

Distinguishing Public Health Practice and Research: a Review of Cases

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Introduction

Public health practice, including epidemiological investigations conducted under state public health authority, while apparently similar to research as defined in regulationⁱ, is justified by different legal authority and involves different but parallel systems of ethical oversight. Criteria developed by the Council of State and Territorial Epidemiologists in consultation with federal officials can be used to distinguish public health practice and research.ⁱⁱ The CSTE criteria build upon the recognition in the Belmont Report of a distinction between practice and research. In making the distinction between research and practice, the Belmont Report emphasized that practice “refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals” (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979) The CSTE criteria also included examples of how the criteria might apply to various case studies.ⁱⁱⁱ CSTE’s inclusion of case studies is not just illustrative. Cases provide detail necessary to appreciate the challenges involved in balancing competing principles. In addition, cases serve the role of precedents, which when used along with the CSTE criteria together provide publicly justifiable rationale for distinguishing public health practice and research. Cases serve to demarcate the moral landscape, identifying areas of clear agreement and and reasons agreement is not present on the boundaries of practice and research (Jonsen and Toulmin 1988). The cases presented here extend previous discussions of the CSTE criteria, providing further examples of how applying the CSTE criteria results in improved understanding of the boundaries between research and public health practice, and suggests that institutions can use records of case determinations to improve distinctions between public health practice and research. Recording determinations about cases made using the CSTE criteria can allow institutions to develop a taxonomy of cases, ranging from those clearly involving public health to those where public health agencies are clearly engaged in research as defined in federal regulation that requires review by an Institutional Review Board. Comparing novel cases against a case taxonomy of determinations based on the CSTE criteria can result in nuanced and consistent institutional decision-making, and can serve as a transparent and publicly accountable record of institutional decisions. After reviewing examples that are intended to serve as clear cases of public health practice, the analysis moves on to more complicated cases.^{iv} In the discussion below, parts of actual cases may have been combined, or details changed for purposes of illustration. Consequently, the cases below do not necessarily indicate actual determinations of a particular state health department, but rather indicate the sorts of things that should be considered when using the CSTE criteria to make distinctions between public health practice and research.

Applying the CSTE principles: Tuberculosis Case Reporting

Public health practice shares apparent similarities with research as defined in federal regulation as a “systematic investigation...designed...to contribute to generalizable knowledge” (45 CFR 46). Epidemiological investigations in public health are “systematic investigations,” the findings of which may be generalizable, and which may contribute to new knowledge. However, beyond these similarities, epidemiological investigations and other forms of public health practice are done for different purposes, and are justified by different authority than research.

Consider an example of disease reporting, which public health agencies are required to report by statute. In the case of tuberculosis, mandatory reporting is required by statutes at both the state and federal level in all jurisdictions in the United States (2007). Statues may provide broad authorization for disease reporting and public health investigations by public health officials. For example, Florida law directs the department of health to create mechanisms for “investigation and study of the incidence, causes, modes of propagation and transmission, and

means of prevention, control, and cure of diseases, illnesses, and hazards to human health.” (381.001(7) F.S.). In addition, state law may provide specific authorization concerning a disease, either in statute or administrative rule or both. Florida law, for example, specifies reporting and contact investigation for each case of tuberculosis (Chapter 392 F.S.). Even though public health officials conduct a systematic investigation involving interviews of persons who may have been exposed, the purpose of the activity is not research but rather to “investigate the source and spread of the disease and in order to require such person to submit to examination and treatment to cure.” (392.54(1) F.S.) A second of the criteria recommended by CSTE is whether the activity is necessary to fulfill a governmental duty. Investigations conducted as part of public health practice are the responsibility of government officials acting within statutory authority for the purpose of promoting health and preventing disease, rather than for the purpose of conducting research with human subjects. Reporting, monitoring, and followup of tuberculosis and other infectious disease are necessary to fulfill public health goals of disease control. A third criterion is whether there is direct performance or oversight by a governmental agency, or whether a state has contracted out a public health activity required under statute to a private vendor, such as a university or private company. When tuberculosis surveillance is operated by public health agencies operating under specific statutory direction, there is a clear justification for viewing the activity as public health practice. Government public health agencies depend on collaborations with universities and private contractors, and when university faculty are acting as agents of public health authorities, it is important to evaluate whether there is an expectation of using data for research also. A fourth criterion recommended by CSTE is to assess the intent of the activity. The authority of public health depends on statute, and statutes serve as a record of the Legislative intent. For example, in Florida the intent of the tuberculosis control is explicitly stated in statute, and is to “protect the citizenry from those few persons who pose a threat to the public” by identifying and minimizing the spread of disease through a coordinated public health response involving surveillance, case investigation and patient care. The purpose is one of public health practice rather than research to generate new knowledge or contribute to the body of research. The conduct of public health foreseeably results in the generation of new knowledge and generalizable findings--such as the identification of extensively drug resistant strains of tuberculosis (Shah et al. 2007). However, the primary purpose of public health is prevention and disease control rather than creation of new knowledge. Assessing the intent may depend on who is conducting the activity. For example, when public health responsibilities are contracted to university faculty by state agencies, where the faculty have incentives for dual-use (practice/program evaluation and research) then the question of intent becomes murky and additional scrutiny may be indicated. Another criterion is whether an activity is reasonably expected to produce benefits, in contrast to activities where the expectation is that the activity may contribute to generalizable knowledge, but may not result in direct benefits to participants. Public health practice is typically designed to result in direct benefits to the individual participant, as well as benefits to third parties. Reporting and case investigation and followup of tuberculosis holds out the prospect of direct benefit to the participant, and like other cases of infectious disease, holds out prospect of population benefit. Another criterion is whether the activity involves experimentation. Case investigation of tuberculosis involves standard methods, and does not involve the use of novel methods per se. Another criterion involves subject selection. In the case of disease reporting subjects are selected based on disease presentation; contact tracing and followup protects others who have been exposed and limits spread of disease. Tuberculosis reporting does not involve differential subject selection or randomization into different public health responses. This standard case of disease reporting illustrates how the CSTE criteria provide a detailed rationale that differentiates disease reporting that is part of the standard practice of public health from research designed to generate new knowledge and requiring IRB review.

As a second example of how the CSTE criteria can illustrate the differences between standard public health practice and research, consider an environmental health emergency response investigation as a result of wildfires in Florida and Georgia in the spring of 2007. A state health department was called upon to investigate impact of widespread forest fires on pulmonary health, including review of medical case records from hospital emergency departments and other medical records. As noted above, public health in Florida has broad statutory authorization that includes purview over “hazards to human health” and is not limited just infectious diseases (381.001(7) F.S.). A county health department director requested assistance from the state’s central public health authority, which tasked a CDC-assigned field agent to conduct an epidemiological investigation. The intent of the investigation was to determine the extent of hazard posed to respiratory health to aid in public health advisories and provide information to the public health agency’s response to the emergency. The epidemiological investigation and recommendations for public health advisories resulted in direct benefits to individuals, in the sense that individuals had information they could use to prevent or reduce exposure and respiratory hazards. Moreover, the activity involved population benefits, because data was needed to provide appropriate emergency response. The activity did not pose a risk of harm to individuals, and the health department had authority in statute to review medical records. The activity did not involve experimental methods, but was done using standard techniques of environmental epidemiology. The case illustrates how an outbreak investigation by environmental health constitutes public health practice by a state public health agency acting within its statutory authorization. This case, and the preceding case of tuberculosis reporting, are intended to represent clear cases of public health practice. The primary purpose of these activities involves promoting health and minimize disease, rather than contributing to the body of research. The activities have broad and specific authorization in state law. The activities are conducted by state public health agencies under state law, rather than under the system of federal regulatory oversight for research. As the particulars of the case change, working through the CSTE criteria helps clarify reasons an activity may resemble research rather than public health practice.

Applying the CSTE principles: Healthy Start Program Evaluation

Consider a case which initially presented as a quality improvement activity intended to produce results used for program evaluation and development. A county health department reported they wanted to work with a student to add several questions to a standard case intake form for the state’s Healthy Start Program, which delivers services to indigent families. The rationale given for adding the questions was to gather data to be used for program evaluation. The activity was supported by a County Health Department administrator, and the local Healthy Start coordinator, who were enthusiastic about the potential for better quality improvement data and for an opportunity to evaluate and improve the delivery of services from the local Healthy Start Program. Although the health department and Healthy Start program have authority to conduct program evaluations, the activity was to be conducted by a student at a university, rather than an employee of the health department. The student was interested in conducting the activity as a basis for dissertation research into resource management and program delivery. Should this activity be viewed as public health practice or research?

Public health programs have authority to add questions for purposes of program evaluation. In this case the activity is not conducted solely by a government agency acting under statutory authority; the additional questions are to be added in partnership with a student conducting dissertation research. The activity does not necessarily result in individual benefits to current program participants, but may hold out the prospect of benefit to future program participants were information to be learned that resulted in program changes. Although adding questions by itself is not an experimental activity, the analysis involved sophisticated tools not normally part of public health practice. Although the activity shares features of public health practice, it was

done with the intent and for the purpose of research by a student pursuing a doctoral degree who was not an employee of the health department. Based on these considerations, the activity includes both a public health practice component and a research component and IRB review was required. The Belmont Report notes that “Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects” (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). CDC in their discussion of program evaluation notes that some program evaluations would be considered public health practice, while others are systematic research investigations that are designed to create generalizable knowledge, and would require IRB review. Even though this was an activity that had components of public health practice, this case illustrates an example where an activity should be considered research requiring review by an IRB under federal regulations because it is not conducted by a public health official acting in the course of their official duties, but rather was conducted as part of a research project by a student pursuing a dissertation.

Applying the CSTE principles: Surveillance of Occupational Exposures to Pesticides

A state department of health participates in a federally-funded system for ongoing, systematic monitoring and investigation of occupational exposures to pesticides and other toxic chemicals, and related workplace illness and injuries. The activity involves surveillance of accidental exposures, but unlike some highly publicized research, is not an intervention study and does not involve systematically exposing participants to pesticides (Oleskey et al. 2004). The activity, ongoing for several years, involves collection and analysis of individual-level identifiable information about living individuals and decedents from existing sources such as the State's cancer registry, electronic hospitalization records, the Poison Control Information Network case files, vital statistics, and workers' compensation records. In addition, the activity may include collection of biological specimens for confirmatory testing. Data used in the system include demographic information, diagnostic codes, medical record review, lab test results, and other sources. Should the activity be viewed as public health practice or research?

There is broad statutory authorization for the activity. For example, the Legislative intent specified in statute is that the public health authority, “in carrying out the mission of public health, focus attention on identifying, assessing, and controlling... [and] monitoring and regulating factors in the environment which may impair the public's health...” (381.001(2) Florida Statutes). Healthcare providers are required to report to public health authorities any pesticide-related illness and injury as mandated law and administrative rule (381.0031 F.S., Chapter 64D-3, Florida Administrative Code). Surveillance of occupational exposures to pesticides and other toxic chemicals is a government duty (381.0031 F. S.). The activity is performed directly by a state public health authority, and is not contracted to a university researcher or private contractor. The activity is the responsibility of the state public health authority, which reports results to the Centers for Disease Control and Prevention. The enhanced surveillance activity is funded by the CDC. The intent of the activity at the state level is to monitor population health and conduct surveillance of occupational exposures to pesticides. The activity involves a reasonable expectation of success by creating improved systems for surveillance of occupational exposures to pesticides. Improved surveillance is a cornerstone of efforts to reduce occupational exposures. The activity does not involve experimental methods, but relies upon standard surveillance methods. Like other surveillance cases, the activity involves monitoring of cases, and does not involve differential subject selection or differential benefits to participants by virtue of participating in the surveillance system.

The activity had been ongoing and was supported with federal funds for several years and had not previously required IRB review. Whether or not related to reorganization at the federal level that placed the National Institute for Occupational Safety and Health (NIOSH) under the administration of the Centers for Disease Control and Prevention, there were apparently changes in how the Department of Health and Human Services viewed the status of grants to states (Kaiser 2004; Key et al. 2004). NIOSH formally requested a determination from the federal Office of Human Research Protections, which concluded that the activity constituted research with human subjects.^y Several States submitted their proposals to their local IRBs. The local IRBs determined that the proposed activities were public health practice, not research. NIOSH did not accept these determinations and NIOSH informed the States that if they did not obtain IRB approval, their proposals would be ruled unresponsive and not considered for funding.

This case is intriguing for several reasons. NIOSH rejected states' attempts to argue that, although an activity may be research at the federal level, it can still be considered public health practice at the state level. In this case there was justification for determining the activity public health practice at the state level because it was conducted under specific statutory authority by a public health authority, and did not involve services contracted out to a research university. In addition, the activity involves a reasonable expectation of success, and standard surveillance,

One possible rationale the case may have been determined to be research by federal officials is based on funding. Federal oversight of public health is grounded in limited powers delegated to the federal government by states, and based on contractual relationships between the federal government and states, whereby the federal government sets conditions on activities based on the terms of the funding contract (Grad 2004). Federal officials can attach a requirement of IRB review as a condition of a contracts awarded to states. The justification for states complying would have nothing to do with public health practice per se, but would be a function of a decision to accept the terms of the contract. Such an argument may or may not be consistent with federal regulations that require institutions to determine when activities constitute human subjects research. Institutions are responsible for making sure that all research in which the institution is engaged is reviewed by an IRB. The fact that NIOSH asserted that institutions had to review the activity using an IRB does not appear consistent with requirements that *institutions* make this determination. State public health authorities, as a condition of their FederalWide Assurance, are required to make determinations of when activities involve research with human subjects. Federal funding agencies stipulated the activity involved research, which appears inconsistent with requirements that institutions make this determination.

The concern over inclusion of stipulations that state and local public health authorities conduct IRB review as a condition of funding is that there may be situations where requirements of oversight under federal regulation conflict with a state's obligations under state public health statutes. Were a state to accept federal funding for the activity, given the determination that the activity requires IRB review, the state could be placed in a difficult situation if an IRB were to determine for whatever reasons the activity could not proceed. Under federal regulations for research, if an IRB determines it is not possible to certify that the criteria for review of research involving human subjects are met by an activity, then the activity may not proceed. There is, then, the potential for conflict between the requirements of state law, which in the case of Florida for example, requires the state to conduct surveillance of pesticide exposures and injuries, and the requirements that an activity be approved by an IRB. The potential for conflict between a state's requirement under statute and federal requirements for IRB review illustrate the unintended consequences of not appreciating the different authority, purposes and rationale for public health and research under law and regulation, and serve to underscore the importance of relying upon the CSTE criteria to help clarify the distinction. This case, and that of

PRAMS surveillance represent two cases where federal determinations diverge from the CSTE guidance.

As these cases illustrate, CSTE criteria can be used to provide publicly-defensible rationales for determining whether an activity is public health practice or research. There are limitations to reliance solely on principles, a point suggested by the fact that CSTE presented case analyses as well as principles. A significant limitation of the current regulatory environment is the lack of a publicly accountable transparent and non-punitive system of case review by institutions.

Developing a repository of borderline cases and case determinations

State public health authorities should to develop capacity to assess, analyze and distinguish between public health practice and research using the CSTE criteria. In addition, state public health authorities should develop mechanisms to identify borderline cases and tracking determinations and the rationale used for making determinations in specific cases. The goal of such a system should be sharing best practices and the development of consensus among public health officials as to the boundaries of practice and research. However, developing such a system would not be without its challenges, some of which turn on knowing more about the current ways state public health authorities make these decisions, and some of which turn on developing ways of sharing information and case determinations that meet the needs of institutions.

More needs to be learned about the current state of oversight of public health research and state of current mechanisms for distinguishing public health practice from research. Public health authorities currently are required to have a mechanism for reviewing research that falls under federal regulation using an IRB, either an internal IRB or one at another institution, such as a university. University IRBs are faced with similar questions of identifying research and distinguishing research from medical practice or quality improvement. It is important to learn more about the experience of public health agencies who rely upon university IRBs to learn whether the university IRBs make attempts to distinguish between public health practice and research, or whether they “default” to reviewing everything presented to them as research and the extent of familiarity with state public health law at the universities public health agencies are relying upon.

State public health authorities need to consider who in the institution should make determinations of whether an activity is public health practice or research. State epidemiologists may be in the best position to assess public health practice, both in terms of experience and in terms of an ability to network with other states to compare best practices. However, because they have other responsibilities, they are likely to not have sufficient time to read through each and every case that comes along and make a determination. It may be possible for state public health authorities to rely upon a more decentralized structure, whereby medical epidemiologists in program areas have responsibility for assessing and identifying public health practice. A decentralized model has an advantage of helping to develop capacity throughout an organization and expand the number of people with the knowledge and skills to assess public health practice. However, much like any decentralized system, such an approach would need to address ways of assuring consistency and knowledge sharing across program areas, especially given the fact that a decentralized system will face higher expected staff turnover and higher training costs. Federal regulations governing research require that institutions make determinations, not individual researchers. State public health authorities that have internal Institutional Review Boards may want to place this responsibility within that program, preferably within the responsibility of the director. IRB Chairs should have expertise sufficient to make these determinations, but Chairs are a role named under federal regulation as part of the research oversight function, and it may be preferable to locate the responsibility

outside institutional roles responsible for fulfilling the institution's IRB mission.

There have been calls for a committee-based oversight structure for public health ethics, though there is consensus does not exist about whether this need has been demonstrated, or whether existing oversight of public health activities is sufficient (Fairchild and Bayer 2004; Middaugh et al. 2004) Even if the need were demonstrated to exist, state public health authorities in many jurisdictions are executive agencies whose authority is limited to that granted in statute, and so likely statutory authorization would be necessary to implement a committee-based structure.

Regardless of where the responsibility is located, state public health authorities may want to adopt training such as the Collaborative IRB Training Initiative (CITI Program) or Public Responsibility in Medicine and Research's training, where they can be adapted to the institution's needs. Currently the Public Health Leadership Institute does not provide specialized training, but this may be an area of workforce development and capacity building for which PHLI may be well-suited. Training should be targeted at professional epidemiology staff, whose work in public health places them on the border between practice and research.

Perhaps more challenging is developing a system that would enable sharing of best practices yet meet needs of institutions. It seems safe to say that there is currently a lack of consensus among public health professionals and federal regulators about the boundaries of public health practice and research. It would be in the interest of public health for institutions to share borderline cases and the rationale used for making non-research determinations about specific cases. However, doing so may place institutions at risk of increased scrutiny by federal regulators in the absence of commitment to dialogue by federal officials about issues where states may have substantive disagreement. One potential avenue would be for states to submit "de-identified" cases to a professional association such as the Council of State and Territorial Epidemiologists, which could possibly serve as a clearing house for borderline cases and which could use these cases to help develop professional consensus beyond existing efforts such as the influential working group report (Hodge and Gostin 2004) Such efforts should be welcomed; the development of the federal regulations occurred in response to a context of a perceived lack of oversight of by professional associations, and such an effort would continue CSTE's existing efforts to provide education and develop consensus about public health practice. Federal officials should welcome continued and ongoing efforts by public health professional associations, because they have done so in other areas. There is precedent for relying on professional associations for regulation of professional practice and research-like activities. In the case of oral history, federal regulators have been willing to defer to professional associations in recognizing that oral history activities in general do not constitute research. The CSTE working group report represents a similar attempt by professional association to engage with federal regulators in the development of a shared understanding of the boundaries of public health practice and research.

Conclusion

The absence of review by an IRB does not imply lack of oversight or lack of accountability. Research requiring oversight and federal regulations and public health practice conducted under state law by public health officials represent parallel but separate systems of oversight and accountability. The CSTE criteria illustrate factors that state public health authorities should consider when making determinations of whether an activity is public health practice or research. State public health authorities should develop repositories of borderline cases and case determinations made using the CSTE criteria to aid in making consistent distinctions between research and public health practice. Because of the importance of protecting the integrity of both systems, state public health authorities should provide training in research ethics and help staff develop expertise to assess, analyze and distinguish between public health

practice and research, and to articulate the legal differences between these different systems of oversight over public health activities.

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- i Research as defined in regulation means a “systematic investigation...designed to contribute to generalizable knowledge.” (45 CFR 46)
- ii The Council of State and Territorial Epidemiologists guidance is found in: Hodge, James, and Larry O. Gostin. 2004. Public Health Practice Vs. Research: A Report for Public Health Practitioners Including Case Studies and Guidance. Currently, the federal Office of Human Research Protections is currently (June 2007) developing proposed guidance on distinctions between research as defined in federal regulation requiring review by an Institutional Review Board under regulation, and a range of other activities such as medical chart review, case reports, public health practice and quality improvement activities.
- iii Critics assert that criteria to distinguish these activities result in “Alice-in-Wonderland-type through the looking glass conceptual contortions,” and imply the criteria are incomplete, or inconsistent, or otherwise fail to uniquely distinguish all cases.<see amy fairchild> Even if an attempt to craft a series of principles to justify a distinction can be found wanting, this is not sufficient to establish the distinction is without merit. Rather, the challenge of articulating principles to distinguish cases may reflect the underlying complexity of the practices, and the need for far more nuanced tools for distinguishing cases.
- iv Other areas of law, ethics and professional practice incorporate systems of adjudication and case law that over time results in the development of settled precedent. A limitation of the current federal regulatory oversight of research in the United States is that it does not include a system of case adjudication, appeals, and the development of precedents.
- v NIOSH (August 2005): although “some state-affiliated surveillance programs claim exemption from [IRB review / 45 CFR 46] because of state regulations and some cited CDC practices related to “routine public health practice”...OHRP determined that NIOSH research

grant awards require IRB review”