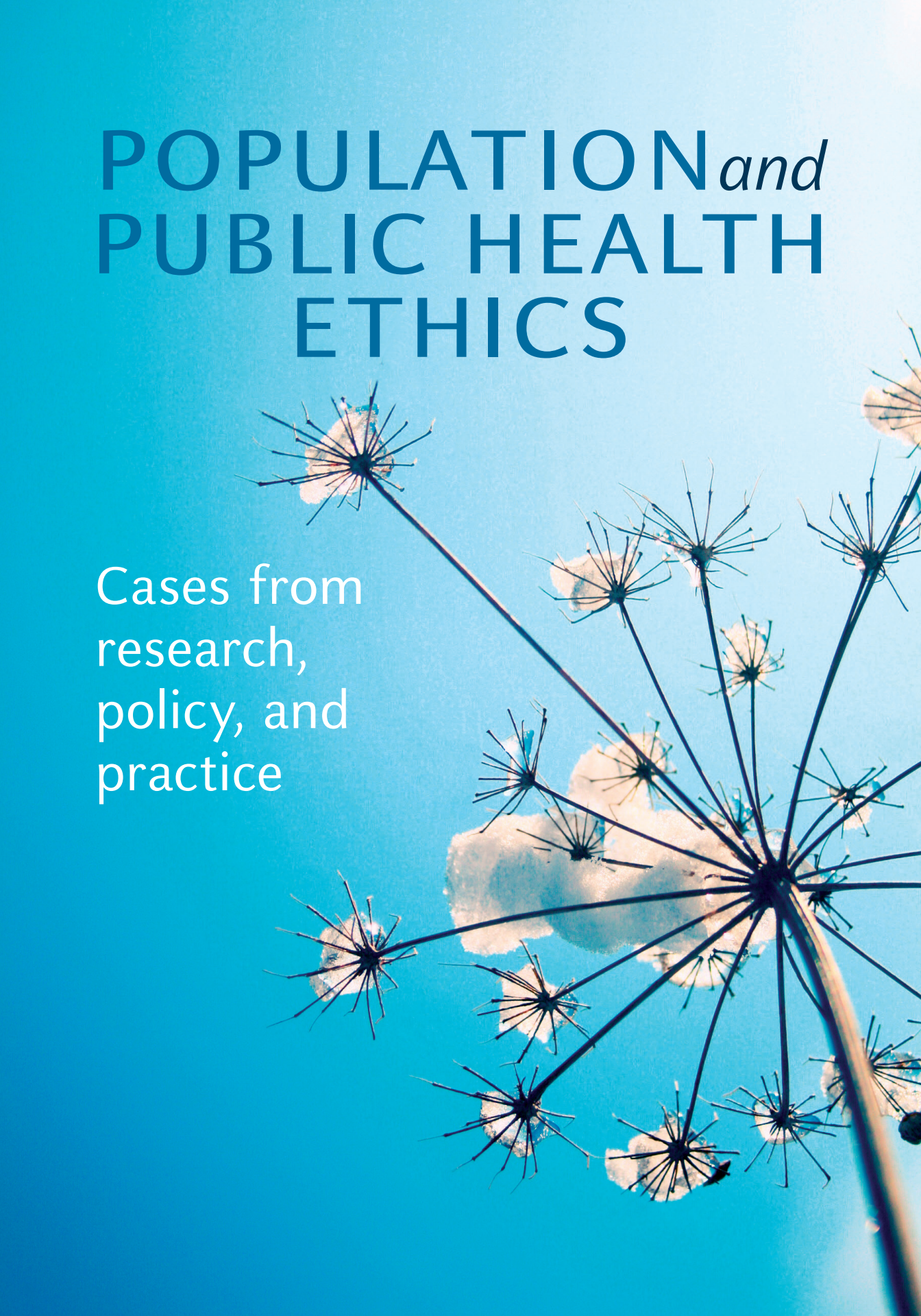
POPULATION *and* PUBLIC HEALTH ETHICS

Cases from research, policy, and practice



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FOREWORD

Sarah Viehbeck *Canadian Institutes of Health Research*
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The field of public health in Canada is evolving. Over the past 10 years, new structures have been created, including our respective organizations, training opportunities have grown, through programs and Schools of Public Health, and the importance of public health in preventing disease, promoting equity and intervening at the population level has been increasingly recognized and reinforced. In the midst of such change, there is a growing need to consider the ethical foundations for and implications of our work.

This casebook is a joint effort of the Canadian Institutes of Health Research (CIHR)'s Institute of Population and Public Health, the CIHR-Ethics Office, the National Collaborating Centre for Healthy Public Policy, and Public Health Ontario. Though our organizations serve different mandates and constituencies, we share a commitment to advancing the field of population and public health (PPH) ethics in Canada and globally[1] and have each undertaken a number of activities to this end. We have repeatedly heard that there is a need for resources to support discussion and debate around ethical dilemmas in population and public health. This casebook aims, in part, to respond to this need, through a collection of realistic cases from PPH research, policy and practice.

The objectives of this casebook are to:

» Increase awareness and understanding of PPH ethics, and the value of ethical thinking in population and public health research, policy and practice;

» Highlight cases from across population and public health research, policy and practice that feature different ethical issues and dilemmas; and,

» Create a tool to support instruction, debate and dialogue related to cases in population and public health ethics research, policy and practice.

The cases contained herein were solicited through an open call in summer 2011, which received a strong response. Case submissions were encouraged to be realistic (either real or a composite based on a real situation) and to focus on: 1) a particular ethical dilemma that arises in practice; 2) the ethical considerations of a specific population health intervention; or 3) how public health organizations deliberate or take ethics into account in their priority-setting or decision-making processes. Cases were selected based on a peer-review process involving experts in public health and ethics and truly represent the breadth of our field. Selected cases represent a mix of fictional cases, real cases with some details changed or fictionalized, and actual cases from the field.

Dr. Ross Upshur opens the casebook with a chapter that provides a helpful introduction to public health ethics — what it is (and isn't), why consideration of ethics matters in practice, how it differs from the bioethics paradigm and key approaches or ways of looking at ethics for and in public health. He elegantly covers fundamental concepts and grounds the chapter in his own experience as a practitioner. As you read the cases and conduct your own analyses, we encourage you to review Dr. Upshur's chapter and explore some of the literature mentioned within it.

The cases presented are organized around the themes of research, policy and practice:

SECTION 1: RESEARCH

The cases in this section cover a range of public health research and research ethics issues, including surveillance activities, research within public health units, data sharing and the process for ethics review at provincial public health organizations.

SECTION 2: POLICY

This section brings together cases from policy in public health and other sectors. The cases here bring to light the ethical foundations and implications of policy at the organizational, provincial, national and international levels.

Within these cases, we learn about challenges facing front-line practitioners in Canada and globally. The cases cover circumstances related to public health outbreaks, evidence-informed public health action and environmental exposures.

Accompanying case discussions provide examples of how an analysis of ethics issues can be done. The purpose of these discussions is to complement the case studies with an analysis of the issues and related considerations from a population and public health ethics perspective. As you read the cases and related discussions, we encourage you to recognize that this is but one perspective in response to the case. As with many things in life, there is no one single approach or "right answer" when thinking through thorny dilemmas. Though each case discussant was given the same general parameters, you will note that each analysis looks slightly different in form and content — each illuminating different ethical issues and principles and using different approaches to analysis.

Using their expertise and field experience, the case discussants were asked to:

» identify the key population/public health ethics issue(s) presented in the case and why they are population/public health ethics issues;

» identify the key relevant information (i.e., biological, economic, social, political, or ethical);

» assess knowledge gaps (i.e., what information is useful to know), as well as the basis for these facts;

» identify the key stakeholders in the case and the most appropriate decision maker(s) and/or legal authorities to approach the ethical issue, if applicable;

» identify the key values and concerns of the identified stakeholder(s) and any potential risks and benefits;

» identify the options available to the decision maker, including reasonable alternative courses of action, and consideration of implications and the potential intended and unintended outcomes; and

» suggest a resolution or decision to the case by choosing the supported option, and justify this decision.

Each of the discussants took on this task admirably, particularly considering the word limit constraints that we asked them to work within! We hope that the points raised in their respective chapters will serve as a springboard for your own discussion of the cases with colleagues or students.

On the cover of this book, there is a dandelion. Dandelions are easily recognizable and symbolic of persistence. It is our hope that through the work of our organizations and through this publication, we can assist in making some of the very real ethical dilemmas encountered in population and public health research, policy and practice just as recognizable, because they certainly are just as persistent! We hope that you, too, will persist and, through resources such as this casebook, be better equipped to deliberate and work through population and public health dilemmas you may encounter.

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Setting the Stage: Population and Public Health Ethics *or* Public Health Ethics: Ineffable, Ignorable or Essential?

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Twenty years ago, during my community medicine residency, I was struck by the number of ethical issues that arose in routine public health practice. The field of communicable disease control had no shortage of ethical issues relating to mandatory reporting requirements, contact tracing and the use of public health powers to compel individuals to alter their behavior. How did one balance individual rights versus protection of community health? Health promotion programs, particularly mass communication of health risks, raised issues concerning truth telling and what constituted appropriate health behaviour. Screening and surveillance programs were a veritable cornucopia of issues. Who defines normal and how do we decide which conditions to screen for or keep under scrutiny? Environmental health raised troubling issues at the interface of evidence and precaution when considering the health impacts of chemical exposures. How does one decide when harm has occurred or may occur? Board of Health meetings were dominated by questions of resource allocation and priority setting. How were priorities set? By what/whose criteria? It seemed to me that virtually every aspect of public health practice had significant ethical dimensions.

While ethical issues and concerns were in abundance, however, one was hard pressed to find a space to discuss the issues and scant resources to assist deliberating on the issues or in advancing one's learning. Aside from the occasional book chapter and a rather vigorous debate centred on HIV/AIDS, there were no courses, no textbooks, few articles and even less appetite for discussion on public health ethics issues.

Twenty years on, things have changed. Recent public health events, such as the SARS outbreak and the Walkerton *e-coli* outbreak, as well as the growing obesity problem and recognition of the ongoing disparities in health both in Canada and globally, have reinforced the need for ethical reflection in practice. The H1N1 influenza pandemic revealed a range of ethical issues most conspicuously relating to priority setting and data sharing. Each of these events raised significant ethical issues, some of which were handled well, others for which it is evident that a better job could have been done.

In this brief introduction, I will highlight some key features of public health ethics. To that end, I will briefly discuss the differences between public health ethics and bioethics; address the context of the application of ethics in public health; outline the role of ethical frameworks and ethical theory; and examine the growing relevance of public health ethics to public health policy. I will conclude by arguing for the need for core competencies in public health ethics.

How is public health ethics different from bioethics?

Public health ethics can be differentiated from much-better-known forms of ethics rooted in biomedicine and the traditions of ethics in the health professions. Modern health-care ethics takes its departure from the analysis of ethical issues as they arise in medical practice, particularly in the context of the application of new technologies in health care. The most influential theoretical elaboration is a principle-based approach as articulated by Thomas Beauchamp and James Childress.[1] Their well-known framework requires weighing and balancing considerations of respect for persons enshrined in the principle of autonomy, concerns for promoting welfare and well being through the principle of beneficence, avoiding doing harm as encapsulated in the principle of non-maleficence and concerns for justice. The first three principles apply primarily in terms of interactions between individuals; consideration of them typically plays out in a health-care provider/patient relationship. Only considerations of justice require the integration of the views of the broader community. Much bioethics scholarship, therefore, has been concerned with individual-level ethical issues.

Public health ethics focuses more on issues related to the interaction of individuals and communities, reflecting on collective responsibilities and common

goods. Following from Dawson and Verweij's conceptualization of public health, it is important to note that there is significant overlap between the values of public health and those of biomedicine.[2] What helps to distinguish public health ethics issues is that they go beyond the level of individuals and require "collective interventions that aim to promote and protect the health of the public." [2] Thus public health ethics is distinct from biomedical ethics in the modes of emphasis that are captured in the set of contrasts below:

» Population focus vs. focus on individual

» Community perspective vs. focus on the person

» Concern for social determinants vs. individual agency and responsibility

» Focus on systems of practice vs. individual decision making

Furthermore, because of the emphasis on communities, groups and collectives, reflection on issues in public health ethics requires the use of concepts and principles that are not necessarily rooted in the concerns of individuals. I term these "gluey" principles, as they draw attention to the shared interests of individuals and groups and reinforce the dimensions of mutuality and relatedness. Analyzing ethical issues in public health requires a conceptual vocabulary that reflects these dimensions. Principles such as reciprocity, solidarity and social trust have been put forth as candidates for analyzing ethical issues in public health ethics. Baylis, Kenny and Sherwin have done pioneering work articulating a theory of the relational dimensions of personhood and solidarity as it relates to public health.[3] I will not define or elaborate on these but simply observe that an overarching theory of public health ethics does not yet exist, although there is clearly considerable activity in this area of scholarship.

The analysis of ethical issues in public health currently draws on many of the theories and traditions of moral and political theory. Roberts and Reich argue that ethical arguments in public health can be grouped into three main categories, each representing a major theme in contemporary public health discourse: utilitarianism, liberalism and communitarianism.[4]

Utilitarianism has a long tradition in public health. Some have argued that public health is the practical implementation of a utilitarian ethic. Utilitarianism focuses on evaluating the consequences of policies and practices to determine their moral worth. Consequentialism is evident in public health where some form of aggregate measure is used to determine the benefit of an

intervention (say reduction in mortality or decrease in disability or quality adjusted life years.) Consequentialism seems a natural analog to the metric-driven aspects of public health practice rooted in epidemiology.

Liberalism, on the other hand, is rooted in the claims of individuals to have inherent value and worth. Originating in the deontological perspective of Immanuel Kant, liberalism places high value on protecting and promoting individual liberty. This is manifest concretely in the wide range of rights that are protected and promoted under international human rights codes.

Communitarianism focuses on the qualities and characteristics of communities that make them salutary. It focuses on the structure of communities that are health promoting and analyzes the character traits and virtues that should be aspired to and encouraged in citizens.

There are now a wider variety of normative theories relevant to public health ethics. Feminism brings a lens of gender to the analysis of ethical issues in public health. How do policies and programs work toward promoting gender equality and reducing the oppression of women? Paul Farmer has argued for the importance of integrating social sciences perspectives, particularly anthropology, to examine the role of oppression in understanding health issues.[5]

Recently, considerable attention has been devoted to the existence of inequities leading to disparities in access to health and health outcomes.[6] Many of these disparities are rooted in the social determinants of health. The existence of marked disparities has lead to the analysis of the relationship between social justice and public health. Powers and Faden elaborate a theory of social justice capable of informing the moral foundation of public health ethics.[7] They are critical of accounts of justice in public health that focus exclusively on outcomes derived from considerations of utility. Instead, they argue that a social justice perspective addresses the twin moral impulses that animate public health:

> *"to improve human well being by improving health and to do so in particular by focusing on the needs of those who are the most disadvantaged. A commitment to social justice...attaches a special moral urgency to remediating the conditions of those whose life prospects are poor across multiple dimensions of well being. Placing a priority on those so situated is a hallmark of social justice"* [p.82].[7]

Powers and Faden's theory recognizes the interdependence of empirical and conceptual approaches to public health ethics. That is, neither philosophical theories of justice nor measurement of health states is sufficient in and of itself to provide a coherent account of public health ethics.

It is important to note that often in public health ethics debates, discussions and analyses cross these various philosophical domains, with utilitarianism predominating in some analyses and rights-based approaches or community-based approaches predominating in others. It can be argued that what is most important is explicit discussion of the moral and philosophical issues and the will to move towards a coherent position.

Dimensions of Public Health Ethics

Ethics can be integrated into various contexts in public health. Larry Gostin distinguishes between three areas of application in public health ethics: ethics *in* public health, ethics *of* public health and ethics *for* public health.[8] Ethics *in* public health analyzes concerns involving the public health enterprise, including tradeoffs between collective goods and individual interests. The ethics *of* public health is concerned with the ethical dimensions of professionalism and the moral trust that society invests in professionals to act for the common good. Ethics *for* public health takes into account the value of healthy communities and the interests of populations, with particular emphasis on the oppressed.

Callahan and Jennings describe four broad areas for describing the field of public health and link these to four approaches to the type of ethical analysis required: health promotion and disease prevention; risk reduction; epidemiology and other public health research; and structural and socio-economic disparities.[9] Similar to Gostin's ethics of public health, they define *professional ethics* as based on professional character and virtues and involving ethical principles regarding trust and legitimacy in the profession. *Applied ethics* involves reasoning from general ethical theories to inform the profession. *Advocacy ethics* is less theoretical but arguably the most pervasive in public health. This type of analysis has a strong orientation towards equality and social justice. *Critical ethics* describes an approach that attempts to combine the strengths of each of the above. It is practically oriented toward real-life problems, but brings larger social values and historical trends to bear. Critical

ethics understands dilemmas not only as the result of behaviours of disease organisms and individuals, but also from institutional arrangements and prevailing structures of cultural attitudes and social power.

Ethical Frameworks

For public health ethics to contribute to applied public health policy and practice, it must be understood as a type of applied ethics and relevant to the quotidian concerns that arise therein. Most practitioners have little inclination to engage with the finer points of moral theory and so, in many cases, they will rely on tools such as frameworks to assist in reflection on ethical issues.

Frameworks can be useful because they attempt to capture what is relevant to ethical reflection in a particular area of practice. They help to simplify and make explicit factors relevant to a decision. However, they can also be problematic if they are applied blindly.[10] It is important that the framework be relevant to the particular area under discussion, and any framework will yield a poor answer if it does not capture all of the factors relevant for a particular issue. The idea of a framework should be regarded as a metaphor: frameworks are simply 'frames', a way of looking at a problem in a systematic fashion.

Susan Sherwin uses the metaphor of lenses to illustrate how to employ ethical theory in practice.[11] Similar to how the various different powers of resolution found on a microscope provide different perspectives and details of cellular structure, and different powers of a telescope permit varying resolution of objects at a distance, different ethical theories illuminate different morally relevant considerations. No one theory will describe and analyze the same issue in the same way. Hence, familiarity, experience and practice are required. Frameworks aim to assist in thinking through an ethical issue, but they will not supply all of the answers, and individual judgment is still required.

Many operational frameworks and principles have been proposed for the analysis of ethical issues in public health practice. As noted, many of these have played a prominent role in pandemic planning documents. Nancy Kass has articulated an ethics framework that provides six primary questions to be addressed in relation to the ethical dimensions of any proposed public health program.[12] Childress et al. enumerate five considerations to be weighed when analyzing the ethical dimensions of public health action. These include

effectiveness, proportionality, necessity, least infringement and public justification.[13] I have proposed the following four principles to guide the justification of public health intervention in the course of health protection activities: the harm principle; the principle of least restrictive or coercive means; the reciprocity principle; and the transparency principle.[14]

Ethical frameworks have been criticized for their lack of theoretical justification, and in the policy realm as being "window dressing".[15] Most ethical frameworks have little empirical support in terms of data supporting the types of values selected. A promising avenue of research would be to examine how public health practitioners actually conceptualize and reason through the ethical challenges they face in practice. This may help inform the development of ethical frameworks that are responsive to the needs of front-line practitioners.

Growing Policy Relevance of Public Health Ethics

Public health policy has significant ethical dimensions, even though it sometimes is not explicit about the values that inform policy deliberations. Policy making is an overtly normative enterprise as it seeks to determine the correct course of action for organizations to take to enhance or protect health. This is seldom an exclusively technical or empirical exercise as it will involve marshalling resources and determining the differential impact of policies on varied members of the community. Thus, there is a non-ignorable ethical component to policy making.

Public health ethics has growing policy relevance, as witnessed by the important role ethical issues have played in pandemic preparedness. Original contributions to the normative basis of public health have emerged from research into ethical issues associated with pandemic influenza, such as the notions of relational autonomy and relational justice.[16] Ethical issues are also prominent in global responses to tuberculosis. The call for concern with remediating health inequities and consideration of these in policy development is also a recent trend. The relevance of public health ethics to policy also extends to managing chronic diseases, obesity and environmental health issues including climate change.

Aside from substantive accounts of public health ethics, attention has been paid to the importance of procedural justice, particularly in the domain of

priority setting.[17] Once more, using pandemic influenza as example, ethical issues related to how priorities were set for vaccines and anti-viral medications have been prominently discussed in policy circles.

Should there be core competencies in public health ethics?

The Public Health Agency of Canada has released a set of core competencies for public health professionals. Unfortunately, few specific competencies for ethics were identified. The following two quotations typify the views in the document:

> *"All public health professionals share a core set of attitudes and values. These attitudes and values have not been listed as specific core competencies for public health because they are difficult to teach and even harder to assess. However, they form the context within which the competencies are practiced.*
>
> *If the core competencies are considered as the notes to a musical score, the values and attitudes that practitioners bring to their work provide the tempo and emotional component of the music. One may be a technically brilliant musician but without the correct tempo, rhythm and emotion, the music will not have the desired effect."* [p.3][18]

It is likely a mistaken belief that all public health professionals share a core set of attitudes and values. Indeed, there is good reason to believe that this may not be the case at all, as public health practice draws on a wide range of professional and academic traditions. There is also good reason to believe that ethical reasoning and the capacity for moral reasoning can be taught. For example, the American Public Health Association created a model curriculum for ethical issues in public health; there are ethics objectives in the training of public health clinicians; and there are a growing number of ethics-related courses at the graduate level across Canada and elsewhere.

There is also abundant evidence of the growth of public health ethics as an academic field with new research and knowledge translation opportunities. Several full-length scholarly monographs have been published, public health ethics has been included in major texts in public health and law, sessions on topics relevant to public health ethics have been held at major international

conferences and there are dedicated scholarly journals such as *Public Health Ethics*, and an ethics section in the *American Journal of Public Health* and *Canadian Journal of Public Health* devoted to the topic.

Finally, ethics cannot be reduced to aesthetic or emotional considerations. There is a strong cognitive and critical dimension to the analysis of normative arguments that requires well-developed reasoning skills and explicit attention to weighing the strength and weaknesses of various perspectives.

Public health professionals often have limited formal training in ethical analysis. If these professionals are to develop skills and competencies in public health ethics, resources to aid in continuing professional development and the elaboration of core competencies will be required. As Roberts and Reich have written: "Understanding alternative ethical arguments has become as important as knowing the advantages and disadvantages of different epidemiological techniques".[19] This case book is an excellent contribution to these required resources.

Conclusion

The publication of this book of case studies derived from field experience, with commentaries from a group of well respected international scholars, is a welcome moment in the evolution of public health ethics. It is a contribution that should aid practitioners in enhancing their ability to identify and analyze ethical issues that arise in public health practice. If it succeeds in that, it will have achieved an important objective. If readers are stimulated to further scholarship and research in the field, perhaps a second edition in the future will be warranted.

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PART ONE

Research

OBESITY SURVEILLANCE IN SCHOOL CHILDREN

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Introduction

The population is becoming increasingly overweight, and high proportions of adults and children are defined as obese.[1] The precise impact of obesity on health is unclear, but evidence suggests an association with a number of conditions, including diabetes, certain cancers, stroke and heart disease,[1] leading to increased costs for the health-care system.

Studies consistently report an increased risk of obese youth becoming obese adults.[2] Children are a vulnerable population. Young children may have difficulty balancing short-term enjoyment against long-term health risks. Prevention of obesity is best addressed through learning healthy eating and exercise habits at a young age, rather than relying upon later treatment.

The Ontario Provincial Public Health Standards require public health units to engage in research and surveillance. In practice, it is often difficult to distinguish surveillance from epidemiological research. Epidemiological research focuses on generating, developing or testing a hypothesis, whereas surveillance is a first step toward identifying and quantifying a problem and is focused on generating robust statistics for future research or policy. Information from surveillance activities may be used to motivate action or leverage funding and as a basis for evaluating future interventions.

Case

A Body Mass Index (BMI) surveillance programme (heights/weights) will be implemented by public health nurses in a representative sample of elementary schools (children aged 4–11 years). Passive ('opt out') consent (with forms mailed to children's homes) will provide robust and representative population-level statistics and contribute to the development of evidence-based public health programs and policy.

It can be argued that surveillance is justified because obesity is a highly prevalent, serious health issue with an acceptable measure (BMI) and an excellent opportunity for data collection. Schools are a logical measurement site because they reach virtually all children. To do nothing might be thought to be analogous to causing harm. However, ethical issues could raise objections to the program. These include whether:

1 possible stigmatization of obese children may pose risks to their health;

2 screening rather than surveillance should be introduced so children identified as "at risk" can be followed up;

3 active consent should be sought because of the risk of harm to children within the program, and;

4 the use of BMI measurements may lead to confusing messages by increasing the legitimacy of using weigh scales at the same time as public health messages are telling people to 'put away the scale, adopt healthy behaviours that will improve overall health.'

These objections can each be addressed:

1 Stigmatization will be minimized by ensuring confidentiality through use of a privacy screen, careful control of records (e.g, codes, locked forms), training and strict adherence to protocols. Care will be taken to ensure children do not see results (e.g. having them stand on the scale backwards). Children (or parents) who request results will be referred to their doctors. An important justification for not providing the data to the child or parents, as would be required if this were a screening process, is the risk to confidentiality if information is given to the children to transmit to parents.

2 Inevitably children will be found who are "at risk." Surveillance does not normally include follow up of individuals as the focus is on measuring the magnitude of trends and changes in populations, while screening is intended to identify "at-risk" individuals with the objective of 'personal' intervention. A screening program may follow surveillance, but it would, arguably, be unethical to introduce one without good evidence about the scale of the problem. Surveillance is the initial priority to ensure good baseline statistics for future interventions, which could include a screening program.

3 There are good reasons not to obtain active consent. The chances of any risk of harm can be reduced so as to be minimal. Consent is often not sought for routine surveillance and active consent will be difficult to obtain in school settings. Such consent could have a negative impact on participations rates and, therefore, on the robustness of the data. Another option would be to not seek consent at all. However, given that there is some risk of harm (e.g., stigmatization) passive consent seems the best balance between the different considerations.

4 This problem can be addressed if key messages to children and parents about healthy eating and physical activity continue.

Scenario shift

» Alternate study participants (adolescents): The program could be implemented in high schools, changing the age of the surveillance activity to an older population (13–18-year-old teenagers). Adolescents may be capable of consenting to the surveillance themselves, reducing or removing the need for parental consent. In this scenario active consent could be sought.

» Alternate activity (screening): Each child would be given his or her results and follow up would occur for children identified as being "at risk."

» Alternate consent process (active consent): An active consent process is implemented that will seek written consent from parents for each child. This may result in fewer children participating, making the sample not representative of the population.

Questions for discussion

1 Is this surveillance initiative appropriate?

2 Can you explain why you consider this surveillance ethically appropriate or not appropriate?

3 If the project sought active consent from parents, would this increase the case for follow up of "at-risk" children?

4 What are the health unit's obligations for action after this activity?

ACKNOWLEDGEMENTS

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Case discussion in response to OBESITY SURVEILLANCE IN SCHOOL CHILDREN

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Introduction

Given the growing obesity problem in children and adults — and apparent links between obesity and illness — the need for more research and surveillance regarding obesity can presumably be taken as a given. Assuming that the general need for obesity surveillance should be considered uncontroversial, the case described by Dilworth et al. raises questions regarding (1) whether such surveillance should be conducted at elementary schools and, if so, (2) the conditions under which such surveillance should be conducted.

An important purpose of surveillance is to identify the prevalence of diseases and/or risk factors. When surveillance reveals that such rates are sufficiently high, public health authorities and policy makers can take action to respond to them. Establishing accurate estimates of prevalence rates requires study of representative populations. Dilworth et al. make a convincing case that elementary schools would provide an ideal representative sample of the study group in question (i.e., young children). The surveillance program they describe would "reach virtually all [young] children" (assuming not many parents will choose to opt out). It is hard to imagine a better, more representative, sample.

Assuming that data regarding obesity prevalence rates in young children will provide useful information, the surveillance program described could have important benefits. This partly depends, however, on what exactly will be done with the data obtained. Analysis of surveillance ethics, to date, has been

relatively limited, but one widely shared idea is that for surveillance to be justified, surveillance data must actually be used in practice.[1] In what follows, therefore, I will assume that those conducting the surveillance program will decide (or have already decided) to take particular actions (e.g., to implement screening and/or specific obesity reduction programs) if prevalence rates are found to be sufficiently high (i.e., beyond some previously specified level).

Considering harms as well as benefits

The fact that a surveillance program might have benefits, however, does not automatically mean that it should be implemented. We must also consider the harms that might result from any surveillance program and determine whether the benefits outweigh the harms. As Dilworth et al. note, a possible harm regarding the surveillance program under consideration is that it could lead to stigmatization of children (and that this may, in turn, pose risks to their health). Maintaining confidentiality of surveillance results in the way they describe would be feasible and would provide one way of reducing stigmatization.

Why should research ethics requirements regarding informed consent and standards of care not apply to this case of obesity surveillance ethics?

Another concern about stigmatization (which Dilworth et al. do not discuss) is that the surveillance activity may focus children's attention on obesity as a "problem," instigating (increased) teasing, etc., of obese children in schools. The same thing could be said, however, about discussion of obesity as part of health education in schools. The idea that no attention should be placed on the problem of obesity in schools because this might focus children's attention on obesity as a "problem" and instigate teasing, etc., sounds implausible. Nonetheless, this concern, given that it may arise even if surveillance data remain confidential, should be addressed somehow. The surveillance activity, for example, could be combined with an educational/socialization activity specifically aimed at reducing stigmatization and bullying. Another option would be to combine the surveillance with routine physical examinations of children in schools, in which case it would not draw children's attention to obesity as a problem.

In any case, for the surveillance to be justified there would need to be reason to expect that the health benefits of the surveillance would outweigh

It would be ideal to get active informed consent from parents if it would be feasible to do so without overly compromising results.

stigmatization harms that result from the surveillance. To help ensure this, monitoring of stigmatization resulting from the surveillance could be combined with the surveillance activity. In what follows, I assume that the expected benefits of the surveillance activity will outweigh expected harms (though this does warrant further empirical study) and, therefore, that conducting such surveillance is, in-principle, justifiable. This then raises questions about the conditions under which surveillance should occur.

Research vs. surveillance

If the study described by Dilworth et al. were considered ordinary medical research, then active informed consent of children's parents would arguably be required in light of research ethics "informed consent" requirements, and action would presumably be taken in cases where children are found to have BMIs that are problematic in light of research ethics "standards of care" requirements.[2] In the surveillance program described, however, consent would be passive (i.e., "opt-out") and parents will not be notified in cases where children are found to be "at risk."

This raises the following difficult questions: (1) What is the distinction between research and surveillance? and (2) What, if any, are morally relevant differences between research and surveillance such that the ethical requirements regarding the latter should be weaker than those regarding the former? We would need to answer both of these questions before concluding that the study under consideration is not subject to standard research ethics requirements.

According to the US Centers for Disease Control and Prevention (CDC), the distinguishing feature of research is the "purpose . . . to generate or contribute to generalizable knowledge"; the distinguishing feature of (relevant) non-research such as surveillance is the "purpose . . . to prevent or control disease or injury and improve health".[3] There are numerous reasons why this technical distinction might be considered problematic. First, purposes — i.e., intentions — are notoriously difficult to verify, and so a distinction based on purposes seems a problematic way of determining whether a study is research or not. Second, it would appear that, by this definition, much prototypical research (i.e., clinical experimentation) might be considered non-research because it

aims at generating generalizable knowledge *precisely in order* to reduce disease and improve health. I cannot resolve this issue here; it requires much further analysis. For the sake of argument, however, I will assume that the obesity study under consideration does not aim to generate (any) generalizable knowledge and that it is a clear case of surveillance rather than research.

This brings us to the second, more important, question. Even if there is a distinction to be made between research and surveillance, what, if any, might be the morally relevant differences between the two such that the ethical requirements for the latter should be weaker than for the former? Currently, surveillance and research are treated much differently with regard to ethical requirements. For instance, informed consent is (usually) required as a central tenet of research ethics, but often/usually not sought in the context of public health surveillance. Both clinical research and public health surveillance (usually) are aimed at generating information that will be used to improve health. Why should the ethical bar be higher with regard to one kind of study (i.e., research) as opposed to the other kind of study (i.e., surveillance) when both are aimed at generating information that will be used to improve health?

There would presumably be benefits, but no clear harms, if those who clearly need help are informed of this fact, and, in such cases, parents should be informed.

The extent to which the ethical principles/guidelines that govern public health surveillance should be similar to, or different from, those that govern research remains largely an open question that requires further ethical analysis. We clearly need some standard international principles/guidelines for the governance of public health surveillance analogous to the Declaration of Helsinki and/or CIOMS guidelines regarding research ethics. This points to another important area for future development in public health ethics.

A virtue of the case provided by Dilworth et al. is that reflection on it may shed some light on what principles/guidelines of surveillance ethics should look like. In what follows I will address the following question: Why should research ethics requirements regarding informed consent and standards of care *not* apply to this case of obesity surveillance ethics?

First, with regard to informed consent, Dilworth et al. suggest that if active informed consent were required, too few parents might agree to their children's

participation, leading to a less representative sample and thus compromised results such as less accurate prevalence estimates. The ultimate concern appears to be that this would have untoward effects on public health. Active informed consent in research, however, may likewise sometimes lead to less representative samples, and thus compromised research results, and this can also have untoward effects on public health. Why can we live with such compromised results in research but not in surveillance?

It should be noted that, in some kinds of research, such as epidemiological research, the usual requirement of informed consent is waived when risks to subjects are minimal and/or when it would be infeasible to conduct the study if (active) informed consent were required. In the case of childhood obesity surveillance, it would be ideal to get active informed consent from parents if it would be feasible to do so without overly compromising results (and thus public health benefits). This approach would both respect autonomy (in this case, of parents) and achieve the public health benefits of the surveillance. On the other hand, if there is good reason to believe that it would not be feasible to seek active informed consent and/or that this would lead to substantially compromised results, with a resultant negative impact on public health, and if the stigmatization risks discussed above truly are minor, then perhaps active informed consent is not necessary. The requirement of "opt out" consent would, in any case, at least allow parents who object to the surveillance study to refuse their children's participation, thus substantially, if imperfectly, protecting the autonomy of parents. In light of the inclusion of this "opt out" consent requirement, the proposed obesity surveillance is not completely at odds with informed consent.

Second, consider standards of care. If the obesity study in question were considered research, it would presumably be required that children who test positive for obesity and/or for risk factors for obesity would receive some kind of intervention, just as clinical research subjects diagnosed with disease (or risk factors) during clinical experimentation would be treated or receive guidance/counseling. In the proposed surveillance study, on the other hand, there will be no follow up; parents will not even be notified if their children's BMIs are problematic. Dilworth et al. say that doing so would "arguably, be unethical." Yet, assuming that it would be feasible for the investigators to at least notify parents in cases where children's BMIs are at levels considered to be dangerous (and in need of intervention) according to standard diagnostic

criteria, it would arguably be unethical *not* to do so. There would presumably be benefits, but no clear harms, if those who clearly need help, such as medical advice, are informed of this fact, and, in such cases, parents should be informed regardless of whether the investigation in question is research or surveillance and regardless of whether the study is subject to research ethics principles/guidelines.

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TO SHARE OR NOT TO SHARE?

Secondary Use in Public Health Emergencies

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All events described in this case are fictitious. All resemblance to past events and persons, living or dead, is purely coincidental.

Introduction

Three years ago, Jonathan Bleau, aged 23, decided to participate in a large-scale biobanking project that was exploring how environment, lifestyle and behaviour contribute to the development of cancer. Very enthusiastic about this project and in solidarity with his mother-in-law who had been diagnosed with breast cancer, Jonathan provided blood and saliva samples to the *PreHealth* Project based in Winnipeg, Manitoba. At the assessment centre, hosted by the local hospital, Jonathan was asked to complete a lifestyle questionnaire and provide authorization for the retrieval of pertinent information from his medical records. The consent form he signed before providing any samples or authorizing the retrieval of any data mentioned that both his data and samples would be stored securely for 50 years and that access would only be provided to researchers partaking in cancer research who had previously obtained the necessary scientific and ethical approval. The *PreHealth* Project is affiliated with a university in the region and the Research Ethics Board (REB) of that university's Faculty of Medicine is in charge of approving any access requests. After providing his data and samples, Jonathan decided to leave the country to pursue a graduate degree in France without leaving his new address with the *PreHealth* Project.

Case

The Canadian government has recently declared a public health emergency following the propagation of a mutated strain of the Ebola virus. Every province in the country is striving to provide the necessary care to individuals affected by the latest strand of the virus and the same level of intense activity is seen in the research setting. In Manitoba, research has focused mainly on small groups of people considered most at risk of developing serious symptoms related to the new Ebola virus. To prevent future outbreaks, however, many researchers in the province believe it is necessary to undertake a larger study of genetic factors contributing to the development of severe symptoms. Only a study involving thousands of subjects could identify any genetic factors involved in this propagation, but no resource of this size is currently available for research on the new Ebola virus. Moreover, setting up a biobanking project specific to the Ebola virus would require a considerable amount of both time and funds before it could be effective and usable by medical researchers. This insufficiency is prompting several researchers to request access to biological materials and genetic information already stored in various pre-existing population biobanks for use as control groups.

The university's REB has received one such request. After a long debate, its full membership decided to authorize a Canadian researcher to access the data and samples collected by the *PreHealth* Project. The declared public health emergency led the REB members to decide that the proposed research is essential and that the infringement to the participants' consent — that their data and samples only be used for cancer research — was justified in these exceptional circumstances. In normal circumstances, participants would have had to re-consent for such secondary use of their data and samples.

On Jonathan's return to the country, he learned through local media that *PreHealth*'s data and samples will be used for studies on the mutated strain of the Ebola virus. He felt concerned that his samples would be used for a purpose other than that he was informed of during the consent process. He also feels a bit betrayed by the project he so eagerly participated in on altruistic grounds. Jonathan decides to complain to the Faculty of Medicine of the university in question, and is contemplating legal action for improper use of his data and samples.

Scenario shift

» What if the biological samples and data now being used for the Ebola virus research were collected directly from clinical settings (e.g, residual tissues, tumor banks, etc.); would that change anything?

» What if the REB had approved the use of the data and samples collected by the *PreHealth* Project outside of a public health emergency context; would your assessment of the case be any different?

» What if Jonathan Bleau remained in the country at the onset of the pandemic?

» What if Mr. Bleau had died 5 years ago? Could a close blood relative object to the use of his samples and data for genetic research on the Ebola virus?

Questions for discussion

1 Was the REB decision to annul the initial consent the right one given the circumstances?

2 What are the competing ethical issues at play?

3 What are the benefits and/or disadvantages for researchers to use a population biobank established for research on cancer to study genetic aspects of the mutated strain of the Ebola virus?

4 What possible repercussions could this dispute have on future participation in the *PreHealth* Project?

5 Do you agree with the decision made by the REB? If yes, why? If not, what would you have decided if you were an REB member?

Case discussion in response to TO SHARE OR NOT TO SHARE?

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Introduction

A Research Ethics Board (REB) in this fictional case gave permission to a researcher to use data and biological samples from a biobank that had collected these materials from participants with consent to be used for cancer research. The researcher wishes to use these materials for a study concerning an infectious disease that is affecting the country so severely that the govenment declared a public health emergency. One participant became upset with the access provision, lodged a complaint and is contemplating a legal action.

While this describes the bare bones of the case, there is much we do not know. The case description does not tell us the time interval between the collection of materials for the cancer research biobank and the request for access to these materials for the infectious disease research. The longer the interval, the less likely the possibility of contacting persons contributing to the biobank for consent to this new use of their donated material, and the more likely that access without consent could be justified. It is also not known from the case description if the researcher requested or was given data and samples together with information that could identify the individuals who contributed to the biobank. Finally, it would be helpful to know the number of participants in the cancer research biobank and the number of participants required for the infectious disease research project, in order to appreciate the effort required to request a new consent.

Many different parties have an interest in this case. They include: the REB and the population of the country, which has a primary obligation to safeguard and protect the interests of participants and is ultimately accountable to the comunity served; the complainant, Jonathan Bleau, who participated in the biobank for cancer research and is opposed to the decision of the REB; other participants in the biobank, whose positions and preferences in this situation are unknown; a researcher in infectious diseases who feels that a rapid access to materials in the biobank would give him or her the best opportunity to contribute to the control of the infection that resulted in the public emergency; the university with which the biobank is affiliated and that supports the REB; population of the country, which is facing a newly emerging and serious infectious disease. In this case, the REB is the most appropriate decision maker.

The public health ethics issues

This case is concerned with the ethics of research involving human participants. Because the decision discussed in the case does not involve a single individual but a class of participants and a community at large, we are in the domain of public health ethics. Several distinct issues can be recognized:

» **Respect for autonomy:** The overarching principle of ethically sound research with human subjects is respect for persons. This principle incorporates the moral obligation of respect for autonomy. The most important mechanism protecting autonomy is free, informed and ongoing consent of research participants.[1 (Chapter 3)] In this particular case, participants (one of them being Jonathan Bleau) enrolled in a biobanking project called *PreHealth.* They consented to participate only in cancer research. Because research participation ought to be a matter of choice and not an obligation, the use of their data and samples for research on an infectious disease would normally require another consent.

» **The role of research in promoting the common good:** Research is an important societal enterprise that not only expands knowledge but also produces common good and enhances the well being of people. REBs, while protecting participants, also serve "the legitimate requirements of the research."[1 (Chapter 1B)] In Canada, where a consensus supports caring for each other by using public funds to pay for the

bulk of health-care needs, health-care research is also a communal enterprise, ecouraging people's participation.

» **The nature of the emergency situation:** In clinical settings, law and ethics generally allow for intervention without consent in true emergency situations. In research settings, the existence of an emergency situation needs to be taken into consideration, but REBs are still expected to demonstrate continuing commitment to the core principles of ethics review. Any exceptions and infringements of the ethics principles and procedures have to be demonstrably justified by those urging the exception or infringement. It is also important that these exceptions should not be unduly broad.[1] (Chapter 6D)

» **Secondary use of data and human biological samples:** Secondary use refers to the use of data or materials originally collected for another purpose. Secondary use of anonymous information or anonymous tissue samples does not require review by an REB or consent of those who provided data or biological samples. However, the researcher in our case is requesting access to data and samples that will have personal identifiers attached. Such access normally requires the consent of each research participant. An REB may authorize the release of the identifiable information and biological samples if the researcher requests it and if the researcher can prove that certain conditions for protection of paticipants are met.[1] (Chapter 5, article 5.5 and Chapter 12, article 12.3)

» **Likely harm or risks to the welfare of participants:** Concern for the welfare of participants is one of the core principles that must guide REBs in all decisions.[1] (Chapter 1B) In this case, the access to data and samples by another researcher is unlikely to result in any new harm or risk of harm to the physical, mental or spiritual health or to the social and economic standing of participants. In fact, these participants, as well as the rest of the population, may benefit from successful control of the infectious disease outbreak, if the new research project is allowed to go ahead rapidly.

» **The perspective of research participants:** REBs, when deciding on access to previously collected data and samples, are expected to be mindful of the perspective of research participants.[1] (Chapter 1B) One participant, Jonathan Bleau, enrolled in the biobank because

of his concern for people who will develop cancer, because of an encouter with this disease in his family. Jonathan felt betrayed by the biobanking program because his data and samples were to be used for research into an infectious disease, in spite of the fact that his consent was limited to participation in cancer research. Other people who enrolled in the same biobanking project may have different motivations, for example, to advance research and diminish human suffering in general or to contribute to knowledge that will help citizens of the country. Participants with such wide altruistic motivation would not likely object to their data and material being used to combat a serious infectious disease. In fact, some of those participants could feel betrayed if the REB did not allow access to their data and tissues, thus missing the opportunity to diminish human suffering and death through research. It also was most likely not participants who explicitly decided to restrict the use of their material for cancer research, but the biobank that inserted this restriction into the consent form. If a participant wished to restrict the use of data and samples to a certain type of research, this restriction needs the utmost respect. Empirical data suggest, however, that most participants providing biological samples for research are not very concerned with which disease will be subject of the research.[2]

The REB decision

There are good arguments on both sides of this dilemma. It could be argued that the REB was justified in the decision to give the researcher the access without consent of participants, because of the serious and urgent nature of the research, which, if successful, would bring major benefit during this outbreak of a serious infectious disease. The fact previous evidence suggests that most participants in cancer research biobanks, if contacted, would permit the use of their materials for the new purpose also supports the decision. Finally, it could be asserted that the infringement on the autonomy of participants is minor unless they specifically forbid the use of their material for research into infectious diseases or any other non-cancer diseases.

On the other hand, it could be argued that ignoring the purpose of the original consent (cancer research only) would be demonstrating grave disrespect for persons participating in the biobank trust in the REB system, and research

in general, that could negatively affect future research endeavors. Further, the inconveience of obtaining consent for the new use of previously collected information and samples is not sufficient reason to infringe on the previous consent, and the researcher did not prove that obtaining new consent would be impossible or even impractical.

The REB, in considering these arguments, must seek an appropriate balance between protecting the autonomy and welfare of participants on the one hand and facilitating a socially useful and even urgent research undertaking on the other hand. It must carefully consider the circumstances and interests of all stakeholders. New, imaginative solutions may emerge as a result of dialogue between the researcher and the REB or through outside consulting.

In this particular case, the REB may justifiably permit the access, providing that the data and samples be anonymized or coded. It could permit access to identifiable materials if there is a distinct possibility that the research study will determine who is vulnerable to the recently emerged infection and that such information provided to participants in a timely manner would advance their welfare. If the cancer research biobank is very large, meaning that contacting all participants would indeed result in a major delay of an urgent study, a survey of a sample of these participants may provide guidance for the REB decision. If there is insufficient community representation, the REB may wish to seek advice from an ad hoc committee representing the community[3] or from another REB in the community or the province.

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RESEARCH ETHICS AND CONFLICTS OF INTEREST AT A LOCAL PUBLIC HEALTH DEPARTMENT

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Introduction

The "Core Competencies for Public Health in Canada" acknowledge the importance of an ethics lens in public health service and delivery.[1] Given that local public health departments (PHDs) frequently conduct and participate in applied research, it is also important that public health staff have an understanding of the basic tenets of research and public health ethics. In this case study, we describe a provincial childhood screening research project involving local PHDs and highlight the relevant ethical principles.

Screening children and families for risks to healthy child development can increase referrals and entry into supportive programs. Currently, front-line practitioners use multiple validated screening tools to identify at-risk families. However, front-line practitioners have expressed a need for a single screening tool. To meet this need, the Provincial Ministry for Children (PMC) in Province X developed a single screening tool for the prenatal, postnatal and early childhood periods. The new tool was based on an unpublished literature review and consultation with experts, but was not previously piloted or validated. The PMC hopes that hospitals and PHDs will participate in a study of the tool so that a cut-off for "high-risk" families can be determined.

Case

The PMC has contacted your PHD to participate in a study to validate the new screening tool against the multiple screening tools used previously. Normally, all families receive a post-partum call from the PHD to screen for risk factors that may affect healthy child development. "High-risk" families then undergo more in-depth screening to determine the level of future intervention and assistance required, if any. Families may also be identified for screening through calls to the PHD's Phone Line or through referrals from other service providers such as midwives. The screening process is the same for every family.

If your PHD participates in the PMC's study, PHD staff would screen all identified families with both their usual screening tool and the new tool. The PMC plans to use this information to determine the cut-off for "high risk" on the new tool, but it has not yet developed a data analysis plan. Additionally, although "low-risk" families would not normally receive any further assessment, every fifth "low-risk" family will now receive an "in-depth assessment." (See Figure 1 for an overview of the current and proposed screening algorithms.) The "in-depth assessment" contains sensitive questions around parental history, such as sexual abuse.

Province X does not have a provincial ethics board, and the PMC does not plan to seek ethics approval through university or local PHD ethics boards. The PMC does not believe ethics review is required as this is a "program improvement," not research, and families would have contact with the PHD anyway. Your PHD management team has expressed interest in participating in the study, but some staff members believe that further information is required to determine if Research Ethics Board (REB) review is necessary. You request a copy of the PMC's literature review, study protocol and associated tools. You receive a bibliography of references and copies of the study tools, and are informed that the new screening tool will replace the current ones within six months; the materials do not contain either a literature review or the study protocol.

The first question is whether ethics review is required for this study. The "Tri-council Policy Statement on Ethical Conduct for Research Involving Humans" can assist with making this decision.[2] The Tri-council uses an ethics framework with three core principles: respect for persons, concern for welfare and justice. Generally, research involving living human participants

and non-public information requires REB review. Your PHD determines that REB review is necessary.

The second question is what ethical issues should be addressed during the REB review. Such issues include, but are not limited to:[2]

» consent process;

» fairness and equity in research participation;

» privacy and confidentiality; and

» conflicts of interest.

You may also want to consider the public health ethics principles of reciprocity and transparency.[3]

The REB review could highlight, seek further information or require the PMC to address specific ethical issues, including:

» background evidence supporting the study, including the unpublished literature review, process to reach expert agreement and experts involved (to reveal possible conflicts of interest);

» methodology, including study design, outcomes of interest, sample size, population of study, study procedures/protocols (e.g., participant recruitment) and data analysis;

» participant risks and benefits, especially for those who are "low-risk" and will be subject to a more intensive assessment using questions about mental health, drug use and others for study purposes. Risk can be considered based on a combination of magnitude or seriousness of harm along with the probability of the harm occurring. Benefits might include any compensation that participants will receive;

» informed consent process and transparency, including how risk is determined and what interventions will be offered based on level of risk;

» privacy, confidentiality, and security of records at the PHD and during data transmission from the local PHDs to the PMC; and

» consideration of pilot testing prior to conducting a province-wide validation study and to assist with formulating an approach to creating cut-off scores.

Scenario shift

Assume that several PHDs have also agreed that REB review is necessary and have proceeded with independent reviews. Conflicting recommendations result, ranging from acceptance without changes to requirements for major revision. As a result, there are now at least three different consent forms that will be used in the study. How might your actions change in light of these new circumstances?

Assume that with the REB reviews the study has been delayed, so the study analysis will not be available prior to implementation of the new tool. How would a delay in timing influence how you balance the ethical and program issues in your PHD?

Questions for discussion

1 How can you determine if a study constitutes "research"? When might program evaluations or continuous quality improvement projects require REB review?

2 What processes can be put in place to increase the consistency in decisions and recommendations from various REBs?

3 Were you concerned about the lack of information on study protocol and methodology? Why or why not?

4 Describe an appropriate consent process for potential participants in the study.

5 Should government policy or program changes be subject to ethical review? Who should conduct the review?

6 What approaches can be used to minimize conflicts of interest between a provincial government (funder) and PHDs when conducting research?

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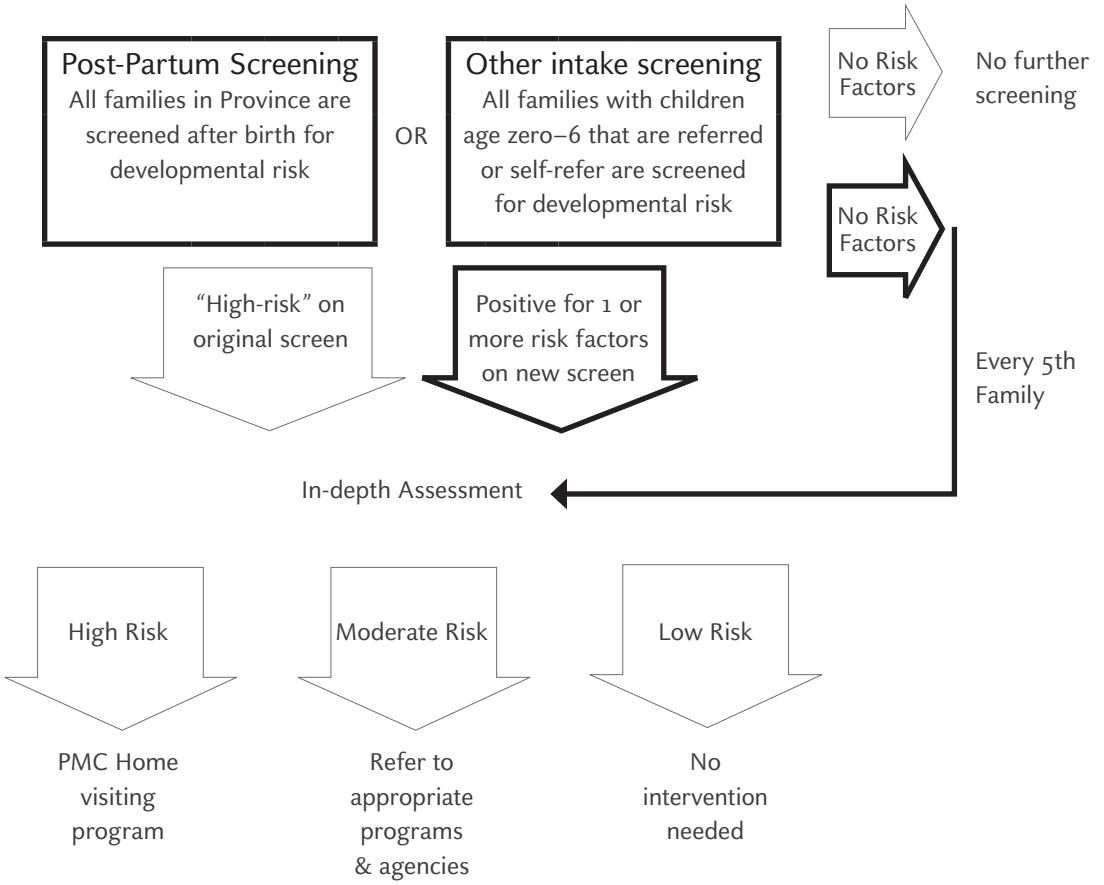
FIGURE 1. CHILD DEVELOPMENT SCREENING ALGORITHM

The current screening algorithm is shown in grey and the validation study algorithm is shown in black.



Case discussion in response to
RESEARCH ETHICS AND CONFLICTS OF INTEREST AT A LOCAL PUBLIC HEALTH DEPARTMENT

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Introduction

One thing is certain in this case: the Provincial Ministry for Children (PMC), through its lack of transparency and heavy-handedness in introducing a possibly legitimate and laudable change to public health practice, has succeeded primarily in alienating the front-line professionals essential to that practice, as well as in raising their suspicions about the motives behind the transition. Indeed, the PMC has so mismanaged the development and implementation of a standardized screening tool to improve identification of children at risk of suboptimal development that there is insufficient space here for a respectable analysis of the research ethics questions raised by the authors, let alone of the public health dimensions of the case. Bearing in mind the ampleness of the existing literature on the application of research ethics principles to population-screening projects, the availability of tools for distinguishing between research and other evaluative activities in public health,* the meagreness of the information by which to adjudicate between the conflicting views of the PMC and the Public Health Department (PHD) and the focus in this volume on the distinctiveness of public health ethics analysis, I propose to use the research ethics angle mainly as a springboard toward less-commonly discussed matters of population health practice and policy as they relate to early childhood development screening and support programs.

* The most notable of these for Canadian health professionals is perhaps the suite of ARECCI guides and tools developed recently in Alberta (http://www.aihealthsolutions.ca/arecci/areccitools.php).

Key ethical dimensions

Perhaps the most glaring moral issue raised here involves not simply the failure of a ministry to provide scientific and ethical justification for a significant program change, but also the appearance that the PMC has failed to seek support and approval for it. Regardless of whether what is being asked of the PHDs constitutes research, it would be highly irregular for there not to be extensive discussion and review, whether by an REB or other institutional committees and expert groups, especially given the provincial scope and compressed timeline of such a politically sensitive program change. If such review has occurred, it is odd for the PMC not to divulge the resulting material to interested PHDs, though this may simply be administrative oversight or miscommunication. If, however, such review has not occurred, PHDs clearly have reason to raise flags. Either way, the lack of supporting documentation and appropriate justification for the change is cause for moral concern, and all the more so in light of the apparently widespread perception by PHDs that what the PMC is proposing is, indeed, research.

The authors are convinced that the project constitutes health research and, thus, that the most pressing ethical issues are REB-related. While this is understandable, it also frames the ethics of the case in such a way that obscures a population health perspective. Consider the difference of opinion about whether the initiative constitutes research. On one hand, the fact that both new and standard tools are to be administered by the PHD to all families suggests some type of comparative study. On the other hand, the clear statement by the PMC that the initiative is "program improvement" rather than research, and the definitive ministry position that ethics review is unnecessary, not only explain the missing protocol and data analysis plan,* but make it impossible to weigh the conflicting views on the matter without additional facts unavailable in the case description. The research ethics/REB questions may be pressing, but they sidestep the possibility that the project is, as the ministry says, simply concerned with quality assurance, in that it seeks to calibrate the new screening tool with already established thresholds.**

* Since the case authors have implied, but not substantiated, their feeling that certain documents are being withheld, it cannot be ruled out that the absence of such is related in this light to their non-existence.

** This would require only that the various screening tools be used on a sample of families, followed by a de-linked chart review to standardize the sensitivity and specificity levels across them.

For these reasons, further discussion of research ethics will not be explored, with the caveat that this is not meant to deny the ethical importance of these issues; it is merely to signal that for those with perspectives from population health and public health practice and policy, the core moral dilemma of this case is the imposition of a new screening tool as a fait accompli. A new policy has been adopted and appears to be binding on PHDs unless they are willing to forego implementation funding. This raises some distinct and distinctly challenging questions

Key values and concerns

It may be that the change of tools is motivated by concern for a combination of equity, universality and efficiency. In this best possible light, the change is related to social justice: it is designed to enhance the sensitivity of the screening program by reducing false negatives and accurately pairing high-risk children and families with support programs, presumably with more support going to those with greater need.

In a climate of fiscal restraint and austerity, it is just as reasonable to suppose that the change is part of a deliberate cost-management strategy. The least-sinister version of this possibility holds that the new tool is simply more efficient: a streamlined universal screen is quicker to administer, reducing staff time and resources for the program as a whole. Such a reform might even ensure genuine universality and equity of the intervention (all children and families are screened to ensure none go without needed support) and might also allow the reallocation of public health professionals and resources in support of other important population health goals or interventions.

The more-sinister version, however, holds that the tool will detect fewer at-risk families because it is less sensitive or will result in fewer high-risk classifications because it employs a higher risk threshold, both of which would alter the number and profile of families referred for support. To understand why a screening tool that alters the number or profile of families eligible for services is not morally neutral, consider various forms of child disability or chronic illness: these will often have profound impacts on development, impacts unlikely to be mitigated without significant and costly medical and social programs. The result of the under-provision of

such support, seen across the country, is that families with severely chronically ill or disabled children frequently feel they must relocate to be closer to the services for which they are eligible, often at significant personal cost.[1]

The possibility that the new screening tool will identify a different pool of children and families is not unreasonably speculative. Purportedly evaluative approaches that distance the aims of screening programs from their actual impact as public health interventions are, after all, already noted in the case itself. Consider the choice of program effectiveness indicators. The authors mention "referrals and entry into supportive programs" as key evaluative measures, but these are empty gauges since they do not measure actual child-development outcomes. Worse still is that a focus on short-term administrative indicators of program channeling may allow ministry officials and health professionals to sidestep vexing questions about whether the screening program makes any real difference to the lives of children and families at risk.

Beyond concern for the stigmatizing effect of the "at-risk" label for parents, children and communities, and the corollary concern for the generally poor predictive value of screening tools for developmental risks,[2] it is essential to realize that the very concept and indicators of "risk" and "support" embedded in screening tools and social services may overstate individual and behavioural factors and understate social ones. Poverty, for example, is likely to be the single-most generalized and determinative risk factor for suboptimal child development. While the decision algorithm suggests that referrals to "appropriate programs and services" will be provided for families at moderate and high risk, there is ample reason to question the appropriateness and adequacy of these when it comes to eliminating or even reducing poverty as a risk factor for poor childhood development. After all, 22 years after both signing the Convention of the Rights of the Child, and adopting an all-party House of Commons resolution to eliminate child poverty, Canada is among the worst OECD countries for children living in poverty, with a rate between 10–15%, depending on the measure.* That translates into 600,000–800,000 children under the age of 18 living in poverty[3] (half of whom are not just poor compared to the average Canadian

* StatsCan totals are about one-third less than those generated by international organizations.

child, but are so materially impoverished as to be deprived of the necessities for healthy daily life).**

The numbers are no more flattering for child development than they are for child poverty. Among the ten wealthiest OECD countries, Canada in 2006 was dead last in public expenditure on early childhood education and care: only 0.25% of GDP was spent on such programs, five times less than the top countries. In a 21-country OECD review of 36 measures of child and adolescent well-being, conducted in 2007, Canada placed 12th overall, 13th on health and safety. And Canada met just one of the ten UNICEF Benchmarks for Early Childhood Education in 2008.[4]

These indicators and rankings, which are clearly and directly related to actual child development outcomes,[5] underscore the value of a critical public health ethics*** perspective when it comes to cases such as this one.[6] The importance of population screening tools that reliably identify children and families living in circumstances that hinder healthy development (and in some cases irreversibly stunt the neurobiological capacities of preschoolers, thereby predisposing them to adverse health outcomes at every subsequent stage of life[7]) can hardly be overstated. But neither can the importance of sustained support programs to mitigate vulnerabilities when they are detected, since a healthy early childhood environment has as much, if not more, to do with social risk factors (those that define access to education, safe nutritious food, education, quality housing and parental employment security and working conditions) than with medical risk factors such as biological disorders or parental lifestyle choices.[8]

** Note as well that all of this occurred as the size of the Canadian economy doubled between 1989 and 2007, and that the counts above surely underestimate current numbers since the effects of the most recent economic recession have not yet been captured.

*** Callahan and Jennings (2002)[6] propose that a critical ethics of public health is a perspective that is "historically informed and practically oriented toward the specific real-world and real-time problems of public health, but … brings larger social values and historical trends to bear in its understanding of the current situation of public health and the moral problems faced." They go on to suggest that such a perspective understands that public health problems "are not only the result of the behavior of certain disease organisms or particular individuals … [but also] of institutional arrangements and prevailing structures of cultural attitudes and social power." Rather ironically, given the data on child poverty and early childhood development investment just reviewed, these American authors point in the subsequent paragraphs to Canada as a model for the conscious attempt to relate public health practice and policy to broader social values.

Proposed resolution

Enabling "all children to attain and sustain optimal health and developmental potential"* is both an obvious and undeniable duty of government, one that Canada is failing to discharge.[9] The authors sought to explore how local research ethics review can be leveraged to respond to the imposition of an inadequately supported policy decision. Instead of attempting to re-mold the project under an impossible timeline, however, a better option might be to use the six-month window, and even a portion of the implementation funds, to develop a research protocol with local, regional or multicentre scope that aims to ascertain whether the new screening tool thresholds are indeed comparable to the old ones, as well as to follow children and families referred for support to determine the impact of both screening and support on health and development outcomes. After all, the fundamental moral requirement of screening programs is that they be connected to support/treatment options with a genuine capacity to avert or mitigate the potential for harm. In the absence of accessible and sustained support for families that is effective in improving child development outcomes, the justification for screening disappears entirely.

Concluding reflections

Ensuring optimal early childhood development is universally important and legitimate on moral, health and economic grounds.[10] Unfortunately, equitable and optimal child health and development appears not to be a top policy priority in Canada.[11] There is, then, good reason to question the motives and goals of under-substantiated changes to developmental risk-screening programs. The authors of this case study describe the first steps on the difficult but essential path toward clarifying an insufficiently justified policy decision, and toward insisting on greater transparency and accountability from decision makers. Public health professionals in Canada and elsewhere have

* As Ontario's Ministry of Health and Long-Term Care Public Health Standards (2010) states is the goal of Ontario's Child Health program. This goal also appears, as Lynch et al. (2008) point out, at the top of the list of recommendations of nearly every population health report of the last half century. Moreover, organizations ranging from the World Health Organization to the Canadian Chamber of Commerce regard optimal early childhood development to be the least expensive and most successful route to healthier children and adolescents and skilled, adaptive and productive adults. It is, finally, "the mark of a civilized society and the means of building a better future."(UNICEF 2010).

begun to recognize this kind of insistence as among their responsibilities. They would also do well to recognize the necessity to lead a deeper discussion around how to address and eventually prevent the childhood material and social deprivations that lead to developmental delays and adverse health outcomes, and the utility of public health ethics for the analysis of policy decisions that may perpetuate such persistent health inequalities rather than help to address them.

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A TOOL FOR ETHICAL ANALYSIS OF PUBLIC HEALTH SURVEILLANCE PLANS

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Introduction

Quebec's *Public Health Act* requires the authorities who are responsible for surveillance of public health and its determinants to produce surveillance plans and submit them to Quebec's *Comité d'éthique de santé publique* (public health ethics committee) for analysis and opinion. Such surveillance plans are often complex and hard to grasp, because they combine many subjects and many indicators from many fields. The analytical tool described here and reproduced in Appendix 1 was developed to make analyzing such plans easier for this committee. It fills a void in the public health ethics literature, where the subject of surveillance receives little attention. The studies that have been done,[1, for example] deal with specific issues and do not provide the desired view of the subject as a whole. Our tool is based instead on studies about the evaluation of surveillance (see *References*); most of the items included in our tool reflect these studies.

Many of the ethical issues that arise from surveillance activities are fairly well known and well documented. For example, the problems involved in managing the data used as inputs to surveillance plans have received ongoing attention in the literature; examples of these problems include protection

of confidentiality and privacy[2] and the risk of stigmatization, especially in relation to dissemination of information on vulnerable groups.[3] It is these problems, among others, that our tool is designed to alleviate.

Components of the proposed analytical tool

This analytical tool is designed to help people in the field of public health ethics or surveillance to obtain an overview of the main issues in this field. More specifically, this tool attempts to guide the analysis through an approach based on grouping typical ethical problems into categories; it is neither exhaustive nor restrictive. Our process for deciding what elements to include was largely intuitive and drew on the Quebec public health ethics committee's experience. Thus this tool can be used both by surveillance professionals (to quickly determine the main ethical issues that their work may raise) and by people who are concerned more with ethical issues in public health — and more specifically, in surveillance — whether in research areas that address these issues or in review processes such as that of the Quebec public health ethics committee.

Here is an overview of the ethical dimensions that this tool examines.

PROPORTIONALITY

Proportionality refers to the idea that the drawbacks of implementing a particular surveillance plan (such as problems related to privacy or to participation in a survey) must be offset by its benefits, which it is hoped will be greater. One of the primary justifications for surveillance is that it informs decision-making about public health programs and activities. But this effect is hard to measure. Also, the number of subjects of surveillance and surveillance indicators continues to grow, which makes the problem of proportionality ever greater.

USEFULNESS

The question of usefulness has been addressed implicitly above. The ultimate usefulness of a surveillance plan is the contribution that it makes to public health. The decisions made regarding surveillance plans must therefore have this potential to improve public health.

TRANSPARENCY

Transparency is the attribute that a surveillance plan has when its purposes

are explicit. In Quebec, surveillance, public health monitoring (for the purpose of protection), and research are separate, complementary functions, but the boundaries between them are not always easy to discern. Also, though it is understandable that some surveillance data may be used for research activities that were not initially planned, the overall objectives of the surveillance plan should nevertheless be known from the outset.

REPRESENTATIVENESS

A surveillance plan that is representative is one in which a) the phenomena to be placed under surveillance accurately reflect the health determinants and health problems that are recognized as important, and b) the populations studied are represented equitably.

EQUITY

While representativeness refers to the extent to which a surveillance plan allows all of the sub-groups in a population to be depicted accurately, equity refers to the need to devote particular attention to certain of these sub-groups, because certain health problems affect them disproportionately; in other words, the burden of disease is greater among them.

PARTICIPATION

Participation, by partners at least, if not by the public, is assuming growing importance in the field of public health. As regards public health surveillance in particular, openness to having partners help develop surveillance plans is nothing new. It helps to ensure that the data gathered will be more relevant and will be put to better use. The advantages of having the public or certain sub-groups within the public participate seem less clear. In some cases, such participation would enable some important health concerns to be highlighted. It might also help to prevent some cases of stigmatization by gauging the sensitivity of the chosen indicators, especially when the data are disseminated.

INDEPENDENCE

The increased presence of players external to the health system who have the financial capacity to take action on certain problems can place pressure on the public health authorities who develop surveillance plans to include subjects and indicators whose importance may not really have been demonstrated. Special care is advisable in such situations.

STIGMATIZATION

Some indicators, when cross-referenced with social and demographic data that identify certain vulnerable sub-groups of the population and that are available for fairly small geographic units, may contribute to the stigmatization of these sub-groups by reinforcing certain prejudices.

PRIVACY

Privacy is the fundamental concern of surveillance authorities not to disclose information that could be used to identify individuals, households, or communities, depending on the kinds of characteristics on which data are being disseminated.

INFORMED CONSENT

Medical administrative data are usually anonymized before being put to secondary use for surveillance purposes. But this is not always the case, particularly in projects attempting to monitor problems of comorbidity and multimorbidity. In such cases, consent to secondary use of data might pose problems, because it might not be possible to give this consent at the time that the data are collected.

UNDERSTANDABILITY

Lastly, the data should be disseminated in such as way that they can be understood by the public, because of course it is with the public's health that these data deal.

Questions for discussion

1 Is this tool complete? Are there any other ethical aspects of surveillance plans that it does not address?

2 Is this tool practical? Are there any ethical dimensions that cannot, realistically, be evaluated?

3 Could this tool be used for other public health activities, such as surveys on health and social issues?

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APPENDIX 1 Tool for Analyzing Public Health Surveillance Plans

Plan element	Standard ethical question	Example of a problem
Purpose of the surveillance plan	Is the surveillance plan proportional? Are its drawbacks offset by the benefits that it will provide? How are the burdens and benefits distributed?	The quantity of data to be collected is disproportionate to the actual use that will be made of them. Few benefits provided to the targeted groups.
	Is the plan transparent as to its purposes?	Some elements will be used for purposes other than surveillance, but that fact is not mentioned.
	Is the surveillance plan useful to the public?	Plan will produce information that will not lead to actions to improve public health.
Choice of subjects and indicators	Are the subjects and indicators dealing with the target population representative of the characteristics of this population and its health?	Excessive weight is given to a certain group within the population or to certain health problems, without any justification.
	Have the public and the partners participated in choosing the subjects and indicators?	Certain key actors are not participating, making certain subjects or indicators irrelevant.
	Did disadvantaged groups and their problems receive special attention when the subjects and indicators were defined?	Certain population sub-groups and problems that affect them especially are omitted or under-represented.
	Have subjects and indicators been included to assess the distribution of fundamental goods?	Plans does not call for any measurements concerning income, education, etc.
	Have any subjects or indicators been included that were submitted by parties who have an undue influence on their choice?	Plan is sponsored by a private organization that has interests concerning a particular health problem regarding which it wants particular subjects or indicators to be included.

Cross-referencing of data	Does the cross-referencing of certain data expose any groups to stigmatization?	Ghettos can be identified by cross-referencing of data on socio-economic status, ethnic origin or country of origin that are available for sufficiently small geographic areas.
	Can the cross-referencing of certain data lead to problems of confidentiality?	Individuals to whom the data refer can be identified inadvertently.
Data management	Do the databases afford adequate protection for people's privacy?	Databases identifying persons are used in an uncontrolled fashion.
	For sensitive data, has the consent of the people concerned been requested?	Use is made of data that come from biological samples and that are produced without consent.
Dissemination of information produced	Have the target populations and the partners been consulted about the dissemination of information?	Information is expressed in jargon, or in a form unsuited to client needs, or in such a way as to be stigmatizing.
	Have the populations concerned been informed about the methods that will be used to communicate the results on the individual (participant) level and the population level in accordance with the surveillance objectives?	No steps are taken to educate the public after the results are communicated.
	Have the comments by the population or the participants under study been considered?	Participatory activities are just for show, designed to co-opt the public rather than to genuinely consider its concerns.

PART TWO

Policy

EQUITABLE CONSEQUENCES?

Issues of Evidence, Equity and Ethics Arising from Outdoor Smoke-free Policies

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Introduction

Kass argues that an ethical approach in public health is one that places the fewest burdens on individuals' health without significantly reducing the potential benefits of intervening.[1] Yet many population health regulations are highly intrusive, compromising individual liberty and imposing penalties for non-compliance. Moreover, the benefits of these regulations and the burdens they impose may not be shared equally. When developing interventions, the state has, therefore, an obligation to consider the benefits and burdens, particularly on those vulnerable to health inequities and other disparities.[2]

The prevalence of smoking in the general population of Canada is low (18%), but remains elevated in certain sub-populations,[3] raising the possibility that universal tobacco control policies may impose disproportionate burdens on some and exacerbate health inequities.[4] Outdoor smoke-free policies are

being increasingly introduced within Canada even as evidence remains inconclusive about the risks of secondhand smoke exposure in outdoor settings and the efficacy of such bans. To remain consistent with Kass' definition of an ethical approach, the design and implementation of outdoor smoke-free policies should question whether these bans could result in an imbalance of benefits and burdens. Further, whether such bans increase the stigmatization of smokers and, in so doing, violate a core ethical principle and potentially increase health inequities should also be considered.[4,5]

Case

Municipalities are increasingly prohibiting smoking in parks, beaches and other outdoor public spaces. Smoke-free spaces are primarily justified on the basis of three goals: (i) reducing exposure to secondhand smoke; (ii) encouraging people to quit smoking; and (iii) preventing youth smoking initiation.[6]

Does evidence demonstrate that such bans effectively, equitably and ethically accomplish these goals? On balance, smoke-free policies in parks and on beaches may have a small positive population health impact. Such policies may reduce secondhand smoke exposure by eliminating the combination of circumstances that creates sufficient concentration of tobacco smoke to pose serious health risk; such bans may also facilitate smoking cessation or reduction for some people. There is little evidence to date, however, that smoke-free policies in parks and on beaches have an impact on the prevention of smoking initiation among youth. As well, the documented positive benefits may be offset by other, unintended consequences, such as when the stigmatization of smoking makes it harder for some smokers to quit or contributes to stigmatization.[4, 7–9]

While smoking prevalence among the general population in Canada (as in many high-income countries) is relatively low and declining, smoking rates are disproportionately high among youth,[3] low-income adults,[10] people with substance use disorders and/or mental illness[11–13] and Aboriginal people.[14, 15] These uneven rates of smoking both reflect and contribute to social and geographical health inequalities.[4] Universal outdoor smoke-free policies may have different effects on such sub-groups of smokers, including their use of tobacco, exposure to tobacco smoke and responses to smoking restrictions.[16] Paradoxically, by limiting the settings in which smoking is

allowed, smoking restrictions in public spaces may increase the concentration of secondhand smoke in private indoor spaces such as homes and cars and prompt strategies of resistance rather than compliance.[4] This could be particularly problematic for those without access to safe outdoor spaces and, by increasing exposure to tobacco smoke indoors, may undermine potential health benefits. Moreover, smoking restrictions in public spaces are intended to reduce the prevalence of tobacco use, in part by reducing the social acceptability of smoking.[17–19] Such denormalization of tobacco segregates smokers, makes them an identifiable minority, may compound experiences of social isolation and marginalization and may contribute to poorer quality of health among individuals who already face discrimination on multiple levels.[4, 7, 8, 20, 21] Stigmatization may contribute to poorer health outcomes and greater health inequity by generating higher levels of stress and contributing to reluctance to seek care.[22] Moreover, some argue that, by definition, the use of stigma as a public health strategy is inherently unethical because it is dehumanizing through its use of shaming to exert social control.[5]

Could proportionate universalism, wherein actions are tailored to the level of need or disadvantage, complemented by the behavioural justice approach, which places the responsibility on society to provide opportunities for all to make healthier choices, help address the ethical challenges posed by this imbalance in burdens and benefits? Applying these principles might lead to structural interventions designed to address the challenges facing disadvantaged smokers, thereby enhancing the positive aims and outcomes of smoke-free policies for all.

Scenario shift

Smoking in private cars when children are present has recently been identified as an environment for public health intervention to further reduce exposure to secondhand smoke. While policies legislating this behaviour are seen by some as an infringement on individual rights, scientific evidence exists which shows there is the potential for significant harm to those exposed to smoke in this enclosed environment.[23] In a discussion about John Stuart Mill's Harm Principle, Upshur[24] argues that public health interventions are justified when a behaviour or action causes undue harm to others, but should not be implemented merely for the benefit of the person who engages in the

behaviour. Therefore, the ethical issues raised by outdoor smoking bans are altered when considering the banning of smoking in spaces such as private vehicles because there is evidence that such behaviour is potentially harmful to both smokers and non-smokers.

Questions for discussion

1 Some have argued that it is never acceptable for the state to use shaming as a mechanism of social control. The stated goal of tobacco "denormalization" policies in Canada and elsewhere is to stigmatize smoking without stigmatizing the person who smokes. Is this possible?

2 A number of jurisdictions have introduced outdoor bans by designating specific spaces for smoking. Does this approach address the equity and ethical issues identified here? Or are we establishing "smoking islands" which cast smokers as outsiders and poor citizens for not taking responsibility for their health?

3 Some might argue that it is ethical to do anything that reduces the prevalence of smoking among vulnerable groups because the benefits associated outweigh the costs. Is such paternalism justified in public and population health practice?

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Case discussion in response to EQUITABLE CONSEQUENCES?

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This case focuses on the designation and legal enforcement of selected outside public spaces such as parks, beaches, etc., as 'smoke free.' The aim of such policies is to discourage smoking in the general population. One consequence is that smokers may find it difficult in certain outdoor places to find somewhere they are able to smoke. This particular policy is, in essence, an extension of the increasingly common idea across the world that smoking should not occur in public places such as the workplace or restaurants and bars. The case suggests, however, that the two situations are relevantly different and that, as a result, there is something wrong with banning such 'outdoor' public smoking. What are the arguments that such an outdoor smoking ban might be ethically problematic? There seem to be two, one focused on ideas about harm and a second on injustice.

The first argument, let's call it the 'Harm to Others' argument, appeals to a common interpretation of the work of John Stuart Mill.[1] As it happens I very much doubt that this is Mill's considered view,[2] but let us assume it is. On this 'Millian' view, the only justifiable reason for the state to intervene in a competent individual's life is if that person is potentially going to harm someone else through his or her actions. We might have a duty to inform people of possible risks to themselves, but if they then choose to submit themselves, knowingly, to that risk, then, on this view, it would be morally wrong to interfere because this would be unjustifiable paternalism. The argument in the case seems to be that, as we have no evidence of harm caused to others

through outdoor smoking, any legal restriction of such behaviour is morally wrong. The second argument, let us call it the 'Stigma and Injustice' argument, is that the intervention is likely to increase injustice, through the production of additional stigma towards minority groups in society that already suffer from disadvantage. The worry is that we know that members of such groups are more likely to smoke, and so this will have a differentially negative impact upon them. Both of these arguments, however, are problematic.

1. The 'Harm to Others' argument

There are a number of potential objections that might be raised to the argument that it is wrong to ban 'outdoor' public smoking based on the harm it might, or might not, cause to others. First, we might doubt whether it is really true that there is no evidence of potential harm to others. Can we assume that the issue is different if we distinguish outside space from inside space? Presumably, the relevant difference is supposed to be that smoking in an outdoor space is much less likely to affect in a negative way other peoples' health, because smoke rises into the 'fresh air.' However, it is surely unlikely that smoke will rise straight up into the atmosphere rather than, say, be blown towards the next group of persons on a crowded beach. The very fact you can smell your neighbours' smoking on the next picnic bench suggests this is too simple. If so, then all of the substantial evidence we have about harm from smoking is relevant (especially the evidence about the benefits from reduced smoking in public places).[3] It does indeed seem intuitively true that there is likely to be less impact than if smoking occurred in a confined space. However, it does not follow from this that it is, therefore, safe. Given that the general negative health risks from smoking are well known and clearly established, the burden of proof should not rest with those seeking to restrict smoking. After all, we are talking about smoking in *public* places, even if it is outside, not restrictions on smoking in private spaces.

The very fact you can smell your neighbours' smoking on the next picnic bench suggests this is too simple.

Second, the notion of 'harm' should not be interpreted too narrowly. The presumption in the case seems to be that only direct physical harm to others will count as harm. Yet there are other harms as well. If it is more likely that others will continue smoking or current non-smokers will begin smoking if they are surrounded by smokers, might this not constitute a harm? There is

certainly nothing in the 'Millian' paradigm that prevents seeing harm in this way. Indeed, a plausible view about harm is that we ought to define it as that which negatively affects our interests.[4] Given the risks to health resulting from exposure to smoke, it seems logical to see smoking in public itself as being such a potential harm, through its potential impact on others.

Where we have good evidence about a potential harm, and we can reduce the chances of such a harm occurring, it is perfectly legitimate for a government to take action to seek to improve citizens' health.

Third, restrictions on outdoor smoking can be supported by the idea that this is the next natural step in the gradual changing of norms relating to smoking in society. The idea is that we want smoking to be seen as something that is unacceptable, as this is the best way to help smokers give up. This, in turn, makes it less likely that children grow up thinking of smoking as normal behaviour, thus decreasing the likelihood that they will, in turn, become smokers themselves. Such a view rejects the idea that it should always be liberty that takes priority as a value in cases of dispute with other values (such as harm prevention). Where we have good evidence about a potential harm, and we can reduce the chances of such a harm occurring, it is perfectly legitimate for a government to take action to seek to improve citizens' health. If people strongly object, within a democratic society, the government is, ultimately, constrained by facing the public at an election.

Fourth, while it is, indeed, the case that the traditional 'Millian' picture suggests that action motivated to bring about beneficial outcomes for competent individuals against their will is paternalistic, and therefore morally wrong, this argument is not so straightforward when applied to public health measures targeted at whole populations.[5] For example, such public health interventions do not aim (at least, directly) at individual benefit. Indeed, perhaps the benefit can only exist as a result of focusing on the population (not individual good at all). Likewise, if the justification of a policy for tobacco restriction is through an appeal to justice, it would seem incoherent to argue that this end could not be pursued because it was 'paternalistic.'

2. The 'Stigma and Injustice' argument

The second argument in the case appeals to the idea that restricting smoking in outdoor places will increase stigma for already marginalised groups, and

that this is an injustice. Whilst it is certainly true that the evidence suggests that smoking is unequally distributed in the population, and that those in lower socio-economic groups are more likely to smoke,[6] this might well be one of the reasons for doubting the effectiveness and morality of the 'Millian' position outlined in the case. It looks as though a focus on the provision of information about harm as being the legitimate limit for our interventions has actually increased inequity, because the richer groups in society have responded to such information, whereas poorer groups have not. Banning smoking in outdoor public places will likely increase equality in this regard. Again, while the matter is complex, it seems reasonable to think that, on balance, egalitarians ought, in fact, to support smoking bans.[7] Of course, such legal restrictions need to be handled carefully and assessment of the likely consequences of policy change needs to ensure that the impact on individuals (and sub-groups) is not disproportionate. Targeted assistance, for example, could be provided to encourage such groups to give up smoking. Certainly, in the calculations of harms and benefits, notice ought to be taken of the impact upon individuals, and individuals should not be needlessly sacrificed for population benefit. However, we have no good reason to assign some subgroups in a population such extra value that their pleasure can trump other kinds of benefit that might accrue to a whole population.

Conclusion

Smoking is a known harm with no safe exposure levels.[8] It is beneficial to all for a society to take the view that it ought to be reduced to the greatest possible extent. What kind of a society do we want to live in?[9] Surely one where we ensure the best possible chance for all to lead flourishing lives. On balance, this will not be a smoking life. Admittedly, we sufficiently value the idea of individual liberty that we allow people to choose to smoke (putting to one side the issue of nicotine addiction). However, this does not mean that individuals ought to be free to potentially influence others to adopt damaging lifestyles. The important issue here is that we are dealing with public behaviour, not that the smoking occurs outside. Discussion of public health ethics ought to take seriously the nature of public health activity[10] and the kinds of values that are important in public health activity.[11, 12]

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DEFERRING BLOOD DONATION FROM MEN WHO HAVE SEX WITH MEN

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Introduction

What are the ethical implications of a public health policy that compromises a minority groups' equality rights? Ensuring a safe and adequate blood supply lies within the mandate of public health. The pursuit of this goal may unfairly come at the expense of men who have sex with other men (MSM) because policies implemented in response to the "tainted blood scandal" prohibit this community from giving blood.

A defining moment in Canadian blood donation policy, the tainted blood scandal resulted in thousands of blood transfusion recipients being infected with blood-borne viruses, including human immunodeficiency virus (HIV), between 1985 and the early 1990s.[1] Improper blood testing and donor screening, as well as inadequate warnings to the public that there were risks associated with the use of blood products, were all acknowledged as having contributed to the failure.[2] In 1988, the national body responsible for collecting and distributing blood in Canada, now known as Canadian Blood Services' (CBS), responded to the crisis by implementing a policy of rejecting blood donations from all MSM, who had even one sexual encounter after 1977. The goal of the policy was, and remains, to decrease the risk of the introduction of

blood-borne viruses into the blood supply by refusing donations from MSM, a population at a statistically increased risk of being infected with HIV. At the time of implementation, there was no test to detect the virus in donated blood, leading to a reliance on donor screening to prevent contaminated blood from entering the blood supply.

Case

The indefinite deferral of blood donation from MSM has recently garnered criticism and has prompted accusations of unnecessary discrimination and stigmatization of this community. The ethical dilemma lies in balancing the safety and sufficiency of the blood supply, a common good, against the rights of the MSM community, and of MSM individuals, to be free from unjust discrimination. Public health in all countries must balance these considerations while fulfilling its obligation to use scientific evidence honestly and fairly. In Canada, it must do so in the shadow of a tainted blood scandal that damaged public trust in the blood supply and continues to shape risk perception of blood-donation policies. Arguments that the MSM blood donation policy should be reviewed in light of current evidence are grounded in significant improvements in blood testing and the emergence of new HIV risk groups.

The science of HIV testing has improved since the late 1980s, and with it the safety of the blood supply. Historically, blood donated in the 'window period' (i.e, the period between infection and ability to detect the virus) could not be accurately tested for HIV. In 2001, the advent of nucleic acid-based tests dramatically reduced the window period to approximately 12 days.[3] As a result of both the deferral and the innovation in testing, the risk of contaminated blood is currently so minimal that it can be approximated only by mathematical models.

The groups of people at risk for HIV infection have changed since the early years of the HIV epidemic, when the virus predominantly affected MSMs. This group still accounts for a plurality of new infections but in reduced proportions. Today, MSM comprise approximately half of prevalent HIV infections, but heterosexual sexual contact, injection drug users, women and Aboriginal groups all have higher levels of infection than in previous decades.[4] The pattern of incident HIV infections is also shifting, with an increasing proportion of women, Aboriginal and ethnic minorities being diagnosed. In 2008,

26 per cent of new infections occurred in women, and 20 per cent resulted from heterosexual sex. In this same time period 44 per cent of incident infections were attributed to MSM.[5] Overall, while MSM still account for new infections, the risk from other groups is significant.

Other countries have already responded to the demographic change in HIV infection: the UK has recently changed its policy to a fixed, 12-month deferral period, while Australia has been using a similar policy since 2000.[6,7] In Canada, however, the CBS continues to employ the precautionary principle as an ethical guide to its policy. This means that the absolute deferral will remain absent conclusive scientific evidence that lifting the MSM deferral would not increase the risk of disease transmission through the blood supply.

Nevertheless, there are competing moral principles to weigh: keeping the blood supply free of disease must be balanced against the public's need for transfused blood. With an aging population comes an increased demand on the blood supply, as many donors become users of the blood system instead.[8] Overly cautious donation policy could lead to a blood shortage, but relaxing the criteria for donation could lead to preventable disease transmission, a risk that is borne, in this case, by individuals for whom transfusion is medically necessary.

Scenario shift

How would the risk of blood-borne disease entering the blood supply be managed if the most significant risk came from a group comprising the majority of the population? Consider a scenario where *heterosexual* sexual activity is associated with the highest risk of transmitting a blood-borne disease. Were this the case, indefinitely deferring all individuals engaging in unprotected heterosexual sex might drastically decrease the number of eligible donors. Faced with a shortage of blood for transfusions, it is possible that CBS would need to acknowledge the disparity in risks within the population and develop more sophisticated screening tools to identify individuals participating in high-risk activities. This hypothetical scenario prompts the question of whether the current policy of deferring all MSM blood donation regardless of individual behaviour is tenable only because it involves a minority group. Would a more nuanced policy alternative be available to address the proposed hypothetical situation?

Questions for discussion

1 How should the current evidence be weighed against the historical context of the tainted blood scandal in considering the ethics of the MSM deferral policy? How would a shortage of blood affect the policy decision?

2 It is relevant that the deferred group is a minority group that has been historically marginalized?

3 In a financially under-resourced setting, how could policy decision making balance the increased cost of using nucleic acid testing to identify contaminated blood against the potentially discriminatory use of donor deferrals?

4 Should the lifetime MSM blood donation deferral policy be lifted? If so, what policy, if any, should replace it?

5 Does a deferral policy of one year, as was recently instituted in the UK, resolve the ethical issues of the lifetime ban? Why/why not?

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Case discussion in response to DEFERRING BLOOD DONATION FROM MEN WHO HAVE SEX WITH MEN

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The broad ethical dilemma as outlined in this case study includes both the balance of safety and sufficiency of blood supply with the rights of the men-having-sex-with-men (MSM) community to be free from discrimination and stigmatization, and the need to balance risks and benefits. Many factors need to be considered in this case, including historical context, legal and political context, scientific evidence related to risk, epidemiology of HIV, public perceptions of risk and the social context. These factors will be considered within the applicable ethical principles used to structure this case, including beneficence, minimizing risk and harm, proportionality and equity. Procedural values such as reasonableness, transparency, inclusivity, responsiveness and accountability will also be discussed.[1]

Minimizing risk and protecting the public from harm are two important concepts that are applicable to this case. Minimizing the possibility of introducing contaminated blood in the blood supply by eliminating donations from at-risk groups is the central issue in this case. The historical context of the harm caused by the tainted blood scandal has created a situation whereby the Canadian Blood Service (CBS) and Health Canada (the regulatory body) have minimized risk to the greatest possible extent by eliminating these donations. Because of this history, protecting the public from harm and ensuring

public trust might also include maintaining the status quo to minimize the harm inflicted by the tainted blood scandal. By changing the criteria for blood deferral and eliminating the permanent ban for specific groups, there is a potential increase in risk to donor recipients, albeit very minimal.[2] It is important to consider whether any increase in risk is acceptable and on what basis.[3] Even as blood-screening technology has improved, and new screening tests have been developed (such as nucleic acid testing, or NAT), obtaining blood donations from low-risk donors is still important, as no one procedure is 100% effective.[4] Most specifically, low-risk blood donors serve to minimize the introduction of infected blood within the period during which HIV is invisible to laboratory screening procedures.

The initial policy was implemented using the justification of the precautionary principle in the absence of scientific evidence or robust tests to determine the presence of HIV.[3] As indicated in the case study, HIV testing has improved significantly since the 1980s, when the permanent deferral was introduced. Should the precautionary principle, then, still be used as a guiding principle when scientific evidence has demonstrated otherwise? If we know that there is potential for infected blood to enter the blood supply, thereby possibly causing harm to the population, should the lifetime ban be lifted? Not all MSM, though affected by the lifetime ban, are at the same risk level for transmitting the disease; the minimal risk posed by many of these men means that their exclusion from donation does not protect the population from any actual harm. In addition, the window period during which HIV is invisible to laboratory screening procedures has been reduced from three months to 12 days, further supporting policy change and minimizing the potential for infected blood in the blood supply. Finally, policies related to other groups considered "at risk" have also been changed, lending support to the re-examination of this policy.[3]

Proportionality involves protecting the public from harm by balancing expected benefits against any possible burdens.[1] One interpretation of the proportionality principle might suggest that, given the minimal increase in risk involved in allowing MSM to donate blood, the broad exclusion of MSM as blood donors is indeed not proportional with the risk assumed. A one-year deferral on monogamous gay men only increases the risk of one HIV-positive unit being potentially undetected in every 11 million collected,[5] meaning that risk of receiving contaminated blood is minimal (albeit not zero).[5]

Looking at the proportionality principle from another perspective, however, might lend support to the continuation of the MSM blood deferral policy in light of the past history of the tainted blood scandal, the damage to public trust and public perceptions of a safe blood supply. While tainted blood could come from any number of sources, permanent deferrals of high-risk groups may preserve public trust. Thus, keeping the policy as is might maintain public trust in a safe blood supply, while changing the policy has the potential to result in a breach of public trust, particularly if the public is not aware or informed of new scientific tests for HIV detection and the minimal risk posed by changing the policy. This is where procedural values (see below) become important.

A one-year deferral on monogamous gay men only increases the risk of one HIV-positive unit being potentially undetected in every 11 million collected.

Beneficence, or acting in the best interests of the population, is a vital ethical consideration. CBS now gets most of its donations from a mere three per cent of the population and that number is continually decreasing.[6] Some cities are making regular appeals to their residents to donate blood, and blood products have even been rationed at hospitals during shortages.[7, 8] Lifting the lifetime deferral has the potential to increase the donor pool by 1.3%.[5] It stands to reason that increasing the number of donors would benefit the population, and provide important justification for overturning the lifetime ban.

Equity is another significant ethical principle that applies to this case study. The marginalization and stigmatization of the MSM community can be traced back for many years, and continues to this day. Stereotypes and prejudices have been consistently portrayed in religious, lifestyle, and moral terms.[9, 10] Statistics do show that the majority of AIDS cases are found among gay men,[3] but if this group had received the same attention as those who were facing lung cancer or another more 'acceptable' disease, or if the high-risk group were heterosexual, history may have played out differently.[9, 11] It is important to note that MSM are treated differently than other groups of potential donors, such as women who have had sex with a man who has had sex with another man, who are only deferred for one year.[3, 11] They are also, however, treated similarly to other groups that are indefinitely deferred, including individuals who have received payment for sex since 1977, intravenous drug users and individuals who have tested positive for HIV. Blood donation deferrals also include other groups such as anyone who has had malaria, anyone who has

lived in certain regions in Africa, those with Hemophilia A and anyone who has possibly been exposed to, or is a descendant of a person that has had, variant Creuzfeldt-Jacob Disease.[6, 12]

Despite the fact that the UK also dealt with a tainted blood scandal in the 1970s and 1980s, this country has recently lifted its lifetime ban on blood donations from MSM. Currently, a deferral period of one year has attempted to resolve any ethical issues surrounding the blood donation ban and has also increased blood supply for the population. Given that other countries are changing their policies, it is certainly beneficial for Canada to ask the same questions and think about changes in the policy. CBS[3] has indicated that it will be exploring the possibility of changing this policy in light of scientific evidence and advancements. However, with this potential change, procedural values should be considered as the discussion of potential policy changes continue.

When one weighs these burdens in light of the minimal increase in risk, the increase in blood donations and the elimination of discrimination for this group in donating blood, it becomes obvious that a change in policy is necessary.

Procedural values include reasonableness, transparency, inclusivity, responsiveness and accountability.[1] They should guide decision making to maintain public trust in a safe blood supply. The value of reasonableness suggests that logical decisions be made that are agreed upon by stakeholders.[1] Thus, stakeholders and the public should be aware of the minimal increase in risk, and of the scientific evidence to support this assertion should a change in policy occur. Transparency, or communication about the policy change, is already occurring as this issue has been discussed in the media and CBS[13] has information on its website regarding further discussions. In addition, stakeholder views should inform decision making, with various groups being involved. As evidence continues to accumulate, opportunities for responsiveness, to revisit policy changes, become evident. Therefore, a strong evaluation plan is important to ensure responsiveness. Finally, accountability is a key procedural value, meaning decision makers must be responsible for their decisions.

In this case study, a safe blood supply and minimal risk is weighed against the need for blood and the potential increase in donors and the burdens of discrimination and stigmatization imposed by this policy on a marginalized

group, MSM. When one weighs these burdens in light of the minimal increase in risk, the increase in blood donations and the elimination of discrimination for this group in donating blood, it becomes obvious that a change in policy is necessary.[14]

In light of the above discussions, we suggest that the blood deferral policy for MSM be revisited, as CBS[13] is currently doing, and that the lifetime deferral for MSM be lifted.[14] The evidence of a minimal increase in risk of a contaminated blood supply and an increase in blood donors supports this recommendation.[2,14] While other countries have lifted the ban to a deferral of one year, we recommend that the decision about the length of deferral not be made until stakeholders and interest groups, along with experts, have opportunity for engagement and discussion. Given the high costs of NAT testing, consideration of scarce resources must inform the policy change. However, the benefit of increasing the blood supply, particularly when blood donation levels are low, must also be considered. Health Canada changed its deferral period for organ donation for MSM from a lifetime ban to five years because of the low rate of organ donations,[3] and this may be an important precedent for the blood deferral policy for MSM. The decision to change this policy must be made with utmost care to preserve public trust in a safe blood supply, and to ensure that the discrimination and stigmatization of MSM is minimized and, if at all possible in this case, eliminated. Although we suggest that the blood deferral policy be revisited, we also suggest that a comprehensive rigorous evaluation plan be implemented. The CBS promotional campaign states, "Blood, it's in you to give." A change in blood deferral policy for MSM would ensure that this campaign applies to a greater proportion of the population.

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WORLDWIDE AND LOCAL ANTI-MALARIA INITIATIVES

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Introduction

The malaria epidemic strikes almost exclusively in the least developed tropical countries of Africa, Asia, South America, and Oceania. This disease is transmitted by the Anopheles mosquito, which injects blood contaminated with the parasite *Plasmodium falciparum*, a protozoan. This parasite attacks the liver and blood cells, causing bleeding, kidney and liver failure, brain disorders, and death. Pregnant women are the most vulnerable to infection. Economically, this epidemic contributes to productivity losses, while socially, it leaves children orphaned.

The countries most affected by malaria lack the material resources to fight it. Medical staff often opt for countries that offer them better incomes. The most affected countries also lack the resources to do research, while pharmaceutical companies give priority to research on diseases of developed countries, which are more profitable. International assistance to developing countries for local research and field intervention risks being diverted to other uses, because corruption and lack of transparency and accountability are real problems in these countries.

Case description

For nearly a century now, experts have believed that it is technically possible to eradicate malaria. Effective intervention methods have emerged over the past 30 years or so. They include use of mosquito nets treated with pyrethroid insecticides, spraying of insecticide inside homes, diagnostic testing, and preventive treatment of pregnant women. Artemisinin-based combination therapies are now recommended, because resistance to monotherapies is a growing problem. In light of the technical resources now available, and out of concern for the welfare of the affected populations and their right to health, it has now become imperative to intervene.

The burden of malaria is borne chiefly by countries that have few resources to deal with it on their own. The only way to overcome this double injustice is for other countries to act in solidarity with them. World health agencies have the expertise and legitimacy needed to assume leadership in an effective, concerted campaign. But anti-malaria interventions that are initiated and managed from outside these countries may compromise their sovereignty and hence the acceptability and legitimacy of the interventions themselves. Consequently, anti-malaria interventions must be locally based, and the methods of funding them must be equitable.

In 2002, the leading world health agencies established a fund to fight malaria (www.theglobalfund.org). Their goal is to put an end to deaths due to malaria by 2015. This fund finances research and interventions in the countries targeted by local scientists and establishes guidelines to address the problems associated with corruption. First, a local applicant must commit to co-fund the proposed research or intervention, and must find an external co-donor. Because the process is initiated locally, the sovereignty of the countries involved is preserved, development of local expertise is encouraged, and the proposed intervention plan is more likely to meet the needs of the population and to employ implementation methods that are respectful of local practices and conditions. Next, the fund's managers evaluate the external donors and the local applicant. Applications for funding are vetted to determine their eligibility. These reviews are required to provide an outside expert opinion and minimize the risks that any funding granted will be misused. These precautions are similar to peer reviews, ethics reviews, and management-practices reviews. In addition, assistance in managing health resources is offered to limit the losses associated with the risks of bad management. The

resulting financial and scientific partnerships among malaria-affected countries and developed countries promote the transfer of expertise and tend to reduce inequalities.

This fund and these partnerships have become the primary tools in the fight against malaria, and direct effects attributable to the investment have been rapidly demonstrated. In total, 190 million insecticide-treated mosquito nets have been distributed and 7.7 million lives have been saved. It is estimated that $US 4.2 billion are needed to fight malaria every year. To ensure transparency and share knowledge, the progress achieved by these projects is reported in the Roll Back Malaria Progress & Impact Series, available at www.rbm.who.int/ProgressImpactSeries/index.html.

Scenario shift

Contributions to the fund remain vulnerable in times of economic crisis, when external donors are tempted to reduce international assistance. Any delay in field interventions may diminish the effectiveness of the eradication methods used. Indeed, resistance of the parasite to anti-malaria treatments and of the mosquito to insecticide have been observed in a number of countries. Immediate, intensive, sustained intervention, independent of the vagaries of the financial markets, could free humanity from this health burden that is so unequally borne. Conversely, any slowdown in field interventions could lead to continued loss of human life in affected countries and continued expenditures for intervention and treatment by all countries. Moreover, if the intervention tools now used were to become less effective, that could have negative impacts on the perceived legitimacy of the solicitation and deployment of major financial resources worldwide.

Questions for discussion

1 Is the concept of a right to health a sufficient basis for a duty to intervene in the case presented? Can this concept be applied in the same way in other contexts, for example, to public health programs in developed countries?

2 What should the eligibility criteria be for proposals submitted to the fund? What should the evaluation mechanisms be for these criteria?

3 Economic conditions could reduce the intensity of the fight against malaria (for example, by altering priorities, or by making funding unavailable, or by resulting in delays that cause intervention methods to become less effective). What ethical issues might arise under these circumstances?

4 What lessons learned should be transferred to other world-health interventions?

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Case discussion in response to
WORLDWIDE AND LOCAL ANTI-MALARIA INITIATIVES

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Broadening 21st century bioethics frames on malaria: From individual choice to 'global public health ethics'

The search for solutions to address the disparities in global public health has intensified recently, owing to an increase in the amount of development aid available over the past two decades.[1] For example, despite a slowdown in the rate of funding with the current global economic crisis, the amount of financial and in-kind aid from public and private channels to improve health in developing countries reached a total of $27.73 billion by 2011.[1] In parallel, global R&D investment increased to $1.1 trillion, doubling the amount invested in 1996.[2] Still, while the development aid flows from rich to poor nations, individuals and populations continue to face serious morbidity and mortality.[3] Moreover, even though development aid has been increasing, overall public spending for population health may be unchanged, or even diminished, given other formidable forces, notably debt repayment in developing countries.

Public health ethics addresses issues that focus on the population as well as on 'collective' components of health care, such as public health infrastructures (e.g., technology and education standards, databases) that carry substantive ethical significance. Identification of the public health ethics issues in malaria requires a broad focus that extends beyond medical ethics and individual autonomy.[4,5] For an analysis of malaria and global public health ethics, it is

essential to examine the history of biomedical ethics over the decades since the Nuremberg Code was formulated in 1947.

The principles of autonomy and individual choice, as well as that of consent, have historically prevailed in 20th century bioethics frames, particularly in the Western developed countries.[6] This narrow framing of biomedical ethics around individual choice and protection of research subjects has overlooked ethics in developing or less affluent countries. It also neglected ethical issues in a context of populations. Moreover, this approach does not recognize that public health extends beyond the immediate treatment of individual patients to include crucial infrastructures in many forms and shapes: medical and health outcomes databases; population biobanks; education of medical staff and doctors; local, regional and international standards on technologies; standards on international development aid; and aid effectiveness in developing countries.[5,7,8]

Indeed, the ethical concern over individual choice, autonomy and consent should be understood as being embedded *within* such broader health infrastructures that together constitute public health and public health ethics. Such public health infrastructures are not distributable goods,[4,5] nor do they represent targeted health interventions (e.g., unlike prescription medication) that can be subject to individual choice and consent. Public health infrastructures sustain, and are sustained by, the global or regional populations and thus raise entirely different sets of ethical issues that relate to collective action.[9,10] Collective action refers to organization of individuals', institutions' or governments' goals, values and priorities to permit sufficient cooperation among them and by extension collective human agency towards common, shared and explicated targets.[9,10] The ethical issues raised by collective action such as free-riders, unlike those addressed by traditional biomedical ethics, are governed by principles such as solidarity and citizenship.[6,11,12]

This case study describes malaria as endemic to, and vastly affecting public health in, tropical nations, nations that are often low- and middle-income countries (LMICs). A broad range of ethical issues seriously affecting 21st century population health in LMICs are raised in this case, issues that cannot be adequately identified or resolved successfully within the individual choice- and autonomy-based protectionist ethics frames inherited from the 20th century ethics discourse.

While protection of research subjects remains crucial, addressing global public health ethics responsibly demands broadening ethics frames to recognize issues that have been previously omitted from the purview of bioethics in developed affluent nations. Additionally, ethics analyses and scholarship are in need of 'symmetry': both protection from risks *and* potential benefits of global health and global science have to be considered in tandem, so as to develop a nuanced and in-depth understanding of public health ethics in LMICs.

The overarching shift and transformation of 21st century bioethics towards public health ethics, summarized above, provides a crucial context for the specific analyses of the ethics issues below, as related to malaria in resource-limited poor nations.

Global public health ethics and the case of malaria

While ethical issues have often been understood as 'impacts', ethics is not simply a consequence of, but rather is embedded in, science, technology and public health practice, and thus 'context-emergent'. The *actual* global public health ethics issues can therefore be identified by empirical engagement with the real-life context of both malaria and LMICs. Moreover, because the 'law in the books' and the 'law on the streets' can be markedly different in LMICs, socio-ethical, legal and policy norms intended to protect research participants or ensure justice in the provision of public health services cannot be assumed to be uniformly applied in practice. Experience suggests that the ethical issues concerning malaria can best be identified, analyzed and addressed when 'ethics is embedded in the design and implementation of' research projects' [13] and in real-life public health practice.[14]

Malaria chemoprevention-related drugs have been the subject of bioethics debates in terms of equitable access, pricing and distribution of these drugs between developed countries and LMICs. However, other and low-cost public health products are also conceivable or already available for malaria prevention and control. Most notable are insecticide-treated mosquito nets but other emerging interventions such as odorants, entomopathogenic fungi and genetically modified mosquitoes are also becoming available.[15] These newer forms of interventions need to be tested, however, for their effectiveness, acceptability and unintended consequences in real-life community settings in

LMICs. Evidence-based introduction of such existing and novel public health products for malaria, funding of the attendant clinical trials, protecting and incorporating the interests of research participants and capacity building for independent scientific merit evaluation by developing country scientists are issues of considerable bioethics significance.

While interventions such as medicines for malaria are targeted to individuals, provision of such health services is embedded within broader systems that crucially and collectively affect both individual and population health.[16] These health infrastructures represent global or regional public goods,[4,5] examples of which have been provided above: e.g., medical databases and standards on technologies, development aid to LMICs or education infrastructures specifically tailored for LMICs such as public education on effective use of mosquito nets.

Public goods are non-rivalrous (cannot be depleted with use by persons) and non-excludable (exclusion of certain individuals are unlikely) by their very nature.[9] For example, a database cannot be depleted with use by a person. Public health infrastructures instead raise issues related to collective action, such as free riders who may not contribute to a public good, or value conflicts due to competing values of stakeholders who need to co-create such infrastructures as public goods. Malaria and many other tropical diseases are currently being tackled through public-private-partnerships (PPPs), which, again, attests to the need for recognition of collective action, the process by which such cooperation comes into being or not, timing, monitoring or enforcement of collective action as legitimate public health ethics issues surrounding the case of malaria in LMICs.

Health as a human rights issue: An incomplete picture for public health ethics

While the idea of framing health care as a human rights issue could suggest a remedy for the ethical issues in treating individuals afflicted by malaria, this still provides an incomplete picture of the nature of public health, which rests on crucial infrastructures well beyond the choice of a single person. Human rights-based solutions to ethical dilemmas on malaria should be considered in parallel with the barriers and facilitators to the collective action that sustains public health infrastructures. The factors that affect public goods and

infrastructures are of ethical significance in much the same way human rights are for individual access to health care and essential medicines for malaria.

Moreover, the idea that medicines and interventions that target a given person occur in a vacuum is inherently false. Consider the case of a population where malaria is highly prevalent, as described in the case study. Treatment or preventive chemoprophylaxis of a person has impacts beyond that individual. It decreases the population reserve of malaria that can be transmitted to other persons in the population. Similarly, although a malaria vaccine is not available at present, current vaccine research against malaria, if successful, would benefit entire communities, not only the persons who are vaccinated, by achieving herd immunity for the population and, thereby, vastly decreasing transmission and epidemics in the entire population. Hence, even for targeted interventions, the individual choice, human rights and autonomy-based ethics frames neglect such broader and often population-level impact of a health intervention for any given person.

Standards on development aid and effectiveness: Reconciling global and regional priorities

While solidarity among nations might, in theory, help overcome injustice due to malaria's disproportionate impact on LMICs and tropical, resource-limited countries, the traditional Westphalian model of independent sovereign nations may preclude the actual implementation of such solutions. Furthermore, development aid is often ineffective and does not reach the intended target populations. In other cases, 'authoritative aid' materializes when there is a gap between what the donor countries want targeted with their aid (e.g., disease A versus B) and what the local population deems as a priority public health issue. Such mismatches between aid recipients and donors are an important ethical issue. Poorly targeted development aid not only results in waste of scarce resources, it sustains the pressing public health burdens in LMICs.

As a response to this ethical dilemma and to accelerate progress towards the Millennium Development Goals (MDGs), and recognizing the need to reform aid delivery and management to achieve improved effectiveness and results, donor countries and aid organizations have developed a reform, with measurable recommendations, called the *Paris Declaration on Aid Effectiveness*. In 2005, more than 100 signatories, including donor and developing-country

governments, regional development banks and international aid agencies, endorsed the Declaration.[7] The Paris Declaration embodies five fundamental principles in making development aid more effective:

» Ownership: Developing countries set their own strategies to reduce poverty, improve their institutions and tackle corruption.

» Alignment: Donor countries align behind these objectives and use local systems.

» Harmonization: Donor countries coordinate, simplify procedures and share information to avoid duplication.

» Results: Developing countries and donors shift focus to development results and results get measured.

» Mutual accountability: Donors and partners are accountable for development results.

It should be noted that the Paris Declaration, with endorsement from a global contingency of signatories, offers a mechanism and a crucial public health-relevant infrastructure for aid effectiveness. Its impact on global health warrants further empirical examination for malaria control/eradication programs as well as other public health priorities in LMICs.

Concluding remarks

The case of malaria in resource-limited developing countries and its intersection with development aid raise global public health ethics issues heretofore neglected by traditional biomedical ethics, as well as by individual choice and autonomy-based ethics frames. Our analysis therefore underscores the need to broaden the 21st century bioethics frames to reconsider ethics at the level of populations and recognize newer issues of direct ethics significance, such as collective action to ensure public health infrastructures and standards for development aid so as to bridge and reconcile global and local population health priorities.

Finally, and most importantly, as the majority of research on malaria is being done by researchers who are not based in LMICs, capacity building for both infrastructure and discovery science is more than essential[5,13,17] and should be recognized as a legitimate public health ethics issue.

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FIRST NATIONS DRINKING WATER POLICIES

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Introduction

Lack of safe drinking water has long been known as a major problem in many First Nations communities. As of September 2012, there was an estimated 116 drinking water advisories across Canada in First Nations communities and many of them were long-term advisories (lasting more than one year).[1] About a half million First Nations people live in Canada in approximately 600 on-reserve communities. Communities are small ranging in population from 13 to 11,449 people.[2]

A recent national two-year survey of more than 4,000 First Nations water and wastewater systems in 571 on-reserve communities indicated that nearly two-thirds (more than 65%) of them were either at high or medium overall risk. Risk ratings were based on overall systems management risk, not on water quality or safety.

Case

In general, the public health of First Nations communities is the responsibility of the federal government, while responsibility for public health in non-First Nations communities falls to the provinces/territories or local agencies. The federal government governs water in First Nations communities through

the use of policy directives and spending conditions.[3-6] Some communities using the First Nations Land Management Act , have developed regulations to provide local services, like supplying drinking water.[7] However, the quality of the relevant water regulations is variable, with some self-government agreements providing no regulatory agreement for potable water.[3-6] Costs related to the operation and maintenance of water and wastewater systems are the shared responsibility of the federal government and the relevant First Nation government.[3, 6] The various jurisdictional responsibilities result in ambiguity. For instance, First Nations communities are responsible for testing for bacteriological contamination in drinking water, but the federal government cannot enforce the testing, other than by withholding funding meant for this purpose.[8] In 2010, a bill was introduced to Parliament regarding safe drinking water for First Nations. The bill provides for the development of federal regulations governing the provision of drinking water, water quality standards and the disposal of waste water in First Nations communities. Importantly, the bill also establishes that federal regulations developed in this regard may incorporate, by reference, provincial regulations governing drinking water and waste water in First Nations communities.[9] Varied provincial and territorial standards were a challenge for the proposed bill and ultimately, the federal government remains responsible for the drinking water and wastewater of First Nations communities. A revised bill is being considered. Critics of the bill have indicated that financial resources need to be in place before new legislation is passed.[10]

The jurisdictional complexity governing First Nations water and wastewater systems contributes to the overall risks associated with managing such systems. Since the national survey showed that so many First Nations water and wastewater systems were at risk, the federal government had to decide what to do about the results. In the end, the government decided to target 15 First Nations communities for improvement in the first year, with 57 more to follow in the next four years.

There are a number of interrelated ethical issues in this case. These issues emerge from the decision to conduct the survey in the first place, and from the need to respond to its results.

First, the federal government was aware of many First Nations communities with high-risk water systems before the study was undertaken. Because the

federal government was aware of the problem in identifiable communities, it had a few options. It could devote resources to improving systems in communities where a problem was known, which meant that communities could benefit quickly from intervention. Instead, it chose the second option, to use the same resources to conduct a study that could assess water systems risk across the country. The merit of this option was that the study could identify communities previously not known to be at risk. The downside, however, is that known high-risk communities might have to wait to have their problems addressed. A third option was to do both: fix the problems that were known already, and conduct a study in order to identify other communities at risk. This option would be costlier than the other two options. Deciding among these options is an exercise in the ethics of resource allocation. The guiding value in such an exercise is justice. A just decision requires a decision maker to weigh the competing interests of communities with known and unknown water system risks against each other, while also considering the financial implications of each option.

A second ethical issue is the need to inform communities identified as high risk of the results before the completion of the full two-year survey. It would be ethically irresponsible to fail to disclose this important information as soon as it is known so that communities could take measures to protect their populations.

Third, although the affected population consists of a small percentage of the Canadian population, there is a great disparity between the risk associated with First Nations water and wastewater systems and most others in Canada. In addition, the risk to small non-First Nations communities is oftentimes similar or greater due to less availability of federal funding for upgrades and training.

A fourth issue is that, with so many communities at risk and limited resources at hand, a decision had to be made about which communities to target first. With limited funding, communities would have to be prioritized. There are a number of possible criteria that could be used for such decisions. For example, the federal government could give priority to:

» communities with the highest water systems risk;

» communities that are most vulnerable because of underlying health or socio-economic factors combined with high-risk water systems;

» the most easily improved and accessible communities; or

» communities with the greatest number of people affected.

Making this decision in an ethical manner would require the federal government to identify the factor(s) that give a community the greatest claim to the limited funding available.

Scenario shift

Consider whether your handling of the case would be different if the following circumstances of the case were different:

» During the study period, a large outbreak of water-borne disease occurs in a First Nations community that was recently inspected.

» A non-First Nations community outbreak occurs during the study and people are outraged that there is no equivalent study occurring in non-First Nations communities.

Questions for discussion

1 What do you think about the federal government's decision to fund a large research study to assess risk rather than spending this money on improving systems of communities already known to be at risk? What ethical values may have been considered in this decision?

2 If the survey is to be conducted in an ethically justified fashion, what should the communities be told about the survey and about how the results will be used?

3 If during the study, a community is assessed as being at particularly high risk, what sort of interventions should be made before first compiling and analyzing survey data? What ethical arguments support these interventions?

4 The federal government has ethical obligations to protect and assist all at-risk communities. What should be done about at-risk communities that will not be helped in the near future?

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Case discussion in response to
FIRST NATIONS DRINKING WATER POLICIES

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Introduction

As the authors note, the problem of drinking water safety in First Nations communities is one of long standing. The Auditor-General of Canada concluded in 2011 that "[f]ederal action on drinking water quality [had] not led to significant improvements" since a previous audit in 2005, and indeed pointed out the recognition by the Royal Commission on Aboriginal Peoples in 1996 of the multiple hazards to health associated with living conditions on First Nations reserves.[1] The Government of Canada (GoC), the actor with primary responsibility for public health in such communities, cannot claim ignorance of the issue. Indeed it can be argued that continued inaction on the drinking water issue should not be viewed in isolation, but rather as part of a larger pattern of privation (including, for example, inadequate housing) that generates health disparities between Aboriginal people as a whole and the rest of the Canadian population[2] and is clearly inequitable based on a definition of health equity as "the absence of disparities in health (and in its key social determinants) that are systematically associated with social advantage/disadvantage."[3] The primary ethical issue in this case is the GoC's apparent neglect of its constitutional responsibilities related to a basic prerequisite for health. The survey that is the focus of the case study served an important purpose in documenting the extent of the problem, but it was far from the first description.

Core issue

Case study authors identify the central issue in choosing among the identified policy options as one of justice in the allocation of resources. The view of justice as "requir[ing] a decision-maker to weigh the competing interests of communities with known and unknown water system risks against each other, while also considering the financial implications of each option" is too narrowly focused and may mis-specify the level of analysis required. The dice are loaded as it were, in favour of accepting the proposition that "with limited funding, communities would have to be prioritized" for post-survey responses. But why must such communities compete against one another for available resources, rather than with others among the myriad expenditure objectives of the GoC?

In the context of resource-allocation decisions with life-or-death consequences, it is useful to consider the view of resource scarcities provided in Calabresi and Bobbitt's remarkable book *Tragic Choices*. Such scarcities are seldom natural or absolute, in the sense exemplified by shortages of compatible donor organs for transplantation or (in a hypothetical example) of a geologically rare mineral that cannot be synthesized and has no substitute in the manufacture of a life-saving medical device. Far more common are situations in which "scarcity is not the result of any absolute lack of a resource but rather of the decision by society that it is not prepared to forgo other goods and benefits in a number sufficient to remove the scarcity."[4] Arguably, the core issue here is the (continuing) refusal of the GoC, and perhaps the society whose values it can be said to represent, to remove the scarcity in question.

Assertions of resource scarcity must be assessed in the context of estimates provided by the survey authors[5] of the costs of meeting official "protocols for safe water and wastewater." The adequacy of these protocols cannot be explored here, but they provide a useful starting point for estimating costs. The survey authors estimated the one-time costs of meeting these protocols as $1.212 billion, including capital costs, non-construction costs, and repairs to existing facilities; they estimated annual operating costs as $18.7 million.[5(p.30)] A much higher cost was attached to meeting future servicing needs over the next 10 years: $4.7 billion, plus $419 million per year for operating and maintenance.[5(p.34)] Considerable imprecision is involved in all such estimates, but they provide at least an order-of-magnitude indication of the amounts involved, which must be compared with total federal program spending

of $239.6 billion the 2010–11 fiscal year. In the absence of a credible claim related to the scarcity of any absolute lack of a resource needed to address the water safety issue, it could be held that the central issue is the ethical strength of the claim of First Nations communities to the provision of safe drinking water at a specified standard, and of the associated claim on public resources necessary to realize that objective, *relative to other claims on public resources*, some of which do not necessarily have any ethical force or merit. This issue exists independently of whether the risks are currently known or unknown, but the GoC's obligations in this regard imply a prior or corollary obligation to take all reasonable measures to discover and inform about those risks through testing and disclosure of results; the Auditor-General's 2011 report concluded that Health Canada's progress in this area had been unsatisfactory since 2005,[1] and the survey that is the basis of the case study did not address this concern adequately as it assessed only system management and not actual water quality.

Proposed resolution

It is difficult to justify either the decision to defer action pending completion of the survey, given the known risks to health in some communities, or the decision to target just 72 water systems (of the much larger number that were characterized as high or medium risk) for investment over the coming five years. The difficulty is compounded by the past history of neglect of on-reserve living conditions, and the fact that considerable information about the extent of the hazards to health was available well before the completion of the survey in question. The preferred course of action from a public health ethics perspective would be the third one of immediately addressing known problems while simultaneously conducting the survey. If health equity is specifically identified as a value of importance, the case for this course of action is further strengthened. In any event, an independent obligation exists to *be absolutely honest and transparent* with affected communities before, during and after the study (as per "questions to consider" 2 and 4).* Although costs are never irrelevant, the *ethical* basis for "considering the financial implications of each option" as part of the choice is unclear.

* This requirement can be derived independently from several foundations, including the intrinsic value of truth-telling and the principle of respect for autonomy, which normally requires providing full information and avoiding deception (e.g, in research ethics).

Additional issues

It may be that additional urgency is added by the apparent lack of recourse on the part of those directly affected: First Nations people living on reserves. These populations may have fewer ways of holding authorities (on reserve or elsewhere) accountable with respect to service provision than do other Canadians living in areas where elected local or regional governments have both authority and (limited) fiscal capacity related to ensuring water safety. The absence of legislated standards for water quality on reserves[6] compounds this problem.

If we adopt an ethical principle of special concern for the most vulnerable or most subordinated, it would seem clear that the disparity in living conditions and health outcomes between Aboriginal Canadians as a whole (especially, although not only, those living on reserves) and the rest of the population demands action as a matter of high priority. Depending on one's view of the current ethical salience of historical wrongs, additional urgency may be added by a long legacy of discrimination against, and disenfranchisement of, Aboriginal peoples, dating back to the colonial era. If this position were adopted, in a hypothetical situation in which resources were available to address only one of two disparities in determinants of health, one involving an Aboriginal population and the other a population of native-born Canadians of European ancestry, the former would have priority. As noted, however, the adequacy of such priority-setting exercises as an ethical response depends on the nature of the resource scarcities being invoked.

Although the focus so far has been on direct expenditures on water and wastewater systems by the GoC, this is not the only area of concern and the GoC is not the only actor with responsibilities. Such systems cannot be operated on a 'set and forget' basis, as the example of Walkerton (Ontario) makes clear.[7] The information provided does not allow us to assess the capacity of on-reserve authorities to operate such systems effectively, but the Assembly of First Nations has identified this as a major problem.[6] What additional activities and programs would the GoC need to undertake to ensure effective operation? Is the legislative and regulatory framework adequate? Wide agreement on the need for legislated standards, which now do not exist for First Nations reserves, suggests a negative answer to this second question. The point here is that additional capital and operating funds as identified by the study, while necessary, are not sufficient to ensure adequate water safety.

A final issue returns us to the question of level of analysis. The preceding discussion of scarcity may be regarded as unhelpful to public servants who must allocate resources within limits dictated by superiors and (ultimately) by Cabinet. While I am aware of this limitation, the approach taken here is a necessary corrective to the tendency in public health ethics to leap into the design of priority-setting algorithms without asking necessary questions about the source and defensibility of resource constraints.* The generic issue, in no way unique to public health, is how to act ethically as an employee in organizations the actions and priorities of which may be ethically questionable or indefensible — a far larger question than it is possible to address here.

Scenario shift

The first hypothetical presented in the case study simply underscores the seriousness of past neglect and the urgency of committing resources to water safety. It may also reflect inadequacies in the way findings were translated into action during the course of the study, indicating the need for having 'triggers' for action in research on social or environmental determinants of health analogous to criteria for offering treatment to all participants in the control or placebo arms of a clinical trial. The possibility must be considered, however, that a requirement for such triggers would create a disincentive to conduct important research on determinants of health because of, for example, the potential fiscal implications.

Continued inaction on the drinking water issue should not be viewed in isolation, but rather as part of a larger pattern of privation that generates health disparities between Aboriginal people as a whole and the rest of the Canadian population.

The second hypothetical raises more basic and complex questions. As noted earlier, poor living conditions and health status of Aboriginal populations as a whole, not just those living on-reserve, are a matter for grave concern. It is not clear whether the hypothetical refers to an off-reserve community with a high proportion of Aboriginal residents. In any event, under Canadian constitutional arrangements, the GoC does not have primary legal authority and responsibility, as it does in the case of on-reserve communities. (The issue of GoC historical responsibility is too complex to address here.) Thus, outrage may well be justified but it is not appropriately targeted at the GoC in the first instance.

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* Thus, a questionnaire distributed by researchers to participants at the First Canadian Roundtable on Public Health Ethics asked respondents to respond to this hypothetical: "You are the Medical Officer of Health of a large health unit that must make dramatic budget cuts. You need to decide how to cut services and programs."[8]

Arguably, an exception might exist first, if the community has a high proportion of Aboriginal residents, or members of another subaltern group with a long history of discrimination and disenfranchisement, *and* second, if their substandard living conditions are taken to represent a violation of Canada's obligations under the International Covenant on Economic, Social and Cultural Rights or the antidiscrimination provisions of the International Covenant on Civil and Political Rights. The situation of Aboriginal people was identified as a concern by many participants in the 2009 UN Human Rights Council Universal Periodic Review of Canada's human rights record.[9] It could be argued that by virtue of Canada's status as a state party to both these agreements, the GoC has ethical and/or legal responsibilities for the health and well-being of Aboriginal populations that do not end at the boundary of the reserve as provided for under domestic law. This, again, is a larger question that must be addressed outside the realm of public health ethics.

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SCHOOL BASED HPV VACCINATION FOR GIRLS IN ONTARIO

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Introduction

On the eve of a provincial election in September 2007, the Ontario government introduced a federally funded, school-based Human Papillomavirus (HPV) vaccination program aimed at girls in Grade 8. The vaccine confers immunity against four (6, 11, 16, 18) of the 100+ strains of HPV. It is the most expensive childhood vaccine for mass use, with a cost of $404 for the three required doses. Despite the publicly funded program, only one-half of potential recipients in Ontario participated in the vaccination program the first year.

HPV is a sexually transmitted infection (STI) that is associated with the development of cervical cancer in women, and genital warts, anal cancer and some throat cancers in both men and women. Strains 16 & 18 are responsible for 70% of all cervical cancer cases and vaccination against these strains is most effective before onset of sexual activity.[1] In Canada, cervical cancer is responsible for 1.1% of female cancer deaths (< 450/year).[2] HPV is transmitted easily through non-penetrative sexual contact, and most infections clear spontaneously: within one year of exposure to HPV, about 70% of infected women clear the infection on their own; within two years, 90% clear it.[3]

Case

Following the pharmaceutical company's lead,[4] the Ontario program frames the product as a cervical cancer vaccine, not an STI vaccine. As a risk-communications strategy, the program deliberately conflates HPV infection with cervical cancer to create the perception of a public health crisis.[5–8] The framing of the product as a "cancer vaccine" also makes vaccination more palatable to parents who may be uncomfortable with vaccinating their children against STIs. The vaccine is not aimed at eradicating the virus, as is typical in most population-based vaccination programs; if it were, males would need to be included to achieve herd immunity.

The National Advisory Committee on Immunization recommends a policy of mass vaccination for all girls aged 9 to 13, yet young girls aged 9 to 15 represented only a small proportion of those enrolled in the clinical trials of the vaccine, and the youngest of these girls were followed for only 18 months.[9] We know that the vaccine is effective in providing immunologic protection for up to five years.[10] The true length of protection it provides is unknown, however, as is whether boosters will be needed and, if so, how many. Also unknown is whether the immunity conferred through mass vaccination will allow other carcinogenic strains of HPV to become dominant.[7]

As is the case for most risks for chronic disease, risks for cervical cancer in Canada are not distributed evenly across the population. The introduction of universal Pap screening in Canada resulted in declines in cervical cancer incidence and mortality among all income groups, with the biggest reductions seen in low-income women.[11] Despite this, a socioeconomic gradient in cervical cancer persists[11–12] and the prevalence of cervical cancer among marginalized groups, such as Aboriginal women, is higher than in the general population.[6] This has been attributed to poor reproductive and primary health care, low socioeconomic status and poor nutrition. If universally accepted, increasing access to HPV vaccination in schools may have a levelling impact and decrease differentials in risk for cervical cancer from HPV strains 16 and 18. However, most girls who receive the HPV vaccine are already at a low lifetime risk for cervical cancer.[6]

Questions about the cost-effectiveness of this vaccine have been raised, due to both its high cost and the fact that it will not lessen the need for Pap testing, other screening and other reproductive health care programs. It has been suggested that, to be cost effective, screening programs for cervical cancer

would have to start when women are older and have wider intervals than they currently do to offset the cost of the vaccine; there would also have to be no need for boosters.[13] A vaccination program that targets girls at high risk for cervical cancer may be more economically efficient, but this poses the risk of (re)stigmatizing marginalized groups as potentially diseased and as posing a health risk to the general population. As well, targeted efforts may not be welcomed by groups who, historically, have been marginalized and pathologized by public health initiatives.

Scenario shift

In light of the recent regulatory approval of the use of this vaccine for men in Canada (2010), the Ontario Ministry of Health and Long-Term Care announces that the school-based vaccination program has been expanded to include boys in Grade 8. This causes the Ministry to change its risk-communication strategy away from the "cancer vaccine" one to an "STI vaccine" strategy. Because of the laws in Canada allowing direct-to-consumer advertising of vaccines, the manufacturer is allowed to expand its marketing to parents and boys. The advertising campaign is pervasive and parents of young girls become increasingly aware that this vaccine prevents the spread of an STI which may have implications on the uptake of the vaccine or other possible outcomes. Concerns about the financial viability of reproductive health services and screening programs arise given the additional costs to the system of adding males to the Grade 8 vaccination program.

Questions for discussion

1 Is it ever ethical to knowingly amplify the perception of risk in order to increase compliance with a public health measure? If so, is this the case for a school-based vaccination program aimed at children in Grade 8? Does it make a difference if it is done with the aim of increasing access for disadvantaged groups?

2 Is it ethical to spend significant public financial and personnel resources on a public health program that is targeted at the population as whole, but where a minority of disadvantaged people are the main benefactors? Does the prevalence and lethality of a disease make a moral difference, i.e, is there a risk-severity threshold that is required to justify such a program? Is this the most ethical and/or efficient way to reduce health inequities at the population level?

3 What potential harms may be incurred by the potential displacement or devaluation of older, highly successful, preventive technologies (Pap screening) by new technologies (HPV vaccination)? Do the benefits outweigh the risks?

4 Is it appropriate to gauge the success of public health programming only by improved *access*? To what extent does improved access to vaccination translate into improved population health and the reduction of health inequalities?

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Case discussion in response to SCHOOL BASED HPV VACCINATION FOR GIRLS IN ONTARIO

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Introduction

Ontario's HPV vaccine program raises more ethical issues than can be considered fully here. Fundamental justification for vaccination programs and competing visions of fair allocation are complicated by issues of socio-economic and gender justice in both the impact of HPV infection and marketing strategies for such a vaccine. Further, any topic involving adolescent sexuality typically challenges social, personal political, and ethical norms, making HPV a focus for broad, multi-layered discussion.

Infectious diseases make all of us stakeholders, although those most at risk and/or most severely affected — in this case, marginalized and low-income women — might be considered primary stakeholders regarding both the risks of illness and the risks of stigma, side effects and coercion in the use of a vaccine. Because the HPV vaccine is targeted to minors, parents should be the primary decision makers. Taxpayers and the governments that represent them, as well as third-party insurers, are stakeholders regarding health-care costs for both prevention and treatment of HPV-related illnesses. The manufacturer has an unambiguous financial stake in increasing the sales of the product.

Foundations of public health ethics

The ethical justification for vaccination programs may focus either on autonomous choices regarding risk exposure and self-protection, as reflected

in the "anti-cancer vaccine" marketed to females, or instead to communitarian and/or utilitarian* attempts to reduce illness rates across populations, as implied by expanding the "anti-STI vaccine" to both sexes.

Who are identified as the primary stakeholders, and what information would be relevant under each ethical model? An autonomy-based, self-protection model allows at-risk individuals (or their parents) to "opt-in" to vaccine use; this requires significant patient/consumer education about individual risks of exposure, risks and complications of the vaccine, its effectiveness and limitations (this product prevents only certain HPV strains, does not prevent other STIs, and may require boosters) and other options to prevent HPV infection. Communal and utilitarian models would focus less on individual choices than on epidemiological data about the threshold of herd immunity needed to reduce cervical cancer rates, the emergence of other HPV strains and economic comparisons of various strategies to reduce HPV's impact; achieving public health targets often requires an "opt-out" approach to routine vaccination.

Policy considerations

When is it appropriate for governments or public health experts to move from an autonomy-based model of offering people means to protect themselves, to a routine (or even coercive) program to protect the common good? The 1905 U.S. Supreme Court case *Jacobson v. Massachusetts* outlined four tests necessary to justify public health measures such as mandatory smallpox vaccination: an avoidable harm to public health must be at stake; the method must have "real or substantial relation" to ensuring protection; any burdens must not be disproportionate to the expected benefits; and the measures must not pose undue health risks.[1] These principles have been updated in recent years for broader public health interventions: James Childress et al. suggest principles of effectiveness, proportionality, necessity, least infringement and public justification;[2] Canadian Ross Upshur offers a harm principle, least restrictive means, reciprocity and transparency.[3]

The harms of cervical cancer and other HPV-related conditions justify making a vaccine available, but HPV does not pose the same extent of public

* Communitarians value groups as more than the sum of their parts, and seek interdependent thriving; utilitarians seek the "greatest good for the greatest number", tabulating individual benefits and harms for a collective net benefit.

health menace as HIV, smallpox, polio or pandemic flu, making mandatory vaccination inappropriate. Whether an intermediate program of routinely offering vaccination would be justified requires more evidence about long-term effectiveness and the emergence of other dominant strains. Few significant side effects appear to be caused by the vaccine itself, but a false sense of protection from sexually transmitted infections (STIs) could inadvertently place recipients at higher risk overall.

Childress et al.'s principle of necessity should give us pause, however: HPV infection can also be prevented by conscientious use of condoms and dental dams, and its spread can be checked by limiting the number of one's sexual partners. The principle of "least restrictive means" may also challenge a program aimed at inoculating an entire segment of a population when only some of that group are likely to be at significant risk.

Principles of public justification and transparency do not appear to have been met in Ontario's vaccination program, which changed both the program model (to include boys) and its essential justification (to prevent cancer vs. STIs) in mid-stream. The extent of a pharmaceutical company's influence in shaping this public health policy along the lines of its marketing approach, as opposed to a wider public and expert consultation on HPV prevention strategies, raises concern. While the manufacturer is certainly a stakeholder, individual patient interests and common goods should outweigh financial benefits to limited parties.

Other policy considerations

Paternalism vs. parentalism: What makes the HPV vaccine particularly interesting is that, because it is most effective if given prior to sexual exposure to the virus, it is essentially a childhood vaccine for an adult illness brought about by adult behaviours. Indeed, for many recipients, the vaccine's effectiveness may wear off before first sexual contact and risk of exposure occurs. It thus does not protect children from a childhood illness, which is an appropriate exercise of "parentalism," or legitimate social protection of minors, rather than paternalism, which is unjustified over-protectiveness of capable adults. Many public health interventions are challenged as unduly paternalistic.[4] Accordingly, is it justifiable to inoculate children of a certain age routinely, as is the case with DPT and polio vaccines that prevent pediatric diseases? Should an HPV vaccine instead be a supplemental option that

adults may choose for themselves and/or their children, like vaccines for influenza, chicken pox or hepatitis A/B?

Fair allocation: Public health programs typically emphasize one of three competing visions of distributive justice: equality, need or utility. It is sometimes possible to maximize two of the three, but it is usually impossible to maximize all three at the same time; something always has to be sacrificed. The equality, or egalitarian, model extends access to everyone. This approach is often unnecessarily expensive, as some recipients may not have needed the intervention, while ensuring equal access in remote areas may be difficult. The high cost of the vaccine and the varying cancer risk across different socio-economic groups makes an egalitarian approach economically unappealing. Because the vaccine was targeted to 8th graders, however, leaving out other age groups, equality was only partly emphasized in the Ontario HPV program.

Targeting the program to those in greatest need would, in this case, focus on vaccine delivery to girls in lower socio-economic strata. The initial emphasis on prevention of cervical cancer, which is more common than HPV-related anal and throat cancers and more serious than genital warts, reflects a partly need-based approach in the Ontario program, although one might also argue that health risks for men — especially gay men — are ignored. However, while the need-based model reduces unnecessary interventions, it also risks (re)stigmatizing the recipients, as noted in the case scenario. When a distributive justice approach aiming to reduce disparate outcomes inadvertently reinforces the social injustices that create and perpetuate those disparities, the appropriate response is to reframe our questions: the issue is not merely whether to provide this vaccine and to whom, but how to address the underlying determinants of health that increase vulnerability.

The utilitarian model of distributive justice seeks to achieve the greatest possible good for the greatest number, within the available resources. Since three doses of this HPV vaccine are required to ensure immunity, and boosters are likely needed to maintain it, utilitarians would consider it unreasonable to offer the intervention to those with a low likelihood of completing the series. Since the HPV vaccine will not prevent other STIs, a "safer sex" campaign may be more beneficial overall at much lower cost. Socio-economic determinants of health must be considered in a voluntary-access program: those at greatest risk of serious health problems are also most likely to face barriers in accessing options to protect themselves; targeted deployment to higher-risk

groups would likely be more effective. The utilitarian model thus often overlaps significantly with the need-based model, avoiding ineffective waste of resources, but it may also abandon some of the people in greatest need if it is too difficult or resource-intensive to help them. The utilitarian model is the most likely of the three to emphasize the comparative costs of various prevention and intervention strategies, as the other two emphasize values of equality and beneficence respectively, rather than efficiency.

Social justice: The vicious circle of socio-economic disparity, increased health risk, compounded stigma and resulting reinforcement of socio-economic exclusion is well illustrated in the HPV example. As noted in the scenario, a need-based approach to HPV prevention risks (re)stigmatizing those at greatest risk of illness; because HPV is a sexually transmitted virus, targeted HPV prevention may also inadvertently imply sexual promiscuity or irresponsibility among at-risk groups. Further, the groups most at risk have often been marginalized and pathologized in previous public health efforts. Given the clear influence of marginalization and poverty in the incidence of cervical cancer, are we attracted to the vaccine in order to avoid undertaking the vastly more difficult, but more ethically compelling and, ultimately, more effective efforts to improve underlying social determinants of health?

Gender justice: Epidemiologically, women suffer the effects of HPV infection more often, and more severely, than men. The extent to which the sexes are considered to be responsible for those health outcomes, however, is an ethical question deserving of reflection. Age-old double standards hold women responsible for sexuality and reproductive outcomes: unplanned pregnancies and infertility have long been "blamed" on women, despite the biological necessity of both sexes in procreation. Have we succeeded in fully rooting out these old sexist attitudes and double standards in contemporary views about sexually transmitted infections?

Reframing the HPV vaccine as either an "anti-cancer" or "anti-STI" vaccine may reflect subtle but important shifts in the assignment of responsibility. Cervical cancer may be perceived as a consequence of women's sexual behaviour; the vaccine may be thus be perceived as a response to "irresponsible" sexuality that increases women's risk exposure, as opposed to a morally neutral response to a common virus. Vaccinating both men and women to reduce the spread of STIs would indicate that both sexes are held equally accountable for the health of their sexual partners as well as themselves.

Men also suffer some HPV-caused cancers, but their health concerns are typically downplayed relative to the more prominent cervical cancer risks. This is likely because gay men are at greater risk for anal and throat cancers, and ongoing stigmas about homosexuality shroud attention to the epidemiology. Thus, even in the "anti-STI" justification, men appear less as potential patients than as disease vectors and risks to women. There is precedent in treating one sex more as a vector than victim: until the mid-1990s, women were more likely to be perceived as vectors of HIV/AIDS through prostitution and gestation, than as at-risk themselves.[5, 6] Does the marketing of the vaccine thus represent an attempt to restore justice for women, but at the expense of men?

Adolescent sexuality: Parents may be placed in an awkward position regarding the HPV vaccine, as they are responsible both for protecting their children's health and for influencing their children's social and sexual behaviours. The vaccine is most effective if given prior to first sexual/HPV exposure. Does routine vaccination of pre-teens, or a parent's consent for inoculation for an individual child, send the message that early sexual contact is to be expected and accepted? It is important to distinguish the two senses of 'norm' here: the typical or frequent age of first sexual contact in a demographic group is not the same thing as the moral norm or acceptability of the behaviour. Rather than establishing social norms of teen sexuality via discussion, reflection, informed choice or even parental dictates, vaccination may prematurely settle any debate in favor of presumed early sexuality, inadvertently making it harder for teens who want to wait to do so.

On the other hand, one might hope that routine use of anti-STI vaccines would encourage greater social dialogue and parent-child communication around teen sex, as it becomes harder to ignore the issue when a specific decision about vaccination must be made. If the provision of a vaccine is part of a comprehensive framework of information, support and dialogue about healthy sexuality, rather than a stand-alone intervention, there is potential to help parents and teens navigate important but typically uncomfortable topics together.

Options and verdict

The HPV vaccine could be offered to girls only, or to both girls and boys, or to adults instead of children; it could become one of the required series of childhood needles, or an optional addition; it could be targeted to certain age

groups (e.g., 8th graders) or high-risk demographic groups, or made available to anyone who wants it. The vaccine could also be ignored in favor of other sexual health measures.

I conclude that Ontario's program was insufficiently justified in both phases of its deployment. Although focusing on an age group rather than highest-risk demographics helpfully reduced the problem of stigma, it also created arbitrary barriers (why not also vaccinate 9th and 10th graders?) and introduced an unnecessary level of pressure to conform. Of greatest concern is that the vaccine provides only partial protection against HPV and may instill a false presumption of broader protection that leaves recipients at greater, rather than reduced, risk. Complex issues of teen sexuality and the socio-economic determinants of serious STI complications cannot be resolved by a vaccine. Comprehensive public health campaigns on safer sex, as well as long-neglected political attention to the conditions that leave some people so much more vulnerable to illness than others, would achieve much more good with fewer ethical complications.

The (limited) protection against the genuine harms of HPV infection justifies adding the product to the provincial formulary of available vaccines, but a cross-population vaccination campaign requires more evidence of long-term effectiveness, necessity and comparative benefits. More important, any policy decision of this sort also requires logical justification; the role of the manufacturer's marketing strategy and the mid-program shift in both target population and justification indicate an ethically inadequate level of public accountability in health policy.

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MANDATORY IMMUNIZATION OF LOCAL PUBLIC HEALTH EMPLOYEES

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Introduction

A local public health unit wants to ensure that all of its employees are adequately immunized according to National Advisory Committee on Immunization (NACI) recommendations.[1] The planned policy mandates each employee to provide documentation that his or her immunizations are up-to-date. Employees with medical or religion/creed-based exemptions must provide documentation of their exclusion. These employees would be re-assigned in the event of a known exposure, to protect their health. Employees refusing immunization without an exemption must sign a declination statement attesting to the fact that they choose not to be immunized. In the event of a known exposure, these employees would be placed on leave without pay to protect their health.

The health unit's employees have a variety of interactions with the public, including with potentially vulnerable clients such as pregnant and breastfeeding women and patients in hospitals and long-term care facilities. A risk assessment of potential exposures and harms was used as the basis for mandated immunizations by job function. For example, hepatitis B vaccination is required to protect employees who may have occupational blood-borne exposures. Varicella (chickenpox) is universally required because any non-immune employee may expose clients or co-workers before they are aware that they are infectious.

Case

Mandatory immunization is contentious in any setting. While most public health practitioners support vaccination as a public good, implementing a policy requiring immunization of employees raises issues of autonomy, leading to resistance to such a policy. An ethical analysis can help identify potential issues and suggest ways to mitigate them.

Ensuring that employees are immune to vaccine-preventable diseases (VPDs) provides a wide range of benefits for the public health unit. It prevents both illness in employees and transmission of VPDs from employees to friends, family or clients. Employees who are health-care professionals may already require immunizations as part of their duty to protect clients under the policies of their college or regulatory body. With well-established safety profiles of routinely recommended vaccines, the potential harms of vaccination are outweighed by the benefits to the individual employee and the community.

Although the benefits are apparent, the need for a mandatory immunization policy to protect employee health should be carefully weighed against less-coercive measures. Occupational health and safety policies addressing other mechanisms to reduce the risk of employee exposure to VPDs, such as personal protective equipment, should be in place. Immunization policies also depend on the target disease. Because some VPDs such as chickenpox, for instance, can be contagious before the individual is ill, immunization is the only way for employees to fully prevent acquiring or transmitting the infection. For influenza, a single immunization appears less coercive than requiring employees to take daily antiviral prophylaxis for extended periods.

A mandatory policy must be fairly, reasonably and consistently applied within the unit. Only applying the mandatory policy to new employees as a precondition of employment, for instance, when these employees are performing the same duties as existing employees is deemed unjust. Additionally, the justification that the policy is needed to protect employee health would be undermined by its differential application to the same job function.

The most significant consideration to a mandatory policy is the infringement of individual rights in imposing immunization. Employees may refuse immunization by claiming a violation of their right to "life, liberty and security of the person" under Section 7 of the *Charter of Rights and Freedoms*.[2] Allowing

for exemptions and declinations helps preserve these rights. To create a true choice, however, the consequences of exemptions and declinations should be reasonable in terms of protecting employee health without being punitive. Re-assignment of work during a potential exposure is likely acceptable, but some staff may view being on leave without pay as punitive.

Based on this analysis, the need for and benefits of employee immunization are re-affirmed. The major argument of infringement of autonomy is mitigated by allowing for exemptions and declinations.

Scenario shift

In the event of an influenza pandemic, if a vaccine is not yet available, a large number of employees would be required to take daily antivirals for weeks to prevent illness. Experience is minimal for using antivirals in this way and, therefore, there is no evidence of their safety and efficacy as prophylaxis for a large, healthy working population. The risk assessment would have to consider the risk of exposure to influenza, severity of the influenza, other preventive measures, time until a vaccine is available, known risks of the antivirals and the unknown risks of using them in a large population for an extended period of time.

In this situation, the ethical consideration of employee autonomy has a stronger bearing compared to mandatory immunization with routine vaccines. Mandatory antiviral prophylaxis may not be justified given its unknown benefit and potential side effects. Voluntary prophylaxis may be preferred, but accommodating all employees who refuse may not be feasible and exposing them without prophylaxis could lead to occupationally acquired influenza.

Questions for discussion

1 A health unit employee who is susceptible to chickenpox signed the declination statement refusing immunization. Without known exposures to chickenpox, the employee was allowed to continue in his or her position of health promoter. However, the employee became infected with chickenpox and was infectious while teaching a class of expectant mothers. Should this event change the immunization policy?

2 An employee feels that she was denied a job transfer to a role that would require immunization for hepatitis B because she is not immune. She makes a claim of discrimination. What elements of the policy are necessary to address this claim?

3 An employee refuses influenza vaccination because his close family member had a significant adverse reaction to the flu shot. His physician provides documentation approving this as a medical exemption, even though family history of an adverse reaction is not a contraindication.[1] How should his refusal be classified?

ACKNOWLEDGEMENTS

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Case discussion in response to MANDATORY IMMUNIZATION OF LOCAL PUBLIC HEALTH AUTHORITIES

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The case study by Murti highlights the ethical challenges related to mandatory vaccination policies for health care workers. On the one hand, such policies are necessary to protect the health of patients. On the other hand, requiring individuals to undergo a medical intervention could be perceived as an infringement of their rights. The case study in particular describes several ethical principles, many of which come into conflict in this particular case. These include autonomy, justice and the need to use minimally intrusive or least-coercive measures. The case study highlights how ethical and legal dilemmas can be at least partly resolved by examining the scientific aspects of the problem.

The vaccination issues the case study puts forth are complex and varied and best to disaggregate. To illustrate the challenges of working through these issues, let us start with looking at mandatory influenza vaccination for healthcare workers — perhaps the most contentious vaccination issue at present.* To many in the public health field, it is apparent that the status quo is unacceptable. Currently, most workplace influenza policies are voluntary but permit sending unvaccinated workers home in times of outbreak. This strategy is problematic for two reasons: first, it may result in a high percentage

* For a detailed discussion of the legal and scientific arguments for mandatory influenza vaccination please see: Rodal, R., Ries, N. M., Wilson, K. (2009). Influenza vaccination for health care workers: Towards a workable and effective standard. *Health Law Journal;*17:297–337.

of workers being absent when the facility needs them most. Second, by the time the worker is sent home, he or she may have asymptomatically already transmitted the virus to co-workers and vulnerable patients.[1] While it would be least coercive for hospitals and other facilities to encourage vaccination policies on a voluntary basis, relying on voluntary compliance and educational programs may create gaps in patient protection, as evidenced by studies demonstrating suboptimal uptake.[2] Facilities could take the initiative to implement employment standards that reflect the importance of vaccination to the health of patients. If such initiatives prove insufficient, governmental authority may be needed to create appropriate legislation — i.e., mandatory vaccination policies. These policies would have the effect of increasing patient health and safety, and at the same time saving costs and reducing worker illness and absenteeism. However, health-care workers have been resistant, and the legality of such an option would be contentious.

When considering the legality of measures, it is apparent that the legal principles involved are based on ethical values and that conflicts are resolved through evaluation of the scientific evidence. Any mandatory vaccination legislation would likely be challenged under s. 7 of the Charter of Rights and Freedoms (the Charter). Section 7 states "Everyone has the right to life, liberty, and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice." Mandatory vaccination, if considered to be a possible violation of s. 7 because it involves an intrusion on bodily security, could be found to be justified within s. 7 of the Charter as being in accordance with the principles of fundamental justice particularly as it protects the sanctity of human life in a non-arbitrary manner. Furthermore, it could otherwise be upheld under s. 1 as a reasonable and justifiable measure to promote health, safety and confidence in the Canadian health-care system.[3] Section 1 ensures that, where the state has compelling and legitimate reasons to infringe rights, it has the authority to act, though these infringements must be proportional and justified. Some of the legal tests to ensure that this is the case are embodied in the Oakes test, based on a decision by the Supreme Court where the standards necessary for the use of s. 1 to limit an individual's rights are described. According to this test the infringement, in this case the vaccination policy, must meet a pressing and substantial objective. In addition, the choice to vaccinate must be rationally connected to the objective of preserving health among patients; the policy must be minimally impairing of rights; the policy must be proportional to

the degree of infringement of rights; and it must be demonstrably justified (scientific evidence should support that these measures are warranted).[4]

The Oakes test exposes some of the scientific knowledge necessary to address the conflict in ethical principles. More explicitly, in the case of mandatory vaccination, I believe the following scientific questions pertaining to the problem are particularly salient:

» Is the agent being vaccinated against highly infectious and likely to spread to patients?

» Can the condition be spread in the asymptomatic phase?

» Are there high levels of morbidity and mortality associated with the condition being vaccinated against?

» Is there a strong body of evidence for the benefits of the vaccine to prevent disease in patients?

» Is there evidence that other mechanisms for controlling spread of the disease do not work.

» Are there minimal harms associated with the vaccine?

» Are there mechanisms in place to provide compensation to individuals who may be harmed by the vaccine?

The greater number of these questions that can be answered in the affirmative, the more justifiable the infringements on civil liberties. Conversely, the greater the numbers of negative answers, the less justifiable are the infringements. Ultimately, societal values will dictate where along the spectrum of affirmative and negative responses the decision to allow infringements of liberty and permit mandatory vaccination is located.

Using this approach to examine the question of mandatory vaccination for influenza demonstrates that such vaccination is justifiable, although with some provisos. Influenza is moderately infectious and transmissible to patients and influenza illness in the elderly can have serious sequelae. Vaccination is moderately effective in preventing illness and, more importantly, vaccination of health care workers has been demonstrated to prevent illness in patients.[5, 6] The most serious consequence of vaccination of health-care workers, the development of Guillain-Barre syndrome, is extremely rare and estimated as a one in one million risk.[7] Less restrictive measures, such as education programs

and sending non-vaccinated health-care workers home during an outbreak, are not effective, since voluntary programs have had unsatisfactory results and removing unvaccinated workers during an outbreak is problematic for the reasons noted above. One argument against mandatory vaccination is the absence of a compensation program in the rare event that a health-care worker is injured from the vaccine. Such a program would demonstrate the reciprocal nature of the contract in which the health-care facility and the worker have engaged. Furthermore, ongoing assessment of all of the vaccine-specific factors, including the ongoing safety and efficacy of the vaccine, would be necessary since the composition of the influenza vaccine changes from year to year. This would require the existence of effective post-market surveillance systems.

The ethical and legal permissibility of other mandatory vaccination policies (apart from influenza) would require a similar assessment of the scientific evidence. For each, the relative weighting of the factors would be unique. For example, in the case of chicken pox vaccine, the main driver in the decision-making process would be the risk of catastrophic illness in elderly and immuno-compromised patients.

The case study put forth by Murti and colleagues nicely demonstrates how ethical, legal and scientific principles are intertwined and must be considered together when attempting to address public health challenges.

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PART THREE

Practice

AN E.COLI OUTBREAK IN WALES — A FAILURE IN REGULATORY AND PROFESSIONAL ETHICS

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Introduction

In September 2005, the largest *E.coli O157* outbreak in Welsh history (and the second largest in the UK) occurred in South Wales, resulting in 157 cases of food-borne illness, 31 hospital admissions and the tragic death of a five-year-old boy. Given the scale of the outbreak, the National Assembly for Wales initiated a Public Inquiry[1] that ran for three years and included more than 45,000 pages of evidence and 191 witnesses, and cost more than £2.3 million.

The butcher shop at the centre of the outbreak had operated as a family business since 1966. It processed and sold a range of raw and cooked meat products and its main customers were public-sector organizations such as schools (it supplied meat for school meals for all primary and secondary schools in a number of areas), hospitals, nursing homes and Meals-on-Wheels services, as well as restaurants and direct sales to the public. Its operations can, therefore, be considered "high risk" in terms of food safety due to the type of food products being processed (meats) and the extreme vulnerability of the customers supplied (children and the elderly). Operations such as these require stringent food-safety standards and strict enforcement of these standards.

Case

The Inquiry found that the outbreak occurred because of a "significant disregard for food safety" by the butchery, which had grossly inadequate procedures and had falsified records and lied to inspectors. It was highly critical of the food-safety inspection and enforcement approaches undertaken by the local government, which allowed these breaches to occur over a number of years without adequate intervention. These regulatory failures included:

» Senior government staff responsible for food-safety activities had no experience with food-safety regimes and inspection processes. They did not sufficiently appreciate their food-safety responsibilities and did not have a system in place to monitor staff performance or to provide guidance on inspection protocols.

» Due to frequent staff changes, the inspectors employed were relatively inexperienced and had relatively little knowledge of HACCP (hazard analysis critical control points — a key food-safety management approach) and its application to meat processing operations.

» The quality of the inspections undertaken was not monitored and inspection practices varied greatly between inspectors, resulting in inadequate inspections.

» There was no system of "red flagging" particular issues of concern from past inspections, resulting in the inadequate monitoring of ongoing issues.

» Inspectors issued warning letters, but did not follow up through serving Improvement Notices or taking substantive regulatory action.[1]

These failures were compounded by annual decreases in the staffing budget, difficulty in recruiting and retaining qualified staff and an increasing inspection load. This resulted in an inability to meet inspection targets and the engagement of consultants to cover staff vacancies.

Overall, the Inquiry concluded that, if the inspections and regulatory process were undertaken appropriately, the food-hygiene failures at the butchery would have been identified and addressed. This case therefore highlights failures in both oversight/regulatory ethics and professional ethics.

The state has a moral obligation to protect the public's health through regulatory oversight, including setting appropriate protective standards; providing appropriate resources to monitor compliance with these standards; and providing effective tools for modifying the behavior of those who do not comply.[2] In this case, standards were set (i.e, there was substantial food-safety legislation in place, including codes of practice for inspections and regulatory procedures); the local government entrusted to implement these standards, however, did not ensure that there was an effective system (in terms of resources, procedures and competent staff) to monitor and regulate compliance. They therefore failed in their regulatory ethics obligations and so placed the community at substantial risk.

In addition, there are a number of individual failures of professional ethics. First, as competence in HACCP auditing is a basic expectation of these inspectors, the professional certification process was inadequate. Second, these inspectors did not fulfill their obligation to undertake ongoing professional development activities to ensure competency. Third, while it should have been clear to the inspectors that they were out-of-their-depth and that the local regulatory system was inadequate, they did not raise concerns. Schwartz[3] would argue that their silence fails a further ethical test that places a high burden of responsibility on public officials.

Scenario shift

As this case involved both systemic and individual failures, consider how the ethical issues of this case would change in the context of the following hypothetical scenarios:

» The inspectors were well-trained, competent and able to detect problems, but they believed the organizational system in which they worked placed the public at risk due to its ineffectiveness.

» The system was functional and was able to identify the ineffective performance of the inspectors through monitoring their performance.

» The business involved was categorized as presenting a lower risk to the public due to not servicing vulnerable groups such as children, hospital patients and the elderly.

Questions for discussion

1 What actions should front-line public health practitioners take if they are being required to undertake duties for which they know they do not have the capacity (either in terms of competence or resources) to complete?

2 How can regulatory failures best be addressed at the systemic and individual levels?

3 The case suggests that there are choices to be made by the state regarding allocation of scarce resources. What are the ethical factors that should be considered when making such decisions?

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Case discussion in response to
AN E. COLI OUTBREAK IN WALES

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Introduction

This case illustrates failures relating to the violation of laws, professional ethics and larger issues in public health ethics. On the surface, assigning blame in this case appears straightforward. The butcher criminally disregarded food-safety measures and, in a cover up, falsified records and lied to inspectors. However, the case is not so simple. The food inspectors failed in their primary duty to properly carry out food inspections. Senior government officials did not appropriately monitor staff performance or provide guidance on inspection protocols. A comprehensive analysis of this case requires examination of broader ethical considerations, including issues about allocation of scarce resources and protections owed to vulnerable populations. These broader issues will be explored in a discussion of the three scenario shifts described in the case.

Adherence to the legally established regulatory mechanism would have averted the outbreak by identifying problems with the butcher at a much earlier stage. However, the inspectors were not properly trained nor did senior officials have the appropriate experience to offer adequate oversight. No one has a legitimate duty to perform tasks for which they have not been trained and for which they lack the appropriate skills. It is the responsibility of health officials to ensure that inspectors are competent and well trained and that necessary follow-up occurs. Ensuring competency of the workforce

is a basic ethical obligation not only for public health but for all professions. Consequently, providing and ensuring completion of proper training is the primary corollary of this obligation.

Public health also has an obligation to advocate for and protect the health of vulnerable populations.[1] As the butcher provided food for children at primary and secondary schools, patients in hospitals, residents of nursing homes and individuals needing food assistance, this case also raises issues of the higher level of professional responsibility that health-care workers owe vulnerable populations. Questions about the level of protection that should be incorporated to protect vulnerable populations, including the possible use of stiffer penalties for offenders in outbreaks involving vulnerable populations, should be discussed. This protection of vulnerable populations will be considered in more detail below under the discussion of the third scenario shift.

Allocating scarce resources

Beyond these issues, this case raises questions about the ability of health departments to carry out core public health functions and the ethical implications of funding decisions, specifically providing adequate funding for preventive services. But who *ultimately* is responsible for the underfunding of public health prevention measures: public health officials, elected leaders, the electorate?

Maintaining adequate funding for preventive services is an ongoing public health challenge. By preventing morbidity and mortality, prevention measures (such as immunization programs) may lull the public into a deceptive complacency regarding some disease risks. The public inquiry into the 2005 *E. coli* outbreak pointed to lessons learned from a similar outbreak in Scotland in 1996.[2] The report expressed disappointment that the "shocking" lessons of the 1996 outbreak were so soon forgotten and emphasized the importance of strengthening the system to ensure that it would function as intended. As we see from this and other crises, a narrow window of opportunity opens when outbreaks occur, during which the public and elected officials may be more amenable to funding and implementing prevention measures. Once the window closes, maintaining funding for prevention measures, especially in times of government spending contractions, becomes difficult, in part because effective measures reduce public attention to public health threats.

Allocating resources fairly is a complex process that involves comparative cost/benefit evaluation of programs and a prioritization of stakeholder values with reference to the local context. Health officials must weigh how to best use funds — should they be used to target protecting the public from harm, preventing harm, or promoting health?

One can readily imagine how much more disruptive and deadly the Welsh outbreak might have been, had the public health department been unable to quickly identify and contain the source of the outbreak. But it is unimaginable that the public would have accepted the explanation that resources could not be diverted to the outbreak, because they were being deployed elsewhere for prevention or promotion. This consideration suggests that the public believes that its protection in the sense of mitigating actual serious harms caused by a breach in food safety should be the top priority. This judgment is in alignment with the "rule of rescue" which demands taking all measures to rescue victims of disaster or serious disease even when the rescue effort demands a disproportionate expenditure of resources.[3]

However, preventing harm through a food inspection system that monitors key components of the existing food chain should also be a priority. Effective prevention spares society the human costs associated with outbreaks. Although quantifying harms that a food inspection system prevents is problematic, the systemic costs of inspection can be compared to the costs of outbreaks. The financial logic operating here is that the burden of paying low incremental prevention costs is preferable to the burden of paying the disproportionately large expenditures caused by outbreaks, even though those incremental costs only reduce the number or possibility of outbreaks.

In the context of food safety, promotion involves changing food processing procedures and the behaviors of people in the food industry. In the short run, such transformations are expensive. Moreover, promotion faces the same challenge as prevention in making palpable the harms that such promotion will prevent. However, promotion efforts may achieve more prevention and cost efficiency in the long run.

From an ethical perspective, prioritizing protection over prevention and promotion is consistent with the common intuition that avoiding serious harm generally takes precedent over acquiring a benefit. However, when the risk of

harm is remote, the cost/benefit balance can shift in favor of the long term advantages of prevention and promotion. In such instances, the challenge of public health is twofold: to make the case that long term advantages outweigh more immediate but less serious harms and costs, while at the same time not losing sight of the fact that the success of prevention can lull one into forgetting the importance of maintaining an adequate inspection system.

Responsibility for correcting the failure of the regulatory oversight system is shared.[4] Elected officials are responsible for ensuring adequate funding. Public health officials are responsible for implementing preventive measures and for providing adequate training. But what is the role of the public? The public has a duty to engage in responsible civic response to public health problems. The role of civic responsibility has been widely discussed in the literature on public health emergency preparedness and response, including obligations of the public to be prepared for emergencies and to make informed choices.[5] Lessons learned from this literature need to be adapted and incorporated into thinking about broader prevention issues, including how public health can successfully engage the public on such matters and develop trust.

Scenario Shifts

The case asks us to consider how the ethical issues would change in the context of the following hypothetical scenarios:

» The inspectors were well-trained, competent, and able to detect problems, but they believed the organizational system in which they worked placed the public at risk due to its ineffectiveness; **or**

» The system was functional and was able to identify the ineffective performance of the inspectors through monitoring their performance; **or**

» The business involved was categorized as presenting a lower risk to the public due to not servicing vulnerable groups (i.e, children, through school lunches; hospital patients; and the elderly, through nursing homes and meals-on-wheels).

In the original scenario, neither the food inspectors nor the system functioned adequately. The first two scenario shifts, which represent situations where either the inspectors or the system is functional, have the effect of shifting both culpability and responsibility.

In the first scenario shift, competent food inspectors uncover food-safety problems that the organizational system cannot address effectively enough to ensure the public's safety. In this situation, professionals have a duty to act even if their individual efforts are not able to immediately correct the system. Here, we make the assumption that professionals have been trained to understand the higher obligations of the profession. In this case, a competent, well-trained food inspector who understands his or her duty would be obligated to bring attention to a dysfunctional oversight system. It goes without saying that efforts should be made first to resolve the issue internally, working within the organization. The point at which professional duty demands going outside of one's organization is that point at which one concludes that working within the organization merely further enables its dysfunction.

If senior government officials have determined that the system dysfunction is primarily a result of inadequate funding, a similar logic applies: work within the system to resolve the matter up to the point where one is merely enabling dysfunction, which by definition means that service has fallen below the threshold of adequacy. The system in this case involves the shared governance structure that includes elected officials and the public. Senior government officials have an obligation to call elected officials' and the public's attention to the dangers that underfunding threatens.

In the second scenario shift, where the system is sufficiently functional to detect the ineffective performance of food inspectors, an ethically straightforward response on two levels is required. First, the inspector's qualifications have to be assessed and appropriate steps taken to address training needs. Is the person so unfit for the position that firing is appropriate or is the employee merely in need of training? Second, the reasons the hiring/screening process or the training was inadequate also have to be assessed and corrected.

The third scenario shift suggests a relation between population vulnerability and professional responsibility. Professional duty arises from two features of the professional-client relationship: the professional's subject matter expertise and the vulnerable condition of the client.[6] Because of these features, the professional-client relationship is necessarily hierarchical and paternalistic on the part of the professional. Paternalism here does not mean the professional treats the client condescendingly or disrespectfully. Rather, paternalism means

that the professional places the client's interests above his own. This higher standard enables the vulnerable client to place trust in the professional. In our case, although the public is not an individual client, the professional food inspector acts as a steward of a public trust, namely, protecting the food supply from contagion or poison, to which all are susceptible or vulnerable. In this regard, we can propose a simple ratio: the greater the degree of susceptibility or vulnerability (which varies in different situations), the greater the obligation to protect and place the interest of the public over personal interest and, consequently, the greater culpability and penalty for dereliction of duty.

This analysis does not attempt to provide specific recommendations. Doing so would require a more penetrating analysis of the facts of the case and a deeper understanding of local conditions and contexts. Hopefully, we have provided sufficient guidance to begin examining the ethical issues raised by this case.

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USE OF EVIDENCE FOR PROGRAM DECISION MAKING

Resources for tobacco cessation

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Introduction

Tobacco use is one of the strongest risk factors associated with morbidity and premature mortality. In Canada, use has declined to 17.5% of the population, but the decline appears to be levelling off.[1] Many population- and individual-based prevention and cessation strategies are implemented by public health workers.[2] "Quit and Win" programs are one example, involving a partnership between the Canadian Cancer Society and local public health/regional health authorities. A media campaign, "Quit and Win," encourages smokers to sign up and commit to quitting smoking for a month. Names are entered in a draw for various prizes in each participating region. In some provinces, the program has been "encouraged" or even mandated as an intervention by the provincial ministry.

Research, even if it is of very high quality, does not solely drive decision making in public health; several other factors have to be considered, such as local burden of illness, community preferences, political will and available skills and resources.[3] But sometimes, programs carry on despite evidence that they may not be effective for your population, the best use of resources

or equitably reaching your population. These decisions reflect, in part, the value placed on different ethical principles.

Case

One health department questioned if the "Quit and Win" program was the best use of resources. Staff followed an evidence-informed approach to defining the question, seeking out and appraising studies and considering the studies' applicability to their region. A high-quality, systematic review by Cahill and Perera[4] on "Quit and Win" contests for smoking cessation informed the practice question.

The review showed the overall effects of contests on community prevalence of smoking were small, with 1 in 556 smokers expected to quit for 12 months as a result of the contest. In the case region, 1,572 of 170,500 smokers had signed up in the past year. Study participants were predominately middle class Caucasian females, while the region's smokers were ethnically diverse and mostly male.

Costs to the health department were about $40,000 per year for the campaign, including promotion of the contest via newspaper advertising. Money for the prizes (car, trips, and credit card gift cards) was donated by private-sector sponsors.

Based on the research evidence and the low participation rates, the team decided to forego the "Quit and Win" program and consider alternate uses of the resources. This decision was communicated to the tobacco control community. The health department is currently exploring the evidence for other smoking cessation interventions, including building capacity with family practitioners.

This case raises certain ethical issues:

1 **Accountability, quality:** Research supporting quit-and-win contests exists, but is either of poor quality or has little applicability to the local setting. This case raises a dilemma: the province encouraged the program but the research suggested it would be ineffective. Is it the responsibility of every local jurisdiction to critically assess evidence

when a program is encouraged by the province? Who is ultimately accountable for appropriate use of funds? How do we challenge mandated programmes or current "best practice"*?* How do we manage the public/private partnerships when goals are conflicting?

2 **Reach, equity and diversity:** These contests have most impact with young, female, white smokers who are highly motivated to quit. The characteristics of the smokers in the case region differ substantially. Ethically, should a local health authority deliver a program with such low reach and which is unlikely to serve an ethnically diverse population of smokers?

3 **Cost effectiveness and valuation:** There is an opportunity cost to delivering an ineffective program, both in direct costs diverted from something more effective, and in indirect costs of the resultant poorer health impact. Local health departments have an important stewardship function for public spending. Ethically, can money continue to be spent on an ineffective program? Is it worth $40,000 of taxpayers' money, plus an additional $40,000 of sponsor money, to have such a small number of people sign up, and even fewer not smoking at 12 months? How can we have higher impact for dollars spent? Is a car an appropriate incentive given implications for activity and carbon emissions?

Scenario shift

An argument can be made that the purpose of these contests is to raise awareness of smoking cessation as the first step to changing behaviour. If the purpose of the contest is redefined as awareness raising, do the ethical considerations of stewardship, quality, and cost effectiveness and reach disappear?

The larger issue is the role and valuing of research findings in decision making. Should we expect program managers to ask the questions *does it work* and *for whom* and consider research evidence when making program and resource-allocation decisions?

Questions for discussion

1 Should we have an expectation that we will consider relevant research when making program and resource-allocation decisions? That is, is there an ethical imperative to consider research findings in program decision making?

2 Does the answer to question #1 change if the program is legislated? What is the role of health units in challenging mandated programs? Can professionals criticize policy choices without endangering their own careers?

3 How do we value the outcome of awareness raising in terms of the costs in health promotion?

4 Would we make a different decision if the research showed that participants were more like those in the target area (more the "at-risk" population)?

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Case discussion in response to
USE OF EVIDENCE FOR PROGRAM DECISION MAKING

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Introduction

The ethically significant dimensions of any system-level decision extend far beyond the decision itself.* The process of ethics analysis should be thought of as a collaborative endeavour with the decision-making body from the beginning of the decision process through to its completion.**

* In my opinion, there are at least five ethically salient dimensions to system-level decisions:
1. The mandate and relationships of the decision team (those charged with making the decisions, and the terms by which they will engage each other throughout the process).
2. The distinct and systematic analysis of facts and values (separating the description of the context from the ideals that the solution should live up to).
3. Consultation with system experts, those affected and the public (provision of information about the facts of the decision and other education as appropriate, an invitation to critically review the operating understanding of the context as well as what should matter in the solution, all through a process of respectful dialogue).
4. Decision rationale and justification (explanation of why a particular solution is chosen, as well as why it is seen as the most appropriate response).
5. Decision follow-up plans (how the decision is to be communicated, implemented and evaluated; what education and downstream ethics support is to be provided to those affected; and how those affected will be able to provide ongoing feedback).

** Based on the five dimensions, my approach to ethics analysis involves stepwise attention to:
· Establishment of the decision team.
· Clarification of the key philosophical problem(s) to be resolved.
· Review of the context, including the evidence for the various factual claims made in the story.
· Critical reflection on the values at stake in the situation, defining what these mean and prioritizing them; and distinguishing what implicitly emerges as important within the story from other considerations that ought to guide the response.
· Brainstorming possible solutions to the problem.

In what follows, I will describe three early steps that an effective ethics analysis should include and illustrate what the conversation might be like if it begins at the front of a decision process instead of being regarded as a distant and detached review undertaken after a decision has been made.

Identifying the Key Question(s)

As this story demonstrates well, a case study is an effective method for surfacing the myriad of messily interwoven issues that are present within most situations. However, when it comes to actually trying to move forward on an issue, it is important to be clear at the outset what specific question(s) within the tangled web of concerns we are trying to resolve.

In my view, this case study raises *three* main sets of questions.

The first is a substantive resource-allocation issue: what criteria should be used to determine which of the competing programs health authorities should provide resources to support? For example, the case study authors ask: "Ethically, should a local health authority deliver a program with such low reach...?" These types of question implicitly suggest what appropriate criteria for choosing among programs should be. The criteria advocated by the authors in the case study, albeit indirectly, include reach, pluralism, effectiveness, impact, promoting health and raising awareness.

The second set of questions relates to the process by which health authorities should make resource-allocation decisions. The authors ask questions such as, "How do we manage the public/private partnerships when goals are conflicting?" The particular questions of this nature the authors raise imply values such as accountability, managing conflicts of interest, ensuring best practice, and having room to challenge decisions.

· Analyzing these against prioritized values.
· Making a preliminary decision.
· Engaging experts and stakeholders.
· Making any revisions to the preliminary decision.
· Developing follow-up plans.
· Implementing the decision and follow-up plans.

Details of this approach are found at Jiwani, B. (2011). Good Decisions: A Map to the Best System-Level Decision, All Things Considered. Edmonton, AB: Alberta Provincial Health Ethics Network. Retrieved online on February 23, 2012 from http://www.incorporatingethics.ca/download-good-decisions.php

Within this set of process questions are sub-questions about the role that evidence should play in the decision process. Again, implicit in the questions is a strong commitment on the part of the authors to making decisions based on good evidence.

Both of the above sets of questions are philosophical in that they are open to a wide variety of answers and invite discussion about the appropriate values that should underpin them.

The case study also raises a third set of questions that concern the specific "Quit and Win" intervention strategy. For example they ask "Would we make a different decision if the research showed that participants were more like those in the target area (more the 'at-risk population')?" Such questions ask for a more calculated analysis about how well this specific intervention achieves certain goals and how the intervention might be altered to do so better.

The importance of all three types of problems underscores the need to specify what questions have to be answered in the scenario, to prioritize which of these will be addressed first, and to have a plan for systematically tackling each.

The reasons for taking time to identify and prioritize questions have to do with efficiency and effectiveness. The systematic analysis of an issue requires time and care. The type of question we choose will determine the type of answer we get: a substantive question (*what* is the best decision?) will yield a substantive answer; a process question (*how* should we decide?) will yield a process answer; a question about a specific solution (what do we think of *this particular option?*) will yield an answer only about that solution. If we aren't clear at the beginning of an analysis about the problem on which we're trying to make headway, we risk having a very broad conversation about a wide range of issues without making progress on any of them.

Notice also that there are different values at stake in the different sets of questions. Developing an ethically justified response to any of the above questions will involve identifying, prioritizing and balancing these values. If we don't separate out and focus on one question at a time, we will end up trying to compare value commitments that don't necessarily relate to each other. For example, if we are trying to determine what decision criteria we should use to slice a pie, but haven't talked about how this decision should be made, we

will end up having to compare *everyone should get the same size of piece* with *we should include whoever made the pie in making the decision.*

When setting out the key question, it is also important to frame questions well. For example, at one point the authors ask, "Can professionals criticize policy choices without endangering their own careers?" As posed, this is an empirical question about what is descriptively true about the landscape. There are at least two concerns with framing issues this way. First, descriptive answers about the way we currently do things do not necessarily tell us how we should do them. My sense is that the authors understand this and the question is rhetorical. The authors believe that freedom of thought and expression is an important value and they wish to explore how it can be incorporated into an analysis of the process by which such decisions are made. The second concern then is that the lack of clarity in our language enables a great deal of confusion to enter the discussion — confusion that can make deliberation about the issues perplexing and painful. More importantly, poorly articulated questions could actually thwart the effort of identifying a justified response to the issue.

Getting a Shared Understanding of the Context

Another central element of effective ethics analysis involves looking at the context to see whether a clear picture of the landscape emerges, where there is shared understanding and where there is not, and determining what evidence grounds the emerging picture. This directly answers one of the questions raised within the case study about whether evidence should play a role in our decision process: yes, good ethics requires good evidence, and any decision about how to allocate resources should take into account what research says about the context within which the decision is made.

The reason for careful assessment of the descriptive context is that the end purpose of an ethics analysis is to bring about a state of affairs where what should matter most is brought to life. This in turn allows decision makers and the broader community they are serving to live with greater integrity. The key here is that the goal is a change — either of personal outlook and behaviour or of social arrangement in some form. In order for one to effectively make change, one needs to understand what the world currently looks like and what impact different change strategies can be expected to have. Ensuring we have the facts right is a crucial step toward ensuring we live up to our values.

However, the matter of facts is not so simple. First, this requires understanding how each of the parties involved in the story sees the context and exploring the reasons for their assessment. This involves tackling difficult questions like what counts as good evidence.

Second, it is imperative to recognize that research and evidence alone do not tell us what we should do. Knowing that only a few people signed up for the "Quit and Win" program, the demographic they come from or that very few quit after enrolling, does not tell us whether or not to support the program. It is only against a sense of what matters that these facts take on meaning. So systematic analysis of evidence must be undertaken alongside systematic analysis of values for us to know how to move forward.

Third, it is important to have a justified descriptive understanding of many areas of the context. The case study itself provides some information in four categories: tobacco use, the "Quit and Win" strategy, the decision-making context in general, and one story of how decisions were made in a particular region. A justified substantive resource-allocation decision would require more details in each of these categories. For example, if certain authorities are proponents of "Quit and Win" despite the evidence, why is this so? Do they understand the evidence differently? What is important to them such that what the evidence shows is less relevant? Because resource allocation is a relative concern — that is, it calls for weighing the benefit of competing options — what are the other options and what are the benefits that these would bring?

In addition, we will need information about areas that go beyond what have been formally studied using traditional research methods. For instance, we also need to understand the values and beliefs about the target population and the meaning of the targeted behavior in their lives.

Good ethics analysis requires an expansive understanding of the descriptive landscape.* This involves identification of the relevant categories of information, good data within each of these categories, and conversation among affected parties.

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* This should not be interpreted to mean that we can't have good ethics analysis without excellent evidence and shared understanding of the facts. Decisions of course have to be made in a timely manner. The point here is that we have to do the best we can at understanding the descriptive landscape given the resources we have, recognizing that the quality of an ethics analysis will in part be proportional to the quality of evidence available.

Getting Clear on What's Important

In this step in the analysis we want to consider what matters or is at stake in the decision and how relatively important these considerations are. The values that are relevant will depend in part upon the type of problem within the story for which we are seeking an ethically justified solution. In the case study, exploring the question of resource-allocation criteria will focus on notions of distributive justice, whereas for the question of who should use the criteria and through what process, the key relevant values will concern procedural fairness.

It is often useful to start the values analysis with what is named as important by those involved. We have already seen that the authors of the case implicitly believe what is substantively important including reach, pluralism, effectiveness, impact, promoting health and raising awareness. Procedurally what matters to the authors includes accountability, managing conflicts of interest, ensuring best practice, and having room to challenge decisions. The questions about evidence that are raised indicate that making decisions based on good research is also procedurally important. In addition, the authors explicitly name a number of values that they suggest are relevant for the wide range of questions they raise. These include accountability, stewardship, quality, equity, diversity and cost effectiveness and valuation.

The case study raises a number of questions under these value headings, but it does not say what these value words mean or how they should be balanced. While the list is useful, it is important to be clear about what is intended by different values because different people may have different interpretations of the same term and because within a term there may still be much content that needs to be negotiated. For example, one could understand equity as the idea that a resource should be distributed based on need as opposed to other criteria (such as ability to pay, social status, etc.). Equity can thus mean equal distribution if everyone has the same need or unequal distribution if the needs of some are greater than the needs of others. Central to figuring this out is how need is defined and measured. And this will depend on the objectives the resource is meant to achieve. So when it comes to the value of equity, what kinds of needs are relevant has to be spelled out for the values analysis to do its work of defining the standards the solution to the issue has to meet for it to be justified.

Aside from the values implicitly or explicitly raised by decision-makers and reviewers, an effective ethics analysis will identify and seek to balance the values of those impacted by the decision as well as other values that are accepted within the broader social context. For example, a cornerstone of public health ethics is the value of social justice.* An ethics analysis that does not include review of this value would be incomplete. But again, while we will likely all agree that social justice is important when we decide what tobacco-cessation strategies to support, what exactly we mean by this may be very different. The meanings we attach may span treating everyone equitably, maximizing overall happiness, building community solidarity, seeking equality of outcome or achieving equality of opportunity. Each of these would lead to different distribution schemes. It is thus also important to name commonly accepted norms in society and then to include it in the discussion of weighing and balancing what should matter most.

Closing Thoughts

Ethics analysis of system-level public health issues requires disciplined and rigorous attention both to the content of the discussion and the way the discussion happens; that is, who is involved and how these individuals are treated. I have highlighted some of the complexities of the content that require attention in this case study, but this remains only part of the equation. Decision makers and analysts need to pay attention to both the what and the how of the discussion, and build skills in both areas, in order to undertake meaningful ethics analysis.

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* See for example Tulchinsky, T. H., Varavikova, E. A. (2010). What is the "New Public Health"? Public Health Reviews, and Buchanan, D. R. (2000). An ethic for health promotion: Rethinking the sources of human well-being. New York, NY: Oxford University Press.

USING PERSONALIZED LETTERS OF INVITATION TO INCREASE PARTICIPATION IN CERVICAL CANCER SCREENING

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An opinion on the case presented in this paper has been issued by Quebec's *Comité d'éthique de santé publique* [public health ethics committee].[1]

Introduction

The goal of this pilot project was to increase participation in cervical cancer screening among women who had never had a Papanicolaou (Pap) test or had not had one in the past three years or more, by mailing a personalized letter to their homes. This goal was consistent with the objective of the public health program of Quebec's ministry of health and social services, which is to achieve a 10 per cent reduction in cervical cancer mortality among women ages 25 to 64.[2]

There are few data on the characteristics of women who do not take Pap tests or who do not take them at least once every three years. According to the data for Quebec in the 2003 *Canadian Community Health Survey*, the following factors appear to be associated with low participation in cervical cancer screening: low household income, lack of a family physician, lack of understanding of French or English, low level of education, and, in the case of older women, living alone. "[translation] However, the vast majority of unscreened

and underscreened women did not necessarily have these characteristics, and 70 per cent of them did have a family physician." [3]

Case

To carry out this pilot project, we would have had to develop a database identifying the women whom we wanted to reach. For this purpose, we planned to cross-reference data from the *Régie de l'assurance maladie du Québec* (RAMQ, Quebec's public health-insurance agency) with data from cytology laboratories in the geographic area of interest. The RAMQ database can be used to identify all women who live in a specified area and have the target characteristics for cervical cancer screening (age 21 to 74, no history of cervical cancer, no hysterectomy). Assuming that if any of these women had previously had a Pap test, there should be a record of it among the cytology laboratories serving their geographic area, then by cross-referencing the laboratories' data with those from the RAMQ, we should have been able to obtain the contact information for those women who had never had this screening test as well as for those whose records indicated a test that dated back three years or more.

Our plan called for a personalized letter to be mailed to these women, inviting them to be screened and informing them that, according to the records that we had consulted, they were not being screened as often as the experts recommend. If a woman did not answer this letter, a reminder letter would be sent to her within 90 days. As a pilot project in a defined geographic area, this study was designed to assess the acceptability and effectiveness of this method of promoting screening.

Quebec's provincial public health ethics committee, the CESP, focused its review on the ethical concern that it deemed most relevant and that let it best meet the research team's needs at this point in the project's development. This concern was the legitimacy of taking personal information, which is usually regarded as private, and using it a) to identify women who were considered at risk because — perhaps intentionally — they had not had Pap tests as recommended by the experts, and b) to invite them to be screened.

With regard to this issue, the CESP saw a tension among three main values: the desire to do good (in this case, to improve the health of the women targeted by the project), privacy, and autonomy. Of these, the first two proved decisive for addressing the ethical concern identified.

Cervical cancer is relatively uncommon, and the mortality rates associated with it are low. In Quebec, the participation rate for cervical cancer screening was estimated at 74% in 2008, up 3% from 2003. The data supporting the strategy to promote screening through personal invitations show modest gains, but the interventions arising from screening can involve some risks, especially for women of childbearing age. The expected population impact on women's health — the amount of good done — would thus be fairly small. From this perspective, the method used to identify the women to be targeted by the letter proportionally loses a part of its justification. The creation of the proposed database to identify women with non-compliant behaviour, in the absence of any mechanism to let them consent to this process, seems out of proportion to the population benefits of the proposed intervention in terms of preventing cervical cancer.

As the ethics committee understood it, the main justification for taking action regarding this cancer was not its prevalence, but that it is considered an avoidable problem. The idea that cervical cancer could be eliminated exerts a powerful attraction both scientifically and symbolically.

The ethics committee found that sending a personalized invitation on the proposed basis did not seem legitimate in the specific context of this project. The committee therefore recommended the exploration of approaches to promoting cervical cancer screening that were more respectful of women's privacy.

Scenario shift

The ethical issues would be different if the reminder to take a Pap test did not involve the cross-referencing of data proposed here to create the database for the target population. This would be the case, for example, if there were a systematic screening program that included a central registry of data on the women concerned. One can imagine that at its launch, such a system would already include all of the data on the women to be targeted.

Questions for discussion

1 Are there any other things that should have been considered in this case but were not and that could have altered the committee's assessment of the project's justifiability?

2 Why did the ethics committee find that a personalized letter of this kind would have been acceptable if it had been sent in the context of ongoing clinical relationships with the women concerned rather than by the government?

3 If the committee had deemed the project legitimate, what restrictions would have had to be established to protect privacy in light of the advanced abilities of today's information systems to store and cross-reference personal data? For example, should systems be developed to do systematic tracking for a whole range of specified pathologies?

4 In attempting to address the low participation rate of some women in cervical cancer screening, this project would have led to overscreening of other women, meaning an excessively high frequency of Pap tests. The treatment (or as some would have it, overtreatment) of lesions that would otherwise disappear spontaneously in these women might lead to significant morbidity.[4] What light does this shed on the ethical issues involved in cervical cancer screening?

5 There are some major differences between cervical cancer screening practices in North America and in Europe. For example, the screening age appears to range from 18 to 21 in North America and 21 to 30 in Europe. The younger the persons screened, the greater the possibility of detecting benign lesions associated with human papilloma virus and hence of treatments that might have undesirable consequences, whereas in general these lesions would regress on their own. How should screening guidelines be designed to take this ethical consideration into account?

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Case discussion in response to USING PERSONALIZED LETTERS OF INVITATION TO INCREASE PARTICIPATION IN CERVICAL CANCER SCREENING

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Introduction

This personalized invitation program for cervical cancer screening is part of a prevention process aiming to screen asymptomatic women as soon as possible, as therapeutic intervention would be more effective if started early. The ability to send invitation letters encouraging women to see a doctor for a screening test (Pap smear) assumes the existence of a database that can cross-reference personal information from cytology laboratories, regional hospitals and the RAMQ, without the prior consent of patients. Even though conducting screening interventions in an asymptomatic population does not seem to raise major ethical concerns, it can infringe on certain values and principles, and this deserves attention.

Case

The ethical justification for screening interventions has to do with striking a balance between two ethical imperatives. The first is public health officials' responsibility under their prevention mandate, based on screening for possible signs of cervical cancer. Failure on their part to address a health problem that can be screened and treated at a reasonable cost would not be ethically acceptable. This situation calls for values of collective responsibility as it relates to prevention, beneficence and even solidarity with those at risk for this type of cancer. Within a universal health system, public health officials can

legitimately use all means of disease prevention. In Quebec's social, cultural and political context, people voluntarily delegate a large part of responsibility for prevention to the State. Where a competent, publicly funded public health system with ample resources is concerned, not intervening could easily be construed as shirking responsibilities. However, even though the Quebec sociopolitical context justifies greater intervention than what would appear justifiable in a society that gives priority to individual responsibility and private involvement in the health sector (most U.S. states), there are still ethical limitations with regard to unwarranted interventionism, the invasion of privacy and solicitation to participate in such prevention programs. These limitations fall within two main categories: those relating to respecting the values and ethical principles that the population shares and those related to the usefulness and efficiency of the interventions in question.

The second category of ethical imperatives therefore has to do with how a personalized invitation for screening may potentially violate the fundamental values that the target population shares. We believe that most of these values are only subject to minor infringements. This includes social justice when screening is done universally for free and access to treatment is also free. It also does not appear as though the expected benefits to the community as a whole would place the onus (especially psychologically) of the intervention on the shoulders of a minority, as the intervention would target all women aged 21 to 74. The autonomy and free will of these women is not infringed upon as, after receiving the letter of invitation, the women are free to accept or decline the invitation and may even ask that their name be removed from the invitation system. If a customized database were created for the purpose of sending a letter of invitation, followed by a reminder 90 days later addressed to women who had not acted after receiving the first letter, there would be a clear violation of privacy and confidentiality of personal information. However, as this database would be used for the sole purpose of sending out invitations and could be consulted only by those responsible for the screening, any consequences on women would be negligible. In addition, public health ethics, as opposed to bioethical logic, requires that we accept a certain level of infringement on individual interests in favour of the interests of the community as a whole.[1] Contrary to the argument raised in the literature of ethics, which considers the confidentiality of personal information inviolable and which was in part mirrored in an opinion produced by the CESP (Québec Public Health Ethics Committee), we believe that this

principle should only be taken into consideration when significant adverse effects on women are expected. We cannot conclude there will be any actual breaches in women's privacy. The only expected adverse effects are those related to the psychological impacts of receiving a reminder that includes expert recommendations on the usefulness of the screening. The mere appeal to the principle of not using data from RAMQ and laboratories is not a justification for inaction, if no negative consequences (other than those connected to mail solicitation) are expected on the people on the list. The principle of non-maleficence therefore does not apply.

However, other types of negative consequences can be foreseen. For example, it is important that the letter be written so that the women who receive it experience the least amount of worry and stress. As long as the letter is not followed up in any other way (phone follow-up), and its form and content are not guilt-provoking, stress-inducing or moralistic, the negative impacts will be kept to a minimum. The risks of stigmatizing or discriminating against women who refuse to take the screening test are non-existent, considering the decision to take the test remains personal and confidential. We also surmise that having a Pap smear does not have any proven impact on the physical health of women who accept to have it done, and that the only impacts to consider are psychological in nature. However, in its opinion, the CESP[2] states that, according to some studies, interventions aimed at identifying precancerous lesions can potentially be tied to an increase in miscarriages or preterm labour. Should new scientific evidence support this, and if the impacts affected a significant proportion of women who underwent screening, the ethical opinion would need to be seriously reconsidered. However, this would affect not only the pilot project on personalized invitations, but also the entire screening strategy set in place by physicians who prescribe the test in their practice. In short, it does not appear as if this preventative intervention, based on sending a letter encouraging women to participate in a cervical cancer screening test, significantly and unjustifiably infringes upon the core values that define, in the view of Quebec society, an ethically acceptable intervention. Even if the interests of the population are given priority over individual interests, just as with any other public health intervention, the project remains ethically justifiable within the scope of ethics applied to populational interventions,[3] in a society that readily delegates great responsibility for prevention to public health officials. The interference in private life and the infringement of liberal principles are justified

by considerations of the common good. Therefore, if ethical principles are respected, if the costs to and consequences on the people who receive the letter of invitation are minimal and, lastly, if it is assumed that the test has a sensitivity and specificity justifying its use, the ethical soundness of the program depends only on utilitarian criteria related to the efficiency of the screening program with respect to the objectives. Regardless of any debate to determine whether such efficiency considerations relate to ethics or a cost-benefit analysis, no screening program would be justifiable if it were inefficient. But, based on the data used in the CESP's opinion, this is the source of the letter project's controversy.

As far as cervical cancer is concerned, the most relevant data have to do with the relatively low prevalence of the problem. Out of the 280 Quebec women diagnosed with cervical cancer in 2008, 70 died of cervical cancer. As it is expected that the personalized invitations will result in a 10 per cent reduction in the mortality rate of women aged 25 to 64, if this objective were reached, about seven lives would be saved. If applied across Quebec, 3 additional cases of cancer and 170 cases of lesions at high risk of progression to cervical cancer would be detected per year. Statistically, cervical cancer is far less prevalent than breast cancer, with 1,400 deaths and 6,000 new cases each year, or colorectal cancer, which is associated with 2,600 deaths in women. We can agree with the CESP's opinion about the net impact of the intervention on women's health being limited. In addition, considering that cervical cancer progresses slowly, that this cancer's five-year survival rate is 74 per cent, that about three-quarters of women already undergo screening without having to receive a letter, that a significant percentage of the lesions that are detected resolve naturally (without an intervention) and, lastly, that current human papillomavirus (recognized as a causative agent of cervical cancer) vaccinations will reduce the number of cases in coming years, the expected benefits of a personalized invitation appear relatively limited. Overall, resource allocation must be taken into consideration. Do financial and human resource investments (though there is no estimate for the cost of the program) by the Quebec public health system offer the greatest return when used for this type of program instead of for other screening programs, especially when compared to more common and severe cancers? The principle of proportionality, which calls for a balance between an intervention's expected effects and infringements on other ethical principles, appears to be adhered to only loosely. Such prevention interventions, when multiplied, could

potentially cause the general population to feel unduly solicited and could squander away their motivation to participate in future calls for screening.

In short, this intervention project is difficult to justify. However, infringements on values and core ethical principles are less of a factor than efficiency and proportionality considerations.

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HEALTH INEQUITIES IN FIRST NATIONS COMMUNITIES AND CANADA'S RESPONSE TO THE H1N1 INFLUENZA PANDEMIC

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Introduction

Access to safe drinking water, adequate sanitation, and housing are internationally recognized human rights essential to the full enjoyment of life and all other human rights, including the right to health.[1–3] Yet, for many First Nations communities in Canada — particularly those in remote areas — clean running water, basic sanitation, and adequate housing are lacking. As of September 30, 2012, approximately 116 First Nations communities were under a drinking water advisory, many of them long-term advisories of a year or more, and more than 65% of First Nations water and wastewater systems on-reserve were rated at either high or medium risk.[4, 5] Recent census data indicates that First Nations are five times more likely to live in crowded homes than non-Aboriginal peoples and four times more likely to live in homes in need of major repairs.[6] First Nations' homes on-reserve are also ninety times more likely to be without piped water.[7] These disparities call into question whether Canada is fulfilling its obligations under the International Covenant on Economic, Social, and Cultural Rights, as well as its respect for First

Nations' constitutional rights to water under the Canadian Charter of Rights and Freedoms and the Constitution Act.[8]

Poor living conditions in First Nations communities — together with limited access to medical care — are associated with a range of adverse health outcomes, from higher rates of gastrointestinal illness and infection, to disease and death.[9] For First Nations people in Canada, who already experience a disproportionate burden of ill-health compared to the non-Aboriginal population, well-documented inequities in water, sanitation, and housing[4–7] played a critical role in the H1N1 influenza pandemic of 2009.[10, 11] This case examines the ethical considerations of poor living conditions within the context of the 2009 H1N1 outbreak and the efficacy of targeted public health interventions.

Case

Canada experienced two distinct waves of H1N1 influenza during the pandemic: the first in the spring of 2009, the second in the fall of that same year. The illness caused generally mild symptoms for most people; some groups, however, appeared to be at higher risk of more complicated or severe illness, with the First Nations population included in this number. This was particularly true for those in remote areas with large distances to travel to hospitals for acute care and with limited access to health services in general. Although a remote and isolated communities task group was established to ensure effective and coordinated federal and provincial/territorial pandemic response, targeted interventions on-reserve were insufficient in many areas because of poor living conditions.

Only 80% of communities had pandemic plans in place at the onset of the outbreak, many of which had not been tested and/or did not clearly articulate aspects of when and under what circumstances they would be implemented.[12] As well, recommended infection prevention and control measures were not well suited to conditions on many reserves. For example, standard practices such as frequent hand washing and keeping common areas clean and disinfected were not realistic for communities without running water and indoor plumbing. Attempts to mitigate water and sanitation challenges, most notably through the provision of alcohol-based hand sanitizers, were delayed during the spring outbreak over concerns that the alcohol content might be abused.[13] Other measures, such as staying at home when sick, did not work

for individuals living in substandard, overcrowded homes where infectious diseases are more likely to spread.

Public health emergencies such as the 2009 H1N1 pandemic highlight governments' ethical responsibilities towards vulnerable populations. Most people recognize that the government had a responsibility to provide the H1N1 vaccine. But the consequences of poverty, such as inadequate water supply and overcrowded housing, created difficulties for an adequate pandemic response within Aboriginal communities. Canada's response to the pandemic could have been improved had the government taken responsibility for alleviating these poverty-based health inequities prior to the outbreak.

While many of the negative experiences of the spring outbreak improved Canada's response in the fall outbreak, poor living conditions such as overcrowding and a lack of running water were not addressed.[14-16] Instead, responses to the fall outbreak included large shipments of body bags to many remote First Nations communities, with a negative and well-publicized reaction.[12] During the spring and summer outbreak, more than one-quarter (25.6%) of the approximately 168 patients admitted to hospitals across Canada for H1N1 influenza were of Aboriginal ancestry,[13] even though they make up only about 4% of the Canadian population.[17] In remote communities, high rates of H1N1 infection also placed significant pressure on air ambulance services, with 76 patients requiring medivac services from northern Manitoba alone at the cost of $5,000 per patient.[18]

Scenario shift

Consider whether the circumstances of this case would be different if:

» a non-Aboriginal remote community experienced high rates of H1N1 infections, serious cases and deaths from a lack of clean running water and basic sanitation;

» the government invests funding to build a tertiary care facility accessible to surrounding First Nations to provide more cost-effective health services in remote communities. However, no additional funds are provided to improve housing, sanitation and water systems. Would this be an improvement?

Questions for discussion

1 All people in Canada have a right to safe drinking water and adequate sanitation and housing. Yet First Nations often have no access to these basic necessities. What are the ethical issues raised by these inequities?

2 The federal government funds First Nations water and sewer services on-reserve, but only a portion of health care-related expenses for First Nations individuals who become ill, are hospitalized or need to be air-lifted out of communities for treatment when these services fail (the rest of the expenses are covered by the relevant province/territory). What are the ethical issues raised by this jurisdictional divide?

3 What ethical issues should be considered in targeted public and population health interventions for First Nations, particularly for those in remote communities?

4 The Walkerton tragedy in 2000 which resulted from *E. coli* contamination was a motivation for meaningful improvements to that community's water management. If similar changes do not arise when Aboriginal communities experience water quality problems, what are the ethical issues? What are the relevant ethical principles that apply?

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Case discussion in response to HEALTH INEQUITIES IN FIRST NATIONS COMMUNITIES AND CANADA'S RESPONSE TO THE H1N1 INFLUENZA PANDEMIC

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Justice and health equity

It is clear from this case narrative that living conditions and health outcomes among Canada's First Nations communities are less than ideal. However, are these conditions *unjust*? Answering this question leads us to consider three theories of justice that are particularly influential in the public health arena: liberalism, egalitarianism, and utilitarianism.

One answer to this question, rooted in the philosophical doctrine of liberalism, requires us to determine whether the conditions violate some basic human right. Modern liberalism holds that (1) all human beings have a fundamental right to develop and implement their own decisions about how to live their lives, free from impediments; and (2) the state thus has an obligation to ensure access to the resources that every individual requires to carry out his or her life plans.[1] It is worth noting that, from a liberal point of view, these rights hold regardless of whether their contravention has a measurable impact on health or welfare.

The case narrative notes that several international organizations and agreements designate access to safe drinking water, adequate sanitation and housing as fundamental human rights. Beyond this, it is widely recognized

that freedom from preventable diseases, such as many infections and waterborne illnesses, is a requirement for normal human functioning, and thus is a fundamental human right. From the point of view of liberalism, then, lack of access to clean running water, basic sanitation and adequate housing is unjust, because it constitutes a violation of fundamental human rights, regardless of its impact on H1N1 morbidity or mortality.

A second answer to the original question, rooted in the philosophical doctrine of egalitarianism, requires us to determine whether these conditions represent an inequitable distribution of resources and/or outcomes. Three factors are important in making this decision. First, we must agree that the *currency* of justice — that is, the thing being distributed — is important enough to be of concern. Most would agree, for example, that access to a life-saving medical treatment meets this criterion, while access to red jelly beans does not. Second, we must determine whether the unequal distribution of a resource or outcome among particular *populations* is of concern. For example, unequal distribution of transplanted organs by socio-economic status may be considered unacceptable, while unequal distribution by age or underlying health status may not. Finally, we must determine whether the *cause* of an unequal distribution is relevant and, if so, whether it warrants intervention. For example, men generally have lower life expectancy than women. Some argue that this inequality is due primarily to genetic or physiologic differences, so it is unavoidable and thus cannot be seen as unjust. Others argue that this inequality is due to social factors such as increased pressure on males to engage in risky behaviors, so it is avoidable and thus unjust.

Most egalitarians would likely consider the inequalities described in the case narrative to be unjust. The currency of justice in this case — safe drinking water, adequate sanitation and housing — is widely considered to be a fundamental human right, so it is clearly important enough to warrant consideration. The inequality in this case puts First Nations communities at a disadvantage relative to other ethnic groups and the overall Canadian population. As this inequality further disadvantages a population that is already subject to considerable social and economic disadvantage, it constitutes an inequity from the perspective of populations affected.[2] (We should note here that this judgment might change in the case of the first "scenario shift.") The case of causation is somewhat more complicated, and will be addressed in detail below. For now, we can say that: (1) unsafe drinking water, inadequate

sanitation and poor housing are clearly avoidable; (2) the Canadian government clearly has the economic and technological resources to eliminate this inequality; and (3) there is no reason to believe that the lack of these resources among First Nations communities resulted from fully informed, freely chosen decisions by the affected communities. From this perspective, then, this distribution is unjust.

A third answer to the original question, rooted in the philosophical doctrine of utilitarianism, requires us to assess the *consequences* of these conditions. Utilitarians assess conditions, policies and interventions according to their impact on the total well-being (or "utility") of a population, with those that maximize total utility judged superior to those that do not. This judgment is often the result of an analysis of the costs and benefits associated with a particular condition, policy or intervention. For example, an unequal distribution of living conditions might be considered just if equalizing housing conditions required such a large expenditure that it would reduce funding for other programs that have a greater benefit for overall well being.

The case narrative argues that, during the pandemic, living conditions among First Nations communities presented a significant impediment to adequate response, that these communities bore a disproportionate burden of H1N1 morbidity and that "Canada's response to the pandemic could have been improved had the government taken responsibility for alleviating" these conditions. The case narrative provides strong evidence that living conditions did impede pandemic planning and response, which in itself is a significant problem. But a utilitarian would likely ask whether this really resulted in a measurable negative impact on health outcomes, and in turn whether alleviating these conditions would reduce this impact in a cost-effective manner. Answering this question requires us to examine the evidence base for this case.

The evidence base for ethical analysis

The poor living conditions of First Nations communities in Canada are well-documented, as are the disproportionately high rates of a variety of health problems, from infant mortality to diabetes to suicide. These factors alone may justify comprehensive government action to improve Aboriginal living conditions, health and health care. However, since this case focuses on the relationship between living conditions and H1N1 influenza, a closer inspection of the evidence in this specific regard is warranted.

The case narrative argues that First Nations communities "appeared to be at higher risk of more complicated or severe illness," and that this was due, at least in part, to poor living conditions, inadequate health services and remote or rural locations. However, the exact contribution of these factors to H1N1 morbidity and mortality is unclear. The case narrative cites a 2009 study indicating that 25.6% of all people admitted to hospital for H1N1-related conditions were of Aboriginal ancestry, even though they only make up about 4% of the Canadian population — clearly a disproportionate burden. The same study notes that obesity, hypertension and a history of smoking or diabetes occurred among 30–40% of the patients, and that "all these conditions are known to be increased in frequency in the Aboriginal population that comprises a substantial portion of cases within this cohort. The extent to which these comorbidities contribute to severity of disease is unclear because a large portion of the Aboriginal population (which may be a risk factor itself on the basis of genetic susceptibility) often have such comorbidities." Indeed, obesity alone — which is significantly higher in First Nations communities than in the general population — has been identified as a significant risk factor for H1N1 hospitalization and mortality.[3] This observation raises the possibility that the increased proportion of Aboriginals among H1N1 hospital admissions was due in large part to underlying comorbidities and health behaviours, not living conditions.

Conversely, the cause of this health inequality may be unknown. One study found that Aboriginal people who were admitted to hospital with H1N1 influenza were no more likely to suffer a severe outcome than any other group.[4] Another study of Manitoba residents found, conversely, that the greater risk of hospital admissions among Aboriginals persisted even after accounting for age, sex, co-morbidities, rural residence and income level. This finding is consistent with findings of higher morbidity and mortality among Aboriginal populations during previous pandemics and in other countries, suggesting some unknown genetic or social factor.[5]

To return to our previous discussion, a utilitarian might argue that, since we cannot yet identify a clear connection between living conditions and increased risk of complicated or severe illness, this increased risk cannot justify ameliorating those living conditions. We may still justify this intervention on the basis of other concerns discussed above, but we do not have adequate information to justify it on the basis of increased utility — in this case reduced risk of severe H1N1-related health outcomes — alone.

Decision making

While the philosophical doctrines discussed above may inform public health decision making, they are not the only criteria against which to evaluate possible responses to the conditions described in this case. A recent review of resource allocation during an H1N1 pandemic noted that, "it is especially important for there to be dialogue between the general public, government and healthcare decision-makers since having the public abide by recommendations requires trust among all interested parties. And in the case of pandemic influenza, everyone is an interested party."[6] This observation raises two key questions about future pandemic planning in Canada: which stakeholders must be represented and what role should they play in the planning process?

While the quotation above suggests that "everyone" is a stakeholder, this case illustrates how different communities may have very different stakes and interests in pandemic planning. In this case, it is clear that representatives of First Nations communities must play a significant role in pandemic planning. In a practical sense, they can improve planning by alerting public health organizations about the particular resource constraints their communities face, thus preventing future problems such as the recommendation of frequent hand washing in a community without running water. From the point of view of justice, they can advocate for increased attention to health inequalities that may disadvantage their communities, including placing the alleviation of these resource constraints on the public health agenda.

Given that First Nations communities have a clear stake in future pandemic planning, what might their actual participation entail? In a limited sense, they must obviously play a role in selecting, designing and implementing interventions targeted at First Nations communities. But what about the distribution of pandemic planning resources more generally? Does the fact that First Nations communities suffered health inequalities during the last pandemic justify a seat at the table in pandemic planning? As a comparison, we might note that women suffered disproportionate morbidity and mortality in the H1N1 pandemic. The 2009 study notes that females comprised 67.3% of hospital admissions and 72% of deaths, despite only making up roughly 50% of the Canadian population. If First Nations communities deserve representation in pandemic planning by virtue of their greater vulnerability to H1N1, then it stands to reason that women — who make up a much larger

proportion of the population — deserve even greater representation. And how might the needs of these populations be weighed against one another?

Conclusion

We have seen that our interpretation of the ethical questions raised by this case depends in large part on the philosophical doctrine that one employs to evaluate the available evidence base. To conclude, let us briefly consider the second "scenario shift," which asks whether the implementation of a tertiary care facility accessible to First Nations communities would be an improvement. From the point of view of liberalism, the answer would likely be 'no,' because it does not address the underlying violation of basic rights. From a utilitarian point of view, the answer may well be 'yes' if, as expected, this improves the health of First Nations communities more generally, and thus makes them less susceptible to serious H1N1 outcomes. Finally, from an egalitarian point of view, the situation is complicated. In a strict sense, this is hardly an improvement if First Nations communities still lack access to adequate housing and drinking water. However, from a broader perspective, the addition of a new health care facility increases First Nations communities' overall health resources, and is thus clearly an improvement.

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ALBERTA OIL SANDS

A toxic mixture of bitumen and economic prosperity

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Introduction

Oil sands contain naturally occurring bitumen, a mix of a thick, sticky oil and abrasive sand. Each sand grain is coated with a layer of water and heavy oil requiring oil producers to search for and develop efficient means of bitumen extraction.

Alberta's oil sands are the second-largest oil reserve in the world. Spanning more than 140,800 square kilometres, the deposits are buried at varying depths beneath the earth's surface. Currently, industry extracts around 1.49 million barrels of bitumen each day, representing about 76% of the province's total crude oil production. As owners of the province's resources, the Alberta government controls the creation and implementation of Alberta oil policies.[1] In 2004, the Alberta government collected $718 million in royalty payments from oil sands output, which was used to pay for infrastructure, services, and programs for all Albertans.[2]

Fort Chipewyan, a fly-in reserve situated on Lake Athabasca, is home to about 1,200 people, most of whom are First Nations. Located just downstream from many major oil sand projects, residents believe leakage and seepage of contaminated water from the tailing ponds has resulted in higher-than-expected numbers of cancer cases.[3]

The oil industry acknowledges that bitumen extraction and refinement procedures can warm underground water, thereby liberating arsenic (a potent carcinogenic) and other heavy metals from deep sediments. Although Canadian Natural Resources reports that an arsenic plume has moved approximately 1,200 feet over a 15-year period, it also indicates that "it would take centuries, if ever" for the arsenic to affect drinking water.[4]

Case

In 2006, a local physician reported a high number of cases of cholangiocarcinoma, a rare form of bile duct cancer, as well as high rates of other cancers in Fort Chipewyan residents. In 2010, the Alberta Cancer Board released a report outlining its findings from its investigation of the incidence of cancer cases within the community.[5] It concluded that the observed cases of cholangiocarcinoma and colon cancer during the period of investigation (1995–2006) were within the expected range of cancer occurrence, although the number of cancer cases overall was higher than expected.

Fort McMurray's Medical Association expressed concerns about the Alberta Cancer Board study's methodology as a result of the narrow inclusion criteria that were used: only cases in the Alberta Cancer Board registry were included in the study. The Vice President of the Cancer Corridor for Alberta Health Services dismissed these concerns by indicating that an increase in observed cancer cases over expected could be due to chance, increased detection, or increased risk, including environmental risk in the community and so continued monitoring and analysis were warranted.

More recently, large disparities have been identified between estimated oil sands emissions and pollutants identified in the Athabasca River watershed.[6] An independent scientific review committee called into question Alberta's water monitoring program and noted evidence of increased arsenic concentrations in Lake Athabasca.[7]

Although questions linger about whether the reported health concerns can be scientifically linked to water contamination,[8] local First Nations, Greenpeace and the Pembina Institute have called for a moratorium on new oil sands projects.[1] Further, the Assembly of Treaty Chiefs, comprising representatives from all First Nations groups in Northern Alberta, unanimously passed a

resolution calling for the provincial government to cease granting approval for new oil sands projects until proper water management strategies have been developed and implemented.

Resolution

Alberta Environment has appointed a Provincial Monitoring Panel to enhance monitoring of the environmental impacts of Alberta's oil sands.[9]

Scenario shift

Consider if a different industry was linked to suspected population health problems. For example, while Alberta and Canada's economic health is deeply rooted in oil and gas exports, the beef industry, with more than 4,000 feedlots producing 39% of Canada's commercial beef, is becoming an important player in Canada's economy. The sheer size of these operations has raised questions about water quality and threats to public health. Are there similarities in the cases? What ethical issues exist?

Questions for discussion

1 What evidence is needed to invoke action based on the precautionary principle?

2 What ethical principles could be used to guide public policy development for oil sands projects?

3 What factors or criteria should be used to assess whether development is "sustainable" development? In particular, what ethical principles should be included in this assessment? What is the role of public health officials in ensuring that ethical principles, in particular health equity issues, are addressed when communities make these determinations.

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Case discussion in response to ALBERTA OIL SANDS

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Prelude

Ethics case analyses can proceed in either of two possible ways: by using a principle-based approach[1] or by casuistry.[2] I will use the principle-based approach, drawing on the bioethical principles of respect for autonomy, beneficence, non-maleficence and distributive/social justice (i.e., fairness/equity that raises the two questions: Whose interests are being served? Who is deriving the benefits while who is taking the risks?). Related to each of these four principles are the additional sub-principles that are relevant in the analysis of this case study: inter-generational equity (under justice), the seventh-generation principle (under both justice and non-maleficence), the precautionary principle (under both respect for autonomy and non-maleficence) and the principle of solidarity (under both respect for autonomy and justice).[3] The principle of respect for autonomy stands in contrast to the principle of paternalism.

Ethical analysis falls under the general area of applied ethics. Applied ethics is context-dependent in that local norms usually take precedence over universal norms; this is more commonly seen in the role of Human Research Ethics Boards (HREBs). However, the primacy of local norms can cause tension when considered under the principle of solidarity. Because the oil industry has global ramifications in terms of the global demand for oil, this case must be properly situated not only in the context of the province of Alberta, but also in the context of Canada and the world. This approach thus helps to ensure that the complex array of over-laying contexts is duly considered.

The principle-based approach to ethical analysis, in deciding if one chosen action is more ethical than another, requires first that we recognize the inherent tensions among the various ethical principles. And, because no one principle takes precedence over any other, we must consider, under each of the various principles, the weight of argument in support of each respective principle. The resulting recommended action then can be defended according to a transparent, documented rationale, allowing for greater accountability for the action taken. Our aim in pursuing an ethical analysis is to maximize the advantages relative to the disadvantages under each of the respective ethical principles that bear on the question at hand.

The generic problem-solving model for ethical decision-making comprises five steps:[4]

1 Gather all relevant information

2 Specify clearly all components of the identified ethical dilemma

3 Specify all options as possible courses of action

4 Select a single best alternative

5 Act and review

This five-step paradigm will be applied in the analysis of this case.

The key population/public health issues

First, industrial activity of any kind has health implications, both good and bad. On the good side, employment and economic activity contribute to health and social well-being, especially in the short-term. Indeed, refined oil helps keep the wheels of industry turning and brings revenues into the province of Alberta and Canada as a whole, adding to both short-term economic prosperity and growth, locally and nationally. On the negative side, some industrial activities cause both worker and environmental harms, especially over the medium-longer terms, where chronic exposure to toxicants can result in diseases with a long latency period, such as cancer. And, on the global scale, growth is seen by some as unsustainable, with the potential to add to global environmental burdens that may result in ecological system failures with consequent calamitous harms.

Second, the process of oil extraction, as oil reserves deplete and become less accessible (i.e., so-called "peak oil"), becomes more risky, more costly, and less efficient in terms of the relative amount of energy gained in extracting each barrel of oil.[5] The greater the risks taken to extract diminishing and more remote reserves of oil, the more likely are toxic spills and ecological disasters, with consequences for human health and well-being. One tension that becomes immediately apparent is between short-term gains for one group of people with longer-term losses for another group of people. For those taking the risks through working or living in proximity to oil extraction industries, are the benefits equivalent to those enjoyed by other stakeholders? And, what about the health and well-being of future generations?

Third, this case analysis focuses more specifically on the harms to the health and well-being of a sub-group of Albertans who live in proximity to water contaminated with effluent from upstream oil industry activities. Under the principle of "justice," this raises concerns about the direct health effects on a vulnerable community located in one area for the benefit of economic activity elsewhere. What obligations fall on the affected community (i.e., the vulnerable by virtue of their exposure), and what obligations fall on those polluting their community (i.e., the oil industry) to respect local culture and well-being? And also, from an enlightened self-interest perspective, with environmental pollution affecting one group, would it not behoove society-at-large to view the affected community's experience as a sentinel event, as one forewarning of potential impacts beyond that community? The principle of respect for life requires that all dimensions be taken into account.

What do we know – and what do we not *know?*

Hazard assessments demonstrate higher levels of pollutants in water flowing past the community; both the community and living organisms, including fish, depend on that water for their sustenance. Thus, these populations, under classical risk assessment paradigms used by the US Environmental Protection Agency (EPA) since the 1960s, demonstrate vulnerability.

The application by powerful interests of the Four-D paradigm (i.e., Deny, Delay, Divide and Discredit) to allegations of harm was used in a cluster of rare cancer outcomes in a community of 1,200 people downstream from oil

sands developments.[6] The record shows serious controversy over these alleged health effects by reputable groups of scientists and with follow-up studies underway at the time of this analysis.[7-11]

The world's need for oil continues under the economic, growth-bound model to which most governments in the world appear committed. Its extraction will thus continue wherever on Earth it can be found. This means extracting oil from the depths of the oceans or from bituminous sands because the easily accessible supplies have been exhausted (i.e., "peak oil" has been reached). It stands to reason that those living and working in proximity, downwind or downstream from any such oil extraction activity are likely to be exposed to effluent resulting from the industry and thus be vulnerable to the health impacts known to be associated with such pollutants.

As noted above, workers and communities do derive benefits through employment opportunities provided by the industry and related economic activity. Whatever the activity, however, workers deserve to be protected from industrial hazards, as do local and distant communities who may be affected by the potential impact of industrial wastes on air, water and soil.

In the face of uncertainties as to precise health-risk estimates, policy-makers can opt to await more certainty in the data about health effects. However, under the precautionary principle, action is required. Further, from indigenous knowledge, the seventh-generation principle could be helpful in redirecting actions that are seen to be harming (physically, mentally and culturally) both present and future generations. The consequences of actions today for future generations would direct policy towards protecting local communities from exposure and taking into account local values and beliefs. Indeed, it is a principle that underscores concern for both sustainability and for intergenerational equity.

The principle, from ecological economics, of "contraction and convergence" needs to be adopted in policy, particularly in industrialized countries, to achieve reduced demand for energy. "Contraction" relates to existing affluent populations reducing their demand for energy, living more lightly on the planet, while "convergence" relates to the narrowing of the gap between emerging economies and those that are developed. If adopted, it would immediately see the demand for any type of energy reduced,

contributing to "contraction." Part of the resources thereby saved then could go towards uplifting developing country economies, thus reducing the gap between rich and poor countries, leading to a world of diminishing, rather than widening, disparities. If achieved, this would contribute to the attainment of the Millennium Development Goals (MDGs) as set in 2000 by the United Nations.

Finally, the precautionary principle encourages policies that protect human health and the environment in the face of uncertain risks. It has been defined as follows: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[12] Its application would require concerted global action in the face of uncertainty on a scale of the harm expected through global warming and, indeed, global heating under existing climate change models.[13, 14] In tandem with this principle is the principle of solidarity. Under the Kyoto Accord, solidarity would trump precaution, and certainly local/regional short-term economic interests in order to act to prevent worsening trends in global warming. The tension between local short-term and global longer-term interests is, in turn, trumped by other principles, including intergenerational equity. Respect for autonomy (i.e., the right to self-determination) in the affected community appears to have been minimized and even marginalized to date in all actions taken by more-powerful interests.

Identify the key stakeholders in the case and the most appropriate decision-maker(s) and/or legal authorities to approach the ethical issue, if applicable

Key stakeholders include elected government officials who, on the one hand, represent regional values, but are not immune to pressure from powerful vested interests; federal and provincial government departments of health, environment and industry; the oil industry; and, the communities, local, downstream, national and global, that not only rely on a secure supply of oil, but also are at increased risk of harm from the pollution resulting from the industry. The medical officer of health for the region is also a key stakeholder, as is the provincial cancer board and its cancer registry.

Identify the key values and concerns of the identified stakeholder(s), as well as any potential risks and benefits

For the purposes of making distinctions, three contrasts are offered: the oil industry values profit; people in industrialized countries value being able to function in an energy-dependent society; and, people in non-industrialized countries value their traditional lifestyles of living off the land. In this dynamic, the tension for government officials is to balance the need to protect public health and promote economic activity. Canadian values must be taken into account separately from provincial values. Furthermore, because the oil industry has global reach, the reader must be sensitive to the principle of solidarity with the global community, first through its economic activity contributing directly to global warming and, second, by the need to think of the global consequences of local actions.

Identify the options available to the decision-maker, including reasonable alternative courses of action, consideration of implications, and potential intended and unintended outcomes (consequences)

Decision makers could demonstrate leadership by keeping the oil in the ground. Instead, they could provide incentives for developing green technologies that depend on renewable sources of energy as opposed to perpetuating dependence on oil as a non-renewable energy source. This would require the adoption of a "steady-state", "no-growth", or even a "de-growth" economy. Transitioning away from non-renewable energy supplies to those that are renewable, could be granted the breathing space to do so through the above-noted principle of "contraction" in demand for energy in rich countries. The need to balance "doing no harm" and "doing good" should be applied here, as well as the precautionary principle, for a fuller ethical analysis.

The alternative is to maintain the *status quo* by continuing to pursue a path that harms local communities, commits to boom-and-bust economic cycles and feeds our dependence on oil, thereby contributing to an array of catastrophic harms through more frequent and extreme weather events around the world. While there are some who dispute this scenario, there are others who dispute that technological solutions are possible. At the end of the day, "who is taking the risks and who is deriving the benefits" from such an uncertain future is the question that needs to be addressed in an ethical analysis.

How might the decision and/or action be evaluated?

An ethical analysis is intended to aid, in a transparent way, in the development of a rationale for action, usually a future action — amid alternatives — to be taken. The analysis should clearly reveal all components of the identified ethical dilemma under each of the relevant ethical principles. In so doing, the basis for the action chosen can be defended. As importantly, the consequences of the action can be revisited in the context of the rationale and a new action could be proposed if warranted.

While the point of an ethical analysis of a past case is not to seek retribution, it does reveal better ways to move forward. One recognizes that the above process was not evident in the present case. One can hope that by adopting an ethical case analysis, better ways exist for deciding on future actions.

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WHOSE ROLE IS IT TO DEAL WITH SOCIETAL DETERMINANTS OF HEALTH?

The case of the Nigerian lead-poisoning epidemic

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Introduction

In February 2010, dozens of infants and children in a remote rural village in northern Nigeria arrived at the local health clinic with symptoms such as lethargy, fever, vomiting, weight loss, bulging fontanels, neck stiffness, partial paralysis and seizures. Despite treatment, many died. A team from an international non-governmental organization (INGO) arrived to provide assistance.

Around this time, the price of gold had surged as a result of the global financial crisis. Gold extraction activities had increased and rock grinding machines proliferated in and around household compounds. Although illegal, artisanal gold mining offered poor subsistence farmers a way to supplement their meagre incomes and alleviate their poverty.

The INGO diagnosed the epidemic among children as lead poisoning, based on high levels of lead in their blood. The ore their parents had been mining contained lead as well as gold, leading to a fine lead dust blanketing homes and village compounds. Young children were highly exposed as they

inadvertently inhaled and ingested the dust. In a period of months, hundreds of children died; thousands more remain at risk for the chronic effects of lead poisoning. Who should respond, nationally and globally, to such crises?

Case

In recent years, the public health surveillance system in northern Nigeria has proven inadequate, with epidemics of measles, meningitis and cholera going undetected through official channels. Aware of this situation, the INGO was conducting active measles and meningitis surveillance in the area when it heard of many children dying in a remote village. Once the INGO arrived on-site, it was told by the local community health worker that he had informed his superiors of the mysterious outbreak, but simply received more of the same antimalarial drugs that were proving ineffective. A calculation of the death rate qualified the situation as a humanitarian emergency. The INGO assembled a team to provide 24-hour medical care onsite and sought special government permission to send blood samples to a lab in Europe for analysis. It was these efforts that led to the diagnosis of a lead-poisoning epidemic.

At the village clinic, the INGO took over management. Then, as a first for the organization, it worked with two local field hospitals to establish a lead-poisoning treatment program, providing free chelation treatment for the worst affected: children five years of age and under and breast-feeding mothers. In both the first village and another that was similarly affected, the INGO provided health education and organized transportation to hospital. Other international organizations arrived to conduct community health surveys and implement environmental remediation (cleaning and soil removal and replacement).

To date, more than 400 children have died, amounting to more than 40 per cent of the children in one village alone, and there is an entire generation of young village residents at risk of death or serious short- and long-term irreversible health effects. It has been described as unprecedented and the worst such lead-poisoning outbreak in modern human history. Yet, despite the well-established role of lead contamination as the source of the epidemic, illicit artisanal mining continues.

INGOs may inadvertently contribute to the continuation of this mining. By providing free environmental remediation (and in many cases, paying the

same artisanal miners to decontaminate their own homes and village compounds) as well as free treatment for lead-poisoned children, the perceived risk of lead poisoning is diminished. At the same time, the forces driving artisanal mining — poverty and high gold prices — remain.

In the time since it stepped into the vacuum of essential public health services, this INGO has become mired without a conceivable exit. Is it sufficient to have saved lives, or is there a further duty to care? While chelation therapy may have treated lead poisoning for many, the physical and cognitive injuries persist. Children are left blind, deaf, paralyzed and intellectually impaired. Once treated, they are discharged home to impoverished and remote rural communities without the necessary support or resources. And artisanal mining persists, along with poverty and a lack of an adequate health system. While the effects of the lead poisoning will remain, the INGO, and others like it, will not.

Scenario shift

At the first sign of the epidemic, there were concerns that it was a newly emerging, highly infectious and deadly communicable disease. Around the world, national monitoring centres were put on alert. Once it was found to be a local environmental problem, international concern subsided. Had this been a newly emerging communicable disease, the response, both nationally and internationally, would have been swift and comprehensive, rather than left to a few charitable organizations. What are ethically relevant distinctions between a lead-poisoning epidemic and newly emerging communicable-disease epidemic, and from a public health ethics perspective, do these distinctions justify an unequal response?

Questions for discussion

1 During the emergency phase of the Nigerian lead-poisoning epidemic, the INGO provided oral chelation treatment to those worst affected, primarily children five years of age and under. It is well known that many older children and adults are badly poisoned and children discharged from treatment still have high (although much reduced) lead levels in their blood. The INGO argues that its intervention was a charitable humanitarian emergency response meant to address immediate health needs while allowing time for a more

comprehensive response from others. However, more than a year later, that comprehensive response has not come. From a public health ethics standpoint, what obligation does the INGO have to provide its services indefinitely? Is it fair if these obligations are tied to the actions (or inactions) of other organizations?

2 The lead poisoning epidemic attests to a *de facto* shift in public health service provision from governments to INGOs. When governments withdraw from essential service provision, INGOs expand to fill the void. This may be mutually beneficial, since government officials are able to delegate their responsibilities and INGO workers are able to benefit economically (and often professionally). Indeed, aid organizations have been criticized as Trojan horses for global neoliberalism and privatization. Yet the Preamble to the Constitution of the World Health Organization (WHO, 1948) speaks of the moral and legal duty of states to protect the health of their citizens as the foundation of public health law. Consider public health crises that are costly and less publicized, like the lead-poisoning epidemic: What are ethical arguments in support of the role of the state in providing essential public health services? Do these arguments preclude private organizations from taking over? INGOs often compete for funding and publicity, and self-promotion may factor into deciding whether or not an INGO chooses to intervene in a public health crisis. To what degree is this self-interest ethically objectionable, or is it a practical necessity to ensure that the best INGOs survive?

3 Poverty, inequality and lack of essential public health services were root causes of the lead-poisoning epidemic (Nigeria has some of the highest mortality rates in the world for infants and child-bearing women). Consider how such vulnerability reduces the likelihood of populations protesting and demanding improvements to public services. By providing 'band-aid' solutions to public health problems, INGOs may make grassroots movements even less likely, thereby getting in the way of societal change. Given this consideration, what are situations where it would be ethically justifiable for an INGO not to intervene during a public health crisis (even with lives at stake)?

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Case discussion in response to WHOSE ROLE IS IT TO DEAL WITH SOCIETAL DETERMINANTS OF HEALTH?

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Prelude

Ethics case analyses can proceed in either of two possible ways: by using a principle-based approach[1] or casuistry.[2] I will use the principle-based approach, leaning on the bioethical principles of respect for autonomy, beneficence, non-maleficence and distributive justice.

Ethical analysis falls under the general area of applied ethics. Applied ethics is context-dependent in that local norms take precedence over universal norms. Especially for a case study developed in Canada, but derived from another country (in this case Nigeria), the reader must be sensitive to the concern about "ethical imperialism". That is, we must be cautious about critiques that impose Canadian norms on the Nigerian context. This case analysis brings such concern to the fore and it exposes the self-interested role of international agencies in providing help.

The generic problem-solving model for ethical decision-making comprises five steps:[3]

1 Gather all relevant information
2 Specify clearly all components of the identified ethical dilemma
3 Specify all options as possible courses of action
4 Select a single best alternative
5 Act and review

The framework provided by the case book steering committee to ensure a more standard approach in each of the case analyses in the casebook follows this model quite nicely.

Key public health issues

Grave harms can arise when a community has neither the infrastructure nor the sophisticated knowledge about the cautions needed before rushing forward to embrace an industrial activity made possible by access to machinery; in this case, grinding machines. Infrastructure needs could include artisanal mining approval processes and compliance monitoring to ensure that the activity should remain within both safety and health limits. It appears that inspections and penalties for operating outside of the law were neither implemented nor enforced, given that, over time, the illnesses occurred. The absence of law enforcement reveals how desperate people will resort to desperate means to make ends meet. And, because poverty drives people to extremes in order to survive, it will remain one of the great predictors of premature morbidity and mortality, exposing how law and reality need to be practical in order to better support community needs. The fact that a group of people was poor enough that its members broke the law in order to engage in artisanal gold mining warrants some attention as an upstream determinant of behaviours (i.e., the law) resulting in grave harms. Indeed, the collision between poverty and economic opportunity in an unregulated and unenforceable social environment is one that has, in this case, resulted in an epidemic of environmentally preventable toxic exposures.

The key relevant information (i.e., biologic, economic, social, political, or ethical) and knowledge gaps, as well as the basis for these facts

It is not clear who provided grinding machines for rock crushing purposes. Given that they were available to the local population, one could ask how it is that the government could not remove them, akin to the classic case of John Snow removing the Broad Street pump handle to control cholera in Britain in the 1850s. Not so acting could be construed as the launch of an industrial activity by virtue of access to machinery that would facilitate illegal work. The consequences of exposures ought to have been considered and should be the responsibility of the entity facilitating the industrial activity. Ways of protecting vulnerable people from hazards ought to be put into place prior to facilitating an activity.

The ethical principle of beneficence (i.e, the desire to introduce or provide access to an industrial activity that might uplift the community) seems to have resulted in widening disparities and grave harms as well, leaving poor subsistence farmers feeling pressure to improve their lot relative to the wealth to be made from the new industry. The principle of non-maleficence would appear to have been absent in the deliberations leading to the introduction of rock grinding machinery for the extraction of gold ore. Respect for autonomy would have required engagement with all stakeholders in allowing local people to determine for themselves what the future path might look like for their community. Finally, distributive justice would have required that the risks and benefits of the new industry would be equitably shared among all stakeholders, including the poor subsistence farmers. Questions about who was deriving benefit and who was taking the risks by the grinding machinery being made available to artisanal workers might provide some answers with a view to preventing such harms in the future. Is it possible that the artisanal workers would provide free labour in an uncontrolled workplace setting by extracting gold that they would then need to sell cheaply to local brokers who, in turn, would then be able to sell it at a substantial profit?

Identify the key stakeholders in the case and the most appropriate decision-maker(s) and/or legal authorities to approach the ethical issue, if applicable

The upstream source of exposure is the responsibility of those who provided access to the rock grinding machinery without providing adequate training and/or protection. Knowing how weak the public health infrastructure was in the region, the authorities ought to have mounted a campaign to strengthen it prior to permitting exposures to arise by virtue of not removing the machines or enforcing the law. Appropriate licensing bodies could have been provided through governmental agencies or, where these are not available, under the oversight of the "good corporate citizenship" of those supplying the machinery. Ultimately then, the capacity for enforcement and for ensuring the separation from harmful activities and exposures to dusts ought to have been sorted out ahead of time between the people providing the rock grinding machines and the government that made artisanal mining illegal. Bringing machinery into an uneducated and untrained population is surely either a thoughtless or a deliberate act of fomenting harms to serve only money-making interests.

Once international agencies realized that the environmental problem was confined to the region, they withdrew their concerns. Had the problem been one that could have spread internationally, their position would have been quite the opposite. Their mandates are, after all, to address health issues that could be internationally communicable. However, making appropriate referrals to international agencies (such as the World Health Organization or the Centers for Disease Control and Prevention in Atlanta, USA) could have been a line of first defense in seeking help on matters of environmental contamination. The fact that international organizations' interest waned when the epidemic was determined to be local, exposes constraints on the role of these organizations and places more pressure on INGOs to step in to help.

Identify the key values and concerns of the identified stakeholder(s), as well as any potential risks and benefits

The epidemic of illness and premature death likely warranted a state of emergency. The fact that the INGO was in the region and stepped forward to try to arrest the epidemic was to do good (i.e., beneficence). However, the harm that could come from such a spontaneous act was that local capacity would not be developed. To act or not to act and the consequences of taking either position have ethical implications. The decision to act unilaterally could be seen as one of paternalism.

Humanitarian assistance provided by INGOs must be balanced against the desire to see governments act to protect public health. By offering such assistance, INGOs, in practice, could be inadvertently complicit in perpetuating the absence of such core services in government. Thus, INGOs may serve to perpetuate a *laissez-faire* attitude of government to defer to international agencies when it ought instead to have at least some capacity to address local emergencies. Government agencies may be better motivated to engage through diplomatic and other means, such as signing conventions to protect human rights, than through the work of INGOs.

Key values are enshrined in international conventions signed by member countries. For instance, the preamble to the constitution of the World Health Organization speaks to the moral and legal duty that states have to protect the health of their citizens as the foundation of public health law.

Identify the options available to the decision-maker, including reasonable alternative courses of action, consideration of implications, and potential intended and unintended outcomes (consequences)

A reasonable course of action could have been the formalization of an agreement between the INGO and the government of the region for the INGO to intervene with its services, subject to investment being made in local capacity building. The assistance thus could have been a collaborative venture between the INGO and the local government. Indeed, a collaborative agreement could have required that local people should help and might learn from their techniques, thus building local capacity.

Suggest a resolution or decision to the case by choosing the supported option, and justify the decision

While each entity/stakeholder has a mandate, it is not necessary to consider solutions with only binary options (i.e., "all" or "nothing"). INGO mandates, for instance, might incorporate aspects of capacity building and education and also of influencing policy.

So, even before entering the region to help, some understanding should have been in place to hand control back to the local authorities/community, by then being adequately trained in the issues at hand. In this way, the government's role would be better defined for points of intervention to investigate, monitor, provide health services, train people and the like.

Whether or not the INGO receives payment for its services should not trump the need to train local people to assume positions to carry forward the work of the INGO once it has left. Setting up agreements in advance to define points for changing the level of action demanded at the time of the crisis by the various players and/or stakeholders could help in clarifying respective roles and responsibilities. Not only would local capacity and infrastructure remain beyond the crisis, but a tax base could be generated from the local economy to support community health in the region into the future.

Finally, if it were possible to determine who provided the grinding machines and who did not enforce the illegality of their use by untrained artisanal workers, this upstream information could be used to address what might well be a case of criminal neglect.

How might the decision and/or action be evaluated?

Net benefits of this course of action could be measured by economic activity and by assessing indicators of social health and well being. Declines in childhood morbidity and premature mortality would be a worthy goal. Infrastructure that supports health and safety and that could be expanded to include diseases other than those related specifically to occupational diseases would be an achievement. Education and training about health and safety would likely improve community health. A reduction in the earnings disparity between poor subsistence farmers and other stakeholders should be set as a short-term goal. Finally, if criminal acts were to be established, case law would then exist to prevent future such harms in the region/country by providing clear disincentives for such exploitation.

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