

LANCET POSTER COMPETITION FINALISTS

International Human Research and Ethics Standards: A Compilation of Legal Protections in Countries

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Background: Human research investigations, including population-based studies and clinical trials, have the potential to alleviate the burden of diseases that disproportionately affects many low- and middle-income countries (1). The advent of globally recognized standards in ethical research conduct has placed human rights at the forefront of investigations (2-4). While standards are not legally enforceable, countries have adopted legislation to protect human subjects. The extent of legal protections varies by country and may be dependent on existing governmental and scientific infrastructure.

Methods: The U.S. Office for Human Research Protections compiles an annual compilation of international human research standards in 120 countries (5). This database reviews thousands of laws, regulations, and guidelines related to the conduct of human subjects research. Each country is appended with legislation from eight core areas: general provisions, drugs and devices, clinical trial registries, research injury, privacy/data protection, biological materials, genetic, and embryo, stem cells, and cloning. A descriptive statistical analysis was conducted to explore the extent of countries with any protections in each of the eight categories. Each country was assigned a binary code if there was some legislation or standard reported in each of the categories and a total score was given to assess total categories covered.

Findings: A total of 118 countries had some information. A majority of countries had general human subjects standards (88.1%) and drugs and devices standards (83.9%) while the least coverage was found for country-level clinical trial registries (18.6%). Among the five regions defined by the database, North American and European countries had an average score across categories of 8 and 5.70, respectively. Contrastingly, Asian, Pacific, and the Middle Eastern countries (score = 3.97), Latin American and Caribbean countries (score = 3.14), and African (score = 2.22) had scores below half of eight categories.

Interpretation: Ethics and IRBs (Institutional Review Boards) are an essential component of human subjects research. While many studies are conducted in low- and middle-income countries, adequate protections afforded to subjects in these areas may not be adequate. This analysis describes the unmet need for legal protections for participants. Further work is needed to delineate appropriate standards.

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Competing Solutions to Arsenic Contamination of Groundwater in Araihaazar, Bangladesh: A Cost-Benefit Analysis

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Background: Exposure to arsenic from drinking water and food has been associated with cancer, skin lesions, developmental effects, cardiovascular disease (CVD) and neurotoxicity. Since the 1990s arsenic contamination in Bangladesh has attracted much attention given its magnitude: about 45 million people were exposed to concentrations above the standard of the World Health Organization. This suggests that preventive measures could be a more efficient strategy to address the problem than investing in treating the adverse health-effects of chronic arsenic exposure.

Methods: A cost-benefit analysis was conducted to compare two solutions to the arsenic contamination at Araihaazar, Bangladesh. We estimate the net present value (NPV) of treating CVD cases related to arsenic exposure at a local primary care clinic, and of building arsenic-free public groundwater wells for 500 exposed households; using a 10-year horizon and a 5% discount rate. Data from the University of Chicago Research Bangladesh Clinic and epidemiological estimates by the Health Effects of Arsenic Longitudinal Study (HEALS) were used to estimate cost of treatment and social cost, measured as lost work output due to premature death attributable to arsenic exposure between 2011 and 2016.

Findings: Preliminary results show that primary care-based treatment of CVD related to arsenic exposure yields a per capita annual cost of \$40.6 USD, while building arsenic-free public groundwater wells yields a cost of \$39 USD per capita for the first year. Nevertheless, the social costs of providing treatment for the CVD cases at the local clinics outweighs the benefits of receiving primary-care based treatment on a 10-year time horizon.

Interpretation: For the 10-year horizon, results suggest that investing in building deep water tubewells generates less direct costs and will reduce social costs by a greater amount. However, building new deep wells represents a high capital cost for the first year, which depending on budgetary constraints, could be unachievable in the context of this community. Additionally, investment in the provision of primary care entails social benefits (externalities) not included in this analysis. Incidence and mortality rates will be updated to achieve more accurate estimations of direct costs.

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Collaborative Governance in Primary Health Care Facilities, Western Kenya: What is the Influence from the Community?

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Program/Project Purpose: Community participation in governance refers to the collective involvement and engagement of people in decision making, either individually or collectively, in assessing