Chapter 9
Public Health Research

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9.1 Introduction

Having a scientific basis for the practice of public health is critical. Research leads to insight and innovations that solve health problems and is therefore central to public health worldwide. For example, in the United States research is one of the ten essential public health services (Public Health Functions Steering Committee 1994). The *Principles of the Ethical Practice of Public Health*, developed by the Public Health Leadership Society (2002), emphasizes the value of having a scientific basis

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for action. Principle five specifically calls on public health to seek the information needed to carry out effective policies and programs that protect and promote health.

This chapter presents ethical issues that can arise when conducting public health research. Although the literature about research ethics is complex and rich, it has at least two important limitations when applied to public health research. The first is that much of research ethics has focused on clinical or biomedical research in which the primary interaction is between individuals (i.e., patient-physician or research participant-researcher). Since bioethics tends to focus on the individual, the field of research ethics often neglects broader issues pertaining to communities and populations, including ethical issues raised by some public health research methods (e.g., the use of cluster randomized trials to measure population, not just individual, effects). However, if our discussion of public health research ethics begins by examining public health activities, it becomes apparent that the process of gaining consent involves more than individuals. We must consider that communities bear risks and reap benefits; that not only individuals but also populations may be vulnerable; and that the social, political, and economic context in which research takes place poses ethical challenges. Public health research, with its focus on intervention at community and population levels, has brought these broader ethical considerations to researchers' attention, demonstrating how ethics guidance based on biomedical research may limit, if not distort, the ethical perspective required to protect human subjects.

The second limitation has to do with how guidelines and regulations are conceived and used. As described in Chaps. 1 and 2 of this casebook, research ethics has mostly evolved out of concern for research abuses. Consequently, the intent of many guidelines and regulations is to strengthen the ethical practice of research with human subjects. These ethical guidance documents include the *Nuremberg Code* (1947); the *Universal Declaration of Human Rights* (United Nations 1948); the *Declaration of Helsinki* (World Medical Association 1964, last revised in 2013); and two documents developed by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO): *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 2002) and the *International Ethical Guidelines for Epidemiological Studies* (CIOMS 2009). In the United States, the primary ethical guidance for protecting human subjects is Title 45, Part 46, of the Code of Federal Regulations (U.S. Department of Health and Human Services 2009). The ethical principles of respect for persons, beneficence, and justice have often framed the discussion on ethical conduct of research with human subjects. These principles were first articulated by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) in the *Belmont Report* and expanded upon by Beauchamp and Childress (1979) in *Principles of Biomedical Ethics*.

Such guidelines and regulations often represent a consensus on landmark issues and show ways to consider ethical issues. However, consensus documents can pose obstacles if used uncritically with overgeneralized rules applied blindly. For example, such documents seem to assume that the randomized controlled trial is the gold standard of research methodology, obscuring the fact that all research methods may raise ethical issues. In addition, it is debatable whether these guidelines adequately capture community- and population-oriented values and issues central to public health (Verweij and Dawson 2009). A general concern is that overreliance on guidance documents encour-

ages a legalistic or compliance approach to ethics, rather than encouraging reflection and analysis (Coughlin et al. 2012). Coughlin and colleagues argue that to be successful, research oversight needs to focus on moral judgment and reflection, not on strict rule-like adherence to regulations documented on a checklist. Though formal training in ethics is desirable, moral judgment and discernment are developed by making ethical judgments. This highlights a problem inherent in research oversight. Review of research protocols requires scientific and ethical expertise. However, members of ethics review committees are often unpaid and uncompensated for service time and are frequently asked to perform review duties in addition to their normal work. This lack of regard for their service often results in considerable turnover among committee members and does not allow sufficient time for new members to develop moral discernment. Review of research protocols for human subjects should include consideration of the wider ethical implications of the research and not just focus on compliance with ethics regulations. When inappropriate, guidance should be adapted or even set aside.

Chapter 1 of this casebook provides an account of public health ethics that builds upon the disciplines of both ethics and public health. Following a similar approach, this chapter advances a view of public health research ethics that builds upon concepts of research ethics and public health research. As a result, many ethical issues discussed apply to all health research, including public health research. However, once we examine public health examples, we see that something beyond the traditional resources of current research regulations is needed. We will discuss these ethical issues by reflecting upon traditional research tenets and studying their limitations in a public health context. We will conclude by illustrating via the case studies included in this chapter how ethical challenges arise in public health research. It is impossible to closely analyze all possible ethical issues that may arise either in health research or public health research; thus our intent is to highlight some of the major ethical challenges and considerations.

9.2 What Is Different About Public Health Research?

The community and population perspective of public health, especially when addressing health issues in resource-poor contexts or in marginalized populations, frequently brings ethical challenges into focus. In public health, research typically occurs outside of the controlled environment that is characteristic of biomedical research. Instead, in public health, research often occurs in real world settings in a particular social, political, and economic context. It may involve interventions with whole communities or populations impacted by catastrophic public health emergencies.

9.2.1 Can Public Health Research Be Clearly Distinguished from Public Health Practice?

Distinguishing between public health *practice* and public health *research* is challenging. Many of the tools and methods are similar. Both involve systematic collection and analysis of data that may lead to generalizable knowledge. Public health

research can take forms ranging from descriptive approaches (e.g., correlational studies and cross-sectional surveys) to analytic epidemiologic approaches (e.g., case control studies and cohort studies, including clinical trials). These same approaches can characterize methods for collecting information as part of public health practice.

A common way to define research is on the basis of its goal to develop generalizable knowledge. For example, the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 2002) defines research as "… a class of activity designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference." Similarly, in the United States, research is defined as "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (U.S. Department of Health and Human Services 2009).

In jurisdictions with legal requirements governing research activities, such as the United States, determining what is and is not research becomes critical. Sometimes, however, the line between research and practice-related activities is blurry. One way to identify if an activity is research is to look at intent. The primary intent of public health research is to yield generalizable knowledge. Key characteristics of public health research include (1) benefits beyond the needs of the study participants, (2) collection of data exceeding what is needed to care for study participants, and (3) generation of knowledge with relevance outside the population from which data were collected. In contrast, the primary intent of activities that constitute public health practice are to "… prevent or control disease or injury and improve health, or to improve a public health program or service …" (Centers for Disease Control and Prevention [CDC] 1999, 2010). Key characteristics of public health practice include (1) benefits that focus on activity participants, (2) collection of data needed to improve the activity or the health of the participants, and (3) generation of knowledge that does not go beyond the scope of the activity (CDC 1999, 2010).

Some researchers suggest that the difficulty in distinguishing public health research from public health practice emerges from a deeper conceptual issue relating to the impossibility of satisfactorily defining "research" and related categories (Fairchild and Bayer 2004). For example, public health surveillance might involve identical interventions and risks for public health research as for practice. This has led many public health professionals to call for reorienting ethical review around an activity's level of risk, which applies to activities in both public health research and practice (Willison et al. 2014). Jurisdictions that do not yet have legal structures or have more flexibility to govern research activities than the United States might have an advantage. Whereas other jurisdictions might need to modify their approach to correlate ethical review with risk instead of on whether something falls under a slippery concept such as research.

9.3 Ethical Considerations for Protecting the Public during Health Research

This section outlines core aspects of research ethics and not only explains their relevance to public health, but also delves into why research ethics principles might need to be applied differently to public health research than to biomedical research.

9.3.1 Informed Consent

Informed consent is often treated as the primary means of protecting research participants. Although informed consent can be defined in different ways, it is foremost an active agreement made by someone with the capacity to understand, on the basis of relevant information, and in the absence of pressure or coercion. The common ethical justification for seeking informed consent is an appeal to the notion of autonomy, which holds that individuals have values and preferences and thus should voluntarily decide whether to participate in research. However, gaining consent can result from a more direct appeal to beneficence or to general welfare. Many research ethics guidelines and regulations require an interactive process between the investigator and research participant to best provide information and ensure comprehension.

Some potential research participants will always lack capacity to look after their own interests (e.g., children, people with dementia, the unconscious) and thus cannot provide consent. To protect people with diminished autonomy, informed consent is usually obtained from a parent, guardian, or legal representative. While it is clear that research participants with diminished capacity need extra protection, empirical evidence shows that even research participants with full cognitive capacity may not understand information presented as part of the consent process (Dawson 2009). For this reason, informed consent cannot be the only mechanism for protecting research participants. For instance, a research ethics committee can protect participants by assessing risks and benefits. Requiring approval by a research ethics committee might be considered a paternalistic judgment, but not an obviously wrong one (Garrard and Dawson 2005; Miller and Wertheimer 2007). Research ethics committees routinely consider waiving informed consent. This is true in public health research where the risk can be less than in biomedical research. Reliance on the judgments of research ethics committees presupposes that members have a high level of professional trustworthiness and have the skills for ethical deliberation and analysis.

Cultural or social influences can challenge the ideal model of informed consent when conducting public health research. Marshall (2007) provides an excellent overview of challenges with obtaining informed consent, especially in resource-poor settings. These challenges include cultural and social factors that affect comprehension, communication of risks, and decisional authority for consent to do research. Language barriers and low literacy, mistaken beliefs about the benefits of

participation, especially when access to health care is limited, and the need to communicate complex scientific information may reduce comprehension of study procedures, benefits, and risks. Marshall (2007) emphasizes the importance of engaging community leaders and soliciting and considering the opinions of community residents when identifying project goals and procedures and establishing consent processes. She notes that in many communities, relying solely on individual consent may not be culturally appropriate. In these situations, adding family or community consent is fitting.

Some research cannot be conducted if the standards of autonomous informed consent are always applied. A good example is emergency research when unconscious victims of head trauma may be randomized to different promising treatments, but the relative effectiveness of each treatment option is unknown. Some countries allow such research via waivers of informed consent if relevant conditions are met (e.g., minimal risk, and the research could not otherwise be carried out) (U.S. Department of Health and Human Services 2009). A public health research method for which it sometimes may be appropriate not to seek informed consent is the cluster randomized trial. By design, a cluster randomized trial compares interventions that target a group (i.e., social entity such as village or town, or a population). Various characteristics of these clusters are matched to ensure a robust comparison of interventions (including no intervention). In some cluster trials, obtaining individual informed consent can seem prohibitively expensive, damaging to achieving study goals, or even impossible to attain (Sim and Dawson 2012; McRae et al. 2011b). Where consent is impossible to attain, is it right to require it at the expense of not doing the research? Attempts have been made to justify research without first attaining individual consent by appealing to an ethics committee for review, soliciting viewpoints from the community about whether the research is acceptable, or even seeking some form of community consent.

Dickert and Sugarman (2005) make a distinction between community consent and community consultation. Consent means seeking *approval*, whereas consultation means seeking *ideas and opinions*. They note, however, that this distinction gets blurred in practice, and that community consultation should not be approached as a box to check off without scrutinizing the input. They identify four ethical goals for any community consultation: enhanced protection, enhanced benefits, legitimacy, and shared responsibility. Adherence to these goals may ensure that risks are identified and protections put into place; that the research benefits not only the researchers, but also the participants and communities being studied; and that the legitimacy of the findings is increased. However, this does not constitute a direct parallel to the individual model of informed consent described previously. Community consent involves meeting with legitimate community representatives empowered to permit researchers to conduct studies involving community members (Weijer and Emanuel 2000; Dickert and Sugarman 2005). The involvement of community representatives in public health research is most clearly seen in community-based participatory research (CBPR). In CBPR, authorities are involved at all levels of research—from initiation of ideas and projects through data collection, analysis and interpretation, and use of research findings to prompt community change (Flicker et al. 2007).

9.3.2 Risk/Benefit Analysis

A central concern for research ethics is the weighing of expected benefits against possible harms. The commonly employed criteria for assessing risk to human subjects who participate in health research are that risks are minimized and reasonable in relation to the anticipated benefits. For example, one can argue that procedures used in research are justifiable when already being used for diagnosis or treatment and the risks are proportional to the importance of the knowledge reasonably expected to result from the research. However, one problem in such a determination is the uncertainty of all judgments about risks and benefits. Such determinations have to be made carefully and fairly and on the basis of the best possible evidence.

Research participants may encounter several types of risks. One obvious risk is physical harm, which may include discomfort, pain, or injury from interventions such as drug regimens or medical procedures. Another risk is psychological harm. Research participants may experience stress, anxiety, embarrassment, depression, or other negative emotions. These emotions, which can occur during or after participation in the research, are common in research involving sensitive topics such as sexual preferences or behavior. Social and economic harms are another type of risk. Participants in research that focuses on mental illness, illegal activities, and even certain diseases such as HIV may risk being labeled or stigmatized if precautions are not taken to provide adequate privacy and confidentially. A person's economic status may be affected if costs are incurred for participating (e.g., transportation expenses to and from the study site) or by loss of employment (present or future) if a breach of confidentiality occurs (e.g., an employer discovers an employee is being treated for substance abuse).

One common problem—about which ethics guidelines are typically silent—is how we should conceptualize study participants (McRae et al. 2011a). Consider, for example, that cluster randomized designs and cohort studies commonly compare a group receiving active intervention with a parallel group receiving no intervention. Does the term "participant" apply to those receiving no intervention? This question has far-reaching consequences. If people who do not receive intervention count as participants, researchers may have obligations to them that otherwise would not exist. Another way to think about this is to identify who might be at increased risk, rather than who is a participant. For example, the U.S. National Bioethics Advisory Commission (NBAC) recommends that whenever researchers anticipate that risks will extend beyond study participants, researchers should try to minimize risks to nonparticipants (NBAC 2001).

The benefits of health research are any favorable or positive outcome received as a direct result of the research. Put simply, without the research, the outcome would not exist. Sometimes the benefits of health research extend beyond study participants to society; other times, however, research participants do not benefit. And in other instances, only a few participants might benefit. Researchers should thoroughly consider what to do in all these scenarios and how benefits could be provided to those in need. Sometimes research involves reimbursement, incentives, or other tangible goods. Although such items may be provided when someone agrees

to participate in research, these items should not be considered benefits arising from the research procedures. In some contexts, such as prisons, offering anything in return for participation in research may be viewed as pressure to participate and therefore should be carefully considered.

The risks of research must be reasonable when compared to the anticipated benefits. This can be difficult to assess because risks will vary depending on the study population. For example, research procedures considered safe for healthy adults may be risky for adults with compromised health or for vulnerable populations such as children, pregnant woman, or seniors. Even if the potential benefits are the same, if the risks differ, the risk/benefit balance is affected. Another consideration for evaluating risks and benefits is the expected result of the research. A higher level of risk may be acceptable if the research can reasonably be expected to benefit the participants. If there is no expectation that the research participants will benefit, the same level of risk may be unacceptable.

Foreseeing the benefits and harms in a study can be challenging. Striking a balance between the two can be difficult and, at times, controversial. A good example of this is the discussion generated by a series of studies conducted in Baltimore that assessed different methods for reducing the exposure of children to lead paint in older rented properties (Mastroianni and Kahn 2002). In this case, the fact was already known that exposure of children to lead is dangerous. However, due to the high cost of removing lead-based paint (the known, best solution), the researchers assessed the effectiveness of cheaper, partial methods of abatement for reducing or even removing the risk of exposure. If found to be effective, these alternative methods would allow treatment of more homes at the same cost, potentially benefiting more children. Monitoring during the study found that some children in the alternative abatement options had elevated blood lead levels. Some health officials believe that the research should not have gone ahead because of this likelihood. Others think that the research was justified because the children were not exposed to any greater level of lead, and in most cases, significantly less than if the research had not been conducted. In other words, no child was put at greater risk through participation, and all children benefited from blood monitoring. This study demonstrates the complexities of evaluating risks and benefits in public health research.

9.3.3 Protection of Vulnerable Populations

Although all segments of society should have the opportunity to participate in research, vulnerable populations may need additional protections to prevent coercion or exploitation. The definition of what it is to be vulnerable is contested (Chap. 7). However, NBAC (2001) defines vulnerability in the context of research as a condition, either intrinsic (e.g., mental illness) or situational (e.g., incarceration), that increases some participants' risk of being harmed. Regardless of how we define vulnerability, it is often interpreted to require special protections for the safety and well-being of populations such as children, prisoners, pregnant women, mentally disabled people,

and economically or educationally disadvantaged people. The CIOMS (2002) international guidelines suggest that special justification is required for inviting vulnerable people to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied. The history of research is replete with examples of unethical treatment of vulnerable populations (Chap. 2).

Despite such worries about protecting vulnerable populations, a strong equity-based argument can be made for ensuring that they are appropriately represented in health research, unless the rationale for not including them is clear and compelling (CDC 1996). To exclude vulnerable populations violates the spirit of the principle of justice, which requires fair distribution of risks and benefits of research. Inclusion of vulnerable populations may require accommodations to address the specific nature of the vulnerability; however, once these accommodations are in place, vulnerable people with the cognitive capacity to provide informed consent should exercise autonomous choice about their participation. For example, it seems arbitrary to exclude pregnant women from research as a matter of course rather than making a decision based on an assessment of risk levels, the ability to control risks, and the likelihood of direct benefit to the participant.

9.3.4 Returning Research Results

Public health research tends to focus on population-level research questions. In some cases, for example where data have been anonymized, even when an issue relevant to the clinical care of one or more individuals in the data set is discovered, there is nothing that can be done about it. However, in other cases, public health data sets or surveillance data might hold information that could be crucial to the care of individuals.

When and how should individual-level data, including incidental and secondary findings, be communicated to research participants? The primary argument for an ethical imperative to offer participants research findings, both summary and individual results, rests on the principle of respect for persons; however, the principles of beneficence and justice are also frequently cited (Presidential Commission for the Study of Bioethical Issues 2013; Miller et al. 2008; Fernandez et al. 2003). The word "offer" is important because giving people the right to decline results is also an expression of respect for persons. The ethical justification for a "duty to disclose research results," especially individual-level data, has been challenged due to the potential harms of disclosure (Miller et al. 2008). Miller and colleagues argue that the lack of consistent policy guidance for disclosures and the ambiguity about what to disclose undermines any generalized ethical duty to disclose. Clearly, before making a decision to return results, especially individual-level data, the potential benefits and harms from disclosure must be carefully assessed.

The research consent process should describe plans for returning results or provide an option for not receiving results. The consent process should explain the potential harms and benefits associated with receiving research results, the possible

strengths and limitations of the results, and the options for follow-up and support if unanticipated consequences occur. If a decision is made to return results, careful considerations must be given to how the results will be returned (e.g., in person, over the telephone, through a letter), whether opt-in or opt-out procedures will be used, and when the results should be returned. Fernandez and colleagues (2003) argue that "research results should, in general, be delayed until the results are published or until they have undergone peer review and been accepted for publication." This recommendation is based on the need to ensure the integrity of the interpretation of the data and to prevent disclosure of inaccurate information.

To illustrate the diversity of opinion about sharing research data, some researchers have taken the obligation for disclosure further by advocating that research participants be granted access to their raw data via a data repository before these data are analyzed (Lunshof et al. 2014). Lunshof and colleagues suggest that access to raw personal data would increase transparency, personal choice, and reciprocity. Further, such access could equalize the relationship between those who donate data and those who use data for research. However, this rather utopian view raises issues with potential breaches of confidentiality, so more discussion is needed. More discussion is also needed about participants increasingly sharing information about research studies through social media, which can result in breaches of confidentiality and further challenge the integrity of research (Lipset 2014).

9.3.5 Conflicts of Interest

The potential for conflicts of interest occurs when an individual or group has multiple interests, one of which can compromise the integrity or impartiality of the other. Research involving human subjects often creates this potential when researchers are also involved with participants in the role of health care providers or through engagement with communities in the context of public health research. In resource-poor contexts, the economic impact of the research enterprise can be of such magnitude that it has sociopolitical ramifications or complexities with potential to spur conflicts of interest. Discussion about conflicts of interest raises issues about integrity in public health and even the very concept of public health as an activity (Coughlin et al. 2012).

Shrinking budgets for public health activities have led many health departments, even those in resource-rich countries, to explore alternative approaches to financing public health research, leading to questions about what constitutes an appropriate partnership and to concerns about real or perceived conflicts of interest. For example, should governments collaborate with vaccine manufacturers to research potential adverse effects of a vaccine? Should researchers collaborate with soda manufactures to study the association between sugar-sweetened beverages and obesity? The U.S. Institute of Medicine (IOM) Committee on Conflicts of Interest in Medical Research, Education, and Practice defines conflict of interest as "a relationship that may place primary interests (e.g., public well-being or research integrity)

at risk of being improperly influenced by the secondary, personal interests of the relationship (e.g., financial, professional, or intellectual gains)" (IOM 2009). When Bes-Rastrollo and colleagues (2013) studied systematic reviews of the association between sugar-sweetened beverages and weight gain, they found instances where conflicts of interest influenced scientific findings. The systematic reviews that identified sponsorship or conflicts of interest with food or beverage companies were five times more likely to report "no positive association" between consumption of sugar-sweetened beverages and weight gain or obesity than the reviews that reported having no industry sponsorship or conflicts of interest. These findings point to the need for guidance on how to identify and avoid conflicts of interest with potential to influence outcomes of public health research, especially when the research shapes public policy (IOM 2014).

9.3.6 Conducting Research during Public Health Emergencies

Sometimes the traditional elements of research ethics are inappropriate frameworks for decision making. Let's consider, for example, a decision being contemplated to conduct research during a public health emergency. The research is deemed vitally important to analyze what happened during the emergency, to plan for future scenarios, and to prevent death and illness during disasters. However, such research raises concerns, including the appearance that health officials are more interested in expanding knowledge than in responding to the disaster and that researchers are insensitive to more urgent needs of affected individuals. Still, the case can be made for a strong, ethical imperative that obligates public health officials to conduct research that could yield data useful in preventing future death and illness during disasters (London 2016). The chief ethical task for conducting research during a disaster is to secure future benefits for people without sacrificing the rights or interests of research subjects (Jennings and Arras 2008; WHO 2015). So to justify research during a disaster, public health officials must first demonstrate a real need for the research, which includes its social and scientific value (anticipated results). Generally speaking, research that can be conducted in a nonemergency setting should not be conducted during an emergency response.

If the decision is made to conduct research during a public health emergency, some unique ethical concerns must be considered: the research should not detract resources and personnel from emergency response activities; research activities should be prioritized by highest social and scientific value; and, as people in an emergency are often affected physically and psychologically, and sometimes traumatized, they should be considered a vulnerable population (Jennings and Arras 2008; WHO 2015). At the very least during an emergency, keep in mind that some people may not be able to make reasoned, informed decisions to participate in the research. Consequently, adequate means of protection for participants must be in place. The procedures for an ethics committee review may need to be modified for disaster research projects (Lurie et al. 2013). Possible approaches for ensuring

appropriate review include developing just-in-case protocols and establishing centralized or specialized ethics review committees that can approve disaster research protocols quickly (Médecins Sans Frontières 2013).

9.4 How Ethical Challenges Can Arise in Public Health Research: Lessons Learned from Cases

The cases presented in this chapter illustrate some of the ethical challenges raised by public health research. These challenges range from compliance with research ethics guidelines to the need to address the economic and political implications from the wider societal context in which public health research occurs. Social, economic, and political factors can directly lead to ethical challenges or may affect a researcher's ability to comply with ethical guidelines.

The case by Boulanger and Hunt illustrates how well-intentioned international efforts to improve access to health care in resource-poor countries can have unintended consequences that present ethical complications. The case raises various interconnected issues that have to do with researchers' responsibilities and obligations and with conflicts between individual and public goods. Within a collaborative international public health research project, such conflicts can easily arise when local investigators find themselves serving multiple roles that create potential conflicts of interest. Boulanger and Hunt provide an excellent summary of the responsibilities and obligations of researchers, including to

- Protect participants from harm and ensure they benefit from the research whenever possible;
- Support and protect research staff, especially students;
- Support and respect research collaborators, building local capacity when possible; and
- Support the research enterprise, which includes building public trust, maximizing the relevance and usefulness of the research, and disseminating findings.

Central to this case is a local researcher's uncovering of how informal fees for obstetric care are being diverted to senior hospital administrators. The local researcher has a dilemma. If he reveals this ethically dubious informal fee structure, he will not only jeopardize his standing at the hospital, but he could also undermine the availability of obstetric care to women in his community. The director of the research program must ethically weigh the research goal of improving access to health care services with supporting the interests of the research staff while also maintaining good relations with local health agencies. In many contexts, this case would be a clear-cut whistleblower issue demanding revelation. However, where informal fees are standard practice, part of the political culture, or the health infrastructure is already fragile or minimal, the issue becomes complicated, forcing one to prioritize competing values and moral considerations.

The case by Makhoul and colleagues involves research on mental health concerns among youth in a Palestinian refugee camp. The case highlights cultural and social factors that may influence the consent process, especially the power dynamics within communities. Beyond addressing central bioethical and medical principles of trust and respect for persons, the case points to the need for considering broad public health concepts such as respect for community values, empowerment, and advocacy. This case also illustrates how researchers are almost always drawn into a community's political dynamics by the economic influence of research in resource-poor settings. Efforts by community members to avoid alienating groups that contribute resources to the community may act as a subtle form of pressure to participate in the research.

The case by Kasule and colleagues illustrates the difficult practical choices that resource-poor countries face in processing the increasingly complex volume of research to be ethically reviewed. In these countries, public health officials struggle to complete basic administrative and regulatory aspects of research review and oversight, let alone provide conditions for careful, conscientious ethical analysis. This scenario questions the adequacy of training for members of ethics review committees. Failure to adequately train committee members and fund research oversight will result in lost opportunities and revenues, setting back a resource-poor country's research or health infrastructure for years. But funding an organization to develop research oversight may divert funds from other more urgent public health needs. Trading short-term public health solutions for long-term research funding presents a classic case of resource allocation and prioritization. Kasule and colleagues consider the pros and cons of reliance upon outside ethics review committees, which might save money at the expense of having less control of oversight.

The case by Kanekar describes the use of an Internet-delivered safe sex health promotion intervention for young black men who have sex with men. This case raises a number of practical and ethical considerations and questions that arise in public health research. How does one differentiate research from public health practice? What approaches are required to serve vulnerable populations? How can one use innovative techniques to target hard-to-reach populations? What are the best ways to protect the privacy of participants and ensure confidentiality of data? How can one reconcile or accommodate conflict among research partners who perceive their primary role or function in radically different ways (e.g., medical provider versus epidemiologist)?

9.5 Conclusions

Many ethical issues can arise in public health research. The social, economic, and political context within which the research enterprise functions further complicates the ethical landscape. Traditional approaches for considering research ethics issues emerged from biomedical research and initially emphasized ethical considerations at an individual level. However, research in public health demonstrates why this

traditional approach to ethics should be expanded. A public health approach to research ethics is apt because it considers community values, the interdependence of citizens, social or population benefit, and social justice. However, as explained in Chap. 1, there is more to ensuring ethical conduct and scientific integrity in public health research than having an ethical review committee apply rule-based guidelines. Researchers need to be familiar with the ethical considerations unique to public health and have sufficient training and experience to exercise moral judgment in all phases of research.

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9.6 Case 1: To Reveal or Not to Reveal Potentially Harmful Findings: A Dilemma for Public Health Research

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This case is presented for instructional purposes only. The ideas and opinions expressed are the authors' own. The case is not meant to reflect the official position, views, or policies of the editors, the editors' host institutions, or the authors' host institutions.

9.6.1 Background

In 1987, African health ministers met in Mali to address access to quality primary health care, particularly in rural areas (Anonymous 1988). The resulting Bamako Initiative promoted universal accessibility, though it drew some early criticism for its support of user fees (McPake et al. 1993). For the next decade, user fees were implemented in many African countries to finance health care services. The World Bank supported the measure as part of its Structural Adjustments Programs, which also included austerity measures, trade liberalization, and privatization (McIntyre et al. 2006). However, user fees have since been shown to create access barriers that tend to affect the poor disproportionately (Macha et al. 2012), suggesting that many vulnerable individuals have been prevented from accessing needed health care services. Against this backdrop, mounting international pressure led to the reform of many user-fees programs, particularly in the last decade. One primary strategy for increasing health care access has been the introduction of selective exemptions of user fees for specific groups (Ben Ameur et al. 2012; Meessen et al. 2011; Ridde et al. 2012). Although this strategy was originally planned in the Bamako Initiative, it was not uniformly implemented. Given the scale of the changes that user fees removal implies for health care systems, there is ongoing research to evaluate their impact (Lagarde and Palmer 2011). Health system investigations such as these may raise ethical questions (Hyder et al. 2014), especially since they involve the study of a public health intervention, often focus on individuals in extreme poverty, and tend to be international and collaborative in nature.

Collaborative international public health research offers the opportunity to build local capacity (Mayhew et al. 2008). However, such research raises a number of issues about researchers' obligations and responsibilities. First is the responsibility to protect research participants from harm, an obligation recognized by all research ethics guidelines. This duty of protection is heightened when the research participants are from vulnerable populations (Hurst 2008), especially when they are recruited from extremely impoverished populations. Researchers' responsibilities toward research participants also include ensuring that they benefit from the results of the research whenever possible. For example, the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* directs that "any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community" (Council for International Organizations of Medical Sciences 2002, guideline 10). A second researcher responsibility is to support students and staff hired as part of the research project and to protect them from harm (Wilson 1992). This responsibility can be thought of both as the duty of an employer and the fiduciary duty of an academic supervisor and must extend to situations of whistleblowing. Third, researchers involved in collaborative research have a responsibility to colleagues and collaborators, especially given that research may play a crucial role in capacity building (Garcia and Curioso 2008). Although partnerships with local researchers have been touted as highly valuable (Costello and Zumla 2000), these ties may also result in unexpected ethical dilemmas for local researchers if conflicts arise

between their research activities and their established local obligations and responsibilities (Richman et al. 2012). A fourth responsibility of researchers is dedication to the research enterprise. The conduct of public health research can have significant implications for the well-being of large segments of the population, but it requires the trust of the public and of relevant authorities. Endangering the relationship of trust in the context of one specific public health study may jeopardize or ruin other research initiatives (Corbie-Smith et al. 1999). Finally, a fifth responsibility of publicly funded researchers is their duty to the public in whose name they conduct research. Good stewardship requires that researchers strive to maximize the relevance and usefulness of their efforts and that they disseminate their findings (Arzberger et al. 2004). Researchers conducting collaborative international public health research may encounter ethically challenging conflicts among these five lines of responsibilities.

9.6.2 Case Description

Dr. Milena A. is the principal investigator of a large research program that is examining approaches for decreasing inequities in access to health care services in a low-resource setting. She works for an American university, and her research is funded by a U.S. agency. One member of her research team, Dr. Timothy N., is a local physician studying toward a public health degree at Milena's institution. He is back in his country after finishing his coursework and is ready to conduct fieldwork research. Timothy has taken leave from his position at a local hospital to pursue his studies and, although he wants to continue his clinical work at the hospital, he also wants to expand his focus to include population-level health issues and, eventually, work with his country's ministry of health. His studies are co-funded by Milena's research grant and by the ministry of health.

Timothy's research consists of an examination of the impact of his country's recent abolishment of health care user fees for children younger than 5 years. User fees had been implemented uniformly in the 1990s without special consideration for poorer families with young children. Initial indicators suggest that health care services continue to be underused in some districts, especially by poor children, despite the recent removal of user fees. Despite the limited uptake, the ministry of health touts the policy abolishing user fees for children younger than 5 years as an important success. Timothy is conducting his study at several urban health centers, including the hospital from which he is currently on leave. The research project has received ethics approval from Milena's institution and from the relevant local review boards.

Recently, Timothy requested a meeting with Milena saying that he needed advice. He reports that he has identified a system of informal fees that undermines the ministry of health's official policy by making health care once again too expensive for many families with young children. From what Timothy understands, the fees are levied primarily to fund better obstetric care locally, but some indicators point toward senior administrators keeping a small share for themselves. Timothy worries that making his findings public is too risky for him, especially since his involvement in this fieldwork is well-known. He does not think it possible to share

his findings without identifying himself as the source of the information. His hospital is one of the sites where he has identified the system of informal payments. He also has good reasons to believe that some members of the ministry of health are already aware of the situation but have not taken action to address it. Disseminating his results will jeopardize his employment at the hospital, his relationships with government officials, and, potentially, the plans to improve obstetric care.

Milena is also conflicted. She recognizes that she has multiple roles, responsibilities, and interests, and that individual and communal goods are at stake. Identifying and seeking to address informal payment structures could improve accessibility of health care services for children, which is the primary goal of her research program. However, the team has responsibilities to Timothy as their student and colleague. Demanding that he upend his career, either for their benefit or for the improvement of health care accessibility, might fail to respect him as an individual. In addition, bringing the situation to light could embarrass the ministry of health. Because the research program depends on the ministry of health's authorization, tensions in relationships could lead to premature termination of the research. Such an event would have unpredictable outcomes on the careers of everyone on the research team and on the future of health care accessibility locally.

9.6.3 Discussion Questions

1. How should Milena and Timothy prioritize their responsibilities, and what should they ultimately do?
2. What preemptive actions could the research team have taken to limit the likelihood that the situation described above would happen?
3. How should the fact that, aside from Timothy, the research team members are not citizens in the country where they are conducting research be considered in the assessment of their obligations?
4. Is this a case where developing partnerships with local researchers might be counterproductive? Or, could a more robust partnership with local researchers have positioned the team to better address this issue?
5. How would the ethical analysis differ if, instead of identifying unequal access due to informal fees, Timothy had observed that those exempted from the fees were being offered a lower standard of care than patients whose fees were not waived?

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9.7 Case 2: Ethical Challenges in Impoverished Communities: Seeking Informed Consent in a Palestinian Refugee Camp in Lebanon

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9.7.1 Background

Beginning in 1948, the United Nations Relief and Works Agency (UNRWA) established camps in Lebanon to house refugees from Palestine. As of 2013, 12 camps remained (UNRWA 2013). The typical UNRWA camp houses three generations of refugees, most of whom are unemployed and face economic hardships from state-imposed legal and political restrictions (Chaaban et al. 2010). Camp housing is substandard, usually lacking adequate health care and educational infrastructures. A household survey of camp residents older than 15 years found that the mean length of school attendance is 6–7.5 years, the mean yearly household income is below $3,000, and more than half the respondents consider themselves poor (Makhoul 2003; Khawaja et al. 2006).

Family structures in the camp vary, ranging from matriarchal families, extended families, and traditional patriarchal families to even modern families where parents jointly make decisions. These family structures also include complex formations where, for example, a remarried father lives with his new wife and stepchildren. In such complex families, children often have several guardians or authority figures. Sociocultural conceptions shared by parents and social workers stress the reliance of children on parental decisions—parents know what is best for children, while children know they must obey parental decisions.

In resource-poor settings like the camps, many nongovernmental organizations (NGOs) supplement UNRWA services, thereby gaining influence. The perceived power that the local Palestinian NGOs hold in the community derives from years of providing supplemental economic and social services to residents. Not surprisingly, if an NGO is politicized, it also will hold political power. In this context, if an NGO agrees to participate in a project, residents may agree to participate without paying

close attention to the details or the scope of work. They participate either because they trust the NGO to decide on their behalf or because they want to avoid being perceived as opposing an organization that provides them with needed services. Similarly, international NGOs hold perceived power by providing essential services and distributing needed supplies, especially during emergencies. Universities can acquire such power, even unintentionally, not only from the prestige and status that educational institutions generally enjoy, but also from the potential benefits that research projects bring to the camps. Intentional or not, exercising such power can raise unanticipated problems for the research enterprise.

To protect research participants, some national and international commissions have published guidance documents about equitable distribution of benefits and respect for autonomy, beneficence, and social justice. These documents include the *Nuremberg Code* (1947), the *Declaration of Helsinki* (World Medical Association 1964), The *Belmont Report* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979), and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Council for International Organizations of Medical Science 2002). Even though these international guidelines acknowledge the need to consider culture and community, they lack adequate guidance for community-based public health research (Racher 2007; Bledsoe and Hopson 2009). In addition, these guidelines are difficult to apply in nonbiomedical research contexts in community settings. This difficulty could be attributed to applying guidelines without first considering local contexts (Dawson and Kass 2005; Benatar 2002; Chilisa 2009). Many community-oriented practitioners find the principles too limiting to guide public health research ethics in community settings and recommend incorporating broader conceptions of respect, trust, inclusion, diversity, participation, empowerment, and advocacy (Racher 2007; Bledsoe and Hopson 2009).

Biomedical guidelines often clash with community interactions, especially in the nonindustrialized world (Bledsoe and Hopson 2009; Matsumoto and Jones 2009; Chilisa 2009). One such clash occurs between individual-oriented societies and more collectivist societies that view personhood and individual decision making through the lens of a person's relation to society (Marshall and Baten 2003). Another clash occurs between the artificially impersonal character of research environments and the centrality of relationships and partnerships in communities. Randomized clinical trials (RCTs), for example, require control of all possible confounders, a nearly impossible standard to achieve in close-knit and dense community settings (Makhoul et al. 2013). Implementing ethical guidelines in the context of power dynamics (Marshall and Baten 2004), like the pronounced power that males wield over females in patriarchal societies, can instigate numerous clashes. In communities like refugee camps that offer few economic or career opportunities, the perceived power that NGOs and, even more so, academic institutions wield is a force that must be taken into account. In such restricted settings, the power dynamics between researchers and research subjects can take on a subtle coercive character.

These same tensions, challenges, and dynamics will emerge in any efforts to obtain informed consent to participate in research. The emergence may stem from

failure to appreciate the unique complexity of local familial, cultural, and political structures, or it may represent limitations in the principles being applied.

9.7.2 Case Description

A community coalition, initiated by researchers from a nearby university, has been meeting for more than a year to prioritize health concerns for youth in a Palestinian refugee camp near Beirut, Lebanon. The camp is a typical UNRWA camp and includes six elementary schools. The coalition comprises camp residents including youth (17–25 years), UNRWA representatives, camp NGO workers, and members of the university research team. The coalition has decided to focus on the mental health of younger adolescents (11–13 years) in this Palestinian refugee camp and to develop a research intervention on this issue. Cross-sectional studies and evaluation of interventions that link social and life skills to mental health outcomes strongly support the view that these skills enhance the mental health of youth; however, most of the evidence comes from industrialized settings.

The goal of the intervention is to enhance positive mental health by increasing the social and life skills of young adolescents, who will be recruited through the schools. The six elementary schools have comparable resources and student profiles. Each school has been randomly assigned either to the intervention or to the control arm of the study, and only fifth and sixth graders will participate. Participating students in the intervention group will receive 45 extracurricular sessions of 1½ h each over 9 months and gain skills in solving problems, making decisions, building self-esteem, and enhancing relationships with peers, parents, and teachers. Parents of the students in the intervention group will receive 15 1-h group sessions, and teachers in the intervention schools will be offered six workshops addressing the same topics. Students randomized to the control group will receive 10 sessions over the course of 9 months, but their parents will not participate in the program. However, because teachers often work in more than one camp school, some teachers at the control schools may participate in the intervention workshops. All participants in either the intervention or control condition must complete pre- and post-assessment questionnaires that measure mental health and social and life skills before and after the intervention and at 6 months follow-up.

Recruitment into the research project will unfold in phases. Toward the end of the school year preceding the intervention, parents will be invited to an informational session about the project that will take place in one of the camp schools. After the informational session, meetings will take place with individual families in their homes to recruit students entering grades 5 and 6. Some youth (ages 17–23 years) who live in the camp will receive training to become part of the recruitment team. These youth will visit the homes of all potential intervention and control participants to explain the study and to obtain parental consent. If the parents consent, students will be invited to the school for further discussion (to ensure confidentiality and autonomy of decision making). Once the study has been explained to them, they'll be asked individually to give their assent.

You are a member of the university research team leading the effort to obtain informed consent. You would like to obtain consent and assent in accordance with standard international procedures, but you realize their application may need to be adjusted to the context of the camp. In particular, you have considered what role principles such as trust, inclusion, diversity, and broad community participation should play in the research project. That is why you chose to have older youth from the camp obtain both parental consent and student's assent, but you are concerned about potential problems that this approach may encounter. Also, given the power dynamics and conditions in the camp, you would like the research team to consider how this project can be used to spearhead a discussion with the community coalition about larger issues of empowerment and advocacy. With this in mind, you plan to address the following questions with your research team.

9.7.3 Discussion Questions

1. How could the history of Palestinian refugee camps potentially impact the informed consent process and the success of this intervention?
2. Who are the stakeholders in this case, and what stake, for or against, do they have in the research project? How would you deal with those who believe the project is not in their or the community's interests?
3. What are the advantages and potential disadvantages of using older youth to obtain parental consent and student's assent? What other steps could be taken to enhance the informed consent seeking process in such social contexts?
4. What incentives, if any, should be given for participation? To whom should these incentives be given? Given the limited opportunities for the inhabitants of the refugee camps and the perceived power of NGOs, at what point would incentives become compulsive to encourage participation?
5. How do relationships of power influence the application of informed consent procedures specifically, in this context? What steps can be taken to minimize the effects of power?
6. What bearing, positive or negative, does the background of the researchers have on the researcher-participant interaction, especially for researchers who have never lived in such camp settings and would be considered outsiders to the camp community?
7. Beyond the informed consent process, are the researchers simply teaching the adolescents how to adjust to an oppressive arrangement instead of exploring, providing and validating strategies to transform the situation? If so, what are some alternative intervention strategies that could foster the latter?
8. By almost any measure, the camp environment is abnormal for a developing adolescent. Given that social determinants severely challenge the health of all members of the camp community, how should the researchers take into account the unusual and extreme circumstances of the adolescents as they implement and evaluate interventions that aim to change individual-level circumstances and attributes?

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9.8 Case 3: Improving Review Quality and Efficiency of Research Ethics Committees to Enhance Public Health Practice in Africa

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9.8.1 Background

Many low- to middle-income countries in Africa face a tremendous burden of infectious diseases. Tuberculosis (TB) causes particular concern, with incidence rising and the greatest prevalence in children. Compounding this concern is the lack of an easy-to-use and accurate diagnostic test (World Health Organization 2012). To address these challenges, the World Health Organization's (WHO) 2011 global plan

to stop TB by 2050 urgently calls for more research to develop diagnostics, drugs, and vaccines. WHO's call reinforces the 2008 Global Ministerial Forum on Research for Health held in Mali, which recommended that each country allocate 2 % of health ministry funds to health care research (Yazdizadeh et al. 2010). All research involving human subjects will require review by institutional review boards (IRBs) or, as they are generally known in Africa, research ethics committees (RECs). But to expedite the process of high-quality ethical reviews necessary to keep pace with these new research initiatives, a corresponding investment in REC funding and training should be made.

In TB-endemic areas of Africa, the volume and complexity of research have increased without a corresponding strengthening in the capacity of local RECs (WHO 2011). At least 190 RECs operate throughout Africa, but the quality and capacity of each vary widely (IJssemuiden et al. 2012). Although some RECs still lack adequate research regulatory frameworks, the major challenge to strengthening capacity is lack of funding (Kass et al. 2007). This means, for example, that few, if any, African RECs have tools like electronic information management systems to coordinate submissions efficiently. It also means that few have trained REC administrators, a gap rightly identified as the missing link to improved quality and throughput of ethical review (IJsselmuiden et al. 2012). These factors can delay ethical reviews and create problems with quality and consistency (Milford et al. 2006; Kass et al. 2007). Whenever significant research funds are wasted on managing inefficient RECs, fewer funds are available to study ways to improve public health care services (Tully et al. 2000). This waste of resources on inefficient ethical review affects the timeliness of health services, which, in turn, affects subsequent health care policy and decision making. Ironically, such wastefulness poses an unethical barrier to potentially beneficial public health research activities. Worse, these inefficiencies can cost research institutions a chance to compete for grants that require prior ethical review of research proposals by the country's internal REC.

In Africa, external grants are often used to fund health research activities, whereas REC funding typically is either nonexistent or constrained by more pressing health care needs. Attempting to prioritize and allocate resources for activities with outcomes linked to funding puts policy makers in a dilemma. On the one hand, diverting funds from the immediate treatment of life-threatening diseases to a weak, inefficient REC can waste critical resources. On the other hand, not allocating funds to strengthen RECs can lead to the loss of external research funding, the very research that could reduce the burden of disease in the long run. Moreover, external funding, though filling a critical gap, often heightens the tensions at play in prioritizing between immediate needs for health care and long term needs for research and RECs.

9.8.2 Case Description

A multinational pharmaceutical company put out a call for proposals to research institutions in sub-Saharan Africa to apply for a research grant. The 3-year grant, which provides 500,000 U.S. dollars per year to develop an effective paediatric TB diagnostic tool, would involve conducting clinical trials in five African TB-endemic countries. Successful award of the grant is contingent upon timely review of the proposal by the applicant's national REC.

In one country eligible for the grant, the ministry of health (MoH) encouraged its National Tuberculosis Research Centre to apply. The grant funding would have boosted the country's long-term efforts to strengthen the capacity of its public health research by restructuring its TB treatment protocol. The Research Centre promptly submitted a proposal to the national REC, which levies 10 % of the grant as overhead to sustain the REC.

Despite the overhead funding, the country's national REC lacks an administrator formally trained in research ethics and a robust ethics review structure. Although the REC receives more than 100 applications annually, it only meets every 3 months, often missing deadlines, because it cannot afford essential tools to coordinate submissions efficiently. To have a proposal reviewed; applicants have to submit 20 hard copies of the research application form and 10 copies of all other study materials. The review procedure typically forces the principal investigator of a clinical trial to submit nearly 20 kg of paper copies, a considerable sum in supplies and manpower. Despite its high profile, the TB Research Centre's grant application does not prove to be an exception to the notoriously slow review process.

Professor Y, a highly capable public health specialist, directs the public health department in the local MoH. She also lectures at a local medical school, serves as Principal Investigator (PI) of an ongoing TB clinical trial in the country, and has extensive experience at all levels of REC activity and oversight. Unfortunately, Professor Y has never had formal training in research ethics, which is critical for anyone involved in managing REC activities. Because of her background, Professor Y became aware of the delays in reviewing the TB Research Centre's application. Recognizing its importance to the country, Professor Y offered to serve as the primary reviewer for the proposal. Professor Y called an ad hoc REC meeting. At this meeting, the other members, who had only received copies of the grant application form to prepare for their review, unanimously agreed to outsource review of the protocol because they lacked the expertise to evaluate the application. Amid these delays, institutions in other countries competing for the same grant, having already received ethical clearance from their RECs, were awarded the grant. Not only did the delays cost the country a funding opportunity to enhance its public health research capacity, but preparing the application also wasted precious time and scarce resources.

In response to this bungled opportunity, the MoH set up a task force to analyse the situation and offer recommendations. In its report, the task force recommended allocating more resources to RECs to strengthen capacity. Due to budget constraints, the MoH had to divert the money allocated to RECs from the antiretroviral program. Meanwhile, the MoH recommended temporarily outsourcing all REC services to a U.S. based clinical research organization.

9.8.3 Discussion Questions

1. What ethical tension or challenges could result from the insufficiencies in REC capacity that forced the MoH's decision to divert funds from the antiretroviral program to strengthen REC capacity?
2. How should a country prioritize between the need to foster research, which can have significant long-term impact and immediate health care needs?
3. Funding for the research grant and temporary outsourcing of ethical reviews will come from multinational or U.S. based partners. What are the advantages and disadvantages for developing countries to accept such funding? What impact does accepting such funding have on a country's ability to determine its own health priorities?
4. Professor Y has public health credentials, TB expertise, and extensive experience as an REC administrator. The case suggests that had she followed the procedures for the review process, the grant application might have been successful, even though she apparently lacks formal ethics training.
   (a) According to international research ethics regulations, what procedures should Professor Y have followed when distributing the proposal for review, allocating reviewers, and setting up the REC meeting?
   (b) How critical is formal ethics training to serving on an REC or to overseeing the development of REC capacity nationwide?
   (c) Is it a good use of time for someone like Professor Y to be serving administratively on an REC?
   (d) Would you recommend that the MoH create a permanent position for a trained research ethics administrator solely responsible for REC administration issues instead of allowing volunteers like Professor Y, who have multiple roles and responsibilities, to oversee the activity?
5. Given the cultural and economic differences between developed Western nations that sponsor research and African host countries, should formal ethics training to prepare for serving on an REC be modelled on Western training or on some other model?
6. Keeping the interests and values of all stakeholders in mind, consider the best ways to address the strengthening of REC capacity in African low- to middle-income countries at the local and global levels.

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9.9 Case 4: Internet-Based HIV/AIDS Education and Prevention Programs in Vulnerable Populations: Black Men Who Have Sex with Men

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9.9.1 Background

Since surfacing more than 30 years ago, the HIV/AIDS pandemic has devastated populations worldwide. Various factors have contributed to this epidemic, such as lack of awareness of HIV status, stigma, homophobia, negative perceptions about HIV testing, socioeconomic factors, behavioral risk factors, and high prevalence of sexually transmitted diseases (Centers for Disease Control and Prevention 2015). In the United States, one goal of the national HIV/AIDS strategy is to reduce HIV-related health disparities. Any reduction in the collective risk of acquiring HIV will require behavior change interventions in communities with the highest HIV prevalence. However, extending the reach of HIV/AIDS preventive interventions in remote areas with limited access to HIV testing and prevention services has proved difficult (Office of National AIDS Policy 2012).

The challenge of reaching some populations has led many practitioners to consider innovative intervention methods that rely on technologies such as the Internet and mobile telephones. Public health professionals are using these technologies to deliver health education to vulnerable populations in big cities, small towns, and

hard-to-reach rural areas. In particular, the past decade has seen more health communication efforts using the Internet to prevent HIV and sexually transmitted diseases (Bull et al. 2007, 2009; Rietmeijer and McFarlane 2009). Studies of interventions that use Internet chat rooms, online modules, and health intervention websites show promising results that bode well for the future of these technologies (Chiasson et al. 2009; Moskowitz et al. 2009).

Studies conducted with marginalized and vulnerable populations such as black men who have sex with men (MSM) can pose difficulties. On the technology front, many difficulties reflect the Internet's relative novelty for conducting studies and the consequent lack of clarity in dealing with the rules, language, and norms of a virtual community culture compared with a traditional community culture (Loue and Pike 2010). On the allocation front, having limited resources usually implies that tailoring interventions to a specific group will mean forgoing benefits to another group. Still, in promoting the health of populations, public health professionals must strive to distribute resources fairly while responding to the specific needs of racial, ethnic, and cultural groups. These concurrent goals require maintaining a delicate balance between targeted and population interventions. On the ethics front, because some projects straddle the line between research and practice, public health professionals can become unsure about whether the ethical guidelines of research or of community work should govern their actions. They must bear in mind that trust, which is essential for conducting community-based participatory research, becomes more crucial when working with vulnerable populations, which tend to show a high degree of mistrust (Loue and Pike 2010). Those who study vulnerable populations need to negotiate community entry either by developing trust or by working closely with local practitioners and building upon established trust.

In the United States, the HIV/AIDS epidemic has hit the African-American population hardest, with black men accounting for 70 % of new HIV infections. Between 2006 and 2009, new HIV infections increased 48 % among black 13- to 24-year-old MSM (Centers for Disease Control and Prevention 2015); by 2009, 37 % of new HIV cases among black men were from black MSM. Given this high prevalence, before the end of 2015, the U.S. national HIV/AIDS strategy calls for a 20 % increase in the proportion of African Americans diagnosed with HIV who have an undetectable viral load (Office of National AIDS Policy 2012). Already, information about HIV issues affecting young MSM (Mustanski et al. 2011) is widely available on the Internet, including messages about how to reduce risk (Hightow-Weidman et al. 2011) and interventions to prevent HIV risk behaviors among MSM (Rhodes et al. 2010) and blacks who inject drugs (Washington and Thomas 2010). Studies show that online delivery of HIV counseling and behavioral interventions for MSM at high risk for HIV are successful, suggesting that the future holds great promise for Internet-delivered interventions for this vulnerable population (Chiasson et al. 2009; Moskowitz et al. 2009).

9.9.2 Case Description

Dr. Albert, a social scientist, and Dr. Baines, a community worker, are employed by a public health agency in a medium-size U.S. town. The agency has asked them to determine whether a skill-based, Internet-delivered intervention to promote safer sex among young Black MSM will increase HIV knowledge and increase the frequency of using safer-sex practices.

Project participants will be recruited via the Internet in gay chat rooms and be verified electronically by using Internet Protocol and Microsoft Access usernames and passwords (Bull 2011). Participants will be surveyed before they begin the training modules and again at 1- and 6-week intervals after completing the modules. Participants will be randomly assigned to control and experimental arms. Those in the control arm will receive 6 h of online training about health and well-being (e.g., nutrition, physical activity, stress reduction). The experimental arm will receive a 6-h online program including two 1-h modules on each of the following topics: (a) HIV/AIDS-related knowledge; (b) development and improvement of safe sex skills, such as partner communication and monogamous sexual relationships; and (c) self-efficacy in using condoms. The modules will include automated reminders for HIV testing. The study will measure improved knowledge on HIV/AIDS, partner communication about safer sex, and condom usage self-efficacy. Data will be analyzed using statistical software.

Dr. Albert thinks the results could be generalized not only to black MSM in the community but also to black MSM overall. He plans to write an article describing the results for publication in a scientific journal. Although Dr. Baines knows the impact of education on health, especially in underprivileged communities, she wants to educate only a subset of the community they will reach. Besides, since their work is for a public health agency, she believes the intervention ought to reach as many community members possible. She claims the project's goal is to provide a vulnerable and disadvantaged population with much needed education on health matters and health-promoting behavior and doubts their project constitutes research.

Dr. Albert worries that, because his colleague lacks academic rigor and underappreciates the role of evidence, she fails to appreciate the project's rationale and design and, as a result, is indifferent to the challenges the Internet poses (e.g., technology-induced bias, protection of confidentiality). Conversely, Dr. Baines believes Dr. Albert has missed the boat and is wasting resources, spuriously introducing statistical analysis of experimental and control arms into what the agency clearly had intended as an education intervention.

9.9.3 Discussion Questions

1. Is this a research project? Should approval from an ethics review committee be obtained? Or should the project be considered nonresearch because it will improve the health of the population? How should you decide?

2. Does the fact that the project is funded by a public health agency play a role in this discussion? Should public health agencies conduct studies to generate evidence about HIV education and prevention interventions? Should agencies focus on the delivery of interventions based on the existing evidence?
3. How is this black MSM population vulnerable, and how should this vulnerability be addressed in research and nonresearch interventions?
4. Do Dr. Albert and Dr. Baines have ethical obligations to other community populations? On what basis is the public health agency justified in advancing interventions that target only a subgroup of the community?
5. How should research studies on Internet-based interventions be conducted to ensure scientific validity, given the difficulties of knowing, for example, whether the participant meets the study's inclusion criteria? Which measures should be taken to protect the privacy and confidentiality of participants?
6. How should you decide what level and type of evidence you need to back a public health educational intervention? Should public health professionals always use science to validate educational interventions?

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