



When BEST Intentions Go Awry: Arsenic Mitigation in Bangladesh Teaching Note

Case Summary

Public health researchers often tackle narrowly defined questions—specific elements of larger, complex systems that may or may not directly affect the populations they study. But occasionally, their work addresses full-blown crises—such as epidemics or environmental disasters—with immediate significance for large numbers of people. In Bangladesh, the widespread contamination of groundwater by arsenic is one such crisis. By some estimates, as much as half the population may be at risk of arsenic poisoning.

This case considers the challenges of conducting large-scale epidemiological research in developing countries, focusing on the clinical trial of a potential treatment for arsenic poisoning. It considers the difficulties of working in rural, less developed and culturally insular communities. It also raises the issue of aiding populations while studying them, which is complicated by funding restrictions and the demands of research.

In 2007, a group of researchers from Columbia University and the University of Chicago began fieldwork for a Bangladesh Vitamin E and Selenium Trial (BEST) in Laksam, a rural, culturally conservative community about 60 miles southeast of the capital Dhaka, and one of three locations for the study. As part of the 10-year trial, and to meet requirements to improve conditions for participants, the researchers distributed free water filters. Despite careful adherence to ethical guidelines and an exacting set of operating procedures, the BEST study ran into problems when a disgruntled former field worker—who ran a small business selling the same type of water filter distributed through the trial--sought to discredit the researchers and their project. The former employee used his extensive connections in the community, the press in particular, to turn sentiment against them.

Caught off-guard, the researchers were forced to devise a strategy to refute the largely fabricated charges in order to dissuade participants from quitting the clinical trial, and to continue

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working in the community. They also had to allay concerns at their home institutions when an anonymous correspondent emailed the accusations to senior administrators.

Teaching Objectives

This case explores the challenges researchers face when conducting large-scale observational studies and clinical trials in developing countries. It also illustrates some potential pitfalls of intervening in a public health crisis.

Use the case to discuss the logistics and ethics of studying human subjects, particularly in geographically remote areas and across cultural divides. What obligations do researchers have to participants and their communities? How can they balance the requirements of the research with an interest in improving conditions? The case also asks students to consider how non-native researchers working in developing countries can navigate local conditions and deal with cultural, economic and political interests. What additional training might help public health specialists and scientists in these settings—organizational management, communications, cultural, political and linguistic studies, crisis management?

The case explores the question of how outside researchers can establish a presence in a community and develop trust and good will. It also invites students to consider how researchers can understand the local context well enough to handle any conflicts that may threaten a project. A related question is how thoroughly can they vet potential partners and employees within budget and without alienating the community?

Existing guidelines for recruiting participants and securing informed consent to some degree turn researchers into science educators. Students could debate whether broader scientific literacy efforts, including outreach to local media, can bolster community relations and inoculate projects against attacks.

Researchers can turn to a raft of practical and ethical guidelines for working with human research subjects, but there is less to help them negotiate the cultural, political and economic terrain. While local review boards, partner organizations and employees can help, outside researchers stand to benefit from a deeper appreciation of the setting and context they're working in. How much background is necessary and when does a public health research project begin to resemble a social science project, or even an intelligence operation?

The case also presents large-scale research operations as financial and employment engines, putting the onus on directors to consider a project's impact on the local economy, and how it might affect the community long term.

Class Plan

This case is suitable for courses or classes on international public health research, human subject research, or crisis management.

Study question. Help students prepare for discussion by assigning the following question in advance:

1) List the kind of training that you think would prepare public health researchers for the social, cultural, logistical and political challenges illustrated in the case.

Instructors may find it useful to engage students ahead of class by asking them to post brief responses (no more than 250 words) to the question in an online forum. Writing short comments challenges students to distill their thoughts and express them succinctly. The instructor can use the students' work both to craft talking points ahead of class and to identify particular students to call upon during the discussion. You can also ask students to revisit these lists at the end of in-class discussion.

In-class discussion. The homework assignment is a useful starting point for preliminary discussion, after which the instructor could pose any of the following questions in order to promote an 80-90 minute discussion. The choice of questions will be determined by what the instructor would like the students to learn from the class discussion. In general, choosing to discuss three or four questions in some depth is preferable to trying to cover them all.

For this case, instructors may find it useful to assign class members the roles of senior US-based researchers and in-country staff (either select individuals, or divide class in half). Use the role play to track decision-making from these two perspectives, and to discuss alternative approaches to setting up the BEST trial in Laksam and to handling the crisis.

- a) Was the BEST trial well designed? Why/why not?
- b) In choosing mitigation strategies, what must researchers take into account? List on board. [For example, institutional review boards, funding agencies, community priorities, research goals, fiscal and bureaucratic realities etc.]
- c) What are a researcher's obligations to human subjects and their communities? Does research itself constitute mitigation?
- d) Given the constraints on mitigation through funded research, should/can researchers try to incorporate "dual use" mitigation in the core research project, or is it preferable to raise mitigation funding independently?

- e) How should public health researchers think about community relations?
- f) What lesson, if any, can we derive from HEALS' positive experience in Araihaazar?
- g) The BEST team's senior US-based researchers and local field directors were Bangladeshi—and yet a lack of local contacts in Laksam left them vulnerable to criticism. What else might they have done in advance? Is it necessary to vet partners and employees?
- h) Even carefully planned and executed studies can run into unanticipated problems. Are field workers and researchers better off with hard and fast operating procedures or the flexibility to use their own judgment?
- i) How should researchers deal with local corruption?
- j) After the media backlash in Laksam, was a press conference the best strategy to respond?

Suggested Readings

Barry Bearak, "DEATH BY ARSENIC: A special report; New Bangladesh Disaster: Wells That Pump Poison," *New York Times*, November 10, 1998.

SYNOPSIS: The article outlines the genesis of arsenic poisoning from wells in Bangladesh. It details the human cost and describes the various cancers and other illnesses associated with arsenic, as well as efforts to gauge the extent of exposure and discover the mechanism for the chemical's release into aquifers. Also mentioned is the controversy over whether UNICEF showed negligence in failing to detect the contamination.

<http://www.nytimes.com/1998/11/10/world/death-by-arsenic-a-special-report-new-bangladesh-disaster-wells-that-pump-poison.html?pagewanted=all&src=pm>

British Geological Survey—BGS Technical Report WC/00/19, Volumes 1 and 2, 'Arsenic contamination of groundwater in Bangladesh,' D.G. Kinniburgh and P.L. Smedley (Editors), February 2001.

SYNOPSIS: This report provides background on the geology and survey data gathered between 1998 and 2001 on the extent of arsenic contamination in Bangladesh. The collation of existing data and compilation of new data was intended to support remediation efforts begun after the discovery of the problem in 1993.

<http://www.bgs.ac.uk/arsenic/bangladesh/>

Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, Geneva, 1993

SYNOPSIS: The document spells out guidelines for respecting the rights of human research subjects, beginning with recruitment and informed consent, and including the treatment of vulnerable populations, confidentiality, and compensation for accidental injury. It includes background and reference documents, international treaties, declarations and guidelines, with an emphasis on research in developing countries.

<http://www.codex.uu.se/texts/international.html>

London, Alex John, "Responsiveness to Host Community Health Needs" (2008), from *The Oxford Textbook of Clinical Research Ethics* (2008) Ezekiel J. Emanuel, Robert Crouch, Christine Grady, Reidar Lie, Franklin Miller, and David Wendler eds. New York, Oxford University Press. Department of Philosophy. Paper 402.

SYNOPSIS: This discussion of international clinical research in the developing world outlines various approaches to balancing scientific goals with the health needs of host communities. In summarizing the consensus documents pertaining to human medical research, the author describes a spectrum of requirements – from closely tying research to the health priorities of the local community and guaranteeing reasonable access to the fruits of that research, to defining benefits more loosely and compensating the community with indirect benefits like healthcare infrastructure improvements, education and jobs. The author suggests that the research and mitigation together should ultimately strengthen the communities' ability to address their key health needs.

<http://repository.cmu.edu/philosophy/402>

Other Resources

National Institutes of Health—policies and information on research involving human subjects

The NIH provides resources for extramural grant recipients and others participating in NIH funded research. Information includes policies, ethical guidelines and training.

<http://grants.nih.gov/grants/policy/hs/index.htm>