

Existing Guidance on Ethical Issues in the Public Health Response to Epidemics

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Methodology

Review included:

- All WHO ethics guidance related to epidemics
- Selected English-language guidance from official governmental bodies, preferably at national level
- Selected guidance/position papers from professional associations, advisory commissions, academics
- Most documents focus on outbreak situations

Process:

- Developed list of most frequently-discussed ethical issues
- Identified key “take away messages” related to these issues in each guidance document

Issues Identified

Restrictions on freedom of movement	Field triage
HCW rights and obligations	Informed consent to treatment of infectious disease
Research ethics	Vulnerable populations
Emergency use of unapproved interventions	Procedural considerations and communication plans
Surveillance/data protection	Ethical issues in deploying workers in the field
Use of biological specimens/biobanking	International obligations
Allocating access to scarce resources	

Restrictions on freedom of movement

- Addressed in 12 guidances (1 general; 2 Ebola; 8 pandemic; 1 TB)
- **Consensus points**
 - Preference for voluntary over mandatory measures (“least restrictive alternative”)
 - But mandatory measures can be justified under limited circumstances (Siracusa principles)
 - Duty to ensure humane conditions
 - Emphasis on need for communication/transparency
- **Observations**
 - Some documents emphasize the potential need for mandatory approaches; others stress the dangers

HCW rights and obligations

- Addressed in 15 guidances (1 general; 4 Ebola; 9 pandemic; 1 TB)
- **Consensus points**
 - HCWs have a moral and/or professional obligation to accept some level of risk
 - This obligation is not unlimited
 - Governments and health care institutions have a reciprocal obligation to support HCWs
- **Observations**
 - There is some disagreement as to whether HCWs are entitled to priority access to vaccines/treatments
 - Few of the documents discuss the consequences for HCWs who do not live up to their ethical obligations (i.e., are these obligations simply aspirational or do they “have teeth”)
 - The extent of governments’ and institutions’ reciprocal obligations remains unclear

Research ethics

- Addressed in 6 guidances (1 general; 4 Ebola; 0 pandemic; 1 TB)
- **Consensus points**
 - General principles of research ethics do not change in epidemic situations, but their application must take into account the climate of fear and desperation
 - Procedures for reviewing research protocols may need to be different in outbreak situations
 - Placebo-controlled trials may be appropriate, but alternative trial designs (e.g., adaptive trials in which all participants receive an active intervention) should also be considered
 - Questions of trial design, informed consent, etc. must take into account the importance of building trust
- **Observations**
 - Few specific recommendations for alternative review processes in outbreak situations
 - Circumstances in which placebo-controlled trials are/are not acceptable remain unclear

Emergency use of unapproved interventions

- Addressed in 3 guidances (0 general; 3 Ebola; 0 pandemic; 0 TB)
- **Consensus points**
 - It is ethically acceptable to give patients unproven interventions in outbreak situations
 - There must be a reasonable basis for believing the potential benefits outweigh the risks
 - Whenever possible, unproven interventions should be provided as part of a clinical trial; in all cases, data should be collected
- **Observations**
 - It is unclear whether “compassionate use” should remain an option once clinical trials are underway

Surveillance/data protection

- Addressed in 3 guidances (2 general; 0 Ebola; 0 pandemic; 1 TB)
- **Consensus points**
 - Surveillance activities should undergo some sort of ethical review regardless of whether they technically fall within the definition of “research”
 - The review process need not involve the same mechanisms used to review activities that constitute research
- **Observations**
 - The role of informed consent in surveillance remains unclear

Use of biological specimens/biobanking

- Addressed in 4 guidances (0 general; 2 Ebola; 1 pandemic; 1 TB)
- **Consensus points**
 - Ethical issues should be addressed in advance (e.g., through material transfer agreements)
 - Benefits should be shared with the communities from which samples are drawn
- **Observations**
 - The role of informed consent remains unclear; some documents state that informed consent is always needed, while others emphasize the practical difficulties of obtaining informed consent in outbreak situations

Allocating access to scarce resources

- Addressed in 15 guidances (2 general; 1 Ebola; 12 pandemic; 0 TB)
- **Consensus points**
 - Allocation principles should be determined in advance through an inclusive and transparent process
 - Criteria should incorporate considerations of both utility and equity
 - Utility considerations should be limited to health-related factors (not general social utility)
- **Observations**
 - Many documents suggest that age-based criteria can, in principle, be ethically acceptable, but no guidelines actually endorse such criteria
 - The guidelines recognize that trade-offs may need to be made between utility and equity, but do not indicate how these trade-offs should be made (other than emphasizing the importance of fair process)

Field triage

- Addressed in 5 guidances (1 general; 0 Ebola; 4 pandemic; 0 TB)
- **Consensus points**
 - To the extent possible, principles should be decided at broad policy level, not by bedside clinicians
 - When resources are scarce, it is appropriate to give priority to those who need the fewest resources to recover
 - Review and appeals processes should be established
 - Patients who do not receive curative treatment should be given palliative care; no patients should be abandoned
- **Observations**
 - Specific triage criteria depend on evolving scientific knowledge about the epidemic, so procedures must be flexible
 - Key goal is consistency across broad geographic areas

Informed consent to treatment of infectious disease

- Addressed in 2 guidances (0 general; 0 Ebola; 1 pandemic; 1 TB)
- Consensus points
 - None
- Observations
 - The two guidance documents reviewed provide contradictory advice
 - The French pandemic guidance suggests that compelled treatment may be necessary
 - The WHO TB guidance states that compelled treatment is never appropriate because those who are infectious can be isolated
 - NB: the WHO TB guidance does not specifically address outbreak situations

Vulnerable populations

- Addressed in 12 guidances (3 general; 5 Ebola; 4 pandemic; 0 TB)
- **Consensus points**
 - Vulnerable populations may require additional resources and protections in outbreak situations
 - Response measures can be especially burdensome for vulnerable populations
 - Communication strategies must be special attention to vulnerable populations
- **Observations**
 - Directing resources to vulnerable populations may conflict with the goal of utility/efficiency; this trade-off is acknowledged in some guidelines, but it is not clear how it should be managed

Procedural considerations and communication plans

- Addressed in 18 guidances (3 general; 5 Ebola; 10 pandemic; 0 TB)
- **Consensus points**
 - The ethical acceptability of a response plan depends in large part on the process by which it was developed
 - The decision-making process must be inclusive, transparent, and accountable
 - Procedures should seek to ensure that decisions are made consistently over time and across geographic areas
 - Communication strategies should seek to reduce stigmatization and discrimination
- **Observations**
 - Most guidelines stress stakeholder engagement as an important – perhaps the most important – ethical requirement

Ethical issues in deploying workers in the field

- Addressed in 3 guidances (1 general; 1 Ebola; 1 pandemic; 0 TB)
- **Consensus points**
 - Agencies deploying aid workers have a duty to provide adequate training and resources
 - To the extent possible, support should be provided following discussion and agreement with the host country
- **Observations**
 - Few documents specifically address the ethical obligations of governments and NGOs providing aid

International obligations

- Addressed in 7 guidances (0 general; 2 Ebola; 4 pandemic; 1 TB)
- **Consensus points**
 - Governments have an obligation to provide assistance to other countries in need
 - This obligation includes a duty to support the surveillance capacity of developing countries
- **Observations**
 - The extent of governments' obligation remains unclear, particularly when in situations of resource constraints (e.g., must governments share stockpiled vaccines or treatments if there are not enough for their own population?)

Closing observations

- Widespread consensus exists regarding most ethical issues
 - This is partly because principles are stated at such a high level of generality (e.g., “resources should be distributed equitably”) that few can disagree
- The challenge is applying these general principles to specific situations. For example:
 - When are mandatory restrictions the “least restrictive alternative”?
 - When is it appropriate to collect biological specimens without obtaining informed consent?
 - When is it appropriate – or not appropriate – to direct scarce resources to vulnerable populations when doing so will result in the faster depletion of those resources?
- Next steps: rather than producing another statement of general principles, develop an **implementation guide** with concrete case examples of how the principles were applied in specific situations
 - Similar to how the “common law” is developed by the continual application of broad principles to specific situations