

Ethics and the Conduct of Public Health Surveillance

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Does the collection and analysis of data always constitute research and therefore require ethical oversight? This question has been raised in the context of quality assurance, program evaluation, oral history, and public health surveillance. In October 2003, for example, the Office for Human Research Protection (OHRP) in the Department for Health and Human Services (HHS) sought to resolve a longstanding controversy over whether those conducting oral history studies had to subject their work to institutional review board (IRB) review by a definitional slight of hand: "Oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by HHS regulations and do not need to be reviewed by an institutional review board" (1). The effort to distinguish radically between research and non-research-related data gathering was also reflected in a 2002 report by the World Bank designed to underscore the central importance of public health surveillance (2) (see quotation, right).

The efforts of the World Bank to draw a sharp distinction between research and surveillance were fundamentally rooted in economics, not ethics. The financial resources required to collect valid research data, it argued, were overwhelming. It was concern for human rights accompanying the AIDS epidemic within the U.S., and internationally, that fostered recent efforts on the part of the Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) to extend to surveillance ethical considerations heretofore restricted to research (3, 4). WHO endeavors represent a response to cumulative years of

"Surveillance is not research. Public health surveillance is essentially descriptive in nature. It describes the occurrence of injury or disease and its determinants in the population. It also leads to public health action. ... If we confuse surveillance with research, we may be motivated to collect large amounts of detailed data on each case. The burden of this approach is too great for the resources available. ..."

—World Bank Group (2)

experience working in different countries and settings, which made clear the need for a systematic response to the many ethical questions that arose when implementing HIV surveillance (5). Examination of the history leading to these undertakings will reveal, in our view, that tortured efforts based on definitions of these activities can only lead to inconsistencies.

In response to federal research protections promulgated in the 1970s, epidemiologists and ethicists began to discuss whether the principle of informed consent extended to the use of medical records and whether the insistence on individual consent would render epidemiological research virtually impossible (6–8). In 1981, HHS regulations for the protection of human subjects explicitly exempted epidemiological research involving already existing data from informed consent requirements, provided the risk to subjects was minimal, the research did not record data in a way that was individually identifiable, and the research could not otherwise be conducted (9). But the discussion did not extend to public health surveillance, which includes not only name-based reporting for conditions like TB and HIV, but also monitoring of food poisonings and blood lead levels.

The 1991 *International Guidelines for Ethical Review of Epidemiological Studies* issued by the Council for International Organizations of Medical Sciences (CIOMS) stated that although the vast majority of surveillance should be subject to approval by ethical review committees,

"[a]n exception is justified when epidemiologists must investigate outbreaks of acute communicable diseases. Then they must proceed without delay to identify and control health risks" (10).

The CIOMS guidelines did indicate there were still areas of uncertainty, such as "when both routine surveillance of cancer and original research on cancer are conducted by professional staff of a population-based cancer registry." To resolve difficult situations, CIOMS called for the guidance of ethical review committees (10).

In the early 1990s, in response to the charge that the CDC's blinded HIV seroprevalence studies among childbearing women constituted research conducted without informed consent, HHS's Office for Protection from Research Risks (OPRR) be-

gan to advance the notion that all surveillance was research and might require particular kinds of review (11). This stance alarmed the CDC as well as the Council of State and Territorial Epidemiologists (CSTE). According to the CDC, "The implications of calling public health surveillance research are broad and far reaching. ... If all surveillance activities were research, it might mean each local health department would have to form institutional review boards (IRBs)" (12). To the CDC, this was more than a bureaucratic consideration: if surveillance activities were designated research, the CDC feared that "people with TB could prevent their names from being reported to the health department or refuse to provide information about their contacts," (13) thus inhibiting disease prevention efforts.

A first set of CDC recommendations drafted in 1996 in response to an OPRR mandate made the case that public health surveillance is differentiated from pure research by intent: Whereas "[t]he intent of research is to contribute to or generate generalizable knowledge; the intent of public health practice is to conduct programs to prevent disease and injury and improve the health of communities" (14).

The CDC is rarely involved in the use of surveillance for public health interventions like contact tracing. However practical their research might be, it remained research requiring IRB review in the minds of CDC officials. As the CDC began to work with state health departments to refine their

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guidelines, the profoundly different ways in which the states and the federal government drew the boundary between research and public health surveillance became clear.

States, typically operating under statutes mandating departments of health to collect and act on individual-level morbidity data for the explicit purpose of controlling disease, tended to view most public health surveillance activities as practice (15). The New York City Department of Health, for example, maintained that “we derive knowledge that may protect the particular ‘victims’ before us. However, it may also be that it is too late to help the particular victims, but that the activity, or the information derived from it, becomes generalizable so as to protect the general population.” CSTE concurred, arguing that “we are rarely able to conduct an investigation that provides any medical benefit to those already infected” (15). For example, in the case of food-borne outbreak investigations, the “major benefit has been to others than those we identified and obtained data and specimens from” (16).

However, it was also the provenance of surveillance undertakings that determined whether an activity was research or practice for the states. CSTE explained that its members consistently collected data with an eye not only to the present but also to the future. By review of previous investigations of trichinosis outbreaks, for example, the Alaska state health department not only developed an early diagnostic test for the disease but also identified an animal species not previously known to harbor *Trichinella*, as well as a new subspecies of the disease-causing organism: “We do not view these activities as research” when conducted by the state; “if conducted by an entity other than the state public health agency,” however, “we would define it as research and require an outside researcher to obtain IRB approval” (16). By definition, then, what public health departments did was not research.

In the end, the CDC maintained that “activities can be viewed differently at federal and state levels” (17). That is, the same initiative might be designated research at the federal level and require IRB review and practice at the state level, requiring no ethical review. But even at the federal level, some health officials have found that they do not distinguish between research and practice consistently and that they sometimes face political pressure to define an activity as practice rather than research (18).

The recent efforts to provide definitional solutions to the question of research and public health practice involve twists and turns that inevitably produce results that are riddled with inconsistencies and that are conceptually unsatisfying. It is time to resolve the matter by acknowledging the

necessity of ethical review of public health surveillance activities at both state and federal levels, whether such activities fall neatly under the classification of research or practice or exist in a gray borderland.

Those involved in public health efforts appear increasingly ready to embrace ethical principles to govern the practice of public health surveillance (19). Not yet have they greeted with enthusiasm proposals to establish mechanisms to assure ethical review. In the history of research ethics, it was only when forums were created to assure consideration of the rights of subjects that guiding principles were given any meaningful force. The creation of institutionally based review procedures was not without conflict, as researchers resisted the notion that they themselves could not be the instruments of their own review (20). Although the establishment of bodies responsible for the review of the ethics of surveillance need not mirror the already extant IRBs, as has been proposed by some experts on human subjects research (21), it is clear that some form of explicit, systematic review is necessary.

As we take the first steps in trying to develop the ethics of public health surveillance, we must acknowledge that the guidelines governing research and clinical practice, so focused on protecting individuals, cannot be imported to the public health setting, where the first priority must be the protection of the communal welfare. In the context of public health, individuals may be compelled to do things or desist from doing things to protect or enhance the common good, even in the face of uncertainty (22). But the invocation to act, especially when the individual rights of privacy and liberty may be impinged, must be subject to limits. Ethical oversight in the public health setting must thus take into account the inevitable tension between the claims of individuals and those of the common good. In developing the ethics of public health surveillance and envisioning a mechanism for oversight, it would be wise to recognize that simple rules will never suffice: ethical sensitivity necessitates an open discussion of how the ethical trade-offs and tensions can be fairly resolved.

Reform may require changes in the legal and regulatory context within which surveillance occurs. That is, states might attempt to legally mandate surveillance practices that ethical oversight would deny, such as linkage of HIV registries with school registries. Alternatively, state law may forbid practices, such as the linkage of HIV and TB registries, which might be ethically demanded if they enhanced the capacity of a health department to fulfill its central mission. The public context of those changes should provide an occasion for a full and

transparent airing of the procedural and substantive issues involved. This will be especially challenging given the fact that the proposed changes are not driven by the kinds of scandal and abuse that spurred the ethical oversight of clinical research.

It is inappropriate to regard ethical oversight strictly as an impediment. In the context of public health surveillance, it can serve as a means of avoiding inadvertent breaches in confidentiality and stigma; it can help to ensure that the public understands that surveillance will occur and what purposes it serves; it can protect politically sensitive surveillance efforts. There is, after all, an ethical mandate to undertake surveillance that enhances the well-being of populations.

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