An Ethical Framework for Public Health Projects

A Discussion Paper

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Public Health Ontario
PARTNERS FOR HEALTH

Santé publique Ontario
PARTENAIRES POUR LA SANTÉ

Contents

Preface

Public Health Ontario (PHO) – the new operating name for the Ontario Agency for Health Protection and Promotion – is a Crown Agency with the mission "to enhance the protection and promotion of the health of Ontarians and to contribute to efforts to reduce health inequities" by providing "scientific and technical advice and support to those working across sectors to protect and improve the health of Ontarians" (OAHPP Act 2007). PHO is developing a set of services to support the ethical conduct of public health projects. The aim is that these services will be responsive to the challenges, needs and responsibilities associated with knowledge-generation for public health. These services will be available to PHO staff and the 36 Public Health Units across Ontario, but it is hoped that the model will be useful more broadly to anyone involved in public health projects.

To guide the ethics review process, a conceptual framework has been developed that takes a public health perspective. This framework has been developed by a working group of public health professionals and scholars, in consultation with a broad range of individuals in public health. This discussion paper describes the proposed framework. We invite comments from all stakeholders, including public health practitioners, investigators and scholars more broadly.

This discussion paper is meant for consultation purposes only.

http://www.oahpp.ca/resources/projects/srke/documents/Ethical%20Framework%20for%20Public%20Health%20Projects_Disucssion%20Paper%20%20June%2030.pdf

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Acknowledgements

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1 Introduction

The generation of knowledge through various types of projects, including surveillance, program evaluation, quality improvement and research is an essential component of public health. While these activities perform different functions, they all involve the collection of data about individuals and populations to inform public health policy and practice, and will be commonly referred to throughout this document as "projects". Although the ultimate purpose of these projects is to improve public health policy and the delivery of public health services, the activities may also pose risks to those involved. The application of ethical principles to the design and implementation of public health projects can play an important role in:

- protecting the rights and welfare of participants[i] and investigators[ii],[iii],
- preserving public trust in public health services providers, and
- supporting the ethical conduct of activities to improve public health.

While there have been significant developments in research ethics over the last two decades, the ethical principles traditionally employed to protect participants tend to focus on protecting individuals. These ethical principles do not always transfer readily to public health projects, which focus on communal good and collective goals, frequently target populations rather than individuals, and which often aim to prevent or reduce harm, rather than treat illness (Verweij & Dawson, 2009).

This paper describes an ethical framework designed particularly for public health projects. It adopts an explicit 'public health lens' which reflects collective interests, broader concerns for justice, and the common good. The purpose of this ethical framework is to provide guidance in the design and implementation of projects, to protect the rights and welfare of participants, members of the public and those conducting public health projects. It does not address broader ethical issues related to evaluation, such as the setting of research agendas at the macro level or issues related to professional integrity of public health practitioners. However, it is our intention that this framework will guide ethical reflection for public health projects throughout the lifecycle of a project, beginning with the initial development of an inquiry and carrying through to the exchange or application of knowledge generated. The goal is to develop a culture of ethical reflection among investigators, reviewers and decision makers, rather than a culture of compliance with an external ethics review body.

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[i] Participants may be individuals, communities or broader populations.

[ii] "Investigators" is used throughout this document to refer to persons conducting a broad range of public health studies.

[iii] The inclusion of investigators within this framework may be somewhat contentious, as protections for this group are covered under various occupational health provisions. We suggest that consideration of risk to evaluators is nevertheless appropriate in this ethics framework, as activities that pose unreasonable risks to evaluators cannot be considered ethical. The identification of risks to researchers in the course of ethics review is supported by the TCPS 2, Article 2.9 "While it is not a formal part of its responsibilities, an REB may raise concerns about the safety of student researchers as part of its communication to the student researchers, and to their supervisors. Based on the level of risk, the REB may consider referring these concerns for review by an appropriate body within the institution".

This framework is intended to be applied to projects involving people, their biological materials or their data, whether or not the data are identifiable. Out of scope are projects involving monitoring of non-personal data in public spaces – e.g. direct monitoring of air and water quality – unless data are being displayed at a particular level of geographic granularity such that there may be an adverse effect on individuals or communities. Routine public health practices such as delivery of programs, are currently beyond the scope of this framework, but may be considered in the future.[iv]

2 What is 'Public Health?'

'Public health' is a highly contested concept. Although widely used, there is no universally accepted definition of 'public health'. Several authors have commented on the range of definitions, and have discussed the challenges in developing a single definition (Coughlin, 1997; Rothstein, 2002; Verweij & Dawson, 2007). For the purposes of this paper, we define the practice of public health as interventions by a collective that aim to promote and protect the health of the public (Verweij & Dawson, 2007). Thus, in this paper, public health activity involves both a particular kind of end (the health of the public as a group or population) and a particular kind of action directed towards that end, carried out by individuals, groups or entities within governments or on behalf of governments.

Building upon this definition we can articulate a number of aims of public health policy and practice such as:

- Protection of citizens from threats to health
  - through, for example, vaccination programs, control of infectious diseases, and food inspection programs; or
  - by monitoring known threats to health and detection of novel threats, through surveillance programs for chronic and acute diseases
- Promotion of individual, societal and environmental factors likely to make a positive impact upon health
  - through programs to prevent chronic disease (e.g. tobacco control);
  - through injury prevention (e.g. through the introduction of bicycle helmet legislation); or
- Promotion of greater health equity
  - through identifying the barriers to achieving maximum health potential for individuals and populations; and
  - by aligning public health programs and services with those of other partners to address the societal influences on health (Ontario Ministry of Health and Long Term Care, 2008).

[iv] Although not included in the ethical framework described here, public health practices such as program delivery, also pose individual and/or collective risks and therefore could benefit from ethics review. Review of some types of routine public health practice is required in some jurisdictions. The Quebec Public Health Act, for example, requires that a "people's forum", created under section 343.1 of the Act, must be consulted before a regional public health plan is implemented. (R.S.Q., chapter S-2.2, Public Health Act.2001, c. 60, s. 15; 2005, c. 32, s. 308.)

These aims are most effectively achieved when public health practice is informed by evidence. 'Evidence-informed practice is responsive to the needs and emerging issues of the [public] health unit and uses the best available evidence to address them' (Ontario Ministry of Health and Long Term Care, 2008, p.15). Evidence to inform public health is generated through a number of activities, including: research, program evaluation, and surveillance.

Public health activities occur across a wide range of settings. They are embedded in the activities of the health care system, often crossing jurisdictional boundaries, such as hospital/community and primary/secondary care. They also cross geopolitical borders, and may involve non-health groups (e.g. school boards, social communities). Because of this, public health activities may fall into the portfolio of a number of government ministries (e.g. Health & Long-Term Care, Health Promotion and Sport, Community & Social Services, Municipal Affairs and Housing, Child and Youth Services, Environment and Aboriginal Affairs). This suggests that the ethical review of public health projects must ensure that the concerns of multiple stakeholders are addressed while avoiding excessive delay and bureaucracy.

3 An expanded scope of ethics review for public health projects

3.1 The need for an expanded scope of ethics reivew

A key innovation in the new model of ethics review described here is the expansion of ethics review to include knowledge-generating public health projects other than research. Currently, the common approach to determining which projects require ethics review is to classify a proposed activity as being either 'research' or 'non-research' and to require ethics board review only for those activities labeled 'research' (TCPS2, 2010). We find this approach problematic for two reasons.

1. First, despite the devotion of considerable attention to the matter, a definition that cleanly differentiates research from non-research remains elusive (Dawson & Yentis, 2007). The Tri-Council Policy Statement (TCPS 2) defines research as 'an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation'. Similarly, the US regulations define research as 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge' (DHHS, 45 CFR 46.102). However, in public health, both research and routine practice may involve systematic investigations to generate knowledge that may be generalizable beyond the target population, making the definition of research difficult to apply (CDC, 2010). Moreover, a project may begin as a quality improvement or program evaluation activity and, at some point evolve to include research elements. This evolution is often unpredictable at the start of the initial project, but additional non-routine data collection may be prompted by unanticipated findings.
2. The risks to individuals, communities, and institutions are similar for many public health projects, regardless of whether they fit any particular definition of research. If one uses a research/non-research distinction to determine whether or not a project requires ethics

review, those activities that are not categorized as research may be subject to limited or no ethical scrutiny. This creates an incentive to frame evaluative activities as non-research to avoid what may be seen as the burden of research ethics review. Moreover, those who wish to have ethics input may find no available forum if their project is deemed 'not research'.

3.2 The New Model

To address these concerns, we propose a new model for ethics review, to be applied to all public health projects, regardless of whether they are labelled research, surveillance, program evaluation, or quality improvement. The degree of scrutiny of these various projects should be proportionate to the degree of risk to individuals, communities, and those conducting the study.[v] Risk to the trust relationship between public health providers and the communities or populations that they serve will also be considered.

This approach addresses both of the concerns with the current approach described above:

a. It avoids the problem of trying to label an activity as research or non-research.
b. It ensures that all studies receive ethical assessment proportionate to the degree of risk. (See next section.)

The approach we are taking differs from the recently launched TCPS 2, which explicitly distinguishes research requiring research ethics board (REB) review versus non-research activities. For example, in the TCPS 2, quality assurance, quality improvement and program evaluation are not included in the definition of 'research' and thus do not REB review. The differences between the TCPS 2 requirements and our proposed model are illustrated in Figure one. Where there may be some convergence, however, is that the TCPS 2 states that activities that are non-research may still raise ethical issues 'that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB' (TCPS 2, 2010, p. 19).

[v] Screening tools will be developed to identify levels of risk and the corresponding level of ethical scrutiny. These will be modeled after the ARECCI Risk screening tools (ARECCI, 2005).

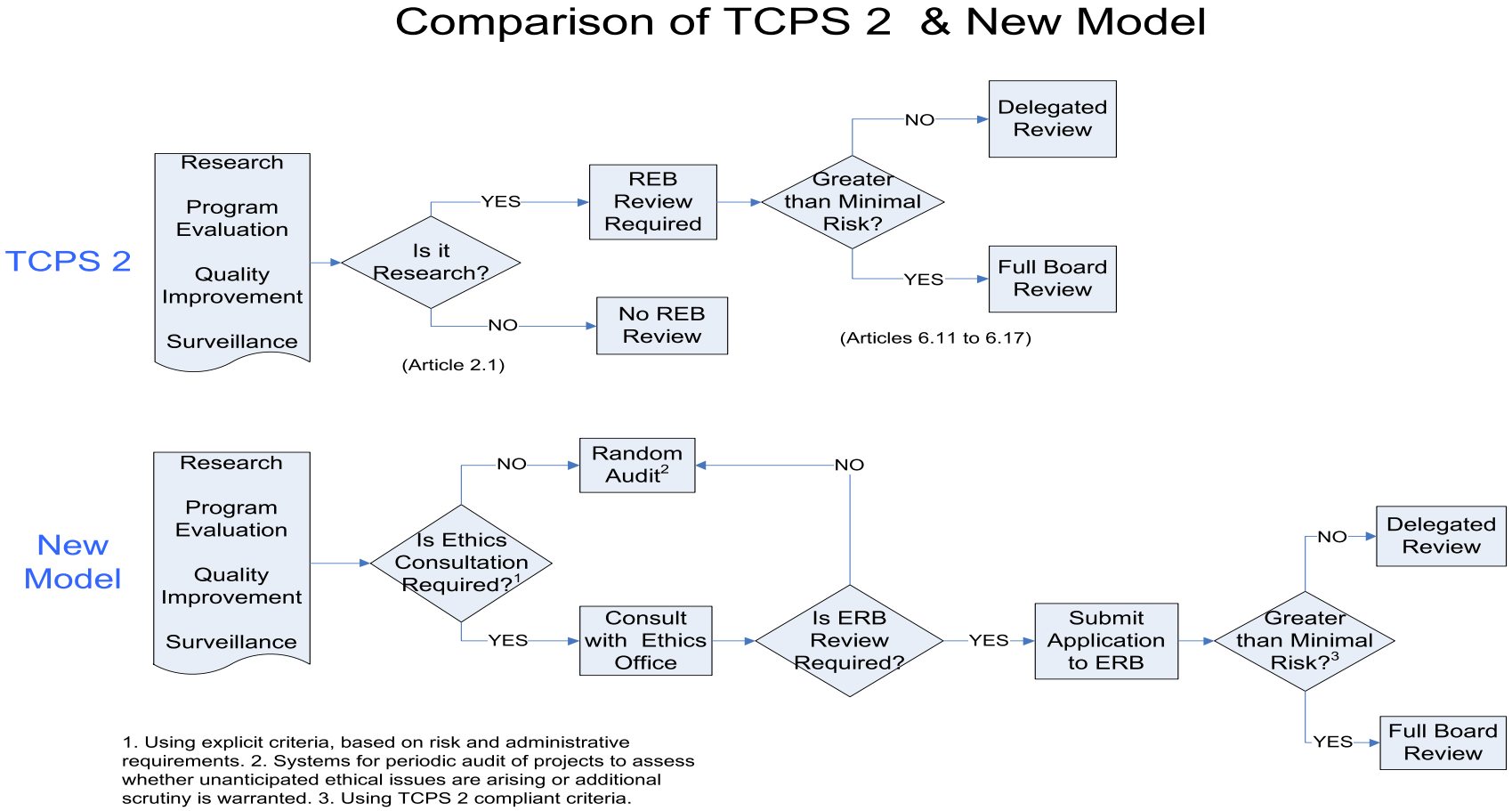

Fig. 1. This diagram compares the ethics review process described by the TCPS 2 with the review process proposed in this document for public health projects. Rather than sorting activities into research or not research, the new model sorts on risk at three levels: i) to determine whether a consult with the ethics office is required, ii) to determine whether review by an ethics review board (ERB) is required, and iii) to determine whether review should be delegated of full board. Projects that clearly require ERB review can go straight to the ERB submission stage where appropriate.

3.3 Proportionate Review

As noted in Figure one, determination of whether a study requires independent review by an ethics review board (ERB) and the degree of scrutiny, will be based on risk of harm, rather than whether or not it fits a particular definition of 'research'.[vi] Explicit criteria for determining whether a study requires ERB review will be developed, and will be customized for various types of projects. If ethics review is required, the need for delegated or full board review will be based on whether projects are assessed as posing minimal, or greater than minimal risk, respectively, as described in articles 2.9 and 6.12 of the TCPS 2. Minimal risk is defined by the TCPS 2 as 'probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research' (TCPS2, 2010, p. 23). Although minimal risk standards are a feature of many ethical guidelines and regulations, application to specific projects has proven challenging (Shah et al., 2004). A risk assessment instrument will be developed by PHO to assist with interpretation of the TCPS 2 minimal risk criteria in the context of public health projects.

4 Interpreting the Tri-Council Policy Statement, 2nd Edition through a Public Health Lens

At the foundation of TCPS 2 are three core principles—respect for persons, concern for welfare, and justice. These principles are sufficiently broad that they require interpretation to be used to inform decision making in a specific context. In this section we discuss how these principles might be interpreted in the context of public health. In particular, we consider how these core principles may be read in the context of community or population interests, including the relational interests of the individual as part of a community. We suggest that these interpretations are consistent with the TCPS 2 core principles.

4.1 Respect for Persons

According to the TCPS 2, 'Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.' (p. 8). Autonomy can be interpreted in many ways, but is generally seen as guaranteeing individuals the right to make decisions about their own lives. Protection for those with diminished autonomy may involve measures such as 'seeking consent from an authorized third party' (p.9) and special conditions for including vulnerable persons in research (TCPS2, 2010).

Respect for individual autonomy has often dominated discussions of ethical issues in many areas of health care. A public health lens emphasizes that while individual autonomy remains important in deliberations about ethical public health policy, it need not always take priority over other ethical principles (Childress, 1990; Dawson, 2010).

[vi] There will also be circumstances when external ethics review is required for administrative reasons (e.g. ethics review required by a funding agency).

Traditional research ethics interpretations of respect for persons include special protections for those with diminished autonomy in terms of capacity or those in a disadvantaged position within a power relationship (e.g. patient, student, employee, or prisoner). A public health lens also brings into focus other forms of disadvantage such as the impact of other social determinants that may impact autonomy. Poverty, for example, may reduce choice or the opportunity to express a preference. It may even affect the perception that an individual has choice. Consequently, persons with limited means may, for example, find it difficult to participate in community forums.

In addition, the interpretation of respect for persons in terms of respect for autonomy has led to an emphasis on individual interests. While the TCPS 2 notes the need, in some circumstances, to consider respect for communities, the discussion focuses on the case of research with Aboriginal peoples. A public health interpretation of respect for persons calls for a much broader application of this consideration of respect to all relevant affected communities or groups. Gostin (1991) has suggested that respect for communities requires investigators 'to observe choices made by local communities, and to avoid any activity which stigmatizes, demeans, harms or disintegrates human populations, intentionally or inadvertently' (Gostin, 1991, p. 192). Fulfilling this requirement, however, raises a number of challenges, including identifying communities and determining the appropriate level of engagement. These challenges are described below in Section 5, Question 7.

A public health interpretation recognizes the role of community engagement and communal decision making, where individual consent is not sufficient, feasible or appropriate. Individual consent is not feasible, for example, for participation in a study of water fluoridation, an intervention that is administered regionally rather than individually[vii].

An expanded interpretation of respect for persons may also include respect for relationships (Baylis, Kenny & Sherwin, 2008). Simply putting individuals or communities in the position of having to make a decision on behalf of the collective can have a profound impact on relationships. Relationships within a community may be damaged, for example, if members become polarized regarding whether to participate in a public health study. Similarly, perceived lack of respect on the part of investigators for individuals or communities when conducting a public health study may erode trust between individuals or communities, and those delivering public health services, such as local public health units. This loss of trust may create barriers to acceptance in the community and a loss of potential public health benefit that extends well beyond the boundaries of a specific study.

4.2 Concern for Welfare

The TCPS 2 states that welfare 'consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances.' Moreover, 'harm includes any negative effects on welfare, broadly construed' (TCPS 2, 2010, p. 9). To protect the welfare of human subjects, ethics boards and investigators are required to ensure that the risks and benefits of projects are favourably balanced, and that risks are minimized. Although the emphasis appears to be on individual welfare, the TCPS 2 does acknowledge that concern for welfare also applies to communities or groups, and notes that individual welfare may be affected by various factors including the welfare of 'those who are important to them' (TCPS 2, 2010, p. 9).

[vii] For a discussion of issues related to obtaining group consent where individual consent is not possible see Grill (2009).

A public health perspective is concerned with the welfare of groups and individuals, but interprets the welfare of individuals to be affected by the welfare of those in their environment more generally, rather than only 'those who are important to them'. In addition, a public health interpretation of concern for welfare recognizes that individual and collective welfare are often not clearly distinguishable, so that consideration is not simply about determining whether individual or collective interests get priority, but identifying the interactions or relationships between the welfare of individuals and their social environment.

Many public health threats risk the health of the whole population and not just that of individuals. The idea of a common good might be used to capture the idea that we *all* benefit from a society with strong public health facilities to address, for example, control and treatment of certain communicable diseases.

Public health is founded on recognition that there are certain common goods that ought to be promoted. Such common goods are often related to those conditions necessary for human flourishing, such as clean air, clean water, adequate nutrition and removal of radiation. Differences of opinion may exist, however, in what measures are appropriate to achieve such goods, or how best to define them. For example, in the minds of some communities, fluoridation of the water supply is not consistent with access to 'clean water'. Limitations on the sale of raw milk will interfere with some individual's perceptions of adequate nutrition. Therefore, if someone justifies a project on the basis of its promoting 'the common good', one must recognize that there may be a diversity of opinions regarding how that good is to be realized. Article 9.6 of the TCPS 2 notes that in engaging communities 'researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors—including individuals and subgroups who may not have a voice in formal leadership' and that 'special measures' may be needed to ensure inclusion of 'those who have been excluded… in the past' (TCPS 2, 2010, p116).

Recognition of the common good acknowledges the interdependence among members within and between various communities. One might appeal to solidarity to promote the common good. While there are many definitions, in essence, solidarity is primarily about standing together as a group, community or nation (Hayry, 2005). It is often appealed to in discussion about justifications for the welfare state or shared risks through insurance pooling, and in thinking about how states might defend the interests of vulnerable groups within their population.

4.3 Justice

The TCPS 2 summarizes the principle of justice as 'the obligation to treat people fairly and equitably' (Article 1.1). In the policy, fairness and equity are considered in terms of the distribution of the benefits and burdens of research, to individuals or in some cases, to communities. Justice also requires recognition of pre-existing vulnerabilities and power imbalances, and the need to ensure that, as a result, some individuals or groups are protected against (a) routinely being denied the benefits of research, or (b) overly burdened as participants. Inclusion of vulnerable groups as study participants requires justification in terms of direct benefit to those groups and scientific merit, and exclusion of groups requires justification in terms of risks and scientific merit (TCPS 2).

A public health interpretation recognizes the above obligations, but also recognizes a positive obligation to intervene where injustice or inequity exists (Kass, 2001). The reduction of health inequities is seen by many as one of the central roles of public health (Faden, 2010). A commitment

to reduce health inequity is recognized in both the OAHPP Act (2007) and the Ontario Public Health Standards (Ontario Ministry of Health and Long Term Care, 2008), which establish the requirements for 'fundamental public health services' to be offered by the province. Reduction of health inequities may at times require 'focussing on the needs of the most disadvantaged' (Gostin, 2006, p. 1053). Consequently, unequal shares of resources may be expended to compensate for existing inequalities. Groups may suffer from health inequities in relation to a wide variety of factors including income and social status, social support networks, education, employment, early childhood health, gender and culture.

Reduction of health inequity may be considered throughout the lifecycle of a project, from the choice of project objectives and outcome measures, to selection of participants and considerations regarding how to facilitate participation of disadvantaged groups, to the development of strategies to promote dissemination and uptake of knowledge among those most in need. The positive obligation to reduce inequity also requires that the risks associated with public health projects should be weighed against not only the potential benefits of the study, but also against the harm to a population of failing to conduct projects that may lead to the reduction of existing inequities.
A public health conceptualization of justice also emphasizes reciprocity – i.e. the idea of 'giving something back' for those who put themselves at risk for the benefit of others. It might include an obligation to minimize the risks to individual participants (by providing protective equipment) as well as positive interventions to compensate if any harm is caused. Compensation may include, for example, planning to make available to control groups interventions that are found to be beneficial in the course of the study after a study is completed.

5 Application of the Conceptual Framework

In the preceding section of this paper we interpreted the TCPS 2 core principles through a public health lens. In this section we propose a set of nine questions to help apply the core principles in the planning and review of public health projects[viii] . These questions apply to a broad range of scenarios, and must be further differentiated or specified before they can provide practical guidance for reviewing a specific project. A detailed set of sub-questions will be developed in a separate document, to further explain how the principles apply to particular types of public health projects.

[viii] These questions are informed by several earlier frameworks developed for clinical research (Emanuel, Wendler & Grady, 2000), and public health (Kass, 2001; ARECCI Network, 2008).

Guiding Questions

1) What are the objectives of the project? How are they linked to potential improvements in public health?
2) Is the proposed method appropriate to meet the above objectives?
3) Who are the expected beneficiaries of the knowledge gained or other benefits?
4) What are the potential burdens and risks associated with the proposed project?
5) Are risks justified in light of the potential benefits to participants and/or to society?
6) Is selection of participants fair and appropriate?
7) Is individual informed consent warranted? Is it feasible? Is it appropriate? Is it sufficient?
8) Is community engagement warranted? Is it feasible? What level of engagement is appropriate?
9) What are the social justice implications of this project?

1) What are the objectives of the project? How are they linked to potential improvements in public health?

An important requirement for any public health project is that the objectives are stated clearly and are explicitly linked to the promotion and protection of the health of the public. Projects may be found to have public health value whether the potential benefit is proximal or distal to the population or participants involved. For example, evaluation of a program designed to increase awareness of risk behaviours associated with sexually transmitted infections, may be used immediately to improve that same program, whereas research into biomarkers may be used to design better vaccinations at some point in the future.

There are no hard and fast criteria to determine whether an activity has public health value. At a minimum, however, a project plan should include a discussion of how any of the findings could inform public health. A surveillance proposal, for example, should include the potential usefulness of the data collected. What would not satisfy this requirement is collecting information only out of curiosity, without a clear and convincing argument for its collection.

2) Is the proposed method appropriate to meet the above objectives?

Poorly designed studies can, among other things, yield poor quality data and may result in invalid conclusions, which could reduce their usefulness or possibly create harm. Scientifically invalid projects fail to show concern for welfare because they waste limited resources, can put participants and others at risk while offering limited or no benefit, and delay knowledge generation, thereby depriving a population of potential benefit. Poorly designed projects also fail to respect persons, because participation in these projects is justified by the expected knowledge benefits.
Many methods are used to conduct public health projects, including:

- experimental and observational research designs,
- qualitative and quantitative approaches,

- empirical and modelling methods ,
- microbiological assays, and
- economic analyses.

Many public health projects are unable, ethically, to use experimental designs such as randomization, that are commonly associated with a higher degree of scientific rigour. Therefore, reviewer requirements for scientific validity must be realistic and take into account the design limitations that public health projects present. Where there is not the opportunity for a methodologically optimal study design, investigators need to articulate the methodological limitations, potential threats to scientific validity, and how they have attempted to address these threats to validity. Where such limits result from careful consideration of ethical issues, reviewers should not necessarily see this as inherently inferior. On the other hand, a project design that is compromised to the point that it presents significant threats to scientific validity should be considered unethical and should not be permitted to proceed as designed.

3) Who are the expected beneficiaries of the knowledge gained or other benefits?

Identification of who are the expected beneficiaries of public health projects has several purposes: i. to ensure that the study is focusing on a population consistent with the public health objectives of the project (Question 1); ii. to inform the consideration of whether risks and potential benefits are balanced (Question 5); and iii. to inform justice considerations (Questions 6 and 9).
Public health projects may have direct benefit to participants, and/or indirect benefit to non-participant members of the same or different populations. For example, testing of a novel anti-smoking campaign may benefit:

a) the target population directly,
b) non-participants through decreased exposure to passive smoking, and
c) society more generally through knowledge gained.

Expectations regarding who reasonably stands to benefit from a public health study must be clearly articulated.

Consideration of who is the beneficiary of a public health project is often framed as a conflict between the interests of a population and the interests of individuals. While such conflicts may at times exist, it is important to recognize the common good as well as the inter-relatedness of individual and community welfare. For example, benefits to a community may also benefit individual members of that community. Alternatively, benefits to individuals may also contribute to a common good. Privacy, for example, is often thought of as an individual interest, but can be seen as having a broader societal interest because (a) everyone values some degree of privacy; (b) it is essential to a democratic political system; and (c) in contemporary society it is hard for any one person to have privacy without all persons having a similar minimum level of privacy (Regan, 1995).

We are looking for an example from the field of a project where determining who were the beneficiaries was challenging, or where there was significant inter-connectedness between community and individual benefit.

4) What are the potential burdens and risks associated with the proposed project?

'Burdens' refer to various costs or inconveniences, such as demands on time, resulting from participation in a project. Burdens associated with participation should be articulated and minimized, unless they are clearly trivial. Unnecessarily burdening a participant is disrespectful, and may harm the goals of a project by discouraging participation or prompting early withdrawal. The term 'risk' is used here to refer to the possibility of a broad range of adverse occurrences (foreseen and unforeseen) related to involvement in public health projects. Harm is traditionally associated with the possible range of physical or psychological hazards that may arise in the context of a project.

While public health projects may be associated with physical or psychological hazards, the collection and use of information, which is the focus of many public health projects, can also cause harm to individuals or communities. These 'Informational harms' may include:

a) Harms to project participants

The collection or disclosure of information may lead to psychological distress, discrimination, or stigmatization of individuals or communities. For example:

- Surveys that ask about sensitive issues may cause participants psychological distress.
- Disclosure of study results may cause an individual or community to suffer psychological distress, damage to reputation, discrimination, stigmatization, or economic loss.
- Projects may also cause 'dignitary harm'[ix], by failing to show respect for persons (individuals or communities), even where no consequential harm or injury has occurred, such as through privacy breaches or use of information without consent. Because they are abstract, dignitary harms may be difficult to identify, and thus may be overlooked. Communities are particularly at risk of sustaining dignitary harm, as has been observed in several instances of research involving indigenous populations, such as the Havasupai (Rothstein, 2010) and the Yanomami (Borofsky, 2005).

[ix] There are different uses of the term 'harm' in the literature. Some use it to refer specifically to those things that impact negatively on the set of human interests. Others expand the category of harm to include other kinds of wrongs, including rights violations. The former position does not dismiss other kinds of wrongs as being morally unimportant but suggests it is incorrect to label them as harms. See Saver RS (2006) and Barbas (2010) for more discussion about this issue.

b) Harms to trust relationships

Public health projects that harm individuals or communities or cause dignitary harm as described above, may also lead to loss of trust in public health service providers, with negative consequences extending beyond the project in question.

It is important to not only identify but also *minimize* burdens and risks associated with public health projects where possible. This includes, for example:

- collection of only as much information necessary to achieve the study objective,
- collecting non-identifying information where possible,
- limiting the data fields, and
- employing appropriate security measures for the protection of privacy.

For each risk that is identified, an effort must be made to eliminate or mitigate it, balancing this against any loss in potential benefit associated with risk minimization. Appropriate planning is important to managing risks. For example, given the public health purpose of a particular project, it may not be possible to avoid asking sensitive questions, however it may be possible to reduce the risk by: i) including a mechanism for referral for counselling if needed, ii) anonymizing the data collected and iii) publication of findings in a manner that avoids stigmatization of communities.

5) Are risks justified in light of the potential benefits to participants and/or to society?

Once risks are managed either by eliminating or mitigating them, there remains a question as to whether the potential benefits of the project are sufficient to justify these risks. Although there is widespread agreement that the benefits must be proportionate to or outweigh the burdens and risks (Emanuel et al., 2000), as Kass notes 'disagreements are all but guaranteed over the details' (Kass, 2001). Disagreements may occur at several points, including: (a) in assessment of how burdensome or risky a project is, (b) how beneficial the project may be, and (c) whether the positive effects outweigh the negative. Although there is no formula to resolve these inevitable differences, it is generally accepted that significant burdens or risks can only be justified in the light of significant potential benefits (Kass, 2001).

Public health is built on a foundation of positive action to promote health, prevent harm, and to reduce health inequities. Recognition of these positive goals suggests that inaction, such as *not* evaluating a program or not conducting surveillance may be regarded as harmful, and so the burdens and risks of a project should be weighed against not only the added benefits, but the harm of doing nothing (Harris, 1985).

In some cases a public health project may offer important potential benefits to a particular group, but the risks are borne by another group, further complicating the weighing of risks and benefits. For example, studies are ongoing to assess whether aggressive early treatment of HIV-positive individuals, before the appearance of symptoms, can reduce the spread of the virus. Early results suggest reduced spread, benefitting the uninfected, but it is not clear whether such early treatment will be beneficial or harmful to those receiving the anti-viral treatment (US DHHS, 2011).

6) Is selection of participants fair and appropriate?

Concern for justice calls for a fair distribution of the possible risks and potential benefits among participants in a public health project. Participant selection should be guided first by the goals of the project, and not by convenience, or other factors not related to the study question (Emanuel et al., 2000). Appropriate selection should also be driven by prior evidence about risks and benefits to subgroups.

Within the potential pool of scientifically appropriate participants, consideration should also be given to minimization of risk and maximization of benefit. This may mean avoiding inclusion of vulnerable or deprived individuals or populations, if they are at greater risk of study-related harm relative to other potential participants. Similarly, if certain vulnerable or deprived individuals or populations are more likely to benefit from participation, they might be given priority for inclusion in a study (Emanuel et al., 2000).

It has been noted that evaluations of public health programs often explicitly select for communities or groups that are the most motivated, organized, and ready for change applied (Glasgow, Vogt & Boles, 1999). In addition to denying more deprived groups the possible benefits of participating, using these selection criteria may generate results that lack external validity as these highly motivated settings may not be representative of the majority of settings to which the results will be applied (Glasgow et al.).

Despite efforts to fairly distribute risks and benefits when selecting study participants, it may be the case that some individuals or communities will bear a disproportionate share of the risk for the benefit of a broader population of which they are a part. Reciprocity requires that we seek approaches to 'give back' to those communities after the study is completed. For example, it might be argued that participants testing early HIV treatment to reduce viral spread might be given continued coverage for the cost of their anti-viral medication beyond the formal study period.

7) Is individual informed consent warranted? Is it feasible? Is it appropriate? Is it sufficient?

Respect for persons means that, where appropriate, individuals (or their authorized representatives in case of incapacity[x]) are given the opportunity to make informed choices about participation in public health projects. The traditional default action in the context of formal research is to require individual consent from all participants, with exemption from this requirement if certain criteria are met:

- The research involves no more than minimal risk to the participants;
- the lack of the participant's consent is unlikely to adversely affect the welfare of the participant;
- it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required
- whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in

[x] For the remainder of this document, reference to "individual consent" includes consent by a legally authorized third party where appropriate.

accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and

- the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.
    - (Article 3.7, TCPS 2, 2010).

In making a judgment about practicability, the cost of obtaining consent and its impact on scientific validity must be taken into consideration. Further discussion of when it may be impracticable or inappropriate to obtain individual consent may be found in the CIHR *Best Practices for Protecting Privacy in Health Research* (2005).

While we agree that individual autonomy ought to be respected, framing the question in terms of whether consent is warranted gives weight to the notion that consent is not always called for, and may not be the most ethical approach. Within public health, data collection (e.g. for certain communicable diseases) may be mandated by law. Similarly, in the event of an emergency, the Chief Medical Officer of Health may request that necessary data be collected to manage the emergency. In these cases, consent is not warranted.

For some routine surveillance activities, informed consent for the indirect collection of information for public health studies is not required. On the other hand, for non-routine surveillance activities or when collecting information directly from individuals, consent may be required because the purpose of information collection has moved beyond the initial public health service purpose. In other cases, notification with the opportunity to opt-out may be warranted.

Informed consent may also be inappropriate when it creates additional privacy risk for participants. For example, requiring individual consent may create a privacy threat by requiring that "otherwise useable coded data" be linked with identifiers so that individuals can be contacted for their consent (CIHR, 2005). In some circumstances, it is the documentation of consent that creates a problem, such as when collecting data about illegal activities. In such cases other approaches, such as forgoing signatures and the use of code names to allow participants to remain anonymous, may be required (Lavery, Boyle, Dickens, Maclean & Singer, 2001; Roberts & Indermaur, 2003).

The Pronovost case demonstrates the harms of requiring consent without sufficiently considering that it might not be warranted. In July 2007, OHRP, the US federal office charged with regulation and oversight of human subjects research, suspended the implementation and evaluation of a new infection control checklist at 103 ICUs across Michigan. The suspension came after a publication describing the dramatic success of the checklist in reducing catheter-related infections. Contrary to the opinion of the Johns Hopkins Institutional Review Board, OHRP determined that individual consent from patients was required, despite the fact that the project involved institution-wide introduction of a checklist to improve adherence to infection control procedures with proven benefit and no increased risk to patients. In February 2008, OHRP lifted its order and permitted the project to resume (Miller & Emanuel, 2003; Beauchamp, 2011).

Where a departure from individual project-specific consent is proposed, alternatives include:

a) carrying out the study with no notification,
b) notification of the participants or community with no opportunity to opt out,
c) notification with opportunity for individuals to opt out, or
d) broad opting into a range of studies, possibly with restrictions.

Justification should be provided for the approach chosen.

Whatever the approach, plans must be described to promote a process (whether consent or notice) that is meaningful. Where individual consent is not practicable, investigators would be wise to consult with relevant representatives of the community or affected parties. Even where individual informed consent will be obtained, it may not be sufficient, and additional consultation with relevant communities may be warranted, as discussed below.

8) Is community engagement warranted? Is it feasible? What level of engagement is appropriate?

Community engagement may be used in lieu of, or in addition to individual consent, depending on the circumstances. Community can be defined as 'a collectivity with shared identity or interests, which has the capacity to act or express itself as a collective' (TCPS2, 2010, p. 107). There are a variety of frameworks describing the range of ways that communities can be engaged (e.g. Lasker & Weiss, 2003; Oliver et al., 2008; Vancouver Coastal Health, 2009) In general these range from notifying and informing, to greater involvement through consultation, consent or consensus, collaboration and empowerment.

Community 'consent or consensus' is used here to refer to some type of agreement to participate, given by a subset of individuals on behalf of a community. As Gostin notes, 'Clearly, community leaders cannot realistically give consent on behalf of the population, for they have no way of knowing what decision each person would make' (Gostin, 1991, p. 194). He suggests the term 'community consensus' is more appropriate.

Communities may be defined by many different factors including geography, biological or social relatedness, although in many instances identifying what constitutes a discrete community remains a challenge (Weijer, Goldsand & Emanuel, 1999; Weijer & Emanuel, 2000). Communities with an interest are those that 'may benefit from, be harmed by or otherwise affected by' a study (NIH, 2008). Community consultation and consent are used very broadly here to include the wide range of ways that a community may be involved in the decision making about a public health study, from notification to active engagement in the planning, implementation, analysis and publication of study results.

There is no simple answer to the question of when community engagement is warranted, or what the appropriate level of engagement is. Since communities vary in social cohesiveness, the challenge frequently is in identifying (a) when it may be appropriate to engage with local communities; (b) who are the appropriate representatives of the community; and (c) the appropriate level of engagement of the community (e.g. consultation vs. collaboration). In the interests of respect for persons and transparency, at a minimum, notification or informing should be considered wherever a community is identifiable that has an interest in a study.

Factors which may warrant great engagement with a community include:

- the nature and probability of harms to the community (i.e. all other things being equal, greater risks may increase the required level of engagement),
- any norms or traditions that should be respected,
- past experience of the community that may require specific attention, and
- the social structure of the community, such as whether it is well-defined with clear leaders or other governance structures (NIH, 2008).

Other factors, such as geographic localization, common economy/shared resources, a communication network and a health-related common culture may also facilitate, and therefore create an obligation to consider, community involvement in decision making (Weijer & Emanuel, 2000).

9) What are the social justice implications of this project?

Question 6 considers fairness and equity in terms of the benefits or burdens associated with public health projects. Social justice/equity pushes us to go further, however, and consider the positive obligation to intervene where injustice or inequity exist. Projects that reinforce existing inequities should be avoided and opportunities to promote social justice should be considered where possible. Populations may be disadvantaged socially, economically, in terms of access to public health services, or in terms of health outcomes.

Social justice should be considered at multiple stages in a public health project. For example, at the point of developing project objectives, one should consider how the expected knowledge generated might promote health equity and which outcomes are particularly relevant to disadvantaged or vulnerable groups. Community consultation may play an important role in helping develop relevant project objectives, although special efforts may be needed to ensure that the perspectives of the disadvantaged or disenfranchised groups or individuals are represented.

Similarly, plans for data collection should include mechanisms to ensure adequate representation of disadvantaged groups. Extra resources or special measures may need to be devoted, for example, to ensure inclusion of populations who don't routinely seek health or social services, and who therefore might be missed if recruitment or data collection strategies are linked to service providers. Providing it is scientifically appropriate, disadvantaged individuals or populations may be given priority for inclusion in a project, if such inclusion has the potential to improve their health status. This is justifiable in the context of an intervention that is known to have equal or greater effect among those who are disadvantaged, or projects where data collected (e.g. surveillance data) might be of immediate use to a disadvantaged population. Inclusion motivated by social justice would not be appropriate, however, for projects developed to evaluate the effectiveness of an unproven intervention. Prioritization of disadvantaged groups should also extend to the development of strategies for knowledge translation after a study is complete, to increase the potential for those with the greatest need to benefit from the knowledge generated.

We are looking for examples from the field of a knowledge-generating public health project that promoted or ignored social justice.

6 Conclusion

The purpose of this framework is to consider how a public health lens might be applied to the ethical examination of projects. It is not meant to be an exhaustive list of issues to consider, but to provide a starting point for ethical reflection.

The framework portrays a related web of responsibilities and relationships between the investigator and those whom he/she is studying. Not all of the above concerns will be relevant to every situation. Conflicts occur and one principle or concern may need to be promoted over another on a particular occasion. For example, in the context of an infectious disease outbreak, a temporary compromise in autonomy, such as collecting certain health data without individual consent, might be acceptable in light of a significant concern for welfare to participants and the broader community; such compromises might not be acceptable in the case of a similar study on a chronic disease, where the same urgency is lacking.

There are no simple rules regarding how to balance principles when they conflict with one another in a specific circumstance. No one principle has any predetermined value over any others, and judgment is required in making a decision about what ought to happen in response to individual circumstances.

> Ethical principles, like other practical principles, state abstract requirements…we cannot expect *any* practical principles—whether ethical or legal, social or technical—to provide a life algorithm…but the fact that principles always underdetermine action means only that they must always be complemented and implemented by the exercise of judgment (O'Neill, 2002, pp. 123-4).

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