



Ethical aspects of epidemiological research in contaminated sites

Colin L. Soskolne

University of Alberta, Edmonton, Alberta, Canada

Health Research Institute, University of Canberra, Canberra, Australia

Abstract

This paper brings understanding to the ethical dimensions of human health research conducted in the context of contaminated sites. Principle-based ethical analysis, complemented with virtuous traits of character, aid in bringing clarity to recommendations for actions following research. Epidemiology is the discipline for conducting health research not only because of its methodological foundations, but also because of its social justice focus. Because contaminated sites include communities that have been exposed to excessive concentrations of hazardous substances, extra care is needed when using epidemiology. For instance, vigilance over potential influence and engagement with affected communities are needed. Community engagement not only aids in understanding the contextual framework, but also demonstrates respect for both community and individual autonomy. Ethical analysis makes transparent the rationale for decisions against which researchers can be held accountable and provides a basis for evaluating observed outcomes as a function of the rationale provided for past actions.

Key words

- applied ethics
- biomedical ethics
- public health ethics
- virtue ethics
- social justice
- public interest science

INTRODUCTION

The discipline of ethics, applied to studying health in any community, is context-related, appropriately taking into consideration the socio-economic-cultural-legal norms of the day. Thus, to appreciate the ethical aspects of epidemiological studies in contaminated sites, a contextual framing of the problem proposed for study is required. In addition, some knowledge is needed not only of relevant ethical principles and their purpose in being applied to health research, but also of the epidemiological dimensions of conducting studies on people resident in or who had resided in contaminated sites.

Epidemiology applied to the study of people in contaminated sites

"In Europe, earlier industrialization and poor environmental management practices have left a legacy of thousands of contaminated sites. Past and current activities can cause local and diffuse accumulation of environmental stressors to an extent that might threaten human health and the environment, by altering air quality, hampering soil functions, and polluting ground water and surface water." (World Health Organization, 2013) [1].

Research that examines the relationship between environmental pollutants of any kind and to which defined groups of people have been – and perhaps continue to be – exposed, along with the diseases that may manifest in such people, in life or in death, falls under the

scientific discipline of epidemiology. More specifically, such studies fall under the sub-specialty of environmental epidemiology.

Contaminated sites constitute an example of a community with a special exposure circumstance. In particular, the exposure circumstances considered in this paper include those communities where the legal and/or illegal dumping of hazardous wastes has occurred and may be continuing. Such communities are deemed resident in a contaminated site. Epidemiological studies may be conducted in any area of concern and are often motivated and justified on the basis of a set of unusual exposure and/or outcome circumstances. These studies are conducted for the health and well-being of affected communities, its survivors, and future generations.

The utility of research findings from epidemiological enquiry is that they are expected to be compiled to inform public health policy with a view to designing interventions to reduce or eliminate any harms associated with past, present and future possible environmental exposures; the knowledge gained can also be used for remediation and compensation purposes. Epidemiology is thus regarded as the applied science central to public health. It is used to inform the translation of evidence observed in experimentation – in the real world as the "natural experiment" or in the laboratory – into public policy that upholds particularly the ethical principles of social justice/fairness, and of doing good (beneficence) in the public interest (see below). It does so

respecting the autonomy of communities (*i.e.*, the community's right to self-determination).

There are some, however, who might prefer not to know about the ill-effects from being resident in a contaminated site through epidemiological enquiry. After all, what one does not know one does not need to act upon. Questions of responsibility and justice, however, are raised in this context. In fact, there are ethical dimensions to any position taken. To conduct research and learn something about harms to health has ethical implications for action; to suppress such knowledge is to deny the rightful claim of harmed people to justice and associated health benefits.

Why considerations of ethics remain foundational to research conducted in the public interest

The fact that contaminated sites exist raises questions of not only ethical, but also of moral conduct among fellow citizens. How such sites became contaminated in the first place bears at least some relation to powerful players in society whose self-interest took precedence over considerations of the consequences of the disposal of hazardous waste in the midst of local communities. The legacy of such (usually, clandestine) actions, often associated with past industrial processes resulting in the production of hazardous wastes, has today become the responsibility of an array of managers that have inherited the problem.

These higher level managers and associated leaders carry the burden of previous decisions to dump wastes, legally or illegally, and contaminate sites, or to locate communities to sites previously contaminated with hazardous wastes. They are now faced with decisions to remediate contaminated places and to compensate those harmed by the contamination if justice is to be served. Being challenged about culpability, some senior management-level people prefer to maintain the *status quo* than to make any change, especially relating to paying out money as a consequence of discoveries made through epidemiological research. Demonstrating harms is often a requirement before compensation of any kind can be considered.

Because of management's concern to protect the interests of stakeholders, various pressures can be brought to bear on the research process. These pressures can themselves have profound ethical implications in the pursuit of justice, and can have seriously deleterious health impacts through interference in the research process in that invalid conclusions are inevitable from poorly, and even deviously, designed research. Such actions have ethical dimensions. Ultimately, the question to be raised relates to explicating whose interests are being served by the action, or inaction, taken [2].

Ethics, essential for ensuring standards of good conduct in any discipline, are normative best practices in a particular domain or realm of collective human activity. Epidemiology is one such activity. As with any science, epidemiology can be used correctly or incorrectly, and it can also be abused. Incorrect or mistaken use arises when ignorance or honest error occurs; peer review is helpful in correcting such honest mistakes. Abuse arises when special interests spur members of the discipline of

epidemiology to lose objectivity, favoring biased as opposed to impartial enquiry; peer review is less capable of correcting such bias.

On research funding: does "he who pays the piper call the tune"?

Any community study requires resources, including funding, to make it possible. From proposing research questions for study in a community, to formulating hypotheses, designing, conducting, reporting, disseminating and archiving of the research, all decisions can be assessed on their ethical appropriateness relative to principles of biomedical and public health ethics.

Ethical considerations become all the more relevant in circumstances where impropriety of any kind could exist. In circumstances where special interests could influence judgment and decision-making, ethics oversight is especially needed to maximize the likelihood of science being conducted in accordance with the goal of science, namely the pursuit of truth. In particular, the ethical principle of "do no harm" is relevant for protecting not only communities, but also the members of such communities who participate in research.

Whether money is made available to a proposed research study assumes that those making funding decisions are amenable to addressing the consequences of information coming to the surface that could cause them any level of embarrassment, or even of culpability. In communities where chemical or other wastes have been illegally dumped or legally stored, this can pose a chronic exposure circumstance for the community.

The SENTIERI project (Epidemiological Study of Residents in Italian Contaminated Sites), illustrated in some detail by Comba *et al.* in the 2014 monographic issue of *Annali* [3], was funded by the Italian Ministry of Health with two subsequent grants. Two documents related to published reports on this research [1, 4] inform this article on the ethical aspects of epidemiological studies intended for and conducted in contaminated sites.

The nature of both reports was expressly to explore and develop technical capacity to study the relationship between environmental exposures and health effects, particularly as measured through death certification, in contaminated sites. The fact of conducting such studies had the tacit ethical goal of bringing justice to communities identified as being environmentally contaminated by current or previous industrial activities, in several instances by hazardous waste and in one case by a naturally occurring asbestiform fibre (fluor-edenite). No ethical aspects were expressed except to recognize the need in 2014 to be more explicit about the ethical dimensions moving forward. This paper was intended to assist in understanding and explicating the ethical dimensions of research conducted in contaminated sites.

OBJECTIVES

Because the scope of each of epidemiology and ethics is broad, this paper is confined to the context of studies conducted in contaminated sites. Its three major objectives are to:



1. bring professional ethics into the discourse on studying people in contaminated areas/sites;
2. identify principles to help distinguish between two identified contexts: (a) the need for more research and the need for action; and (b) historically contaminated sites and sites experiencing ongoing contamination;
3. conclude with a generic framework for better integrating ethics into public health decision-making.

THE EPIDEMIOLOGIST AND EPIDEMIOLOGY IN THE CONTEXT OF STUDIES IN CONTAMINATED SITES

From the broader definition [5], the epidemiologist is a professional who strives to study and control the factors that influence the occurrence of disease or other health-related conditions and events in defined groups of people. The control of disease in populations is often considered to be a core task for the epidemiologist involved in the provision of public health services.

In studying people in contaminated sites, all members of the community with potential for exposure to known pollutants or hazards are at-risk for adverse health effects and would warrant investigation. The aim of a descriptive study would be to establish baseline health data with ongoing monitoring with a view to the early detection of disease processes. Such studies lend themselves to secondary prevention strategies for interventions appropriate to the early detection of disease, given the fact of prior exposure.

Analytical studies would be those where health effects are hypothesized and tested by virtue of the natural experiment that was set in motion by proximity to a contaminated site. Such studies would be focused less on individual benefit and more on contributing knowledge for establishing possible cause and effect. Depending on the community's priorities, descriptive as opposed to analytical studies would be seen, from an ethical perspective, as having greater potential to do good locally. One might argue that those affected would thereby be better served and justice would thus be seen to prevail.

WHY ETHICS IN THE PROFESSIONS?

Having referred above to various ethical principles applicable in different contexts, ethics training is deemed essential. This is needed not only to keep thoughtful people intent on doing good on track, but also for socializing students. We need to equip students with the skills needed to speak truth to power based on valid science anchored in an ethical framework. Such a framework brings clarity to arguments and aids in making transparent the rationale for all research actions taken and recommendations that flow therefrom.

Ethical decision-making is required at every step in both epidemiological research and practice. In neither realm can epidemiologists be naïve, needing at all times to remain aware not only of their own innate biases, but of forces at play that may be introduced to influence both the scientific design of a study and its interpretation, as well as how they may be used to inform policy formulation.

Every decision-point has ethical implications. Great vigilance and personal integrity thus are needed, especially to counter the influence, where this exists, of financially interested parties and corrupt and morally bankrupt governments. Understanding ethical norms can help professionals in various circumstances to navigate their way to an ethically formulated and grounded decision.

CORE VALUES AND MISSION STATEMENTS AS ANCHORS FOR PROFESSIONAL ETHICS

The articulation of epidemiology's core values and mission statement is intended to provide the anchor not only for the work done by the profession, but also for its collective motivation. The latter in the public health disciplines includes the need to maintain, enhance, and promote health in communities worldwide, and to work to protect the public health interest above any other interest. Ethics and values serve as the anchor for the ethical norms that determine, in large part, the behaviors of those engaged in the profession. In essence, good ethical conduct and good science are inextricably linked and are mutually reinforcing.

BIOETHICS EXTENDED TO PUBLIC HEALTH

Medical ethics, as currently applied, is most commonly based on the four bioethical principles described by Beauchamp and Childress [6] as:

- respect for autonomy, requiring that the researcher respects the research participant's right to self-determination;
- beneficence, requiring that the researcher does good by way of the research participant;
- non-maleficence, requiring that the researcher does no harm to the research participant;
- justice, requiring of the researcher the fair and equitable allocation of risks and benefits to all research participants without discrimination.

These four principles must be applied in the evaluation of any proposed clinical/health research project. In terms of their practical application, there is no hierarchy among the four principles and, in every situation, there is a tension among each of them. The researcher must aim to maximize each of the four principles through every step of the research process. What these principles do is facilitate the researcher's transparent defense of any position being taken in proposing the series of actions in relation to each of the four principles. In so doing, a basis for accountability and subsequent review or evaluation is made possible. In the same way, the researcher can apply these principles to evaluate any decision or action needing to be made in both public health research and practice.

Those engaged in public health research, and particularly in studies of communities in contaminated sites, must, in fact, elevate the four biomedical principles above to a community perspective, recognizing the duty to:

- protect the most vulnerable in society (*e.g.*, unborn, children, aboriginal, frail elderly). This principle is akin to that of justice in biomedical research;
- involve communities in our research (*i.e.*, verify the

community relevance of the research being proposed). This principle is akin to that of respect for autonomy in biomedical research;

- integrity in public health (*i.e.*, the researcher must serve the public health interest above any other interest). This principle is akin to that of both beneficence and non-maleficence in biomedical research.

Other principles flow from the above three identified duties in public health as follows:

- environmental justice;
- the polluter pays
- precautionary principle;
- solidarity;
- post-cautionary principle;
- the seventh generation principle.

The first of these – environmental justice – is related to “justice” under the biomedical framework. We can ask while our research is being done:

- Who is taking the risks?
- Who is deriving the benefits?

This has a direct bearing on the need for action in the face of evidence in tension with demands for greater certainty.

The second of these – the polluter pays – also is related to “justice” under the biomedical framework. From this we seek justice by incentivizing the internalization of costs related to any harms associated with the polluting source.

The third of these – the precautionary principle – is related both to “non-maleficence” and “respect for autonomy” under the biomedical framework. This is applicable when examining where there is a risk from a certain agent; the presence of uncertainty shall not be used as a reason for postponing cost-effective measures to prevent such exposure and, indeed, to engage in secondary prevention programs.

The fourth of these – the principle of solidarity – is related to all four biomedical principles. This becomes apparent from The Golden Rule in which we are reminded to not do unto our neighbor that which we would not wish to have done to ourselves. We want for ourselves to be treated with respect in our right to self-determination, to do good, to do no harm, and to see justice done.

The fifth of these – the post-cautionary principle – is related to each of “beneficence,” “non-maleficence” and “justice” under the biomedical framework. This principle is invoked when we come to recognize that precautionary actions not taken in a timely fashion leave as the only alternative the need to be prepared to adapt to a range of anticipated likely harms [7].

The sixth of these – the seventh generation principle – is related to all three of “beneficence,” “non-maleficence” and “justice” under the biomedical framework. This principle is made apparent when we consider the potential consequences of a decision taken today on the children to be born seven generations hence. Decisions approved only if no ill-effects are anticipated seven generations hence not only support the principle of inter-generational equity, but also maximize the potential for resilient, life-sustaining environments.

ETHICS COMPLEMENTED WITH VIRTUOUS TRAITS OF CHARACTER

To complement considerations of principle-based ethical analysis, Weed and McKeown [8] suggested that virtue ethics be considered. They note that to be a professional of integrity we must appreciate the traits of a virtuous character. Virtues, they note, do not replace ethical rules or duties (see “scientific duties” above). Rather, an account of professional ethics is more complete if virtuous traits of character are identified, such as:

- humility – respect the input and opinions of others/self-effacement
- fidelity – honour one’s commitments/promote trust
- justice – act fairly
- patience – take time to hear others’ viewpoints
- industry – do your level best/excel
- veracity – tell the truth/be honest
- compassion – empathize
- integrity – demonstrate good moral character
- serve – protect the most vulnerable/serve the public interest
- prudence – err on the side of caution/demonstrate good judgment.

These virtues resonate with most in the public health field and are self-explanatory. Some professionals do attempt to be assertive when it comes to protecting the public interest. This assertiveness emanates from a consideration of both principles and virtues, and particularly when considering one’s duties as a scientist to protect the public interest.

For evidence-based policy that serves the public interest, the professional familiar with the pressures arising from competing interests and the contextual narrative will be best equipped to navigate the system within which she/he works in support of public interest science. Familiarity with both principle-based and virtue-based ethics contributes to keeping our collective house in order.

CONCLUSIONS

Each step in the research process has ethical dimensions that need to be made transparent if the researcher is to be guided to “do good”. In so doing, the researcher can be held to account for actions taken and have a basis for evaluating over time the outcomes observed as a function of the rationale provided for past actions. A generic framework can help in guiding this process:

1. gather all relevant information (*e.g.*, biologic, economic, social, political, or ethical) and identify knowledge gaps, as well as the basis for these facts;
2. identify the key stakeholders and the most appropriate decision-maker(s);
3. identify the key values and concerns of the identified stakeholder(s), as well as any potential risks and benefits from the accumulated body of knowledge;
4. identify the options available to the decision-maker, including reasonable alternative courses of action, consideration of implications, and potential intended and unintended consequences;
5. suggest a resolution or decision by choosing the supported option, and justify the decision;

6. describe how the decision and/or action might be evaluated;
7. in light of new information, emphasize the need to be willing to evaluate earlier decisions.

By being mindful of the inequalities in health from contaminated sites and using ethical approaches to decide actions, we will be more likely to see justice delivered to those vulnerable to harm.

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