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Ethical Dilemmas in Publishing a Journal of Public Health Practice

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Publication is a gateway where an ethics checkpoint can be established. Institutional Review Boards (IRB) and Ethics Review Committees at academic institutions and medical facilities grant prior approval for and then monitor biomedical and behavioral research involving human subjects, primarily to minimize or avoid ethical problems. The end product of research is generally the dissemination of findings in a professional journal. Journals, then, can provide additional ethical safeguards after the research has been completed (Creinin and Shields, 2005). Editors and editorial boards of most scientific and professional journals have been willing to assume the role of voluntary, that is, non-governmental gatekeeper and enforcer of federal guidelines for the protection of human subjects.

While publishing both research and practice findings is essential to improving the health and well-being of individuals and society, human subjects participating in both health and behavioral research and public health practice have a right to privacy that should not be breached. Public health authorities have a long history of respecting the confidentiality of public health records, data, and other information. The majority of states as well as the federal government have laws that govern the use of, and serve to protect, identifiable information collected by public health authorities (MMWR, 2003) .

The International Committee of Medical Journal Editors Uniform Requirements for Manuscripts states that:

Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published. Identifying details should be omitted if they are not essential. Complete anonymity is difficult to achieve, however, and informed consent should be obtained if there is any doubt (ICMJE, 2006).

Many journals perform this ethics check by requiring authors to either affirm or submit documentation that their project received prior review and approval from an Institutional Review Board or Ethics Review Committee. This ethics check, however, varies greatly from journal to journal and by research area. While over 500 journals have adopted the Uniform Requirements, Amdur and Biddle (1997) found that less than half (47%) required IRB approval for studies involving human subjects as a prerequisite for publication. In addition, the journal *Pediatrics* reported that 97 percent of randomized, clinical trials claimed IRB approval, compared with 70

percent of prospective cohort studies, 37 percent of retrospective cohort studies, but only 9 percent of large dataset analyses (Bauchner, 2002).

These findings reflect the distinction between research and practice. The *Belmont Report*, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission, 1979) identified the three ethical principles of respect for persons, beneficence and justice, and defined the boundary between biomedical and behavioral research and the accepted and routine practice of medicine. Practice was defined as interventions designed solely to improve the well being of an individual patient or client while research was to test a hypothesis and contribute to generalizable knowledge. The *Belmont Report* held that if any element of research is present in an activity, that activity should undergo review for the protection of human subjects. These recommendations were incorporated into federal regulations known as the *Common Rule (45 CFR 46)*.

It is quite clear that most existing medical and research codes fail to take public health into account (Kass, 2001). The National Commission did not have any members directly involved in public health, and neither the *Belmont Report* (National Commission, 1979) or Levine's (1978a, 1978b) two commissioned background papers mention public health or epidemiology. This placed public health in a sort of ethical limbo. Two issues need to be addressed: first, how to distinguish public health research, which requires IRB approval, from public health practice which does not always require IRB approval, and second, how to reconcile regulations designed to protect individuals with the need to protect communities and populations.

DISTINGUISHING PUBLIC HEALTH RESEARCH AND PRACTICE

Defining the boundary between public health research and practice is problematic (Burris, Buehler and Lazarini, 2003). In his background paper for the *Belmont Report*, Levine (1978a) briefly explored the boundaries between the research activities and professional practices of social scientists. Epidemiology is not mentioned, and Levine (1978a:23), almost as an afterthought, wonders whether it is to society that we ought to offer the opportunity to give informed consent. State authorization is surely the equivalent of societal informed consent, and society has created, tasked and financed public health research and practice.

Public health practice is authorized and governed primarily by state rather than federal laws that require health departments and agencies to systematically collect data for surveillance, disease control and prevention, and program development and evaluation (MacQueen and Buehler, 2004). Since these practice-based activities are also carried out by researchers, it may be difficult to determine which public health activities constitute research and which represent public health practice, or when practice activities evolve into research activities.

In January 1999, the Director, Division of Human Subject Protections, Office for Protection from Research Risks (OPRR) issued a memo (Puglisi, 1999) requiring each institution engaged in human subjects research to provide OPRR with a satisfactory Assurance to comply with the federal regulations at *45 CFR 46.101(b)*. In response, the Centers for Disease Control and Prevention prepared *Defining Public Health Research and Public Health Non-Research* (Speers, 1999). This document stated that the federal regulations or *Common Rule (45 CFR 46)* did not directly address many public health activities and did not recognize the statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers. This meant that the human subject protections applicable for activities occurring at the boundary between public health research and non-research (practice) were not readily interpretable from the regulations.

The document claimed that CDC could decide what research was and whether the Federal regulations were applicable, although final determination ultimately rested with the Office for Protection from Research Risks (OPRR). The CDC wanted to provide guidance to state and local health departments and other institutions that conduct research with CDC staff or were recipients of CDC funds. But it did not describe how this collaboration would be achieved or how the ethical guidelines would be adopted or even recognized by the IRBs of various CDC partners including universities and health/hospital systems.

The CDC document (Speers, 1999) asserted that what distinguished research from non-research (practice) was the primary intent or, in the words of the regulations, the design of the activity. Levine (1978a) first identified the importance of intent when he recognized that clinical research involved a set of complex activities some of which may be administered for therapeutic purposes, while other procedures were undertaken solely to answer a scientific question. Weijer (2001) explained that therapeutic procedures, that is medical practices, are justified by their potential to benefit the subject, while non-therapeutic procedures, that is research, are justified by their potential to generate knowledge. He agreed that the difference in intent is what is morally relevant.

But the CDC (Speers, 1999) then goes on to assert that the primary intent of non-research (practice) in public health is to protect the health of the population through such activities as disease surveillance, prevention, or control. Non-research activities systematically gather information designed to benefit a specific community, although occasionally they may provide unintended generalizable benefits to others by, for example, preventing the spread of a disease to other vulnerable populations (MMWR, 2003). Knowledge generated by such non-research activities does not extend beyond the scope of the activity.

Furthermore, CDC argued that even if a non-research project may produce generalizable knowledge after the project is completed, the initial non-research classification remains in force. But if subsequent analysis is undertaken that involves gathering or using identifiable private information to generate or contribute to generalizable knowledge, then the analysis constitutes human subjects research and requires IRB review. Finally, if a project includes multiple components and at least one of those components is designed to generate generalizable knowledge, then the entire project is classified as research unless the components are separable.

The CDC (Speers, 1999) also stated that publication or dissemination of findings do not necessarily differentiate research from non-research. From an ethics perspective, information collected through public health practice falls under the HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) which expressly permits certain information to be shared for specified public health purposes. For example, some information may be disclosed without individual authorization to a public health authority legally authorized to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability [45 CFR § 164.512(b)]. Further, the Privacy Rule permits covered entities to make disclosures that are legally required for public health purposes (MMWR, 2003). This differs substantially from the Institute of Medicine's (IOM, 2000) research focused approach to publication *Protecting Data Privacy in Health Services Research*, which suggested that if the intent or possible intent of the investigator is publication, then the project represents research and IRB approval is necessary.

Table 1: CDC Distinctions between Research and Practice (Non-Research)

	Research	Practice (Non-Research)
Definition	“...systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (ref. 45 CFR 46)	May use scientific methods to identify and control a health problem with benefits for the study participants or their communities.
Primary Intent	To generate new or generalizable knowledge (information that can be applied in other settings)	To benefit study participants or the communities from which they come
Methodology	Scientific principles and methods used. Hypothesis testing/generating Knowledge is generalizable	Scientific principles and methods may be used. Hypothesis testing/generating Knowledge may be generalizable
Examples		
Surveillance Projects	Scope of data is broad Analytic analyses Hypothesis testing Subsequent studies using cases	Regular, ongoing collection and analyses to measure occurrence of health problem (disease registry) Scope of data is health condition or disease, demographics, and known risk factors Invokes public health mechanisms to prevent or control disease or injury
Emergency Response	Samples stored for future use Additional analyses performed beyond immediate problem Investigational drugs tested	Solves an immediate health problem No testing of methods or interventions
Program Evaluation	Test an intervention Systematic comparison of standard and nonstandard interventions	Assess success of established intervention Evaluation information used for feedback into program (management)

Defining Public Health Research and Public Health Non-Research (Speers, 1999) contained a table that compared research and practice (or non-research) in terms of definition,

primary intent, and methodology, as well as providing examples of each for surveillance, emergency response and program evaluation. As already mentioned, a key difference is in intent and not in methods used. The main distinction appears to be that research involves additional data collection using cases (surveillance) or investigational drug testing (emergency response) or systematic comparisons of standard and non standard interventions (program evaluation) that goes beyond the regular, routine collection and analyses of data related to known risk factors or the immediate health problem or program under study.

PROTECTING COMMUNITIES AND POPULATIONS

Four basic principles—autonomy, dignity, integrity, and vulnerability—are offered as a simple, accessible, and culturally neutral approach to thinking about ethical issues in health care (Gillon, 1994). But Levine (1982) asked whether such principles are universal valid standards or if some degree of cultural relativism should be accepted, permitting each culture to decide how it should show respect for its own members. Weijer (1999) concluded that the only way to take community into account was to propose a new ethical principle which he called ‘Respect for Communities.’ This principle acknowledges that the community has rights and interests separate from those granted to individual community members.

Weijer and Miller (2004) argued that people generally identify themselves as members of one or more communities that help form their values and self-understanding. Furthermore, many communities possess the authority to make binding decisions on behalf of individual members and can legitimately curtail individual liberty and free will in certain situations. They also recognized that the primacy of the individual versus the community varies from one community and culture to another. In particular, individual rights and liberties are held in high esteem in western liberal nations, but that is not the case in many non-Western nations and in certain groups such as Native American communities.

In a discussion of ethics and public health, Callahan and Jennings (2002) noted the tension between the orientation towards individual liberties and autonomy found in the bioethics literature, regulations, and guidelines on the one hand, and the interests of public health to limit the freedom of the individual for the sake of (a) his or her own greater good or best interests or (b) the common good or public interest. They asked whether the bioethical research model focused on individual informed consent and tightly regulated studies of human subjects at risk of exploitation is an appropriate model for public health research that may either pose no medical or other risks to the individual or make consent impractical to gain in research encompassing large communities.

The *Belmont Report* does not mention the word community at all, and the *Common Rule* (45 CFR 46) does not focus on communities *per se* although it is highly concerned with vulnerable groups—the mentally ill, children, etc. (Levine, 1988, Weijer, Goldsand and Emanuel, 1999). Levine (1978a:24), however, mentioned that the community, of which the subject is a member, is also put at risk as the social scientist uses the information in his publications or as the basis of his consultative opinion leading to formation of public policy. Note that public health is conspicuous by its absence or is lumped in with the social sciences.

On the other hand, *The International Guidelines for Ethical Review of Epidemiological Studies* (CIOMS, 1991) attempted to apply general ethical principles at the community or population level, that is, how one community related to another, and how a community treated each of its members and members of other groups with different cultural values. Specifically the

Guidelines stated that investigators must respect the ethical standards of their own countries and the cultural expectations of the societies in which epidemiological studies are undertaken.

The *Guidelines* then recommend that when individual informed consent cannot be obtained, community agreement may be sought from a community representative and, if the study is objectionable to the community, individual informed consent may not be sufficient to render a study ethical. Whenever possible, investigators should not expose groups to harm, including the harm of disruption of social mores. Where findings could be applied in public health measures to improve community health, they should be communicated to the health authorities and be publicized in the community by whatever suitable means are available.

The *Guidelines* warned epidemiologists against bringing disadvantage to communities or transgressing their values. Although cultural values and social mores must be respected, the *Guidelines* noted that the purpose of an epidemiological study may be to stimulate change in certain customs or conventional behaviors that would hopefully improve the health and wellbeing of the community and its members, for instance, with regard to diet or a hazardous occupation. Epidemiological studies may inadvertently expose groups to harm. When the location or specific circumstances of a study are important to understanding the results, care should be taken to protect the confidentiality of respondents and the community itself.

A more serious problem may emerge when telling the truth and openly disclosing scientific findings are opposed by certain community leaders or interest groups, or could lead to economic loss or withdrawal of health and other services. This may depend on how the data is presented and interpreted, that is, the style and tone of the report or publication should avoid adverse or moral criticism and be discrete in communicating and explaining the findings. Weijer and Emanuel (2000) suggested that if agreement between researchers and the community representatives cannot be attained within a reasonable amount of time, the competing interpretations of the study should both be published.

CONCLUSION

Scientific journals have been assigned an after the fact policing role in the enforcement of human research protections. This is a form of self-censorship and suppression of scientific knowledge which reflects social, political, and cultural pressures on what is studied, how studies are performed, how data are interpreted, and how results are disseminated (Kempner, Perlis, Merz, 2005). This can include refusing to publish material that might be detrimental to national security or studies that obtained data through unacceptable means, such as experiments that harm humans.

Public health journals face a challenge in supporting human research protections. The journals clearly need to distinguish between research and non-research or practice articles. Weijer (1999) thought that a reasonable formulation of the principle of respect for communities conferred on the researcher an obligation to respect the values and interests of the community in research and, wherever possible, to protect the community from harm. By extension, this suggests that public health journals should develop a set of guidelines for publication that encompass respect for communities.

Institutional Review Boards (IRBs) do not routinely consider the benefits and risks to communities or populations. Further IRBs may not recognize that the collection of data for surveillance, disease control and prevention, and program development and evaluation may be legally mandated, covered by the HIPAA privacy rule, or be eligible for a waiver or qualify as exempt from informed consent. Public health journals should not require that all authors obtain

IRB approval in order to be published since some articles concern practice not research. The journals, however, should require documentation that funding agencies or data sources have released the data or made it public, and that the data collecting process observed the HIPAA Privacy Rules in obtaining the information for publication.

Journals should be more proactive through editorial policies. Journals should alert reviewers to the possibility, however remote, that data can be falsified and to check that the work has proper and sufficient references and citations to avoid charges of plagiarism. Editors should ensure that the tone of the article is respectful and not inflammatory or prejudicial. Many journals and government publications will not identify smaller governmental subdivisions and will not publish data in a cell that contains less than 50 respondents or subjects, especially if they are members of a minority group or vulnerable population. In case studies and program evaluations, journals should not publish names or otherwise link an individual to a specific data item and should carefully consider whether a community should be identified or a pseudonym used.

Of course the editor, editorial board, and peer reviewers can and should decide which section of the journal they think is appropriate for a manuscript. Certainly peer review and publication involves many of the same questions that IRBs ask: what were the methods used to recruit or select subjects, were reliable and valid scientific methods used, was the data collected in a way that protected privacy, does the manuscript protect the identities of individual subjects and communities when appropriate. But journals should maintain their independence, meaning they should not rely solely on IRB decisions or automatically enforce them after the fact.

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REFERENCES

Amdur Robert J. and Biddle C. Institutional review board approval and publication of human research results. *JAMA*.1997; 277:909 –914

Bauchner, Howard (2002) COMMENTARY: Protecting research participants *Pediatrics* Vol. 110 No. 2 August 2002, pp. 402-404

Burris Scott, Buehler James and Lazzarini, Zita 2003 Applying the Common Rule to public health agencies: Questions and tentative answers about a separate regulatory regime *Journal of Law, Medicine & Ethics* vol 31

Callahan, Daniel and Jennings, Bruce (2002). Ethics and public health: Forging a strong relationship, *American Journal of Public Health* 92:169-176.

Christakis, Nicholas (1992) Ethics are local: Engaging cross-cultural variation in the ethics for clinical research *Social Science and Medicine* 35 1992:1079-91

Council for International Organizations of Medical Sciences CIOMS (1991). *International Guidelines for Ethical Review of Epidemiological Studies* Geneva: CIOMS 1991
http://www.cioms.ch/frame_1991_texts_of_guidelines.htm

Creinin, Mitchell D. and Shields, Wayne C. (2005) How do we ensure ‘high quality’ clinical research? Editorial *Contraception* 72:2 (Aug) <http://www.arhp.org/editorials/august2005.cfm>

Gillon, Raanan (1994) Medical ethics: four principles plus attention to scope, *British Medical Journal* 309:184

Institute of Medicine. (2000) Protecting Data Privacy in Health Services Research. Washington, DC: National Academy Press. Accessed Nov 29, 2006.
<http://www.nap.edu/books/0309071879/html/>

International Committee of Medical Journal Editors ICMJE (2006) *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication* Updated February 2006 <http://www.icmje.org/>

Kass Nancy E. (2001) An ethics framework for public health. *American Journal of Public Health* ; 91:177 6-17 82.

Kempner, Joanna, Perlis, Clifford S and Merz, Jon F (2005) Forbidden knowledge *Science*. Feb 11, 307:854,

Levine, Robert J. (1978a) The boundaries between bio-Medical or behavioral research and the acceptance and routine practice of medicine, in *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical*

Principles and Guidelines for the Protection of Human Subjects Research Appendix 1.
Washington DC DHEW Pub (OS) 78-0013, 1978 US Doc Y3 H33 2B 41

Levine, Robert J. (1978b) The role of assessment of risk benefit criteria in the determination of appropriateness of research involving human subjects, in *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research Appendix 1.* Washington DC DHEW Pub (OS) 78-0013, 1978 US Doc Y3 H33 2B 41

Levine, Robert J. (1982) Validity of consent procedures in technologically developing countries. In Bankowski, Z, Howard-Jones N. eds *Human Experimentation and Medical Ethics: Proceedings of the XV CIOMS Round Table Conference.* Geneva. Council for International Organizations of Medical Sciences, 1982:16-30.

Levine, Robert J. (1988) *Ethics and Regulation of Clinical Research* (2nd ed). New Haven: Yale University Press.

MMWR (2003) HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services May 2, 2003 / 52(S-1);1-12 Accessed Oct 12, 2006 at <http://www.cdc.gov/MMWR/preview/mmwrhtml/su5201a1.htm>

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* April 18, 1979

Puglisi, J. Thomas (1999) *Memo on Engagement of Institutions in Research*
Office of the Director, Division of Human Subject Protections, OPRR January 26, 1999
<http://www.cdc.gov/OD/ads/docs/engage.pdf>

Speers Marjorie (1999)
Guidelines for Defining Public Health Research and Public Health Non-Research
Office of the Director, Office of the Chief Science Officer, Human Research Protection Office
Revised October 4, 1999
<http://www.cdc.gov/OD/ads/opspoll> 1.htm

Weijer, Charles (1999) Protecting communities in research: philosophical and pragmatic challenges. *Cambridge Quarterly of Healthcare Ethics* 8, 501-513 (1999).

Weijer, Charles (2001) The ethical analysis of risks and potential benefits in human subjects research: history, theory, and implications for U.S. regulation in *Ethical and Policy Issues in Research Involving Human Participants* Vol II—Commissioned Papers and Staff Analysis
National Bioethics Advisory Commission: Bethesda MD Aug 2001
<http://onlineethics.org/reseth/nbac/hweij> er.html#t6

Weijer, Charles, Goldsand, Gary and Emanuel, Ezekiel J (1999)
Protecting communities in research: Current guidelines and limits of extrapolation
Nature Genetics 23 (1999): 275-80

Weijer, Charles and Emanuel, Ezekiel J (2000) Protecting communities in biomedical research *Science* 289:1142-44

Weijer, Charles and Miller, Paul B (2004) Protecting communities in pharmacogenetic and pharmacogenomic research *The Pharmacogenomics Journal* 4:9–16