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Beyond Research Ethics: Novel Approaches of 3 Major Public Health Institutions to Provide Ethics Input on Public Health Practice Activities

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Abstract

Public health institutions increasingly realize the importance of creating a culture in their organizations that values ethics. When developing strategies to strengthen ethics, institutions will have to take into account that while public health research projects typically undergo thorough ethics review, activities considered public health practice may not be subjected to similar oversight. This approach, based on a research-practice dichotomy, is increasingly being criticized

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as it does not adequately identify and manage ethically relevant risks to those affected by nonresearch activities. As a reaction, 3 major public health institutions (the World Health Organization, US Centers for Disease Control and Prevention, and Public Health Ontario) have implemented mechanisms for ethics review of public health practice activities. In this article, we describe and critically discuss the different modalities of the 3 approaches. We argue that although further evaluation is necessary to determine the effectiveness of the different approaches, public health institutions should strive to implement procedures to ensure that public health practice adheres to the highest ethical standards.

Keywords

ethics review; public health ethics; research-practice distinction

Public health institutions increasingly realize that creating a culture that values ethics in their organizations is important to ensure public trust and effectiveness of implemented policies and programs. This is reflected, for example, by the adoption of a revised set of accreditation standards by the Public Health Accreditation Board overseeing the accreditation process for health departments in the United States. The 2013 revised set of standards requires documentation of a health department's ability to identify, analyze, and resolve ethical issues.[1,2] When developing strategies to strengthen ethics, institutions will have to take into account the long-established differences in dealing with public health practice and research. Describing an activity as research or practice has considerable normative, procedural,and regulatory implications. Research activities are typically subject to regulatory oversight and external review by research ethics boards/committees in order to ensure that the research is conducted in accordance with ethical principles and regulations. This regulatory oversight is typically not applied to activities considered public health practice.

Increasingly, the ethical appropriateness of making determinations regarding review activities based on the research practice divide has been drawn into question. Many public health activities traditionally not considered research—such as public health surveillance or program evaluation activities—involve extensive data collection and employ some of the same methods as research projects. They also exhibit ethically relevant risks to participants. We consider these risks to include not only potential for incurring harm, but also instances of disrespecting other relevant normative principles, such as autonomy or justice. For example, privacy concerns have been raised about collecting and using data for public health surveillance without obtaining informed consent.[3,4] It has been recognized in academic debates that ethics review or consultations might be important to ensure accountability and adequate management of relevant risks for many nonresearch activities in public health.[5–11] The same has been noted for the clinical context.[12,13]

While the need for ethics review of practice activities is increasingly being recognized, best practices and modalities for conducting this review, especially in the context of public health, are in the early phases of development and have—to the best of our knowledge—not been subjected to a comprehensive critical review or evaluation. Some authors have warned that subjecting all public health practice activities to full review by ethics committees might

be unfeasible because of limited resources, competencies, or even becoming an unnecessary bureaucratic hurdle.[6,8,14] In the research context, ethics review has sometimes been shown to be a barrier, creating risks instead of averting them, by delaying or precluding important studies.[12,15,16]

Currently, only a few major public health institutions have developed and implemented mechanisms that offer ethics review/consultations for practice activities. The World Health Organization (WHO), the US Centers for Disease Control and Prevention (CDC), and Public Health Ontario (PHO) in Canada were among the first to implement initiatives of this kind. In the United States, additional examples at the local health department level include Clark County, Washington,[17] and Mahoning County, Ohio,[18] which have established public health ethics committees [PHECs]; and many more health departments are seeking guidance on establishing an ethics committee because of the revised health department accreditation standards. In Canada, the Comité d'éthique de santé publique was established in Québec[19] to provide ethics review and recommendations on new provincial plans for surveillance or health/social issues surveys, but there are probably more initiatives that the authors are not aware of. To advance the critical evaluation of the ethics review and consultation process for public health practice, we share information about the modalities and underlying rationale of the WHO, CDC, and PHO approaches. With this, we hope to enrich the discussions of possible strategies to ensure ethical conduct in public health practice activities and to identify promising ways to move forward.

The 3 Initiatives

WHO Public Health Ethics Consultation Service

Through the WHO Public Health Ethics Consultation Service (ECS), ethics advice is offered to WHO staff members who support public health activities that are not considered research and are, therefore, not required to undergo ethics review from the research ethics review committee. Staff dealing with ethically sensitive issues in their practice activities can request an ethics consultation with the ECS on a voluntary basis, regardless of whether interventions are in the development or implementation stages.

The Public Health Ethics Consultative Group was established in 2015 to address the growing need for advice and guidance on ethical issues that arise in WHO's nonresearch projects. The ECS was initiated to supplant the informal discussions with the WHO Global Health Ethics Unit that were sought by staff. The Consultative Group comprised WHO staff members from different departments and with diverse professional expertise, gender, and geographical representation. Training in public health ethics is periodically offered to all members. The WHO Global Health Ethics Unit serves as secretariat and coordinates the work of the group. Projects are discussed during in-person meetings with the staff member(s) responsible for the project. The secretariat invites members of the ECS to consultations according to their expertise and availability.

Ethics consultations are guided by a review template based on a comprehensive review of public health ethics frameworks.[20-30] The tool identifies normative *substantive criteria* that should be understood as *prima facie obligations* (action-guiding duties as long as they do not

conflict with further obligations) for public health practitioners. Questions relating to those obligations are formulated to guide the reviewer through the analysis, for example:

- What harms are perceived as potential consequences of the proposed activity?
- Is solidarity among members of the community undermined by the proposed activity?
- Is information about the proposed intervention adapted to the informational needs of the affected population?

Those reviewing the planned activity check whether those obligations are sufficiently addressed in the supplied protocol. Sometimes aspects of a planned activity that appear problematic can be easily changed to fulfill existing obligations. Sometimes they cannot because of particular barriers (eg, limited resources) or because certain benefits can only be realized to the detriment of other obligations (eg, health benefits realized only when accepting privacy breaches). For the later cases, the tool identifies *deliberative criteria* (eg, necessity, proportionality) to guide weighing and balancing of principles to make justifiable trade-offs and to give reasonable recommendations regarding project design or implementation. The template additionally identifies *procedural criteria* (eg, transparency, community participation) for the implementation of a planned activity. Although an intervention might be considered ethically adequate, moral controversy between project teams and communities might arise and it is important to ensure buy-in from communities. The procedural criteria ensure that attitudes and values of affected communities are adequately considered. They cannot be traded against substantive criteria.

The secretariat provides a written summary of the discussion during in-person meetings including non-binding recommendations to the technical team requesting advice. If needed, the secretariat can invite external experts to conduct further ethical analyses. The costs for the service to the organization are difficult to measure as it is provided by internal experts alongside their other tasks.

In 2015 and 2016, 10 projects were reviewed at the request of technical units. They were mostly concerned not only with surveillance and data collection but also with resource allocation, rationing, and patient safety issues. One ethical issue that has repeatedly come up in deliberations is whether setting up a surveillance system and corresponding database on sensitive issues could endanger the subjects in case of a leak and how this risk should be dealt with.

CDC’s Public Health Ethics Consultation Service

In 2005, the CDC established the Public Health Ethics Committee (PHEC) to provide leadership in public health ethics within the agency. The creation of the committee was influenced by the need for CDC to have a systematic process for addressing ethical issues that arise in the practice of public health. The importance of this was highlighted by the shortage of the 2004–2005 seasonal influenza vaccine that required public health officials to make decisions regarding who would receive the limited supply of the vaccine. Following this incident, the CDC created the committee that is composed of CDC staff who have been designated as public health ethics leads and their alternates from each of the agency’s

centers. However, any CDC staff member who has an interest in public health ethics is welcome to join. Leadership for the committee is provided by the public health ethics unit within the office of the associate director for science.

The PHEC provides a Public Health Ethics Consultation Service (ECS) to assist program leaders in addressing ethical concerns that arise in public health practice. A consult subcommittee made up of PHEC members assists with the consultation function. There are separate offices within CDC for the ethical review of public health research activities and for compliance with ethical standards and policies governing the behavior of CDC employees. Costs for the service have not been measured, but the public health ethics unit is staffed by 2 employees (a health scientist and an ethicist) who work full time on public health ethics issues. Other members of the committee participate in PHEC as an additional activity to their other work duties.

At CDC, public health ethics consults involve a systematic approach to clarifying issues, determining pertinent ethical principles and values, and identifying possible alternative courses of action. The process of an ethics consult can be categorized into 3 actions—to identify, analyze, and resolve. The “identification phase” is used to gather relevant information from program staff, to identify the stakeholders and consider their values, and to clarify the public health ethics question. The “analyze phase” is used to evaluate the collected information, to consider different ethical perspectives, and to critically weigh the various factors that have been discussed. This includes a discussion of the public health goals, the possible risks and harms, the historical context, and whether there are potential legal authorities or ethics frameworks that can provide guidance. The “resolution phase” is used to identify alternatives, to weigh options, and to develop recommendations. The consult subcommittee identified a series of questions for each of the phases to stimulate discussion. For example, during the “analyze phase,” relevant questions include the following:

- What ethical principles and theories are related to the issue (eg, duty-based concerns, professional obligations, utilitarian concerns for protecting the public)?
- What harms and benefits of the public health action have been identified? Have the burdens and benefits been distributed fairly?
- Does the public health action represent use of the least intrusive or restrictive means?

No formal training in ethics is required for CDC staff to join PHEC; however, monthly PHEC meetings are devoted to educating members about the process of ethical analysis and the application of this process to public health decision making, often using case studies. Case studies are a mechanism for illustrating the types of ethical concerns that may arise in the practice of public health and they provide opportunities to practice the ethical analysis process using realistic scenarios. For example, the CDC has developed cases on ethical considerations for allocating scarce medical counter measures, decision making regarding restricting use of electronic nicotine delivery systems in indoor public spaces, and obligations regarding notifying individuals who may have been exposed to unsafe health care practices, which include respecting patient autonomy, minimizing harm, and engaging relevant stakeholders. In addition, the public health ethics unit maintains Internet and

intranet Web-sites listing various public health ethics resources for ongoing training. The PHEC members are also encouraged to become familiar with the *Principles for the Ethical Practice of Public Health.*[30]

The CDC program staff can request a consult by contacting either their center's public health ethics lead or the public health ethics unit. The consult may proceed in a relatively informal manner that involves discussion of the issue between the requestor, the center's public health ethics lead, and public health ethics unit staff. No formal written request or approval of this type of consult is required. The product of this type of consult typically includes an e-mail to the requestor containing a summary of the discussion, including a list of nonbinding recommendations.

A second approach involves a more formal consult request procedure and the convening of the PHEC consult subcommittee. This formal approach requires the approval of the center's public health ethics lead and appropriate science leadership within the center. This more formal consult approach results in a written report detailing the background of the ethics question, actions taken by the PHEC consult subcommittee, a summary of the discussion of the issues, and the conclusions and nonbinding recommendations. One additional resource at the CDC for addressing ethical issues is the emergency operations center ethics desk. The ethics desk is staffed by the public health ethics unit and members of PHEC, and provides ethics input on issues that arise during emergency responses. Furthermore, public health ethics unit staff provide ethics input and consultation through a variety of other activities (eg, participation on CDC programmatic planning and policy work groups).

In 2015 and 2016, 22 consults were provided, all using the informal process. In addition, ethics input was provided by participation on 8 CDC work groups and through the CDC emergency operations center's ethics desk for 3 emergency responses (Ebola, Flint water crisis, and Zika).

PHO's Ethics Consultation and Review Model

Public Health Ontario provides scientific and technical advice and support to clients working in government, public health, health care, and related sectors across Ontario, Canada's largest province with approximately 14 million people. In 2013, PHO established an integrated system of ethics consultation and review for new evidence-generating initiatives, whether or not they meet a particular definition of "research." Ethics review is mandatory for new projects unless they meet the criteria for exemption as a result of being classified as routine business (eg, outbreak investigation). Ethics consultation is available upon request, whether or not formal ethics review is required. All projects involving PHO staff or resources are eligible for ethics consultation or review. Public Health Ontario adopted this expanded scope of mandatory ethics review to ensure appropriate protections for participants and others affected by evidence-generating public health initiatives not classified as research.

The ethics program is delivered by the equivalent of 2.7 ethics office staff. The coordinator and ethics officer work full time on the program, and a manager and ethics review board (ERB) chair contribute approximately 50% and 20%, respectively, of their time to the

program. Volunteer ERB members meet approximately 6 times per year, with travel costs covered for out-of-town members to attend the meetings.

The PHO model includes a range of options for ethics review, proportionate to project risk. The risk level of new evidence-generating initiatives is assessed using the PHO Risk Screening Tool.[31] The Risk Screening Tool generates a score of 0, 1, 2, or 3, corresponding, respectively, to no further review required, review by the research ethics officer (REO, a member of the ethics office staff) or an ERB member, delegated review by 1 or 2 PHO ERB members, or full board review at a convened meeting. Public Health Ontario has also developed a number of fast-track checklists (FTCs), which include conditions or parameters for several types of commonly conducted low-risk projects (eg, secondary data analysis using anonymized data). The FTC conditions describe limits on project details, which must be adhered to for the project to be acceptable without further ethics review (eg, data collected will contain no identifiers). Fast-track checklists are developed in consultation with project teams and reviewed and approved by the full ERB. Projects that meet all of the conditions specified in an FTC are considered approved and do not require further review.

Ethics review board composition is consistent with national guidelines for institutional research ethics boards.[32] Ethics review board members are selected to provide expertise across a broad range of disciplines, research methods, and public health roles—including community representation. Community members are not affiliated with the organization and have experience as a participant in public health studies or are members of a community that might be targeted for public health study or intervention. Ethics review board members are required to complete the nationally endorsed Tri-Council Policy Statement 2 online research ethics training module (http://pre.ethics.gc.ca/eng/education/tutorialdidacticiel/), become knowledgeable about PHO's ethics guidance documents,[11,26] and receive additional training at full board review meetings and special events (eg, retreats). Ethics consultation and review of minimal risk projects are provided by the REO, who has advanced training and experience in research ethics. As needed, the REO will seek input from the ERB chair or other ERB members.

All levels of ethics review and consultation are guided by PHO's ethics framework, which interprets the research ethics principles of respect for persons, welfare, and justice,[32] through a public health lens. The framework includes 10 questions to guide the ethical assessment of public health initiatives, for example:

- Are burdens and potential harms justified in light of the potential benefits to participants and/or to society?
- Is community engagement warranted? Is it feasible? What level of engagement is appropriate?
- What are the social justice implications of this initiative?

A form developed from the 10 questions is used for all levels of ethics review to help ensure consistency. Ethical concerns or need for additional information is communicated in writing to the project team members who are required to address the concerns prior to approval.

Project teams are encouraged to consult with the REO, ERB chair, and ethics office staff to discuss concerns and possible solutions.

Voluntary consultation at any point in the life cycle of a project is encouraged. Ethics consultation is also available upon request for activities that do not require ethics review. Consultations may occur through informal phone conversations or e-mail, or more formally at a face-to-face meeting, depending on the nature of the request. Ethics input from consultations is provided as a written recommendation to be used at the discretion of the requestor.

Eighty-one projects were reviewed in 2015 and 63 in 2016. Projects captured by our approach that would likely not be reviewed by a traditional research ethics committee include program and product evaluations, new surveillance activities, expanded data collection as a part of routine outbreak investigations, and projects for which the classification of research or "other" activity was unclear.

The risks identified with these projects are similar to those with public health research projects including potential stigmatization of participants or communities during recruitment or dissemination of results, consent form or process deficiencies, and lack of community consultation during study design to ensure minimization or mitigation of risks.

Discussion

Comparing the 3 approaches

The 3 approaches described previously differ with regard to various aspects (see Table 1). However, the main difference in the 3 approaches is the categorization of activities into "research" and "nonresearch" or "practice," with mandatory ethics review for the former and voluntary consultation for the latter (although at CDC additional voluntary consultations are available for research projects as well), versus a single mandatory process for all activities whether or not they are "research," with ethics review level determined by degree of risk. The WHO and the CDC have taken the first approach while PHO has introduced a uniform review process for all evidence-generating initiatives (although not for PHO programs and services like health promotion programs).There are advantages and disadvantages associated with both approaches. One advantage of the WHO and CDC approach is potentially higher staff acceptance of a system of voluntary consultation and, therefore, possibly less opposition to its introduction. Other advantages include ease of implementation as the approach can be added on as a new service without impacting existing processes and consistency with the current research ethics paradigm that differentiates research from practice activities.

A key challenge for approaches that treat practice and research activities differently is having to make the determination in which category a project belongs, a distinction that can be difficult to operationalize.[11,33] Research has been commonly defined on the basis of its primary purpose to develop generalizable knowledge.[34,35] However, a number of researchers have argued that this distinction is not practical because it may be difficult to articulate a primary purpose of an activity.[36,37] It is, furthermore, unclear what degree of

generalizability is required.[12] The example of implementation research—which describes enquiries into the process of translating evidence into practice—makes the difficulties with generalizability particularly visible: While its main purpose is to produce knowledge about the local context with limited generalizability, it is still generally considered research.[38] Those and further conceptual difficulties have resulted in considerable frustration and inconsistencies in identifying activities as practice or research.[33] Apart from these practical difficulties, a voluntary review process cannot solve the problem that practice activities may be associated with risks to participants and others but might simply not be reviewed with an ethics lens if the project team decides so. In addition, the mandatory "single system" approach may be more efficient at growing a culture of ethical integrity within an organization because it draws in even those staff who do not accept the need for ethics review and gives the ethics team the opportunity to demonstrate the value of bringing an ethics lens to activities.

To ensure ethics review of all activities that involve risks to participants, a mandatory approach based on risk instead of the research practice divide seems most appropriate. Such an approach, however, would necessitate a clear definition of risk and an independent mechanism for assessing it. Public Health Ontario has developed and successfully tested such a mechanism.[31] Furthermore, it might require significant capacity-building measures: first, staff need to be trained to review practice activities and sensitized to the specific ethical concerns arising in public health practice; second, the increase in number of projects having to undergo review might require additional staff. At PHO, overwhelming of the system has been avoided by providing a range of different review levels, use of a screening tool to assign projects to different levels based on risk, and introduction of a number of mechanisms to streamline review of low-risk activities. Another significant challenge to introducing a mandatory requirement for ethics review is gaining acceptance from those who deliver public health practice, for what can be seen as an interference or an obstacle to their work. Given the challenges of implementing a mandatory approach for high-risk projects, a voluntary system might be a good first step that would allow building acceptance of ethics reviews of practice activities and refining review processes.

Another interesting aspect is that all 3 institutions have developed tools to guide ethics review of practice activities. Those tools might help in sensitizing people to important issues and for possible differences between research and practice. Codes and frameworks developed for other contexts (eg, research ethics but also clinical ethics) often give imperfect guidance in public health practice contexts.[20,21] Members of review boards might not be aware of these differences, and tools can ensure that all relevant aspects are considered. The tools employed by the 3 institutions are question-based but they include different questions and are differently derived. However, they are all based on certain established normative principles that underlie the questions making up the frame-works. For example, in keeping with the scope of its global mission, when WHO developed its public health ethics consultation tool, it considered a wide range of ethical principles and frameworks and aimed to be as inclusive as possible (eg, the principle of solidarity is included even though this concept appeared in only a few, mainly European, frameworks). Public Health Ontario, on the contrary, has used nationally codified research ethics principles interpreted for the public health context as the basis for its tool.

Whether a certain principle is justifiably included in a particular tool can be debated and the justifiability of the inclusion decision might possibly depend on the specific context the tool is developed for. Furthermore, the principles and their corresponding questions do not provide full guidance but only a starting point for further deliberations. Those responsible for providing ethics input will still have to interpret normative concepts (eg, what constitutes a community in the given context) and weigh conflicting principles for the specific project and issue at hand (eg, whether the risk of stigmatization of a targeted health promotion program can be accepted in the face of considerable anticipated health gains). Although the users of the tools employed in our organizations have found them helpful, evaluations of the tools will have to show whether the guidance provided is sufficient. Further normative scholarship might also be necessary to identify possible gaps in tools employed.

There are further differences between the approaches that warrant reflection. Public Health Ontario is the only organization that requires community representation on the review group. While consideration of stakeholder interests is also an important part of WHO's and CDC's ethical analysis processes, mainly for pragmatic reasons their ethics committees or groups are staffed with internal experts. While the importance of community representation on ethics committees has been emphasized by organizations such as the US National Association of County & City Health Officials,[39] the manner of community participation deserves further critical thought. One issue that remains unresolved is the issue of who should represent the community. Given the numerous variables that may form the basis of a community in relation to a public health activity, such as ethnicity, geography, use of a common service, or other type of social relatedness, as well as the heterogeneity of values and perspectives that are usually present within a community, there will always be a limitation to the degree to which one or a few individuals will be able to be "community representatives." A similar challenge is faced by research ethics committees.[40,41] To address this limitation, the PHO ERB, for example, also includes members from several public health units across the province, who bring understanding of the local context for the populations they serve. In addition, where there is concern that a project may pose particular risks to specific communities, additional engagement with the affected communities is undertaken, either by the project team or occasionally by inviting the input of an ad hoc community member.

Irrespective of which approach is chosen and which tools are employed, obtaining buy-in from staff is—in our experience—critical for successful implementation of a new ethics program. All 3 organizations have used a mix of the following approaches to ensure staff acceptance: ongoing endorsement from senior leaders within the organization; extensive staff sensitization on the opportunity for and advantages of ethics services; raising organizational awareness about key issues; provision of a range of options to permit a truly proportionate review process rather than a "one-size-fits-all" approach; involving the users in development of services; and adapting and improving services in response to user feedback. Furthermore, it will be important to regularly reflect on and improve existing processes to ensure ethics review does not become a mere bureaucratic checklist.

Finally, the organizations whose ethics procedures have been discussed in the preceding paragraphs are acting on a provincial, national, or even international level. While their

approaches can provide orientation to local health departments, these institutions might lack the necessary resources to implement formal ethics review services of their own. However, that does not mean that there are no possibilities for improvement; a core element for any approach is to increase the sensitivity of public health practitioners to ethical issues that may arise in their work. Smaller organizations can support this by promoting user-friendly ethics educational materials within the organization or by introducing ethical considerations into existing operational review or approval processes. The CDC has also been working closely with National Association of County & City Health Officials to develop tools and resources for use by local health officials. This has included the development of public health ethics training materials[42] and guidance on how to establish PHECs.[39] The CDC also funded National Association of County & City Health Officials to conduct a pilot program with a local health department to assist in their development of an ethics committee.

Future evaluations of ethics processes needed

In this time of limited resources, it is important to document the impact of public health decisions and activities. The need to measure impact extends to ethics services, as has been shown by increased interest in evaluation of ethics consultations in the clinical context.[43] With this in mind, each of the 3 institutions has begun considering how to best evaluate its ethics consultation/review processes. The CDC's efforts in this regard have included the development of a logic model to describe the desired components of an ethics activity at the local health department level, the inputs needed to support this activity, and the desired short-term, intermediate, and long-term outcomes (see Table 2). Working with a group of external advisers, the CDC also identified key substantive ethical dimensions and key attributes of a successful ethical process that might serve as quality indicators for ethics consultations (see Table 3). The next step is to identify potential indicators/measures and possible data sources for each identified outcome so that comparisons over time and across institutions can be done. It may be necessary to begin with assessing process measures, such as data on the number of staff receiving training about public health ethics or the number of requests for an ethics consult. Therefore, it will be important to establish processes for documenting the number, topic, and outcome of each consult (including perceptions about the usefulness, timeliness of the consult process, and satisfaction with the outcome). This can be particularly challenging when less formal consult procedures are used (eg, informal discussions).

Public Health Ontario completed a formative evaluation of its ethics review process after 1 year of implementation, using a mixed-methods approach. Process measures included number and type of review according to the risk level of projects. A variety of short-term outcomes were assessed, including researcher and ERB member satisfaction with the review process, adequacy of educational materials, and ethics staff observations regarding service delivery. This early feedback was used to modify forms and instructions to enhance clarity and to streamline administrative processes.

An evaluation of WHO's ECS is planned after 2 years of its establishment. Currently, WHO is designing evaluative procedures fitting its specific organizational structure and mission.

More creative process and outcome measures will be needed to document the long-term impact of an ethics activity on building public trust and ultimately improving health outcomes. Hopefully, as more health departments establish ethics infrastructure, it will be possible to design empirical studies investigating the impact of public health ethics activities and compare results across institutions. In any case, public health institutions should develop and implement evaluation capacities alongside ethics measures to allow such studies.

Conclusion

There can be no doubt that public health has an obligation to conduct both research and practice activities that respect and promote the highest ethical standards. This includes identifying high-risk projects and ensuring that risks are adequately managed. There is a long history of ethics review and oversight of public health *research* activities. This is the first article to describe and compare approaches to ethics review of public health *practice* activities. We encourage other public health organizations to consider establishing ethics processes for public health practice, building upon the models presented in this article.

The approaches taken by the CDC, the PHO, and the WHO each have their advantages and disadvantages. To assess the relative value each approach brings to protecting the ethical integrity of all public health activities, additional work is needed to evaluate the impact of these approaches. The development of robust evaluation tools will be essential to further demonstrate the value of public health ethics consultation and review processes (for practice as well as research activities), to increase transparency, and to allow learning from each other.

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Implications for Policy & Practice

- While research and practice activities in public health can both entail ethically relevant risks, traditionally, only research projects are subjected to thorough ethical oversight. Public health institutions should accordingly consider implementing processes for providing ethics input on practice activities ensuring that ethical risks are adequately managed.
- A mandatory approach to ethics review for practice activities will be most effective in preventing ethically relevant risks from materializing. However, public health organizations considering implementation of a review mechanism will also have to ensure their fit to the specific context and goals of the organization.
- The effects of ethics review mechanisms on service provision have so far not been studied. Public health organizations should consider implementing evaluations to allow learning about and improvement of existing mechanisms.
- A core element for any approach is to increase the sensitivity of public health practitioners to ethical issues that may arise in their work. Smaller organizations that lack resources to create a formal consultation or review process can support this in their organization by promoting user-friendly ethics educational materials or by introducing ethical considerations into existing operational review or approval processes.

TABLE 1

Comparison of Different Approaches

	WHO Ethics Consultation Service	CDC's Public Health Ethics Consultation Service		PHO's Ethics Review Model			
Who is eligible for consultation?	WHO staff supporting public health projects that do not require research ethics review (separate mechanism exists)	CDC program leadership can request consultation		PHO staff involved in nonroutine evidence-generating initiatives are eligible for consultation and review Health Units across Ontario are eligible for consultation			
Voluntary or mandatory?	Voluntary	Voluntary		Mandatory—an (additional) voluntary consultation can be requested			
Tools employed?	Tool for ethical analysis identifying key ethical questions based on a review of published public health ethics frameworks	Procedural heuristic that divides the consultation in 3 phases: identification, analysis, and resolution phase		Risk Screening Tool and fast-track checklists (FTCs) that determine level of risk and extent of review; 10-question review framework based on research ethics principles applied to the public health context			
Different types of consultation?	In-person meeting with requestor and at least 3 members of the Consultative Group; further input from external experts can be requested	Informal discussion for time-sensitive and noncomplex issues	Formal consult with subcommittee of Public Health Ethics Committee for other issues	No review for projects with no risks identified or if conforming to FTCs	Review by ethics officer or ethics review board member	Delegated ethics board review (by 1–2 members)	Full ethics board review
Who provides consultations?	The Consultative Group consists of WHO staff representing different disciplines, gender, geography, and experience with WHO regions	Public Health Ethics Unit staff and center ethics lead	Consult subcommittee of the Public Health Ethics Committee		Research ethics officer	PHO ethics review board compris ing experts representing a broad range of disciplines, roles, and research methods	
Specific training of reviewers?	No specific previous training required, training in public health ethics continuously offered	Public health ethics unit staff has advanced training in ethics	No specific previous training required to serve on the public health ethics committee; however, monthly committee meetings are devoted to discussion of cases and ethics topics and thus serve as ongoing training		Advanced training and experience in research ethics	Online research ethics training module to be taken before serv ing on ethics board; additional training offered regularly	

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	WHO Ethics Consultation Service	CDC's Public Health Ethics Consultation Service	PHO's Ethics Review Model
How is ethics input to be used?	At the discretion of requesting staff	At the discretion of requesting staff	Project teams have to address ethical concerns otherwise projects will not be approved (exception: recommendations from consultations are nonbinding)

Abbreviations: CDC, Centers for Disease Control and Prevention; FTCs, fast-track checklists; PHO, Public Health Ontario; WHO, World Health Organization.

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TABLE 2

Public Health Ethics Activity Logic Model

Inputs	Activities	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Health department leadership and staff Key stakeholders Community organizations Professional associations Academic institutions Ethics codes and other public health ethics resources Financial resources Equipment	Health department leadership establishes and supports a public health ethics infrastructure mechanism Establish a framework for conducting ethical deliberations Provide public health ethics training to staff Disseminate public health ethics information Conduct internal public health ethics reviews and consults that provide recommendations[a] Identify and engage key stakeholders to provide input on public health ethics issues	Increase in staff • Awareness and knowledge about what constitutes an ethics issue • Systematic thinking about ethics and ethical choices • Ability to analyze and resolve ethical issues • Awareness and utilization of resources that assist with ethics issues Increased engagement with key stakeholders in public health ethics decision making Increased use of public health ethics infrastructure to inform decision making	Staff and programs employ ethics guidance and consult services Staff apply ethical principles in their daily work Staff and programs make ethical decisions Leadership and staff have ethics-based justification for difficult and controversial decisions Public health decision-making process is ethical and perceived as ethical within health department	General public perceives public health decision-making process as ethical Public health decisions are more positively perceived by the public and stakeholders leading to increased health department credibility and public trust Public health policies and programs are better/more sound • responsive • targeted • meet needs Improved public health and health outcomes/reduced adverse outcomes
Contextual factors that may impact public health ethics activities at all levels in the logic model: Leadership support; economic, environmental, and political climate; and community and social factors.				

[a]Consistent with key substantive ethical dimensions and attributes of an ethical process (see Table 3)

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Table 3

Key Substantive Ethical Dimensions and Attributes of an Ethical Process

Key substantive ethical dimensions
• Weighing benefits vs harms, costs, and risks of a decision
• Considering rights, values, interests, and needs of individuals and particular communities vs obligation to protect the general public good
• Using least restrictive measures necessary to protect the common good
• Ensuring fair distribution of public health benefits/burden
• Addressing health equity/protection of vulnerable populations
• Working toward social justice
Key attributes of an ethical process
• Is open, honest, and transparent
• Makes explicit the facts, values, principles, and assumptions used
• Prioritizes values according to a fair, inclusive process; judicious weighing of competing values and goods
• Allows for fair hearing of the interests, values, and perspectives of all
• Consistently applies standards across people and time (treating like cases alike)
• Appropriately engages stakeholders in decision making
• Involves affected, informed, experienced, and neutral individuals and representatives of communities
• Provides information to affected stakeholders in a timely manner and in culturally and linguistically appropriate ways
• Uses best available scientific evidence
• Monitors and evaluates the process to allow for updating, revision, or correction of procedures in the light of new information, questions, criticisms, etc