

Public Health Research ...or is it practice?

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Emerging Issues in Research with Human Subjects
NIEHS, Research Triangle Park, NC
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Overview

- What is public health?
- Practice v. research considerations
- 2 case studies

“Public health is what we, as a society, do collectively to assure the conditions in which people can be healthy.”



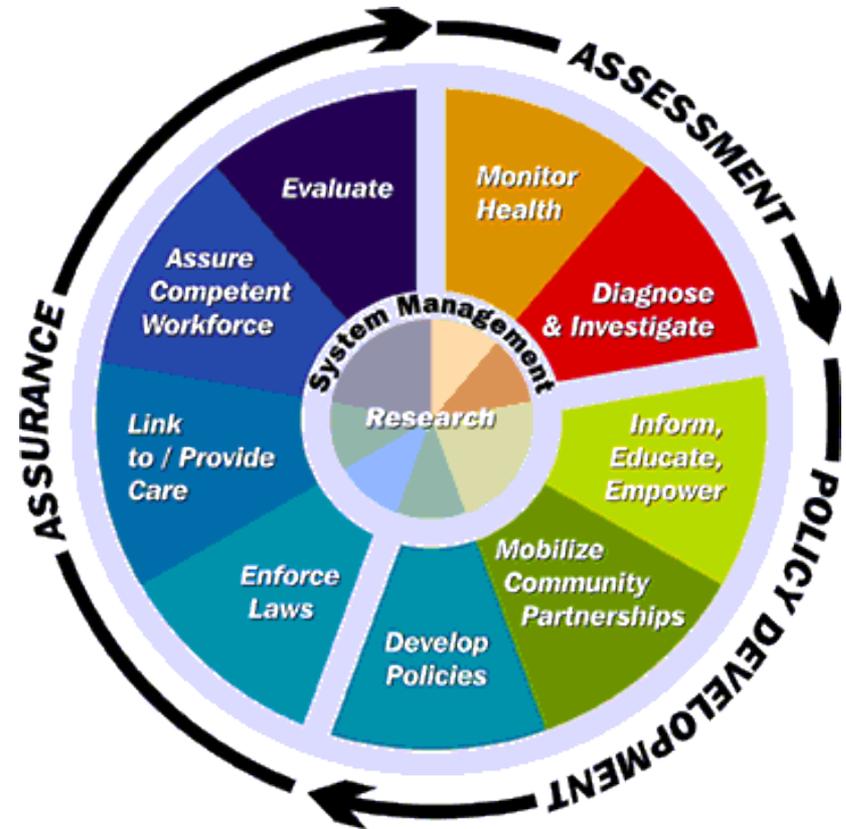
Hygieia, Greek goddess of health.
CDC, Atlanta, GA.

Institute of Medicine.
The Future of Public Health.
Washington, DC. National Academy Press, 1988, p. 1

Public Health

6 Purposes:

- Prevents epidemics and the spread of disease
- Protects against environmental hazards
- Prevents injuries
- Promotes and encourages healthy behaviors
- Responds to disasters and assists communities in recovery
- Assures the quality and accessibility of health services



10 Essential Services: The Practice of Public Health

Public Health Practice vs. Research

*A Report for Public Health Practitioners
Including Cases and Guidance for Making Distinctions*

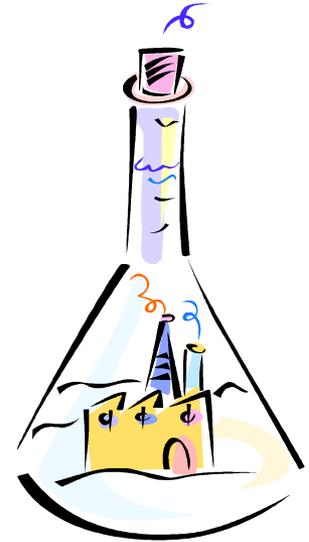
James G. Hodge, Jr., J.D., LL.M.
Lawrence O. Gostin, J.D., LL.D. (Hon)
With the CSTE Advisory Committee



Council of State and Territorial Epidemiologists
May 24, 2004

<http://www.cste.org/pdffiles/newpdffiles/CSTEPHResRptHodgeFinal.5.24.04.pdf>

Public health research



- Generates knowledge that benefits those beyond the participating community who bear the risks of participation
 - Explore hypotheses
 - Advance current knowledge
 - Contribute to the welfare of persons beyond the study itself
- IRBs are legally & ethically responsible for protections

Public health practice



- Collection & analysis of identifiable health data by a public health authority
- For purpose of protecting the health of a particular community
- Benefits & risks primarily designed to accrue to the participating community

“The responsibility to protect human participants in public health practice is addressed through federal, state, and local administrative and regulatory oversight and protections.”



CSTE Report on
Public Health Practice & Research

“No set of principles or checklist may completely distinguish between public health research and practice.”

CSTE Report on
Public Health Practice & Research

Criteria that don't work



- “Primary intent”
- Who is performing the activity
- Intent to publish
- Urgency
- Funding source
- Data collection methods

CSTE Report on
Public Health Practice & Research

Public health practice *Characteristics*



- Legal authorization for activity at federal, state, or local levels
- Governmental duty to perform activity
- Performance or oversight by governmental public health authority with public accountability
- Legitimate authority for non-voluntary participation
- Supported by principles of public health ethics that focus on populations while respecting the dignity and rights of individuals

CSTE Report on
Public Health Practice & Research

Consent vs. coercion



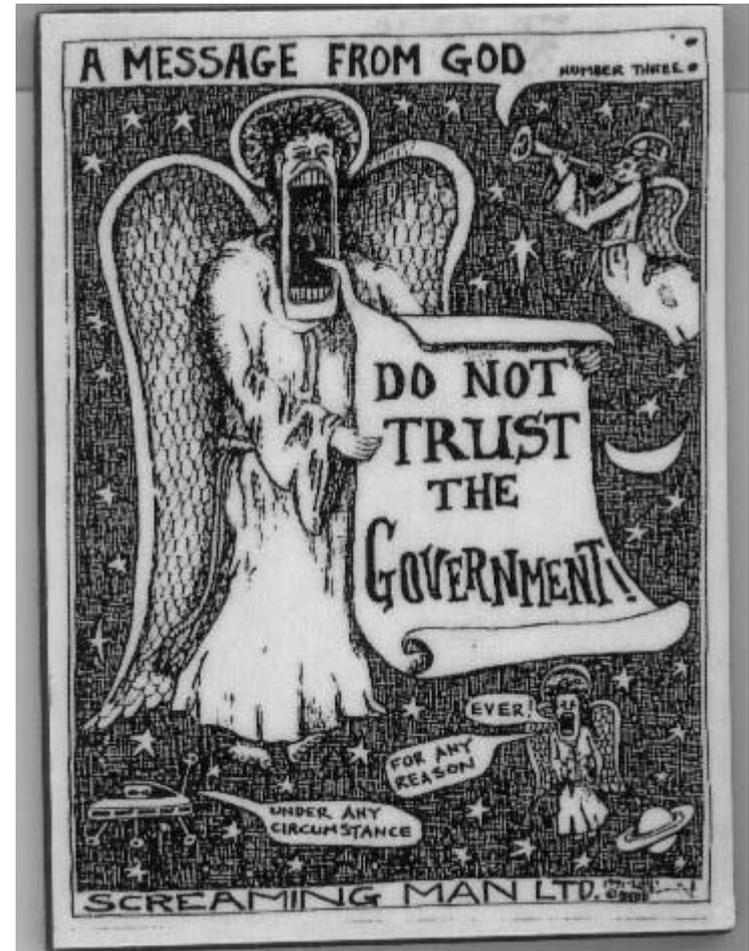
Does a coercive intervention truly reduce aggregate health risks?

What, if any, less intrusive interventions might reduce those risks as well or better?

Gostin, Lawrence O. *Public Health Law: Power, Duty, Restraint*. Berkeley, University of California Press, 2000

Imposing vs. expressing

- Imposing community involves mandating or compelling action through coercive measures.
- Expressing community involves taking steps to express solidarity with individuals, to protect their interests, and to gain their trust.



Childress JF et al. Public health ethics: mapping the terrain.
Journal of Law, Medicine & Ethics 2002;30:170-178.

Case Studies

- Tuberculosis in a prison
- Evaluation of a program for improving HIV prevention services
- Originally presented & discussed at a CDC workshop in January 2002

From: MacQueen KM, Buehler JW. Ethics, practice, and research in public health. *AJPH* 2004;94(6):928-931.

TB in a prison: Setting

- HIV dormitory in a state prison
- 300 HIV+ inmates exposed to infectious inmate
- 30 developed active TB
- “Large number” had documented conversion of TB skin tests
 - Anergy possible in others
- Potential for rapid progression from TB infection to active disease in HIV+’s
- CDC officially requested to assist in handling the outbreak

TB in a prison:

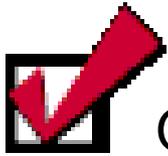
Treatment options for latent TB

- 9-month isoniazid or 2-month pyrazinamide + rifamycin-class drug (usually rifampin)
- Approx 10 inmates released per month
 - Potential loss to follow-up
 - 2-month course therefore optimal
- Rifampin contraindicated with some HIV medications
 - Substituted with rifabutin
 - Interactions with rifabutin occur but dose adjustment recommendations not known for all antiretrovirals in use at prison
 - Serum rifabutin levels monitored during outbreak response to maintain safe & effective levels

TB in a prison: Uses of data

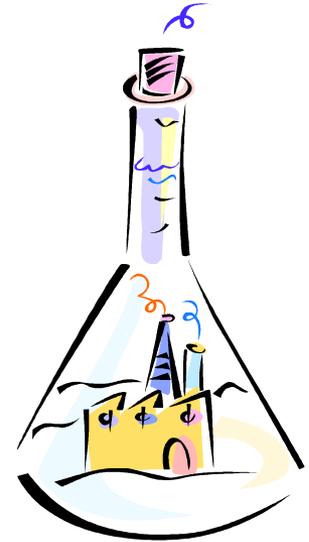
- Intervention constituted best practice
- Objective of monitoring was to provide optimal medical care for inmates
- Systematic safety & effectiveness data of nonstandard treatment regimes generated
 - Assisted in providing optimal care to inmates
 - Led to revisions of recommendations on dose adjustments for rifamycins used combination with ARTs
 - MMWR, Vol 49, No 09;185, 03/10/2000

TB in a prison: Public health research?

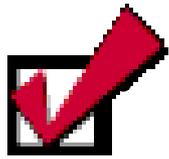


Generates knowledge that benefits those beyond the participating community who bear the risks of participation

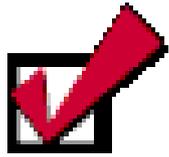
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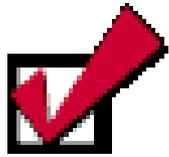
TB in a prison: Public health practice?



Collection & analysis of identifiable health data by a public health authority



For purpose of protecting the health of a particular community



Benefits & risks primarily designed to accrue to the participating community

HIV program evaluation: Background

- CDC funded 5 health departments to develop HIV prevention & referral services for HIV+'s
 - Health departments contracted with CBOs for provision of most services
- Grantees encouraged to tailor interventions to local circumstances
- Funding supported local evaluations of effectiveness of interventions
 - Technical assistance provided via project-wide contract with an evaluation center
 - Anticipated that evaluations could also generate lessons learned useful elsewhere

HIV program evaluation: Research/practice determinations

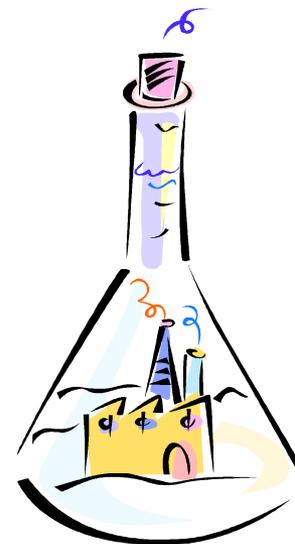
- CDC/NCHSTP determined evaluation component to be practice
- Some health departments determined evaluation was research
 - IRB review delayed implementation
 - at one site by a year
 - Formative pilot data lost at one site when IRB determined appropriate approvals were not in place

HIV program evaluation: Public health research?



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HIV program evaluation: Public health practice?



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Summary

- Public health practice shares many characteristics with research
 - E.g., systematic, data-driven, empirically-based
- Public health practice is authorized and governed by local, state, and federal laws
 - Oversight and accountability mechanisms in place
- Public health ethics includes an emphasis on communal good that is generally lacking in research ethics
- Public health research is still research
 - Human subjects protections may apply