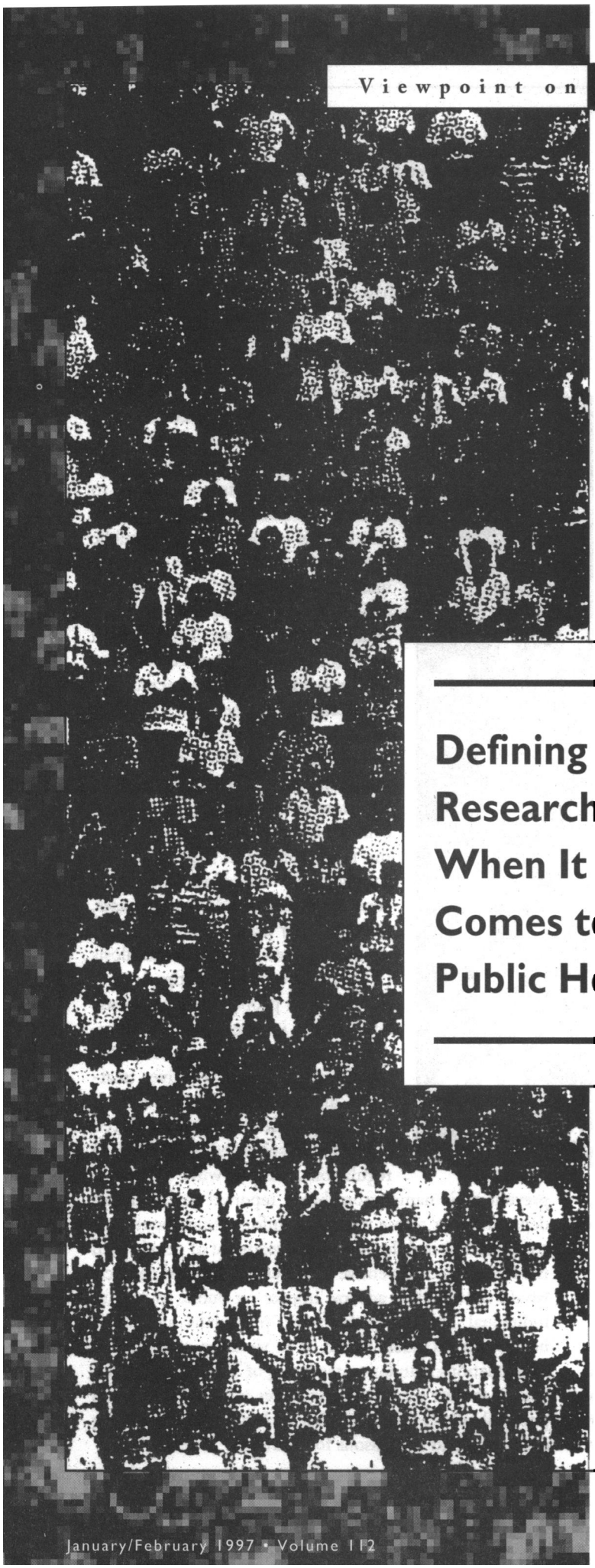

Defining Research When It Comes to Public Health

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Effective public health activities require a trusting relationship with society and ethical principles must be followed when conducting public health activities, especially research.[1] In this commentary, we describe the problems created for public health by the current definitions of research in the Code of Federal Regulations for the Protection of Human Research Subjects. (Title 45 CFR, Part 46, the Public Health Service Act of 1985, Public Law 99-158). We suggest an approach to determining when public health activities are or are not research. This distinction is critical to the timely and effective practice of public health because routine public health practice activities—like routine clinical practice activities—cannot be effectively carried out in a timely manner if they are subjected to the considerable administrative burdens associated with an Institutional Review Board (IRB) review. This determination is important to the Centers for Disease Control and Prevention (CDC) and its public health partners since much work in public health is accomplished by state and local health departments, schools of public health, community organizations, and other partners, often in collaboration with CDC.

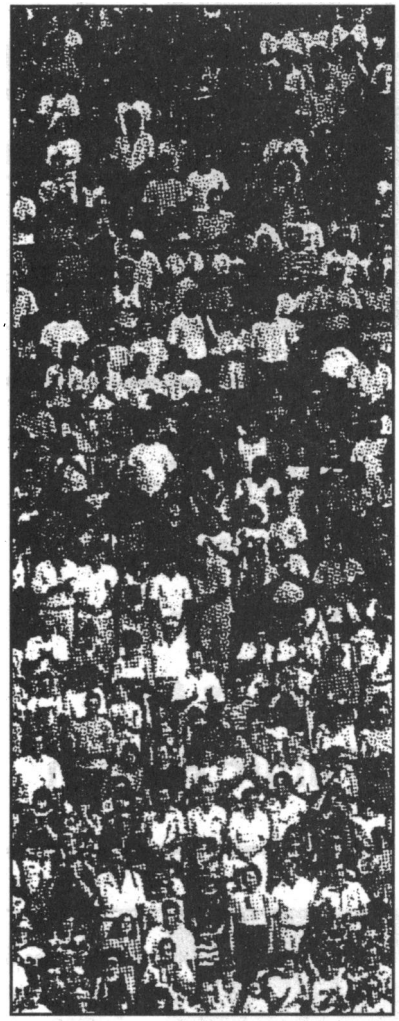
The Office for Protection from Research Risks (OPRR), National Institutes for Health, has the responsibility for developing and promulgating regulations on the protection of human research subjects for the Department of Health and Human Services (DHHS).[2]

CDC is the public health agency within DHHS that is committed to preventing diseases and injury and improving health for all Americans and to the protection of human subjects participating in public health research. CDC follows the Code of Federal Regulations for the Protection of Human Research Subjects (45 CFR 46). These regulations require that research projects involving human subjects be reviewed by an IRB, composed of scientists, non-scientists (such as lawyers, ethicists, clergy), and non-members of the institution

(community representatives) to ensure that the welfare and rights of human research subjects are protected. For this purpose, the regulations define research as

> a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.[2]

This broad definition of research appears to have been developed primarily within the context of clinical research sponsored by the National Institutes of Health and academic medical centers and is not easily interpreted in the context of public health.



Although some public health activities can clearly be classified as research or not research, others are not as clear-cut. In particular, as a result of a site visit by OPRR staff to CDC in 1993, CDC has identified three critical areas of public health practice for which confusion exists with regard to which activities are and are not research: *public health surveillance*, *emergency responses*, and *program evaluation*.

The difficulty public health practitioners and regulators have in classifying public health activities as research or nonresearch may stem from misunderstandings or disagreements about what constitutes routine public health practice, a lack of understanding of 45 CFR 46, or the fact that 45 CFR 46 does not directly address many public health activities. As we shall discuss in the following sections, we do not believe that the criteria of conducting "systematic investigations," generation of "generalizable knowledge," or the methodology used provide adequate basis for classification.

Research or Practice?

Public health surveillance. The concept of public health surveillance dates back many centuries[3] and was originally entirely concerned with protection of the populace against infectious diseases.[4] It was defined by Langmuir as the ongoing, systematic collection, analysis, and interpretation of outcome-specific data and the timely dissemination of these data to those responsible for preventing and controlling disease or injury.[5] More recently, a wide variety of health events—such as childhood lead poisoning, birth defects, injuries—and behavioral risk factors have been included in surveillance practice.[6] State and local health departments use surveillance information for control and prevention of disease. Most surveillance activities are mandated or authorized by state statute.[7]

Although the collection and analysis of surveillance data is systematic and may lead to generalizable knowledge, the primary goal is to monitor the health of a given population for the purpose of taking public health action in the community under surveillance. Therefore, we believe such activities are mandated or authorized by state legislation, in part because they recognize that routine surveillance is not research.[8] Furthermore, the benefits to society of public health surveillance are great and the risks to individuals are minimal, especially when strict Federal and state laws regarding privacy and confidentiality are followed.[9] Indeed, the failure of health departments to conduct such surveillance might be considered illegal and, in some cases, unethical. For example, effective prevention of the spread of tuberculosis (TB) involves an investigation to identify both people with the disease and people infected with *Mycobacterium tuberculosis* who do not have the disease in order to deliver treatment and preventive treatment. If these activities were considered research and subjected to 45 CFR 46 regulations, people with TB could prevent their names from being reported to the health department or refuse to provide information about their contacts. The inability to ensure treatment of people with the disease and preventive treatment of infected contacts would have a clear adverse impact on public as well as individual health. Furthermore, physicians and other health care providers would be in violation of state laws or regulations mandating reporting of TB.[7] Although we believe routine surveillance activities are not research, the public should be informed that such surveillance is being conducted and the reasons for doing so.

Emergency response. A second public health activity that poses a problem for the definition of research is emergency response to urgent public health threats.[10] Public health work is frequently done in urgent or emergency situations, usually because of a perceived imminent health threat to the population. The primary purpose of emergency responses is to determine the nature and magnitude of a public health problem in the community and to implement appropriate measures to address the problem.[11] It is often not possible to produce a meaningful protocol for the investigation of an emergency situation since, like criminal detective work, the path of the investigation unfolds sequentially; that is, the second step often is never obvious until the first is completed.

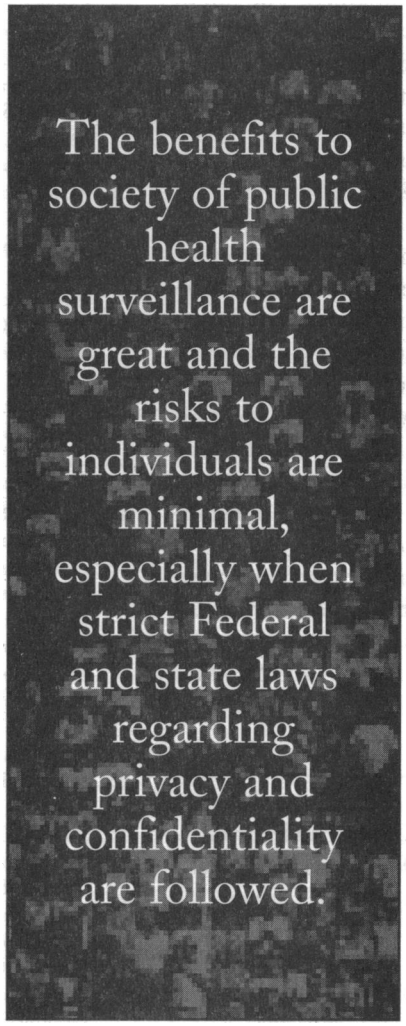
Requiring emergency responses to include the traditional development of a written protocol and IRB review is not practical nor would it be in the best interests of either the individuals or the community affected by the problem because the resulting delays in identifying the nature and magnitude of the community health problem and in instituting control measures to take such steps would frequently result in excess disease and death.

Even though we believe most emergency responses are not research and should not be subjected to the standard procedures of protocol development and IRB review, we do believe participants in emergency responses should be appropriately informed and should give their consent to participate. In many if not most situations "emergency response" consent forms could be developed and used routinely in emergency public health responses as they are in emergency clinical settings.[12] These consent forms could address such issues as the purpose and nature of the emergency response, whether participation is voluntary, how the data will be used, whether subsequent publication of the data might identify an individual participant,[13] and how any specimens obtained might be used, especially for DNA banking[14] or the development of new technology.

To control an outbreak, standard proven interventions would have to be utilized for the outbreak response to be considered nonresearch activity. Ongoing review of outbreak investigations by those supervising such investigations is necessary, however, since an emergency response could evolve into a research activity after the initial problem is brought under control.

Program evaluation. Program evaluation is a third area of concern. Program evaluation is the systematic application of scientific and statistical procedures to the measurement of a program's concept, design, implementation, and utility. The intent is to make comparisons based on those measurements and to use the resulting information to optimize program outcomes, efficiency, and quality management (adapted from two evaluations texts—references 15 and 16—and Wilma Johnson, CDC, personal communication, 1996). The evaluation of program performance is an integral part of routine public health practice, ensuring efficient allocation of resources.

The Council for International Organizations of Medical Sciences recognized the difficulty of distinguishing research from program evaluation but noted that "the defining attribute of research is that it is designed to produce new generalizable knowledge as distinct from knowledge pertaining to a particular individual or program."[17] They concluded not only that program evaluation proposals need not be submitted for ethical review but that "it could be considered poor practice and unethical not to undertake this type of quality assurance."[17]



Conclusion

The difficulties in classifying activities as research or nonresearch were recognized by the 1978 *Belmont Report*, which states:

> Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.[18]

Levine has pointed out that "activities of some epidemiologists may be difficult to classify as either research, program evaluation, or surveillance. The latter two categories, which refer to the practices of epidemiologists, need not ordinarily be reviewed by an IRB."[19]

From our perspective, the key word in the regulations' definition of research is *designed*. The major distinction between research and practice is in the *intent* for which the activity was designed. The 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. In some cases of public health practice, knowledge gained may be generalized, but this is not the primary intent of the activity.

Thus, the answer to the question of whether a particular public health activity is research can be determined by answering two questions: *(a)* What is the primary intended purpose of the activity? *(b)* Are standard, proven interventions being used? Using this approach, surveillance, emergency responses, and program evaluation activities would be classified as research only if they were primarily intended to develop generalizable knowledge or utilized nonstandard, unproven interventions, or both.

While we believe our proposal for resolving questions of what is and is not public health research is reasonable, we encourage the public health community and others to engage in a discussion of this issue through letters to the editor, meetings, Internet discussion groups, and other venues.

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