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ETHICAL AND PHILOSOPHICAL ISSUES IN ENVIRONMENTAL EPIDEMIOLOGY

Report on a WHO Meeting

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ABSTRACT

An international workshop was convened by the WHO European Centre for Environment and Health and the International Society for Environmental Epidemiology to address both recognized and emerging ethical and philosophical issues of concern to the practice of environmental epidemiology. The workshop was attended by epidemiologists and moral philosophers from Europe and North America whose working papers formed the basis for discussion. The participants were divided into three groups during the workshop to discuss: accountability, disclosure and confidentiality; morals and principles; and research and reporting – standards of practice. The participants agreed on a definition of the mission of environmental epidemiology as well as on the reasons for developing ethics guidelines in this field. They also addressed issues related to the ethical conduct and reporting of studies involving stakeholders and made various recommendations for practitioners, universities and training institutions, professional organizations, other institutions and sponsors. Finally, the participants, recognizing that legislation on data protection might to a certain extent limit the possibility of carrying out epidemiological studies, invited WHO to bring together data protection advocates and researchers to address the implications of data protection on the conduct of social and health research.

Keywords

ENVIRONMENTAL HEALTH
ENVIRONMENTAL MONITORING
ETHICS

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INTRODUCTION

The International Workshop on Ethical and Philosophical Issues in Environmental Epidemiology was convened jointly by WHO and the International Society for Environmental Epidemiology (ISEE) from 16 to 18 September 1994. Epidemiologists and moral philosophers from Europe and North America were asked to identify, discuss and make recommendations on both recognized and emerging ethical and philosophical issues in environmental epidemiology. The working papers and the participants are listed in Annex 1 and 2, respectively. The Workshop was chaired by Professor B. Terracini and Dr S. Coughlin served as Rapporteur.

The main objectives were:

- to stimulate discussion of ethical values and principles among professionals engaged in environmental epidemiological research, practice and teaching and in moral philosophy;
- to lay the groundwork for guidelines on ethical practice within environmental epidemiology;
- to establish priorities in the areas of ethics and philosophy warranting future attention; and
- to address recognized and emerging ethical and philosophical issues of concern to the profession and to identify possible resolutions of these issues.

In the light of the complexities of the issues as well as the heterogeneous backgrounds of the participants, the Workshop was professionally facilitated. Three working groups were formed to discuss: accountability, disclosure and confidentiality; morals and principles; and research and reporting – standards of practice. Each group made a list of recommendations which were then discussed in plenary.

DEFINITION AND MISSION OF ENVIRONMENTAL EPIDEMIOLOGY

The participants defined environmental epidemiology as a subspecialty of epidemiology that deals with the identification, assessment and prevention of environmental health hazards in communities and population groups. Environmental epidemiologists may be roughly divided into those who are involved in public health practice, those who are researchers based in academic, governmental or research institutions, and those who work in industry.

The mission of environmental epidemiology is to investigate, interpret and disseminate information about environmental causes of disease and exposures in human populations, to assess complex environmental risks and provide stakeholders and the public with information about such risks, to help set priorities in public health and to maintain, enhance and promote environmental health in communities worldwide. Environmental epidemiologists contribute to increasing scientific knowledge about environmental risks and environmentally induced diseases and to protecting public health at the local, regional, national and global levels. They also inform the public and health policy-makers about potential health risks and help them to interpret and understand this information and to propose possible interventions.

ETHICS GUIDELINES FOR ENVIRONMENTAL EPIDEMIOLOGISTS

The participants agreed that ethics guidelines are needed in environmental epidemiology at this time and that such guidelines should serve as a visible basis for self-regulation. While the development of statements on core values and ethics guidelines should be an important goal, the process of initiating, promoting and revising such statements should also be recognized as a goal in itself.

The extent to which professionals could be held accountable in relation to such guidelines is less clear. Although ethics guidelines

for epidemiologists have been drafted by various national and international professional organizations,[1] existing guidelines may not have taken into account the specific needs and requirements of environmental epidemiologists. Since an important objective of the Workshop was to lay the groundwork for future ethics guidelines for environmental epidemiologists, extensive thought was given to what such guidelines might consist of, how they could be formulated and what their purpose would be. The participants agreed that ethics guidelines should:

- provide practical guidance on ethical problems to practitioners and stakeholders;
- provide a teaching tool that will help orient and socialize students to the profession; and
- provide a benchmark against which the profession and stakeholders can assess the profession's progress.

Both practitioners and stakeholders (e.g. members of communities exposed to environmental health risks) should be involved in the development of ethics guidelines. There is also a need for the profession to articulate its core values and to include these in a preamble to the guidelines. By definition, each profession has a unique set of values. The value statements of other professions do not necessarily substitute for or make unnecessary those being developed by environmental epidemiologists. The preamble should identify the distinctive ethical concerns of environmental epidemiology. The guidelines should incorporate, where appropriate, the traditional principles of autonomy, beneficence, non-maleficence and justice into a comprehensive concern for environmental health and quality[2] at community, national and global levels. The possible value of refinements and alternatives to principle-based methods for ethical decision-making ought to be explored.

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[1] Including the Council for International Organizations of Medical Sciences (CIOMS), the International Epidemiological Association, the Industrial Epidemiology Forum and the International Commission on Occupational Health (ICOH).

[2] Quality in this context refers to "environmental quality". The preferred term for this concept is "environmental integrity". However, "environmental integrity" has not been used in the text to avoid ambiguity.

Environmental epidemiologists need to assess their practice from an overall perspective that includes concern for the integrity and sustainability of all regional, national and global life-support systems.

Prevention measures and sanctions against professional misconduct must be included in the guidelines, as they should promote scientific and collegial integrity in research and in the practice and teaching of environmental epidemiology.

Because guidelines or normative rules can sometimes be in apparent or actual conflict with one another, there is a need to develop strategies for deciding which guideline should take precedence over any other guideline or to develop a process for resolution of difficult problems on a case-by-case basis.

CONCLUSIONS

1. There is a need to recognize and openly debate the potential presence of conflicting interests at any stage of research in environmental epidemiology, including the identification and choice of a research question. Public health interests should always take precedence in the resolution of such conflicts. Financial sponsorships should be disclosed when reporting results. Sponsorship and authorship should not, however, be used to prejudge the validity of a study.

2. Concern was raised that environmental epidemiologists could find themselves in a situation that makes the conduct of a study impossible because it was proscribed by ethics guidelines. This could lead to a situation where, by not doing a study, more harm than good to the public's health was done. Therefore, the ethics of *not* doing a study because of any barrier posed by such guidelines need to be addressed.

3. When feasible, members of affected groups or their representatives should be consulted. It was acknowledged that there were circumstances in which the validity of a study would be impaired if such consultations had taken place. Study protocols

should address potential concerns of affected groups and should relate potential negative consequences of the study to any individuals or groups. Environmental epidemiologists should inform the public both about health and economic risks and about benefits to individuals and communities resulting from environmental epidemiological research and practice.

4. Whenever practical, informed consent from study participants should be obtained. The guiding principles should be to avoid harm to the individual and communities and respect autonomy while pursuing potential benefits for individuals, communities and societies affected. It is the responsibility of all researchers to protect and ensure the confidentiality of any data that would reveal the identity of individual study participants. Where comprehensive safeguards for data protection exist and where other ethical concerns have been considered, access to data sets (such as hospital records, biological samples, historical data sets and cancer registries) is acceptable without seeking prior consent from the individual. Informed consent should be required, however, in later stages of the investigation if and when direct contact with study participants is necessary.

5. Financial compensation to study participants should be limited to payment for time and expenses (i.e. reimbursement for actual costs only) to avoid manipulation.

6. Given the obligation of environmental epidemiologists, as for any other scientist, to employ the best scientific standards of practice, valid and reliable mechanisms for quality assurance and control must be in place. This is especially critical in those cases where the possibility of replicating the study is small.

7. Bias in the communication of scientific findings poses a serious threat to the accurate understanding of the effects of environmental exposures on health. There is a need to balance the timely conduct of studies and the reporting of scientific findings with the need for thorough peer review. A more appropriate

peer review process for scientific papers and abstracts submitted for conferences should be developed.

8. The objectivity of the scientific literature is also of concern. The direction of the findings (i.e. positive or negative results) should not influence the decision on whether to publish a study.

9. Standards that facilitate appropriate record keeping for audit, validation and further study should be developed.

10. When undertaking a study, making an assessment and reporting results, environmental epidemiologists have an obligation to provide decision-makers and the public with usable information and make known the level of scientific uncertainty involved.

11. To redress the present imbalance, more research should be conducted of understudied population groups, especially in view of the severe consequences of poverty and famine (including malnutrition, premature mortality and adverse reproductive effects).

12. Discussions should be initiated at international, national and regional levels to facilitate community involvement in the resolution of such issues in environmental epidemiology as genetic monitoring, potential conflicting interests in the dissemination of results and the use of biological banks and historical data sets.

RECOMMENDATIONS

1. The development of ethics guidelines should be seen as a continuing effort. Practitioners, as well as professional organizations and institutions, should invest in programmes that continually update knowledge of ethics and of how to put them into practice.

Practitioners

2. Environmental epidemiologists have a personal obligation to become more informed about ethical issues and practices. They should ensure that literature, conferences and continuing education on ethical issues are part of their practice and study. In addition, practitioners should regularly consult with communities affected by their work about potential ethical concerns.

3. Practitioners should assist their peers in the continuing education process through counselling and advice and peer review.

Universities and training institutions

4. Any institution offering training in environmental epidemiology should ensure that ethical issues and practice are part of the training curriculum. In particular, there is an urgent need for universities to offer leadership in this area by supporting professionally developed model curricula in the ethics of environmental epidemiology, and by compiling ethically analysed case studies.

Professional organizations

5. Organizations serving the profession of environmental epidemiology should increase their support to ethical concerns. Specifically, they should offer assistance to members in identifying ethical issues and provide guidance and, where necessary, mediation to facilitate conflict resolution, perhaps through the development of a formal counselling service on ethics.

6. Such organizations should ensure that an accountability process is developed, consistent with the principle of professional self-regulation. This process might include the reception of complaints about unethical practice and their investigation, while recognizing the need to adhere to principles of due process in the conduct of investigations and in any imposition of sanctions.

Institutions and sponsors related to environmental epidemiology

7. Institutions and sponsors that promote and support the profession must show leadership in the improvement of ethical practices.

Specifically, they should ensure that: (a) stakeholders outside the profession are consulted, (b) ethical practice is included in information given to practitioners, and (c) there are opportunities to discuss ethics at conferences and workshops.

8. Such institutions should ensure that an accountability process is developed to demonstrate the responsible self-regulation of the profession.

WHO

9. Data protection advocates and social and health researchers should be brought together by WHO to address the implications of data protection on the conduct of social and health research.

Annex 1

WORKING PAPERS[3]

EHAZ 14/WS01/6	Interim report on the ISEE-GEENET ethics survey by C.L. Soskolne
EHAZ 14/WS01/7	Guidelines/codes of ethics: merging process and content by M.S. Frankel
EHAZ 14/WS01/8	Scientific conduct and integrity: mailed surveys to uncover the magnitude of problems of scientific misconduct in the risk sciences by M.R. Greenberg
EHAZ 14/WS01/9	Realities of decision making and social issues: implications for developing and implementing ethics guidelines by C. Summers
EHAZ 14/WS01/10	Reflections on the relevance of the Georgetown paradigm for the ethics of environmental epidemiology by E. Winkler
EHAZ 14/WS01/11	Informed consent in the Czech Republic by V. Bencko
EHAZ 14/WS01/12	Science, advocacy, human and environmental health by H. Rolston III
EHAZ 14/WS01/13	Scientific uncertainty: When to communicate research findings with the public by D. Jamieson
EHAZ 14/WS01/14	Environmental Integrity and health: environmentalism without racism, some cases L. Westra
EHAZ 14/WS01/15	Ethical aspects of genetic predisposition to disease by P. Grandjean
EHAZ 14/WS01/16	Balancing the interests of patients, science and employers: A case study of RF (microwave) exposures by J. Goldsmith
EHAZ 14/WS01/17	Cancer hazard identification and risk assessment by B. Terracini

[3] Copies can be obtained from the Rome Division of the WHO European Centre for Environment and Health, Via Vincenzo Bona, 67, 00156 Rome, Italy.

EHAZ 14/WS01/18	Causal evaluation in environmental epidemiology: the role of implicit values by C. Botti
EHAZ 14/WS01/19	How to identify and analyse ethical conflicts by T. Nilstun
EHAZ 14/WS01/21	Scientific and ethical problems related to the application of genetic monitoring and genetic screening of employees by M. Sorsa
EHAZ 14/WS01/22	Legislation to protect individual confidentiality: the case of cancer registration in Germany by B. Bellach
EHAZ 14/WS01/24	Communication of research findings in peer-reviewed journals: publication bias, timing of publication, conflict of interests and fraud by M. Szklo
EHAZ 14/WS01/25	Epidemiological research data in litigation by H. Inskip
EHAZ 14/WS01/26	Monitoring the worker and the community for chemical exposure and disease: legal and ethical considerations in the United States by N. Ashford
EHAZ 14/WS01/27	Environmental justice: Reflections on the role of epidemiologists in protecting unempowered communities from environmental hazards by S.S. Coughlin
EHAZ 14/WS01/28	Consent and the electronic person by R.C. James
EHAZ 14/WS01/29	Ethics in community-based environmental epidemiology and public health practice: some considerations by D. Wartenberg

Annex 2

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