

Public Health Practice vs. Research

A Report for Public Health
Practitioners Including Case Studies
and Guidance for Making
Distinctions

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Project Sponsor

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CSTE is the nation's leading professional association of public health epidemiologists in states and territories.

Principal Objectives

- n To assess legal and ethical environments underlying public health practice and human subjects research
- n To clarify existing definitions of public health practice and research
- n To provide meaningful cases on practice and research
- n To make distinctions between public health practice and research through foundational and enhanced guidance

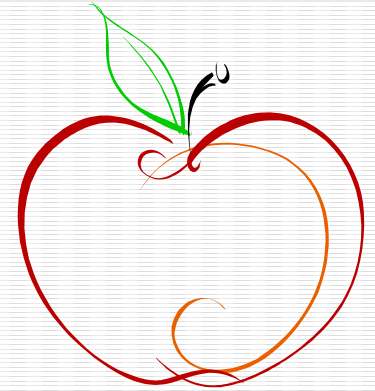
Major Assumptions

- n Acceptance of existing legal principles and environment
- n Focus on public health activities involving the acquisition, use, or disclosure of identifiable health data is part of the activity

Principle Justifications

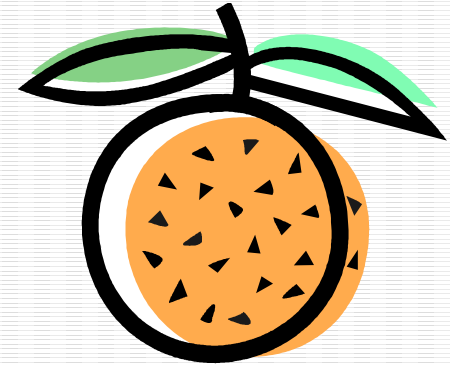
- n Key differences in the legal support for public health practice and research
- n Misclassification of activities leads to multiple complications
- n Varying standards for the disclosure of identifiable health data pursuant to the HIPAA Privacy Rule
- n Widespread variation in existing models and methods for making distinctions

Similarities



- n Public health practice and research may entail the collection and use of identifiable health information
- n They are conducted to protect or further individual or population health, but may also involve actual or potential risks to participants
- n They may be justified as laudable, communal activities that further the public good

In Reality



- n Public health practice is not human subjects research
- n They differ in:
 - n methodology
 - n objectives
 - n legal support
 - n ethical framework
 - n design

Public Health Practice

The collection and analysis of identifiable health data by a public health authority **for the purpose of protecting the health of a particular community**, where the **benefits and risks are primarily designed to accrue to the participating community**.

Public Health Research

The systematic collection and analysis of identifiable health data by a public health authority for the purpose of **generating knowledge** that may **benefit those beyond the participating community** who bear the risks of participation

Existing Approaches

- n Governmental – e.g., CDC
- n Private Sector – e.g., Johns Hopkins
- n Academic – e.g., Casarett D, Karlawish J, Sugarman J.
Determining when quality improvement initiatives should be considered research. *JAMA*. 2000;283:2275-80

Legal Frameworks



- n **Public Health Practice** – grounded in constitutionally-approved authority of government to protect the public's health, safety, and general welfare
- n **Public Health Research** – grounded in the principles of the federal Common Rule that focus on protecting individuals while pursuing knowledge through research

Legal Frameworks (cont.)

- n **HIPAA Privacy Rule** – provides different rules for the disclosure of PHI for public health and research purposes, but fails to provide meaningful guidance on how to distinguish these purposes

Guiding Principles

- n Essential Features (e.g. foundations) of Public Health Practice and Research
- n Rejected Criteria
- n Enhanced Guidelines
- n Checklist

Guiding Principles (cont.)

- n The analysis is geared toward providing:
 - n **Essential** guidance to resolve the **easy** cases, and
 - n Enhanced guidance to address hard cases.

Essential Features

n Foundations of Public Health Practice

- Involves specific legal authorization at the federal, state or local levels;
- Includes a corresponding governmental duty to perform the activity to protect the public's health;
- Involves direct performance or oversight by a governmental public health authority (or its authorized partner) and accountability to the public for its performance;

Essential Features

n Foundations of Public Health Practice

- May legitimately involve persons who did not specifically volunteer to participate (i.e., they did not provide informed consent);
- Supported by principles of public health ethics that focus on populations while respecting individual rights; and
- Broad range of activities may be conducted in the interests of protecting the public's health.

Essential Features

n Foundations of Human Subjects Research

- Involves living individuals or identifiable information about them;
- Involves identifiable data that are not publicly available or for which the individual has not already consented to their use for research purposes;
- Involves research subjects who voluntarily participate (or participate with the consent of their guardian), absent a waiver;

Essential Features

n Foundations of Human Subjects Research

- Supported by principles of bioethics that focus on individual interests while balancing the communal value of research; and
- Limited to specific, defined activities (e.g., the use of control groups), subject to exemptions.

Rejected Criteria

- n **Performance** – who is performing the activity?
- n **Publication** – are the results of the activity to be published?
- n **Urgency** – are exigencies driving the activity?
- n **Funding** – who is funding the activity?
- n **Data Collection Methods** – what are the techniques for acquiring identifiable data?

Enhanced Guidelines

- n General Legal Authority
- n Specific Intent
- n Relationships/Accountability
- n Participant Benefits
- n Interventions
- n Subject Selection

Enhanced Guidelines

- n **General Legal Authority** - the existence of general legal authorization supports a finding of public health practice, but does not conclusively lead to this end.

Enhanced Guidelines

- n **Specific Intent** - intent is a viable guideline, but requires refinement
- n The intent of **public health research** is *to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity's participants.*

Enhanced Guidelines

n Specific Intent -

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

Enhanced Guidelines

- n Relationships/Accountability –
 - n **Research** is dominated by relationships between an accountable PI and research subjects.
 - n **Public health practice** does not necessarily feature this direct relationship between individuals and public health practitioners.

Enhanced Guidelines

n Participant Benefits –

- n **Public health practice** is premised on providing some benefit to participants or the population of which they are members. Though these benefits may be limited due to failures in design or implementation, improving the health of participants and populations remains the objective.
- n **Public health research** does not assure benefits to participants. Correspondingly, whenever risks are imposed on participants to make the results generalizable beyond the participants, the activity should be classified as **public health research**.

Enhanced Guidelines

n Interventions

- n **Public health research** typically involves interventions that introduce something non-standard to the research subjects or their identifiable health data
- n **Public health practice**, however, is dominated by the use of standard, accepted, and proven interventions to address known or suspected public health problems

Enhanced Guidelines

n Subject Selection

- n **Public health research** - principles of justice typically require that subjects be randomly or fairly selected to reduce bias
- n **Public health practice** - participants are not typically selected like human research subjects. They choose or are required to participate in the interests of protecting the public's health

Checklist

- n Step 1 - Check Key Assumptions
- n Step 2 - Assess the Foundations of Public Health Practice
- n Step 3 - Assess the Foundations of Human Subject Research
- n Step 4 - Consider Enhanced Guidance
- n Step 5 - Conclusions

New Developments

- n In June 2006, the federal Office for Human Research Protections (OHRP) distributed a draft document, “Guidance on Research” to DHHS agencies for internal comment
- n This Guidance focuses on recommendations for making distinctions between research and non-research activities
- n OHRP continues to work toward finalizing its draft Guidance to seek public comment

OHRP Guidance - *What To Expect*

- n Part of the Guidance is likely to focus on the distinction between public health surveillance and research
- n Initial reactions from CDC are that OHRP's initial interpretations are narrower than many public health agencies.
- n OHRP may be inclined to view some public health surveillance activities as research, and not public health practice
- n Additional areas of concern may include:
 - n "Dual designations"
 - n Secondary uses of surveillance data
 - n Outbreak investigations

Conclusions

- n Distinguishing public health practice from research is not always easy (nor is it always hard)
- n Varying legal standards, methodologies, and frameworks complicate the distinctions
- n The public health community agrees that clarification is needed

Conclusions (cont.)

- n No guidance may resolve all cases under existing definitions, but these guidelines seek to clarify foundational and enhanced criteria
- n Whether performing **public health practice** or **public health research**, the objective is the same: *to perform public health activities that respect and protect the legal and ethical rights of individuals while improving or promoting the public's health.*

Additional Information

- n Hodge, JG, An enhanced approach to distinguishing public health practice and human subjects research. Journal of Law, Medicine, and Ethics 2005; 33:1: 125-141.
- n Kutkat, L, Hodge, JG, Jeffrey, T., Bonta, D. The HIPAA privacy rule: Reviewing the post-compliance impact on public health practice and research. Journal of Law, Medicine, and Ethics 2004; 31: 4 (Supp): 70-72.
- n Hodge, JG, Gostin, LO. Public Health Practice vs. Research: A Report for Public Health Practitioners Including Case Studies and Guidance. Council of State and Territorial Epidemiologists, May 17, 2004; 1-96, available at <http://www.publichealthlaw.net/Research/Affprojects.htm#CSTE>
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- n ***Thank You!***