability of epigenetic effects shown in early animal studies suggests that even trauma experienced by one's parents and grandparents may have a tangible effect at the molecular level (1). While the effects of colonization on population health have been previously well-documented in epidemiological studies, it has been suggested that epigenetics research may help to separate the socio-cultural effects from the biological. Research with other racialized and marginalized populations suggests that the experience of racism itself may produce epigenetic effects on the body (13). Caution is necessary, however, in separating out the correlation between behaviour or experiences and epigenetic markers. As previous ethical, legal and social issues (ELSI) research in epigenetics has noted, studies that seek to link the social environment of marginalized populations to epigenetic outcomes can in turn cause harm by pathologizing the environment itself, alongside accompanying social and cultural activities (1,7).

The history of research in Indigenous spaces has been marked by harm, and genetics research in particular has replicated colonial violence through improper, incomplete, or invalid consent; unethical use of material gathered; and an unwillingness to return useful research results to participating or enlisted communities. For example, in British Columbia, Canada, researchers collected DNA samples from the Nuu-chah-nulth in order to conduct research on high levels of rheumatoid arthritis present in this Indigenous population. When no genetic link was uncovered, the researchers used the samples in a number of other unconsented studies, including those on intravenous drug use (14). Similarly, in Arizona researchers collected samples from the Havasupai Tribe for diabetes research, then used the information without consent for sensitive studies, including those on migration patterns and on schizophrenia (15). In Canada, some of the trauma outcomes under investigation were first perpetuated in the name of scientific experimentation; in the 1940s and 1950s, the Canadian government used widespread malnutrition in Northern Manitoba Indigenous communities to test nutritional supplements, leaving a control group in starvation (16). Another group of researchers performed experiments on children in residential schools, withholding milk, vitamin C supplements, iron-fortified bread, and preventive dental care in order to examine the effects of deprivation (17).

With 370 million Indigenous persons worldwide in approximately 90 countries, there is clearly no single approach to health research or health promotion that will apply universally (18). Nevertheless, it is true that the medical impacts of colonialization on Indigenous populations are astronomical in scope of harm.[3] Much of this harm stems from the social and economic impacts of genocide; cultural eradication has led to multi-generational "psychological, physical, and structural disadvantages" that manifest at the cellular level (19). Colonialism functions as an "ongoing structure of domination", including interference via invasive research and suppression of traditional medicine, food, and ways of living (20). This is compounded by factors such as rural location, communication challenges, and socio-economic status, which create barriers to accessing healthcare (21).

The ongoing nature of colonialism makes it very challenging to untangle causation of harm; non-Indigenous researchers are only now beginning to recognize and acknowledge the full scope of the situation. Over the last decade, researchers have undertaken research into the direct epigenetic link between intergenerational trauma and health disparities, including the epigenetic effects of malnutrition, psychosocial stress, and environmental toxicant exposures, making research with Indigenous communities one of the clearest examples of studies of inherited epigenetic effects of trauma in humans (19). While much of the interest in Indigenous epigenetics research stems from the ability to track intergenerational historical trauma, it must also be recognized that violence and discrimination continue to exacerbate health risk factors; for instance, at any given time there are more than 100 drinking water advisories on First Nations reserves across Canada (22).

[1] The term "Indigenous communities" is extremely broad, and the health and socio-cultural considerations for different communities will vary enormously; here, we highlight just some of the research that has been framed as "Indigenous" epigenetic research.
[2] "Obesity" is frequently included in the list of health disparities facing Indigenous populations. However, the classification of weight as a disease is considered controversial amongst critical theorists and a growing number of health researchers, in part due to increasing evidence that the association between weight and negative health outcomes has been overstated in the scientific literature, to the detriment of the health of individuals whose BMI classifies them into this category. As such, we have excluded obesity from our list, but do note that it is another factor considered by researchers.
[3] For a more comprehensive look at the widespread violent impact of colonization in Canada, see the Truth and Reconciliation Commission of Canada's Truth and Reconciliation Report, as well as the report on Missing and Murdered Indigenous Women and Girls.

Ethical and Legal Considerations

Research conducted with Indigenous populations, particularly research conducted by non-Indigenous researchers, is inherently fraught, not only because Indigenous populations represent a uniquely vulnerable population, but because that vulnerability in the medical context has been both generated and reinforced by scientifically and morally flawed research practices and approaches to healthcare delivery (15). Concerns around epigenetics research in Indigenous populations more specifically show that the epigenetics context intensifies and complicates existing bioethical concerns (19). In particular, by conducting research into epigenetic harms that are themselves the result of state-sanctioned violence, researchers continue to harm Indigenous communities in the name of science, perpetuating a cycle of trauma.

Epigenetics research in Indigenous populations also exacerbates concerns around the harms raised by stereotyping in medical research; by classifying Indigenous peoples as epigenetically harmed, there is a risk that the group will come to be perceived by others as somehow biologically "damaged". As Warin notes, "the shaping of the right to protection from biosocial injury is potentially empowering but also has the capacity to conceal forms of governance through claimants' identification as "damaged," thus furthering State justification of biopolitical intervention in Indigenous lives" (19). In particular, scholars have expressed concerns that epigenetics researchers risk reifying a biological conception of race and pathologizing cultural practices (7).

It is unclear if existing guidance on research with Indigenous Peoples is sufficient to fully address these concerns. The legal and policy work addressing research ethics with Indigenous populations has primarily focused on issues of informed and culturally appropriate consent to research. Epigenetics research, in engaging conversations about both genetics and behaviour/environment, requires particular attention regarding informed consent. While policy documents do not necessarily carry legal weight, they do set the tone for how research is to be conducted and non-compliance may give rise to important penalties, such as removal of funding. For example, Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (3), adherence to which is a pre-requisite for receiving federal research funding for research with human participants, contains a separate chapter on research involving the First Nations, Inuit and Métis Peoples of Canada. Notably, researchers are required to view ethical considerations through the appropriate Indigenous lens, in addition to involving communities in research planning and approval and prioritizing Indigenous-led research initiatives. Similarly, in New Zealand, the *Te Ara Tika Guidelines for Māori Research Ethics: A Framework for Researchers and Ethics Committee Members* outlines a framework for addressing Māori ethical issues, with a focus on including Maori individuals throughout research ethics decision-making processes (23). In Australia, the *Australian Institute of Aboriginal and Torres Strait Islander Studies Act 1989* outlines the ethics framework for Indigenous research and is underpinned by the Guidelines for Ethical Research in Australian Indigenous Studies. These and other documents highlight the importance of inclusion of Indigenous peoples at all stages of the research process, and the need to develop effective and culturally appropriate consent mechanisms (18).

AUTISTIC POPULATIONS

Epigenetics, Health, and Research Context

Another population of interest to epigenetics researchers are autistic individuals[4]. The current medical model of autism describes it as a neurodevelopmental condition featuring impairments in social interactions, communication, and restrictive behaviour patterns. Advocates of the neurodiversity movement, by contrast, describe autism as a natural human variation with its own combination of strengths and challenges (24). The breadth of experiences and traits associated with autism creates a significant challenge for any research that seeks to discover a singular marker as being associated with autism. Research that has aimed to paint the autistic experience with one brush has typically failed to do so without missing out on significant parts of the population, while simultaneously pathologizing the parts that it manages to capture.

In part for this reason, research ethics in the autistic context has long been fraught with problems. Historically, researchers have focused on the pathologization of maternal environmental influences in autism in harmful ways, particularly through the now-debunked theory of "refrigerator mothers" (e.g., cold and non-nurturing mothers) as the cause of autism (25). Bioethicists have already raised concerns that epigenetics research presents analogous issues in its focus on animal models and maternal influence (1); given this history, epigenetics research that focuses on maternal exposures as the locus of autism development and that ignores the potential role of paternal exposures may raise similar and repeated concerns around pathologization and sexism. Finally, gender and racial bias in autism research has resulted in widespread underdiagnosis outside the context of white men (26).

In general, research seeking to pinpoint a singular root environmental or biological cause of autism has come up empty, and researchers have seen potential for epigenetics to bridge these complex factors. Research into the epigenetics of autism is relatively advanced; however, theoretical frameworks underpinning epigenetics autism research show a murkier path than the correlation between Indigenous experience and trauma. While studies have shown high heritability, and a large volume of genetic studies with increasing sample sizes have identified numerous candidate genes, none have demonstrated large effect sizes (27). At the same time, several epidemiological studies have found associations between prenatal exposures, including stress and various infections, to the development of autism (28). Meanwhile, it is known that neurodevelopment, particularly

[4] There is debate within the use of identity-first language, "Autistic individuals", or person-first language, "individuals with autism". We here use the identity-first language preferred by many advocates within the autism community and neurodiversity movement, including one of our authors.

during the prenatal period, is tightly controlled through patterns of gene expression. This makes the neurodevelopmental process susceptible to epigenetic modifications affecting gene regulation and provides a potential mechanism by which environmental exposures could have an influence on the development of autism. Indeed, studies identifying differences in gene expression in post-mortem samples between brains of autistic and non-autistic individuals further suggest a potential role for epigenetics (28). Based on this potential, research has begun to confirm a role of epigenetics in autism. However, in the face of ableism and a history of excluding autistic individuals from decisions about research, there are concerns that causative research will be used (or instrumentalized) to diminish or eliminate the autistic community.

With regard to health concerns faced *by* autistic individuals, there are a number of medical and mental health conditions associated with autism, although it can be difficult to separate whether they share a biological basis with autism or are the result of unjust social forces such as insidious discrimination or other forms of mistreatment (29). Epilepsy, sleep difficulties, and gastrointestinal issues such as irritable bowel syndrome and gluten-intolerance are health issues that affect quality of life for many autistic individuals, in addition to broad autoimmune diseases. Anxiety and depression, which are also frequently co-diagnosed with autism, may stem from similar causal factors, or may be the result of stigmatization and discrimination. Finally, schizophrenic disorders, obsessive-compulsive disorder, bipolar disorder, and attention-deficit disorders also appear frequently in autistic individuals and are themselves stigmatized conditions (29). Autism advocates have expressed concern that the focus on the causal roots of autism, rather than on these health concerns, has ignored the priorities and needs of the autism community, including the treatment of these associated conditions (30). Additionally, in tying specific exposures in the mother pre-conception and during pregnancy to autism, epigenetic research risks exacerbating rhetoric that overburdens mothers with “responsibility” for their children’s autism (in the same vein as the “refrigerator mother” rhetoric), while simultaneously reinforcing the medical model idea that autism is an undesirable outcome, rather the social/neurodivergence perspective of autism as a difference.

Ethical and Legal Considerations

Health researchers working in the field of autism research have typically examined two broad categories of questions: 1) what are the causes of autism, and 2) what are the health concerns faced by autistic individuals? The first of these questions is considered significantly more controversial than the second, as it raises concerns amongst autistic individuals that causal research will be used as part of cure/prevention paradigm, leading to prenatal tests or treatments that could be used to diminish the autistic population (31). Existing therapies that are employed with autistic children aimed at reducing the appearance of overt autistic behaviours, such as applied behavioural therapy, have faced intense criticism from within the neurodiversity movement for focusing on creating more compliant, rather than healthier and happier, autistic individuals (29). As such, genetic and epigenetic research that seeks to examine the root causes of autism have been met with skepticism and concern.

Legal protections for autistic individuals are generally subsumed under larger categories of laws protecting against discrimination on the basis of disability. For instance, the United Nations’ *Convention on the Rights of Persons with Disabilities,* of which 163 countries are signatories, includes commitments that researchers will not require disabled individuals to be disproportionately burdened by research risks, and addresses concerns broadly related to underrepresentation of disabled individuals in health research. Legislation surrounding autism specifically has not necessarily focused on the protection of autistic individuals directly involved in research or clinical contexts, but rather on plans for raising awareness of autism and access to treatments, or on the use of medical insurance to fund these treatments (32).

One concern in autism research has long been the distribution of research funding, where past studies have shown that funding for autism has been largely distributed to researchers in the fields of nervous system studies and genetics, to the exclusion of other important research on psychosocial well-being and non-medical care (33). As epigenetics autism research grows, more attention may be drawn from these other necessary forms of research and care, refocusing attention on the science of causality and cure. Finally, attention must be paid to the history of autism researchers’ focus on the appearance of autism in men and boys, which has resulted in an underdiagnosis of autistic women and girls (as well as transgender and non-binary children, who are disproportionately represented in autistic populations) (33). As we will see below, sex and gender differences in epigenetics research raise challenges of their own.

TRANSGENDER POPULATIONS

Epigenetics, Health, and Research Context

“Transgender” is a broad designation belonging to people who have physical, psychosocial, or behavioural characteristics relating to sex or gender that do not conform to socially dominant expectations. More narrowly, the term refers to those whose gender identity, that is, their strongly felt sense of themselves across a spectrum of gender experiences and expressions (e.g., boy/man, girl/woman, non-binary person, etc.) (34) is inconsistent with the gender category that is normatively associated with their birth-assigned sex, the latter being typically inferred from visible sex characteristics and based on a binary understanding (i.e., male/female) (35). Individuals whose gender identity corresponds with their natal sex categorization are referred to as “cisgender” (35). The term “transgender” was not coined until 1971; however, the existence of individuals who would likely be characterized as transgender today, as well as the presence of hostile prejudicial attitudes toward them, often resulting in harassment and discrimination, are present across human history.

Many, yet not all, transgender persons experience *gender dysphoria*. Gender dysphoria refers to the discomfort or distress associated with, or caused by, the felt discrepancy between gender identity and physical sex-typed traits or categorization, and this can be experienced in many different ways and to different degrees, including with respect to certain aspects of one's body or to the gendered social role expectations associated with their assigned sex (36). The presence of dysphoria is often used as a metric for determining access to gender-affirming care, despite not being a universally experienced by transgender individuals (34).

In the context of science and medicine, early studies classed the feelings or behaviours of transgender individuals as normatively "deviant" and focused on attempts to "cure" their perceived psychiatric illness; the recent backlash against the emergence of transgender rights has re-ignited and re-intensified this rhetoric. Accordingly, there has long been inappropriate and harmful treatment of the transgender population, both in clinical and research practices (37). Such treatment can occur in the course of general medical care, including the refusals of necessary medical services and the use of disrespectful identity-based language (e.g., misgendering), or in the course of transgender-specific care, for example, involving hormones or surgery. In the research context, the proportion of participation of the transgender population, compared to the general population, remains low (38). This may be the result of a) deliberate exclusion by researchers in their sample, possibly due to their impression that cisgender individuals will provide fewer confounding factors, or b) "self-exclusion", deriving from, among other factors, a lack of trust in the medical establishment based on experiences of transphobia.[5] Research with transgender adolescents has been especially exploitative; a prime example is a well-known 1993 study assessing the physical attractiveness of pre-adolescent transgender girls, framed in the paper as boys with gender identity disorder (39).

Compared to the autistic community discussed above, there is relatively little epigenetic research currently being conducted with transgender participants. Nor, as is in the case of Indigenous populations, has there been as widespread enthusiasm for this research as it pertains to health. However, the questions raised in research in general suggest that epigenetics research with transgender populations will likely emerge in the near future. Current epigenetic research on transgender populations falls into two main categories: first, research on the potential epigenetic *origins* of gender identity variance, and second, research on the possible epigenetic *consequences* of transitioning, with a particular focus on the effects of so-called cross-sex hormones. The etiology of gender dysphoria and gender identity variance is not fully known, although most researchers in the field point to a combination of social and biological factors. For instance, according to Theisen et al. (40), recent research has indicated that certain rare gene variants might be associated with sexually dimorphic brain development, which could contribute to gender dysphoria. Given this combination of social and biological factors, as well as the reliance of sex development – and, on some views, certain aspects of gender identity-development – on multiple levels of transcriptional control of DNA, epigenetics research in gender identity has emerged as a field of particular interest. Transcriptional control of DNA is partly governed by epigenetics, as well as by the differing exposures to potential epigenetic modifiers of sex and gender. Thus far, much of the work examining how epigenetic modifiers impact sex development has been conducted in animal models, limiting its usefulness in understanding human sex, much less gender identity. Moreover, medical practice with transgender individuals has trended and, in many cases, continues to trend toward pathologization and research that seeks to forcibly change gender identity. As such, this work is treated with concern by the transgender community, as it is unclear how research that seeks to examine the causes of gender variance would be harnessed to improve the lives of the population being studied.

Secondly, epigenetic research on transgender populations is examining the possible epigenetic consequences of transition, with a particular focus on the effects of cross-sex hormones (i.e., methylation of the oestrogen receptor following oestradiol treatment). "Transitioning" refers to the process by which an individual changes their gender presentation from the one associated with their assigned sex at birth to another gender expression (36). When transgender individuals transition, they are often embarking on changes aiming at lessening dysphoria caused by the incongruence between their gender identity, their physical appearance, and their treatment in society. As each of these factors differ for individuals, so too will their transition and the age at which they choose to embark on it (41). This may mean starting to wear or use gendered clothes or products that are socially associated with their gender identity. They may also be more likely to engage in behaviours or other activities that are expected to signal the gender by which they wish to be recognized by others. Further, they may choose to take so-called "feminising" or "masculinising" hormones. These typically include oestrogen, testosterone and gonadotrophin hormone analogues, which block the release of LH and FSH from the pituitary, as well as downstream release of oestrogen and testosterone. Finally, they may undertake surgical procedures to further align their bodies with their gender identity. While this research has thus far focused primarily on the epigenetic effects of hormonal transition, recent research suggests that some factors that accompany gender identity and expression can affect the epigenome due to differing environmental exposures, such as chemical properties in cosmetic makeup, or gendered behavioural differences in substance consumption (42).

Finally, although it is not an experience specific only to transgender individuals, high levels of stress and adversity, like those faced due to gender-based violence and discrimination, carry additional epigenetic implications. Stress and trauma early in life are particularly relevant in transgender populations; a recent study in the United States found that transgender and genderqueer adolescents report polyvictimization – the experience of multiple forms of abuse – at significantly higher rates than their cisgender counterparts (43). Early life stress has been shown to act as an epigenetic modifier in human tissues. Cicchetti and colleagues (44) used saliva samples from children who either had or had not suffered from certain adverse childhood events, e.g., physical or emotional abuse, in order to show differential methylation in genes associated with major

[5] Many, although not all, of these concerns are shared amongst the intersex population, i.e., individuals who do not fit into a binary sex categorization at any number of levels, including chromosomal, hormonal, or genital. However, for the purposes of this case study, we are specifically focusing on transgender vulnerability in epigenetic research.

illness, including cancer, cardiovascular disease and psychiatric disorder. This difference in life exposure has been postulated to have enduring effects. However, caution is needed in attributing the epigenetics effects of these stressors to epigenetic markers carried by transgender individuals; this experience of victimization and abuse is not an intrinsic or inevitable mark that appears on the transgender body, but rather, a consequence of stigmatization and violence.

Ethical and Legal Considerations

While epigenetic research has the potential to highlight specific healthcare needs, it also has the potential to create or enhance certain vulnerabilities. First, it may increase existing social stigma that has accompanied the historical classification of gender variance as a physical or psychological illness. The inclusion of gender dysphoria in the DSM-V, the manual for diagnosis of psychiatric disorders, as well as the reliance on the presence of gender dysphoria as a gatekeeping measure for access to hormones and surgeries, is widely condemned within the transgender community as dehumanizing and stigmatizing (45). Instead, an approach may be taken that recognizes gender incongruence as being related to sexual health, but in a non-pathologizing way, in line with its classification in the *International Statistical Classification of Diseases and Related Health Problems*. The investigation of these potentially "causal" epigenetic factors raises concerns around curative rhetoric, particularly given the continued use of coercive measures around the world that attempt to change transgender individuals' self-conceptions (i.e., "conversion therapy") (46). Researchers who choose to investigate the potential epigenetic background of gender dysphoria will need to be exceedingly cautious in knowledge translation of their findings to minimize the instrumentalization of their research and to mitigate its use in further pathologization.

Second, such research may lead healthcare professionals to withhold the use of cross-sex hormones if these are found to be associated with specific epigenetic changes. While information on the potential health impacts of hormonal treatments is crucial for the provision of informed consent, as well as for determining the safest and most effective ways to deliver hormones when appropriate, it will be important for physicians to keep in mind that a certain degree of physical risk may be ethically outweighed by expected psychosocial benefits depending on the needs and values of the given patient. Further, access to medical transition when appropriate is itself considered a life-saving treatment, demonstrating a significant increase to quality of life and decrease in suicidality in longitudinal studies, with a corresponding increase in suicidality in the face of undue barriers to transition (37).

Also, special attention will need to be paid to research with transgender minors. There remains a significant knowledge gap with regard to the potential short and long-term epigenetic effects of pubertal suppression and hormone replacement use in adolescence, and further long-term studies are needed. However, apart from the usual challenges of pediatric research, including questions around informed consent, transgender adolescents face disproportionately high risks of abuse within their homes compared to their cisgender counterparts, leaving them at higher risk of being coerced by others in their medical decision-making (43). Some scholars have suggested an ethical framework that exempts transgender and other LGBTQIA2+ (lesbian, gay, bisexual, transgender, queer, intersex, asexual, and two-spirit) youths with sufficient capacity from parental consent requirements in research, when seeking such consent would put the youth at risk, in order to make sure that this doubly vulnerable population is not excluded from research altogether (47).

Finally, it is important to remember that the transgender population is small, geographically dispersed and heterogenous in terms of exposures, self-understanding and experiences. This can lead to bias and a risk of over-generalisation of small studies. For example, methylation patterns are known to differ according to ancestry (48). Underrepresentation of the transgender populations from some countries, particularly the exclusion of those where gender variance is criminalised or heavily stigmatized, could lead to skewed results in epigenetic studies. Studies should be large enough and include extensive phenotyping to attempt to control for these factors and, at a minimum, consider separately trans women, trans men and non-binary populations.

DISCUSSION

In this paper, we have presented three case studies of vulnerable populations of interest to epigenetics researchers and considered the various ways in which their vulnerabilities may be directly or indirectly increased via epigenetic research. In the case of Indigenous populations, for example, where there is already a long history of researchers contributing to harm via unethical and unconsented research, studies that seek to explain health disparities and epigenetic differences that have largely resulted from colonial interference may further entrench racialization and "othering" of already vulnerable populations (22). In the case of autistic populations, a focus on framing epigenetic differences as the results of environmental "deficits" may create further stigmatization and generate fear around behaviours and practices that may contribute to the autistic neurotype. Finally, research with transgender populations that seeks to examine the epigenetic differences that may lead to or result from social or medical transition could result in further unjust forms of gatekeeping that limit access to medical care for a population whose needs are already underserved. The thread tying these populations together in the realm of epigenetics research is that by engaging in this research, there is a risk of pathologizing traits of the vulnerable population in a way that increases their vulnerability, either by increasing the risk of stigmatization and discrimination, decreasing access to necessary care, or both. This is particularly the case when a social or cultural behaviour or experience is tied to a biological marker or outcome. There are additional challenges to conducting research with these populations, as widespread discrimination makes it difficult to disentangle "causal" variants from the population stress and lack of access to care and social and economic goods. Finally, in

all three cases examined here, diversity of these populations provides a further challenge, and researchers must be careful not to over-extrapolate.

Points to Consider in Conducting Epigenetic Research with Vulnerable Populations

Despite these challenges, there are several ways in which researchers can mitigate the vulnerabilities that could potentially be caused by epigenetic studies:

1. Involvement of the vulnerable population in study development, design, and progression from research question to knowledge translation

Researchers should engage with community stakeholders from vulnerable populations from the earliest stages of research planning and identify ways in which their research can address the needs expressed by the population and otherwise be beneficial to them. This approach can be used by both researchers and funding bodies to set research priorities and to allocate funding accordingly. While this is important for all vulnerable-population research, it is particularly important in the epigenetic context, where the research may uncover epigenetic causal links between social behaviours and biological health outcomes that are intrinsically linked to questions of personal and community identity.

2. Attention to the broader implications of the research beyond the immediate research question

Researchers should attempt to foresee not only how their research will advance scientific understanding, but how it might affect the population more broadly. In the case of epigenetic research, this will mean paying particular attention to the ways in which research that examines behavioural and lifestyle factors might further stigmatize a culture or community, as well as the ways in which research examining the epigenetics of a vulnerable population might be used for an unasked-for curative approach.

3. Free, informed, and supported consent

Researchers should pay special attention to the particular challenges to consent raised both by the complexities of epigenetic science and research with vulnerable populations. Community members and advocates should be involved in the development of consent documents and procedures, with special consideration given to any additional needs of the population. Privacy risks should be assessed and communicated to participants based on an understanding that vulnerable populations may be at a higher risk in the case of a confidentiality breach, given the combination of medical with social and lifestyle information in epigenetic research, and considering its potential implications for others through shared environments. Researchers should also be cognizant of the potential for epigenetic research to provide information on intergenerational experiences. While privacy and confidentiality are of utmost importance in all research, vulnerable participants may face an increased risk of discrimination and violence if their privacy is breached, particularly to potentially abusive family members or discriminatory employers and researchers (49). Particular attention needs to be paid to the language that is used in developing consent forms and study documentation, using language that is respectful of an individuals' self-identification and ways of discussing their body and experience (for example, by encouraging participants to use whatever terminology is most comfortable for them in describing themselves) (6).

4. Caution in the extrapolation from animal models

While animal models provide an excellent opportunity to study inherited epigenetic effects, researchers should be careful in extrapolating from animal models to human research, particularly when the epigenetic factor being studied involves social or behavioral factors. Researchers should pay particular attention to the way that human presumptions around social, cultural, and gendered behavior become implicitly embedded in assumptions surrounding animal research.

5. Study design

Epigenetic researchers working with vulnerable populations should be aware of the potential harms of both under-inclusion and over-extrapolation. Because epigenetic research incorporates social and environmental context, extrapolation to individuals with similar vulnerabilities but who differ significantly in terms of geography, socio-economic factors, and other confounding variables risks returning skewed data. Researchers should attempt to include representative numbers of vulnerable populations in all epigenetic studies, not only those that target that population, and research that focuses on a vulnerable population should be careful to use appropriately powered studies to answer the questions being asked.

6. Careful communication of results

Epigenetic researchers should bear in mind the broader implications of their results for the populations concerned, even when they are not directly involved in further knowledge translation of their research. Researchers seeking to determine the underlying epigenetic mechanisms of adverse health outcomes in vulnerable populations should be conscious of the potential for this information to affect stereotyping and stigmatization, and to communicate their results in a culturally conscious way that recognizes this concern. When an additional vulnerability is identified in an already vulnerable population (e.g., epigenetic effect from an exposure), study authors should seek to mitigate this if it is in the expressed interests of the population (e.g., informing participants of individualized findings). As with all communication of scientific results, accurately depicting the strength of research findings and stressing study limitations will help guard against misinterpretation (50).

CONCLUSION

When epigenetics and vulnerable identities intersect, there is a risk of increased pathologization of those identities and associated behaviours. In communities where medical research historically contributed to harms against that population, epigenetics researchers need to take into account not just what scientific advances might occur because of their research, but how the communication of their research results may feed back into positive or harmful stereotypes and narratives about that population. While this is true of research in general, epigenetics research, in examining the molecular effects of environments and behaviours, may risk furthering stigma in more profound ways than genetics-era research. The populations discussed here are of interest to epigenetics researchers for different reasons, including inheritance and cultural factors, neurodevelopmental epigenetics, and social epigenetics, and have been subject already to different levels of scrutiny by epigenetics researchers. However, they share the challenge of being groups that are of interest to researchers because of their marginalization and vulnerability, but who also risk being further marginalized in the pursuit of more answers. Ethical epigenetic research will need to remain conscious of the challenges of conducting research on vulnerability without increasing stigma and pathologization, and take the steps necessary to mitigate related harms.

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K. Saulnier était affilié au Centre de génomique et politiques lors de la rédaction de cet article et est maintenant affilié au Conseil de recherches en sciences humaines. C. Dupras est un ancien membre du conseil d'administration de l'*Revue canadienne de bioéthique*. Le contenu de cet article reflète leurs propres opinions et celles de l'équipe de recherche uniquement.

Conflicts of Interest

K. Saulnier was affiliated with the Centre of Genomics and Policy during the drafting of this article and is now affiliated with the Social Sciences and Humanities Research Council. C. Dupras is a former Executive Board member of Canadian Journal of Bioethics. The contents of this article are reflective of their own views and those of the research team only.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Van Rensselaer Potter : Penser la bioéthique autrement

Guillaume Paré[a], Michel Bergeron[b]

Résumé

En 2021, le livre de Van Rensselaer Potter intitulé *Bioethics: Bridge to the Future* a célébré son cinquantième anniversaire de parution. Or, la conception de la bioéthique proposée par l'auteur diffère de celle d'André Hellegers, qui a fait école. Pourtant, conçu comme guide, Potter y présente des éléments importants pour penser la place de la bioéthique dans le contexte sociétal et le développement actuelle des connaissances. Dans le texte qui suit, nous abordons certains éléments du contexte dans lequel ce livre a pris forme. Nous nous arrêterons brièvement pour décrire la perspective dominante de la bioéthique. Puis, nous ferons ressortir certains éléments importants de la conception qu'a l'auteur de ce que devrait être la bioéthique. Nous terminerons en examinant les répercussions de cette pensée dans deux dossiers : celui de l'université et celui du développement durable dans sa perspective onusienne. Cette démarche nous conduira vers un élément que nous considérons important de la pensée de l'auteur, celui de l'ouverture. Ouverture qui est offerte à la bioéthique par l'inclusion de perspectives ayant cours quant aux compréhensions variées du vivant, ouverture à la considération des savoirs ancestraux et des savoirs communs, ouverture aussi à tout autre contexte, qu'ils impliquent des situations minoritaires, des personnes défavorisées ou autres. Cette ouverture donne un sens particulier à une valeur primordiale de la bioéthique, celle du respect de la dignité humaine.

Mots-clés

Van Rensselaer Potter, bioéthique, environnement, connaissances, sagesse, bien commun, développement durable, adaptation, université

Abstract

In 2021, Van Rensselaer Potter's book *Bioethics: Bridge to the Future* celebrated its fiftieth anniversary. The author's conception of bioethics differs from that of André Hellegers, who set the standard in the field. However, as a guide, Potter presents important elements for thinking about the place of bioethics in the societal context and the current development of knowledge. In the following text, we discuss some of the background to the book. We first briefly pause to describe the dominant perspective of bioethics. Then we highlight some important elements of the author's conception of what bioethics should be. We conclude by examining the implications of this thinking for two issues: the university and sustainable development from a UN perspective. This approach will lead us to an element that we consider important in the author's thinking, that of openness. This openness is offered to bioethics by the inclusion of perspectives on the various understandings of life, openness to the consideration of ancestral knowledge and common knowledge, openness also to any other context, whether they involve minority situations, disadvantaged people or others. This openness gives particular meaning to a primary value of bioethics, that of respect for human dignity.

Keywords

Van Rensselaer Potter, bioethics, environment, knowledge, wisdom, common good, sustainable development, adaptation, university

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INTRODUCTION

C'est dans un article allemand de Fritz Jahr en 1927 que le terme « bioethics » ou « Bio-Ethik » est paru pour la première fois, mais dans la littérature américaine il survient sous la plume du biochimiste Van Rensselaer Potter dans un article intitulé « Bioethics, the science of survival » paru en 1970 (1). C'est toutefois à partir de son livre *Bioethics: Bridge to the Future,* paru en 1971, que Potter marqua l'histoire de la bioéthique sur le continent nord-américain (2). Il nous est apparu que la portée de ce livre pour le présent de la bioéthique perdrait énormément en signification sans un arrêt sur le contexte dans lequel il a émergé. Il nous sera ainsi possible de mieux envisager comment cet ouvrage peut éclairer nos contemporains.

Nous sommes donc au début des années 1970. Deux perspectives émergent presque simultanément à partir du même mot, celui de « bioéthique ». D'une part, la bioéthique de VR Potter s'avère une « entreprise écologique et globale » (3, p.38). D'autre part, André Hellegers « trouvait le terme particulièrement significatif pour exprimer l'idée de renouvellement qu'il envisageait pour l'éthique biomédicale » (3, p.39). C'est cette deuxième perspective qui dominera au cours des années subséquentes. Toutefois, la bioéthique nord-américaine naît au cœur de changements qui traversent les sociétés où elle s'implante. Ces changements sont de quatre ordres : sociologique, éthique, économique et écologique.

Pour le sociologue québécois Guy Rocher, ces changements impliquent 1) une culture marquée par un réaménagement des classes sociales dont la montée de la classe moyenne, 2) un désenchantement du monde et de l'histoire au sens entendu par Max Weber, 3) une mutation des rapports sociaux et 4) une fragmentation des sphères de la vie et de la culture (4). Parallèlement aux changements sociétaux, l'horizon éthique dans lequel Potter se retrouve prend de l'ampleur. En effet, des auteurs comme l'historien Roderick Nash (5) et le spécialiste en médecine sociale David Rothman (6) décrivent un élargissement des cercles éthiques qui passe, aux États-Unis, par l'émancipation des esclaves (1863), le droit des

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femmes (1920), le droit de ceux qu'on appelait alors les Amérindiens (1924), celui des travailleurs (1938), celui de ceux qu'on appelait alors « les Noirs » (1957) et de la protection des espèces (1973) (7). Quant aux personnes avec un handicap, le 1973 US Rehabilitation Act se révéla particulièrement important pour le mouvement de promotion de leurs droits et leur inclusion dans cet élargissement des cercles éthiques.

Dans le contexte médical américain, les préoccupations d'ordre éthique émergent au fur et à mesure que le corps médical se voit confronter aux répercussions d'événements passés tout autant qu'il l'est par les nouvelles technologies qui repoussent les limites de la vie. Il prend alors conscience des choix qui s'offrent en termes, notamment, d'allocations des ressources et de leurs impacts (8). Sous-jacent à ces enjeux se cache celui des relations de pouvoir entre les divers groupes sociaux marginalisés qui, légitimement, soulève la question du vivre ensemble et du bien commun; en termes de justice, notamment. Par ailleurs, au Québec et dans tout le Canada, la progression de l'horizon éthique s'inscrit dans ce qu'il a été convenu d'appeler l'« éthique appliquée », un calque de l'anglais « applied ethics » qui comprend au départ la bioéthique, l'éthique des affaires et professionnelles ainsi que l'éthique de l'environnement a contrario du modèle américain. Selon Marie-Hélène Parizeau, dans un rapport publié en 1989 (9), il est préférable de parler d'éthique sectorielle (p.9). Or, selon ce même rapport, les premières publications canadiennes en bioéthique apparaissent dès le milieu des années 1970 et portent sur l'expérimentation humaine dans les réseaux de santé (9, p.206). Peu à peu, les éthiques « sectorielles » ou « appliquées » s'inscrivent en contexte universitaire et la bioéthique poursuit son avancée dans le secteur biomédical.

Le contexte canadien de la bioéthique se voit par ailleurs teinter d'une manière différente par l'entremise d'un de ses volets, l'éthique de la recherche, le rapprochant ainsi de la pensée de Potter. Dès les années 1970, le Conseil des Arts du Canada crée le *Groupe consultatif de déontologie au sujet de la recherche impliquant des sujets humains*. Ce groupe, considérant qu'aucune science humaine n'est moralement neutre, publiera en 1977 un texte intitulé en français *Déontologie* (10) et en anglais *Ethics*. Par ce document, le Conseil des Arts du Canada recommande de prendre en compte les aspects éthiques des projets de recherche en sciences humaines et la mise sur pied, par les universités, de comités d'évaluation de ces projets. Après avoir décrit certains principes en puisant dans des textes, entre autres, de Bernard Dickens, de Margaret Mead et de Robert Veatch, on y souligne les particularités de leur application en sciences humaines et, plus particulièrement, en anthropologie, en archéologie et en éducation (10). Pour sa part le Conseil de recherches médicales du Canada mettra sur pied en 1976 un groupe de travail sur les problèmes éthiques dans la recherche avec des sujets humains qui publiera, l'année suivante un texte intitulé *Déontologie de l'expérimentation chez l'humain* (11). Ainsi, dès le milieu des années 1970, la bioéthique canadienne prend une couleur qui est sienne.

Parallèlement, toujours en contexte canadien, l'écologie fait son apparition dans la formation universitaire québécoise vers le début des années 1970. À la source de cette formation, on retrouve un livre de Eugene P. Odum (12) considéré par plusieurs scientifiques, tant canadiens qu'américains, comme le père de l'écologie moderne (13). Dans cette œuvre datant de 1975, il s'intéresse à la proche racine des mots « écologie » et « économie. » Les deux proviennent du grec « oikos » qui veut dire « maison » ou « habitat. » Au premier, on ajoute « logos » qui renvoie à la parole (la discussion qui en éthique appliquée est le propre de l'éthique) et au deuxième « nomos » qui signifie « loi » ou « droit ». Quant à l'éthique de l'environnement, bien que paru comme discipline académique au cours des années 1970, ses racines s'étendent bien avant 1949, année de la publication du livre *A Sand County Almanach* (14) d'Aldo Leopold[1] qui inclut comme texte final *Land Ethic*. Dans ce texte, Leopold énonce qu'une chose est bonne quand elle tend à préserver l'intégrité, la stabilité et la beauté de la communauté biotique. Et qu'elle est mal lorsqu'elle tend à faire autrement. Pour lui, l'idée d'une éthique de la terre se définit simplement comme une éthique du prendre soin : Prendre soin des personnes, prendre soin de la terre et renforcer l'interrelation entre les deux[2].

Cette approche prend appui sur des valeurs découlant de la Magna Carta (1215), de la Déclaration d'indépendance américaine (1776), de la Révolution française (1789) et sur le romantisme anglo-saxon. Ainsi, aux États-Unis, la reconnaissance de la sensibilité des animaux et de la justice qui devrait leur être appliquée voit le jour. Fait à noter, les personnes impliquées dans la promotion de la justice envers les animaux et la nature étaient souvent celles qui firent la promotion de l'abolition de l'esclavage. Courant mineur de l'écologie américaine, celui-ci se révéla comme sous-jacent à un courant majeur privilégiant une approche anthropocentrique issue d'un discours axé sur la conservation des ressources dont les tenants sont issus de la classe dominante blanche (15, p.63). Ce contexte, comme celui plus général de son temps, semble avoir teinté le discours de Potter. Dans un contexte marqué par d'importants changement sociaux et par l'articulation d'une réflexion environnementale qui s'appuie sur la science, naît la bioéthique en Amérique du Nord. Guy Durand la définit ainsi : « une préoccupation commune, un champ d'étude, une approche nouvelle, une pratique nouvelle et un mouvement socioculturel » (16, p.9-10).

Dans les sections qui suivront, nous aborderons brièvement l'approche dominante de la bioéthique – celle d'André Hellegers. Nous nous arrêterons ensuite aux concepts qui nous apparaissent comme majeurs dans la pensée de Potter telle que proposée dans son livre *Bioethics: Bridge to the Future*. Nous présenterons quelques impacts possibles de sa pensée sur des dossiers contemporains comme la mission de l'université et le dossier environnemental. Puis nous terminerons avec quelques ouvertures que nous permet cette œuvre.

[1] En 1990, ce livre d'Aldo Leopold et celui de Rachel Carson, *Silent Spring*, publié en 1962, furent choisis comme les deux livres les plus vénérés et significatif du XXième siècle par les membres de l'American Nature Study Society.
[2] Pour approfondir le sujet voir The Land Ethic du Aldo Leopold Foundation.

LA VISION D'ANDRÉ HELLEGERS : APPROCHE DU VIVANT ET PRATIQUE NOUVELLE DANS LE DOMAINE BIOMÉDICAL

Parmi les situations qui conduisirent à la naissance de la bioéthique, il est question de l'éthique médicale américaine, du discours éthique des médecins et du lien entre moralistes catholiques et protestants avec la morale médicale (3). Du côté de la recherche, les effets secondaires de la thalidomide, utilisé comme sédatif et anti-nauséeux, marque le monde. Comme le souligne le Sénat américain, « la tragédie de la thalidomide ne fut pas que ce médicament causa des malformations, mais plutôt qu'il continua pendant si longtemps à causer des malformations par milliers avant que le tout ne soit pris en considération et que les causes n'en soient cherchées » (17, p.919; *traduction libre*). L'ensemble des cas de scandales stimule alors le Sénat et les US National Institutes of Health (NIH) à porter une plus grande attention aux problèmes posés par la recherche impliquant ce qu'on qualifiait alors de « sujets humains. » À l'époque, la référence à la notion d'assujettissement auquel l'expression « sujet humain » renvoie, ne tient pas compte d'un contexte de non-respect de certaines tranches de la population assujetties au colonialisme. Dans une entrevue de Mark Frankel avec Joseph S. Murtaugh des NIH, ce dernier indique que ces scandales, dont celui impliquant l'étude Tuskegee sur la syphilis (1939-1972), mettent à l'avant-scène un élément fondamental : « dans les situations où un patient est impliqué dans une procédure expérimentale, le jugement du chercheur ne constitue pas une base suffisante permettant d'atteindre une conclusion concernant les questions éthiques et morales dans cette relation » (18, p.23; *traduction libre*). C'est aussi dans ce contexte de recherche que le champ de la bioéthique a vu le jour.

Lorsqu'André Hellegers propose l'utilisation du mot « bioéthique » en 1971, il n'est pas surprenant que ce gynécologue-obstétricien, premier directeur du Kennedy Institute of Ethics, souligne que le but de cette institution lors de sa fondation la même année est d'apporter son expertise concernant les nouveaux problèmes éthiques de la médecine moderne qui s'accroissent (19). D'autre part, pour les pionniers de la bioéthique, ceux dont le nom était mentionné dans la version de 1975 de *Bibliography of Bioethics,* présents à la conférence intitulée *The Birth of Bioethics*, de septembre 1992, trois événements marquèrent significativement la bioéthique, confirmant l'influence de son volet biomédical. Ce sont 1) la parution, en novembre 1962, de l'article du magazine *Life* intitulée « They Decide Who Lives » portant sur l'utilisation d'une ressource retreinte, l'appareil à hémodialyse (20), 2) la publication de Henry Beecher en 1966, dans le *New England Journal of Medicine,* portant sur l'éthique de 22 expérimentations cliniques sur des êtres humains (21) et 3) la première transplantation cardiaque réussie en 1967 par le Dr Christiaan Barnard (7)[3] qui posa la question du siège de la personnalité au niveau des organes du corps humain.

La vision actuelle de la bioéthique, s'enracinant dans les éléments qui précèdent, apparaît limitée aux questions de santé. S'articulent alors les questions de droits des patients, d'avancement des connaissances au sein de sociétés nord-américaines politiquement et socialement divisées, comme l'a démontré la pandémie de la COVID-19, et d'encadrement des éthiques sectorielles. Souvent considérée dans un contexte essentiellement administratif et légal, la bioéthique se voit dévier de son sens original d'éthique appliquée (ou situationnel). Or, l'éthique appliquée est une démarche réflexive et délibérative accordant une importance aux situations concrètes où se rencontrent et se nourrissent mutuellement théories et problèmes pratiques. Située au cœur de l'action, « souvent, la démarche en éthique appliquée consiste à documenter et à préciser la situation problématique au moyen d'informations factuelles [… avec, pour] objectif de préparer le terrain pour évaluer les différentes options du point de vue des valeurs et des principes […] » (22).

C'est donc en contexte souvent marqué du *sens* et du *devenir* de l'être humain situé dans le cadre des développements biomédicaux que les volets majeurs de la bioéthique s'institutionnalisent aujourd'hui. On y fait référence à la recherche du bien commun ou du bien sociétal qui, lorsqu'il n'est pas simplement défini sous l'angle de l'économie comme système de référence prioritaire, n'est pas défini du tout, laissant place à toute interprétation. Par ailleurs, on a vu s'articuler une rectitude des comportements professionnels, notamment en recherche, déterminés par les réglementations et une casuistique des situations difficiles. Ainsi, peu à peu, de nouveaux clercs sont apparus aux fonctions administratives bien définies, axées sur le respect des procédures et des normes[4] laissant peu de place à une éthique réflexive et discursive s'inscrivant dans un échange constant entre la théorie et la pratique. C'est dans ce cadre que la pensée et Van Ressenlaer Potter vient nourrir notre regard critique et ouvrir des avenues différentes et oubliées car la bioéthique est un pont vers le futur. Mais, avant d'en examiner les implications actuelles, prenons le temps d'articuler les points forts de sa pensée d'origine.

LA PENSÉE DE VAN RENSSELAER POTTER : PRÉOCCUPATION COMMUNE ET PROPOSITION DE MOUVEMENT SOCIOCULTUREL

Dès le point de départ, Potter dédie son livre *Bioethics: Bridge to the Future* à Aldo Leopold qu'il présente comme celui qui a anticipé l'élargissement progressif des cercles éthiques vers la bioéthique. Citant Leopold dans *A Sand County Almanach* (13), Potter se distancie d'une perspective anthropocentrique de la bioéthique pour en faire une éthique du vivant prenant en considération le sens étymologique strict du terme grec « bios » qui signifie « vie ». Soulignant que la relation à la terre demeure strictement économique, Leopold, repris par Potter, conclut que cette vision n'implique que des privilèges sans aucune obligation. L'éthique peut alors devenir un guide qui permet de prendre en considération les situations écologiques (2).

[3] À partir d'une référence de AR Jonsen et RA Pearlman, on y précise que les pionniers de la bioéthique étaient les personnes figurant dans la première édition (1975) de la *Bibliography of Bioethics*.

[4] Pour approfondir cette question, voir entre autres les textes publiés dans en 2010 (vol. 12, no. 1) dans la revue *Éthique publique*, ayant pour thème « Responsabilité sociale et éthique de la recherche ».

Sur la perspective écologique, se référant à Teilhard de Chardin dans le deuxième chapitre de son livre, Potter place sa conception de l'objectif de la bioéthique dans le courant holistique inhérent à l'écologie qui a marqué la première moitié du XXième siècle. « He [Teilhard de Chardin] sought to channel the new powers into a unified worldwide cultural community, but did not clearly distinguish between biological and cultural evolution nor did he consider the desirability of multiple alternative evolutionary pathways » (2, p.30). La bioéthique proposée par Potter s'inscrit dans une démarche réflexive visant l'atteinte d'une forme de sagesse pratique. Tout en évitant les considérations épistémologiques de la réflexivité chez le praticien comme le ferait Donald A. Schön (23), Potter envisage la sagesse comme la capacité d'arbitrer les connaissances entre elles aux fins du bien commun : « Bioethics […] would attempt to generate wisdom, the knowledge of how to use knowledge for social good from a realistic knowledge of man's biological nature and of the biological world » (2, p.26). Ce faisant, Potter articule son projet de bioéthique autour de quatre piliers : les connaissances, la sagesse, le bien commun et l'adaptation. Ces quatre notions sont, de notre avis, les éléments essentiels permettant de mieux comprendre le projet de Potter et comprendre comment il peut éclairer la pratique contemporaine de la bioéthique.

Connaissances

Les connaissances qu'évoque Potter sont de deux ordres : les connaissances dites scientifiques et celles relatives à une forme de méta-connaissance.

Dans le premier cas, Potter oppose les connaissances issues des sciences reposant sur la méthode scientifique à celles issues des « humanities » que nous assimileront, pour les besoins de la discussion, aux sciences humaines et sociales, sans nier l'apport que les arts et lettres peuvent avoir. Il importe de souligner que Potter adopte une approche réductionniste des sciences humaines et sociales en faisant reposer leur robustesse sur l'unique acceptabilité sociale (2). La bioéthique prend appui sur le dialogue entre ces deux corpus de connaissances qui, de l'avis de l'auteur, permettent de développer chez la personne une forme de sagesse :

> In seeking wisdom by consensus of interdisciplinary groups we need to examine all the old ideas by means of the scientific method, and we need to establish a continuing exchange of new ideas between scientists and humanists. We need to develop a new breed of scholars: men who combine a knowledge of new science and old wisdom, men who have the courage of the men of the Renaissance who thought truth was absolute and attainable. (2, p.66)

En considérant la perspective actuelle de la bioéthique, nous serions tentés – et c'est là une erreur qui prévaut dans la bioéthique contemporaine, nous y reviendrons – de réduire la pratique de la bioéthique à l'acquisition *ad infinitum* de connaissances issues de plusieurs disciplines. Or, l'approche de Potter de la bioéthique appelle à une prise en considération plus que multidisciplinaire soit interdisciplinaire de la connaissance de la connaissance, une méta-connaissance.

Reposant sur une version déductive et positiviste de la méthode scientifique, cette méta-connaissance vise à encadrer la pensée des praticiens en leur rappelant comment utiliser et arbitrer les connaissances entre-elles. En effet, les connaissances à elles seules ne suffisent pas à développer la sagesse pratique inhérente au projet de la bioéthique de Potter. C'est pourquoi la *conception scientifico-philosophique du progrès* reconnaît que la connaissance n'a pas un caractère absolu, que la seule frontière de la connaissance est l'ignorance, que la connaissance complète n'est pas accessible à personne, que la connaissance devrait être diffusée largement et que la meilleure solution à la mauvaise connaissance est plus de connaissance (2, p.49). Cette méta-connaissance invite donc le praticien à acquérir une connaissance de l'utilisation de ses connaissances: « that wisdom is moral knowledge, the knowledge of how to use knowledge, and the most important knowledge at all » (2).

Avant d'aborder plus en détail la notion de sagesse (i.e., la connaissance de comment utiliser la connaissance), il importe d'effectuer un bref détour sur le caractère éthique qu'accorde Potter aux connaissances (i.e., bonnes ou mauvaises). En fait, Potter affirme que la connaissance n'est pas intrinsèquement dangereuse, aidante, bonne ou mauvaise. Sa dimension morale – pour reprendre ses termes et faire court – repose sur l'utilisation qui en est faite : « No one worries about knowledge that is not used » (2, p.70). Le danger ou le caractère moralement douteux des connaissances émerge donc de l'écart qui peut s'opérer entre les chercheurs ayant développé lesdites connaissances et les praticiens qui les utilisent : « Basically, the problem arises from the gulf that is driven between the knowers and scientists and the doers or technologists » (2, p.76)[5]. Toutefois, ce caractère éthiquement douteux prend racine de manière plus intriquée dans la pensée de Potter, soit au coeur même de la sagesse: « Dangerous knowledge was defined as knowledge that has accumulated faster than the wisdom to manage it. […] in other word, knowledge that has produced a temporary imbalance by outpacing other branches of knowledge » (2, p.75-76). Ainsi, Potter considère que les connaissances deviennent mauvaises ou dangereuses quand la sagesse – arbitrage des connaissances entre elles – n'est pas encore au rendez-vous, soit quand une anticipation éclairée des conséquences qu'elles soulèvent n'est pas encore possible.

[5] Nous pourrions ici souligner l'importance des écrits de Donald A. Schön sur la rationalité technique qui tend à distinguer le rôle des chercheurs de ceux des praticiens où les premiers répondent aux problèmes rencontrés par les seconds, mais où les premiers se considèrent supérieurs et dénigrent le savoir pratique sous prétexte que ce dernier ne répond pas aux postulats positivistes prévalents (23).

Le caractère éthique de la connaissance a aussi fait l'objet d'une réflexion chez le physicien Richard P. Feynman en avril 1963 dans le cadre d'une série de cours à la University of Washington (24) alors qu'il se questionne sur la valeur de la science:

> I think a power to do something is of value. Whether the result is a good thing or a bad thing depends on how it is used, but the power is value.
>
> Once in Hawaii I was taken to see a Buddhist temple. In the temple a man said, "I am going to tell you something that you will never forget." And then he said, "To every man is given the key to the gates of heaven. The same key opens the gates of hell."
>
> And so it is with science. In a way it is a key to the gates of heaven, and the same key opens the gates of hell, and we do not have any instructions as to which is which gate. Shall we throw away the key and never have a way to enter the gates of heaven? Or shall we struggle with the problem of which is the best way to use the key? That is, of course, a very serious question, but I think that we cannot deny the value of the key to the gates of heaven.
>
> All the major problems of the relations between society and science lie in this same area. When the scientist is told that he must be more responsible for his effects on society, it is the applications of science that are referred to. If you work to develop nuclear energy you must realize also that it can be used harmfully. Therefore, you would expect that, in a discussion of this kind by a scientist, this would be the most important topic. But I will not talk about it further. I think that to say these are scientific problems is an exaggeration. They are far more humanitarian problems. The fact that how to work the power is clear, but how to control it is not, is something not so scientific and is not something that the scientist knows so much (24, p.6-7)

Cette anecdote nous permet d'observer la fracture franche que Feynman opère entre les savoir dits scientifiques et ceux provenant des « humanities », *a contrario* de Potter, il renvoie la réflexion sur les conséquences des usages de la connaissance aux domaines des humanités. Par ailleurs, à l'instar de Potter, il reconnaît que le caractère éthique (bien/mal) de la connaissance scientifique dépend de ses usages. L'anecdote prend toute sa force quand on se souvient que Richard P. Feynman a été recruté à l'âge de 24 ans pour travailler sur le Projet Manhattan au sein de la garde rapprochée responsable de la création de la première bombe atomique.

En somme, la conception des connaissances de Potter suppose que leur caractère éthique dépende des usages faits – perspective illustrée dans les propos anecdotiques de Feynman – et du décalage entre notre capacité à mettre les nouvelles connaissances en dialogue avec celles déjà établies. De ce décalage émane une forme de myopie qui limite la capacité des personnes utilisant les connaissances à en anticiper l'ensemble des conséquences menant ainsi à des « connaissances dangereuses » au moment de les utiliser. Or, la connaissance et l'accumulation de connaissances, même en provenance de plusieurs domaines, ne suffisent pas à constituer la bioéthique et prévenir cette myopie cognitive. Il importe alors de se pencher sur la notion de sagesse qui est centrale dans le projet de Potter.

Sagesse

« Science is knowledge, but it is not wisdom. Wisdom is the knowledge of how to use science and how to balance it with other knowledge » (2, p.49). Tel que mentionné précédemment, la collection de connaissances interdisciplinaires ne suffit pas pour Potter – il argumente que la sagesse implique une connaissance de la connaissance et un arbitrage des connaissances issues d'une multiplicité de disciplines. Toutefois, Potter propose peu de piste afin d'expliciter ce qu'il entend par *sagesse*.

D'emblée, mentionnons que la sagesse de Potter partage une parenté avec celle d'Aristote – alors qu'il ne s'en revendique pas – à savoir que la sagesse est « à la fois intuitive et science, science munie en quelque sorte d'une tête et portant sur les réalités les plus hautes » (25, Livre VI, 7, 1141 a 15). Tout comme la sagesse prudente d'Aristote, la démarche réflexive que soutient Potter implique que la personne doive exercer une forme de prudence dans le raisonnement qu'elle opère *in situ* de l'action. Mais ici encore, la définition que propose Potter s'avère plus ou moins précise. Au dernier chapitre, il élabore que la sagesse est une action d'ordre politique dont le but est la survie de l'humanité et correspond à une « compétence ou un savoir-faire sociétal. » Ainsi, Potter assimile la sagesse à un savoir-faire sociétal qui est fonction des connaissances particulières. Cette perspective a des répercussions importantes puisqu'elle envisage que le savoir-faire d'un individu s'amenuise à mesure que le volume de connaissances détenue par l'humanité s'accroit.

Le credo final de Potter apporte aussi quelques éléments additionnels afin de mieux comprendre ce qu'il entend par *sagesse*, soit – la collaboration avec autrui fondée sur une écoute tant des groupes minoritaires que de la majorité (2, p.196). La sagesse implique donc une disposition à l'écoute d'autrui. De plus, la sagesse suppose une posture réaliste et humble comme prérequis intellectuel à l'arbitrage des connaissances :

> What I am calling for is neither optimism nor pessimism, but an informed *realism* that included *humility*: a humility in which we admit that no one of us knows how society should proceed, a humility that causes us to listen in order to utilize the thoughts of others. We need humility that is not merely a mask for incompetence but rather a humility that is willing to lay its measure of competence on the line, willing to step over the disciplinary boundary, willing to criticize and be criticized, and willing to modify and evolve a cherished personal insight into an effective working hypothesis or an action policy for a group (2, p.151).

Somme toute, la sagesse de Potter n'est qu'indirectement détaillée sur le plan opérationnel à travers les références diffuses à la collaboration et l'écoute envers autrui et en évoquant un savoir-faire sociétal fonction des connaissances intrinsèques à la personne mis en rapport avec l'ensemble des connaissances de l'humanité. Toutefois, la sagesse de Potter sous-entend une posture de la part des acteurs qui soit ancrée dans une humilité permettant un arbitrage des connaissances qui soit réaliste allant au-delà d'une accumulation simpliste de ces dernières et engageant la personne dans un nécessaire dialogue avec autrui.

Bien commun

Le troisième concept central du projet bioéthique de Potter est le *bien commun,* bien qu'il ne soit pas nommé comme tel et désigné par l'appellation *social good*. Potter n'offre pas une définition propre du bien commun, mais évoque plusieurs éléments qui, ensemble, nous permettent de mieux en comprendre la portée. Le concept de bien commun pour Potter se décline en trois dimensions tout au long de son ouvrage : la première concerne la visée de la bioéthique qui peut se résumer à assurer le futur de l'espèce humaine; la seconde, le progrès individuel et sociétal. La troisième dimension repose quant à elle sur un système de valeurs communes qui reste à définir.

… et la survie de l'espèce

La première dimension est évoquée à moult reprises et nous ne chercherons pas à nous y attarder de manière exhaustive puisqu'elle agit comme trame de fond au projet de Potter : la survie de l'humanité. Cette visée du projet de la bioéthique oriente l'ensemble des préoccupations de Potter, allant jusqu'à dicter l'agir des détenteurs de connaisances spécialisées : « The great dilemma of modern society is the problem of how to harness the talents of the specialist, and the dilemma of the modern intellectual is how best to utilize his talents to promote the survival and improvement of mankind" (2, p.149). Bref, le bien commun fait référence à la survie de l'espèce.

… et le progrès de l'humanité

La seconde dimension du bien commun concerne, comme en témoigne le précédent passage, le progrès de l'humanité. Potter reconnaît que le progrès prend racine dans une conception matérialiste de la vie menant souvent à rechercher le *mieux* et le *plus* (*more and better*). Sa compréhension du progrès de l'humanité s'inspire de la tradition darwinienne où le progrès sous-entend la survie des individus les mieux adaptés. Toutefois, Potter reconnaît l'influence de ces deux traditions (matérialisme et darwinisme) sur la conception du progrès tout en nous mettant en garde à l'effet que la survie du mieux, du plus et des plus adaptés n'implique pas nécessairement un progrès tendant vers la perfection (2). En fait, le progrès de l'humanité s'appuie sur la productivité de l'espèce.

Le bien commun repose alors sur un progrès attribuable à la productivité des individus ; productivité pouvant se réaliser quand l'environnement est optimal. Ici, la productivité réfère non seulement au développement de ce qui nous rend plus sage comme groupe, mais aussi ce qui contribue au bien-être des autres de manière locale (famille, communauté) ou extensive (nation, humanité) (2, p.104).[6] Potter insiste que son projet met à l'avant-scène les universités comme lieu de production de ces éléments qui soutiennent le bien commun à la fois dans la perspective matérialiste – « Universities have the basic ingredients of *more* and *better* » (2, p.57) –, mais aussi en permettant de mieux comprendre les systèmes complexes qui se maintiennent en équilibre entre l'ordre et le désordre et permettent de créer un environnement optimal dans lequel les personnes peuvent être productives, soit des « happy and productive lives ». Il questionne d'ailleurs le rôle des universités dans la création de cet environnement optimal : « How can we in the university system help to develop a society in which individuals are able to live happy and productive lives? » (2, p.103). Nous constatons ici la tentative de Potter de créer une boucle de rétroaction positive où l'Université est placée en résonnance avec la société et les personnes qui la constituent.

…et les valeurs partagées

Enfin, la troisième dimension du bien commun dans le projet de Potter tient au système de valeurs renouvelé qu'il considère nécessaire, mais qu'il se défend bien d'expliciter. Cela dit, l'ouvrage de Potter aborde ponctuellement certaines de ces valeurs comme l'humilité dont doivent faire preuve les personnes face aux connaissances. Au moment où il prescrit une réflexion sur les conséquences des technologies sur l'humanité et les efforts de contrôle que peut déployer l'humanité (2), il y évoque la dignité humaine, la non-violence, le droit des minorités comme balises à cette réflexion. D'autres valeurs se trouvent en filigrane de l'environnement optimal tel que la bienveillance permettant d'éviter l'exposition aux menaces physico-chimiques, le respect envers la nature et le bonheur des individus (2). Enfin, le courage et la recherche de la vérité des penseurs de la

[6] Certains peuvent voir une dérive possible de cet argumentaire afin de soutenir une conception du développement durable qui puisse accentuer les inégalités sociales. Bien que cette dérive soit possible, il importe de rappeler l'importance qu'accorde Potter à la prise en compte des divers discours. En phase avec cette approche, soulignons au passage le travail de Kate Raworth dans son ouvrage « Doughnut Economics: Seven Ways to Think Like a 21st-Century Economist » qui permet de palier à certaines de ces dérives possibles, mais qui ne feront pas l'objet du présent article.

Renaissance sont autant de traces permettant de mieux appréhender le système de valeurs guidant sa conception du bien commun.

Ainsi, sans offrir une définition étayée et complète du bien commun, Potter place la survie de l'espèce comme point focal de son portrait du bien commun. Pour ce faire, il appelle au rôle des universités dans la société et leur capacité à soutenir le progrès de l'humanité. Enfin, sa conception du bien commun met en lumière un système de valeurs permettant de mieux circonscrire sa portée : l'humilité, le courage, la dignité, le respect, la vérité, la non-violence et une considération pour la voix des minorités.

Adaptation

Potter ne distingue pas de manière explicite la capacité d'adaptation des compétences sociétales nécessaires à la sagesse. Toutefois, les attributs qu'il lui accorde et son articulation avec le désordre et la culture lui confèrent un statut particulier et central dans sa pensée. En fait, Potter place l'adaptation au cœur même de la survie de l'humanité: « We live in a changing environment from the day we are born until the day we die. We live because we adapt, and we live only if we adapt » (2, p.123)

… pour mettre de l'ordre dans le désordre

Potter reconnaît que les sociétés sont traversées par des épisodes d'ordre et de désordre qui appellent les personnes à prendre action. En outre, le désordre offre des opportunités pour réfléchir et réviser les objectifs de l'action tant que les personnes n'abdiquent pas leur rationalité : « Disorder is a force to be utilized, the raw material for creativity. The problem is to harness it and keep it within the bounds of reason, that is, to be rational about irrationality » (2, p.25). Le désordre est constitutif de la vie. Ainsi, une première caractérisation de l'adaptation en fait un processus inhérent au vivant et nécessaire à sa survie en ceci qu'elle permet de rétablir l'ordre dans le désordre.

… culturelle

Outre les considérations liées à la vie biologique et la survie de l'humanité, Potter considère que l'adaptation est également une compétence permettant de répondre aux changements et désordre qui traversent la culture. Cette adaptation culturelle implique, chez les personnes impliquées, des changements psychologiques et comportementaux (2, p.24). Reprenant les travaux de Clifford Greertz, le citant (1965) : « culture is a set of control mechanisms for governing behavior and… man is precisely the animal most desperately dependent on such extragenetic control mechanisms for ordering his behavior » (2, p.36-37). Ici, Potter range la culture comme mécanisme de contrôle des comportements et de l'utilisation des connaissances. Il importe de rappeler que Potter prétend qu'en réaction à la multiplication des connaissances, les personnes tendent à déployer des mécanismes de contrôle associé. Ainsi, la sagesse décrite précédemment vise aussi à poser un regard critique sur ces mécanismes de contrôle afin qu'ils ne limitent pas (trop) les possibilités qu'offrent la science et la technologie.

Autrement dit, si on revient sur le propos central de Potter concernant les connaissances et la science et leurs rôles dans le développement d'une sagesse, la science est considérée comme une source de désordre culturel stimulant le progrès social : « Science as a force in cultural evolution. […] science is in fact a source of considerable disorder and of knowledge that society is by no means prepared to manage » (2, p.64). La gestion évoquée ici fait référence à la sagesse que cherche à développer Potter. L'adaptation culturelle implique donc que les personnes développent une forme de compétence dans la gestion de la science et des connaissances. Elle agit donc comme compétence complémentaire au savoir-faire propre à la sagesse de Potter, l'équivalent psychologique à l'adaptation physiologique des espèces (2, p.124).

Somme toute, l'adaptation est une compétence fondamentale permettant l'atteinte de la sagesse que propose Potter en parlant de bioéthique.

LA PENSÉE DE POTTER : UN PONT ENTRE LE PASSÉ ET LE FUTUR

Dans *Bridge to the Future* (2), Potter présente la bioéthique comme un pont posé entre le passé et le futur, comme une démarche qui vise le progrès global. Prenant la parole devant un groupe de philosophes du collégial du Québec, en 1994, Guy Rocher nous rappelle la fonction d'un pont au niveau de la connaissance, en ces mots : « Il y a un petit texte que je trouve très beau d'un vieux sociologue allemand du début du siècle, Georg Simmel, un petit texte sur « la porte et le pont ». Il montre comment la porte, si elle s'ouvre, peut toujours se refermer. Elle permet de s'isoler, elle sert à éviter les autres. En revanche, le pont est là pour demeurer ouvert : il est fait pour être traversé et pour établir la communication. » (4, p.5).

L'éthique appliquée et en particulier une de ses composantes, la bioéthique telle que conçue par Potter, nous invite à une traversée communicationnelle. Cette traversée ne peut s'effectuer que part la mise en place des conditions nécessaires à la réflexion et à la discussion de problématiques touchant les valeurs et les principes d'une situation prise dans son contexte. Certains pourraient dire que l'approche proposée constitue un relativisme éthique. Or, cette critique est loin de la perspective présentée. Pour éviter le piège du relativisme et pour s'engager dans une démarche éthique complète, Potter invite, non seulement par son image du pont mais aussi par la perspective qu'il propose, à construire des canaux de communication qui visent un développement des connaissances et de la sagesse, d'un bien commun axé sur la survie et le progrès de tous par des valeurs partagées. Cette image du pont et le développement des canaux de communication qu'elle favorise permet alors la prise en compte des débats qui peuvent exister, en particulier lorsqu'il est question de développement durable, dans une démarche éthique ou réflexion et discussion où les valeurs en jeu en constituent le cœur. À l'opposé du relativisme, est-ce

que Potter trace la voie à un universalisme éthique? Laissons à l'Organisation des Nations Unies pour l'éducation, la science et la culture (UNESCO) une possible réponse.

Dans un texte portant sur la Déclaration universelle sur la bioéthique et les droits de l'homme (26), nous pouvons lire :

> Quand l'Organisation des nations Unis pour l'éducation, la science et la culture (UNESCO) a été établie en 1945, son acte constitutif déclarait que la paix devait avoir comme fondement la solidarité intellectuelle et morale de l'humanité. Julian Huxley, le premier directeur général de l'Organisation, soulignait qu'afin de faire de la science un facteur de paix, de sécurité et de bien-être de l'humanité, il était nécessaire de relier les applications de la science à une échelle de valeurs. Guider le développement de la science pour le bienfait de l'humanité impliquait donc « la quête d'un nouvel énoncé de la moralité […] en harmonie avec le savoir moderne (p.17).
>
> Depuis sa fondation, l'UNESCO s'est préoccupée des questions morales liées à la science (p.19).

Il nous faut ici comprendre la référence à la moralité comme en étant une à l'éthique. Dans notre texte, nous considérons la morale dans une perspective reliée aux croyances où les valeurs et principes sont habituellement déjà déterminés (ex. : la morale chrétienne). Quant à l'éthique, elle prendra en considération les valeurs et principes existant dans un contexte (explicite) ou les fera ressortir s'ils ne sont pas clairement exprimés (implicite). Or, le texte en exergue ci-dessus nous situe dans une perspective ouverte tenant compte de la perspective des 193 États membres de l'époque ayant approuvé unanimement le texte de la Déclaration lors d'une conférence annuelle tenue à Paris le 19 octobre 2005 (26).

Cela étant, examinons maintenant à partir de deux exemples contemporains, celui de l'université et celui du développement durable, la perspective d'ouverture que Potter propose à partir de son livre *Bioethics: Bridge to the Future* (2).

Potter, la bioéthique et l'université contemporaine

Comme nous avons vu, le projet de Potter avec la bioéthique porte sur plusieurs aspects liés au développement des connaissances et de compétences sociétales comme l'adaptation; l'objectif ultime étant de développer une réelle sagesse chez les personnes utilisant les connaissances, sous réserve d'un environnement optimal leur permettant de contribuer au bien commun et suivant un certain système de valeurs. À cet égard, Potter met l'accent sur le rôle des universités dans l'atteinte de ces objectifs. La question est alors de voir comment la bioéthique de Potter permet de renouveler le modèle de l'université contemporaine.

Sans entrer dans une revue exhaustive de l'historique et des mutations des universités, notre point de départ tient aux trois missions de base épousées par la majorité d'entre elles, soit : l'enseignement, la recherche et le service aux collectivités. Nous discuterons de l'apport de Potter sur les enjeux contemporains de nos universités en lien avec ces missions. Par la suite, nous esquisserons les pistes permettant de répondre aux attentes de son projet afin de soutenir le développement d'universitaires capables de développer la sagesse propre à la bioéthique. Autrement dit, pour reprendre les termes de Potter : « How can we in the university system help to develop a society in which individuals are able to live happy and productive lives?" (2, p.103).

L'enseignement

Le projet de Potter est simple – allier les connaissances dites scientifiques à celles des *humanities* dans un effort raisonné pour développer une connaissance de la connaissance permettant de mieux anticiper les conséquences associées à l'application desdites connaissances dans l'espoir de contribuer à la survie de l'humanité. Potter soutient que l'université peut jouer ce rôle si elle intègre les trois notions de progrès (matérialiste, religieux[7] et scientifico-philosophique) dans leur cursus (2); rappelons aussi que Potter considère initialement que la bioéthique serait une nouvelle discipline. Mais, comment? Bien que son ouvrage ne contienne pas de prescriptions quant au programme précis que devraient mettre en œuvre les universités, sa *sagesse* nous offre quelques pistes.

D'abord, les étudiants devraient être exposés à des connaissances issues d'autres disciplines afin d'être en mesure d'arbitrer ses connaissances entre-elles, mais aussi apprécier l'étendue des incertitudes qui traversent leur discipline. Une autre voie serait de soutenir le développement des compétences sous-jacentes à la sagesse de Potter comme l'écoute et la collaboration dans un rapport égalitaire à l'autre. Par ailleurs, Tom Nichols, dans son ouvrage provocateur *The Death of Expertise* (27), cherche à élucider pourquoi les experts – principalement issus des universités – font l'objet d'une rupture de confiance qui se traduit par un rejet de leur expertise par leurs concitoyens. Il importe de souligner que la pensée de Nichols rejoint celle de Potter quant au rapport de la personne avec les connaissances tout en y ajoutant la notion de confiance dans son rapport à l'Autre :

> Knowing things is not the same as understanding them. Comprehension is not the same thing as analysis. Expertise is a (sic) not a parlor game played with factoids. […] Doing something well is not the same thing as becoming a trusted source of advice or learning about a subject" (27, p.37)

[7] Il importe de souligner que Potter considère qu'il existe deux visions des aspects religieux : une approche « primitive » empreinte de magie, de superstition et d'ignorance, et une approche « humaniste » qui s'appuie sur une maximisation des valeurs humaines et de la compréhension du monde qui nous entoure (2, p.85).

Sa pensée vient apporter un éclairage sur ce que pourrait viser un cursus universitaire cherchant à développer les compétences sociales de Potter chez les étudiants. En effet, plutôt que d'aborder la notion de sagesse, Nichols considère que les experts possèdent une *métacognition*, soit : « …the ability to know when you're not good at something by stepping back, looking at what you're doing, and then realizing that you're doing it wrong" (27, p.45). Cette métacognition présente, de notre avis, une proximité avec la sagesse de Potter en ceci que cette dernière rappelle que la connaissance n'est pas absolue et que l'ignorance en définit les contours chez la personne. De plus, Nichols s'attaque en particulier aux divers biais cognitifs qui distinguent les experts des non-experts comme le biais de confirmation (i.e., la tendance naturelle à retenir et sélectionner que les faits qui répondent à nos attentes et préjugés), le rasoir d'Okham (i.e. l'explication la plus simple est la plus probable) ou le Dunning-Kruger effect (i.e., une personne ignorante a tendance à surestimer son niveau de compétence). Or, peut-être qu'une formation sur les biais cognitifs et le rapport aux connaissances et à leur utilisation pourraient contribuer à développer des étudiants capables de sagesse pottérienne.

Cet enseignement sur la métacognition ou l'usage des connaissances n'est pas étranger au modèle de la méthode scientifique de David Lilienthal que reprend Potter. Ce modèle énonce six postulats de cette méthode, soit, si l'on traduit librement (2, p.50) : l'imagination, l'appel à la raison plutôt qu'à l'autorité, le réalisme fondé sur des faits, l'indépendance intellectuelle reposant sur une écoute active des critiques et avis d'experts reconnus, l'universalité de la science et le fait que la science doit donner espoir. Il s'agit, de notre avis, d'une piste susceptible d'orienter tout professionnel en devenir. Or, cette réflexivité pratique n'est peut-être possible que si des changements s'opèrent quant à l'épistémologie dominante des disciplines plus distantes des sciences humaines et sociales. Notons que Donald A. Schön critique la rationalité technique – hérité de l'épistémologie positiviste dominante – qui favorise la dichotomie entre les moyens et les fins, la recherche et la pratique, et le savoir et le faire (23, p.165). En outre, Schön propose, sans même prendre acte des écrits de Potter, d'inclure le savoir-faire (i.e., "the art") du praticien dans la formation : « It is this entire process of reflection-in-action which is central to the « art » by which practioners sometimes deal well with situations of uncertainty, instability, uniqueness, and value conflict" (23, p.50)

Enfin, le cursus académique pourrait aborder les enjeux relatifs aux systèmes de valeurs qui exercent une influence sur l'action et notre rapport à l'autre comme aux connaissances. Ainsi, comme nous l'avons vu précédemment, le système de valeurs de Potter comprend la dignité humaine, la non-violence, le droit des minorités, la bienveillance envers l'environnement, le courage et la recherche de la vérité. Nous ne pouvons passer sous silence que ces valeurs partagent des similarités avec les travaux empiriques de Shalom H. Schwartz sur sa théorie universelle des valeurs humaines. En effet, plusieurs des valeurs évoquées par Potter se retrouvent ou résonnent dans le système des valeurs élucidé par Schwartz, notamment l'humilité, la bienveillance, le respect de la nature et des personnes, la bienfaisance et l'autonomie de pensée (28). En somme, un enseignement universitaire qui s'inscrit dans la pensée de Potter exposerait les étudiants à une multidisciplinarité, certes, mais aussi une familiarisation avec les biais cognitifs fréquents, un rapport avec la pratique et une connaissance des systèmes de valeurs susceptibles d'orienter la pratique.

La recherche

Potter place la science et la recherche comme moteur permettant la survie de l'espèce si ces dernières contribuent à soutenir l'adaptation nécessaire dans un environnement en constant changement. Il propose une liste non exhaustive permettant de mieux saisir les secteurs de développement des connaissances qu'il estime capable de renforcir la capacité d'adaptation, soit, si nous traduisons librement ces derniers : les finalités et méthodes d'enseignement, les relations interraciales, la surpopulation, la surconsommation, l'intolérance religieuse, la conservation des ressources naturelles, l'énergie solaire, la désalinisation des eaux, la libération du talent créatif et le rôle de la publicité dans nos sociétés (2, p.52). Cette liste partage bon nombre de points en commun avec les 17 objectifs du développement durable de l'ONU (29), notamment ceux liés à la consommation et l'utilisation des ressources.

Le défi est de susciter l'intérêt des personnes engagées en recherche – en premier lieu, les chercheurs – envers ces enjeux. Malheureusement, Potter n'offre pas de piste de solution à cet égard ce qui nous amène à se questionner à savoir si le prestige et la réussite – deux valeurs susceptibles d'être considérées comme fondamentales suivant la théorie des valeurs de Schwartz (28) – pourraient être évoquées et favorisées pour que certaines personnes engagées en recherche s'intéressent davantage à ces enjeux. Une autre piste peut être, à l'instar de l'analyse que Samuel C. Florman fait de la profession d'ingénieur, de chercher à susciter un plaisir existentiel profond chez qui contribue au bien-être de ses semblables; ce qu'il considère être un concept de maturité professionnelle où le professionnel prend plaisir à contribuer au bien-être de ses semblables (30, p.147). Comme le souligne Potter, c'est l'utilisation des connaissances qui leur confère un caractère éthique. Nous avons vu que cette perspective était partagée par Feynman qui pourtant, rappelons-le, a activement contribué à la fabrication de l'arme atomique responsable de la mort de plus de 200 000 personnes. Toutefois, il appert que les personnes engagées en recherche pourraient bénéficier d'une boucle de rétroaction avec les utilisateurs de leurs connaissances afin de mieux développer leurs propres connaissances sur les conséquences ignorées ou inconnues. Par ailleurs, comme propose l'analyse de Nichols, les experts contemporains – et les personnes engagées en recherche par extension – font face à une crise de confiance au sein de leur relation avec leurs concitoyens, ce qui nourrit la fracture entre les deux camps et menace la démocratie (27, p.216). Serait-ce alors que la recherche en milieu universitaire doive contribuer à soutenir le lien de confiance entre les personnes engagées en recherche, l'université et la société civile? Nous posons la question sans toutefois y répondre.

En somme, Potter rappelle que la finalité des connaissances doit être prise en compte afin d'anticiper les conséquences. Les objectifs de développement durable offrent un horizon permettant d'orienter les travaux en recherche qui serviraient à promouvoir la survie de l'espèce et penser les conséquences des connaissances développées. Le défi reste de susciter l'intérêt des personnes afin qu'elles s'engagent dans une telle démarche réflexive sur les visées de leurs travaux. En outre, des boucles de rétroaction positive permettant de mieux appréhender les conséquences des connaissances antérieures pourrait peut-être soutenir la consolidation de la sagesse chez ceux engagés en recherche. Enfin, il importe de se questionner sur le lien de confiance entre la société civile et le milieu de la recherche.

Le service à la communauté

Le service à la communauté est la dernière mission des universités et pourrait aussi bénéficier du projet de Potter, notamment en invitant les personnes qui y évoluent à porter une attention particulière aux besoins de la société afin de servir le progrès humain et contribuer à la survie de l'espèce. Lorsque nous faisions mention précédemment des boucles de rétroaction, c'est en ayant en à l'esprit ce type de dialogue nécessaire qui permet aussi aux personnes engagées en recherche et aux étudiants à acquérir les connaissances nécessaires au développement de leur sagesse. Toutefois, le service à la communauté, dans une perspective bioéthique, prend une direction importante, soit celle de l'engagement sociétal. Cet engagement revêt même une dimension politique pour Potter :

> Our basic devotion to the dignity of the individual, to nonviolent change, to the right of the minority to be heard, are minimal guarantees that must be maintained in any attempt to foresee the consequences implicit in the application of new knowledge *and to take more vigorous political action to control technology*, while at the same time preserving its magnificent potentialities (2, p.77)

La question est alors de définir la portée de cet engagement pour les universités et les personnes y évoluant ou y ayant étudié. Pour mieux comprendre les dimensions de l'action sociétale, nous ferons le parallèle avec la profession d'éthicien telle que l'a définie Daniel Weinstock en déclinant les quatre modalités par lesquelles l'éthicien parvient à accomplir son rôle d'accompagnateur capable d'éclairer la réflexion (31, p.43-44). Selon l'auteur, l'éthicien contribue au développement des connaissances scientifiques afin d'éclairer le débat public, offre des conseils à un auditoire professionnel, participe aux instances de gouvernance et peut participer au « jeu médiatique » pour partager ses connaissances et questionnements sur les enjeux donnés. Autrement dit, l'apport des chercheurs – comme des professionnels – ne se limite pas à une forme de solutionnisme technologique où ces derniers répondent aux besoins d'une clientèle citoyenne ou industrielle, mais prennent part au débat médiatique, l'éclaire et y contribue activement. En ce sens, le service à la communauté prend une dimension politique au sens où l'université affirme sa place dans la Cité, pour paraphraser Weinstock, en plaçant le professionnel comme « serviteur de la démocratie » (31, p.59)

Somme toute, le service à la communauté ne peut se limiter à répondre aux commandes des divers acteurs sociétaux, mais commande aux professionnels formés au sein des universités et les personnes engagées en recherche y œuvrant à prendre une part active dans l'espace médiatique afin d'éclairer le débat. Nous irons jusqu'à faire l'hypothèse que ce service à la communauté contribue non seulement à la diffusion des connaissances – condition nécessaire à un environnement optimal selon Potter –, mais aussi à développer une sagesse chez les citoyens en les exposant à une multitude de connaissances et en leur transmettant les rudiments leur permettant d'arbitrer eux-mêmes les connaissances entre elles. Comme le mentionne Nichols dans sa conclusion sur la fracture de confiance entre les experts et les citoyens :

> Experts need to remember, always, that they are the servants and not the masters of a democratic society and a republican government. […] Experts, likewise, must accept that their advice, which might seem obvious and right to them, will not always be taken in a democracy that may not value the same things they do. (27, p.238)

Potter, la bioéthique et le développement durable

Comme nous l'avons vu précédemment, la bioéthique de Potter ouvre à une prise en considération du rôle de l'université dans la société. Or, un des apports de la connaissance des connaissances est lié bien concrètement au maintien du vivant sur la terre. Cette bioéthique du maintien du vivant traverse son œuvre de la première page, avec sa dédicace à Aldo Leopold, jusqu'à ses dernières phrases du dernier chapitre « Survival as a goal for Wisdom » où il écrit: « Now the whole world is influenced by events in any part of it. Change in outlook is needed, but will change come in time? » (2, p.195). Rappelons certains éléments de la vision de Potter sur la bioéthique en lien avec l'environnement qui peuvent constituer une interpellation à revoir ce champ du développement des connaissances que constitue la bioéthique.

Le livre *Bioethics: Bridge to the Future* (2) a été écrit dans un contexte d'émergence de l'écologie moderne, à un moment de grands changements sociaux et d'éveil aux impacts environnementaux, apportant à la bioéthique une perspective à long terme qui lui fait parfois défaut aujourd'hui. Sans entrer dans le détail du texte, ce que nous ne pouvons faire ici, il nous suffit de simplement regarder les titres de chapitre du livre pour nous rendre compte de l'importance que les impacts du développement des connaissances peuvent avoir sur l'environnement et sur la place que la bioéthique devrait y occuper. Qu'il suffise d'en rappeler quelques-uns : *Bioethics, the Science of Survival* (chapiter 88), *Bridge to the Future : The Concept of Human Progress* (chapitre 3), *How Is an Optimum Environment Defined?* (chapitre 10) ou *Survival as a Goal for Wisdom* (chapitre 13). Il est intéressant de noter que certains principes de la *Déclaration de Montréal pour un développement responsable de l'intelligence*

artificielle[8] sont en ligne avec la perspective de Potter sur la bioéthique démontrant ainsi une actualisation possible de cette dernière à partir d'un élément à la fine pointe du développement actuel des connaissances. On peut penser par exemple au principe de bien-être de la Déclaration qui vise le développement et l'utilisation des systèmes d'intelligence artificielle permettant « d'accroître le bien-être de tous les êtres sensibles » (principe 1), au principe de solidarité qui vise « le maintien de liens de solidarité entre les personnes et les générations » (principe 4) ou au principe de développement soutenable qui vise à « assurer une soutenabilité écologique forte de la planète (principe 10).

Au chapitre 10 (p.144-145), Potter propose sept points pour définir un environnement optimal qui, tout en prenant en considération la perspective d'Aldo Léopold, s'en éloigne quelque peu. Le premier point vise à répondre aux besoins fondamentaux qu'ils soient physiques, éthiques ou intellectuels, ce qui n'est actuellement pas atteint dans bon nombre d'endroits du globe. Des exemples marquants sont les situations de délestage dans certaines parties de l'Afrique et, dans le contexte pandémique actuel, l'impossibilité, faute d'appareils pour le faire, de séquencer les échantillons de porteurs de la COVID-19 pour en déterminer le variant, ou, plus près de nous, l'absence d'eau courante et d'électricité au sein de communautés autochtones situées à proximité de ces ressources. Le second point vise à bénéficier d'un environnement libre de produits chimiques toxiques, de trauma ou de maladies prévisibles ce qui ne saurait se faire sans une évaluation environnementale libre de tout conflit d'intérêts. Troisièmement, la vision pottérienne de la bioéthique propose d'avoir une culture qui respecte des principes écologiques solides aux perspectives à long terme. Se rencontrent alors des positions différentes comme l'écocentrisme, la morale humaniste ordinaire ou l'anthropocentrisme. Quatrièmement, Potter propose de compter sur une culture qui nous prépare à l'adaptation. Le cinquième principe vise l'oscillation entre satisfaction et insatisfaction dans un monde aux changements rapides. Sixièmement, la visée de la bioéthique proposée, permet de concevoir une productivité qui implique un engagement envers les membres de la société qu'ils soient proches ou plus distants. Peut entrer ici des dimensions géographiques tout autant que la perspective d'un développement durable intergénérationnel. Et, septièmement, Potter propose de favoriser une évolution de la culture tenant compte du rôle des individus, du désordre existant et du développement des connaissances.

… et les objectifs du développement durable de l'ONU

Nous y avons fait allusion précédemment, la bioéthique de Potter partage bon nombre de points en commun avec les 17 objectifs du développement durable de l'ONU (29), notamment ceux liés à la consommation et l'utilisation des ressources.

Cette actualité de la conception pottérienne de la bioéthique en lien avec l'environnement ne manque toutefois pas de nous surprendre car depuis 1971, les concepts liés à l'environnement ont évolué. Étape marquante de cette évolution, le rapport Brundtland intitulé *Notre avenir à tous,* (32) rapport de la Commission mondiale sur l'environnement et le développement paru en 1987, fait entrer dans la réflexion le concept de développement soutenable (p.59-77) qui prendra aussi la forme de développement durable. Une recherche en littérature fait état qu'au cours des années, de multiples versions du développement durable ont été promues visant à répondre aux besoins particuliers de groupes aux orientations différentes (33). Dans ces avancées, en septembre 2015, les membres de l'ONU acceptent dix-sept objectifs visant le développement durable énoncés en version anglaise comme des objectifs du *sustainable development.*

Afin de répondre aux besoins fondamentaux physiques, éthiques et intellectuels, l'ONU pose un objectif de croissance économique partagée visant la création d'emplois durables et la promotion de l'égalité et le développement d'un secteur de l'alimentation et une agriculture qui seront au cœur de l'éradication de la faim et de la pauvreté. L'environnement libre de produits toxiques, de trauma ou de maladies prévisible prend forme, du côté de l'ONU, dans les moyens de vivre une vie saine et de promouvoir le bien-être de tous à tous les âges et d'assurer un approvisionnement en eau propre et accessible pour tous. Avec son quatrième principe, Potter souligne que la culture doit nous préparer à vivre dans un contexte d'adaptation. Or l'objectif 4 de l'ONU fait un pas dans ce sens en proposant le développement d'une éducation de qualité assurant le fondement nécessaire à l'amélioration de la vie des gens et au développement durable.

Ce qui ressort de cette analyse préliminaire, c'est que la bioéthique de Potter et les perspectives actuelles d'organismes internationaux sur le développement durable s'appuient, se complètent et permettent de mettre en lumière les avancés et les carences de chacune.

CONCLUSION

En proposant une bioéthique aux caractéristiques que nous avons rapidement énoncées, Potter favorise le développement d'une discipline, que nous appellerons champ de connaissances, qui se développe en milieu universitaire et qui prend en compte l'apport de tous. Cette ouverture de la bioéthique pottérienne nous renvoie au respect de la dignité humaine qui caractérise un de ses volets, l'éthique de la recherche. Elle prend appui dans des racines étymologiques fortes qui permettent la rencontre de l'écologie et de l'économie puisque les deux proviennent de la même racine et concernent la vie sur la terre, mais pose la nécessité d'une réflexion et d'une conversation entre les deux. Par sa considération intégrale du terme « bios », la bioéthique de Potter permet l'ouverture à toute forme et conception du vivant qu'elle soit écoféministe, provenant de l'écologie profonde, du biocentrisme ou autre courant de pensée environnementale. Et par-dessus tout, elle permet l'intégration des savoirs traditionnels, du sens commun et des points de vue minoritaires dans une bioéthique axée sur la solidarité avec l'Autre. Elle invite aussi à un questionnement sur l'université, son rôle et sa capacité à permettre aux personnes

[8] https://www.declarationmontreal-iaresponsable.com

y évoluant d'acquérir cette forme de sagesse définie et promue par le projet de Potter. Après notre démarche, il nous apparait que la bioéthique pottérienne comporte des volets qui ne peuvent être passés sous silence dans une perspective évolutive de la bioéthique.

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Guillaume Paré agit à titre de conseiller à la Direction de la recherche et de l'innovation de Polytechnique Montréal. Il siège à titre de membre des conseils d'administration de l'Association canadienne des comités d'éthique de la recherche (ACCER) et de l'Association des administratrices et administrateurs de recherche universitaire du Québec (ADARUQ). Michel Bergeron est professeur associé à l'École de santé publique de l'Université de Montréal et travailleur autonome. En ce sens, il remplit divers mandats auprès d'organismes locaux, nationaux et internationaux. Les opinions, faits et positions exprimées dans le présent article n'engagent que les auteurs et ne représentent la position d'aucun organisme ou d'aucune institution auxquels ils sont rattachés ou pour lesquels ils remplissent des mandats. Les auteurs n'ont bénéficié d'aucune aide financière pour la préparation de ce texte.

Conflicts of Interest

Guillaume Paré is an advisor to the Direction de la recherche et de l'innovation of Polytechnique Montréal. He is a member of the Board of Directors of the Canadian Association of Research Ethics Boards (CAREB) and of the Association of University Research Administrators of Quebec (ADARUQ). Michel Bergeron is an associate professor at the School of Public Health of the Université de Montréal and is self-employed. In this sense, he fulfills various mandates with local, national and international organizations. The opinions, facts and positions expressed in this article are those of the authors alone and do not represent the position of any organization or institution to which they are attached or for which they carry out mandates. The authors have not received any financial support for the preparation of this paper.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Van Rensselaer Potter, Climate Change, and Justice

James Dwyer[a]

Résumé
Lorsque Van Rensselaer Potter a inventé le mot anglais « bioethics », il a imaginé un domaine qui réunirait la compréhension biologique et les valeurs éthiques pour aborder les problèmes environnementaux mondiaux. Suivant la vision large de la bioéthique de Potter, j'explore les idées éthiques dont nous avons besoin pour faire face au changement climatique. Cependant, je développe et souligne les idées de justice et de responsabilité d'une manière que Potter n'a pas faite. À certains moments clés, j'oppose les idées que je développe à celles de l'œuvre de Potter, mais j'essaie d'éviter les débats savants et de rester concentré sur la tâche pratique : développer des idées pour nous aider à faire face au changement climatique. Pour commencer, je décris le problème du changement climatique. Ensuite, je montre comment il soulève de profondes et sérieuses questions de justice. Puisque les questions de justice sont relativement claires et convaincantes, je concentre mon attention sur les questions de responsabilité – sur le pourquoi et le comment de la réponse aux injustices structurelles du changement climatique. Je note également comment l'accent mis sur la justice et la responsabilité soulève deux nouvelles questions. Pour conclure, je mentionne le rôle des citoyens écologistes dans la réalisation du changement social.

Mots-clés
Van Rensselaer Potter, bioéthique, changement climatique, justice, responsabilité

Abstract
When Van Rensselaer Potter coined the English word "bioethics", he envisioned a field that would bring together biological understanding and ethical values to address global environmental problems. Following Potter's broad vision of bioethics, I explore ethical ideas that we need to address climate change. However, I develop and emphasize ideas about justice and responsibility in ways that Potter did not. At key points, I contrast the ideas that I develop with those in Potter's work, but I try to avoid scholarly debates and stay focused on the practical task: developing ideas to help us address climate change. To begin, I describe the problem of climate change. Then I show how it raises deep and serious issues of justice. Since the issues of justice are relatively clear and compelling, I proceed to focus attention on issues of responsibility – on why and how to respond to the structural injustices of climate change. I also note how my emphasis on justice and responsibility raises two new issues. To conclude, I mention the role of ecological citizens in bringing about social change.

Keywords
Van Rensselaer Potter, bioethics, climate change, justice, responsibility

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INTRODUCTION

In an article published in 1970, Van Rensselaer Potter coined the English term "bioethics" (1). The following year, this article served as the first chapter of *Bioethics: Bridge to the Future* (2). Potter coined the term bioethics because he saw the need to bring together biological knowledge and ethical values. For Potter, the "bio" in bioethics always included ecology and evolution, and ethics always included caring about the future and acting with wisdom. He hoped the new discipline of bioethics would address broad and pressing issues about our relationship to nature, population health, and acceptable survival. He urged scholars, students, and future leaders to take up this discipline and bring about change.

Potter always acknowledged a great debt to Aldo Leopold. Potter's 1971 book *Bioethics* was dedicated to Leopold and his 1988 book *Global Bioethics* was subtitled *Building on the Leopold Legacy* (3). Potter drew on Leopold's understanding of ecology, interactions, and carrying capacity – the healthy population of a species that an ecosystem can sustain. He also drew on and interpreted Leopold's articulation of a land ethic. Leopold's work resonated with Potter because they both saw that human beings were altering ecosystems and impoverishing the future (4).

In the 1970s, a field developed at Georgetown University, the Hastings Center, and elsewhere in North America that focused most of its attention on research ethics, new medical technologies, and the doctor-patient relationship. This field also came to be called bioethics, but the "bio" referred more narrowly to biomedicine and biotechnology. *Principles of Biomedical Ethics*, by Tom Beauchamp and James Childress, became the dominant book in this field (5). It was first published in 1979 and is now in its eighth edition. In retrospect, the contrast between these two views of bioethics is striking. It's as if these views agreed that the twenty-first century will be the century of biology but that they disagreed on what that means: the century of biotechnology or the century of the biosphere (6).

Potter's work showed me the need to conceive of bioethics in broad way. Many environmental problems are more serious and urgent than ever: climate change, extinction of species, overconsumption of resources, depletion of fish stocks, shortages of freshwater, deforestation, and more. These environmental problems raise ethical issues about our relationship to nature, ecosystems, people, and other living beings. Potter's work also showed me the need to think globally. His ethical concerns

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extend, as should ours, well beyond North America and well beyond the present generation. Furthermore, his work showed me the need to think more deeply about how to respond. Reading Potter reinforced a felt need to change how I (and many other people) inhabit and think about the world.

Although Potter's work helped me to live and think in a better way, this essay tends to emphasize my differences with Potter. Whereas Potter discusses acceptable survival, and focuses extensively on the control of fertility, I tend to emphasize issues of justice. I believe that taking up a perspective of justice is crucial to understanding and responding to contemporary environmental problems. Whereas Potter relies on a general concept of responsibility, I tend to emphasize a conception of political responsibility for structural injustice. I believe this conception fits, and helps guides responses to, many environmental problems. To respond more adequately to environmental problems, I think that we will need to change social structures, background conditions, economic systems, political processes, and accepted practices. This kind of change requires political action, in the best and broadest sense of that term.

What we do and should emphasize depends on the historical situation. The philosopher and social activist John Dewey makes this point in a discussion of perspectives, statements, and matters of emphasis. He writes:

> We have indicated that since general aims are but prospective points of view from which to survey existing conditions and estimate their possibilities, we might have any number of them, all consistent with one another. As a matter of fact, a large number have been stated at different times, all having great local value. For the *statement* of aim is a matter of emphasis at a given time. And we do not emphasize things that do not require emphasis – that is, such things as are taking care of themselves fairly well. We tend rather to frame our statement on the basis of the defects and needs of the contemporary situation; we take for granted, without explicit statement which would be of no use, whatever is right or approximately so. We frame our explicit aims in terms of some alteration to be brought about. It is, then, no paradox requiring explanation that a given epoch or generation tends to emphasize in its conscious projections just the thing which it has least of in actual fact. (7, p 118, italics in original)

Dewey thinks that we should look carefully at the defects, needs, and potentials of our current situation, and then emphasize what needs to change. That is what I will try to do.

I tend to emphasize the idea of justice and the idea of responsibility for injustice because I believe these ideas are underdeveloped in Potter's work relative to the needs of the contemporary situation. This belief raises both scholarly and practical issues. The scholarly issues concern how the idea of justice may be implicit in Potter's work and why he did not develop it more. The idea of justice may be implicit in his concern for the future, his move to think beyond mere survival, and his vision to bring humanities together with sciences in order to address important environmental issues. His implicit idea of justice may be underdeveloped because, although he read broadly, he didn't seem to read explicit accounts of justice. Or the idea of justice may be underdeveloped because our current situation is different from his – because history changes. Our current situation and scholarship are making more visible how whole groups are marginalized and affected by environmental problems (8). Although the scholarly issues about what's implicit but underdeveloped in Potter's work are important, they are not my focus in this essay.

My focus, instead, is on a practical task: to develop and emphasize conceptual tools that we need to address the major environmental problem of our time: climate change. In particular, I aim to show what the current situation demands, conceptually and ethically, in terms of justice and responsibility. The ultimate test of how well I do that is not my dialectical ingenuity or argumentation; it is how these conceptual tools could and should be used to address the problem of climate change. At points in this essay, I compare and contrast my ideas with Potter's, but I am not trying to score points in a scholarly debate. I am really trying to respond to an urgent problem, in a way that builds on Potter's vision of bioethics.

My plan is as follows. In the first section, I briefly describe the problem of climate change – this is the biggest bioethical problem that we face, in Potter's sense of bioethics. Then in the second section, I show how the problem of climate change raises issues of justice. Since the issues of justice seem relatively clear, and the judgments of justice seem warranted, I proceed to focus more attention on issues of responsibility and responsiveness. In the third section, I make use of Iris Marion Young's account of responsibility for structural injustice. This account of responsibility fits the ethical problem and helps to guide responses, but it also brings up new issues. So, in the fourth section, I describe two of these new issues, but I do not offer definite solutions. The best I can hope for is to describe the issues in a way that will inspire further work. In the fifth section, I offer a few concluding remarks.

CLIMATE CHANGE

The evidence that human activity is causing climate change is very extensive and robust (9). The data and accounts in support of anthropogenic climate change come from physics, chemistry, biology, earth sciences, oceanography, history, ethnology, and other disciplines. The accounts include theories and models that explain past changes and predict future changes. The robustness of the evidence is reflected in both the scientific consensus, as indicated in peer-reviewed articles, and corporate strategy. Following the strategy used by tobacco companies to counter the evidence that smoking causes health problems, fossil fuel companies have tried to create the appearance of doubt about climate change (10).

Because emissions of greenhouse gases are higher than the natural world can absorb, the levels of these gases are increasing in the atmosphere. This increase is apparent in the levels of carbon dioxide, the greenhouse gas responsible for about two-thirds of the rise in Earth's temperature (11). The preindustrial level of CO_2 was probably about 280 parts per million (ppm); by 1960, it was about 315 ppm; and then it began increasing more rapidly. By 2019, it was over 410 ppm (12). The high level of carbon dioxide traps heat in the atmosphere and profoundly affects earth systems. Air and water temperatures are increasing, precipitation patterns are changing, storms are becoming more intense, droughts are becoming more severe in some regions, ice masses are melting, sea levels are rising, oceans are becoming more acidic, and much more.

These changes in earth systems increase the likelihood of particular environmental problems: heatwaves, floods, prolonged droughts (in some regions), wildfires, crop failures, soil degradation, salinization of freshwater, water shortages, etc. (13). These environmental problems have a profound impact on human health and well-being (14). Heatwaves and the associated thermal stress contribute to heatstroke and cardiovascular failure, especially among people who are very young, very old, work outdoors, or lack indoor cooling. Storms and rising sea levels contribute to surges that kill people, damage infrastructure, and ruin croplands. Shortages of freshwater contribute to dehydration and use of unsafe water. Crop failures tend to increase food insecurity, especially among small farmers and people with low incomes. The changes in temperatures and ecosystems tend to increase vector-borne, water-borne, and food-borne diseases like malaria, dengue, cholera, and many other diseases.

At least in the medium term, the biggest impact of climate change on health may be indirect: climate change will diminish the livelihood of millions of people, especially among people whose economic situations are already marginal and precarious. This may first become apparent among people who depend most directly on healthy ecosystems for food and income. We know, from decades of research on the social determinant of health, that income and social position have profound effects on health (15). Climate change will also lead to more migration, both within and between countries (16). Some people will migrate because storms and disasters displace them. Others will migrate because of diminished livelihoods. The differences between environmental and economic migrants, and between forced and voluntary migrants, may not be clear nor morally salient.

Climate change is the kind of environmental problem that concerned Potter and prompted him to propose the new discipline of bioethics. Indeed, he mentions climate change in his 1988 book *Global Bioethics* (3, p.41-42). This was not some prescient moment, two years before the first IPCC assessment, but was part of a larger discussion of survival. In the course of this discussion, Potter considers two examples of climate change – one natural, the other anthropogenic. He notes that the extinction of the dinosaurs may have been caused by climate change that resulted from the impact of asteroids on the earth. He also notes that use of powerful nuclear weapons might alter earth systems in ways that would trigger a nuclear winter. This nuclear winter would threaten the survival of those who were not killed by the nuclear blasts. Regardless of what Potter would have said about climate change produced by greenhouse gases, it is the kind of problem that concerned him. It shows the need to bring an understanding of biology, especially ecology, together with ethics. It is a problem that is global in its effects and threatens the future even more than the present. And it calls on many of us to change the way we inhabit and think about the world.

However, the problem of climate change also shows where and how my thinking goes beyond Potter's. As I explain in the next section, I don't find Potter's focus on survival very helpful. I find accounts of justice more helpful. Furthermore, I think we need a conception of responsibility that fits the injustices of climate change. Whether this way of going beyond Potter is a development of his original vision is an important scholarly issue that I put aside. I am more concerned to show how the current situation requires us to think about justice and responsibility.

JUSTICE[1]

Almost all of us are at risk from climate change, but we are not equally at risk. Almost all of us contribute to climate change, but we do not contribute equally to the problem. Almost all of us act as agents at least some of the time, but we are not equally empowered to shape the practices and structures that affect climate change. Since these differences bear on justice, I want to consider in more detail the distribution of risks, contributions to the problem, and power to shape practices and structures.

People's particular risk from climate change depends on many factors: their age, health, location, neighbours, social position, the wealth of their society, and other factors. I will consider various risks in four broad categories. The first risk category is temporal position. As I noted in the last section, greenhouse gases are accumulating in the atmosphere faster than they can be absorbed and recycled by the natural world. Without more adequate measures to reduce emissions and build resilience, younger people face greater risks over their lifetimes than older people over theirs. Future generations will be at even greater risk – they will be born into a world with a much less hospitable climate.

The second risk category is geographical location. People who live in drought-prone areas will have to deal with more severe and prolonged droughts. Millions of small farmers who depend on regular patterns of rainfall will be at greater risk. People who live in flood-prone areas will have to deal with more intense and frequent flooding. People who live on coasts, river deltas, and low-lying islands are threatened by rising sea levels and storm surges. Billions of people in Asia depend for water on the regular accumulation and melting of the Himalayan glaciers (17). They are at greater risk of flooding in the short term and

[1] Some ideas in the first part of this section are drawn from previous work (16).

water shortages in the long term. People who live and work in hot regions are at greater risk of heatwaves that pose health risks and limit outdoor work. People who live in cold regions can be threatened in different ways. The Inuit sources of food, ways of transportation, infrastructures, and culture are threatened by rising temperatures and melting Artic ice (18). As I note below, the geographical risks of climate change can be attenuated or exacerbated by social factors, structures, and practices.

The third risk category is the kind of society in which people live. Low-income countries lack the economic resources to make some needed changes: to reconstruct infrastructure, fund insurance schemes, invest in public health, and more. Although high-income countries have the economic resources to make needed changes, they often lack the foresight, political will, and governance needed to make deep changes. The category of the kind of society includes more than income and governance. When civil society cultivates civic engagement and social solidarity, people are usually better protected. Even neighbourly care makes a difference. People are better protected from climate change, especially from some of the effects of so-called “natural” disasters, in places where people look in on and look out for their neighbours.

The fourth risk category is people’s position within their society. Power, wealth, income, occupation, formal education, housing, gender, race, ethnicity, and other factors make a difference. Years of research on the social determinants of health show how relative social position affects people’s health risk (15). The Whitehall study showed that, at least in the United Kingdom, a small difference in occupation makes a large difference in health. Similar differences seem to affect the risks that climate change poses for people’s health, well-being, and recovery from disasters.

Sometimes these risk categories will diverge, as they do for wealthy people who live on the coast of Florida. Although their location places them at higher risk, their wealth offers some protection – insurance, connections, second homes, and so on. However, sometimes these risk categories will converge, as they do for agricultural workers in coastal areas of Bangladesh. One feature of these categories bears especially on justice: people are simply born at a certain time, in a certain place, in a kind of society, and into a social position. By saying this, I do not mean to deny that people can exert some control of some factors and that some forms of individual responsibility make sense. But I do mean to focus attention on the background conditions and social structures that shape the ethical problem, and on the need to change these conditions and structures. I will return in the next section to the relationship between social responsibility and individual responsibility.

Contributions to climate change also bear on judgments of justice. Many people who are at high risk from the effects of climate change have contributed relatively little to the problem. Per capita emissions in the United States are 60 times as high as in Bangladesh. Although national per capita averages are important and bear on issues of justice, especially justice between countries, they tend to obscure the differences within countries. In every country, wealthy people tend to have higher carbon footprints. Putting aside governmental investment in infrastructure, the wealthiest 11% of the world’s population is responsible for about 50% of all carbon emissions, while the poorest 50% is responsible for only 10% (19). Yet the wealthiest people face fewer risks because of their wealth, power, and social positions.

Opportunities for meaningful participation also bear on judgments of justice. Ideals of social democracy emphasize the need to empower and encourage the participation of people who are affected by policies and practices (20). Fostering meaningful participation respects the dignity of people, gathers insights from people who are differently situated, and increases the effectiveness of plans to bring about change. As philosophers from Jean-Jacques Rousseau to Elizabeth Anderson have emphasized, forms of respect and participation can be as important as the distribution of risks and wealth (21,22).

It seems unjust that people have not been empowered and encouraged to deliberate, in meaningful ways, about changing structures and practices that so profoundly affect their lives. And it seems unjust that people who have very low emissions face very high risks from climate change, while people who have contributed to and benefitted from high emissions face much lower risks. At least, these are my considered judgments of justice. I am not going to try to derive these judgments from an abstract theory of justice. Among people who have studied and reflected on climate change, there is more agreement on these judgments than on abstract theories (23). This situation is familiar in clinical bioethics: even when people disagree about abstract ethical theories and principles, they often agree on particular judgments and actions (24).

I believe that the idea of justice is a helpful conceptual tool to address climate change. The idea helps us to survey existing conditions, attend to salient features, identify particular problems, and consider relevant responses. However, using an idea or concept like justice is more than looking through a lens. Ethical concepts and perspectives often depend on historical development, social context, people’s past experience, the development of habits, etc. Furthermore, the existence of multiple concepts and perspectives “does not mean that all approaches are equally valid nor that all proposed solutions are morally acceptable; it is just that we cannot always predict in advance which formulations are going to be the most morally instructive” (25, p.204).

My emphasis on justice contrasts with Potter’s approach. In his approach to environmental problems, he does not develop and emphasize the concept of justice. Indeed, he only uses the word “justice” five times in *Global Bioethics*. What he develops and emphasizes is the idea of survival, a word he uses 196 times. In focusing on survival, he draws on and interprets ideas from Aldo Leopold. After Leopold graduated from the school of forestry at Yale University, he took a job with the U.S. Forestry Service in Arizona and New Mexico. There he saw first-hand what can happen to the deer population. Government-sponsored programs and short-sighted prejudice worked to eliminate wolves. As a result, the deer population increased rapidly. The deer browsed whatever they could find and denuded mountains. Then the deer population crashed. Leopold reflects deeply on this

problem in his famous essay “Thinking Like a Mountain” (4). Potter extracts and interprets a lesson from the problem that Leopold saw: “Aldo Leopold saw that human survival depended on the maintenance of a healthy ecosystem and the control of human fertility – at a time when neither of these ideas was widely understood” (3, p.17).

Potter distinguishes five kinds of human survival: mere, miserable, irresponsible, idealistic, and acceptable. Mere survival of some of the human population is not what Potter has in mind. After all, some deer survived the population crash brought on by over-browsing in Arizona and New Mexico. Neither is miserable survival a worthwhile goal. A life beset by malnutrition and preventable diseases is not what Potter has in mind when he talks of survival. Irresponsible survival is that path that we are on now: many people, groups, and societies in the present generation are surviving, but at the expense of future generations. On Potter’s list of kinds of survival, only idealistic survival and acceptable survival are options worth considering. Potter gives some reasons, which I do not find convincing, for rejecting idealistic survival. He says, “I shall not discuss *ideal* survival because that is something we shall never see and besides, each person has a private notion of what Utopia would be” (3, p.44-45, italics in original). But then he notes that people can and do agree on trying to eliminate preventable diseases, malnutrition, and starvation (3, p.45). Yet Potter rejects this approach because of its long-term consequences. He asks rhetorically, “Can any program that decreases infant mortality and thereby increases demands on the ecosystem, without concomitant educational measures that would protect the ecosystem and promote the idea of zero population growth, be anything but a disaster in the long run” (3, p.46)? We now have a better answer to his rhetorical question. Ethical forms of development can and have worked to reduce the burden of disease, improve education, and lower birth rates. When girls have been accorded rights, educational opportunities, and occupational choices, the birth rate has gone down dramatically. The state of Kerala in India is a good example.

After characterizing and rejecting the other forms of survival, Potter favours acceptable survival, but when it comes to characterizing acceptable survival, he says very little. In the chapter on “Human Survival” in *Global Bioethics*, he simply refers to Lester R. Brown’s work on sustainable societies (3, p.51-52). I will leave it to scholars of Potter to debate whether some basic view of justice is implicit in his idea of acceptable survival. The point I tried to make in this section is that we should use and emphasize the concept of justice in our response to climate change. In the next section, I will try to show how ideas about justice should shape our thinking about responsibility to address climate change.

RESPONSIBILITY[2]

Although Potter does not develop and emphasize the idea of justice, he has a lot to say about responsibility: he uses the word 66 times in *Global Bioethics*. In that book, he devotes a section to “A Bioethical Commitment for Person and Family Health” (3, p.159-161). The first seven points include responsibilities to avoid drug abuse, attend to diet and exercise, avoid sexually transmitted diseases, drive carefully, avoid unwanted and unintended pregnancies, avoid exposure to harmful chemicals and radiation, and seek timely medical advice. These seven points tend to focus on individual actions and responsibilities, but the eighth point brings in a social dimension. Potter states this responsibility as follows: “I will support local and national government officials and private organizations who provide responsible policies and decisions that facilitate the above individual actions by means of education, economic justice, environmental protections, and public health measures” (3, p.160). This responsibility even includes mention of economic justice. In “A Bioethical Creed for Individuals,” which is printed in both his books on bioethics, he formulates seven beliefs with corresponding commitments. In this creed, he starts with a social dimension of responsibility. The first commitment states, “I will work with others … to seek a worldwide movement that will make possible the survival and improved development of the human species in harmony with the natural environment and fellow humans” (3, p.193). Here, some social dimensions and background conditions are explicit. However, the other beliefs and commitments tend to focus on individual actions and responsibilities. The seventh belief states, “I believe that each adult person has a personal responsibility for his or her own health as well as a responsibility for the development of this aspect of personhood in any offspring that may be produced” (3, p.195). The corresponding commitment, states, “I will endeavor to carry out the eight obligations described as a Bioethical Commitment for Person and Family Health. I will limit my own reproductive powers in accordance with national and international goals” (3, p.195).

I want to comment on three features of Potter’s discussion of responsibility. My purpose is more practical than scholarly: to begin to articulate a conception of responsibility that would help us to respond to anthropogenic climate change. The first feature is the aim or point of the responsibilities that Potter discusses. These responsibilities aim to contribute to the future survival and the improved life of human beings. Because Potter believes that continued population growth endangers the survival of human beings, he places great emphasis on controlling fertility. Although he recognizes some social dimensions and the role that education might have, his emphasis is on personal and familial responsibility.

The second feature concerns the ground of these responsibilities. I believe Potter grounds these responsibilities in humanitarian concerns and natural duties to reduce avoidable suffering, foster good lives, and allow civilization to develop. He often groups these concerns and duties under the term “acceptable survival.” I do not doubt that natural duties are part of the picture. I recognize the need for humanitarian responsibility – for a sense of duty to assist other human beings simply because we are human beings in a position to help – but this form of responsibility is incomplete. It needs to be complemented with a conception of the responsibility to address injustice.

[2] Some ideas in the middle part of this section are drawn from previous work (16).

The third feature that strikes me is that Potter's account does not emphasize a responsibility to address injustice. There is a difference between our responsibility to respond to naturally occurring harmful events and our responsibility to respond to injustice, especially injustice that we have contributed to or benefitted from.

Before her untimely death, Iris Marion Young was working on a book that became *Responsibility for Justice* (26). This book could have been entitled *Responsibility for Structural Injustice* because it focuses on people's responsibility to address and try to change structural injustice. Structural injustice is not brought about by a particular person's actions or vices. Nor is it brought about by a particular governmental policy. Structural injustice is brought about when social practices and processes work to unfairly threaten, dominate, and deprive some groups. In her book, Young uses the example of practices and processes that work to deprive some people of housing and make them vulnerable to homelessness (26). In the article from which the book developed, she uses the example of practices and processes in the global apparel industry (27).

My purpose here is to extend Young's insight and reasoning to climate injustice. Because much of the injustice of climate change results from practices and processes that cannot be traced to particular people and policies, I want to use Young's account to discuss people's responsibility, including my own, to address and try to change social practices and processes. I shall sketch her account as I use it to address four important questions about taking responsibility for climate change.

1. What should I (and people who are situated like me) take responsibility for?

Some of the injustice of climate change is due to individual actions that are intentionally harmful or reckless. The actions of executives at Exxon come to mind. Some of the injustice of climate change is due to explicit government policies. The corporate tax codes in the USA that favor oil extraction come to mind. But I want to suggest that much of the injustice of climate change is due to social structures, background conditions, economic systems, political processes, and accepted practices. It is due to human constructs that I sometimes refer to as social structures.

When Young reflects on justice, she follows John Rawls in focusing attention on social institutions rather than individual actions, but she also notes problems with his account of basic institutions (26). So, she develops a more nuanced and contextual account of social institutions and processes:

> Depending on the issue, the structural processes that tend to produce injustice for many people do not necessarily refer to a small set of institutions, and they do not exclude everyday habits and chosen actions. Social structures are not a part of the society; instead they involve, or become visible in, a certain *way of looking* at the whole society, one that sees patterns in relations among people and the positions they occupy relative to one another. (26, p.70, italics in original)

I tried to look at climate change in this way and to make visible some of the unjust relations among people. Social structures encourage activities that emit greenhouse gases, and thereby change the probability of heat waves, flooding, droughts, vector-borne diseases, loss of livelihood, migration, and much more (28). Rarely can we trace a clear causal link between a particular action or policy and some individual's harm, but social constructs change the probability of harm, and they position certain people and groups in ways that place them at greater risk of harm. This is what I and other people need to take responsibility for: social structures that unfairly contribute to climate change and place people at risk.

2. Why should I (and people who are situated like me) take responsibility?

As I go about my life, I participate in, reinforce, and reproduce social structures that increase climate change and position other people unfairly. By relying on these social structures in the background, I do not intend to harm anyone. Nevertheless, my involvement grounds my responsibility to work to change these constructs. Young writes:

> The ground of my responsibility lies in the fact that I participate in the structural processes that have unjust outcomes. These processes are ongoing and ought to be transformed so they are less unjust. Thus I share with others the responsibility to transform these processes to reduce and eliminate the injustice that they cause. My responsibility is essentially shared with others because the harms are produced by many of us acting together within accepted institutions and practices, and because it is not possible for any of us to identify just what in our own actions results in which aspects of the injustice that particular individuals suffer (26, p.110).

This responsibility is not grounded in or explicated by humanitarian concerns and natural duties – it is grounded in how I, and millions of other people, are related to the constructs that frame and shape climate change. Because of the way I am related to the social structures that create risks and position people, I have a shared responsibility to change those structures that unfairly disadvantage people, including people in distant places and future generations.

3. How should I (and people situated like me) take responsibility?

Because I and many other people are implicated in unjust social structures, we share some responsibility to change them. With respect to climate change, we need to change social structures so as to reduce greenhouse gas emissions and build resilience, especially for people and communities who are most affected. Appropriate actions may include capping emissions,

instituting carbon taxes, creating new forms of economic life, reducing the influence of money in politics, changing energy generation, reconstructing infrastructure, changing agricultural practices, creating insurance schemes for people at risk, developing more responsive public health systems, fostering more responsive networks of neighbors, reconceiving good lives, and so on. Changes like these require political action, in the best and broadest sense of that term.

Young views political action as "public communicative engagement with others for the sake of organizing our relationships and coordinating our actions" more justly (22, p.112). This form of engagement takes place in public spaces – indeed, it sometimes needs to defend or create public spaces. It relies on different ways to communicate meaning: conversations, written materials, arguments, plays, humor, photographs, protests, strikes, etc. We should not try to limit in advance the modes that this communication will use. Political action includes not only action that tries to change policies and programs, but also actions that citizens take in civil society. Young notes that those "who share responsibility for structural injustice may also find ways of making social changes … through collective action in civil society independent of or as a supplement to state policies and programs" (26, p 112).

Since governments are often protected by autocrats, vested interests, and dominant parties, civil society is sometimes the better or only place to begin. I have often thought that many of us have a lot to learn from dissidents in Central Europe who emphasized the role of civil society (29). Action in civil society also allows and encourages building networks that span international borders, just as the effects of climate change do. In discussing how to respond to structural injustice, Young emphasizes the need for political action, but I sometimes wonder whether a life with this emphasis is a good life. Thinkers like Aristotle and Rousseau see political engagement and citizenship as deep expressions of our nature. Rousseau esteems and idealizes the role of citizens in cities like Geneva, and he sees political engagement as "the privileged *locus* of the good life" (30, p.334). That's not my view, and I do not think it is Young's view.

In Young's view, political engagement aims to change aspects of relationships by changing how social structures position people with respect to one another. This broader view of politics comports with a view of human beings as relational; it recognizes our enmeshment in webs of relationships and how social structures shape those relationships. Political action is an attempt to adjust relationships, including relationships in civil society. However, successful attempts require a lot of awareness, skill, and work – there is no getting around that. The hope is that many people will find this awareness, skill, and work to be important aspects of a good life.

Although the response to structural injustice often finds expression in collective action, the responsibility is individual. Too often individual and social responsibility are opposed in some simplistic way: emphasis on one is taken to reduce the other in some mathematical way. Part of the merit of Young's work is to reconceptualize the relationship between individual and social responsibility. A good part of the responsibility for climate change arises when individual people are structurally situated, have the capacity to communicate, and can act politically to try to bring about social change. However, the task is enormous – to generate political will to address injustices that are built into social forms of life. This daunting task leads to the next question.

4. How much responsibility should I (and people who are situated like me) take?

I do not have an exact answer to this question, but I want to mention three factors that seem morally salient. How much responsibility I should take depends on how serious is the problem. I believe that climate change is the most serious public health problem in this century. It exacerbates injustice. It threatens the lives and well-being of billions of people. It endangers the cultures and civilizations that groups have constructed together over time. The more serious the problem, the more responsibility I should take.

How much responsibility I should take also depends on my relationship to the social structures. The more privileged I am by the unjust structures that shape climate change, the more responsibility I should take. Many high-income countries and people have profited from and depend on high levels of greenhouse gas emissions. Although I am an ordinary person who tries to live a modest life, when I examine my own situation, I see that I am relatively privileged by the social structures and background conditions of the carbon-intensive society in which I live. Like many people in this society, I ride in automobiles, fly in airplanes, use a computer, take hot showers, and do many other things that depend on fossil fuels (31). At least in the current context, these and other activities have unsustainable carbon footprints that disadvantage other people, nonhuman animals, and plants. The amount of responsibility that I should take may also depend on the nature of the unjust structures. There may be important distinctions between some of the factors that place people at risk. Other things being equal, social structures that privilege race, for example, seem even worse than factors that privilege geographic location. In the United States, Black people face a higher risk of permanent displacement from hurricanes than white people (32). Part of the differential risk may be due to wealth, but existing distributions of wealth are shaped by past practices of discrimination and exclusion. Even if we cannot neatly separate different factors, the general point seems sound – the moral nature of the privilege is relevant to how much responsibility I should take. However, the general point seems to suggest that we must change many things at once: greenhouse gas emissions, economic inequality, racial exclusion, and much more. I will return to the implications of this point in the next section.

I extended Young's account of responsibility for structural injustice to climate change because I think her account illuminates people's responsibility to address that problem. Of course, I do not mean to contend that her account is the only account of responsibility that can help to guide responses to the problem. I'll briefly compare and contrast her account with one other

account of responsibility to address climate change. In “It’s Not *My* Fault: Global Warming and Individual Moral Obligations,” Walter Sinnott-Armstrong takes up issues about responsibility and climate change (23).

In his essay, Sinnott-Armstrong focuses on a particular question: whether a person has a responsibility not to go out for a Sunday drive, just for fun, in a gas-guzzling car. After reviewing key features of causation and responsibility, he comes to the conclusion that there is no such responsibility. In many legal and everyday contexts, we only pick out an act as a cause if that act is intentional (or grossly negligent), stands out from the usual background conditions, and can be linked clearly to a particular harm. For example, a person striking a match may count as a cause of a house fire, but the presence of oxygen would not. With these features in mind, Sinnott-Armstrong claims that “we should not hold people responsible for harms by calling their acts causes when their acts are not at all unusual, assuming that they did not intend the harm” (23, p.335). He adds, “No storms or floods or droughts or heat waves can be traced to my individual act of driving” (23, p.336).

Young herself notes that the liability model of responsibility does not work very well when the conditions and structures are accepted as the background, the acts are not intentionally harmful, and it is difficult to link acts to particular harms (26). So, she develops a model of political responsibility for structural injustice as a complement to the liability model. Even when my individual act cannot be linked to a particular harm, I should take some responsibility for changing unjust social structures if I participate in and help to reproduce these structures.

In an indirect way, Sinnott-Armstrong comes to agree that a political conception of responsibility is more fitting and appropriate in the context of climate change. Toward the end of his essay, he writes, “My fundamental point has been that global warming is such a large problem that it is not individuals who cause it or need to fix it. Instead, governments need to fix it, and quickly” (23, p.343-344). Rather than focusing on individual acts like driving, he suggests we focus on “our real moral obligations, which are to get governments to do their job to prevent the disaster of excessive global warming” (23, p.344). Although this shift to political responsibility is promising, Young’s account focuses attention in a more helpful way. Sinnott-Armstrong simply asserts that we have an obligation to get governments to change course, but Young’s account helps to explain why many of us, depending on how we are situated, come to have and share responsibility to address climate change. Sinnott-Armstrong focuses on government responses, but Young emphasizes social structures, which include more than government policies and responses. Sinnott-Armstrong focuses on political action aimed at getting governments to take action, but Young has a broader view of political engagement, a view that includes engagement in civil society. When governments are unresponsive, political engagement may need to focus on civil society and build political will.

NEW ISSUES

To address the issue of climate change, I developed and emphasized ideas about justice and responsibility for injustice. However, these ideas and perspectives raise new issues and problems – that’s probably a good thing. At their best, new approaches in science, philosophy, and social life solve or dissolve some old problems, but they also raise new issues (33). In this section, I sketch briefly two issues that my approach raises. I do not have the time and insight needed to offer definitive solutions, but I want to describe them in a way that encourages other people to help address them.

The first issue concerns the need for selection in ethical life. Towards the end of his life, John Rawls (1921-2002) wrote an account of international justice (34). Because he did not want to presuppose traditional views about the sovereignty of nation-states, he referred to his work as the Law of Peoples. In this passage, he makes explicit the ideas that motivate this work:

> Two main ideas motivate the Law of Peoples. One is that the great evils of human history – unjust war and oppression, religious persecution and the denial of liberty of conscience, starvation and poverty, not to mention genocide and mass murder – follow from political injustice... The other main idea, obviously connected with the first, is that, once the gravest forms of political injustice are eliminated by following just (or at least decent) social policies and establishing just (or at least decent) basic institutions, these great evils will eventually disappear. (34, p.6-7)

With this motivation, Rawls tries to specify a conception of justice that will address these great evils. My purpose here is not to defend or criticize his conception, but to note the large number of serious injustices that we face. When we look at the world from a perspective of justice, we see many patterns of relations that we judge unjust.

To the list of injustices that destroy lives, we now need to add anthropogenic climate change. We also need to make visible the social-structural processes. Furthermore, we need to address connections between what seem at first to be disparate problems. For example, I already noted how climate change places racial groups and indigenous peoples at greater risk. So, we have a long list of serious injustices and complex connections between these injustices. To adequately address the risks of climate change, we must address greenhouse gas emissions, economic inequalities, systematic racism, legacies of colonialism, the role of money in politics, and other issues. These connections raise conceptual, ethical, and strategic questions about whether we should isolate or integrate our responses, but I want to focus on a narrower question: Are we, or at least people who are situated like I am, to take responsibility for addressing all these structural injustices and the connections between them?

I see three possibilities. The first possibility is the heroic response. We could claim that yes, all of us who are implicated in relevant social structures need to take responsibility to address all the serious injustices. I am not sure this would be ethically sound and practically effective. The second possibility is the opposite – to deny that involvement in social structures brings with it any responsibility to address social injustices. This seems ethically unsound and practically disastrous. The third possibility is to accept that ethical life needs to involve selection and emphasis. If we accept this possibility, we will need more discussion of guidelines for selection and better habits to counter the tendency to excuse ourselves from responding.

The second new issue concerns ethical relationships to the rest of nature. Young examines with great care and insight how humans are related, through social structures, to other humans, and she considers how to adjust those relationships. However, we can and should raise questions about our relationship to the rest of nature. Aldo Leopold does exactly that in his famous essay on “The Land Ethic” (4). By land, Leopold means much more than dirt and soil. He writes, “The land ethic simply enlarges the boundaries of the community to include soils, water, plants, and animals, or collectively: the land” (4, p.204). The land includes the whole biotic community that has developed on this earth system. Leopold tries to shift the relationship of humans “from conqueror of the land-community to plain member and citizen of it” (4, p.204). This new relationship requires humility and natural piety – a recognition of our dependence on a much larger community. Leopold’s essay – indeed, his whole book – culminates in his guideline: “A thing is right when it tends to preserve the integrity, stability, and beauty of the biotic community. It is wrong when it tends otherwise” (4, p.225-226). This guideline includes an aesthetic aspect and depends on an emotional response because Leopold does not believe “that an ethical relationship to land can exist without love, respect, and admiration for land” (4, p.223). A study of ecology should help to inform these attitudes, and the attitudes should help to inform our perceptions and actions.

I take it for granted that we can and should examine our relationship to the rest of nature. The issue that I am unsure about is how our relationship to nature connects to justice. Two views come to mind. The first view is that ideas of right and wrong are much broader and more encompassing than justice and injustice. Justice concerns relationships and harms to other people. It is related to fairness, forms of equality, recognition of dignity, and more. Reactions to injustice include resentment, indignation, forms of protest, etc. We can commit and react to injustice to future generations, but these are generations of human beings. In this view, we can ethically mistreat nonhuman members of the biotic community in many ways, but this mistreatment is strictly speaking not injustice. Injustice is narrower than mistreatment, and ethically appropriate treatment is broader than justice. Many ethical dispositions and attitudes extend beyond justice: compassion for non-human animals, gratitude for the earth system that provides a home, and reverence for the complexity, diversity, and workings of the biotic community.

The second view is that justice should extend beyond our relationships to other people, present and future. The evidence is mounting that primates, elephants, and other mammals have a moral sense (35). Mistreatment of these mammals involves not only cruelty, but injustice. Failure to try to understand and communicate with non-human animals is not only narrow behaviour, but a failure of respect that should count as injustice. Furthermore, the way we dominate, deprive, or even eliminate other species should count as injustice. In this view, as we expand our ethical relationships, we should also expand our view of justice.

I do not have enough time and insight to sort out these two views. Instead, I am beginning to think about a more limited question: do these two views overlap enough to support political action to address climate change? I think they do, but I recognize that I need help in addressing the underlying issues.

CONCLUSION

When Van Rensselaer Potter coined the English term “bioethics”, he conceived a field that would bring together biological understanding and ethical values to address global environmental problems. Following Potter’s broad vision of bioethics, I discussed ethical ideas that we need to address climate change. However, I developed and emphasized ideas about justice and responsibility in ways that Potter did not. In particular, I emphasized the need to take political responsibility for the structural injustices of climate change.

My emphasis on political responsibility brings us closer to the problem of social change – closer but not quite far enough. To change how we inhabit the world, we really need more and better ecological citizens. Ecological citizens would bring together ecological understanding and a deep sense of justice, and they would find effective ways to communicate that understanding and sense to their fellow citizens. However, ecological citizens face many obstacles. I’ll mention two that worry me. In our current world, the work of ecological citizens is dangerous. The NGO Global Witness documented that about three environmental defenders were murdered every week in 2018 (36). Many of the murdered activists were indigenous people, defending land and communities from extractive industries, agribusiness, logging, and dams. So, the first obstacle to address is the need to make the world safer for ecological citizens. The second obstacle is more abstract. Influenced by Young’s work (26,37), I think of politics as public engagement that tries to communicate to different people the need to organize our collective life more justly. I realize that this way of thinking about political engagement is somewhat distant from the actual practice of politics. So, the second obstacle to address is the need to change the dominant vision and practice of politics. Climate change shows how enormous the task is, and how short is the time that we have before us.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

À la recherche du chaînon manquant entre *bio* et *éthique*

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Résumé
Van Rensselaer Potter (1911-2001), le biologiste à l'origine du terme « bioéthique » dans les écrits nord-américains, considère que « real bioethics falls in the context of the ideals of […] Aldo Leopold », un forestier, philosophe et poète ayant marqué le XXe siècle. Associer Leopold à Potter a pour effet de placer la bioéthique dans la famille des éthiques de l'environnement, ce qui la différencie du sens conventionnel retenu en médecine et en recherche depuis le Rapport Belmont (1979), une déclaration ayant propulsé l'institutionnalisation de la bioéthique en Amérique du Nord. Cependant, diviser la bioéthique entre le médical et l'environnemental est réducteur. Potter propose au contraire une bioéthique globale s'intéressant aux enjeux situés à leur interface, dont ceux concernant la terre, la vie sauvage, la surpopulation, la consommation, etc. Cet article vise à amorcer un nouveau chantier d'analyse de la pensée de Potter en s'appuyant sur l'héritage de Leopold en biologie. Une synthèse de cette vision potterienne est proposée de manière à considérer son œuvre comme un tout cohérent s'intégrant aux grands débats qui transcendent les XXe et XXIe siècles. Sa vision apparaît comme une sagesse collective et prospective sous la forme d'une science de la survie et d'un code de bioéthique. Dépassant l'éthique de l'environnement, son association avec Leopold offre un modèle de la complexité s'imposant comme cas indissociable du contexte qui l'englobe, en améliorant nos façons d'intervenir en pratique dans un monde en constante transformation, à titre de gouvernance adaptative et de sagesse de la responsabilité.

Mots-clés
Van Rensselaer Potter, Aldo Leopold, bioéthique globale, éthique environnementale, biologie

Abstract
Van Rensselaer Potter (1911-2001), the biologist who coined the term "bioethics" in North American scholarship, considers that "real bioethics falls in the context of the ideals of [...] Aldo Leopold", a forester, philosopher and poet who marked the 20th century. Associating Leopold with Potter has the effect of placing bioethics in the family of environmental ethics, which differentiates it from the conventional sense held in medicine and research since the Belmont Report (1979), a declaration that has driven the institutionalization of bioethics in North America. However, dividing bioethics into the "medical" and "environmental" is reductionist. Instead, Potter coins the idea of a global bioethics that addresses issues at their interface, including "land, wildlife, overpopulation, consumption, etc." This article aims to start a new analysis of Potter's thinking, drawing on the legacy of Aldo Leopold in biology. A synthesis of this Potterian vision is proposed to consider his work as a coherent whole that integrates into the great debates that transcend 20th and 21st centuries. This Potterian vision appears as a collective and prospective wisdom in the form of a science of survival and Bioethical creed. Going beyond environmental ethics, this association with Leopold offers a model of complexity that is indistinguishable from the context in which it is embedded, improving the ways in which we intervene in practice in an ever-changing world through an adaptive governance and the wisdom of responsibility.

Keywords
Van Rensselaer Potter, Aldo Leopold, global bioethics, environmental ethics, biology

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INTRODUCTION

Van Rensselaer Potter (1911-2001) est à l'origine du terme « bioéthique » dans les écrits nord-américains (1-3)[1]. Cinquante ans après la parution, en 1971, de *Bioethics: Bridge to the Future* (5), il est pertinent de relire cette œuvre en se référant aux auteurs lui ayant inspiré ce terme. D'ailleurs, pourquoi avoir joint le « bio » à l'éthique? Quelle est la critique faite à l'éthique classique (sans le *bio*)? Selon Potter, elle est insuffisamment « Biological » (6), trop « Fragmented » (7) et n'est pas « Real Bioethics » (8,9). Les éthiques doivent devenir prospectives en reconnaissant davantage la complexité du monde, le « bios » (5). Son mode opératoire doit devenir « global » de manière à transcender la sphère des idées et des pratiques (11). Par « Global Bioethics »[2] (11-15), Potter critique la réponse des éthiques centrées sur l'humain (humanistes ou anthropocentristes) aux défis contemporains des individus, des sociétés et de la planète (8,9). Seule la prudence, la précaution, voire la responsabilité, semblent avoir cette force englobante (11). Sans ce global, l'humanité navigue sans phare ni outils adéquats pour « agir dans ce monde incertain »[3], dont les caractéristiques sont en continuelle transformation (5). Dès lors, il n'existe pas « des bioéthiques », mais bien une seule (7,9). Il propose une bioéthique globale s'opérant par communauté vivante (biotique) et par le fonctionnement d'une « Science of Survival » (5,11) : une nouvelle branche des sciences devant se construire sur l'héritage d'Aldo Leopold (1887-1948).

[1] Le mot « bioéthique » (bioethik en allemande) est formulé par Fritz Jahr (1895-1953) en 1927, mais sous une autre signification (1,4)
[2] « Global » n'est pas une dimension spatiale « mondiale » (un anglicisme, dictionnaire Antidote, 2021, 6.0.9). Pour Potter, le « global » renvoie à une approche par communauté construite sur le legs de Leopold, voir *The Community Concept* (10, p.156).
[3] Une formulation empruntée à Callon et collègues dans *Agir dans un monde incertain: essai sur la démocratie technique* (16).

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Pour Potter, la solution ne se trouve pas dans une nouvelle discipline experte hors de la société. Elle se situe dans une bioéthique devenant un environnement intellectuel adéquat pour favoriser les coopérations au sein des communautés vivantes (7). Construisant sur la pensée de Leopold, Potter introduit une nouvelle perspective de « The Community Concept » (10)[4]. Puisque l'humain en est une partie prenante, la communauté comprend des ensembles collectifs intelligents : cette communauté devient alors un système *social-écologique* (17,18), voire une organisation globale unissant une bio-éthique (11). Ces êtres *vivides* doivent venir supporter le développement de pratiques soutenables (12) et s'enrichir de courants intellectuels, dont *Une seule santé* [5]. Cette nouvelle communauté cherche à réconcilier les positions anthropocentristes, biocentristes et écocentristes (19) afin de responsabiliser l'action humaine à l'égard de son environnement. Opérée par communauté, cette bio-éthique adopte un mode de fonctionnement analogue aux organisations vivantes (5) : « Bioethics, the Science of Survival ». Son fonctionnement doit intégrer les disciplines en un système des savoirs. Son organisation doit transcender la cloison séparant sciences et société (20). En 2017, certains auteurs ont proposé d'intituler cette science transdisciplinaire : « The ecosystem of bioethics » (21). La métaphore de l'écosystème donne à cette bio-éthique un mode de fonctionnement biologique pour une survie globale (5). On lui reconnaît alors une formule concentrique (par *matriochka* ou fractal) posant certains processus (micro) nichés dans d'autres les contextualisant (macro). L'objectif est l'adaptation humaine, voire sa résilience. Sans le nommer, Potter introduit l'idée d'une résilience sociale comme processus rendant possible la *survie* humaine[6], appuyer sur une conscience collective ayant la visée de responsabiliser l'action de chacun 22,23). Potter envisage un processus critique venant apprendre des crises à la manière d'une « cultural evolution » (20,24,25). Cet apprentissage prend la forme d'une « adaptive governance » rejoignant par ceci les travaux conduits par le groupe de recherche Resilience Alliance, initié par Crawford Holling (1930-2019) (26). La résilience devient le résultat de ce processus de gouvernance adaptative des organisations (26,27) et donne une piste pour opérer la vision potterienne de la bioéthique, notamment à la lumière de la philosophie des sciences par les ouvrages de Bryan Norton et de Thomas Kuhn (1922-1996)[7].

L'intention de cet article est de revisiter l'œuvre de Potter au regard de son contexte historique à partir d'ouvrages lui ayant été sources d'inspiration. L'article ressort les grandes critiques de Potter à l'égard des Sciences naturelles, sociales et humaines ainsi que des Éthiques et des Bioéthiques avisant ses lecteurs des limites d'une éthique reposant sur la *Nature* (une bio-éthique). Ainsi contextualisé, l'objectif est de souligner les rapprochements entre la vision pottérienne de la bioéthique et plusieurs controverses étant toujours d'actualité, notamment à propos de l'opération de la résilience des sociétés humaines par les approches de développement durable et la reconnaissance des systèmes social-écologiques. La question se décline ainsi : doit-on prioriser, intégrer ou réinventer un nouveau concept pour *santé* et *biodiversité*? Si la réponse est d'intégrer, comment opérer une bonne intégration de ces deux valeurs? Comment éviter un « réductionnisme disciplinaire » comme l'explique Daniel Callahan (1930-2019) (28)? Et, comme poursuivi par Potter, qui a la responsabilité d'opérer ce pont interdisciplinaire? Est-ce la science ou la société?[8] L'article vise aussi à amorcer un nouveau chantier d'analyse de la pensée de Potter par l'étude du legs intellectuel de deux auteurs incontournables à l'interprétation du livre *Bioethics: Bridge to the Future* (1971). Ces auteurs marquants sont Leopold, un forestier à qui Potter consacre une dédicace (5) et le titre d'un livre (11) référant à « The Land Ethic » (10), puis Kuhn, un physicien de formation, dont la philosophie des sciences a inspiré à Potter la structure des révolutions (29) en bioéthique à la manière d'une science adaptative (6). Ceci amènera à synthétiser l'œuvre de Potter en un cadre reposant sur trois composantes : l'objet d'étude d'une *Science de la survie* (6), la matière évolutive d'un *Code de bioéthique* (Bioethical creed) (22) et l'organisation d'une *Bioéthique globale* (11).

UNE BIOÉTHIQUE COMMUNAUTAIRE PLUTÔT QU'HUMANISTE OU ENVIRONNEMENTALISTE

La bioéthique s'est institutionnalisée aux États-Unis à partir de 1970 (30) autour du Hastings Center (Garrison, NY) et du Kennedy Institute of Ethics à l'Université de Georgetown (Washington, DC). Fondé en 1969, le Hastings Center avait déjà plusieurs ressources pour promouvoir la bioéthique dans le contexte de la santé (31). La bioéthique est ainsi apparue en Amérique du Nord comme une éthique de la vie, du vivant, voire de la biologie (32). Elle s'est, dès lors, liée aux éthiques appliquées à la pratique médicale, aux sciences de la vie et aux politiques de santé (cliniques et publiques). Dans l'Encyclopaedia Britannica, Ruth Chadwick définit cette vision ainsi :

[4] Leopold débute *The Land Ethics* (10) par *The Ethical Sequence* et *The Community Concept* donnant lieu à *The Ecological Conscience* en soulignant « All ethics so far evolved rest upon a single premise: that the individual is a member of a community of interdependent parts. His instincts prompt him to compete for his place in that community, but his ethics prompt him also to co-operate (perhaps in order that there may be a place to compete for). The land ethic simply enlarges the boundaries of the community to include soils, waters, plants, and animals or collectively: the land. » (10, p.156-57). Potter consacre sa dédicace de son œuvre marquante de 1971 en terminant par les mots suivants de Leopold : « Ethics are possibly a kind of community instinct in-the-making » (5).

[5] Une Seule santé est une nouvelle perspective issue de la médecine (voir: One Health, One Medicine) visant à améliorer la pratique clinique par la convergence des sciences de la santé humaine, animale, végétale et environnementale, voire en réconciliant les savoirs provenant de la médecine, des technologies et de l'écologie (17,18,19). L'association de la pensée de Potter à Une seule santé est fréquente, mais posthume (17,20,21).

[6] À comprendre comme *sur-vie* à la manière d'une amélioration de la vie humaine (5).

[7] Potter ni Leopold ne mentionnent « résilience » dans leur œuvre. Cependant, Potter adopte la perspective que les sciences avancent. Donc, les « mots » utilisés en 1971 par l'un (5) ou 1949 (10) par l'autre doivent progresser. Suivant cette logique, Norton, en 2005, explique la technique d'aménagement adaptatif des écosystèmes initié par Leopold, puis poursuit par Holling et plusieurs autres ayant introduit l'idée d'une « résilience écologique », voire d'une dynamique de résilience caractérisant le fonctionnement de toute organisation complexe (26,27). Enracinée dans le pragmatisme (Dewey et Pierce), Norton explique la philosophie de Leopold à la lumière de plusieurs philosophes des sciences, dont Kuhn, un auteur ayant une place prépondérante dans la pensée de Potter en 1970-1971 (5,6).

[8] Potter marque cette interrogation en 1964 : « Can science aid in the search for sophistication in dealing with order and disorder in human affairs? How can science contribute to the betterment of the human condition? » (20)

> Bioethics [is a] branch of applied ethics that studies the philosophical, social, and legal issues arising in medicine and the life sciences […] concerned with human life and well-being, though it sometimes also treats ethical questions relating to the nonhuman biological environment. (33, p.1)

La bioéthique s'est aussi liée aux éthiques des professions en environnement, aux Sciences de la Terre et aux politiques d'aménagement du territoire (21,34,35). D'ailleurs, Potter (9) critique le Hasting Center pour leur vision réductionniste de la bioéthique. Toujours selon Potter, le Hasting Center, notamment par les travaux de Callahan et Paul Ramsey (1913-1988), a développé progressivement la bioéthique autour de cas spécifiques : les technologies médicales et les sciences de la vie (ici, humaine). Rappelons que les grandes tensions éthiques du XIX[e] sont survenues en médecine autour des recherches biologiques. La possibilité d'améliorer la condition humaine a conduit cependant à des dérives notables soulignées par le Code de Nuremberg (1946-1947) et le Rapport Belmont (1979). Cette nouvelle condition de vie est, toutefois, devenue la source d'enjeux encore plus alarmants – l'avenir est-il toujours *vivable* (pour traduire les concepts employés par Potter et Peter Whitehouse : « lifeable » (14) et « vivid » (36)? Les souffrances, les vulnérabilités et la survie de l'humanité s'aggraveront-elles jusqu'à « Getting to the Year 3000 » (15,36)[9]? Ainsi, l'avenir ne doit pas être envisagé au travers des lentilles de la médecine ou de la santé, ni de celles de la recherche ou des technologies, ni encore de celles de l'écologie ou de l'environnement, mais bien par une multitude de lentilles provenant de la communauté.

Chaffee (35) signale que la majorité des manuels de référence en bioéthique font transparaître la perspective de Georgetown développée dans l'étroit « field of medicine and health care » (31). Considérons cette prise de conscience critique (voire cynique) d'un réductionnisme volontaire, « Bioethicist David Resnik calls abortion, euthanasia, informed consent, privacy, reproductive health, and access to care the "bread and butter" bioethics topics » (35). À plusieurs moments dans son œuvre, Potter différencie sa vision de celle du Hasting Center (8,9) : « From any point of view, real bioethics falls in the context of the ideals of two Wisconsin professors who lived in the early part of the twentieth century, Aldo Leopold and Max Otto » (8). La mise à l'œuvre d'une *bioéthique véritable* (8) comprendrait une communauté extensive d'êtres, de choses, voire d'idées, incarnée par un collectif d'êtres responsables d'étudier cette organisation vivante : les professions scientifiques (incarnées par Leopold) et les sciences humaines académiques (incarnées par Otto).

La bioéthique potterienne n'est pas centrée sur l'humain. Par la figure de Leopold, Potter souligne qu'elle doit aussi se centrer autour des forêts et, plus encore, autour de ce qui nous « environne » (11). La bioéthique ne vise pas à améliorer la condition humaine *per se*, mais envisage une conduite humaine responsable, riche d'une conscience collective. Par exemple, l'aide médicale à mourir, le service de diagnostic génétique, les technologies de contraception, etc., doivent être contextualisées dans les savoirs environnementaux pour responsabiliser les conduites humaines (37), ex. : la consommation, la pollution, la reproduction, etc. (11). Cependant, une controverse demeure encore aujourd'hui autour du « bio » de Potter, à savoir jusqu'où va sa critique – comment délimiter ce pont nécessaire entre la société et la forêt? Comment bien balancer ces deux pôles que sont la santé et l'environnement, les professions et la théorisation? Comment négocier les valeurs sous-jacentes renvoyant à de profondes positions éthiques comme l'anthropocentrisme, le biocentrisme ou l'écocentrisme (19,21,24,34,35,38,39)?

LES GRANDES CRITIQUES DE VAN RENSSELAER POTTER

Potter est un biologiste de formation, spécialisé en évolution et qui s'est intéressé à la biochimie, puis à ses applications en médecine comme professeur d'oncologie à l'Université du Wisconsin (3). En posant les sciences fondamentales, dont la biologie de l'évolution, en relation avec les pratiques, dont les techniques en oncologie, il devient plus facile de comprendre l'œuvre de Potter proposant plusieurs analogies entre le modèle théorique de l'évolution, le monde technique de la médecine et la perspective d'une éthique des sciences en biologie.

Critique 1 : Les sciences humaines doivent outiller des pratiques

Entre 1964 et 1971, Potter critique le rôle de la science en société, puis du pouvoir de l'éthique sur la science (5,20). Enfin, sa réflexion aboutit à une critique générale soulignant l'incapacité des sciences humaines, de l'éthique et des sciences fondamentales à responsabiliser les communautés humaines à l'égard de leurs actions (5). Deux possibilités sont détaillées dans l'œuvre de Potter : celle d'un *recadrage* et celle d'une *redirection* de la trajectoire de développement des sociétés.

D'abord, les sciences humaines doivent *recadrer* les idées à mesure que les disciplines se transforment pour éviter le réductionnisme disciplinaire. En réduisant la valeur d'une discipline, l'analyse qui en découle est dès lors déphasée des connaissances acquises sur le réel, ce qui affecte l'exactitude des actions en pratique[10]. L'oxymore, une figure de style introduit par John Law en sociologie des sciences (40), permet d'analyser cette critique de Potter. Un oxymore assemble deux mots en apparence contradictoire. Sans dialectique entre eux, l'action manque de profondeur, car l'attention leur étant apportée tend à se déséquilibrer vers l'une plutôt que l'autre, perdant ainsi la vision d'ensemble. Une réponse déséquilibrée à un oxymore est source de tensions éthiques. Par exemple, la globalité est un oxymore lorsque définie par les termes de l'holisme : un *tout* valant plus que la somme de ses *parties*. Sous le cadre de la complexité, la globalité introduit un pont (le système) connectant les parties au tout. Sous cet angle, les individus (*parties*) et les communautés (*Tout*) ainsi que les personnes

[9] Potter fait un clin d'œil aux *Objectifs du Millénaire* signés à New York (8 septembre 2000) avant son décès (36). Ces *Objectifs* pré-visionnaient des jalons pour 2015, voire un développement à court terme pour le millénaire à venir. Pour articuler une vision acceptable de changement, Potter propose de pré-visionner déjà l'horizon à « long terme » (l'an 3000) (12,14,15).
[10] Callahan encapsulera l'idée, en 1973, sous la formule du « disciplinary reductionism » (28).

(*responsabilité individuelle*) et les collectifs (*responsabilité sociale*) s'assemblent en des organisations ayant le pouvoir de s'adapter (41). Pour concevoir une intervention globale, on comprend que des actions doivent être posées par des personnes conscientes et critiques, non pas par la figure abstraite des collectifs sociaux. Par exemple, ces personnes agissent de manière distribuée : par un soin respectueux accordé au patient en clinique (ex. : une éthique du soin). Ces personnes doivent aussi s'unir et dépasser la relation une-à-une en agissant ensemble via des politiques applicables à tous (ex. : une éthique collective passant par les politiques publiques, le droit, la science, les technologies, etc.). Posés en dialectique, soins et politiques habilitent (*empowerment*), ce qui pose les conditions propices à une justice pour les personnes et les communautés. Un renvoi d'échelle dichotomisant le *Tout* et les *parties* est inexact et source d'injustice, notamment en opposant les biens privés au bien commun. Si non traité adéquatement, un oxymore conceptuel réduit la valeur des pratiques.

Ensuite, il revient aux sciences humaines d'étudier, voire de critiquer et de conseiller, le sens choisi pour conduire un bon développement des sociétés (5). Ce sens prospectif renvoie aux valeurs humaines. Ces valeurs doivent être construites collectivement en s'appuyant sur les appréhensions singulières et les savoirs scientifiques pour adopter la formule d'une vision de changement : « Moving the culture toward more vivid utopias with survival as the goal » (36). Potter (6) souligne que le travail des sciences humaines ne doit pas se réduire à la remise en question des nouveaux savoirs générés par les révolutions scientifiques et les cultures humaines. Par exemple, les changements climatiques – à titre de variations biogéochimiques impliquant le cycle du carbone – existent indépendamment des controverses sociales à son égard. Le travail éthique des sciences humaines est de chercher une bonne manière de critiquer l'usage (ou le non-usage) qui sera fait de ces savoirs émergents en sciences, en technologies, voire en société. Compte tenu de l'état de nos connaissances, on pourrait se demander si le médecin, en pratique, devrait considérer – par précaution et responsabilité – la biodiversité lorsqu'il prescrit un antibiotique ou s'en tenir aux soins de son patient (17,42)? L'expérience de pensée proposée par Potter est celle de la reproduction humaine en connaissance des changements climatiques (43). Qu'est-ce qu'un expert d'aujourd'hui doit conseiller aux couples? Doivent-ils devenir parents ou non (44)? Ces questions éthiques sur l'avenir de l'humanité sont globales et, donc, ne doivent pas être confinées à une bioéthique rivée sur le laboratoire de recherche, le chevet du malade ou le cabinet de médecine. Dit simplement, le patient a besoin d'antibiotiques et le parent peut avoir un enfant, mais ces deux *parties* ont un effet sur l'environnement *global* contextualisant la situation.

Critique 2 : La science perd sa vision d'ensemble au travers d'une lentille positiviste

En 1964, Potter critique les grandes théories à l'origine des sciences et des éthiques normatives développées dans le cadre d'une rationalité positiviste. À la même époque, cette logique est remise en question par les philosophes des sciences, dont Kuhn (29) et Karl Popper (45). Leurs échanges ont conduit à développer les bases de la rationalité post-positiviste. Ces logiques présupposent une progression des connaissances par l'accumulation historique des observations et des réflexions :

> Starting with essentially religious motivations, men like Copernicus, Galileo, Newton, Bacon, Descartes, Hobbes, Locke, Hume and Kant began to develop all an understanding of science and to feel that all the facts of the universe could be sufficiently explained by the existence and nature of matter. It was felt that there were no problems too big for man to solve, and the concept of natural order in the world probably reached its highest point among philosophers. Many felt that the universe was a mighty clock that had been wound for all time, and that each individual was born to suffer and die to serve a cosmic purpose. (20)

Avide d'accumuler les savoirs, cette perspective entraine la spécialité de l'expert. Le spécialiste devient ainsi spécifique (précis) et ainsi spécial en société, utile pour remplir une fonction particulière, par exemple la médecine clinique dans un département d'oncologie (20). Cependant, ce clinicien spécialiste doit s'appuyer sur ses pairs, tant à l'intérieur (ex. : département de médecine interne) qu'à l'extérieur (ex. : fabricant pharmaceutique) de l'établissement de soins pour raffiner le diagnostic, le traitement et, en somme, pour assurer la qualité du soin. Une survalorisation du spécialiste empêche, cependant, l'acquisition d'une vision de l'ensemble. Le spécialiste pris comme entité seule devient, par conséquent, inapte à mesurer les limites de son propre savoir (6), ce qui introduit un biais cognitif incommensurable par son action, lorsque systématisée, car l'expert spécialiste est privé d'une vision de l'ensemble. Au contraire, la prise de conscience du contexte et de l'incertitude entourant sa connaissance permet à l'expert généraliste d'apprécier le contour de cette vision d'ensemble. Toutefois, les spécialités sont nécessaires, mais doivent émerger d'une expertise générale provenant d'équipes cherchant à diversifier sa perspective interdisciplinaire.

> As individuals we cannot afford to leave our destiny in the hands of scientists, engineers, technologists, and politicians who have forgotten or who never knew these simple truths [i.e., the knowledge of survival, some of which comes from biology, including in the foreground: "man cannot live without harvesting plants or killing animals"]. In our modern world we have botanists who study plants and zoologists who study animals, but most of them are specialists who do not deal with the ramifications of their limited knowledge. (6, p.128)

Potter remarque un défi fondamental pour les champs du savoir transmettant une expertise générale, dont la philosophie et les champs interdisciplinaires comme la bioéthique. En effet, « No individual could possibly master all of the components of [the] branch of knowledge [of bioethics], just as no one today knows all of zoology or all of chemistry » (6, p.128). Interdisciplinaire, la bioéthique doit ainsi être « [not] merely anthropocentric » (8). Être anthropocentrique consiste à être *subjectif*, c'est-à-dire à cibler ce qui est le propre d'un individu ou d'un être, sans possibilité d'en transférer la connaissance à tous, dont les autres espèces vivantes, ce qui peut être influencé par les sentiments, les opinions ou les intérêts, dont les

ambitions d'exploitation et d'utilisation des ressources naturelles, si l'analyse est réalisée par cet être-sujet (ici un humain). En confiant aux sciences le rôle de comprendre la santé par un pont intersubjectif entre humains (ex. : groupe, congrès ou journaux citoyens, cliniques ou scientifiques), elle retire l'accès à une connaissance générale des êtres vivants dans leur milieu de vie : une prise de recul face à la connaissance humaine centrée sur l'humain. La bioéthique doit aussi être « [not] merely biocentric » (8). Être biocentrique consiste à devenir *objectif*, littéralement, à porter une attention à ce qui existe hors de la pensée (ici humaine) et à ce qui lui est indépendant – jusqu'à comprendre (analytiquement) l'humain comme objet écologique et partie prenante de la « biodiversité » des écosystèmes. Nouer des ponts interobjectifs entre les sciences et les communautés (en action) vivantes nous permet de donner la parole à des « objets » comme des animaux et des lieux. [11]

En 1964 (20), Potter prend le concept d'une « capacité de support des écosystèmes » pour illustrer cette différence entre anthropocentrisme et biocentrisme (11). La société peut supporter une charge maximale de mauvaises idées (des objets humains comme des plans, des stratégies, des conduites) avant de se traduire en souffrance et en vulnérabilité réelles (des subjectivités). Cette illustration est analogue aux pertes de biodiversité réduisant la capacité de résilience des écosystèmes. Ainsi, s'intéresser à la capacité de support (le contexte) équivaut à s'intéresser à la personne; même si l'objet de l'étude n'est pas l'humain, mais les organisations humaines (le *Social*), voire leur environnement (l'*Écologique*). Ainsi, étudier l'écologie revient – par extension – à étudier l'humain (un bio-anthropocentrisme). Le médecin devrait, dès lors, comprendre le patient dans son environnement lorsqu'il prescrit un traitement. Cet environnement comprend des normes de pratiques médicales que l'on doit construire au regard de la communauté sociale-écologique (bio) à l'intérieur de laquelle ce patient et ce médecin se situent. La bioéthique a un rôle à jouer, selon Potter, dans ce processus de communication et de traduction.

La traduction entre *subjectif* et *objectif* est compliquée à exécuter sous une rationalité positiviste. La logique linéaire d'accumulation des connaissances devient un obstacle intellectuel pour bien traduire, car elle nécessite des itérations. Les caractères objet ou sujet sont indissociables (une interdépendance) : nous sommes à la fois des *êtres* pensants et des *choses* observables. L'interdépendance entre sujet (observateur) et objet (contexte) nécessite une réflexivité constante posant en dialectique les analyses objectives, décrivant l'état des lieux, et subjectives, appréciant ce nouveau savoir. Potter suggère une piste de réflexion en proposant l'étude de la rationalité des logiques de la complexité, dont la biologie, l'évolution et l'écologie, et des approches éthiques découlant du pragmatisme de John Dewey (1859-1952) comme le souligne ten Have (2). Ceci demande une refonte de nos modes de pensées, mais aussi des organisations sociales, vers un paradigme de la complexité capable d'opérer par itération et rétroaction.

Le pragmatisme n'est pas synonyme de relativisme. Le processus pragmatique cherche à faire la lumière sur la vérité, alors que cette quête est secondaire pour le relativisme. Dewey propose une approche par enquête alors que Charles Peirce (1839-1914) développe l'idée d'une logique abductive. Sylvie Catellin (47) définit l'abduction comme : « une forme de raisonnement qui permet d'expliquer un phénomène ou une observation à partir de certains faits. C'est la recherche des causes, ou d'une hypothèse explicative. » L'enquête scientifique et l'itération abductive sont au cœur de la vision contemporaine de la complexité, dont se rapporte l'aménagement adaptatif des écosystèmes découlant des travaux de Leopold (48). Toutefois, comme le relativisme, le pragmatisme considère une symétrie (analytique) des valeurs entre les différents êtres-choses caractérisant un collectif ou un écosystème : une perspective se rapportant à l'écocentrisme (19). Ainsi, l'humain et les êtres non humains (ex. : plantes, technologies et bâtiments) doivent devenir un sujet d'attention d'égale valeur *a priori* pour l'enquêteur (11). Le défi émergent de ce constat est de prioriser au cas par cas la valeur de chaque chose en fonction de la voie d'action décidée collectivement – la bioéthique acquière, pour Potter, le rôle de structurer ce processus réflexif.

Critique 3 : L'éthique est trop déductive – elle doit coconstruire

En 1970, Potter critique l'appropriation de l'éthique par la philosophie et les *sciences humaines*. Ainsi experte, l'éthique devient trop déductive, rationalisée à partir de grands systèmes de pensées métaphysiques déconnectés des réalités biologiques (6).

> In the past ethics has been considered the special province of the humanities in a liberal arts college curriculum. It has been taught along with logic, esthetics, and metaphysics, as a branch of philosophy. Ethics constitutes the study of human values, the ideal human character, morals, actions, and goals in largely historical terms; but above all ethics implies action according to moral standards. What we must now face up to is that human ethics cannot be separated from a realistic understanding of ecology in the broadest sense. (6, p.127)[12]

Potter considère comme essentielles les grandes théories axiologiques tout comme scientifiques ; elles conservent en mémoire les leçons et les appréhensions humaines dans leurs détails. Cependant, il critique leur déductivisme (5,9,23). Si Tom Beauchamp et James Childress définissent la bioéthique comme « the application of general ethical theories, principles,

[11] Les travaux de l'anthropologue Tim Ingold (46) propose un cadre utile pour organiser ces rapports entre la connaissance scientifique et l'expérience vivante. L'humain (civil et expert) expérimente la vie comme personne-organisme rendant pertinent d'intégrer les savoirs objectifs (exemple, la santé biologique) et subjectifs (exemple, la volonté d'être en santé). Le « Land » se perçoit donc toujours sous la position de l'*observateur* regardant le *paysage* de manière externe (*objective*) et à titre de partie prenante (*subjective*) comme un *être observé* ayant une expérience vécue de ce *territoire*.

[12] Pour Potter, l'écologie « in the broadest sense » apparaît comme l'étude, les connaissances et l'existence des/dans le système(s) biologique (le monde empirique) incluant, par cela, la psychologie, sociologie, économie, écologie, etc. Cette nuance devient évidente à la lumière de l'œuvre de Leopold où la « biologie » n'est pas une discipline, mais l'expérience de vivre en communauté : le vivant (*biota*, communauté) et la matière (*abiota*) donnant les conditions d'existences de l'habitat (the *Land*).

and rules to problems of therapeutic practice, health care delivery, and medical and biological research » (49, p.ix-x), Potter (9) soutient que cette approche tend à se déconnecter d'une compréhension réaliste de l'écologie au sens large (6).

> In the humanities the only test of an idea is its acceptance by society, and if society chooses on the basis of conventional but ill-founded wisdom or individual short-term gratifications, it may perpetuate an idea that might better have been buried. We need to reexamine our premises and look for better ways to reach a consensus among disciplines, based insofar as possible on objective verification and adequate monitoring of the trends in environmental quality. (6, p.132)

Au lieu d'une approche philosophique de la bioéthique, Potter (6) nous propose de considérer ces savoirs humains comme des hypothèses réfutables (abductives) plutôt que des prémisses catégoriques, bien que ces hypothèses visent à atteindre un consensus entre les experts ; dès lors l'hypothèse devient un *paradigme* (29). D'une part, les communautés doivent avoir le pouvoir de critiquer les standards moraux afin de se défaire d'une éthique réduite à une dichotomie entre *bien* et *mal* (6). D'autre part, l'expérience vécue ne doit pas être la seule source de critique permettant à ces valeurs éthiques – comprises comme hypothèses – de progresser. Les communautés doivent être en mesure de faire progresser leur éthique collective en acquérant la capacité d'apprendre des retours en expériences vécues, voire en approfondissant l'idée du *test* d'acceptabilité (12) qui doit passer par la mesure d'une « acceptable survival » fondée sur « [the] understanding of ecology in the […] sense [of Leopold Legacy] » (6, p.127). Aucune éthique ne devrait être comprise comme universelle par défaut. Par ailleurs, c'est son application qui doit déterminer sa valeur en pratique (6).

La bioéthique conduit ainsi à une forme d'éthique collective. D'abord, nous devons apprendre des crises. Ensuite, nous devons réexaminer ces valeurs par des processus interdisciplinaires. Potter (6) nous propose, ainsi, une logique itérative par enquête abductive de la coconstruction de l'éthique. Il s'inscrit, en 1964 (20), dans la conversation académique sur le post-positiviste (29,45). Cependant, il souligne les limites de l'application de ces logiques à l'éthique. La rationalité scientifique est insuffisamment critique. Elles doivent intégrer une logique critique fondée sur le doute et l'incertitude capable de remettre en question les sciences, les technologies et les sociétés dans leur ensemble (20). Par cela, Potter (5) propose une logique scientifique intégrée aux processus sociaux. En proposant une « science de la survie » (6), il se dissocie de la vision de Kuhn en s'associant davantage aux penseurs qui suivront dans les années 1990, dont l'idée des *sciences post-normales* des philosophes en sciences et technologies Silvio Funtowicz et Jerome Ravetz (50). Cette science de la survie vise en quelque sorte à coconstruire localement, par communauté, un langage commun pour responsabiliser l'action humaine (11).

La communication devient ainsi le plus grand défi pour opérer la *conscience collective* ou la *pensée globale* proposée par Potter. Les sociétés ont besoin d'outils de communication pour coconstruire un langage commun. Les hypothèses proposées par Potter deviennent le vocabulaire de ce langage. Par ce mécanisme, le langage s'active par une dynamique de coconstruction : les écrits sont critiquables, réfutables et marquent une progression par leur réécriture. Ainsi, un *manuel* de bioéthique, pourtant complexe à délimiter, doit émerger du processus. D'abord, la bioéthique doit compter sur des professionnels actifs en société : « Real bioethics is not pure, traditional, reasoning ethics. » (8, p.1) Ensuite, elle doit inclure des scientifiques pro-actifs intéressés à améliorer la pratique de ces professions : « Real bioethics is done by realistic scientists and concerned biologists and physicians who have an intuition to help build a "Bridge to the Future", whether or not their effort is labeled "bioethics". » (8, p.1) Enfin, sa propre conduite doit reposer sur les sciences humaines, ici représentées sous la figure de Max Otto (1876-1968), analysant et critiquant ces dispositions *pro* (avant) actives, c'est-à-dire le raisonnement, le discours, puis les justifications des professions, des sciences et des politiques en société. Ce jugement critique permet de fonder les savoirs humains sur l'humilité (23), la complexité (37) et la globalité (11), c'est-à-dire la responsabilité (23).

Critique 4 : Une critique à l'égard de la bioéthique – elle est centriste, trop linéaire et trop confinée

La vision de la bioéthique retenue après 1978 est davantage celle de Warren Reich : « the systematic study of human conduct in the area of the life sciences and health care, in so far as this conduct is examined in the light of moral values and principles » (51, p.xix). Cette définition est centrée sur l'humain, les sciences de la vie et les soins de santé, tous fort éloignés d'une compréhension véritable de l'écologie (6). En revisitant *The Land Ethic*, Potter (9) souligne que « Two kinds of bioethics » est en train de se former, bien qu'ils s'entendent avec Callahan sur l'innovation première de la bioéthique : « In that sense, not only is medicine itself being tested by ethics, but ethics itself is being tested by medicine » (52). Par la figure de Leopold, Potter signale qu'un joueur manque à cette scène et c'est la communauté : « ethics itself is being tested by ecological, population, and pollution crises all over the world. » Ainsi, le(a) bioéthicien(ique) agit comme pont médiateur entre les pratiques, leur éthique et la communauté : « [Contemporary] problems call for actions that are based on values and biological facts. All of them involve bioethics, and survival of the total ecosystem is the test of the value system » (6, p.127).

La recherche clinique et la médecine appartiennent à une vision étroite de la biologie appliquée à quelques pratiques. Cette vision néglige le champ de l'*Écologie & Évolution*. Ainsi réduite, la biologie revient à un organe en fonction dans une société bien plus complexe. Le savoir, moteur de nouvelles connaissances, est évacué. Évidemment, la médecine, l'expérimentation et l'ingénierie humaines, animales, végétales, microbiennes, écosystémiques, etc., apportent aux sociétés des savoirs pratiques fort utiles, soit les connaissances spécialisées, les innovations techniques et les découvertes technologiques. Toutefois, cette vision axée sur l'outillage (l'opération) perd de vue l'ensemble, c'est-à-dire la fine compréhension des interactions complexes, dont les répercussions entrainent les problèmes de santé globaux ; des exemples notables incluant

les épidémies zoonotiques, les famines mondiales et les migrants climatiques (19,34,53). Elle tend à réduire la valeur, la portée et l'utilité des savoirs en *Écologie & Évolution*, notamment celles permettant d'appréhender les conséquences des pertes en biodiversité, de l'écotoxicologie et de la résistance microbienne (17,54).

Potter est associé aux thématiques suivantes : « [the] major problems of our time [are] population, peace, pollution, poverty, politics, and progress » (5). Ces problèmes sont globaux et transcendent les (dé)limitations classiques (ex. : les disciplines, les cultures et les États). La *globalité* n'est pas synonyme de mondial, de planétaire ou de générationnel. Pour Potter, l'intervention globale demeure accessible bien que ses (dé)limitations soient dynamiques et évolutives (ex. : les dimensions *mondiale*, *planétaire* et *générationnelle* sont peu ou pas *finies*). La globalité est une question d'approche, de cadrage, d'analyse et de stratégie d'interventions dont les rudiments nous sont présentés par la science et l'éthique développées par Leopold (11). La globalité devient une approche à mettre en pratique, voire une méthodologie de l'intervention en société. Potter formule le processus ainsi :

> In suggesting a new discipline called bioethics and specifying that we look outside the traditional sciences, I am not suggesting that we abandon the traditional treatment for a new idea, but rather that we cross the disciplinary boundaries more freely and look for ideas that are susceptible to objective verification in terms of the future survival of man and improvement in the quality of life for future generations. (6, p.132)

Le global dépasse donc largement la situation pratique du cabinet et de l'hôpital, mais ne doit pas amener à un « abandon du traitement traditionnel pour une nouvelle idée » (6, p.132; *traduction libre*), notamment pour plus de rigueur disciplinaire et d'acquis scientifiques, technologiques et éthiques.

POTTER, UNE ÉTHIQUE ÉVOLUTIONNISTE?

Selon Potter, « Man's survival may depend on ethics based on biological knowledge, hence bioethics » (6, p.152). Même s'ils occupent une place centrale dans l'œuvre de Potter (5,6,11,22), la science de la survie et le « Bioethical creed » ont peu été retenus dans les écrits contemporains (2). Plusieurs raisons peuvent expliquer ceci, dont l'apparent rapprochement entre cette *survie* et le darwinisme social de Herbert Spencer (1820-1903), une forme d'éthique évolutionniste reconnaissant « The survival of the fittest » au sens propre. Autrement, il y a la proximité historique entre la science (ici, Écologie & Évolution) et la vision positiviste du Cercle de Vienne (20). Cependant, les perspectives de Spencer et de Vienne sont fort éloignées de la vision de Potter (2). D'ailleurs, Potter critique les sciences positivistes (20). Cette science de la survie doit devenir « more than a science alone », voire plus qu'une science normale comme conçue par Kuhn (6). Par ailleurs, l'évolution n'est pas synonyme de progrès tel que Spencer l'entend. La progression des sciences et des éthiques collectives demeure fondée sur la valeur de la responsabilité humaine (17,35,54) comme l'explique Juan Lecaros (55) par l'idée d'une « Ecological ethics ». Cette responsabilité évolue par son rapport avec la réalité empirique – elle doit viser à améliorer la capacité de l'humanité à (sur)vivre en ajustant ses valeurs à la mesure des transformations du monde ambiant, c'est-à-dire de l'écologie dans un sens large (6).

La science de la survie s'appuie, toutefois, sur une métaphore empruntée à la biologie – « The struggle for existence » (56). La théorie de l'évolution de Charles Darwin (1809-1882) utilise la métaphore d'une *lutte* pour décrire la quête perpétuelle des espèces pour *exister*, alors qu'elles sont soumises à une pression sélective les amenant à *évoluer* vers de nouvelles formes biologiques. D'un côté, l'évolution de la vie transite vers des formes alternatives d'organisation, mais ne progresse pas vers une nouvelle forme avantageuse pour l'humain comme l'entendait Spencer. De l'autre côté, la « cultural evolution » (5, p.150) initiée au sein des sociétés humaines peut faire progresser l'environnement social vers de meilleures conditions humaines par sa prise en charge de l'avenir de la communauté (5). Toutefois, la connaissance de ces conditions est toujours à refaire, car aucun *corpus* de connaissances n'est garanti comme le défend Vienne.

À l'époque de Potter (20), plusieurs analogies apparaissent entre écologie et société, puis écosystèmes et sciences (57). En la figure d'Otto, Potter souligne l'importance des sciences humaines pour rationaliser cette philosophie de la nature de manière à en tirer des leçons. James Trosko (38) discute de ce défi des éthiques évolutionnistes en soulignant les contributions d'Otto à ces réflexions.

> The universe is run by natural forces and laws, not by moral laws. However, human societies, which live in the natural world, must live by moral laws. If those moral laws contradict or ignore the natural laws, it will be the human societies, not the physical universe (or the global ecology), which will suffer the consequences of such defiance. (38, p.302)

LA BIO-ÉTHIQUE GLOBALE COMME CODE DE BIOÉTHIQUE ET SCIENCE DE LA SURVIE

La bioéthique globale apparaît comme une opération conjointe – « co-operation » (10, p.156-57) – entre deux organisations[13]. L'une *politique* à l'origine du « Creed » (un crédo, un cri du cœur, voire ici traduit par code) et l'autre *scientifique* à l'origine de l'évolution culturelle, ces organisations réalisent deux *fonctions* jugées essentielles pour vitaliser l'éthique selon Potter (7) :

[13] Cette perspective du concept de « coopération » à titre d'opération conjointe entre le *naturel* et le *social* provient d'Aldo Leopold.

1. un *code de la bioéthique* fondé sur une vision *prospective* coconstruite sur la base d'un dialogue collectif critique sur l'avenir (5);
2. une *science de la survie* fondée sur une pensée *globale* organisée en multiples échelles (11).

Potter met l'accent sur l'importance d'un guide, d'un code ou d'un manuel de référence posant en évidence les lois, les principes, les théories et les standards dirigeant les actions humaines : « a new discipline to provide models of life styles for people who can communicate with each other and propose and explain the new public policies that could provide a 'bridge to the future' » (6, p.128). Le Tableau 1 propose une synthèse conceptuelle de l'œuvre de Potter de manière à en dégager les éléments d'un bon code de la bioéthique[14]. La théorie éthique fondant la pensée axiologique de Potter renvoie aux approches écologistes et féministes de Leopold et de Carol Gilligan (11). Notamment, leurs valeurs de responsabilité, d'humilité, de compétence et de compassion donnent sens au discours de Potter à propos des souffrances, des vulnérabilités et de l'épanouissement (ou la survie) humain, social et planétaire.

Tableau 1. Code de bioéthique se détachant d'une synthèse du cadre théorique et conceptuel de l'œuvre de Potter

Caractéristiques de la bioéthique	Rudiments d'un bon code de la bioéthique
Sagesse Posée entre science et société (5)	**Responsabilités** (23) comme une notion tirée des approches féministes et écologistes **Humilité** (23) comme une notion d'appréhension de l'incertitude en tant que condition inhérente aux décisions et aux savoirs **Compétence** (12,20) interdisciplinaire et interculturelle comme une notion soulignant le défi, mais la nécessité d'une bonne dialectique entre sciences (ou connaissances) et valeurs humaines **Compassion** (12) comme une notion proactive envers la souffrance, les vulnérabilités et les pressions posées sur l'humain et le non-humain
Adaptation Comme une science de la survie (6)	**Adaptation biologique** comme processus de transformation des organismes en interaction avec leur milieu d'ordre physique (ex. : génétique), comportemental (ex. : éthologique) et cognitif (ex. : psychologique) **Apprentissage social** comme normes (le droit, les cultures, l'économie, etc.) ou conduites faisant progresser l'existence humaine, individuelle et collective
Prospective Comme un pont vers le futur (5)	**Science** comme levier de pouvoir et de savoir ordonnant la compréhension du monde **Technologie** comme agent perturbateur de l'ordre compris du monde tantôt pour le mieux (ex. : cure médicale) tantôt pour le pire (ex. : les armes nucléaires) **Société** comme agence organisant l'existence humaine en rapport avec son environnement (facteur externe) et ses appréhensions (facteurs intrinsèques)
Gouvernance Pour surmonter la fatalité de l'évolution (15)	**Micro-organisationnelle** comme processus à court terme se rapportant à des mécanismes ou à des séquences d'événements observables (donc, *pré-visibles*) **Macro-organisationnelle** comme processus à long terme se rapportant à des phénomènes inaccessibles (donc, *non prédictibles*) sans savoir préalable pour affuter l'œil de l'observateur
Global Comme la communauté comprise par les héritiers de Leopold (11)	**Aménagement** comme processus pour anticiper les risques, pour agir en amont de la prévention et pour justifier la protection d'éléments structurant l'organisation d'ensemble (l'habitat) sans la connaissance du mécanisme d'action spécifique, mais avec une compréhension du phénomène en œuvre **Communauté** comme ensemble de systèmes opérant en interdépendance (une coopération), car tous soumis à une pression commune définissant leur contexte, c'est-à-dire la problématisation venant de l'*habitat* ou de la *compétition* entre deux systèmes
Profonde Pour appréhender un 3e millénaire vivable (14)	**Interdisciplinarité** comme mode de collaboration et de communication permettant une dialectique entre thématiques d'étude (*superficielle*) ou paradigmes disciplinaires (*profonde*) **Transdisciplinarité** comme mode de construction des savoirs humains en vue d'une production de connaissance pratique intégrant faits (l'objet d'étude des sciences) et valeurs (l'éthique induite des sociétés et déduite par les sciences).

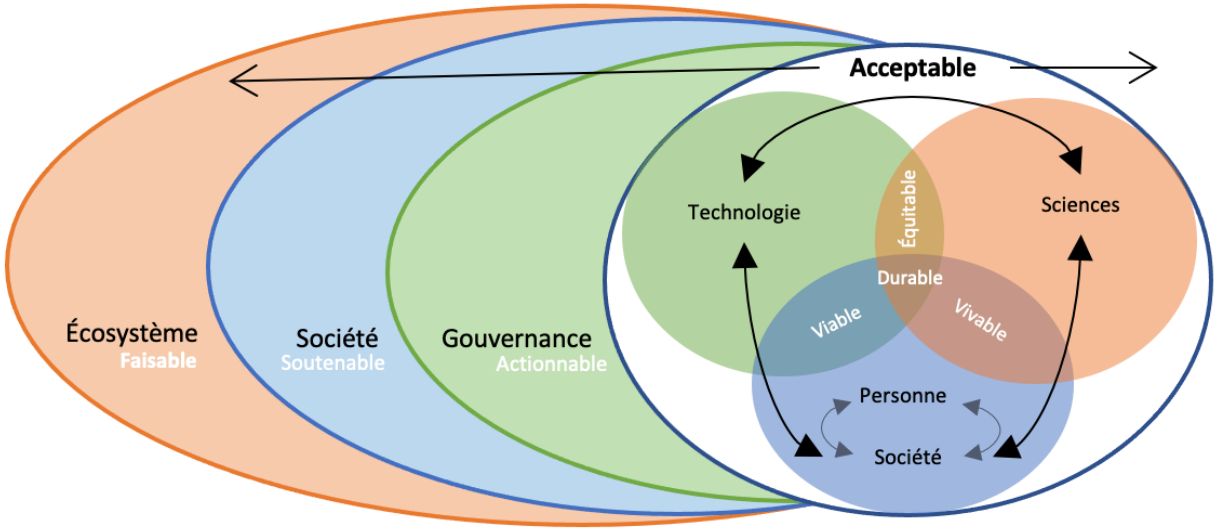
Métaphoriquement, nous avons besoin d'une alliance se matérialisant par l'intermédiaire d'un code. Gruen et Ruddick proposent une « Biomedical and environmental ethics alliance » (58) en reprenant ainsi le discours critique de Potter adressé au Hasting Center en 1987. Tel que souligné précédemment, ce type d'alliance doit cependant être appréciatif (à titre d'hypothèse) et non normatif (ou catégorique). L'alliance doit apparaître comme un « terrain d'entente » (voir plus loin comme traduction conceptuelle de *The Land Ethic* de Leopold à Potter) devant passer le *test* des communautés pour en faire émerger une formule locale. Ce processus de test apparaît comme une sagesse pratique et une gouvernance collective se posant à trois échelles : le *personnel* (individuel), le *culturel* (social) et l'*intellectuel* (générationnel) (20).

Cette alliance est cependant évolutive et doit délimiter le cadre à l'intérieur duquel la gouvernance peut justifier ses décisions. Pour dynamiser ce processus, la communauté doit pouvoir communiquer aisément les réalités, notamment par des procédés mettant en interaction les sciences, les technologies et les sociétés. La sociologie des organisations propose divers cadres

[14] Potter propose *A Bioethical Creed* dès 1971 venant ainsi illustrer la teneur pratique d'un tel document (l'auteur renvoie le lecteur aux grilles montées par Potter à cet effet). Ici, nous reprenons leurs rudiments, non pas leurs énoncés, pour ressortir le socle de principes devant fonder l'écriture de ces codes.

analytiques pertinents pour opérer cette vision systémique (59,60). La Figure 1 pose trois échelles d'opérations concentriques (faisable, soutenable, actionnable) contextualisant l'existence humaine. Chacune d'elles *coopère* une dynamique. Cependant, par leur assemblage, l'action des collectivités (la gouvernance, **vert**) se niche dans le fonctionnement de l'écosystème (la biologie, **rouge**). Ainsi, les savoirs biologiques (**rouge**) doivent orienter l'action politique (**vert**), car ils possèdent une information sur la faisabilité de son opération, mais doivent reposer sur une société pour la diffuser (**bleu**). Le message diffusé par cette société se transforme par le biais de son système de valeurs (**blanc**). Ces valeurs, lorsque singulières, peuvent corrompre l'information, mais peuvent tout autant, lorsque partagées, conduire vers une acceptabilité collective. Cet arbitrage du système de valeurs en rapport aux savoirs biologiques devient la mission de la « bio-éthique », c'est-à-dire démocratiser « [the] "knowledge of how to use knowledge" for man's survival and for improvement in the quality of life » (5, p.1).

Figure 1. Carte conceptuelle positionnant les éléments introduits par la bioéthique potterienne



Ce cadre esquisse la carte où se réalisent les acteurs et leurs idées lors de la résolution de problèmes humains selon la perspective d'une *soutenabilité acceptable* proposée par Potter. Cette vision s'opère en trois organisations emboîtées l'une dans l'autre : une première « between individuals » (« entre individus », **blanc**), une seconde « to integrate the individual to society » (« pour intégrer l'individu à la société », **bleu**) et une troisième à coconstruire avec le vivant à la manière d'une éthique des « communities » (**rouge**) (5). L'approche proposée par Leopold est d'introduire une coopération entre le contexte (*acentique* ou objectif, **rouge** et **bleu**) et l'humain (*centrique* ou subjectif, **blanc**) en conscientisant et en responsabilisant sa dynamique de gouvernance (**vert**).

À partir de 1990, Potter reprend la logique de la soutenabilité en critiquant son réductionnisme face à la complexité humaine (12). Ce discours critique de Potter à l'égard de cette soutenabilité justifie de représenter sa vision en réassemblant le cadre du développement durable. Il reconnaît que le développement durable met habilement l'économie, l'environnement et la société en relation interdisciplinaire (une *alliance*) par les valeurs de la durabilité (vivabilité, viabilité et équité). En pratique, cette alliance pose un socle pour démocratiser le jugement critique, c'est-à-dire que la qualité des projets, des études et des disciplines peut dès lors s'évaluer en société. Toutefois, Potter critique le manque de contexte dans les réflexions durables (**rouge**, **bleu**, **vert**) : cette interdisciplinarité doit être plus profonde. Le développement durable (**blanc**) introduit un faux sentiment de certitude et ainsi la conviction d'un contrôle. Le promoteur d'un projet croit maîtriser la technique acceptée(able) avant d'engager un développement responsable en société, mais cette fausse certitude le rend inapte à *écouter* la critique et à remettre en question ses prémisses en vue d'une acceptabilité à long terme de son projet, voire de sa technique de développement (12,15). Notamment, la valeur de soutenabilité d'un projet à un moment donné ne peut nullement substituer l'avis au quotidien des personnes ni de la communauté (12).

LA BIOLOGIE COMME SOCLE DE LA BIOÉTHIQUE

Pour Potter, la biologie ne se réduit ni à l'objet étudié (le *matériel biologique*) ni aux champs de pratique axés sur le médical et la santé. Elle renvoie au monde ambiant et à une source de savoirs. D'ailleurs, elle lui inspire un nouveau mode opératoire pour l'éthique en société. La biologie contemporaine est l'une des sciences de la complexité et des systèmes, largement interdisciplinaires, se posant à l'interface entre le vivant (ex. : zoologie, botanique et anthropologie) et le non-vivant (ex. : chimie, géologie et climatologie) pour comprendre le comportement, l'évolution et l'écologie des organismes. La branche intéressant particulièrement Potter dépasse la portion descriptive de la biologie, c'est-à-dire ses *sciences naturelles*. Il s'intéresse davantage à sa branche normative, par exemple les techniques d'ingénierie génétique et les politiques de développement durable, et il valorise ses branches appréciatives cherchant à opérer l'éthique médicale (en oncologie) et l'éthique de l'environnement (en écologie) en science et en société.

Leopold est un auteur ayant influencé, voire propulsé, plusieurs courants de pensée, champs d'expertise et disciplines en biologie, en gestion et en philosophie (48), dont l'écologie appliquée ou « *Wildlife Ecology* » (61), l'aménagement adaptatif ou « *Game Management* » (62) et l'éthique de l'environnement (10). La pensée de Leopold en a inspiré plusieurs, dont Arnes Naess (1912-2009), Norton et Potter. Chacun peint sa philosophie sous différentes perspectives, dont la « *Deep ecology* » (63), la « *Sustainability* » (48,64) et la « *Ecological bioethics* » (11, p.xiv). Pour comprendre la pensée de Potter, il apparaît nécessaire d'étudier Leopold sous ces différents aspects ; notons la pensée *profonde* de Naess et la gestion *soutenable* de Norton.

CONSTRUIRE SUR L'HÉRITAGE D'ALDO LEOPOLD

Au cœur de l'œuvre de Potter (1988) se trouve l'idée que la bioéthique aurait émergé de *croquis ici et là* esquissés par un forestier ayant vécu sur le territoire d'*un almanach du comté de sable* (10)[15]. « Leopold was unquestionably the first bioethicist: he was first to envision a new ethical basis for human conduct » (11) et « anticipated the extension of ethics to bioethics » (5). Potter situe ainsi l'origine de la bioéthique entre les années 1925 et 1949 plutôt que 1971. D'ailleurs, c'est à cette époque de grands bouleversements (guerres, crises économiques et exploitations sociales) que prennent forme les grands débats scientifiques en écologie (64). L'histoire de la bioéthique et de l'écologie se rejoignent selon Potter à travers les débats scientifiques et sociaux qui les ont faits naître : « Bioethics can serve no useful ends if it is to be merely a watered-down version of contemporary biology. » (6, p.130)

La communauté selon Leopold : un ensemble de systèmes coopérant dans l'écosystème

Leopold est incontournable et ses idées sont radicales. *The Land Ethic* ne désigne ni une étiquette amenant un habitant à réclamer les droits de propriété de sa *terre*, ni une déontologie ou une économie catégorisant la nature *sauvage* comme milieu à conserver ou à utiliser, ni un attachement à la *Terre* accordant une valeur intrinsèque ou esthétique à un lieu. Sa philosophie – influencée par le pragmatisme américain issu de George Marsh (1801-1882) – vient réunir ces positions (64) : *terre*, *sauvage* et *Terre* deviennent l'idée d'un *habitat écologique* de vie, nommé *écosystème* par Tansley (65), apparaissant comme un *paysage* (61,62) à aménager pour les sociétés qui ont la responsabilité de coopérer dans cet habitat (48,63,66). Cette coopération devient possible lorsqu'elle s'appuie sur la connaissance de suivis (les *Croquis d'ici et là*) donnant les retours d'expérience nécessaires pour faire progresser l'opération vers un aménagement responsable (par *The Land Ethic*)[16]. Plus encore, Leopold *niche* l'humain dans une société, elle-même partie prenante d'une communauté, puis d'un habitat écologique[17]. Cet habitat (ou écosystème) pose en interaction les espèces avec leur milieu. Ces interactions (coopération ou compétition) déterminent la survie des espèces et structurent leur communauté. Pour Leopold, la dynamique de coopération incarne une forme d'*éthique de la nature*, c'est-à-dire une éthique de base, un terrain d'entente minimal forcé par les conditions du *Land* pour une coopération optimale entre ses parties.

Leopold est connu pour avoir redéfini la notion de communauté comme une dynamique de coopération entre les êtres vivants, lorsqu'un ensemble d'entre eux partage une pression commune (10). Cette coopération se réalise naturellement (involontaire); mais bénéficie d'une prise de conscience conduisant à une responsabilisation sociale : « Knowledge of adaptation is needed for wisdom » (11, p.6-7). Cependant, cette responsabilité sociale est mise à l'œuvre par le biais des systèmes d'éducation, de communication et de gestion rendant possible une collaboration entre personnes et institutions (Figure 1, **blanc**). Les études scientifiques doivent traduire la « voix » du *Land*, dont ses perspectives humaines et non-humaines, afin d'engager des populations, des espèces, voire des lieux, demeurant invisibles (5). Cette traduction se complexifie davantage lorsqu'elle est portée à la dimension planétaire (la communauté humaine). « Converting sustainable development to global survival » (10) signifie donc de démocratiser le « Knowledge of how to use [that power emerging from] knowledge » et, cela, « whether or not [it] is labeled "bioethics" » pour faire coopérer l'humanité avec les autres ensembles planétaires.

Ce processus de traduction bénéficie d'un langage commun. Ainsi, une même base linguistique doit pouvoir poser en dialogue les *voix* traduites par la médecine et l'écologie, par exemple : santé (53), résilience (54), biodiversité (17), consommation (67), capacité de support (20), etc. La sociologie contemporaine propose l'idée d'un système d'objet-frontières, voire d'acteur-réseau formant un collectif de traduction[18]. La communauté devient ainsi un concept éthique par la coopération locale entre les êtres pour survivre (ou sur-vivre, voire chez Potter comme un « bien-vivre »). Pour Leopold, l'éthique pose un pont de négociation social-écologique : un terrain d'entente entre les sciences appliquées, dont la *Wildlife Ecology* (61,62), et le code collectif, ici *The Land Ethic* (10). L'éthique aide donc à assurer une bonne *évolution culturelle*, notamment en rendant *audible* la parole des *oubliés*, par le recrutement continu de traducteur, dont les disciplines de l'écologie, de l'anthropologie, de la philosophie, etc., en mobilisant la poésie, la communication et l'éducation.

[15] L'œuvre posthume de Leopold (10) rapporte, avec poésie, le travail de terrain d'un forestier ayant la responsabilité de l'aménagement adaptatif d'un terrain (un « comté »). Le forestier tient un registre (« Croquis ») de suivi compilant des indicateurs relatifs (« ici et là ») de l'état de croissance de la faune et de la flore (le « comté de sable ») de manière à y étudier le processus de la succession écologique selon les saisons (un « almanach »).
[16] Leopold dénoue ainsi la controverse historique incarnée par Henry Thoreau (1817-1862) et John Muir (1838-1914) (48). Pour situer l'apport de cette réflexion pour Potter, il apparaît pertinent de contextualiser Leopold parmi les figures marquantes de son époque, dont Arthur Tansley (1871-1955) pour le concept d'écosystème (1935), Uri Bronfenbrenner (1917-2005) pour le modèle de l'écologie humaine (1970) et Steward Pickett pour les études en écologie urbaine (1970).
[17] Une référence au concept de la niche écologique en biologie.
[18] Une référence au modèle de Michel Callon (68) issu d'une réflexion sur l'aménagement adaptatif des pêches à la coquille Saint-Jacques de la société Parisienne.

La résilience selon Crawford Holling : le mode de gouvernance des communautés

Leopold introduit les bases de ce qui sera développé plus tard sous le concept de la *résilience écologique* (1973) par Holling (26). La résilience caractérise le processus d'adaptation des organisations complexes agissant comme une gouvernance multi-échelle panarchique (69) fonctionnant par cycle adaptatif (27,48). Cette perspective de la résilience a été motrice de plusieurs analogies pour avancer les théories en gestion et en éducation (voire les cycles apprenants). L'œuvre et la biographie de Leopold permettent de préciser le rôle social du (de la) bioéthicien(ique) dans la communauté. Potter réfère fréquemment à Leopold, puis à d'autres biologistes, pour appliquer le modèle de *The Land Ethic* à l'ensemble de la société (5,11). Il propose par cela un modèle de gouvernance et de capacitation (*empowerment*) des communautés (11). Son modèle intègre des approches ascendantes (*bottom-up*) et descendantes (*top down*) provenant de modes de régulation biologiques et politiques (9,13,20,22).

La résilience est une notion fondamentale à l'écologie contemporaine (26,27,69). Elle est liée à la biodiversité et à la dynamique de transformation des écosystèmes, c'est-à-dire la succession écologique. Comme qualité, la résilience donne une valeur à la trajectoire et au rôle des interconnexions entre les parties du système. Cette opération se réalise en cycle adaptatif (70) et peut être modulée par un « co-aménagement adaptatif des écosystèmes par communauté » (71). Elle apparaît ainsi comme le type de legs conceptuels auquel Potter fait référence. Par « aménagement » (48), Leopold s'oppose à la logique d'une intendance de l'humain sur les forêts. L'intendance renvoie à la charge des affaires administratives de l'État ou d'un établissement[19]. Cette logique est toujours en vigueur pour gérer certains problèmes biologiques, par exemple : l'intendance de l'utilisation des antibiotiques prenant un sens plus profond sous l'idée de la gouvernance des antimicrobiens (antibiogouvernance). Cependant, l'antibiogouvernance devrait, dans un premier plan, être conceptualisée comme un aménagement des écosystèmes microbiens (Figure 1, **rouge**). Dans un second plan, il devrait se rapporter à un problème d'intendance des affaires pharmaceutiques, économiques et sociales (**bleu**). Dans un troisième plan, il devrait se rapporter aux enjeux d'intégrité et de conduite responsable des pratiques professionnelles et des citoyens-utilisateurs d'antibiotiques (**vert**). L'aménagement permet de partager la responsabilité de l'opération entre toutes les parties constituant la communauté en retirant la relation de pouvoir introduite par l'intendance et en portant la parole des *oubliés*. Cependant, un agent doit lier ces parties lors de l'opération de leur responsabilité – ceci prend la forme de *The Land Ethic*.

Toutefois, Potter poursuit les idées de Leopold à partir de raisonnements logiques, alors qu'Holling dérive le modèle de la *résilience* d'une expérience (26). Pour Potter, la Science est une source d'ordre par la traduction des diverses réalités qui composent la communauté. Elle sert à démystifier le *contexte* (le *bios*, un désordre), c'est-à-dire l'habitat écologique (ex. : le climat), la compétition entre espèces (ex. : les maladies) et les comportements de notre espèce (ex. : l'usage de technologies). Cependant, par cette traduction, la Science bouleverse l'ordre même qu'elle cherchait à comprendre, car les connaissances acquises conduisent à des technologies qui changent l'ordre local. Si ces technologies ouvrent à de nouvelles possibilités, elles deviennent aussi sources d'incertitude biologique (ex. : l'automobile *vs* les changements climatiques ou les antibiotiques *vs* la résistance microbienne). Les technologies sont autant source de bienfaits que de méfaits, car ils ont, par exemple, le double rôle de cure et de polluant. L'utilisation d'antibiotiques est rendue possible par la fine compréhension scientifique de la physiologie et de la chimie (la *cure* pharmaceutique). Cependant, leur usage *réarrange* la physiologie. De prime abord, la *cure* guérit la maladie par un rétablissement de l'homéostasie de l'organisme, mais l'antibiotique agit aussi comme polluant. Par définition (en biologie), l'antibiotique modifie la trajectoire de l'évolution microbienne conduisant à l'extinction de la population ciblée (*cure*), à l'adaptation de son espèce (résistance) ou à la transformation imprévisible de sa communauté (polluant). La pénicilline a d'ailleurs pu soigner plusieurs malades (1941 à ce jour) avant de perdre en efficacité en raison de l'accumulation de gènes de résistances. Pour Potter, l'éthicien (et l'éthique) doit aider à faciliter la coopération entre les sciences (pharmacie, médecine, politique, etc.) et la société, dont les réalités sont émergentes (technologie, maladies, biologies, etc.). Son rôle est de négocier les positions, puis de formuler un discours consensuel posant une alliance, un terrain d'entente, *The Land Ethic* ou encore un code de bioéthique pour favoriser la coopération au sein de la communauté vivante.

Le paradigme selon Thomas Kuhn : la structure des révolutions scientifiques

En 1971 (5), Potter construit les bases de sa théorie sur le modèle philosophique conceptualisé par Kuhn (29) : « As I understand [Kuhn's] message, it is that a paradigm is much more than a widely accepted hypothesis or postulate; it is a statement that no one among the experts expects to see disproved » (6, p.133). Le paradigme apparaît comme l'unité justificative la plus sophistiquée sur laquelle doit s'appuyer une action. Le paradigme pose la valeur scientifique d'un savoir, c'est-à-dire sa scientificité (ex. : la validité). Le paradigme encapsule ainsi un raisonnement collectif sur l'exactitude : « I will present in this chapter twelve fundamental biological concepts that seem important to me as a mechanistic biologist, because of my conviction that bioethics must be based on modern concepts of biology and not on unsupported introspection. » (6, p.130) Cependant, les paradigmes sont des connaissances sophistiquées et, donc, souvent hermétiques pouvant confondre aussi bien l'auditeur que l'utilisateur de la notion. Potter critique ainsi la *Structure des révolutions scientifiques* de

[19] L'auteur critique le terme anglais « stewardship » référant au « steward », un maître d'hôtel. Sur un plan historique, l'intendance rappelle la relation de pouvoir du propriétaire d'une habitation sur ses employés, ses domestiques ou ses esclaves, voire, sur un plan philosophique, l'intendance réfère à l'économie politique (*Oikos nomos* les règles de la maison, de la société, de l'habitation). Les « affaires naturelles » sont trop compliquées à déchiffrer pour être administrées par cette relation asymétrique du pouvoir, d'ailleurs seule une partie de l'*affaire* n'est habituellement visible à l'intendant (ici l'humain) comme l'explique Charles Churchman (1913-2004) par l'idée du *Wicked problem*. L'usage du terme « gouvernance » pose le même défi conceptuel que « intendance », bien qu'il ouvre à la possibilité d'une gouvernance démocratique, voire adaptative. Cependant, le concept de gouvernance demeure lié à l'idée d'avoir le contrôle sur l'entièreté d'une *embarcation* par le biais de son *gouvernail*, alors que, en réalité, aussi bien l'*eau* que le *bateau* sont des organisations complexes, dont un gouvernail est incapable d'avoir à lui seul le contrôle sur la direction de cette technologie (bateau) et de cette société (équipage) dans l'environnement (eau).

Kuhn soulignant le défi d'inférer cette perspective directement à l'éthique, comme discuté ci-dessus. La logique de cette structure appliquée à l'éthique doit chercher à briser cet hermétisme à l'aide d'outils médiateurs (des ponts interdisciplinaires), car les *révolutions politiques*, notamment des techniques et des pratiques, n'émergeront que d'une négociation entre ces valeurs scientifiques et les valeurs en société.

Potter s'intéresse davantage au modèle logique de la *structure des révolutions* qu'au paradigme lui-même. Il utilise ce modèle pour expliquer le fonctionnement de la bioéthique. Il souligne l'analogie entre ce modèle philosophique et la théorie de l'évolution de Darwin. Sous cette métaphore, le paradigme devient un marqueur traçant la structure du programme scientifique analogue au gène pour le « programme » du vivant, l'ADN (6). Le paradigme apparaît comme un moteur social de l'innovation des techniques et des technologies en fournissant le *programme spécifique*. Par cette analogie, Potter propose en 1964 l'innovation technologique comme un phénomène d'adaptations culturelles, souvent involontaire (non dirigé), mais pouvant être démocratisé (20). Par exemple, les sciences médicales peuvent appuyer la progression des normes de pratique – ils traduisent ainsi le paradigme en *vocabulaire* social. Ces normes peuvent aussi progresser par l'application des techniques ; à titre d'exemple, le retour en expérience de la chimiothérapie auprès des patients. Cet élargissement du cercle organisationnel permet d'englober plus de considérations, dont l'inaccessibilité aux soins qui est cause de souffrance échappant à l'œil soignant rivé au patient en clinique (5).

L'évolution du programme est toutefois déterminée par son contexte, c'est-à-dire son *écosystème*. Ainsi, Potter souligne l'importance d'une bioéthique médicale (en se focalisant sur le programme) et d'une bioéthique écologique (en élargissant jusqu'au contexte), mais souligne le besoin d'une bioéthique les englobant toutes deux (11). Par le contexte, Potter souligne que l'opération du paradigme est influencée par des intérêts pouvant modifier le *plan* initial prévu par le programme. Ces intérêts sont non seulement collectifs, c'est-à-dire scientifiques (ex. : facultés, départements et chaires) et politiques (ex. : ministères et organisations mondiales), mais aussi particuliers (ex. : citoyen, industrie et groupes sociaux) (11). Puis, la confluence entre ces valeurs et ces intérêts donnent lieu à des mouvements sociaux comme l'actuelle « aide humanitaire » ou « santé planétaire ». Ces mouvements se matérialisent en événements (ex. : les Sommets de la Terre comme rencontres décennales organisées par l'ONU depuis 1972 entre les dirigeants du monde) et en documents (ex. : la Déclaration de Rio de Janeiro du 3 au 14 juin 1992 comme réaffirmation de la Déclaration de la Conférence des Nations Unies sur l'environnement adoptée à Stockholm le 16 juin 1972) marquants le discours émergeant (ex. : concilier santé, développement et environnement). Une dialectique s'installe donc entre science (bio), humanité (éthique classique) et communauté (éthique pratique). Cette dialectique ne doit pas se restreindre à des équipes ou à des départements (inter)disciplinaires, mais se concevoir comme une *éthique-action* posant une alliance entre les diverses réalités de la communauté à la manière d'un système de communication ou de traduction (59).

LA BIOÉTHIQUE GLOBALE COMME L'ORGANISATION COMPLEXE DE LA BIO-ÉTHIQUE

La bioéthique se construit sur un savoir plus que scientifique (5, p.1). Ce savoir vise à la responsabilisation des communautés. Potter introduit ainsi le processus de « self-governance » émergeant du phénomène de coopération au sein des communautés et de leur résilience. Un vaste système de gouvernance est nécessaire pour opérer le jugement critique émergeant d'une éthique exercée en continu au regard de l'action humaine (12). Cette gouvernance vient proposer un *modus operandi* aux deux cadres introduits plus haut (Tableau 1 et Figure 1). Cette *bio-éthique* comprend, donc, une dynamique organisationnelle complexe analogue aux organisations biologiques. Andrew Light formule cela en analysant l'organisation de la bioéthique en milieu médical :

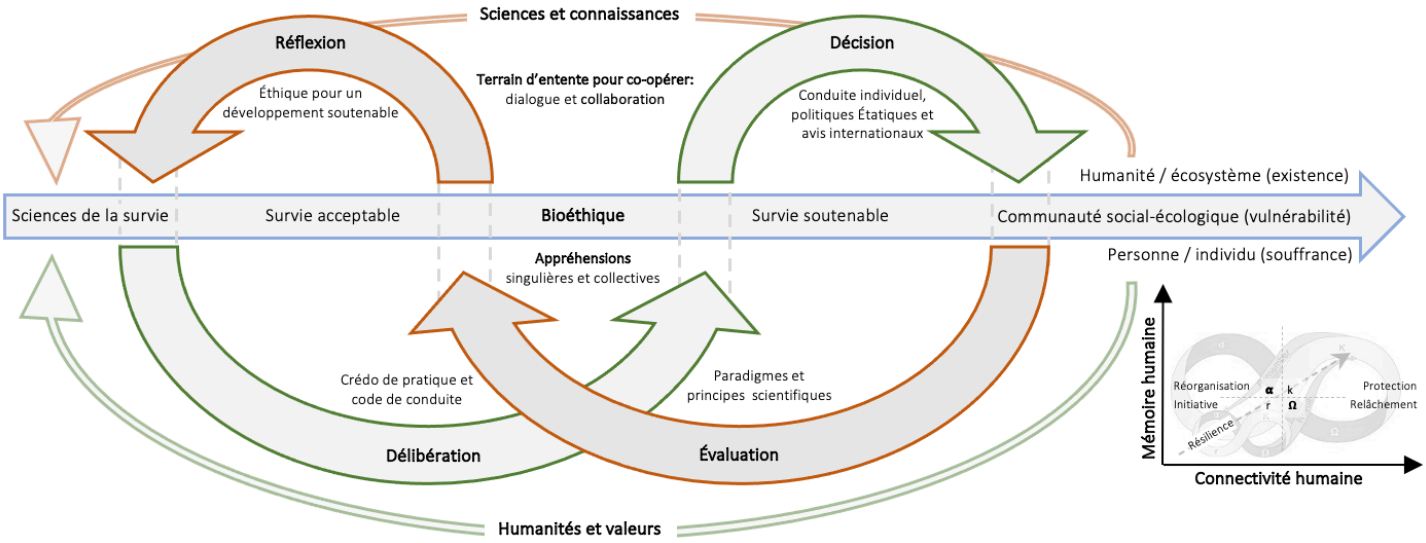
> Bioethicists are thoroughly integrated into the medical establishment at almost every level from education to professional, national, and international policymaking. The best ethicists are experts in the particular questions they work on and are valued core members of interdisciplinary teams working on solutions to particular problems. (69)

La Figure 2 synthétise le mode de fonctionnement de cette gouvernance adaptative en fondant l'explication sur le cadre conceptuel du modèle panarchique de la résilience social-écologique (27,71). La science de la survie (6) et le code de bioéthique (19) structurent la dynamique (adaptative, prospective, globale et profonde), le programme (sagesse et gouvernance) et la mission (communautaire : science, société et politique) de la bioéthique (Tableau 1). Potter propose donc une organisation (profondément) transdisciplinaire, plutôt qu'interdisciplinaire sur la surface, s'opérant de manière communautaire comme une faculté collective à s'adapter par l'*écosystème* d'une *bio-éthique* (21). La bioéthique a ainsi pour mission d'avancer la vision collective de changement en définissant les problèmes partagés par l'ensemble de la communauté (Figure 2, *Reflexion*) : « major problems of our time » (5, p.154-55). La bioéthique doit être profondément interdisciplinaire (Figure 2**,** *Délibération*): « The new disciplines will be forged in the heat of today's crisis problems, all of which require some kind of a mix among basic biology, social sciences, and the humanities. » (6, p.128) Elle doit adopter un nouveau mode critique formulant les innovations par communauté (Figure 2**,** *Décision*) : « We are in great need of a land ethic, a wildlife ethic, a population ethic, a consumption ethic, an urban ethic, an international ethic, a geriatric ethic, and so on. » (6, p.127) Chacune de ces éthiques se pose comme pont médiateur, c'est-à-dire un terrain d'entente entre des parties devant coopérer par la formule sophistiquée d'une traduction entre leur science respective, c'est-à-dire une interdisciplinarité. Par exemple, *Land* ne renvoie ni à la société humaine, ni à l'environnement biologique, mais à l'habitat où y coopère la communauté située sur cette terre. Ainsi, « Science of survival must be more than a science alone, and I therefore propose the term "bioethics" in order to emphasize the two most important ingredients in achieving the new wisdom that is so desperately needed: biological

knowledge and human values » (5, p.1) (Figure 2, *Évaluation*). Enfin, la mission commune visée est de collaborer, de s'engager et d'améliorer le monde dans lequel nous vivons.

> We who follow Aldo Leopold are obligated to note not only his pioneering efforts but also the publications of the new breed of concerned biologists, ecologists, and people of many disciplines who are concerned with the problem of acceptable survival for human species. The issue, in plain English, is "What we must do", to use the title of a 1969 article by John Platt, published in Science (11).

Figure 2. Le cycle adaptatif appliqué à la bioéthique



Inspirées du concept des cycles adaptatifs conceptualisé par Holling (26), quatre fonctions de l'écosystème de la bioéthique (r, k, **Ω**, **α**) sont détaillées (respectivement, la délibération, la décision, l'évaluation et la réflexion) et le phénomène conduisant à l'émergence des *Sciences et connaissances* (**rouge**), des *Sciences humaines et valeurs* (**vert**) et de la *Bioéthique* (**bleu**). La *Science de la survie* (**bleu**) apparaît comme un pont entre les sciences naturelles, sociales et humaines venant intégrer, critiquer et recommander une trajectoire acceptable à la bioéthique pour constituer un ensemble de savoirs prospectifs visant à commander l'action de façon à l'intégrer à de multiples échelles d'organisation de l'existence humaine. Par des compétences interculturelles, les sciences et valeurs humaines (**vert**) visent à développer un savoir sur les systèmes de valeurs coconstruits auprès d'un cercle extensif d'acteurs coopérants dans la communauté de manière à y saturer les perspectives y émergeant. Par compétence interdisciplinaire, les sciences et connaissances (**rouge**) visent à développer un savoir de la complexité sur les sciences, les technologies et les sociétés.

CONCLUSION

Selon Potter, les décisions politiques doivent s'appuyer sur une sagesse plus profonde et pratique ainsi que sur une connaissance plus globale tout en demeurant locale. Potter fonde les rudiments nécessaires pour concevoir cette sagesse. Elle doit opérer par communauté, progresser par cycle d'aménagement et diffuser par divers modes de communication. Cette communication prend la forme de ponts médiateurs venant négocier et traduire les positions et les réalités des acteurs de la communauté (59). L'intention est de démocratiser les savoirs en enseignant comment bien utiliser les savoirs humains (ex. : les technologies). En guise d'ouverture, cet article vient s'inscrire dans la réflexion amorcée par Beever et Whitehouse (21) et plusieurs autres en 2017 visant à « relancer la bioéthique ». Cette relecture de l'œuvre de Potter à la lumière du legs de Leopold a pour effet d'ajouter un mode opératoire à ce que ces auteurs soulignent : « a reinvigoration of bioethics demands transdisciplinary intersections of ecology, value, and health – as a bridge connecting across to the identified projects of public health ethics ».

Cet article a donc pour but d'amorcer un nouveau chantier d'analyse de la pensée de Potter axé sur l'opérationnalisation de cette pensée au moyen d'un cadre théorique, puis par la pratique des projets scientifiques mis en action en société. Les rudiments de ce modèle pourraient jouer le rôle de chaînon manquant entre Sciences et Société, et s'avérer la solution recherchée par le paradigme de la complexité, les études sur la soutenabilité et l'approche écosystémique déployée en santé et en environnement à la suite de leur mention lors du Sommet de la Terre en 1995 à Rio. Au Canada, cette approche donne une étude de cas portée par les véhicules des Ministères fédéraux et provinciaux œuvrant en santé publique depuis Lebel (73) et en aménagement de l'environnement, notamment depuis Lajoie (74). Pour opérer cette vision, le défi est de situer l'objet de la bioéthique suffisamment à la frontière des savoirs et suffisamment en pratique pour démocratiser le processus de négociation et de jugement critique des systèmes de valeur afin de conduire véritablement cet examen collectif (75). L'idée d'*Une seule santé* fait émerger une approche, voire un paradigme, venant revoir ces délimitations conceptuelles entre les

savoirs (ex. : l'interface humaine, animale et environnementale). Comme le soulignent les bioéthiciens Beever et Whitehouse (21), cette dynamique doit aussi venir transcender les pratiques (ex. : l'intersection écologie, valeur et santé). Pour rendre tangible cette opération de la pensée de Potter, nous recommandons de retourner à l'origine des savoirs scientifiques – la donnée. L'émergence des nouveaux systèmes de technologies de l'information et de la communication, dont les environnements numériques, les approches par données massives et les méthodes d'intelligence artificielle, ne peut que matérialiser davantage ce processus collectif. Par cette voie, ce nouveau chantier d'analyse de la pensée de Potter a l'opportunité d'être aussi bien une source d'innovation pour l'avancement des théories que des pratiques.

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

La bioéthique selon Van Rensselaer Potter : une perspective pertinente à la réflexion ergothérapique contemporaine

Marie-Josée Drolet[a], Mélanie Ruest[a]

Résumé
Ce commentaire présente trois arguments de la pensée potterienne à partir de la lunette ergothérapique afin de soutenir les réflexions relatives au développement des pratiques durables en ergothérapie. Il permet ainsi d'initier les ergothérapeutes à une perspective de bioéthique globale susceptible de les soutenir dans l'actualisation d'une approche écosystémique respectueuse de l'environnement.

Mots-clés
bioéthique, éthique biomédicale, éthique environnementale, écologie, ergothérapie, Potter

Abstract
This commentary presents three arguments of Potterian thought from an occupational therapy perspective in order to support reflections on the development of sustainable practices in occupational therapy. In this way, it introduces occupational therapists to a global bioethical perspective that can support them in implementing an ecosystemic approach that respects the environment.

Keywords
bioethics, biomedical ethics, environmental ethics, ecology, occupational therapy, Potter

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INTRODUCTION

La réflexion sur les enjeux environnementaux actuels transcende les différents groupes sociaux et convie tout un chacun à analyser ses choix et ses comportements. Les professions de la santé et des services sociaux sont concernées par les questions entourant les enjeux environnementaux, puisque les recommandations qui découlent de leur exercice respectif (c.-à-d. maintien et amélioration de la santé des individus et des populations) s'inscrivent nécessairement dans un contexte où l'environnement fait (ou devrait faire) partie inhérente des variables à considérer dans une définition cohérente de la santé pour tous. À titre d'ergothérapeutes membres de la Communauté ergothérapique engagée pour l'équité et l'environnement (C4E), la lecture de l'œuvre de Potter (1,2) a mené à l'écriture de ce commentaire qui s'adresse aux ergothérapeutes[1] désireux d'actualiser une approche holiste de la personne et de sa santé.

La réflexion en ergothérapie ainsi que dans les sciences occupationnelles, consacrée à la durabilité écologique et aux pratiques durables de la profession, a plus spécifiquement été initiée en 1997 par Do Rozario (3). Avec la documentation croissante des changements climatiques à l'échelle mondiale et ses effets sur la santé des populations (4), les enjeux environnementaux suscitent de plus en plus de réflexions en ergothérapie (5,6), notamment dans les écrits anglophones (7-18). Par l'entremise de la présentation de trois arguments, nous visons spécifiquement à répondre à la question suivante : pourquoi les ergothérapeutes – peu importe leur environnement professionnel (réseau de la santé et des services sociaux, milieux de l'éducation, de la recherche ou communautaire, etc.) – devraient-ils lire l'œuvre de Van Rensselaer Potter (1,2)?

APPORTS DE L'ŒUVRE POTTERIENNE À LA RÉFLEXION ENVIRONNEMENTALE EN ERGOTHÉRAPIE

La réflexion de Potter mérite d'être connue par les ergothérapeutes, et ce, peu importe leur degré de sensibilisation à l'importance de la durabilité écologique en santé, pour trois raisons principales : 1) connaître une vision globale de la bioéthique; 2) appréhender les liens entre les échelles locale et globale de l'environnement pour soutenir la pratique éthique en ergothérapie; et 3) cerner l'ensemble de leurs responsabilités éthiques à l'endroit des générations présentes et futures d'êtres humains.

Compréhension globale de la bioéthique

Premièrement, les ergothérapeutes devraient lire Potter pour comprendre ce qu'est la bioéthique, telle qu'elle fut initialement définie. À partir du constat selon lequel la capacité de production actuelle des sociétés contemporaines menace la préservation et la régénérescence des écosystèmes desquels l'humanité dépend pour survivre, Potter crée le néologisme « bioéthique » en 1971 (1). Il stipule que l'éthique appliquée au monde du vivant est nécessairement un domaine pluridisciplinaire qui allie les sciences du vivant (ex. : biologie et médecine) aux sciences humaines et sociales (ex. : philosophie et littérature). La vision dominante de la bioéthique nord-américaine, articulée notamment par Beauchamp et Childress (19) et plusieurs auteurs en

[1] Le terme ergothérapeute renvoie ici à l'ensemble des membres de la communauté ergothérapique, c'est-à-dire l'étudiant en ergothérapie, l'ergothérapeute clinicien, l'enseignant, le chercheur, le gestionnaire, l'ergothérapeute retraité, etc.

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santé (19-21) tout comme dans les ouvrages généraux consacrés à la bioéthique (22-24), a plutôt tendance à circonscrire la bioéthique au domaine de l'éthique médicale ou clinique ou encore à l'éthique de la recherche. Peu d'auteurs reconnaissent l'origine de la discipline à partir des écrits de Potter. Or, la lecture de l'œuvre de ce dernier permet d'élargir la compréhension et l'application du concept de la bioéthique, en considérant l'éthique environnementale au même titre que l'éthique biomédicale (voire paramédicale afin de s'adresser aux professionnels de la réadaptation) pour soutenir l'acquisition d'une vision globale de l'éthique et de la santé. En effet, Potter détaille les liens d'interdépendance qui relient la santé humaine et l'environnement naturel et va au-delà des préoccupations de nature biomédicale pour considérer les capacités environnementales dans la discussion philosophique cherchant à résoudre de manière éthique les diverses problèmes rencontrés. À l'instar du philosophe Hans Jonas (25), Potter articule une éthique de la responsabilité à l'égard de l'environnement qui se présente comme une éthique de la survie du genre humain.

Considérant que les changements climatiques constituent l'une des plus grandes menaces contemporaines à la santé mondiale, voire à la survie de l'humanité (26), la pensée potterienne s'avère visionnaire à maints égards. Plusieurs scientifiques estiment, par exemple, que la crise sanitaire actuelle de la COVID-19 n'est pas étrangère à la crise climatique (27-28), en ceci que la crise écologique actuelle, occasionnée par les activités humaines et industrielles depuis la Révolution industrielle, a vraisemblablement contribué à la pandémie. La destruction des milieux de vie de maintes espèces animales aurait notamment facilité la migration du virus des animaux vers les humains (27). Ainsi, la lecture de l'œuvre de Potter donne accès à une vision globale de la bioéthique, c'est-à-dire à une vision de l'éthique qui englobe l'ensemble des êtres vivants, dont font partie les êtres humains, et qui fait percevoir les liens d'interdépendance entre la santé de l'environnement, celle des animaux et celle des êtres humains. Cette vision de la bioéthique, qui évite de compartimenter l'éthique en sous-catégories appliquées à divers domaines de l'action humaine, donne accès à une vision systémique biocentrée (plutôt qu'antropocentrée) qui permet aux professionnels de la santé, dont les ergothérapeutes, de comprendre les tenants et les aboutissants de la santé mondiale, voire de la survie de l'humanité.

La réflexion potterienne convie en effet à un changement paradigmatique dans la résolution des enjeux environnementaux actuels, passant d'une vision anthropocentrique (c.-à-d. centrée sur l'être humain) à une vision biocentrique (c.-à-d. centrée sur l'environnement incluant les êtres humains et les animaux) (1). Ce changement interpelle plus spécifiquement les ergothérapeutes à questionner, réviser, voire perfectionner, l'actualisation de plusieurs conceptualisations, pratiques et valeurs de la profession (ex. : approche centrée sur le client) afin que celles-ci soient davantage en harmonie avec une approche bioéthique biocentrique (1,4).

Compréhension des liens entre le local et le global

Deuxièmement, les ergothérapeutes devraient lire Potter afin d'appréhender les liens entre les échelles locale et globale de l'environnement, et ainsi, développer des outils de réflexion qui permettent de déchiffrer les enjeux éthiques dans leurs dimensions micro et macro systémiques. De fait, la réflexion potterienne permet d'appréhender les liens de dépendance qui relient de manière bidirectionnelle la santé des personnes à l'échelle individuelle (locale) à celle des populations à l'échelle mondiale (globale), voire à celle des écosystèmes. La bioéthique, telle que définie initialement par Potter, montre que les événements qui surviennent à l'échelle mondiale affectent ce qui se passe à l'échelle locale, et vice versa. Par exemple, la crise mondiale relative au COVID-19 affecte actuellement tout un chacun dans l'accomplissement des occupations qui caractérisent sa vie quotidienne pour limiter la propagation du virus et leurs conséquences. À l'inverse, les comportements individuels (respectueux ou non des diverses consignes de santé publique en vigueur) amènent une propagation plus ou moins rapide du virus et une évolution de la situation sanitaire plus ou moins favorable qui aura des conséquences sur la santé mondiale.

Lorsque Potter a écrit initialement son ouvrage *Bioethics: Bridge to the Future* (1) en 1971, l'humanité comprenait environ 3,7 milliards d'êtres humains (29). Le discours de Potter sur la limitation du nombre d'êtres humains sur la terre, pour assurer la survie du genre humain et soutenir la justice sociale (1), a pu initialement en étonner plusieurs. Or, cinquante ans plus tard, considérant que l'humanité a plus que doublé et compte maintenant 7,8 milliards d'êtres humains sur la planète (29) et qu'elle utilise les ressources naturelles du globe 1,75 plus vite que ce que les écosystèmes peuvent régénérer (30), la capacité de Potter à anticiper les enjeux futurs de l'humanité mérite une réflexion approfondie. Ainsi, sans avoir accès à des données aussi précises et robustes que celles détenues aujourd'hui à l'instar d'épidémiologistes contemporains qui montrent que les femmes ont en moyenne moins d'enfants et enfantent à un âge plus avancé dans les sociétés davantage égalitaires (32), la pensée potterienne rejoint celle d'auteurs actuels qui discutent de la pertinence éthique de limiter le nombre d'enfants pour des raisons écologiques (33).

S'ils ne sont pas contextualisés, ces énoncés de Potter peuvent s'avérer facilement contestés. Au regard de la justice sociale qu'il souhaite défendre dans sa réflexion, ce sont les situations problématiques qui sous-tendent cette augmentation démographique (ex. : faible accès à l'éducation des femmes dans certaines régions du globe) qui doivent être analysées[2]. La question soulevée par la situation démographique actuelle est également liée au niveau de vie valorisé (c.-à-d. consommation élevée de biens et de services), qui est revendiqué par une proportion croissante de populations à travers le monde. Plusieurs de ces choix occupationnels fragilisent de manière plus prononcée nos écosystèmes. Dans cette perspective, la justice sociale

[2] Potter discute de différents éléments qui ont contribué à l'augmentation démographique sur la planète, parfois controversés (ex. : faible contrôle des naissances respectueux des libertés et des volontés des femmes dans les pays en voie de développement). Plusieurs autres facteurs tels que l'évolution de la médecine et de la santé publique (ex. : augmentation de l'espérance de vie) participent aussi au phénomène d'augmentation de la démographie.

à laquelle réfère Potter fait aussi écho à la justice occupationnelle[3] pour l'ensemble des groupes sociaux d'une société. Les ergothérapeutes sont ainsi à même de constater à quel point l'organisation des sociétés humaines, notamment la répartition des richesses et des opportunités sociales est à même d'affecter la justice occupationnelle.

La lecture de la réflexion potterienne a donc également le potentiel de soutenir les ergothérapeutes dans l'identification des dimensions systémiques (souvent difficiles à percevoir) qui contribuent à expliquer les enjeux éthiques auxquels ils peuvent être confrontés dans le quotidien de leur pratique professionnelle. Ils seront ainsi plus à même d'entreprendre des activités d'*advocacy*, c'est-à-dire des activités qui visent la défense et la promotion des droits et des intérêts des clients (34).

Identification des responsabilités éthiques en ergothérapie

Troisièmement, les ergothérapeutes devraient lire Potter pour cerner l'ensemble de leurs responsabilités éthiques. La notion de responsabilité, un des concepts clés de la réflexion potterienne, peut être déclinée sous plusieurs formes. À l'échelle individuelle, Potter définit notamment le concept de santé de la personne à partir de la perspective selon laquelle les individus ont une grande part de responsabilité dans la préservation de leur santé et la prévention des maladies. Dans le même ordre d'idées, à l'échelle sociale, la responsabilité éthique de la sollicitude dans les relations entre les êtres humains, mise de l'avant notamment par l'approche éthique de Gilligan sur laquelle Potter s'appuie (35-37), permet d'appuyer l'analyse bioéthique des enjeux environnementaux actuels sous l'angle de responsabilités conflictuelles ou non actualisées par l'ensemble des êtres humains, plutôt qu'exclusivement sous l'angle de droits concurrents.

À l'échelle professionnelle, les ergothérapeutes peuvent concevoir de manière relativement aisée les responsabilités éthiques qui leur incombent lorsqu'ils planifient leurs interventions en clinique auprès de clients en particulier. Cependant, il peut s'avérer plus difficile pour eux d'envisager les responsabilités éthiques qu'ils ont ou pourraient avoir envers les clients qui ne sont pas directement en leur présence ou sous leur responsabilité immédiate (20). Par exemple, il peut leur être plus ardu de se sentir responsables des clients inscrits sur la liste d'attente, particulièrement lorsqu'ils ont une grande quantité de travail ainsi que peu de soutien de leur organisation. Il peut aussi être difficile pour certains ergothérapeutes de se sentir concernés par les clients non actuellement desservis par les organisations de santé et de services sociaux en raison d'injustices systémiques ou de vides de services. Enfin, il peut être encore plus complexe pour maints d'entre eux de percevoir leurs responsabilités à l'égard des générations futures d'êtres humains. L'œuvre potterienne amène donc une conception qui se révèle, *a priori*, ni évidente ni intuitive pour la majorité des professionnels de la santé, dont les ergothérapeutes. Potter suggère une piste de réflexion différente sur la définition de la santé et sur la manière dont les ergothérapeutes peuvent amener une contribution différente, mais complémentaire avec leur perspective occupationnelle.

Potter décrit initialement cinq stades dans l'actualisation de cette vision bioéthique globale au sein des organisations et des sociétés humaines (38) : 1) les dommages environnementaux deviennent visibles pour « l'individu moyen », suscitant l'indignation morale; 2) la connaissance de ces dommages fait évoluer une nouvelle discipline, c'est-à-dire – la bioéthique écologique; 3) l'indignation morale exige des contre-mesures préventives; 4) la pression morale et les informations factuelles génèrent des directives bioéthiques et 5) les directives sont converties en sanctions légales. Plusieurs organisations professionnelles en ergothérapie se situent présentement aux stades 3 et 4. Par exemple, le College of Occupational Therapists (39), le Réseau pour le développement durable en ergothérapie (40), la Swedish Association of Occupational Therapists (41), la Fédération mondiale des ergothérapeutes (42) et le Sustainability Occupational Therapy Network (43) soutiennent les arguments selon lesquels les ergothérapeutes devraient : 1) comprendre ce qu'est la durabilité écologique; 2) explorer les modes de vie durables; 3) soutenir les personnes et les communautés dans les adaptations occupationnelles à prévoir et à actualiser au regard des dommages causés à l'environnement; 4) renforcer la durabilité des communautés et 5) développer leurs compétences professionnelles pour traiter les questions de la durabilité dans leurs interventions.

Pourquoi l'ergothérapeute devrait-il devenir un professionnel écoresponsable comme l'enjoignent de le faire ces organisations et ces regroupements professionnels? Comme l'a vu Potter (1-2) et le confirme de nos jours le Groupe intergouvernemental d'experts sur l'évolution du climat (GIEC) (44), la crise climatique constitue l'une des plus grandes menaces à la santé humaine, voire à la survie du genre humain. Considérant aussi que les occupations humaines sont les principales responsables des changements climatiques, nombreux sont les auteurs qui considèrent que les ergothérapeutes doivent contribuer à la lutte aux changements climatiques (1-13). En effet, puisque les ergothérapeutes sont les spécialistes de l'occupation humaine (45), ceux-ci détiennent l'expertise nécessaire pour soutenir les personnes et les communautés à entreprendre les transitions occupationnelles (ex. : alimentation, transport) qui sont les plus susceptibles de respecter les capacités de régénérescence des écosystèmes (éthique environnementale) et d'améliorer la santé des populations (éthique biomédicale, éthique de santé publique).

Somme toute, la lecture de la réflexion potterienne peut finalement aider les ergothérapeutes à mieux comprendre leurs responsabilités éthiques envers les générations futures d'êtres humains. Si les ergothérapeutes valorisent véritablement l'engagement de tout être humain dans des occupations qui sont porteuses de sens pour lui et qui contribue à sa santé et à son bien-être, ils devraient dès lors également valoriser le fait que les êtres humains de demain puissent faire de même : c'est une question de justice occupationnelle intergénérationnelle (12).

[3] Justice occupationnelle : Principe éthique visant à reconnaître et à promouvoir le droit de tous d'avoir accès équitablement à des conditions de vie qui leur permettent de s'engager dans des occupations variées et signifiantes (31).

CONCLUSION

En ce début du XXIe siècle, la crise environnementale convie les professionnels de la santé, dont les ergothérapeutes, à devoir réfléchir sous un nouvel angle plusieurs notions éthiques dans la prestation des soins de santé et de services sociaux. Parmi les penseurs qui ont significativement influencé le développement de la bioéthique, Potter fait partie de ceux dont la réflexion a le potentiel d'outiller les ergothérapeutes dans la définition d'une offre de services écoresponsables et, ainsi, faciliter les transitions occupationnelles à venir afin de diminuer les conséquences environnementales négatives des occupations humaines sur la santé des populations et des écosystèmes. Trois arguments furent présentés afin d'inviter les ergothérapeutes à lire et à analyser l'œuvre de Potter afin d'alimenter la réflexion sur la définition des pratiques durables à promouvoir en ergothérapie. Les ergothérapeutes doivent prendre part activement à ces réflexions afin d'orienter le développement et l'exercice de la profession qui se veulent soucieux de la promotion de la santé et du bien-être de tous, dans le respect de la préservation de l'environnement.

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

Lessons from the COVID-19 Pandemic: A Call to Implement (and Reimagine) Bioethical Principles

Vugar Mammadov[a], Lala Jafarova[b]

Résumé
Ce commentaire analyse les dilemmes éthiques auxquels la communauté mondiale a été confrontée pendant la pandémie de coronavirus. L'importance des droits de propriété intellectuelle dans le contexte de la distribution des vaccins est particulièrement soulignée. Les auteurs mentionnent les principes bioéthiques – « oubliés » mais si importants – dans le contexte de la distribution des vaccins.

Mots-clés
COVID-19, pandémie, principes bioéthiques, vaccins, propriété intellectuelle, santé mondiale

Abstract
The commentary analyses ethical dilemmas faced by the global community during the coronavirus pandemic. The importance of the intellectual property rights in the context of vaccine distribution is particularly emphasized. The authors highlight bioethical principles – "forgotten" but so significant – in the context of vaccine distribution.

Keywords
COVID-19, pandemic, bioethical principles, vaccines, intellectual property, global health

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INTRODUCTION

The coronavirus 2019 (COVID-19) pandemic revealed the vulnerability, not only of the medical and social spheres of life, but also of the practical implementation of bioethical principles. Historically, the development of modern bioethical principles was in response to the infamous events of World War II. The Nuremberg Code, adopted after the Nazi doctors' trial in Nuremberg, Germany, was the starting point for a new international medical-legal and bioethical discourse. It proclaimed the need for special protection of the research participants (1), an ethical concept articulated as respect for autonomy and informed consent to participate in research. However, modern bioethical principles address much broader issues than individual consent to medical research, as become evident during the COVID-19 pandemic. For example, internationally recognized individual-oriented bioethical principles turned out to be practically unrealizable during the emergency of a global scale, especially where conceptions of global justice are still in their infancy. These gaps in bioethics discourse resulted in declarative (non-legally binding) bioethical principles being mostly left out of the international response to the virus.

To address this situation, we argue that the Universal Declaration on Bioethics and Human Rights (UDBHR) should evolve into a component of international law – i.e., be the predecessor of a new document, an "International Convention on Bioethics" (2). The COVID-19 pandemic should become a starting point for both reimagining bioethical principles and developing the legal mechanisms for their practical implementation. A parallel development in political and scientific circles is the widely discussed need for a pandemic treaty (3,4). The International Convention on Bioethics and the Pandemic Treaty should thus develop in tandem. Specifically, the Treaty's provisions ought to be articulated through the lens of newly envisioned bioethical principles. The COVID-19 pandemic allowed us to identify both weaknesses and omissions in bioethical principles and offers a unique opportunity to re-think their practical implementation on an international scale. We propose that an International Convention on Bioethics include 4 principles: *global sharing of benefits*, *global health equity*, *social responsibility for health*, and *global solidarity and cooperation*.

PRINCIPLE 1: GLOBAL SHARING OF BENEFITS

A bioethical principle of G*lobal sharing of benefits* would ensure that the benefits "resulting from any scientific research and its applications" are shared not only domestically but within the global community, especially with economically developing countries (5). In current practice, the vaccines (and other medications) are granted Intellectual Property (IP) rights and protected by the Word Trade Organization's TRIPS agreement (6), and these monopoly rights are very often used to limit sharing. On the one hand, transnational corporations, e.g., the leading multinational pharmaceutical companies, spend considerable resources (primarily financial) to pay scientists, conduct research, purchase modern equipment and create an infrastructure for conducting clinical trials. On the other hand, these innovations result from considerable public investment (principally governments) and may involve clinical research in low- and middle-income countries. As such, states should arguably have the authority to share resources (innovations) to which they contributed, while low-income countries that helped with the development of vaccines deserve reciprocity and access. The low-income countries often cannot afford to pay costly licensing agreements to patent holders, nor produce vaccines on their own; neither can they fund vaccine development due to a lack of resources, both scientific and financial. Thus, vaccines, especially during the pandemic, can become a "stumbling

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block" for the implementation of an effective fight against a pandemic, for those countries. The fact that funding for the development of most COVID-19 vaccines came largely from national governments (7) and charitable foundations challenges the idea that the control (i.e., patents) and financial benefits should be the exclusive province of private pharmaceutical companies. This public source of financing gives grounds for calling these "people's vaccines" (8), thereby implying equal access rights by all people.

Operating on the possibility of waiving exclusive rights, in October 2020, India and the Republic of South Africa came up with a joint proposal to abandon certain types of intellectual property rights during the pandemic (9). However, the proposal has not gained the unanimous support of members states at the World Trade Organization, which is required to amend TRIPS (10). Unfortunately, the principles of fair sharing have not been implemented and applied during the COVID-19 pandemic. Instead, high-income countries have launched mass vaccination programs, which today also cover children and booster doses, whereas in many low-income countries, even vulnerable groups and individuals at increased risk of infection are still waiting for their first dose. This situation has widened vaccine inequality and prolonged the pandemic.

Unfortunately, in terms of bioethical principles, vaccine distribution has not been a case for the "*sharing of benefits*". Attention was focused more on economic-legal aspects instead of ethical; some media have even called upon the need to discontinue the "practice of treating drugs as a commodity" (11). The bioethical aspect of the issue was not widely discussed, although bioethical principles, due to their "universality" and as internationally recognized values, have the potential to form the basis in this regard. In June 2021, the European Union made a new proposal to the WTO, which includes a "multilateral trade action plan to expand the production of COVID-19 vaccines and treatments and ensure universal and fair access" instead of waiving IP rights (12). Proposals include expanding the production and supply of vaccines and medicines for COVID-19. Further, the EU recently drafted a Declaration concerning IP rights (13), and according to the TRIPS Council, debates about the IP response to COVID-19 will continue (14).

However, it is not only vaccines that should be considered as a "common good" – also included should be drugs, masks, ventilators etc., as these are all necessary to save patients' lives during the pandemic. Unfortunately, in countries where there is a shortage of even basic medical masks or a lack of stable electrical supply necessary to maintain the operation of refrigeration units, it is difficult to talk about access to or the production of innovative vaccines, especially those that require special cooling units for storage and transportation. In the current pandemic, a significant obstacle to the acquisition of vaccines was precisely the lack of appropriate infrastructure in the purchasing country. Through foreign economic intervention, many African countries have even been provided with solar-powered refrigerators; however, their temperature did not match the storage requirements of many COVID-19 vaccines (15). Complicated vaccine storage requirements have discouraged even the most modern hospitals in the United States and had a negatively affected availability in rural areas (16). It is not surprising that for countries where resources are far more limited, such a task is practically impossible without the help of donor states or the world community. Thus, the TRIPS agreement is not the only obstacle to the provision of vaccines; even if self-production rights are granted, many countries do not have the capacity to start this process. The issue is not just technology transfer, but also training, development of regional capacity, infrastructure, etc. Vaccine production, purchase and distribution cover many issues within healthcare that may have direct or indirect implications for the fight against the pandemic; there are not only medical but also social aspects underlying this problematic situation. Therefore, we are now seeing, in debates about the pros and cons of the IP waiver, discussions of logistics, technology pooling and opposition from the pharmaceutical sector (17). By mobilizing a principle of global sharing of benefits in a "pandemic treaty on the bioethical principles", it would then be possible to adopt and implement numerous collective measures/strategies, including conditions for temporary IP rights waivers or the creation of a universal vaccine database and production infrastructure.

PRINCIPLE 2: GLOBAL HEALTH EQUITY

The economic development of states has had a direct impact on their ability to respond to the COVID-19 pandemic, as well as contributing to global economic inequality. A 2020 study conducted by the Health Foundation showed that the population living in the wealthiest regions was 50% less likely to die from COVID-19 than those in the poorest regions (18). High-income countries purchased much more than the required amount of COVID-19 vaccine for their populations. According to data for November 2020, "developed countries, where 14% of the world's population lives, purchased 53% of all world stocks of promising vaccines" (19). As a result, many low-income countries, especially in Africa, were left without access to vaccines or with major shortages, and so mass vaccinations in these countries are not expected to begin before the end of 2022. Some have called COVID-19 a "*syndemic*, a convergence of biosocial forces that interact with one another to produce and exacerbate clinical disease and prognosis" (20), thus pointing to its numerous synergistic features. The crisis has demonstrated that social factors such as poverty are one of the decisive factors when it comes to public health. In addition, the level of socio-economic development itself raises *ethical* issues. Eliminating the roots of inequality among different groups and countries, i.e., striving for global health equity, should become a primary goal for an eventual pandemic treaty.

PRINCIPLE 3: SOCIAL RESPONSIBILITY FOR HEALTH

A further bioethical concern regarding vaccines relates to social responsibility for health. Given the emergency context, vaccines began to be distributed before they went through the full phases of clinical trials, under "emergency authorization" (21), with the result that populations were both patients and real-time research participants. There is no doubt that, amidst high rates of mortality, states were ethically compelled to release vaccines prior to trial completion. However, was

the bioethical principle of respect for autonomy, operationalised through *informed consent*, implemented appropriately? During an emergency, setting aside this principle can be ethically justified; however, do all people consider the pandemic to be an emergency? Did the doctors have enough time to explain all aspects of vaccination to the patient, to take blood tests in case of potential health-related conditions? Unfortunately, in the background of the pandemic has been a mass of false and misleading information about vaccines (22), which made many people reluctant or frightened to be vaccinated. How can one measure a person's responsibility for refusing vaccination? Does the person understand and fully realize the responsibility to other members of society? Further, how can a state "promote health and social development" during such an extreme situation as a pandemic? Is it possible to supersede individual interests for the interests of society? During the COVID-19 pandemic these concerns were not adequately addressed and point to the need for two interconnected bioethical principles: *solidarity and cooperation* and *social responsibility for health.* It is a social responsibility to protect people's informed consent and choice, which requires regulating social media and ensuring public health campaigns that are culturally appropriate and meet the needs of a diverse public. And it requires social solidarity and cooperation to agree on collective responses; but this solidarity cannot be simply local (within a community or country), it must also be global.

PRINCIPLES 4: GLOBAL SOLIDARITY AND COOPERATION

Vaccine distribution has become a prime example of the urgency of implementing bioethical principles, and it illustrates their interconnection. Adopted in 2005, the UDBHR principles outlined the general mechanisms for international solidarity and cooperation in the field of science and medicine. The bioethical principles of *global solidarity and cooperation* promote international cooperation aimed at the encouragement of public health practices and collaborative agreements that are not only local, but also global. The distribution of vaccines was a perfect example of a failure of such global solidarity. Discord between countries was rooted in concerns to defend and respond first to national interests. The purchase and distribution of vaccines between high-income countries has left low-income countries at the end of the vaccine cue, dependent on international aid. According to the data from July 2021, "only 1.1% of people in low-income countries have received at least one dose" (23). This data should be cause for concern all countries, because pandemic viral disease can be stopped only when most of the world's population is vaccinated – "No one is safe, until everyone is" (24,25).

The UDBHR, unfortunately, does not include definitions of the bioethical principles; the meaning and application of solidarity, in practice, thus remains somewhat vague. While some authors describe it as "enacted commitments to accept costs to assist others with whom a person or persons recognise similarity in a relevant respect", they also stress that in practice it may include more factors of "social interconnectedness" (20). The bioethics literature covers different contexts of solidarity but in terms of national and global interests, values of solidarity may clash with a struggle for survival. During the COVID-19 pandemic, where risks and interests are very unevenly disturbed, it is unlikely that the entire population "will accept the costs of containing pandemics *out of solidarity with each other"* (26). If there is inadequate or limited solidarity among the population of one country, how can we expect all countries to act in global solidarity? Collective struggle "is particularly pertinent to situations where no other ties exist to bind people together" (27). In the context of global health, solidarity during the early stages of the COVID-19 pandemic was significantly disrupted, especially with regards to vaccination – each country tried to obtain as much as possible. Today we see that even in the face of a common threat, human solidarity ends where health issues begin; the same applies to countries protecting their own population first.

The COVID-19 pandemic, in addition to mobilizing purely medical aspects, should be also considered from the bioethical point of view in its broadest context. Nunes describes the pandemic as a "global vulnerability" (28) because it showed that public health is the key to a sustainable life of *solidarity* at the global level. Building on this analysis, the pandemic emphasized the *vulnerability of the global* community and showed that during the emergency no state can return to "normal" unless the entire world is protected – this should be accepted as a basis for both local and global solidarity.

CONCLUSION

The unequal global distribution of COVID-19 vaccines showed how the bioethical principles of the UDBHR and other treaties were incomplete and inadequate, and so readily "forgotten". From the point of view of international relations, a sharp tension emerged between state and international interests, which led to self-defeating actions. During a global pandemic, no one's interests are served by forgetting ethics or by acting out of narrow national self-interest. The practical difficulty of implementing bioethical principles during an emergency has challenged states and international groups alike and so points to the need for a joint International Pandemic Treaty and an International Convention on Bioethics. Following the African Ebola epidemic, an Independent Panel on the Global Response to Ebola analysed the global response to the outbreak and produced 10 recommendations that provided a roadmap for strengthening disease prevention and improving response (29). However, as the COVID-19 pandemic demonstrated so clearly, these recommendations were not put into practice. It is urgent that declarative bioethics principles be implemented in global treaties and policies so that they can lead to better collective practices, and thus a better world. The need to do this is part of our larger *responsibility to future generations*. We can and must do better.

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

The Case for the Vaccine Passport

Jocelyn Maclure[a,b], Keven Bisson[a]

Résumé
Dans ce commentaire critique, nous abordons la critique égalitaire selon laquelle l'utilisation d'un passeport vaccinal est contraire à l'éthique car elle entre en conflit avec le principe d'égalité, compris comme exigeant que les citoyens soient traités de la même manière. Nous soutenons que cette critique est vulnérable à l'objection de nivellement par le bas souvent adressée à certaines théories égalitairistes. Nous ajoutons que le passeport vaccinal est moralement justifié si deux conditions éthiques minimales sont remplies : 1) il doit être conçu comme une restriction de santé publique temporaire et transitoire, et 2) les disparités de traitement qu'il introduit doivent empiéter le moins possible sur les droits fondamentaux et ne doivent pas empêcher l'accès aux services publics essentiels.

Mots-clés
passeport vaccinal, preuve d'immunisation, Covid-19, égalité, équité, éthique de la santé publique

Abstract
In this critical commentary, we address the egalitarian critique according to which the use of a vaccine passport is unethical because it conflicts with the principle of equality, understood as requiring that citizens ought to be treated in the same way. We argue that this criticism is vulnerable to the levelling-down objection often addressed to some egalitarian theories. We add that the vaccine passport is morally justified if two minimal ethical conditions are satisfied: 1) it must be designed as a temporary and transitory public health restriction, and 2) the disparities of treatment it introduces ought to infringe as little as possible upon fundamental rights and should not negate access to essential public services.

Keywords
vaccine passport, immunization proof, Covid-19, equality, fairness, public health ethics

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INTRODUCTION[1]

Managing a pandemic at the national level requires a strategic plan that articulates a range of public health measures to contain the spread of the virus. The current epidemiological context at the time of writing – often associated with the "fourth wave" in the Covid-19 pandemic – has persuaded many countries to use a new tool: an immunization certificate granting access to certain services or activities.

The introduction of this immunization certificate, known as the "vaccine passport" in Quebec, the "vaccine record" in Newfoundland, and the "vaccine certificate" in Ontario for example, has been highly controversial. This reaction is understandable, because the policy establishes a two-tier system of rights for citizens based on their immunization status. Thus, people who have received the second dose of a two-dose vaccine can benefit from nonessential activities such as going to the theatre, eating in restaurants, or siting in the stands to watch their child's hockey game, while others cannot take advantage of the same opportunities. The ethical questions related to these disparities in treatment between the vaccinated and the unvaccinated is a growing concern as some countries, like Austria, have implemented a temporary lockdown for all citizens and then lifted it only for the vaccinated. In Austria, a vaccine mandate will go into effect in February 2022 (2).

In countries where everybody aged 12 and over who wish to be vaccinated have been able to do so, it is now the freedom of choice regarding vaccination and the rights and duties of those who are not vaccinated that are central to the ethical debate on vaccine passports. Is it fair to grant rights and opportunities to those who are adequately vaccinated and deny them to those who are not?

DOES FAIRNESS REQUIRES IDENTICAL TREATMENT?

The modern democratic era was propelled, according to Tocqueville, by a "passion for equality". If the "democratic individual" generally tolerates disparities in wealth, she dislikes what she sees as privileges reserved for the members of certain categories of citizens. The democratic individual has more "ardent and enduring love, Tocqueville wrote, of equality than of liberty" (3). Equal rights or, to refer to John Rawls' first principle of justice, "equal liberty", are seen as sacrosanct and as a bulwark against a return to the *Ancien Régime*.

Unsurprisingly, most critics of the use of the vaccine passport at the national level[2] base their criticisms on the two key principles of political legitimacy: *freedom* and *equality*. On the one hand, some critics see public health measures in general,

[1] This paper is a substantially revised and augmented version of a French-language manuscript by the authors, to be published in 2022 (1).
[2] A growing set of objections to vaccine passports are related to the disparities in vaccine access between countries. Even though this is an important issue, this article will solely focus on the national question (5).

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and the vaccine passport in particular, as unduly restricting basic freedoms. Although widespread, we will only allude to the criticism of those who oppose public health measures on the grounds that they restrict the freedom of citizens in an excessive and unjustified manner and that the harm caused by the Covid-19 pandemic is exaggerated. We do not agree with this general view, but we will not here attempt to provide a sustained refutation.

On the other hand, criticisms of the vaccine passport based on the principle of equality argue that citizens should all be treated in the same way (4). If the epidemiology of a region calls for restrictive public health measures, they should apply equally – that is, identically – to all citizens. The Achilles' heel of this egalitarian critique is that it requires the levelling down of citizens' freedoms and opportunities. Social justice is understood as requiring that everyone's situation remains equally bad.

In contrast, we will argue that differential treatment at the national level is justified with regard to the use of an immunization certificate system during the Covid-19 pandemic. Of course, the use of this vaccine passport can only be justified if the vaccine passport is sufficiently effective, and it is. Even though many point out that the vaccine is not perfect[3], the data is crystal clear that vaccinated people do not catch the virus as much, are much less sick after an infection, and do not die as much as unvaccinated people. The use of a vaccine passport, combined with other measures such as masking, greatly reduces the risk of transmission.

Being suspicious about differentiated treatment is a healthy reaction. But fairness, as many philosophers from Aristotle to Rawls have argued, is in some circumstances best served by treating certain classes of citizens differently. This position is based on the argument that the ethical benefits of such a public health measure outweigh the harm that it causes. We add, however, that the introduction of a vaccine passport is acceptable only if two minimal conditions of ethical acceptability are present: 1) that its application is designed to be temporary and transitory, and 2) that the disparities of treatment it introduces infringe as little as possible upon fundamental rights and do not negate access to essential public services. We will end this position paper by answering a further egalitarian criticism which asserts that a two-tier regime of rights and opportunities is likely to aggravate existing economic inequalities.

ETHICAL BENEFITS AND BURDENS

We believe that the introduction of a vaccine passport is morally justified because its ethical benefits are greater than the prejudices that it causes. The main reason is that the use of a vaccine passport is "Pareto optimal". Pareto optimality invites us to choose, as a matter of course, resource allocation schemes that improve the lives of some without making others worse off; in a Pareto optimal situation, at least one gains, whereas no one loses. Here we compare the use of a proof of vaccination to the *status quo ante*, namely the phases of the pandemic when more restrictive and universal public health measures prevailed. This contrasts with the libertarian critique that compares a situation in which proof of immunization is required to one in which public health measures have been abandoned. In other words, libertarian critics challenged universal public health measures during the earlier phases of the pandemic, and they now oppose the combination of the lift on some of these measures and the use of a vaccination proof. Because we believe that these critics greatly underestimate the harm caused by non-interventionism, we will set aside that comparison.

Seen from that perspective, the introduction of a vaccine passport satisfies the principle of Pareto optimality because it allows fully vaccinated citizens to resume certain activities and, in so doing, to return to a richer social life, whereas those who have not yet been fully vaccinated must wait or forego these opportunities until the health crisis is over. The use of vaccine passport allows, for example, some people who are heavily affected by the pandemic and the associated public health interventions to relaunch their professional projects, whether it is the reopening of a restaurant or the possibility of returning on stage for an actor or a musician. The use of a vaccine passport thus allows vaccinated individuals to live fuller lives and contributes significantly to the recovery of sectors adversely affected by the pandemic.

One could note here that the Pareto optimality-based argument sketched out is compatible with a widening of socioeconomic inequalities (the most disadvantaged do not lose, but the privileged win). Let us remember that a (green) economic recovery is in the interest of all citizens, including the most disadvantaged. We must not make the mistake of thinking that there are, on the one hand, ethical considerations such as those relating to equality, freedom and wellbeing and, on the other hand, economic considerations related to slowdown, unemployment, fiscal stimulus and so on. Economic issues always have an ethical dimension, and ethical issues very often have an economic dimension. For instance, many argued that an ethic of solidarity was called for in the first waves of the pandemic (6). An ethic of solidarity requires that states support and compensate the citizens who are the most negatively affected by the crisis. The principle of solidarity involves recognizing that our fate as individuals is inextricably connected to the fate of others, and that we act in the interest of the most vulnerable within our community (7).

The majority of states in wealthy countries have chosen to run significant deficits since the beginning of the pandemic (8). While governments have readily agreed, in a Keynesian spirit, to accept large deficits in order to support citizens and businesses hard hit by Stay-at-Home orders and physical distancing measures, they will need in due time need to phase out

[3] The duration of the protection might be limited, their ability to protect against new mutations is uncertain, the protection is not complete, vaccinated people can also transmit the infection, and so forth.

these deficits. This could lead policy-makers to reduce or freeze funding for some universal public services or wealth redistribution policies, which will in all likelihood have a detrimental effect on the worst-off.

A TEMPORARY MEASURE

Our argument based on the comparison between the ethical benefits and harms of the vaccine passport can be seen as morally justified if and only if the measure is conceived as temporary and transitory. It goes without saying that, if the measure was conceived as permanent, a much stronger ethical justification would be required to justify such a departure from the principle of equal rights and opportunities.

That being said, it is true that the epidemiological uncertainty about the possibility of achieving herd immunity, the likely emergence of new variants, or the transformation of SARS-CoV-2 into a virus which is easier to live with entails that it is not possible at the time of writing to anticipate how long the use of a vaccine passport will be an effective and justified public health measure. That notwithstanding, our ethical horizon must be to stop using it as soon allowed for by the epidemiological situation. Many scenarios are possible. If the reproduction rate of the virus were to increase rapidly and the hospital capacity of the health system was once again strained, then a return to universal confinement measures may be necessary. In the opposite direction, a cautious and gradual phase-out of the use of a vaccine passport should accompany a decrease of the virus' reproduction rate. Finally, if the virus becomes endemic while remaining virulent, we will need to go back to the drawing board and deliberate on the optimal ways to mitigate the damage done by the virus.

BASIC RIGHTS AND ESSENTIAL PUBLIC SERVICES

The second condition of acceptability rests on the distinction between, on the one hand, essential public services and, on the other, social opportunities that are important but less closely connected to the respect of constitutionally protected rights. For the differential treatment of citizens on the basis of their vaccination status to be deemed acceptable, such disparities in treatment should spare fundamental rights as much as possible. As such, access to education and health care, the right to vote and, with some exceptions[4], the right to work should not be subject to the vaccine passport scheme. Fundamental rights are not absolute but restricting them requires particularly strong justifications. At the time of writing, it seems plausible to think that a continued increase of the immunization rate combined with other public health measures such as the application of the vaccine passport in the context of nonessential activities will be sufficient to control the spread of the virus and avoid exceeding the hospitalization capacity of the health care system.

WILL THE VACCINE PASSPORT AGGRAVATE INEQUALITIES?

Egalitarians might grant that it is true that the benefits arguably exceed the cost, especially if the two conditions of acceptability are followed diligently. However, the benefits, even if largely surpassing the costs, might be reaped significantly more by some groups than others, and more importantly, by those who are already more privileged. The distribution of the benefits coming from differential treatment might well increase already existing inequalities. Thus, egalitarians might say that if differential treatment increases already existing inequalities, then it is still unethical to use the vaccine passport, even if the benefits exceed the burdens and prejudices it causes.

This is a serious issue. The data about the relations between vaccination rates and income is complex; vaccination rates tend to be high among older people, who have on average lower incomes, but they tend to be lower among less educated people among younger generations. Although we cannot here fully do justice to the complexity of this issue, let us reiterate that we are comparing the constrained use of a vaccine passport to the *status quo ante*. It is firmly established that the members of the less economically advantaged social classes suffered more from both the spread of the virus and the universal lockdown and physical distancing measures (9). A vaccine passport scheme allows many profit and non-profit organizations to resume with their activities and many low-skills workers to go back to work. The *status quo ante* can hardly be seen as preferable for the worst-off to the combination of lifting some universal restrictions and requiring a vaccination proof. Hence, unless egalitarians join forces with libertarians and call for a more rapid phasing out of all public health restrictions, they should welcome a limited use of a vaccination proof.

CONCLUSION

In conclusion, we consider the use of a vaccine passport to be desirable if it is temporary and only required to access nonessential activities. In addition, to be ethically acceptable, a vaccine passport scheme should not be viewed as an indirectly punitive measure for those who refuse to be vaccinated. If it seems reasonable to ask those who choose not to be vaccinated to bear some responsibility for the adverse social consequences of their choice, the vaccine passport should be seen first and foremost as a public health policy among others designed to bring about valued outcomes such as reducing virus transmission and reinvigorating social life. In France and in Quebec, the implementation of a vaccination passport has proven to be a powerful incentive to get the jabs for some hesitant or reluctant individuals. That said, access to the targeted activities should no longer be conditional to the possession of a vaccine passport once the vaccination threshold necessary for herd immunity has been reached, or when the virus has mutated into a sufficiently mild version. However, it should be kept in mind that there

[4] Think, for instance, of health professional treating people susceptible to be gravely sick if they contract an infection.

is great uncertainty about the evolution of the pandemic, and if it turns out that such immunity is not achieved due to the evolution of the virus or to behavioural factors, a democratic deliberation will be needed on the possible longer-term use of proof of immunization, on mandatory vaccination or on a return to a more universal lockdown and physical distancing measures. Fortunately, the announced vaccination of children under twelve will help – other things being equal – in reducing transmission.

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

Accès aux soins de santé et respect des consignes sanitaires en temps de pandémie : deux notions indépendantes

Emmanuelle Marceau[a,b], Marie-Alexia Masella[c]

Résumé
Aux États-Unis, le bioéthicien Arthur L. Caplan, ainsi que trois collègues ont affirmé dans un texte publié dans le PennLive Patriot-News, en mai 2020, que toute personne atteinte de la COVID-19 qui n'aurait pas suivi les consignes de la santé publique concernant le port du masque ou la distanciation sociale ou qui serait responsable d'une éclosion de COVID-19 devrait se porter volontaire pour être soignée en dernier. Pour se faire, ils s'appuient sur le principe du philosophe John Stuart Mill voulant que l'expression de la liberté ne peut pas causer du tort à autrui. Bien que l'on puisse comprendre les arguments évoqués par Caplan et ses collègues, cette position ne peut pas s'appliquer en contexte québécois, et ce, tant pour des motifs philosophiques (éthiques) et de santé publique.

Mots-clés
respect des consignes de santé publique, pandémie, COVID-19, triage, accès aux soins

Abstract
In the United States, bioethicist Arthur L. Caplan, along with three colleagues, stated in a paper published in the PennLive Patriot-News in May 2020 that anyone with COVID-19 who has not followed public health guidelines regarding mask use or social distancing, or who is responsible for a COVID-19 outbreak, should volunteer to be treated last. They do this based on the principle of the philosopher John Stuart Mill that the expression of freedom cannot cause harm to others. While one can understand the arguments raised by Caplan and his colleagues, this position cannot be applied in the Quebec context, for philosophical (ethical) and public health reasons.

Keywords
public health compliance, pandemic, COVID-19, triage, access to care

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INTRODUCTION

La pandémie de COVID-19 a soulevé beaucoup d'enjeux éthiques, notamment en santé publique. Certains de ces enjeux, tels que la rareté des ressources de santé, humaines ou matérielles, soulèvent des enjeux fondamentaux d'accès aux soins qui ne sont pas nouveaux (1-3). En effet, dans un contexte de soins de santé limités, il est nécessaire de décider d'une approche permettant de réguler l'attribution des traitements, matériels ou soins médicaux. Différents critères ont été proposés pour réguler cette attribution, parmi lesquels les choix de style de vie des individus. En effet, sachant que plusieurs études de l'Organisation Mondiale de la Santé (OMS) ont mis de l'avant qu'une part importante de la morbidité des pays développés peut être associée à des modes de vie dits malsains (1,3), des auteurs ont proposé que les habitudes de vie des individus puissent conditionner leur accès aux soins.

La pandémie de COVID-19 a donc remis de l'avant l'enjeu éthique lié à l'adoption d'un critère d'accès aux soins basé sur les comportements de vie des individus, dans un système actuellement saturé et débordé par l'afflux massif de malades. Ainsi, dans une volonté de réguler cet afflux, certains bioéthiciens, dont Arthur Caplan (4,5), ont émis la proposition suivante : demander aux personnes ne respectant pas les mesures sanitaires de ne pas solliciter les services de soins en priorité lorsqu'ils sont malades. De nombreuses réactions ont émergé face à cette proposition et nous nous sommes demandées si celle-ci pourrait être acceptable et applicable au Québec. Afin de répondre à cette question, nous présenterons tout d'abord la proposition de ces bioéthiciens, ainsi que les réactions qui s'en sont suivies dans les médias. Nous évoquerons également succinctement le cadre juridique canadien qui affecte directement la mise en application de cette proposition au Québec et nous ferons un retour sur le protocole québécois de triage *Priorisation pour l'accès aux soins intensifs (adultes) en contexte extrême de pandémie* (6), recommandé par un groupe d'experts au Québec, au printemps 2020. Par la suite, nous poserons les arguments théoriques et pratiques sous-jacents à la proposition de Caplan et ses collègues, afin de mieux cerner les enjeux philosophiques qui y sont associés. Finalement, avant de conclure, nous émettrons quelques recommandations sur l'approche à privilégier pour favoriser l'adhérence aux mesures sanitaires, sans utiliser une approche punitive.

Nous tenons à préciser que nous avons conscience que le contexte sanitaire évolue rapidement. Par exemple, au moment d'écrire ces lignes en décembre 2020, aucun vaccin n'était disponible. Tout laisse présager que l'arrivée des vaccins soulèvera de nouveaux enjeux éthiques. L'analyse juridique, philosophique et pratique que nous effectuons sur le cas particulier de la COVID-19 et la proposition de Caplan et ses collègues n'est bien sûr pas spécifique au contexte pandémique actuel. Les arguments, enjeux et risques que nous abordons soulèvent plus fondamentalement le dilemme suivant : comment répondre à des besoins en santé quasi illimités, dans un contexte de ressources limitées? Dit autrement, quels soins prioriser et pour

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quels patients? Ainsi, les réflexions et arguments soulevés dans ce commentaire pourront aider, nous l'espérons, à éclairer les débats actuels et ceux à venir.

PRÉSENTATION DE LA POSITION DE CAPLAN, RÉACTIONS MÉDIATIQUES ET PRINCIPES FONDAMENTAUX DU SYSTÈME DE SOINS CANADIEN

La proposition de Caplan

Dans un texte publié le 11 mai 2020 (4), et une vidéo rendue disponible le 16 juin 2020 (5), les bioéthiciens américains Arthur Caplan, Dominic Sisti, Moti Gorin et Emily Largent affirment que si une personne souhaite désobéir aux consignes de santé publique, au nom de l'expression de sa liberté, elle devrait du coup accepter d'être soignée en dernier, si elle venait à contracter la COVID-19 et nécessiter des soins. Leur argument, ancré en philosophie morale et politique, se fonde essentiellement sur le principe de non-nuisance (7, p.20, note 6), formulé par John Stuart Mill en 1859, dans son livre *De la liberté* (8). Le principe stipule qu'il est légitime de contraindre une personne contre sa volonté pour une seule et unique raison : empêcher de causer du tort à autrui (*to prevent harm to others*). Ainsi, pour Mill, l'expression de la liberté individuelle est quasi totale, tant et aussi longtemps qu'elle n'affecte pas autrui (8). Parallèlement, pour Mill, l'État ne peut pas contraindre ou punir quelqu'un pour son propre bien, car cette action n'est tout simplement pas légitime. On peut l'inciter à adopter un comportement prudent ou sage, mais pas le forcer à agir.

Dans un propos nuancé, Caplan et ses collègues affirment donc que tous les réfractaires aux mesures actuelles de santé publique afin de stopper la pandémie mondiale de COVID-19 devraient se souvenir que les droits sont accompagnés de responsabilités (4,5). Ainsi, si une personne refuse de porter le masque ou de maintenir une distanciation sociale au nom de l'expression de sa liberté, elle devrait se placer à la fin de file d'attente pour obtenir des soins, si elle contracte la COVID-19 et nécessite des soins.

Réactions médiatiques

Cette position de Caplan et de ses collègues a fait beaucoup réagir l'opinion publique et les experts. Yann Joly, professeur du Centre de Génomique et politiques de l'Université McGill, soulève tout de même que leur approche mettant de l'avant le fait que les libertés et décisions d'un individu s'accompagnent de responsabilités est intéressante, et parfois un peu oubliée (9). Ceci dit, de nombreux experts du Canada et des États-Unis, dont Joly, s'accordent notamment pour dire qu'il n'est pas concevable de rationner les soins de santé sur la base du comportement des individus, au risque de s'engager sur une pente glissante (9-11).

Ainsi, est-il réellement possible, souhaitable et faisable d'appliquer la proposition émise par Caplan et ses collègues dans un souci de rationnement des soins de santé et d'application du principe de la responsabilité individuelle? À cette question nous répondons par la négative, puisque le principe d'universalité en matière d'accès aux soins prévaut. Cela signifie que tous doivent avoir accès aux soins de santé en cas de besoin, et ce, peu importe les comportements, des personnes. Ce principe se justifie tant en fonction des principes juridiques, philosophiques et de santé publique. Nous nous intéresserons plus particulièrement aux principes philosophiques et de santé publique qui appuient notre réponse, mais nous souhaitons tout de même mentionner que le cadre juridique a ici un rôle également central puisqu'il encadre l'offre et l'accès aux soins.

Cadre législatif

Le Canada, comme d'autres pays occidentaux (3), a déterminé que l'accès aux soins de santé devait se faire sur une base universelle, c'est-à-dire qu'un résident peut avoir accès aux soins de santé couverts par un régime d'assurance-santé, s'il respecte les modalités administratives préalablement définies et homogènes (12). Le principe d'universalité est inscrit au niveau fédéral, avec quatre autres critères d'accès (la gestion publique des services de santé, l'intégralité, la transférabilité et l'accessibilité), dans la *Loi canadienne sur la santé*, adoptée en 1985 (12). Cette loi-cadre prévoit des principes que les provinces doivent intégrer dans la gestion des soins de santé et encadre donc l'accès aux soins de santé, de telle manière qu'elle va à l'encontre de la proposition de Caplan. Cependant, nous souhaitons tout de même analyser la possibilité de mise en place de cette régulation d'accès aux soins.

Protocole de triage en cas de sursaturation du système de soin de santé au Québec, en contexte de COVID-19

L'accès universel aux soins de santé est d'ailleurs retenu et déjà mis de l'avant au Québec, dans le contexte actuel de pandémie. En effet, un groupe d'experts formé de bioéthiciens et de professionnels de santé ont déployé des critères de prise de décisions d'allocation des ressources médicales en cas de saturation des soins, en contexte de COVID-19, dans un protocole de triage (6, p.43). Les critères présentés pour définir la priorisation des soins sont essentiellement en lien avec la condition médicale du patient. Plus particulièrement, ils sont liés à l'âge du patient, son état de santé général, son autonomie ou encore son niveau de démence. La prise en compte d'un comportement ou d'une habitude de vie n'apparait pas comme élément d'analyse de triage pour l'accès aux soins. D'un point de vue médical, de mauvaises habitudes de vie rendent les patients plus à risques d'avoir des formes graves de la COVID-19 (13-15). Ceci dit, à gravité égale et à pronostic égal, deux patients ne seront pas traités différemment selon leurs habitudes de vie qui ont pu conduire à leur état de santé actuel.

Cette position adoptée par le groupe d'experts est appuyée par Bartlett, « selon les bonnes pratiques médicales : vous devez donner la priorité aux patients en fonction de leurs besoins cliniques [...] vous ne devez pas refuser ou retarder un traitement parce que vous pensez que les actions ou le mode de vie d'un patient ont contribué à sa décision. » (2, p.311; *traduction libre*). Cappelen rappelle pour sa part que l'accès à un soin doit se faire selon des critères en lien avec la gravité de la pathologie, les bénéfices espérés du soin et le rapport coût-efficacité de ce soin (16). Ainsi, là encore, les comportements ne font pas partie des critères communément acceptés et utilisés en pratique pour la décision d'accès à des soins donnée par un professionnel de la santé (16), même si bien sûr, nous reconnaissons qu'ils peuvent avoir une influence sur les critères décrits. En bref, le principal critère pour définir l'accès à des soins à un patient repose sur ses besoins médicaux et son profil médical (2).

Pour toutes ces raisons, il apparait impossible d'envisager la mise en application de la proposition formulée par Caplan et ses collègues, au Canada et au Québec. Afin de mieux discuter de leur proposition, il nous apparait important de détailler certains arguments évoqués en lien avec la littérature en santé publique et en philosophie.

FONDEMENTS DE LA POSITION DE CAPLAN : RISQUES ET ENJEUX ÉTHIQUES

Arguments théoriques sous-jacents

L'un des premiers arguments est présenté par Cappelen. Selon lui, « la répartition des charges et des avantages devrait être liée à la manière dont les différents individus ont contribué à la création de ces charges et avantages » (1, p.476; *traduction libre*). Ainsi, une personne qui, comme le décrit Caplan, n'a pas respecté les mesures sanitaires et qui viendrait à être à l'origine d'un foyer d'éclosion, devrait assumer davantage les conséquences du fardeau pour le système de santé que lui-même a créé ou a aidé à créer.

L'argumentaire de Wynia rejoint également cette conception de la responsabilité individuelle, puisqu'en s'appuyant sur la conception de la liberté par Mill, il indique qu'un individu a le devoir (et donc la responsabilité) de ne pas faire de mal ou de tort à autrui, en ayant recours à sa propre liberté (17). Ainsi, en temps de pandémie liée à la COVID-19, le fait qu'une personne refuse de suivre les mesures sanitaires prescrites, qu'elle mette ainsi potentiellement en danger la vie d'autres personnes, impliquerait, comme le propose Caplan, qu'elle doive dès lors renoncer à l'exercice de sa liberté (17) et assumer les conséquences de son choix. Elle devrait ainsi renoncer à accéder aux soins en priorité en cas de surcharge du système de santé, afin de laisser la priorité de soins aux personnes qu'elle a potentiellement infectée de fait de son non-respect des mesures sanitaires.

Ces arguments théoriques ne sont pas nouveaux et ont déjà été soulevés face à d'autres comportements pouvant mettre à risque la santé des individus (ex. : consommation de tabac, d'alcool, de drogues, manque d'exercice physique, obésité). Elles pourraient d'ailleurs éventuellement s'appliquer à d'autres situations complexes soulevées par la pandémie, comme le fait de refuser de se faire vacciner. Toutefois, comme nous allons maintenant les présenter, il existe plusieurs objections à ces arguments.

Arguments contre la position de Caplan

Arguments théoriques

Selon Cappelen, la première de ces objections se nomme « l'objection humanitariste » (1, p.477; *traduction libre*). Cette objection indique qu'il est obligatoire d'aider toute personne qui se trouve dans le besoin, sans égard à la raison qui l'a conduit à être dans cette situation de besoin (1). Dit autrement, on ne s'intéresse pas à la raison qui a mené un individu à nécessiter de l'aide ; l'obligation porte plutôt sur la nécessité de l'aider. D'autre part, nous pouvons également présenter un deuxième argument nommé « l'objection d'équité » (1, p.477; *traduction libre*). Cette objection défend que les conséquences d'un choix ou d'une habitude de vie par exemple ne dépendent qu'en partie de l'individu. En effet, ce choix est également modulé par le contexte et l'environnement physique, social ou encore politique dans lequel évolue l'individu. Il serait donc injuste et inapproprié de sanctionner des individus qui n'ont pas un contrôle total sur leurs propres comportements. Ce deuxième argument est soutenu par différents auteurs dans la littérature. En effet, il est reconnu que les décisions des individus ne sont pas totalement de leur fait, mais sont aussi influencées par leur environnement direct (1,2,16,19-21). Ainsi, son contrôle (et sa liberté) sont limités (1,2). Parmi les décisions qui peuvent être affectées par ces déterminants, mentionnons celui de respecter les directives de santé publique. Buyx explique à cet effet que « L'accent mis sur le libre choix ignore le fait que le comportement ne relève pas de l'une des deux catégories dichotomiques "librement choisi" et "pas choisi du tout", mais qu'il existe de nombreux degrés de liberté de choix » (19, p.872; *traduction libre*). Dès lors que les individus ne sont pas totalement libres, il paraît difficile de les tenir totalement responsables de leur choix également.

Objections pratiques

Ce dernier argument permet de voir que par-delà des considérations théoriques, il demeure qu'en pratique, il y existe plusieurs obstacles à la mise en place sur le terrain de la proposition de Caplan et collègues, au Québec. Tout d'abord, la responsabilité causale ne peut être garantie et prouvée de manière certaine (16,20). En effet, comment être sûrs qu'une personne qui n'a pas respecté les consignes sanitaires et qui s'est retrouvée dans un foyer d'éclosion soit réellement la personne qui ait causé cette éclosion? Si le comportement devient un critère d'accès aux soins, il peut être difficile de le mettre en place du fait que la causalité entre l'irrespect des consignes à un moment donné et l'apparition des symptômes ne soit pas assurée totalement.

Il serait alors injuste et non défendable d'avoir recours à ce critère dans ce cas, d'autant plus que les conséquences pourraient être tragiques, voire mortelles.

Finalement, il faudrait également penser aux enjeux pratiques que pose l'évaluation des comportements passés d'une personne. Le temps et les ressources (humaines et matérielles) nécessaires pour surveiller et documenter tous les manquements au respect des consignes sanitaires, ainsi qu'à leurs conséquences (20) seraient importants. Et qui serait en mesure de mener l'enquête sur les agissements d'un nouveau patient? Une solution, proposée par certains, serait de demander aux professionnels de santé d'effectuer cette enquête, du fait qu'ils sont en première ligne et directement en contact avec les patients, ce qui leur offrirait la possibilité de sonder le passé de chaque patient atteint de la COVID-19 qui a recours à des soins (1). Mais les ressources nécessaires pour mener celle-ci seraient considérables, dans un système déjà lourdement affecté par la pandémie (22). Qui plus est, mener une « enquête » nécessite du temps, élément dont les patients gravement atteints de la COVID-19 ne disposent pas. Enfin, des bais cognitifs ou des préjugés pourraient influencer le jugement des professionnels responsables d'évaluer cette causalité (2). Ainsi, plusieurs auteurs ont évoqué le risque que l'adoption d'une telle proposition puisse soulever : la stigmatisation et la discrimination d'une partie de la population (16,21).

Enfin, le refus de soins à des patients qui n'auraient pas respecté les directives sanitaires pourrait plonger les professionnels de santé dans une détresse morale, comme cela va à l'encontre de l'essence même de leur profession (12). Ce refus pourrait aussi grandement atteinte à la relation de soins entre un patient et son soignant (1,20), créer une crise de confiance et pourrait même être à l'origine de discrimination, découlant de biais personnels et préjugés de certains professionnels (2), tels que mentionnés précédemment.

COLLABORATION, SENSIBILISATION ET ÉDUCATION

À la lumière de ce qui précède, nous voyons bien en quoi la proposition de Caplan et ses collègues n'est pas viable dans le contexte québécois. Mais que faire alors pour diminuer la résistance croissante face aux consignes de santé publique, sachant que, lorsque nous écrivons ces lignes, 50% des Québécois indiquent ne pas se sentir en mesure de respecter ces consignes encore 6 mois (23)? Nous pensons qu'il faut miser sur la sensibilisation et la collaboration de chaque citoyen, pour amortir les impacts de la pandémie actuelle. Ainsi, dans le cas de la COVID-19, il est nécessaire d'offrir à la population des messages clairs, simples, adaptés aux différentes populations qui composent notre société et non stigmatisant, afin d'éviter la confusion ou d'exposer les individus à une trop grande anxiété qui risquerait de porter atteinte à la volonté de prévention (24,25). L'Institut National de Santé Publique du Québec (INSPQ) a par exemple réalisé un document permettant de mettre de l'avant des recommandations quant aux messages qui devraient être communiqués et relégués, tant vis-à-vis du contenu que de la forme (24).

Une autre recommandation qui pourrait être faite est de miser sur la collaboration et le soutient au sein des communautés. Comme le mentionne Van den Broucke, en prenant l'exemple de la pandémie d'Ebola en Afrique, l'implication de la communauté permet d'offrir un espace empreint de confiance et qui favorise la participation de partenaires communautaires à l'adaptation et la dissémination des mesures de santé publique, tout en respectant la sensibilité et les particularités de la communauté (24). Il ajoute également :

> Une telle approche permet non seulement d'éviter la stigmatisation et les réactions de peur chez les personnes, les familles et les communautés touchées, qui peuvent entraver les efforts de prévention, mais elle constitue également un puissant levier pour renforcer l'adhésion et mobiliser l'engagement communautaire. (24, p.3; *traduction libre*)

Il est donc important de favoriser non seulement une approche d'éducation et d'information sensible aux particularités des populations, mais il est également important d'impliquer les communautés afin de renforcer l'entraide et le soutient à l'échelle locale, dans un contexte pandémique qui bouscule toutes nos relations sociales.

Finalement, si les approches décrites précédemment ne suffisent pas et si le besoin s'en fait sentir, le législateur peut également intervenir par voie législative. L'État peut forcer l'application de mesures sanitaires en contexte de pandémie (couvre-feu, port du masque, vaccination obligatoire, etc.), dans une volonté de protection de la santé de la population.

CONCLUSION

En somme, la position de Caplan et ses collègues nous semble loin de la réalité actuelle. L'accès universel aux soins de santé est une valeur affirmée, tant dans le cadre juridique qu'en santé publique au Québec. Dans une perspective plus internationale, nous pensons d'ailleurs qu'une telle approche ne serait pas plus envisageable, car celle-ci ne s'inscrit pas nécessairement dans le cadre juridique des autres pays, ni dans les valeurs démocratiques de protection de la personne ou dans les droits fondamentaux. En France, par exemple, le *Code de la santé publique* défend l'accès égal des personnes aux soins requis par son état de santé (article L1110-1) (25), et ce, sans égard à leur comportement. Comme le mentionnait Cappelen (1), cet accès se fait donc uniquement sur les besoins et non sur les causes l'ayant mené à nécessiter des soins. Pour conclure, il est certes vrai que la résistance actuelle face aux mesures de santé publique au Québec pour ralentir, voire stopper, la progression du virus demeure préoccupante. Nous privilégions toutefois une approche positive, fondée sur la collaboration, la sensibilisation et l'éducation pour une sortie de crise. Au besoin, la voie législative peut aussi pallier les manquements de la part de certains et imposer des mesures sanitaires communes.

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

Enjeux éthiques à mieux définir le tourisme médical et ses protagonistes au Québec

Annie Liv[a]

Résumé
Ce commentaire analyse les enjeux éthiques soulevés par la circulaire 03-01-42-07 qui prescrit l'application d'une majoration tarifaire de 200 % à toute personne non affiliée à la RAMQ (assurance maladie publique) pour des soins délivrés dans un établissement du réseau de la santé et des services sociaux. Cette règle tarifaire s'applique aussi bien aux personnes qui ne résident pas au Québec (touristes) qu'à celles qui y habitent sans couverture d'assurance santé. En ayant pour hypothèse qu'elle vise à protéger le réseau de santé du phénomène de *tourisme médical*, ce commentaire en démontre l'aspect inéquitable et injuste lorsqu'elle s'applique à des personnes qui résident au Québec.

Mots-clés
éthique organisationnelle, migrants, inégalités de santé, migrants sans assurance maladie, accès aux soins, Québec

Abstract
This commentary analyzes the ethical issues raised by circular 03-01-42-07, which prescribes the application of a 200% fee increase to any person not affiliated with the RAMQ (public health insurance) for care delivered in a health and social services network establishment. This fee rule applies both to people who do not reside in Quebec (tourists) and to those who reside in Quebec without health insurance coverage. Assuming that it is intended to protect the health network from medical tourism, this commentary demonstrates its unfairness and inequity when applied to persons residing in Quebec.

Keywords
organizational ethics, migrants, health inequalities, migrants without health insurance, access to care, Quebec

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INTRODUCTION

Au Canada, la Loi fédérale sur la santé énonce cinq principes qui veillent à l'accessibilité et au partage équitable et juste des ressources entre les assurés sociaux des différents systèmes de santé provinciaux : gestion publique, intégralité, universalité, accessibilité et transférabilité (1). La notion de « partage équitable et juste des ressources » est au cœur du principe éthique d'allocation des ressources qui justifie notamment la mise en place de politiques de rationnement et de priorisation d'accès des différents systèmes publics médico-hospitalier (2).

Au Québec, la circulaire 03-01-42-07 qui prescrit l'application d'une majoration tarifaire de 200 % à toute personne non affiliée à la RAMQ ayant eu recours à des soins de santé effectués dans des établissements publics répond à ce principe d'allocation et de rationnement des ressources puisqu'elle a pour effet de prioriser l'accès au Réseau de la Santé et des Services Sociaux (RSSS) aux bénéficiaires de la couverture de santé de la Régie de l'Assurance Maladie du Québec (RAMQ) (3). De plus, le Ministère de la santé et des services sociaux (MSSS) justifie cette majoration par le fait qu'elle « compense, entre autres, les coûts de la composante immobilière non comprise dans le prix de journée » (4).

Au Québec on identifie 4 catégories de personnes non affiliées à la RAMQ : 1) les touristes dont la présence est transitoire, 2) les personnes sans statut qui ont décidé de rester après l'expiration de leur visa ou à la suite de l'échec de leur demande d'asile, 3) les Résidents Permanents (RP) et les citoyens canadiens en période de carence, 4) les Résidents Non Permanents (RNP) non éligibles à la RAMQ. C'est ainsi qu'en 2020, on estimait la présence d'environ 50 000 personnes qui habitent au Québec sans aucune couverture d'assurance santé – autant de personnes sinon plus qui seraient donc concernées par la circulaire en question (5). Ce commentaire a pour objectif d'évaluer la nature éthique de cette norme institutionnelle en utilisant le groupe des RNP non éligibles à la RAMQ comme cas d'étude. L'analyse des effets de la circulaire sur ce groupe permettra d'en illustrer le caractère injuste et inéquitable, particulièrement lorsqu'elle s'applique à des personnes qui font partie intégrante de la communauté québécoise par le fait qu'elles y habitent, y travaillent ou y étudient (6).

C'est la définition du Bilan démographique du Québec qui sera retenue pour définir le statut de RNP : « étrangers admis de façon temporaire au Canada (…) par exemple, les travailleurs temporaires, les étudiants étrangers ou encore les demandeurs d'asile » (7). En 2020, ils étaient au nombre de 60 700 parmi lesquels on estimait près de 50 000 non éligibles à la RAMQ et 13 600 dépourvus de couverture d'assurance santé privée (5,7). Les RNP qui sont éligibles à la RAMQ sont principalement les étudiants étrangers en provenance des 10 pays européens ayant une entente de sécurité sociale avec le Québec, et les travailleurs étrangers ayant un permis de travail fermé de plus de 6 mois. Les demandeurs d'asile qui bénéficient de la couverture de santé fédérale dans le cadre du Programme Fédérale de Santé Intérimaire (PFSI) sont exemptés par la circulaire.

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La principale critique de ce commentaire est que la majoration tarifaire de 200 % vient se surajouter au fardeau initial de ne pas être éligible à la RAMQ. Il s'agit donc d'une entrave additionnelle qui est opposée aux personnes dont l'accès aux soins est déjà limité par le fait de ne pas être protégé par une couverture d'assurance santé publique. Cette entrave est d'autant plus importante envers les personnes qui n'ont pas les ressources financières de souscrire à une couverture d'assurance santé privée. Ainsi, la circulaire alourdit le bilan financier des démarches médicales des individus, ce qui a pour conséquence de les inciter à ajourner voire à renoncer à leurs soins. Cela participe à l'altération de certains tableaux cliniques qui à terme sont plus complexes et surtout encore plus onéreux à prendre en charge (8).

Ce commentaire sera basé sur l'hypothèse que la circulaire 03-01-42-07 serait un outil pour protéger les ressources des établissements médico-hospitaliers du RSSS du phénomène de *tourisme médical.* Cette hypothèse provient d'abord de l'existence au Canada et au Québec de discours politiques et médiatiques qui se préoccupent de l'augmentation de ce phénomène (6,9). De plus, l'intitulé de la circulaire indique qu'elle vise explicitement « certains ressortissants étrangers » ce qui manifeste un désir de répondre à cette inquiétude. Ce titre est par ailleurs fallacieux car ce sont précisément les « non assurés sociaux » qui en sont réellement la cible. En effet, au sens de la Loi sur l'immigration au Québec, est considérée à titre de ressortissant étranger une personne qui n'est ni citoyen canadien ni résident permanent (10); ces derniers sont pourtant tout aussi concernés par cette mesure lorsqu'ils sont en période de carence ou qu'ils ont perdu le statut de résident. Cette erreur est évocatrice d'un amalgame entre « non assurés sociaux » et « ressortissants étrangers ». Cette confusion nominale sous-entend que la majoration tarifaire serait justifiée par le fait qu'elle s'appliquerait uniquement à des personnes qui solliciteraient les services hospitaliers publics alors même qu'elles sont extérieures à la communauté québécoise. Cette idée est renforcée par le fait que la circulaire s'adresse indistinctement, et ce de manière permanente, aussi bien aux RNP non éligibles à la RAMQ qu'aux touristes. Cela témoigne d'une négligence politique des implications variées de certains RNP non éligibles à la RAMQ au sein de la communauté québécoise à travers toutes sortes d'activités notamment économiques et académiques.

Dans le but d'inciter au dialogue proposant au mieux la suppression, au moins une modification de la circulaire 03-01-42-07 qui exclurait toute personne ayant un statut migratoire officiel de résident au Québec permanent ou non, ce commentaire s'articulera en deux parties. La première sera consacrée à une description succincte du phénomène de *tourisme médical* en supposant que cette circulaire a été mise en place dans le but de le prévenir. Il s'agira d'en souligner l'inefficacité d'une part, et ses effets potentiellement délétères sur la santé des populations qu'elle vise d'autre part. La deuxième partie ajoutera que l'assimilation erronée entre touristes et RNP, sur la base de leur passage transitoire, procède à une réification de ces derniers dont la présence au Québec répond en premier lieu à des besoins démographiques et économiques. Cette réification contrevient aux valeurs de solidarité, de justice sociale, d'équité et de réciprocité. Cette partie s'appuiera sur le *Référentiel des valeurs pour soutenir l'analyse éthique des actions en santé publique* publiée par l'Institut National de la Santé Publique du Québec (INSPQ) (11).

UNE MAJORATION TARIFAIRE INEFFICACE AUX CONSÉQUENCES DÉLÉTÈRES POUR LA SANTÉ

Le *tourisme médical* est un voyage d'une durée limitée, entrepris dans le but de bénéficier d'une offre de soins curatifs ou thérapeutiques dans un autre pays que celui de résidence (12). L'intérêt de ces voyages à visée médicale est de bénéficier d'un meilleur cadre de soin « plus propice au rétablissement ». Dans le monde, ce phénomène s'observe majoritairement des pays développés du Nord vers les pays émergents du Sud (13). L'intérêt des patients est de bénéficier de soins à prix modiques, au sein de structures privées assurant des services de qualité supérieure aux services hospitaliers des pays d'origine. Le recours au *tourisme médical* pour les Canadiens est souvent motivé par : une impatience à l'égard des temps d'attentes imposés par le système de santé quant à la prise en charge de soins médicaux non urgents, le désir de recourir à des soins de santé non couverts par l'assurance maladie provinciale, ou d'accéder à des soins non approuvés par les autorités sanitaires et indisponibles au Canada (14-16). Les déplacements observés dans le sens inverse, des pays du Sud vers les pays du Nord, sont moins nombreux et concernent des populations nanties (13). Au Canada et au Québec, c'est le phénomène de *tourisme obstétrical* qui est le plus médiatisé. Ce phénomène fait l'objet de contestations dans la mesure où les touristes planifient un voyage au Canada dans le but d'y accoucher et garantir l'obtention de la citoyenneté pour les enfants à naître. Cette réalité concerne des personnes n'ayant aucun projet d'installation au Québec, capables de dépenser entre 30 000 et 40 000 CAD en frais médicaux, d'hébergement et d'avocat (17,18), contrairement à certaines femmes enceintes RNP qui en l'absence de RAMQ rencontrent des difficultés à répondre à leurs besoins de soins périnataux (8,9).

En supposant que la circulaire 03-01-42-07 s'inscrit dans une démarche de lutte contre le *tourisme médical*, ce commentaire souhaite en souligner la double inefficacité. Premièrement parce que cette barrière financière est un élément peu dissuasif pour les personnes ayant la capacité financière de venir au Canada uniquement pour y effectuer un séjour à des fins médicales. Deuxièmement, parce que cette majoration ne s'applique que dans le réseau public, alors même que les acteurs du *tourisme médical* ont davantage recours à des cliniques privées (14). En revanche, ce que cette circulaire génère est un accroissement des inégalités d'accès aux établissements publics médico-hospitalier. En effet, une majoration tarifaire de 200 % procède explicitement à une sélection sur la base des ressources économiques des patients. Elle dissuade de fait les patients économiquement désavantagés qui souhaiteraient bénéficier de services de soins publics. Il s'agit donc d'une mesure discriminatoire dans le sens où elle procède à une différenciation entre les individus. Cette dernière – en étant basée sur la capacité des individus à payer – œuvre à une marchandisation de la santé alors même que la gestion publique de cette dernière témoigne qu'il s'agit d'un droit fondamental et non d'un bien marchand (19,20). Cette situation incite les RNP à

consulter dans des cliniques privées et favorise une médecine à deux vitesses, toujours au profit des plus favorisés, ceux ayant une assurance privée, le cas échéant, ceux ayant la capacité financière de subvenir à leurs besoins de santé.

Les entraves d'accès aux soins favorisent les inégalités de chances de travailler et d'étudier dans un état de plein potentiel défini comme un bien-être global, physique et psychique (11). Au Canada, elles participent à l'altération des états de santé que l'on observe chez des individus issus de populations immigrées non européennes. Cette altération s'accroit graduellement au fur et à mesure de l'expérience migratoire (8,21). De manière évidente, la majoration de 200 % contrevient à l'acquisition de la santé telle que définie dans la Charte d'Ottawa : « la mesure dans laquelle un groupe ou un individu peut d'une part, réaliser ses ambitions et satisfaire ses besoins et, d'autre part, évoluer avec le milieu ou s'adapter à celui-ci (…) il s'agit d'un concept positif mettant en valeur les ressources sociales et individuelles, ainsi que les capacités physiques » (22). *A contrario,* elle concoure au constat que les travailleurs étrangers sont durant leurs premières années d'immigration plus fréquemment victimes de lésions, notamment graves et irréversibles, comparativement aux Québécois. Les raisons identifiées à cette situation sont notamment un accès aux soins rendu difficile par les coûts financiers et la langue (23) ; force est de constater que la circulaire alourdit le bilan financier des soins.

Les RNP non éligibles à la RAMQ habitent au Québec notamment pour y travailler ou y étudier. Il est indispensable de les dissocier de toutes mesures politiques qui viseraient des touristes qui pratiqueraient le *tourisme médical*. À la différence de ces derniers, ce n'est pas exclusivement la qualité du système sanitaire québécois qui motive leur présence dans la province, mais plutôt le désir légitime de bénéficier d'une meilleure qualité de vie globale. Au 1er juillet 2020, les RNP étaient à 46 % des travailleurs et à 23 % des étudiants (7). Leur présence au Québec est autant une opportunité pour eux-mêmes que pour la province d'un point de vue économique, social, culturel et académique. C'est l'ensemble des résidents du Québec qui compose la communauté québécoise et l'enrichisse. Le fait que le 31 mars 2020 le MSSS ait émis une directive visant à assurer la couverture publique à tous pour l'ensemble des soins liés à la COVID-19 témoigne de l'appartenance à la communauté québécoise de l'ensemble des résidents – qu'ils soient permanents ou non, assurés ou non, au statut légal ou non.

MAJORATION TARIFAIRE ENVERS LES RNP ET RÉIFICATION DES CORPS

L'assimilation erronée entre RNP et touristes qui est produite par le ciblage populationnel de la circulaire 03-01-42-07 témoigne d'une négligence de leurs apports économiques, sociaux, culturels et académiques au sein de la province puisqu'ils y travaillent et/ou étudient et y consomment. Le fait d'attirer les RNP à travailler ou à étudier au Québec associé à une limitation renforcée de leur accès aux structures sanitaires procède à une réification de leur corps. La réification des individus s'opère lorsque l'usage des corps n'est pas justement récompensé – ou peu valorisé – au vu des profits générés par ces derniers (24). Cela favorise de surcroît l'idée selon laquelle les opportunités d'emploi ou de scolarité autorisées aux RNP seraient le produit de gestes généreux de la part des politiques migratoires alors même qu'elles s'inscrivent dans des politiques économiques grâce auxquelles les provinces s'enrichissent. La réification est d'autant plus flagrante aujourd'hui dans la nature éphémère et spécifique des directives de couverture universelle des soins liés à la COVID-19. Dans sa tribune publiée dans Le Devoir le 27 avril 2020, la sociologue Estelle Carde souligne que le caractère inédit de cette directive du MSSS témoigne qu'il s'agit davantage d'une méthode pour venir rapidement à bout de la pandémie, que d'une reconnaissance effective d'une communauté québécoise composite (25).

Le ciblage des RNP non éligible à la RAMQ est révélateur d'une négligence de leur appartenance et leur contribution au dynamisme du Québec. Elle contrevient aux valeurs d'équité, de justice sociale, de solidarité et de réciprocité qui, d'après le *Référentiel des valeurs pour soutenir l'analyse éthique des actions en santé publique* publié par l'INSPQ, sont des paramètres primordiaux à la mise en œuvre éthique d'une politique sanitaire. La réciprocité prend forme lors d'échanges mutuels s'instaurant dans le cadre d'une relation entre individus ou groupes d'individus. Ces échanges se répondent les uns aux autres de manière à être respectivement équivalents, c'est-à-dire de valeur similaire (morale, financière ou matériel). La réciprocité est à la base du Contrat social défini par Rousseau. Le système d'équivalence proportionnée qu'elle implique garantit l'harmonie au sein d'une société entre les groupes d'individus d'une part, mais également entre le corps politique et le corps social d'autre part. Ainsi, si les individus acceptent de renoncer à certains droits – en l'occurrence ici, celui d'un accès différentiel au droit à la santé pour les RNP – cela doit être compensé par une protection morale du corps politique (26). D'après l'INSPQ, la réciprocité est respectée lorsque la relation est « compréhensible pour autrui, appropriée et proportionnelle (…) une relation de réciprocité peut être considérée du point de vue de la justice sociale et de l'équité (…) en l'absence d'équité, l'exigence de réciprocité risquerait de donner lieu à des relations de servitude et de dépendance marquant la domination d'une partie sur l'autre. » (11). Dans le domaine de la santé, l'équité vise à l'atteinte du plein potentiel pour chaque individu par le biais de politiques de distribution des ressources tenant compte des disparités existantes au sein de la population. Cette circulaire va donc à l'encontre de l'équité puisqu'elle a la potentielle capacité de nuire aux états de santé des individus ciblés, particulièrement pour ceux ayant pour ambition de s'installer de façon pérenne au Québec (27). À terme cela peut même les empêcher d'accéder à des démarches d'obtention de résidence permanente au Canada puisqu'un bon état de santé est requis pour ce statut (21). Ce risque déséquilibre la relation de réciprocité entre les RNP et le corps politique puisqu'on requiert un état de santé satisfaisant tout en entravant son acquisition. En outre, la majoration tarifaire contrevient à l'équité puisqu'elle se surajoute au désavantage social déjà lourd d'être exclu *de facto* de l'assurance maladie publique. Compte tenu de leurs contributions et de leur appartenance à la communauté québécoise, cette barrière supplémentaire à l'accès aux soins est injuste et inéquitable.

Un des enseignements de la pandémie de COVID-19 est que la préservation du bien commun au sein d'une société est un travail collectif qui repose sur la reconnaissance réciproque d'une communauté inclusive. Bien que cette situation soit inédite, il serait opportun d'en extraire les enseignements de façon plus générale dans un but de santé publique et de préservation du bien commun. Contrairement à la circulaire, le SRAS-CoV 2 et les autres agents infectieux avant lui circulent d'un individu à l'autre sans distinction administrative.

CONCLUSION

Alors même que la circulaire 03-01-42-07 s'inscrit dans une visée de gestion financière (4), d'un point de vue de santé publique, les barrières d'accès aux soins favorisent des états de santé dégradés. En effet, elles encouragent des renoncements aux soins découlant sur des retards de prises en charge médicales pouvant aboutir à des états de santé altérés dont la complexité implique des dépenses de santé plus onéreuses pour les établissements de santé. En sachant que ces derniers ont le devoir déontologique et légal de prendre en charge toute personne présentant un état sanitaire aggravé urgent, la majoration favoriserait le risque de factures impayées par les patients auxquels elle s'applique et qui n'auraient pas la capacité de payer. C'est face à cette éventualité économique que des pays tels que la France assurent une couverture de santé publique réellement universelle, accessible à toute personne résidant sur le territoire français depuis au moins trois mois, et ce, quel que soit le statut migratoire légal ou non (28). Au Québec, le choix politique est d'attribuer l'accès à la couverture de santé publique sur la base du statut migratoire ce qui a pour inconvénient de délaisser des personnes résidentes, parfois pour plusieurs années. Ce commentaire s'est intéressé au cas des RNP travailleurs temporaires et/ou étudiants non éligibles à la RAMQ et assujettis à la circulaire 03-01-42-07. L'entrave additionnelle que constitue la majoration tarifaire est non seulement discriminatoire, elle procède à la réification de leurs corps tant elle néglige les contributions sociales, économiques, culturelles et académiques de ces résidents. Comme le dit Maryse Gadreau, le calcul des dépenses de santé doit, dans une réflexion éthique, éviter d'être pourvoyeur de jugements de valeur (29). Le rationnement des ressources de santé est certes un moyen efficace de les protéger pour mieux les partager, toutefois, il convient de veiller à ce que ce moyen ne devienne pas une fin aux conséquences délétères.

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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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ÉTUDE DE CAS / CASE STUDY

Retaining Hope While Respecting Patients' Presumed Wishes: How Substituted Judgement Can Help

Natalie Hardy[a], Nico Nortje[b]

Résumé
Il n'est pas rare que les familles attendent dans l'espoir de recevoir des résultats de tests qui révèlent une mutation traitable, comme dans le cas du cancer du poumon. L'attente de ces résultats peut empêcher les familles de se concentrer sur la douleur et la souffrance actuelles du patient, en particulier lorsque les familles éprouvent des émotions intenses et un deuil anticipé. La norme du jugement substitué peut être utile pour résoudre les dilemmes éthiques en encourageant les familles à réfléchir à la décision que le patient aurait prise s'il était compétent, évitant ainsi une douleur et une souffrance inutiles. Cette étude de cas met en lumière la manière dont la norme de jugement substitué a été utilisée avec la famille d'un patient et comment l'espoir de la famille d'une mutation traitable a affecté sa perception de l'état clinique du patient.

Mots-clés
jugement substitué, prise de décision, éthique, cancer du poumon

Abstract
It is not uncommon for families to wait in hopes of receiving test results that show a treatable mutation, such as in the case of lung cancer. Waiting for such test results can distract families from focusing on a patient's current pain and suffering, especially when families experience heightened emotions and anticipatory grief. The substituted judgement standard can be helpful in resolving ethical dilemmas by encouraging families to think about what decision a patient would have made if competent, thus preventing unnecessary pain and suffering. This case study sheds light on how the substituted judgement standard was used with a patient's family and how the family's hope for a treatable mutation affected their perception of the patient's clinical condition.

Keywords
substituted judgement, decision making, ethics, lung cancer

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INTRODUCTION

It is not uncommon for ethics consultations to be requested when families and providers disagree on how to proceed with a patient's care. Oftentimes, families request aggressive treatment in hopes of honoring and respecting their loved one, while the healthcare team strives to prevent suffering. Ethicists play a key role in facilitating conversation, mediating conflicting viewpoints, and helping surrogate decision makers. It is the role of the ethicist to mediate each party's goals and reach a resolution that respects each party's interests.

CASE STUDY

B.C. was an elderly woman presenting with metastatic lung cancer, a cancer that forms when cells abnormally cluster together and spread to other parts of the body (1). B.C. was admitted as a new patient to the cancer hospital via the emergency centre (EC) and had shortness of breath and respiratory failure. Of note, she also had COVID-19 three months prior to being admitted to this institution. Given her poor lung capacity she had to be emergently intubated in the EC and was sent to the Intensive Care Unit (ICU) with metabolic acidosis (when the body produces excessive amounts of acid). In addition, she was also in septic shock (a dangerous and potentially life-threatening condition that can occur after an infection (2)) which resulted in extremely low blood pressure. As a result, B.C. needed to be on multiple vasopressors to help keep her blood pressure up. Her clinical picture was further complicated by progressive multisystem organ failure (a decline in the functioning of her respiratory, cardiac, and renal functions). Overall, the patient was extremely weak and was also of altered mental status, not able to recognize anyone or participate in any conversations. Since the patient was new to this institution, molecular testing was done to determine the kind of variant for her lung cancer and whether it could be treated.

Metastatic lung cancer is typically treated through aggressive chemotherapy (drugs that kill abnormally growing lung cancer cells). Unfortunately, this treatment also kills healthy cells. In recent decades, molecular testing, a method allowing for more precise identification of abnormal mutations, insertions, and deletions in the patient's DNA, has been developed (3). Although molecular testing can increase the precision of care and thus reduce side-effects, it can take 1-4 weeks to receive test results *after* tissue is sent for analysis (1). Such prolonged wait time can cause patients and families to hope for a treatable mutation, while patients like B.C. suffer, and when palliative care options are likely more appropriate. The patient's family was informed that an untreatable mutation might be found, yet they decided not to "believe it." It can be difficult for families and surrogates to choose palliative care when the results of the test are unknown – some might feel as though they are giving up on the patient, while others continue to operate through an ethos of "fighting" and doing everything clinically possible.

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SURROGATE DECISION-MAKING AND ETHICS

B.C.'s family was holding on to hope of an answer that their mother might have a treatable cancer. Her family was denying all the other issues at hand, which included B.C.'s declining mental status, poor physical condition, and increasing pain and suffering with continued care. The primary care team felt there was a disconnect by the family between what was happening to their mother (organ failure and her cancer prognosis). Consequently, the care team wanted to have a goals of care meeting with B.C.'s family to address realistic goals and to avoid further suffering for the patient.

A goals of care conference was held with the family, which included the patient's three daughters. The healthcare team gave a detailed clinical update and described B.C.'s sudden decline. The team recommended transitioning the patient to comfort care due to her decline and likelihood of demise. The daughters did not want to be disrespectful of their mother and had great difficulty in changing any code status or focus of care (away from aggressive to end-of-life care). They asked the team for more time until the molecular results were available before deciding. On the morning of the patient's eventual death, she further desaturated, was on a 100% ventilation setting, and her blood pressure medication had to be increased.

The ethical issue in the case of B.C. stems from respecting the decisions of surrogates who are unrealistically hopeful despite a patient's poor prognosis, especially when the surrogates' refusal to implement comfort care causes the patient additional suffering. In this case, the care team could not engage B.C. to elicit what her wishes would be, and there were no available advanced directives to guide decision-making. Thus, the ethicist mediated the care conversations in accordance with the substituted judgement standard. According to Dubler and Liebman (4), the substituted judgement standard asks surrogate decision makers to make decisions based on the patient's inferred wishes and what the surrogate knows about the patient's values, behavior, and past pattern of decision making. In other words, surrogates must "stand in the shoes" of the patient and make decisions in the manner they would have if decisional. Importantly, the standard acknowledges family members as having the most intimate knowledge of the patient, their worldview, and identity as a person (5). It is the role of the ethicist to help families to make decisions solely in terms of what the patient would have wanted if they had decisional capacity.

During the goals of care conference, the ethicist asked each sister to explain what their mother was like as a person, how she lived her life, and what her values were in difficult times. If the patient was capable of making a decision at this moment, would she want to wait for the molecular results, or would she prefer to be receiving comfort and palliative care? The daughters described their mother as a stoic kind of woman who always got on with the job. They believed that waiting for the laboratory results and hoping for a potential chance of treatment would be what their mother would have done if she were able to make the decision.

The family was going to discuss change in care focus from aggressive to comfort. However, recent changes in legislation of the local jurisdiction (Texas, USA) had precluded any physician from unilaterally (with the support of a second physician who has not been involved in the care of the patient) changing a patient's code status and change the focus of care (6). As several discussions were ongoing about what the patient would have wanted, the care team had to wait for the family to guide the way forward pertaining to interventions. Sadly, B.C. declined even more and had a cardiac event – she passed away 3 hours before the molecular results were known. The results indicated that B.C. had a non-treatable mutation.

CONCLUSION

Using the substituted judgement standard is beneficial when a patient's wishes are unknown, there are no advanced care documents, and surrogates wish to respect what the patient would have wanted in a given situation. The ethicist in this case had an essential role in facilitating conversation around a patient's values and history of decision-making. As B.C.'s case shows, it can be difficult to put familial concerns aside when thinking about what decision a patient would make, but ethicists are an important part of helping families keep a patient's values at the locus of decision-making.

QUESTIONS

1. When operating through the substituted judgement standard, what mediation techniques can ethicists employ to prevent families from clouding their judgement about what the patient would have done?

2. If the sisters had disagreed on what their mother would have wanted, how should the ethicist have proceeded?

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ÉTUDE DE CAS / CASE STUDY

The Asset of Subjectivity: Applying Mujerista Theology and Family Interest Assessment to Case Analysis

Rebecca Dawn Hood-Patterson[a]

Résumé
L'application de deux théories à des contextes complexes permet d'obtenir une analyse de cas plus complète. Ce cas, qui concerne une famille latino-américaine en pédiatrie, nécessite une approche multidimensionnelle pour mieux évaluer les besoins culturellement spécifiques du patient et du système familial. Une approche théologique Mujerista souligne la nature subjective des valeurs familiales et de la sagesse vécue. Cette approche Mujerista ajoute une autre dimension, ainsi qu'un modèle d'intérêt familial, pour la prise de décision médicale.

Mots-clés
théologie Mujerista, méthode théologique, prise de décision familiale, contextes latino-américains, pédiatrie

Abstract
Applying two theories to complex contexts results in a more well-rounded case analysis. This case, involving a Latinx family within pediatrics, requires a multi-faceted approach to better evaluate the culturally specific needs of the patient and the family system. A Mujerista theological approach highlights the subjective nature of family values and lived wisdom. This Mujerista approach adds another dimension, along with a Family Interest Model, for medical decision making.

Keywords
Mujerista theology, theological method, familial decision making, Latinx contexts, pediatrics

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INTRODUCTION

Applying two theories to complex contexts results in a more well-rounded case analysis. This case, involving a Latinx family within pediatrics, requires a multi-faceted approach to better evaluate the culturally specific needs of the patient and the family system. A Mujerista theological approach highlights the subjective nature of family values and lived wisdom. This Mujerista approach adds another dimension, along with a Family Interest Model, for medical decision making.

CASE

Lucas,[1] a Latino male, was born with Jarcho-Levin syndrome. He went from one Neonatal Intensive Care Unit (NICU) to a higher acuity NICU because he had trouble breathing. Lucas was discharged home after three months but remained at home only ten days before being readmitted for a respiratory infection. The initial goal was to help maintain Lucas' respiratory health and capacity until he was stable enough to have corrective surgery to expand his rib cage and correct his cervical vertebrae. As it was, his lungs could grow at pace with his body's need but because of his neck, Lucas could not safely maintain his airway.

Eventually, the healthcare team recommended a tracheostomy until they could get him to his corrective surgery. Lucas' mom, Sandra, agreed to the procedure and successfully completed trach-training. After several more months, a few stays in the Pediatric Intensive Care Unit, and never being able to wean Lucas to home-ventilator settings, the burden of caring for Lucas in the hospital while also caring for her other toddler, Leo, at home, Sandra recognized Lucas' diminished quality of life. Lucas was no longer playful, he acted agitated when being held, and he had several infections that kept him in intensive care. After each infection cleared, it seemed like Lucas had a lower base line than before the infection. Sandra asked the healthcare team to decannulate Lucas, allowing natural death, saying that he was "tired of fighting."

THEORY EXPLAINED

Two theories can work in tandem to better understand the intricacies of this case. The first is a narrative theory that comes from Mujerista theology (a Latin@ feminist theology) – *la vida cotidiana* or "everyday life". The second is a theory comes from an ethical assessment framework. I begin by briefly defining these two theories and then describe, in greater detail, how each highlights different aspects of the case.

La vida cotidiana is a narrative theory (or a system of explaining how a narrative functions) that provides a culturally-specific manner to engage and evaluate lived wisdom. When narrating *la vida cotidiana* we are not simply telling a story to understand the ideas or meanings embedded within the story; instead, we begin to see how lived experience has the capacity to change

[1] All names have been changed, the family dynamics were altered, and a few details about the case were modified to better deidentify this case.

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or shape our theology, our values, our experiences, or the meanings we assign to those experiences. This narrative theory elevates lived experience in a way that puts it at the same level of importance as education, faith doctrines, values, or expert knowledge. It recognizes that, at times, the best course of action emerges through analysis of the seemingly mundane events of daily life, amplifying our learning-by-doing.

The second theory that can help shine light on this case emerges from an ethical assessment framework. The Family Interest Model takes into account the varied positions that a family may take when making choices about medical treatment and care (1). This model highlights how the centre of gravity (so to speak) is different for each family as they weigh the needs of each member of the family and/or as the family as a whole. It accounts for the fact that no family is alike when making a choice. Assessing different models of family decision-making and needs can strengthen the ability to offer a recommendation informed by the family's own constraints, contexts, and circumstances. Arguably, this model also highlights the many, sometimes opposing, needs that a family must grapple with when determining the best course of action for the family and for the patient.

Let me first examine in more detail what it means to narrate *la vida cotidiana*. In their work with Latin@ women, Ada María Isasi-Díaz (2) and Carmen Nanko-Fernandez (3) identified specialized knowledge emerging from *la vida cotidiana*, or common, everyday life.[2] *Lo cotidiano* is an intersectional, hermeneutical, and epistemological position encouraging subjective reflection on the "stuff" that makes up the "shared experience" within daily lives of Latina women (2, p.67). *Lo cotidiano* is a heuristic device used to understand and solve complex problems in a way that elevates lived experiences and learned expertise. In this framework, subjectivity is key. Subjectivity, within *lo cotidiano,* is not a detriment to this way of contextual evaluation or learned expertise. Embracing subjectivity is a way of extoling difference while simultaneously resisting individualizing ideals that often make humanity more isolated (2).

Nanko-Fernandez's (3) approach assumes that useful knowledge is embedded in *la vida cotidiana*.[3] Meanings given to life are constructed from doing the work of life – we know because we do. The subjective narratives and experiences of daily life agitate implied theories and social discourses about what it means to live with a "non-normal" body. Similarly, listening to the stories of daily life, as parents care for their children, can uncover broader concepts about familial and cultural values that might otherwise go unnoticed. The objective of narrating *la vida cotidiana* is to offer juxtapositions that "interrupt the norm and offer opportunities to entertain new ways" of thinking about our lives and the meanings that we give (3, p.xx).

Narrating *la vida cotidiana* is not simply telling a detailed life story; it is not a biography or medical history. Graham et al. (4) note that this form of narration extracts the embedded, implicit, values-laden constructs that materialize in the daily routines of parents caring for their children – those stories which might otherwise be overlooked. Asking about the "stuff" that makes up common, everyday life when caring for a child with a complex medical condition generates unique sets of knowledge. Oftentimes these experiences are so routine, write Holland and Ramazanoğlu (5), a "knowing in the doing," that they are "not yet discursively appropriated" (p.73). Healthcare providers and clinical ethicists must ask about the "common" and "routine" sources of knowledge that parents learn, simply because of the cares, tasks, and labour that is part and parcel to the close, every-day interaction with the body of their child.

I now turn to the second theory, one derived from assessing family interests within ethical decisions. In conjunction with knowledge gained from her daily lived experience, Sandra must also evaluate what is in the best interest for her family. This is where the four models described by Groll becomes helpful (1). Groll reminds us that not all families prioritize the same things when making decisions. Through Groll's perspective, taken with *la vida cotidiana*, we can see that some families may not even know to articulate the "common" or "mundane" things that happen as they care of their child(ren) or they may undervalue the beliefs embedded in the prosaic. Drawing conclusions using a Family Interest Model (1) we know that the right decision for a patient is never ascertained without considering the impact of the decision within a larger familial or societal framework. The Jarcho-Levin syndrome and respiratory infections were particular to Lucas' body but each member of the family, to varying degrees, shared an experience of that illness (6-7). In making a decision about Lucas' care, Sandra must consider all parties involved – her own, Leo, Lucas, their father, her extended family and her in-law's family (the extended families help with transportation, childcare, and spiritual and emotional support).

Sandra had to evaluate her values with regard to determining what it means for Lucas to "be alive" and what it means to be an attentive and well-bonded parent to her son Leo. Sandra also had to consider the contextual constraints of remaining in the hospital with Lucas, far from home, and with limited transportation. Each family member, her values, the values of her family, and the contextual constraints, when examined together, highlight conflicting priorities and points of agreement. Yet, when reading the conflicting priorities and points of agreement through the lens of *la vida cotidiana*, it becomes possible to see how Sandra and her family prioritize their values.

APPLICATION

First, ethicists must pay attention to the cultural-contextual. The Western-centric training that many clinicians receive can undervalue the lived knowledge gained from daily life. Clinicians should become accustomed to helping families and caregivers

[2] One must proceed with trepidation and awareness, however, and not usurp a methodology particularly tied to a cultural *lucha* (fight) for identity and survival. When White clinicians and researchers use a method from a people group outside of their own, they must pay attention to the historical function of that method.
[3] The knowledge generated, particularly for Nanko-Fernandez, is for theological reflection but the method is transferable to other disciplines and contexts of practice.

articulate the wisdom that they have gained through the daily acts of caring for their child. This wisdom is revelatory in unmasking family values, cultural resources, or religious beliefs that foster decision-making. Understanding the "why" of what a family does can help both clinicians and families. Investigating *la vida cotidiana* is achievable with humble curiosity about daily practice and cares.

Second, clinicians must consider the multiple ways that families weigh varying interests when deciding if procedures, like a tracheostomy, are "manageable." This same weighing of interests is also applicable when a family is making end of life decisions. Clinicians cannot presume that they understand a family's cultural and contextual constraints. Nor should clinicians assume to understand why or how a family evaluates the needs of each member as a part of the whole. Sandra, having cared for both Lucas and Leo, had conducted a months-long comparative case analysis. She recognized the impact of Lucas' illness on both sons and their respective qualities of life. Sandra began to detect the toll that the extended hospitalization was taking on Lucas. She noted how little bonding she had been able to do with Leo since most of her time was in the hospital with Lucas.

Over months of paying attention to the common, everyday struggle for Lucas to breathe and his multiple attempts to overcome respiratory infections, Sandra observed that his ability to play, to eat, to be held, and move were all hindered by his vent dependence and his bone structure. When Sandra began to realize that "*sus luzes*" or "his lights" from his baby soother, which danced on the hospital room ceiling, were Lucas' primary source of joy, Sandra questioned if the repeated respiratory infections and Jarcho-Levin syndrome were manageable or survivable, and to what end.

RECOMMENDATIONS

1. Ethicists must learn to ask parents and caregivers about the emerging knowledge that comes from the daily care of a child. Ask questions like, "What has changed for you as you learn to care for your child?" This knowledge is valuable in revealing learned wisdom about the manageability of diseases as well as family values.

2. Ethicists must ask about how the illness affects the parents and caregivers as well as other members of the family. Questions like, "How has your child's sickness changed the way your family works?" This vein of question demonstrates how the family is negotiating the various interests among affected parties.

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ÉTUDE DE CAS / CASE STUDY

Truth Telling as an Element of Ethical Behaviour and Professional Commitment in Dentistry: A Case Study Assessing Non-Disclosure Action

Leyla Sadighpour[a,b], Greg S. Anderson[b]

Résumé
Dire la vérité aux patients est un fondement essentiel de la relation médecin-patient et est indispensable au développement de la confiance. Un engagement professionnel à dire la vérité peut parfois contredire d'autres principes de bioéthique, ce qui peut remettre en question la prise de décision du médecin ou de l'équipe traitant. Les praticiens peuvent ne pas aborder tous les aspects éthiques ou juridiques d'un cas et donc prendre des décisions inappropriées.

Abstract
Being truthful with patients is a critical foundation of the doctor-patient relationship and is fundamental to development of trust. A professional commitment to truth telling may sometimes contradict other principles of bioethics, which may challenge decision-making for the doctor and/or the treatment team. Practitioners may fail to address all ethical or legal aspects of a case and therefore make inappropriate decisions.

Mots-clés
bioéthique, professionnalisme, dire la vérité, approche de non-divulgation, tromperie

Keywords
bioethics, professionalism, truth telling, non-disclosure approach, deception

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INTRODUCTION

Adherence to ethical precepts embodies conduct expected of health care professionals. In modern bioethics, the concept of patient preference or autonomy is considered a principle of evidence-based care (1). Indeed, it is a major focal point in practitioner-patient relationships in comparison with the older paternalistic approach (2). As a result, the patient's contribution to their treatment options and choices has been emphasised and is represented through the process of obtaining informed consent. To accomplish the latter, it is crucial to provide relevant, accurate and understandable information to the patient to facilitate decision-making. Truthfulness as a component of medical professionalism is a basic tenet that supports patient autonomy, beneficence (positive benefit) and non-maleficence (do not harm). However, disclosing truth may be considered challenging in situations involving distressing news such as life-threatening diagnoses. Additionally, there may be situations where truth telling contradicts beneficence and/or non-maleficence (3,4).

Practitioners may elect not to disclose all information to patients or perhaps offer such information in a less than transparent manner especially when discussing serious medical conditions. This may occur intentionally in an effort to preserve a patient's positive outlook, or it may simply be due to lack of experience, skills, and confidence (5,6). A review of the following case study may help clinicians recognize such situations and develop the skills required to manage such circumstances. In the case discussed below, which was managed by one of the authors (LS), we show that despite the aspiration for adherence to several underlying ethical obligations, the practitioner must be able to appreciate the patient's vulnerability and desire to fully comprehend the current medical reality in the context of a particular family dynamic.

A CASE STUDY: MIDDLE EASTERN MAN WITH CHONDROSARCOMA

A 65-year-old self-employed man had come to a dental clinic for implant-supported overdenture treatment. He has a history of two surgical procedures for a jaw joint cartilage malignant tumor (chondrosarcoma), including partial ablation/resection of the lower jawbone (Fig. 1). Having experienced a prior recurrence of the tumor, he is very afraid of another. The oncologist had opined that the risk was not very high. The patient therefore received his physician's approval for dental implant treatment to proceed. During treatment, the dentist noticed a temporal swelling adjacent to the previous surgical site. The patient's children privately asked the dentist not to disclose any information about the disease to him, because their father had recently recovered emotionally and knowing about a recurrence would distress him greatly. Additionally, thinking that the dentist might be reluctant to proceed with treatment based on the costs to their father, the children assured the dentist that he had paid for part of the treatment and would pay the rest when the denture was delivered.

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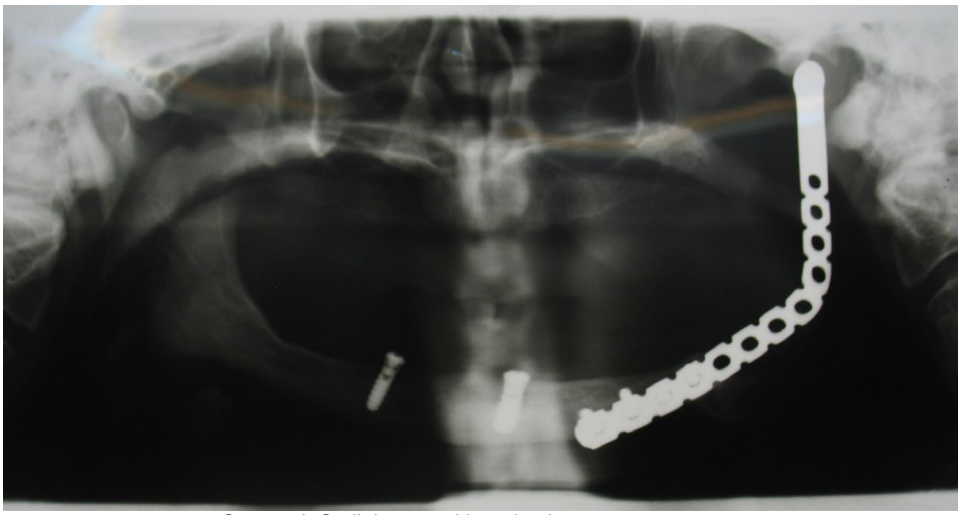
Figure1. Patient with hemimandiblectomy with titanium chain reconstruction and two dental implants



Source: L Sadighpour, with patient's consent

ETHICAL ANALYSIS

In the current scenario, several considerations may discourage the dentist from telling the truth about the possibility of tumor recurrence, including the patient's mental state and related fear, his children's request, and concern that the patient may not return for his follow-up treatment. The latter may result in delayed treatment and/or non-payment of fees. However, the decision to withhold information or to resist complete disclosure could violate both respect for autonomy and the professional obligation to inform the patient about his health and treatment. An appropriate approach to such issues requires consideration of different factors, such as the nature of the disease, the patient's social, mental, and economic status, the patient's quality of life, and the social-cultural background. Hence, the dentist must justify a non-disclosure decision, should this be the case (7). The reasons presented for not revealing the truth usually follow the principle of "non-maleficence", and they include consideration of the emotional, mental, or physical capacity of the patient to cope with the truth about their disease (5,7,8).

In the present case, the children's wish to preserve hope may be a significant factor motivating the dentist toward a deceptive action. Generally speaking, if the practitioner is convinced that deception is a better option for the patient, perhaps other alternatives may first be sought (7). This may include indirect (or ambiguous) statements. For example, in this case, the dentist must consider their professional responsibility to refer the patient to the oncology surgeon for treatment. This would potentially distress the patient and prompt him to ask further questions. In order to implement so called "non-lying deception", appropriate statements can be practiced beforehand to convey a cautious, and "opaque" response. For instance, "I can modify your implant-supported dentures, depending on what your surgeon decides, so I'd like to consult with him before we proceed". In this way, the response is carefully balanced between concealing the entire truth and providing a more limited explanation. If practitioners must contend with the potentially uncomfortable non-disclosure approach, it must be understood that non-disclosure is usually not a desirable option – it would be prudent for the practitioner to carefully consider all reasonable alternatives. It follows that the doctor is required to exercise extremely careful judgment in balancing the reasons for and against full disclosure. If justification of deception outweighs objections, the doctor must then consider how to defend the decision and their reasoning before professional colleagues, a regulatory authority, "the court of public opinion," and even their own conscience (7). In the present scenario, and despite the children's assertions, the doctor was uncertain about the patient's preference for non-disclosure and decided to contact the oncology surgeon for more information about the disease and the significance of the new temporal swelling. Before referring the patient to the surgeon, a meeting was arranged with the patient's family to review the implication(s) and/or necessity of disclosure as well as to inquire about the family relationship relative to care-giving. It was influenced by the importance of the family's role in decision-making in Eastern country culture where the elderly are taken care of by their families (8,9).

CONCLUSION

Whether discussing adverse events, admitting to errors, or conveying bad news, health care professionals have an obligation of honesty and transparency in their communication with patients. This can nonetheless be challenging as it requires an element of self-reflection, preparation, and sensitivity. An additional aspect in this case was the fact that a doctor's approach to and the society's expectation toward truth-telling, especially when it is associated with a great emotional burden, are different in Eastern and Western countries. In many jurisdictions, there is a legal requirement to obtain patient consent prior to revealing any information about the patient's health information to any third party. However, in certain Eastern societies, the family plays a key role in decision-making, especially when the elder has serious disease and are looked after by the family.

Therefore, in critical situations, the family plays an important role in decision-making, often a more significant role than the patient themselves. Such a case may have several outcomes, which ultimately results from how certain difficult questions are answered, including:

- Are there indeed circumstances when deception is warranted?
- Are we responsible for the patient's reaction, especially if there is harm?
- How much should cultural norms be considered?
- Are we the best individual to deliver difficult news?
- Is a partial truth acceptable or is this still deceptive?

Such questions deserve further attention and the answers in such ethical dilemmas may never be agreed upon or entirely satisfactory.

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COMPTE RENDU / REVIEW

Revue du livre : « *De l'éthique à l'ergothérapie* » de Marie-Josée Drolet et Mélanie Ruest

Élise Courcault[a]

Résumé

« De l'éthique à l'ergothérapie » de Marie-Josée Drolet et Mélanie Ruest vise à outiller l'étudiant et le professionnel en ergothérapie face à des situations complexes soulevant des enjeux éthiques. Combinant théorie, cas tirés de la pratique de l'ergothérapie et courts exercices d'application des connaissances, les auteures guident le lecteur sur le chemin de l'analyse éthique. Ce livre s'adresse à toute personne désireuse d'intégrer l'éthique à sa pratique, pour un cheminement personnel mais aussi collectif et interdisciplinaire.

Mots-clés

ergothérapie, cadre éthique quadripartite, éthique appliquée, ontologie axiologique, éthique occupationnelle

Abstract

"De l'éthique à l'ergothérapie" by Marie-Josée Drolet and Mélanie Ruest aims to equip occupational therapy students and professionals to deal with complex situations that raise ethical issues. Combining theory, cases drawn from occupational therapy practice and short knowledge application exercises, the authors guide the reader along the path of ethical analysis. This book is intended for anyone wishing to integrate ethics into their practice, for a personal but also collective and interdisciplinary journey.

Keywords

occupational therapy, quadripartite ethical framework, applied ethics, axiological ontology, occupational ethics

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« *De l'éthique à l'ergothérapie* » de Marie-Josée Drolet et Mélanie Ruest (1) propose une approche concrète en dix étapes afin d'identifier et tenter d'adresser les enjeux éthiques liés à la pratique de l'ergothérapie. Dans un système de santé où les ressources tendent à se limiter, l'organisation et l'allocation des soins, ergothérapie incluse, peuvent exposer les professionnels et étudiants à des questionnements sur leur pratique afin d'offrir le service le plus approprié et le plus équitable à leur clientèle. L'identification et la définition des enjeux éthiques telles que proposées par les auteurs ont pour but de soutenir les ergothérapeutes dans une prise de décisions informée, pluridisciplinaire et ce, malgré des situations complexes.

Composé de cinq chapitres, le livre guide le lecteur de notions éthiques générales vers leurs applications à la pratique de l'ergothérapie. Le premier chapitre résume les grands outils et définitions supportant l'analyse éthique, tels que les valeurs, principes, vertus et différents types d'enjeux éthiques. Les auteures offrent une définition de l'éthique en décrivant principalement ce qui la distingue du droit et de la morale. Le chapitre suivant s'appuie sur la théorie de Kohlberg afin d'illustrer l'évolution du raisonnement éthique chez tout individu. Cette partie est essentielle afin de souligner au lecteur que les compétences en éthique vont s'acquérir à travers l'exposition aux situations et à la pratique. L'étudiant ou le professionnel en ergothérapie peut donc se prêter à une introspection régulière au cours de sa carrière afin d'autoévaluer sa capacité à comprendre les enjeux auxquels les différentes parties prenantes peuvent faire face dans une situation donnée.

Les trois derniers chapitres se concentrent ensuite sur la méthode d'analyse éthique et le cadre dans lequel elle s'inscrit. Les auteures ont choisi un cadre éthique quadripartite afin de supporter leur approche. Ainsi, elles proposent au lecteur un survol des grandes théories éthiques constituant ce cadre : deux théories dites universalistes, l'utilitarisme et le déontologisme, puis deux théories dites particularistes telles que l'éthique des vertus et l'ontologie axiologique de l'ergothérapie. Le chapitre 5 reprend ensuite ces notions afin de proposer une démarche en dix étapes, guidant le professionnel dans la définition de la situation complexe, l'identification des enjeux auxquels il fait face puis dans la prise de décision informée, justifiée et transparente.

Tout au long de l'ouvrage, les auteures expliquent leurs choix quant aux théories et au cadre éthique sélectionnés et mis en pratique. La combinaison d'enjeux d'allocation équitable de ressources en santé, de performance et de qualité des soins amène à porter attention aux notions de justice, notamment distributive. Le point fort de cet ouvrage est d'offrir une perspective plus large de ce principe, non uniquement à travers la lentille utilitariste souvent déployée dans ces contextes, mais en incluant aussi des théories particularistes telles que l'éthique des vertus et l'ontologie axiologique. La complémentarité de ces approches *top-down* et *bottom-up* offre un pont intéressant entre l'impératif d'ancrer la pratique ergothérapique au sein de l'organisation du système de santé, plus universel, avec la particularité des situations rencontrées avec les patients quant aux soins offerts par l'ergothérapeute. La bioéthique doit être à même d'offrir ces analyses multi-niveaux et c'est avec agilité que les auteures en proposent une approche à travers ce livre.

L'organisation du livre est judicieuse et les auteurs portent une attention particulière à souligner ce lien entre la théorie et la pratique, à travers de nombreux exemples tirés d'études de cas en ergothérapie. L'illustration des propos invite le lecteur à se projeter dans sa pratique et entreprendre un travail réflexif. Plusieurs exercices de consolidation des connaissances sont

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proposés à la fin de chaque partie du livre. Si ces derniers permettent au lecteur d'assoir les notions présentées lors des chapitres, certains exercices de type vrai/faux ou questions fermées devraient être entrepris de manière collective et collaborative, par exemple avec d'autres confrères. La dimension réflexive, interdisciplinaire et d'échange indispensable à la pratique de l'éthique pourrait alors mieux accompagner le lecteur dans les activités d'apprentissage afin d'intégrer dès lors une pratique de discussion, de nuances et d'intégration de différents points de vue plus qu'une autocorrection légèrement fermée de type correct/incorrect.

Enfin, le livre proposé par les deux auteures adresse aussi l'enjeu essentiel d'intégration de la réflexion éthique dans une pratique professionnelle. Comment amener cette réflexion, comment la nourrir au sein d'une équipe et comment l'utiliser lors de la prise de décision. Cet ouvrage offre un exemple d'approche dans le cadre de la pratique de l'ergothérapie, pertinent pour tout professionnel et étudiant, mais aussi pour tout bioéthicien se questionnant sur un tel exercice. C'est un formidable outil pour ces différents publics, comme source d'une réflexion sur sa pratique, mais aussi au sein d'échanges interdisciplinaires.

Le public plus expert en éthique trouvera là aussi des éléments pertinents de réflexion et biais potentiels dans notre société actuelle, à travers par exemple la prédominance de théories utilitaristes lors des analyses éthiques. Les auteures réussissent là aussi à éveiller le lecteur sur d'autres approches et perspectives pouvant être habilement incluses dans l'analyse éthique. La complémentarité proposée des approches universalistes et particularistes, à travers le cadre éthique quadripartite, illustre bien cette tension d'une pratique idéale, juste et équitable de l'ergothérapie au sein d'un système de santé à visée collective et populationnelle avec ses contraintes associées.

En conclusion, ce livre est une proposition généreuse d'intégration de l'éthique à la pratique de l'ergothérapie. La lecture est fluide et propose au lecteur une boîte à outils s'emplissant au fil des pages. Au-delà de la profession d'ergothérapeute, un tel ouvrage peut aussi se positionner comme un exemple voire un point de départ pour d'autres pratiques professionnelles désireuses d'accéder à une prise de décision mieux informée, principalement en situation complexe.

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COMPTE RENDU / REVIEW

Review of: Kristen Jones-Bonofiglio, *Health Care Ethics Through the Lens of Moral Distress*

Canadian Bioethics Society / Société canadienne de bioéthique
En collaboration avec / In collaboration with

Clarisse Paron[a]

Résumé
Les préoccupations relatives à la détresse morale dans le domaine des soins de santé n'ont jamais été aussi pertinentes. Dans son livre intitulé *Health Care Ethics Through the Lens of Moral Distress*, Kristen Jones-Bonofiglio présente un examen complet des effets de la détresse morale sur les fournisseurs et la prestation des soins de santé, tout en soulignant la complexité des décisions éthiques à prendre dans la pratique. La rigueur de Jones-Bonofiglio et son recours à des études interdisciplinaires, historiques et culturelles font de ce livre une excellente ressource d'introduction à la détresse morale pour les prestataires de soins de santé et les chercheurs.

Mots-clés
détresse morale, relationnelle, éthique des soins de santé

Abstract
Concerns of moral distress in health care have never been more relevant. In her book, *Health Care Ethics Through the Lens of Moral Distress*, Kristen Jones-Bonofiglio provides a comprehensive review of the effects of moral distress on providers and health care delivery, while highlighting the complexities of making ethical decisions in practice. Jones-Bonofiglio's thoroughness and use of interdisciplinary, historical, and cultural scholarship makes this book an excellent introductory resource on moral distress for health care providers and researchers alike.

Keywords
moral distress, relational, health care ethics

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INTRODUCTION

The COVID-19 pandemic has strained healthcare systems across the globe, leading to widespread moral distress and burnout among frontline workers. Written just prior to the pandemic, Jones-Bonofiglio's book (1) is a timely and relevant resource for interdisciplinary health researchers and practitioners alike. The book aims to redirect attention towards the needs of carers by highlighting the negative effects of moral distress on providers, teams, healthcare systems, and patients. Jones-Bonofiglio emphasizes that experiences of moral distress in health care workers not only affect the resiliency of providers but their ability to provide patient-centred care. She approaches the topic from a relational perspective to highlight the complex and multi-faceted experiences of moral distress in various contexts. The strength of Jones-Bonofiglio's position is her use of wide-ranging interdisciplinary, historical, and contemporary scholarship – a refreshing deviation from bioethics works that frequently ignore Indigenous and non-western frameworks. She draws on other cultural concepts and frameworks, such as *ubuntu*, *kintsugi*, and *sisu*, as well as narrative reframing and fables, to underscore the importance of compassion and relationality of health care providers and their practices. Jones-Bonofiglio encourages empathy and self-compassion, while combating the harmful norms and expectations of providers as "detached impartial observers" who should distance themselves from patients to prevent moral suffering and preserve their objectivity.

In the first two chapters, Jones-Bonofiglio defines moral distress and related concepts, highlighting the widespread impact of moral distress on health care practitioners and teams. She defines moral distress as "an experience where a moral decision has been made about what to do in an ethically challenging situation, but the desired action cannot be carried out" (1). Positioning this definition as too narrow, Jones-Bonofiglio adopts Kälvemark Sporrong and Wilkinson's definitions of moral distress as a psychological state of disequilibrium, where going against one's better judgment and the perception of being unable to meet one's professional obligations results in a complex physical, emotional, cognitive, and behavioural reaction. In her view, moral distress does not arise in all situations where there is a moral dilemma or moral uncertainty; but it can arise where there are unavoidable external pressures such as resource and policy constraints, poor communication, and problematic workplace cultures. Over time, these features erode moral confidence, leading to what Jones-Bonofiglio describes as moral stress (a "more physiological [response]…that results from health care providers possessing a sensitivity for moral issues"), moral residue (the experience of emotional, psychological, and even existential pain that can linger long after one's values have been compromised), or moral outrage (the experience of anger that arises in response to a violation of one's morals and integrity).

In Chapter 3, Jones-Bonofiglio uses a socio-ecological framework to trace the effect of moral distress on the provision and consumption of healthcare from a holistic and contextual perspective. In considering structural, institutional, systemic, relational, and individual contributions to the experience of moral stress, Jones-Bonofiglio argues that moral distress has a ripple effect on each of these components of the healthcare system – ultimately impairing the ability to provide patient-centred

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care. In addition to considering temporal and spatial factors, she calls on future researchers to consider how macro, meso, and micro systems contribute to a provider's experience of moral distress and potential solutions.

Chapters 4 and 5 contextualize moral distress research in acute care and community settings. By the end of the fifth chapter, the author presents a convincing argument as to why moral distress leads to negative outcomes for individual carers and the healthcare system that leaves readers keen to mitigate moral distress in practice. However, in Chapter 6, Jones-Bonofiglio argues that moral distress should not be completely avoided because that "would mean that ethical questions are not being raised, addressed, or resolved. It would mean that individuals would choose to silence the call of their ethical beliefs and ignore their moral compass". After five chapters that detail the negative effects of moral distress, Chapter 6 introduces moral distress as an indicator that health care professionals are engaging with ethics in practice. In her opinion, health care (especially nursing) has a moral component, therefore moral distress is unavoidable – the problem "is in the response to suffering that has costs and consequences".

Moral distress does not simply occur because providers are in close proximity to patient suffering (Chapter 7) or because they care too much (Chapter 6); it occurs because providers act against their better judgment or feel like they have not met their professional obligation. Since moral distress strongly relates to a loss of agency or moral identity, the impact of agency and institutional support should not be overlooked. Jones-Bonofiglio argues that moral courage, team collaboration, institutional support, and ethical competence help to prevent and mitigate the negative effects of moral distress on providers. These solutions work by improving agency and aiding providers in developing strong moral identities and confidence.

Based on this argument, I wonder whether moral distress is truly necessary for providers to engage with ethics in practice. Admirably, Jones-Bonofiglio has realistic goals for ethics in practice. In a non-ideal world, where there are resource constraints, communication issues, and novel situations that existing systems are ill-equipped to handle, a level of moral distress is valuable because it means that providers are engaging with ethical issues instead of ignoring or disengaging from them. However, missing from this analysis is a comprehensive description of what is an "acceptable" level of moral distress, what it looks like, or how it might be achieved. If providers are empowered to be involved in ethical decision-making and develop strong moral courage, then I wonder if moral distress must remain an unavoidable part of practice, particularly if it leads to such negative outcomes. As a philosopher, I was left wondering whether moral distress should be accepted as an unavoidable aspect of contemporary health care. I hope that Jones-Bonofiglio expands further on the idea that there is some value to moral distress. In Chapters 8 to 10, Jones-Bonofiglio summarizes protective factors for health care providers, noting how they can practice ethics and compassion, learn to be more resilient, and set healthy boundaries. Chapter 10 offers practical recommendations for providers, teams, and institutions for preventing moral distress. Although Jones-Bonofiglio details numerous evidence-based, individual-level strategies for providers, greater attention to institutional-level strategies – perhaps in a sequel or second edition – would be useful. In taking a relational approach to the topic, more discussion about the external factors that are outside of providers' control and that contribute to moral distress is critical.

Health Care Ethics Through the Lens of Moral Distress is an excellent introductory resource for researchers and providers who are interested in an evidence-based view of moral distress. Jones-Bonofiglio provides a comprehensive review of the relevant research and offers many resources for further reading. She notes that one of the biggest challenges to researching moral distress is the lack of clarity and agreement on how to separate moral distress from related moral emotions, and, arguably, this lack of conceptual precision permeates this book as well. While her arguments mostly relate to a nursing experience, a wide range of health care providers in acute and community settings would benefit from reading this book if they are looking to make sense of their experiences of moral distress, and for methods to mitigate moral stress or distress in their practice.

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TÉMOIGNAGE / PERSPECTIVE

Qu'est-ce que la justice occupationnelle intergénérationnelle?

Marie-Josée Drolet[a]

Résumé
Ce texte discute d'une nouvelle vision de la justice, en l'occurrence de la justice occupationnelle intergénérationnelle. En plus de présenter la genèse de cette vision occupationnelle de la justice climatique, la définition et l'explication de cette valeur sont mises en contraste avec d'autres concepts apparentés en ergothérapie et dans la science de l'occupation.

Mots-clés
ergothérapie, science de l'occupation, changements climatiques, crise climatique, justice, durabilité

Abstract
This text discusses a new vision of justice, that is, intergenerational occupational justice. In addition to presenting the genesis of an occupational vision of climate justice, the definition and explanation of this value are contrasted with other related concepts in occupational therapy and occupational science.

Keywords
occupational therapy, occupational science, climate change, climate crisis, justice, sustainability

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INTRODUCTION

L'ergothérapie et la science de l'occupation manifestent un intérêt contemporain grandissant pour la crise climatique et défendent la pertinence d'opter pour une perspective occupationnelle pour identifier des pistes de solution afin de surmonter cette crise (1-3). Depuis que do Rozario (4) a publié, en 1997, un article soutenant qu'un changement de paradigme à la fois en ergothérapie et dans la science de l'occupation était requis pour affronter la crise climatique, une littérature émergente de plus en plus abondante adopte une perspective occupationnelle pour discuter de cette crise sans précédent dans l'histoire de l'humanité (5-33). La crise climatique, considérée par l'Organisation mondiale de la santé comme la plus grande menace contemporaine à la santé humaine (34), au bien-être et à la survie du genre humain (35,36), attire l'intérêt d'un nombre croissant de chercheurs dans la science de l'occupation et en ergothérapie, et ce, de partout de par le monde (ex. : Angleterre, Afrique du Sud, Australie, Brésil, Canada, Espagne, États-Unis, Japon, Nouvelle-Zélande, Suède). Pourquoi? Parce que les changements climatiques sont principalement dus aux occupations humaines (37), objet central d'intérêt à la fois pour l'ergothérapie et la science de l'occupation.

Plusieurs associations professionnelles (38-40) ont pris position et secondent la vision de do Rozario (4) suivant laquelle l'environnement doit être perçu et conceptualisé autrement en ergothérapie. On doit transiger d'une vision anthropocentrique à une vision écosystémique de l'environnement afin que les occupations humaines soient respectueuses des capacités de régénérescence de la planète. Maints penseurs de la profession développent des critiques similaires de la vision dominante au sein de l'ergothérapie, selon laquelle l'environnement est instrumentalisé pour permettre aux êtres humains de réaliser leur nature profonde, soit leur être occupationnel, et ce faisant, ils détruisent par plusieurs de leurs occupations non écoresponsables les écosystèmes pourtant nécessaires à leur participation occupationnelle (7,17,18,22,23,41-43). Alors que les occupations non écoresponsables contribuent aux changements climatiques, les occupations écoresponsables correspondent à celles qui sont respectueuses des capacités de régénérescence de la planète, que celles-ci soient individuelles, organisationnelles ou sociales, de même qu'à celles qui participent à la régénérescence des écosystèmes. Dans cette mouvance critique, un nombre croissant d'auteurs s'appuient ou se réfèrent à une nouvelle vision de la justice, soit la *justice occupationnelle intergénérationnelle* (42-45). Le but de ce texte est de présenter cette vision occupationnelle de la justice. Pour ce faire, sa genèse est d'abord résumée. Ensuite, cette valeur est expliquée, en prenant soin de la définir et de distinguer les différents types d'injustice occupationnelle qui en découlent. Enfin, un nouveau type de justice et d'injustice occupationnelles est présenté – la justice et l'injustice occupationnelles intergénérationnelles.

GENÈSE DE LA JUSTICE OCCUPATIONNELLE INTERGÉNÉRATIONNELLE

C'est Sarah Thiébaut-Samson[1] qui m'a sortie de mon sommeil dogmatique. C'était en 2018, à Montpellier, au colloque *Expériences en ergothérapie*. Le titre de sa communication « Quels fondements pour une pratique durable en ergothérapie? » (41) avait piqué ma curiosité. En écoutant Sarah, je réalisais qu'il était possible de relier mes valeurs écologiques avec l'ergothérapie. J'étais complètement chamboulée, mais gonflée d'espoir – un horizon de possibilités s'ouvrait devant moi! Tel le prisonnier de la caverne platonicienne qui se libère petit à petit de ses chaines, je sortais, me semble-t-il, de la caverne et j'avais le sentiment de progresser vers le monde des Idées. À la fin de sa conférence, je me précipitai sur Sarah pour la remercier chaleureusement. Une amitié et une collaboration de recherche venaient de naître.

[1] Sarah Thiébaut-Samson est ergothérapeute et coordonnatrice des enseignements à l'Institut de formation en ergothérapie ADERE à Paris, en plus d'être co-fondatrice du Réseau pour le développement durable en ergothérapie (R2DE).

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Le concept de justice occupationnelle intergénérationnelle est né de cette rencontre. Après avoir écouté Sarah qui présentait une critique à la fois intelligente et pertinente de la vision anthropocentrique de l'environnement en ergothérapie, je me suis dit que cette vision devait changer pour que les ergothérapeutes de demain soient en mesure de soutenir la justice occupationnelle comme le font les ergothérapeutes depuis la naissance de la profession. En effet, puisque la réalisation de la plupart des occupations humaines requiert des ressources environnementales pour être effectuée et qu'en ergothérapie les êtres humains sont considérés comme des êtres occupationnels – c'est-à-dire des êtres vivants qui se développent et donnent un sens à l'existence par l'entremise de leur engagement dans des occupations –, j'ai alors pensé que les droits occupationnels des êtres humains d'aujourd'hui étaient en tension avec les droits occupationnels des êtres humains de demain. Plus encore, il me semblait que les êtres humains d'aujourd'hui avaient des responsabilités envers les êtres humains de demain, pour que ces derniers puissent eux aussi jouir de leurs droits occupationnels. Mais qu'est-ce qu'un droit occupationnel et, plus largement, la justice occupationnelle?

PRÉCISIONS CONCEPTUELLES ENTOURANT LA JUSTICE OCCUPATIONNELLE

La justice occupationnelle peut être conçue comme une valeur qui reconnaît et promeut le droit de tous les êtres humains d'accéder de manière équitable à des opportunités occupationnelles contribuant à leur survie, leur santé et leur bien-être (46,47). La justice occupationnelle se fonde sur une vision particulière de l'être humain, disions-nous plus tôt. En effet, en ergothérapie et dans la science de l'occupation, l'être humain est conçu comme un être détenteur de droits occupationnels (46,47). Considérés en quelque sorte comme un certain type de droits humains, les droits occupationnels se déclinent généralement ainsi : le droit à la participation et l'engagement occupationnels, le droit à l'équilibre occupationnel, le droit à la signifiance occupationnelle, le droit à l'épanouissement de son être occupationnel et aux choix occupationnels (47), lesquels sont des droits éthiques et non pas des droits juridiques, c'est-à-dire enchâssés dans des textes de droit. La justice occupationnelle est une réalité factuelle lorsque ces droits sont respectés. A contrario, une injustice occupationnelle se manifeste lorsque l'un ou l'autre de ces droits est bafoué. Les écrits distinguent en règle générale cinq types d'injustices occupationnelles, soit : la privation occupationnelle (qui bafoue le droit à la participation et à l'engagement occupationnels), le déséquilibre occupationnel (qui bafoue le droit à l'équilibre occupationnel), l'aliénation occupationnelle (qui bafoue le droit à la signifiance occupationnel et le droit à l'épanouissement de son être occupationnel), la marginalisation organisationnelle et l'apartheid occupationnel (qui bafouent l'ensemble des droits occupationnels) (47).

Dans tous ces cas de figure, une contrainte externe à l'individu l'empêche d'évoluer ou de s'actualiser en tant qu'être occupationnel comme il pourrait ou souhaiterait le faire. Par exemple, la *privation occupationnelle* correspond au fait pour un individu d'être empêché, contre sa volonté, de réaliser une occupation ou une activité[2], et ce, de façon prolongée. La pandémie mondiale de la COVID-19 a empêché un grand nombre d'êtres humains de réaliser des occupations qu'ils réalisaient avant sa survenance et qu'ils auraient aimé poursuivre. Pour ce qui est du *déséquilibre occupationnel*, celui-ci se manifeste lorsqu'un individu est contraint de s'engager dans une occupation ou une activité plus qu'il ne le souhaiterait. Par exemple, lorsqu'une personne doit marcher plusieurs heures pour aller chercher l'eau nécessaire à sa subsistance et à celle de sa famille, cela consiste en un déséquilibre occupationnel. Dans le monde occidental, le surinvestissement de la sphère du travail comparativement à d'autres sphères occupationnelles (occupations familiales, loisirs, soins personnels, activités spirituelles, etc.) est généralement considéré comme un déséquilibre occupationnel. Il y a *aliénation occupationnelle* lorsqu'une personne est contrainte de réaliser des occupations qui ne correspondent ni à son potentiel ni à ses aspirations personnelles ou professionnelles. Un exemple de ce type d'injustice occupationnelle correspond au fait que plusieurs états occidentaux peinent à reconnaitre les diplômes et les expériences professionnelles des immigrants, les confinant ainsi dans des emplois qui ne correspondent ni à leur plein potentiel ni à leurs aspirations. La *marginalisation occupationnelle* se présente lorsque des personnes se voient privées de choix occupationnels et contraintes de réaliser des activités qui s'inscrivent au sein de normes sociales discriminatoires. Le fait par exemple que plusieurs femmes de par le monde soient contraintes de réaliser certaines activités et empêcher d'en réaliser d'autres sur la seule base de leur genre constitue un exemple de marginalisation occupationnelle. Enfin, l'*apartheid occupationnel* se présente lorsque la marginalisation occupationnelle est institutionnalisée au sein d'une société, c'est-à-dire lorsqu'elle devient à la fois systémique et systématique et influence ainsi le fonctionnement de l'ensemble de ses institutions. Kroneberg et Pollard (48) ont forgé ce concept en s'appuyant sur la marginalisation occupationnelle systémique et systématique vécue par les personnes noires en Afrique du Sud. Tels sont les cinq types d'injustices occupationnelles généralement discutés dans les écrits en ergothérapie et dans la science de l'occupation (47). Mais pourquoi avoir ajouté le qualitatif « intergénérationnelle » après l'expression « justice occupationnelle »? Qu'est-ce que cet ajout apporte de plus à la vision occupationnelle de la justice?

CONCEPT DE JUSTICE ET D'INJUSTICE OCCUPATIONNELLES INTERGÉNÉRATIONNELLES

La justice occupationnelle s'intéresse aux liens présents qui existent entre les humains, voire à ceux qui existent entre les individus et les institutions sociales. Pour sa part, la justice occupationnelle intergénérationnelle met en lumière les liens éthiques qui existent non seulement entre les êtres humains d'aujourd'hui les uns à l'égard des autres ainsi que ceux entre les individus et les institutions, mais également et surtout les liens éthiques qui existent entre les générations successives d'êtres humains (44). Aussi, elle atteste du fait que les êtres humains de demain ont eux aussi des droits occupationnels, et

[2] Bien que des différences sont souvent établies entre les termes activité et occupation, dans cet article ils sont utilisés comme des synonymes pour simplifier le propos et le rendre accessible à un large public.

ce, comme tous les êtres humains, que ceux-ci soient vivants aujourd'hui ou demain (44,45). Sans se restreindre à la seule contemporanéité, elle s'ouvre sur les liens d'interdépendance qui existent de fait entre le passé, le présent et le futur. Elle permet ainsi de conceptualiser l'idée suivant laquelle les êtres humains d'aujourd'hui ont des responsabilités éthiques de nature occupationnelle envers les êtres humains d'aujourd'hui, mais également envers ceux de demain (45), ce que ne fait pas la justice occupationnelle qui ne se penche que sur le temps présent. Suivant la valeur qu'est la justice occupationnelle intergénérationnelle, pour que les générations futures d'êtres humains puissent exercer leurs droits occupationnels, les êtres humains d'aujourd'hui doivent s'engager dans des occupations écoresponsables (45). Ils ont le devoir d'adapter leurs occupations de façon à ce qu'elles cessent de détruire les écosystèmes et de changer le climat, voire qu'elles participent à la régénérescence des écosystèmes. Autrement dit, la justice occupationnelle intergénérationnelle permet de réfléchir aux droits et aux devoirs occupationnels des êtres humains dans le contexte spécifique de l'actuelle crise climatique. Tel est l'apport de cette nouvelle vision de la justice occupationnelle. La *Communauté Ergothérapique Engagée pour l'Équité et l'Environnement* (C4E) que j'ai cofondée avec des ergothérapeutes et des étudiants en ergothérapie, en 2020, vise précisément à développer des ressources pour actualiser cette valeur (49).

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LETTRE À L'ÉDITEUR / LETTER TO THE EDITOR

Bioethics: "The Science of Survival"?

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Mots-clés
Van Rensselaer Potter, bioéthique, science, qualité de vie, survie

Keywords
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In 1970, the American bioethicist and biochemist Van Rensselaer Potter, from the University of Wisconsin, defined bioethics as a "science of survival", in an article published in the journal *Perspectives in Biology and Medicine* (1). He repeated this definition in his book *Bioethics: Bridge to the Future,* published the following year (2,3). Potter is not necessarily recognized as the inventor of bioethics (4), but he was undeniably one of its first major theorists and deserves more recognition today, as well as others.

According to Potter, bioethics can be considered to reforge the broken link between life sciences (not only biomedical sciences) and ethics – it re-establishes the meaning of the life sciences, notably by asking why and how their applications can improve quality of life and the survival of humanity (5). In other words, bioethics should not judge innovations on the basis of moral and theoretical values or norms, instead considering these innovations scientifically, for ethical and pragmatic purposes. However, many bioethicists currently take the opposite view, considering bioethics as a means of restricting innovations (6-9). There are several possible explanations for this. But one possible explanation is the founding of the Kennedy Institute of Ethics by the American bioethicist and obstetrician André Hellegers, from the University of Georgetown (7,10). Together with The Hasting Center, this institution went on to achieve global recognition in the field of bioethics, due largely to the major works of the Americans bioethicists and philosophers Tom Beauchamp and James Childress, and their book *Principles of Biomedical Ethics*, published in 1979 (11). "Principlism" corresponds to the application of four ethical principles (autonomy, beneficence, non-maleficence and justice) to moral dilemmas in biomedical sciences. And it could be considered as a means of restricting innovations, at least in practice (12).

Principlism has been strongly criticized, at least since the 1990s, especially by the Canadian bioethicists and theologians David Roy and Guy Durand (13,14). For Roy and Durand, bioethics cannot be reduced to a deductive method which infers morality of all clinical or scientific practices according to only four ethical principles (13,14). They prefer inductive methods that infer ethical issues and potential solutions, practice by practice, based on direct observation and moral contextualization (13, 14). Moreover, it is clear now that moral values or standards could vary considerably between societies or individuals in space and time (15,16).

We consider these elements relevant and therefore propose the development of a synthesis of the ideas of Potter, Roy, Durand and others, like the Belgian bioethicist and philosopher Gilbert Hottois (1,2,12-14,17). Bioethics could be the "science" that studies new practices in life sciences (not only biomedical sciences) to try to identify and resolve ethical issues (tensions between values, norms and practices) based on empirical research, interdisciplinary studies (life sciences, human and social sciences, etc.) and inductive methods (probabilistic inference), as well as the actual or potential effects on the quality of life and/or the survival of the individuals and/or the societies directly or indirectly concerned by these practices, and the social and complex phenomena that they constitute.

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LETTRE À L'ÉDITEUR / LETTER TO THE EDITOR

Research Misconduct Case Oversight

Anonymous

Mots-clés
responsable de l'intégrité de la recherche, plaignant, accusé, université

Keywords
research integrity officer, complainant, accused, university

Disclaimer: The author requested anonymity because they do not want to disclose the identities of the complainant, accused, and university. The Editor of the CJB/RCB has seen the details of the allegations and encouraged the author to follow the appropriate administrative channels and national regulations. The current letter aims to shed light on failures with the current misconduct governance system at North American universities and proposes a modification to procedures to ensure that they are handled impartially and with due diligence.

INTRODUCTION

Most American and Canadian research universities have similar procedures for submission and adjudication of claims of research misconduct. The point person for handling cases is generally the Research Integrity Officer (RIO). If a case is submitted, there is naturally a sense of urgency. It is unlikely that someone would take the risk of a frivolous or ungrounded allegation; a false allegation that is not considered to be in good faith would itself be considered misconduct, e.g., see the British Medical Journal (BMJ) criteria (1). It takes a great deal of courage to bring forward research misconduct allegations because accusers reasonably fear retaliation even when peer-review procedures are kept confidential.

Universities normally require that the RIO rapidly perform a preliminary review to either dismiss the case or appoint a review committee to try the case. But since these cases are usually complicated, involving multidisciplinary expertise, as well as having potential conflicts of interest, giving the power to the RIO to unilaterally dismiss a case is arguably not in the best interests of the university. It would be better to get things right by doing a complete and impartial investigation.

CASE

I filed a scientific misconduct case against a faculty member at a North American university with absolute proof to support my allegations. In unilaterally dismissing my case, the RIO committed no less than ten fouls including the following: 1) Dismissing from their definition of misconduct two BMJ defined criteria; 2) Having no expertise in any of the three scientific disciplines involved in the case, failing to seek out expert assistance; and 3) Using deception no less than 5 times in their report to divert attention from the focused issues in the case, to other irrelevant items.

RECOMMENDATIONS

To avoid such problematic management of what are clearly very sensitive situations, I suggest that research misconduct cases could be better conducted as follows:

Step 1: Complainant files an unofficial draft with the RIO.

Step 2: The RIO reviews the document, then asks questions and/or makes recommendations to the complainant.

Step 3: The complainant reviews the feedback and (a) makes a formal submission; (b) goes back to Step 1; or (c) drops the case.

Step 4: If the official complaint is filed, the RIO tries the case according to institutional mandated procedures, and in conformity with regional and national guidelines. For example, such national standards are clearly defined in the US (2) and Canada (3).

To protect the identity of the complainant, the accused should not be informed about the case until it is officially filed.

CONCLUSION

Although research misconduct is relatively rare, it is also receiving increased public attention, especially when it leads to scandals. So, when allegations are made, it is vitally important to the reputations of not only the affected parties, but to the entire research community, that these cases be managed and resolved impartially and include experts in the involved fields of research. Universities, through their RIO and Integrity Offices, should be proactive in training their researchers in what constitutes responsible conduct of research and how to prevent research misconduct; this would help promote research that meets leading standards of scientific rigor and integrity amongst students and colleagues, and empower the academic community to better detect and prevent misbehavior or misconduct by their colleagues.

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