



Ethics, Practice, and Research in Public Health

Kathleen M. MacQueen, PhD, MPH, and James W. Buehler, MD

Ethical issues that can arise in distinguishing public health research from practice are highlighted in 2 case studies—an investigation of a tuberculosis outbreak in a prison and an evaluation of a program for improving HIV prevention services.

Regardless of whether such public health investigations represent research or practice, we see a need for ethics oversight procedures that reflect actual risks and enable timely responses to crises.

Such oversight should accommodate the perspectives of persons and communities affected by public health threats and by governmental responses to those threats; it should further recognize that

public health ethics is a distinct field combining bioethics, political philosophy, human rights, and law. (*Am J Public Health*. 2004;94:928–931)

DEFINING THE BOUNDARY

between public health research and practice remains a critical challenge within the evolving field of public health ethics.¹ To achieve their mission and meet their responsibilities, public health practitioners in government agencies systematically collect data for surveillance, disease control and prevention, and program development and evaluation. The objectives and methods of these practice-based activities often overlap with those of re-

searchers. As a result, it is sometimes difficult to determine which public health investigations constitute research, as defined and governed by federal human subjects regulations, and which represent public health practice, as authorized and governed primarily by state public health laws.

In January 2002, the National Center for HIV, STD, and TB Prevention (NCHSTP) at the Centers for Disease Control and Prevention (CDC) convened a 2-day workshop to examine a series of questions in public health ethics, drawing on case studies from NCHSTP projects and the expertise of a diverse group of invited participants (listed in our Acknowledgments). The workshop

was aimed at informing efforts to ensure the ethical conduct of NCHSTP projects and more broadly at contributing to ongoing national discussions concerning the ethical conduct of public health practice. In this article, we present 2 case studies discussed at the workshop that illustrate the ethical dilemmas inherent in distinguishing public health practice from research, and we consider their ethical implications for future efforts to redefine or clarify the research–practice boundary.

Within public health, the prevention and treatment of what are sometimes described as “social diseases” present special challenges. For example, people at highest risk for HIV infection,



sexually transmitted diseases, and tuberculosis (TB) are often socially, economically, or politically vulnerable. Stigma, poverty, and discrimination are interwoven with the conditions that affect both the transmission and the outcome of these infections. These vulnerabilities heighten the importance of ensuring that public health investigations and interventions are conducted ethically and that appropriate protections and oversight procedures are followed when public health agencies conduct research, including proper institutional review board oversight. If public health investigations are deemed not to represent research, then institutional review board procedures for protecting research participants do not come into play, and the interests of both directly affected individuals and the communities at large are protected under public health laws.

The 2 case studies presented in this article illustrate the importance of carefully distinguishing research from practice. The CDC bases its criteria for distinguishing research from “nonresearch” on federal human subjects regulations that include the intent of investigators as an essential part of the definition of *research* (see 45 CFR §46.102[d]).² Under these regulations, if the *primary* intent is to contribute to “generalizable” knowledge, then the project is deemed to represent research. For example, when investigators seek to address a public health question and conduct an investigation to generalize the findings to other settings, then the project would be considered research

and institutional review board oversight would be required. In contrast, if a project is done in the context of a public health agency’s role in preventing or controlling disease or promoting health and is aimed at a specific public health problem, then it is deemed to represent nonresearch or public health practice. Thus, it would not be considered within the purview of an institutional review board. For example, outbreak investigations, public health surveillance, or program evaluations conducted by public health agencies as part of their legally authorized mandate are usually considered nonresearch. In such nonresearch investigations, there may be secondary benefits when investigations yield insights of generalizable value that merit dissemination, but the research versus nonresearch determination would be unchanged because it is based on the primary intent.³ As noted by the National Bioethics Advisory Commission, drawing the boundary between these 2 activities, research versus practice, can be difficult.⁴

THE CASE STUDIES

Case Study 1: Tuberculosis in a Prison

A TB outbreak occurred in an HIV dormitory in a state prison.

Three hundred HIV-infected inmates were exposed to a fellow inmate with infectious TB, 30 developed TB, and a large number had documented conversion of their tuberculin skin tests, indicating extensive transmission of *Mycobacterium tuberculosis* within the facility. Because of the possi-

bility of skin test anergy in HIV-infected persons with *M tuberculosis* co-infection, the potential rapid progression from *M tuberculosis* infection to active disease in those with HIV, and the apparent high rate of transmission, all exposed inmates were considered infected with *M tuberculosis*, regardless of tuberculin skin test status. In total, 225 exposed inmates were treated for latent *M tuberculosis* infection.

Recommended options for the treatment of latent *M tuberculosis* infection included a 9-month course of isoniazid or a 2-month course of pyrazinamide and a rifamycin-class drug, such as rifampin. Because of the rate of inmate release (approximately 10 men per month) and their potential loss to medical care once released, the shorter course was chosen so that as many men as possible would be fully treated. The usual short-course regimen consists of rifampin and pyrazinamide. However, rifampin is contraindicated in persons taking certain anti-HIV medications. Therefore, rifabutin, another member of the rifamycin class that can be used in concert with the anti-HIV drugs, was substituted when necessary, in line with CDC/American Thoracic Society recommendations.

Even with rifabutin, interactions can occur with certain antiretroviral medications, requiring dose adjustments of rifabutin or the anti-HIV medications. Published recommendations for dose adjustments for some antiretroviral regimens existed; however, many men were taking combi-

nations of interacting antiretroviral medications for which there were no dose adjustment recommendations. To provide dose adjustments for such drug combinations, the physicians conducting the outbreak investigation consulted with experts in the area of HIV/TB drug interactions, and a consensus opinion was reached. It was also decided that serum rifabutin levels should be monitored so that the regimens could be adjusted as necessary to maintain safe and effective drug levels.

This intervention was determined by the CDC to not constitute research because the anti-TB regimen reflected existing recommendations and because the primary objective was to provide optimal medical care for individual inmates, despite the paucity of data for optimal dosages in this group of patients receiving complex anti-HIV therapy. The CDC medical officers felt a strong obligation to collect systematic data on the safety and effectiveness of the nonstandard treatment regimens that had been tailored to meet the specific needs and circumstances of each patient to assist in providing optimal care to the patients as well as in developing general guidance.

In this case, the question of whether data collection on the safety and effectiveness of nonstandard regimens represented research or practice hinged on whether the *primary intent* was to inform the management of the local response or to inform the conduct of similar interventions in the future or in other locations.³ Clearly, the activity had



dual utility. It was essential for evaluating and managing the ongoing care of affected inmates during the epidemic, which was deemed the primary intent, and it offered the potential for yielding new knowledge that could be applied in other settings. One result of this investigation was that it informed the revision of recommendations on dose adjustments for rifamycins when used in combination with complex antiretroviral regimens.⁵

If such data collection during outbreak investigations were deemed to represent human subjects research, it would be subject to the regulatory constraints imposed on research. In this case, the occurrence of the event in a prison meant that additional levels of review would have been required, even though the collection of safety and efficacy data posed no more than minimal risk (see 45 CFR §46, subpart C).² The CDC determination that such an activity did not constitute research allowed a more flexible and timely approach to data collection during the outbreak. Nonetheless, the criteria for distinguishing research from practice should not be based on expediency, as abuses can occur under the guise of urgency. Regardless of whether public health projects are deemed to represent research or practice, it is essential that they be conducted ethically, emphasizing the need for public health ethics review mechanisms that are responsive to crises and sensitive to levels of risk, especially when projects involve vulnerable groups such as the prisoners in this case.

Case Study 2: Evaluation of a Program for Improving HIV Prevention Services

NCHSTP funded 5 health departments to develop programs to provide HIV prevention and referral services to HIV-infected persons. The project objectives included increasing the proportion of HIV-infected persons who know their HIV serostatus as early as possible after infection, providing HIV prevention services to infected persons to reduce the risk of transmission to others, and assisting HIV-infected persons in accessing medical and other needed services. Grantees were encouraged to tailor their interventions to local circumstances, and the funding supported local evaluations of the effectiveness of the interventions in each site.

The grantees provided an array of services to a mix of target populations. The CDC's perspective was that the primary intent of the program was to provide services targeted to local community needs, and the primary intent of the evaluations was to improve those services. Thus, the project was deemed to represent nonresearch. However, it was anticipated that, as a secondary benefit, the projects also would provide information—or lessons learned—that might be useful elsewhere.

Although NCHSTP did not consider the evaluation component of the program to constitute research, some participating health departments differed in this assessment and sought institutional review board oversight. At sites where local institutional re-

view board review was invoked, implementation was delayed as long as 1 year. Confusion over whether the program constituted human subjects research resulted in the loss of formative pilot data at 1 site when a local institutional review board determined that appropriate approvals had not been in place.

Unlike clinical trials, in which risks may be substantial, the level of personal risk associated with participation in a program evaluation activity is generally minimal. In the case described here, the main risk associated with the evaluation was the potential loss of confidentiality or privacy if the project managers failed to exercise appropriate cautions, beyond whatever risk is inherent in providing HIV prevention services. This differential in potential risk compared with clinical trials does not negate the need for informed consent under most circumstances, but it should influence the framing of the informed consent process relative to that usually sought for clinical research.

When program evaluation is interpreted as constituting human subjects research, it may result in the imposition of an informed consent process that would not be expected by clients seeking prevention services. Many of the required elements of informed consent specified under 45 CFR §46.116 are superfluous for minimal risk program evaluations and could be waived. But in the current climate of institutional review board suspensions and research ethics lawsuits, institutional review boards may be reluctant

to waive these requirements even for minimal-risk research. As a consequence, informed consent for program evaluations deemed to be research may be unnecessarily complex and may inappropriately raise participants' concerns about the actual level of risk involved. An overly complex consent process also introduces the potential for a misperception among clients that the program of prevention services, and not just the evaluation component, constitutes research. Unlike the *therapeutic misconception* in clinical research, in which an experimental method is confused with treatment,⁶ this situation creates the potential opposite, a kind of *programmatic misconception*, in which a service may be confused with experimentation. Unintended consequences may be that potential clients decline services that could be of benefit to them and that the validity of the evaluation is undermined because of biased participation rates. This is an area in which empirical research on the informed consent process for minimal risk research is needed, along with better guidance for institutional review boards on the appropriate use of waivers and exemptions.

CONCLUSIONS

The voice of public health needs to be heard among the often-louder voices addressing ethics specific to clinical research. In this regard, action is needed on the National Bioethics Advisory Commission's



call to clarify the boundary between research and practice, to reform systems of ethical oversight so that reviews are commensurate with the levels of risk, and to appropriately situate the regulation of human subjects protections relative to public health more broadly.⁴ Ethics guidance is especially needed for the conduct of public health research and practice in crisis situations. Ongoing efforts to develop a public health code of ethics will help to ensure that public health practitioners are prepared to contribute to this dialogue from an informed and carefully reasoned perspective.⁷ Panel members at the NCHSTP workshop were generally reluctant to address the question of whether or how the boundary between research and practice could be more carefully defined under current regulations, instead favoring the development of alternative methods of oversight for public health investigations that are less dependent on the research versus practice distinction and more geared to assessing the level of risk and ensuring ethical conduct.

The criteria that the CDC uses to distinguish research from practice is legally derived from federal regulations and based on the “primary intent” of investigators working in governmental public health agencies.³ Although public health practitioners may be comfortable with this approach, given their familiarity with the roles and responsibilities of public health agencies, others may view this legal distinction with skepticism.⁸ In-

stead, they may be more apt to see the need for formal ethics oversight as based on the objectives, methods, population vulnerability, or risks of an investigation. However it is configured, oversight needs to be sensitive to the fact that public health is already heavily regulated through formal means as well as indirectly through the operation of political authority.⁹ The utilitarian underpinning of public health, evident in its mission to ensure the conditions for health for the community as a whole,¹⁰ needs to be clearly articulated and situated with reference to other values in our society. As highlighted by the case studies presented here, public health ethics is emerging as a distinct field combining bioethics, political philosophy, human rights, and law. ■

About the Authors

Kathleen M. MacQueen is with Family Health International, Durham, NC. James W. Buehler is with the Center for Public Health Preparedness and Research, Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, Ga. A substantial part of the work for this analysis was completed while both were with the National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Ga.

Requests for reprints should be sent to Kathleen M. MacQueen, PhD, MPH, Family Health International, PO Box 13950, Research Triangle Park, NC 27709 (e-mail: kmacqueen@fhi.org).

This article was accepted January 17, 2004.

Contributors

K.M. MacQueen conceived and led the development of the intellectual content for the workshop on public health ethics, practice, and research and led the writing of the article. J.W. Buehler contributed substantively to the develop-

ment of the workshop and to the writing and revision of the article.

Acknowledgments

CDC staff contributing to the development of the case studies included in this report were Philip Spradling, Renee Ridzon, Walt Senterfitt, and Sam Dooley. Expert panel members for the workshop were Ronald Bayer, School of Public Health, Columbia University, New York City, NY; Scott Burris, Temple University Beasley School of Law and Johns Hopkins School of Public Health, Philadelphia, Pa; Carlos Del Rio, AIDS International Training and Research Program, Emory University School of Medicine, Atlanta, Ga; Jean W. Pape, Centres GHEKIO, Institut National de Laboratoire, Port-au-Prince, Haiti; Michael Richardson, Bureau of Chronic Disease Control, District of Columbia Department of Health, Washington, DC; Marjorie Speers, Association for the Accreditation of Human Research Protection Programs, Inc, Washington, DC; James Thomas, School of Public Health, University of North Carolina, Chapel Hill, NC; Pauline Thomas, Office of AIDS Surveillance, New York City Department of Health, New York City, NY; Jon Ungphakorn, Bangkok, Thailand; Steve Wakefield, HIV Vaccine Trials Network, Fred Hutchinson Cancer Research Center, Seattle, Wash; Angela Wasunna, The Hastings Center, Garrison, NY; Charles Weijer, Department of Bioethics, Dalhousie University, Halifax, Nova Scotia; Jonathan Zenilman, Johns Hopkins University School of Medicine, Baltimore, Md.

Members of the CDC planning committee were Kathleen MacQueen (chair), James Buehler, Naomi Bock, James W. Carey, Danni Daniels, Dale Hu, Michael Iademarco, Kathleen Irwin, Marguerite Pappaioanou, Nathan Shaffer, Dixie Snider, and Katherine M. Stone. Additional CDC staff contributing to the development of case studies for the workshop were Patricia Sweeney, Denise Jamieson, Jami Leichter, Esther Sumartojo, Carolyn Guenther-Gray, Sandra Wright-Fofonah, Caroline Ryan, Paul Arguin, Andrew Vernon, and Janet Moore. Other contributors included Patricia Kissinger, Tulane University; and Christopher Whalen, Case Western Reserve University School of Medicine.

We gratefully acknowledge Thekla Holder, Janella Dodson, and Clara Johnson for their help in organizing the workshop.

Human Participant Protection

The development of this article did not involve human participants in research, and therefore no institutional review board approval was required or sought.

References

- Burris S, Buehler J, Lazzarini Z. Applying the common rule to public health agencies: questions and tentative answers about a public health exemption. *J Law Med Ethics*. 2003;31:638–653.
- 45 CFR §46.
- Guidelines for Defining Public Health Research and Public Health Non-Research*. Atlanta, Ga: Centers for Disease Control and Prevention; 1999.
- Report and Recommendations of the National Bioethics Advisory Commission*. Bethesda, Md: National Bioethics Advisory Commission; 2001. *Ethical and Policy Issues in Research Involving Human Participants*; Vol 1.
- Centers for Disease Control and Prevention. Notice to readers: updated guidelines for the use of rifabutin or rifampin for the treatment and prevention of tuberculosis among HIV-infected patients taking protease inhibitors or nonnucleoside reverse transcriptase inhibitors. *MMWR Morb Mortal Wkly Rep*. 2000;49:185.
- Appelbaum PS. Clarifying the ethics of clinical research: a path toward avoiding the therapeutic misconception. *Am J Bioethics*. 2002;2:22–23.
- Thomas JC, Sage M, Dillenberg J, Guillery VJ. A code of ethics for public health. *Am J Public Health*. 2002;92:1057–1059.
- Fairchild AL, Bayer R. Ethics and the conduct of public health surveillance. *Science*. 2004;303:631–632.
- Gostin LO. *Public Health Law: Power, Duty, Restraint*. Berkeley, Calif: University of California Press; 2000.
- Institute of Medicine. *The Future of Public Health*. Washington, DC: National Academy Press; 1988.