Public Health Practice or Research?

The philosophical framework DHSS uses to differentiate public health practice from research is as follows:

> "Public health practice is distinct from public health research.
>
> In clinical medicine, while screening procedures, diagnostic tests and evaluation of therapeutic interventions may be performed as part of research protocols, often they are not. It is the context in which these activities are performed, not the fact they are done, that allows for this determination. In an analogous way, in public health practice, the community is the patient and surveillance, specialized investigations, program operations, and program evaluation are the screening, diagnostic, and therapeutic tools. If these activities are conducted under the auspices of a government agency for the purpose of providing care to the community, they are public health practice. Reporting the results of these activities similarly is public health practice.
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> If these procedures are initially or subsequently modified for the purpose of advancing scientific knowledge rather than providing care to the community, those modifications fall outside the realm of public health practice.
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> Defining an activity as public health practice does not absolve the practitioner from attending to issues of patient consent, protection and confidentiality. Rather, it moves the focus for oversight of these activities from the IRB to the appropriate state legislative and administrative codes, rules and regulations governing these activities."

Adopted from June 8, 2001 memo from the Centers for Disease Control and Prevention, David W. Fleming, M.D., Deputy Director for Science and Public Health to Centers/Institute/Offices and CDC Partners.

I. General Guidance

The intent of research is to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity's participants. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected.

The intent of public health practice is to assure the conditions in which people can be healthy through public health efforts that are primarily aimed at preventing known or suspected injuries, diseases, or other conditions, or promoting the health of a particular community.

If the primary intent changes to generating generalizable knowledge, then the project becomes research.

Attributes of research:

- intent is to generate generalizable knowledge to improve public health practice
- benefits may or may not include study participants, but always extend beyond the study participants, usually to society
- data collected exceed requirements for care of the study participants or extend beyond the scope of the activity.

Attributes of non-research:

- activities that identify and control a health problem or improve a public health program or service
- intended benefits are primarily or exclusively for the participants, clients or community
- data collected are needed to assess and/or improve the program or service, the health of the participants or their community
- knowledge that is generated does not extend beyond the scope of the activity
- project activities are not experimental.

II. Specific Guidance

Evaluation

When the purpose of an evaluation is to test a *new, modified or previously untested intervention, service or program* to determine whether it is effective, the evaluation is research. *The systemic comparison of standard or non-standard interventions in an experimental-type design is research. In these cases, the knowledge gained is applicable beyond the individual, specific program.* Thus, the primary intent is to generate new knowledge or contribute to the knowledge to other sites or populations.

> Example: Evaluation of home visiting program to determine effectiveness in achieving healthy birth outcomes.

When the purpose is to *assess the success of an established program in achieving its objectives in a specific population* and the *information gained from the evaluation will be used to provide feedback to that program,* the evaluation, referred to as program evaluation, is non-research.

> Example: Survey of health provider practices that encourage breastfeeding.

If an evaluation is done to provide information on how to tailor a proven-effective intervention, service, or program in a specific setting or context the evaluation is not research.

> Example: WIC client satisfaction survey.

Evaluations of CDC's national programs, i.e. state health department programs that CDC funds and in which evaluation is one component, are not research. These evaluations are ongoing and involve generally the collection of minimal, standard data elements across all sites. The data are generally used at the local level as a management tool as well as at the national level for the same purpose.

Emergency Response

Most emergency responses tend to be non-research because these projects are undertaken to identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit those participants involved in the investigation or their communities.

An emergency response may have a research component if

- samples are stored for future use intended to generate generalizable knowledge, or
- additional analyses are conducted beyond those needed to solve the immediate health problem. For emergency responses, whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

Surveillance

The primary intent of public health surveillance systems is to prevent or control disease or injury in a defined population by producing information about the population from whom the data were collected. Subjects are rarely selected according to a design, rather, all cases are entered into the surveillance system. Hypothesis testing is not part of the system.

Surveillance systems may be research when they involve the collection and analysis of health-related data conducted either to generate knowledge that is applicable to other populations and settings than the ones from which the data were collected or to contribute to new knowledge about the health condition. The primary intent of these surveillance systems is to generate generalizable knowledge. Characteristics of systems that fit this category are: longitudinal data collection systems (e.g., follow-up surveys and registries) that allow for hypothesis testing; the scope of the data is broad and includes more information than occurrence of a health-related problem; analytic analyses can be conducted; and cases may be identified to be included in subsequent studies.

Adapted from CDC, Office of the Director of Science Coordination and Innovation, Guidelines for Defining Public Health Research and Public Health Non-Research, 1999.

Definitions

Emergency response
A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health program in the community and to implement appropriate measures to address the problem.

Evaluation
The systematic application of scientific and statistical procedures for measuring program conceptualization design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes.

Program evaluation
An essential organizational practice in public health using a systematic approach to improve and account for public health actions.

Surveillance
The ongoing, systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury.