

Guidance for Managing Ethical Issues in Infectious Disease Outbreaks



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Foreword



Infectious disease outbreaks are periods of great uncertainty. Events unfold, resources and capacities that are often limited are stretched yet further, and decisions for a public health response must be made quickly, even though the evidence for decision-making may be scant. In such a situation, public health officials, policy-makers, funders, researchers, field epidemiologists, first responders, national ethics boards, health-care workers, and public health practitioners need a moral compass to guide them in their decision-making. Bioethics puts people at the heart of the problem, emphasizes the principles that should guide health systems, and provides the moral rationale for making choices, particularly in a crisis.

I therefore welcome the development of the *Guidance for managing ethical issues in infectious disease outbreaks*, which will be key to embedding ethics within the integrated global alert and response system for epidemics and other public health emergencies. The publication will also support and strengthen the implementation and uptake of policies and programmes in this context.

Research is an integral part of the public health response – not only to learn about the current epidemic but also to build an evidence base for future epidemics. Research during an epidemic ranges from epidemiological and socio-behavioral to clinical trials and toxicity studies, all of which are crucial. I am pleased

to see that the guidance touches upon this important area with advice, not only on research and emergency use of unproven interventions, but also on rapid data sharing see: http://www.who.int/ihr/procedures/SPG_data_sharing.pdf?ua=1.

The importance given to communication during an infectious disease outbreak can make or break public health efforts, and WHO takes this very seriously. This document outlines the ethical principles that should guide communication planning and implementation at every level from frontline workers to policy-makers.

The guidance represents the work of an international group of stakeholders and experts, including public health practitioners in charge of response management at the local, national and international level; nongovernmental organization representatives; directors of funding agencies; chairs of ethics committees; heads of research laboratories; representatives of national regulatory agencies; patient representatives; and experts in public health ethics, bioethics, human rights, anthropology, and epidemiology. I am grateful for their support and input.

Dr Marie-Paule Kieny
Assistant Director-General
Health Systems and Innovation

A handwritten signature in black ink, appearing to read 'M. Kieny', with a stylized star-like flourish above the first name.

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Introduction

This guidance grew out of concern at the World Health Organization (WHO) about ethical issues raised by the Ebola outbreak in West Africa in 2014–2016. The WHO Global Health Ethics Unit's response to Ebola began in August 2014, immediately after it was declared a "public health emergency of international concern" pursuant to the *International Health Regulations (2005)* (IHR).¹ That declaration led to the formation of an Ethics Panel, and later an Ethics Working Group, which was charged with developing ethics guidance on issues and concerns as they arose in the course of the epidemic. It became increasingly apparent that the ethical issues raised by Ebola mirrored concerns that had arisen in other global infectious disease outbreaks, including severe acute respiratory syndrome (SARS), pandemic influenza, and multidrug-resistant tuberculosis. However, while WHO has issued ethical guidance on some of these outbreaks,^{2,3,4,5} prior guidance has only focused on the specific pathogen in isolation. The purpose of this document is to look beyond issues specific to particular epidemic pathogens and instead focus on the cross-cutting ethical issues that apply to infectious disease outbreaks generally. In addition to setting forth general principles, it examines how these principles can be adapted to different epidemiological and social circumstances.

While many of the ethical issues that arise in infectious disease outbreaks are the same as those that arise in other

areas of public health, the context of an outbreak has particular complexities. Decisions during an outbreak need to be made on an urgent basis, often in the context of scientific uncertainty, social and institutional disruption, and an overall climate of fear and distrust. Invariably, the countries most affected by outbreaks have limited resources, underdeveloped legal and regulatory structures, and health systems that lack the resilience to deal with crisis situations. Countries that experience natural disasters and armed conflicts are particularly at risk, as these circumstances simultaneously increase the risk of infectious disease outbreaks while decreasing needed resources and access to health care. Moreover, infectious disease outbreaks can generate or exacerbate social crises that can weaken already fragile health systems. Within such contexts, it is not possible to satisfy all urgent needs simultaneously, forcing decision-makers to weigh and prioritize potentially competing ethical values. Time pressures and resource constraints may force action without the thorough deliberation, inclusiveness and transparency that a robust ethical decision-making process demands.

This guidance document on ethical issues that arise specifically in the context of infectious disease outbreaks aims to complement existing guidance on ethics in public health. It should therefore be read in conjunction with more general guidance on issues such as public health surveillance,

research with human participants, and addressing the needs of vulnerable populations.

Setting up decision-making systems and procedures in advance is the best way to ensure that ethically appropriate decisions will be made if an outbreak occurs. Countries, health-care institutions, international organizations and others involved in epidemic response efforts are encouraged to develop practical strategies and tools to apply the principles in this guidance document to their specific settings, taking into account local social, cultural, and political contexts. WHO is committed to providing countries with technical assistance in support of these efforts.

Relevant ethical principles

Ethics involves judgements about “the way we ought to live our lives, including our actions, intentions, and our habitual behaviour.”³ The process of ethical analysis involves identifying relevant principles, applying them to a particular situation, and making judgements about how to weigh competing principles when it is not possible to satisfy them all. This guidance document draws on a variety of ethical principles, which are grouped below into seven general categories. These categories are presented merely for the convenience of the reader; other ways of grouping them are equally legitimate.

Justice — As used in this document, justice, or fairness, encompasses two different concepts. The first is *equity*, which refers to fairness in the distribution of resources, opportunities and outcomes. Key elements of equity include treating like

cases alike, avoiding discrimination and exploitation, and being sensitive to persons who are especially vulnerable to harm or injustice. The second aspect of justice is *procedural justice*, which refers to a fair process for making important decisions. Elements of procedural justice include due process (providing notice to interested persons and an opportunity to be heard), transparency (providing clear and accurate information about the basis for decisions and the process by which they are made), inclusiveness/community engagement (ensuring all relevant stakeholders are able to participate in decisions), accountability (allocating and enforcing responsibility for decisions), and oversight (ensuring appropriate mechanisms for monitoring and review).

Beneficence — Beneficence refers to acts that are done for the benefit of others, such as efforts to relieve individuals’ pain and suffering. In the public health context, the principle of beneficence underlies society’s obligation to meet the basic needs of individuals and communities, particularly humanitarian needs such as nourishment, shelter, good health, and security.

Utility — The principle of utility states that actions are right insofar as they promote the well-being of individuals or communities. Efforts to maximize utility require consideration of proportionality (balancing the potential benefits of an activity against any risks of harm) and efficiency (achieving the greatest benefits at the lowest possible cost).

Respect for persons — The term “respect for persons” refers to treating individuals in ways that are fitting to and informed by a recognition of our common humanity, dignity and inherent rights. A central

aspect of respect for persons is respect for autonomy, which requires letting individuals make their own choices based on their values and preferences. Informed consent, a process in which a competent individual authorizes a course of action based on sufficient relevant information, without coercion or undue inducement, is one way to operationalize this concept. Where individuals lack decision-making capacity, it may be necessary for others to be charged with protecting their interests. Respect for persons also includes paying attention to values such as privacy and confidentiality, as well as social, religious and cultural beliefs and important relationships, including family bonds. Finally, respect for persons requires transparency and truth-telling in the context of carrying out public health and research activities.

Liberty — Liberty includes a broad range of social, religious and political freedoms, such as freedom of movement, freedom of peaceful assembly, and freedom of speech. Many aspects of liberty are protected as fundamental human rights.

Reciprocity — Reciprocity consists of making a “fitting and proportional return” for contributions that people have made.⁶ Policies that encourage reciprocity can be an important means of promoting the principle of justice, as they can correct unfair disparities in the distribution of the benefits and burdens of epidemic response efforts.

Solidarity — Solidarity is a social relation in which a group, community, nation or, potentially, global community stands together.⁷ The principle of solidarity justifies collective action in the face of common threats. It also supports efforts to overcome inequalities that undermine the welfare

of minorities and groups that suffer from discrimination.

Practical applications

The application of ethical principles should be informed by evidence as far as it is available. For example, in determining whether a particular action contributes to utility, decision-makers should be guided by any available scientific evidence about the action’s expected benefits and harms. The more intrusive the proposed action, the greater the need for robust evidence that what is being proposed is likely to achieve its desired aim. When specific evidence is not available, decisions should be based on reasoned, substantive arguments and informed by evidence from analogous situations, to the extent possible.

In balancing competing principles during infectious disease outbreaks, countries must respect their obligations under international human rights agreements. The *Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights* (the “Siracusa Principles”)⁸ are a widely accepted framework for evaluating the appropriateness of limiting certain fundamental human rights in emergency situations. The Siracusa Principles provide that any restrictions on human rights must be carried out in accordance with the law and in pursuit of a legitimate objective of general interest. In addition, such restrictions must be strictly necessary and there must be no other, less intrusive means available to reach the same objective. Finally, any restrictions must be based on scientific evidence and not imposed in an arbitrary, unreasonable, or discriminatory manner.

For both pragmatic and ethical reasons, maintaining the population's trust in epidemic response efforts is of fundamental importance. This is possible only if policy-makers and response workers act in a trustworthy manner by applying procedural principles fairly and consistently, being open to review based on new relevant information, and acting with the genuine input of affected communities. In addition, a synchronized approach is indispensable to the success of any response effort. All members of the global community need to act in solidarity, since all countries share a common vulnerability to the threat of infectious disease.

How the Guidance was developed

Many individuals have helped shape this guidance document, directly or indirectly, starting with the Ethics Panel that was convened by the Director-General on 11 August 2014, and the ad-hoc ethics working groups that met in Geneva, Switzerland between August and October 2014 to provide guidance on the use of untested interventions during the Ebola outbreak in West Africa. Subsequently, in May 2015, a group of experts and stakeholders met in Dublin, Ireland to review existing ethical statements on infectious disease outbreaks and develop a methodology to create a more comprehensive document. To assist this process, an analysis and synthesis of all existing guidance documents relevant to ethical considerations in infectious disease outbreaks was prepared (Annex 1). Reflecting on lessons learnt from previous outbreaks, particularly the recent experiences with Ebola, participants emphasized the need for

guidance that could be tailored to different epidemiological, social, and economic contexts. They also discussed the importance of focusing on broader questions of global health governance, community engagement, knowledge generation, and priority setting. Finally, participants emphasized the urgent need to develop concrete operational tools to help individuals involved in epidemic response efforts to incorporate ethical guidance into practical decision-making. The group met again in November 2015 in Prato, Italy to review an initial draft of the guidance and to hear from additional experts and stakeholders, including survivors of the recent Ebola outbreak. Following this meeting, a new draft was developed and circulated for international peer review. The experts that participated in these meetings to prepare the Guidelines are listed in Annex 2.

This document is organized around 14 specific guidelines, each of which addresses key aspects of epidemic planning and response. Each guideline is introduced by a series of questions that illustrate the scope of the ethical issues, followed by a more detailed discussion that articulates the rights and obligations of relevant stakeholders. It is hoped that this document will be useful to policy-makers, public health professionals, health-care providers, frontline responders, researchers, pharmaceutical and medical device companies, and other relevant entities involved in infectious disease outbreaks planning and response efforts in the public and private sectors.



Ebola in DRC
Source: WHO

Guidelines

1. Obligations of governments and the international community

Questions addressed:

- What are the obligations of governments to prevent and respond to infectious disease outbreaks?
- Why do countries' obligations to prevent and respond to infectious disease outbreaks extend beyond their own borders?
- What obligations do countries have to participate in global surveillance and preparedness efforts?
- What obligations do governments have to provide financial, technical, and scientific assistance to countries in need?

Governments can play a critical role in preventing and responding to infectious disease outbreaks by improving social and environmental conditions, ensuring well-functioning and accessible health systems, and engaging in public health surveillance and prevention activities. Together, these actions can substantially reduce the spread of diseases with epidemic potential. In addition, they help assure that an effective public health response will be possible if an epidemic occurs. Governments have an ethical obligation to ensure the long-term capacity of the systems necessary to carry out effective epidemic prevention and response efforts.

Countries have obligations not only to persons within their own borders but also to the broader international community. As the United Nations Committee on

Economic, Social and Cultural Rights has recognized, "given that some diseases are easily transmissible beyond the frontiers of a State, the international community has a collective responsibility to address this problem. The economically developed States Parties have a special responsibility and interest to assist the poorer developing States in this regard."⁹

These obligations reflect the practical reality that infectious disease outbreaks do not respect national borders, and that an outbreak in one country can put the rest of the world at risk.

Countries' obligations to consider the needs of the international community do not arise solely in times of emergency. Instead, they require ongoing attention to ameliorate the social determinants of poor

health that contribute to infectious disease outbreaks, including poverty, limited access to education, and inadequate systems of water and sanitation.

The following are key elements of the obligations of governments and the international community:

- **Ensuring the sufficiency of national public health laws** — As discussed later in this document, certain public health interventions that might be necessary during an infectious disease outbreak (e.g. restrictions on freedom of movement) depend on having a clear legal basis for government action, as well as a system in place to provide oversight and review. All countries should review their public health laws to ensure that they give the government sufficient authority to respond effectively to an epidemic while also providing individuals with appropriate human rights protections.
- **Participating in global surveillance and preparedness efforts** — All countries must carry out their responsibilities under the IHR to participate in global surveillance efforts in a truthful and transparent manner. This includes providing prompt notification of events that may constitute a public health emergency of international concern, regardless of any negative consequences that may be associated with notification, such as a possible reduction in trade or tourism. The obligation to provide prompt notification to the international community stems not only from the text of the IHR but also from the ethical principles of solidarity and reciprocity. In addition, countries should develop

preparedness plans for infectious disease outbreaks and other potential disasters and provide guidance to relevant health-care facilities to implement the plans.

- **Providing financial, technical, and scientific assistance** — Countries that have the resources to provide foreign assistance should support global epidemic preparedness and response efforts, including research and development on diagnostics, therapeutics, and vaccines for pathogens with epidemic potential. This support should supplement ongoing efforts to build local public health capacities and strengthen primary health care systems in countries at greatest risk of harm from infectious disease outbreaks.



Avian Influenza in Indonesia
Source: Gary Hampton, WHO

2. Involving the local community

Questions addressed:

- Why is community engagement a critical component of infectious disease outbreak response efforts?
- What are the hallmarks of a community-centred approach to infectious disease outbreak response?
- What should decision-makers do with input they receive during community engagement activities?
- What is the media's role in infectious disease outbreak response efforts?

All aspects of infectious disease outbreak response efforts should be supported by early and ongoing engagement with the affected communities. In addition to being ethically important in its own right, community engagement is essential to establishing and maintaining trust and preserving social order.

Involving communities fully in infectious disease outbreak planning and response efforts requires attention to the following issues:

- **Inclusiveness** — All persons who could potentially be affected should have opportunities to make their voices heard in all stages of infectious disease outbreak planning and response, either directly or through legitimate representatives. Adequate communication platforms and tools should be put in place to facilitate public communication with health authorities.
- **Situations of particular vulnerability** — As discussed further in Guideline 3, special attention should be given to ensuring that persons who face heightened susceptibility to harm or injustice during infectious disease outbreaks are able to contribute to decisions about infectious disease outbreak planning and response. Public health officials should recognize that such persons might be distrustful of government and other institutions, and make special efforts to include them in community engagement plans.
- **Openness to diverse perspectives** — Communication efforts should be designed to facilitate a genuine two-way dialogue, rather than as merely a means to announce decisions

that have already been made. Decision-makers should be prepared to recognize and debate alternative approaches and revise their decisions based on information they receive. Reaching out to the community early, and allowing for consideration of the interests of all people who will potentially be affected, can play an important role in building trust and empowering communities to be involved in a genuine dialogue.

- **Transparency** — The ethical principle of transparency requires that decision-makers publicly explain the basis for decisions in language that is linguistically and culturally appropriate. When decisions must be made in the face of uncertain information, the uncertainties should be explicitly acknowledged and conveyed to the public.
- **Accountability** — The public should know who is responsible for making

and implementing decisions in relation to the outbreak response, and how they can challenge decisions they believe are inappropriate.

The media will play an important role in any infectious disease outbreak response effort. It is therefore important to ensure that the media has access to accurate and timely information about the disease and its management. Governments, nongovernmental organizations, and academic institutions should make efforts to support media training in relevant scientific concepts and techniques for communicating risk information without raising unnecessary alarm. Media training is important for public health sector employees who may interact with media covering public health issues. In turn, the media has a responsibility to provide accurate, factual, and balanced reporting. This is an important component of media ethics.



3. Situations of particular vulnerability

Questions addressed:

- Why are some individuals and groups considered particularly vulnerable during infectious disease outbreaks?
- How can vulnerability affect a person's ability to access services during infectious disease outbreaks?
- How can vulnerability affect a person's willingness and ability to share and receive information during an infectious disease outbreak?
- Why are stigmatization and discrimination particular risks during infectious disease outbreaks?
- In what ways might vulnerable persons suffer disproportionate burdens from infectious disease response efforts, or have a greater need for resources?

Some individuals and groups face heightened susceptibility to harm or injustice during infectious disease outbreaks. Policy-makers and epidemic responders should develop plans to address the needs of such individuals and groups in advance of an outbreak and, if an outbreak occurs, make reasonable efforts to ensure that these needs are actually met. Doing this requires ongoing attention to community engagement and the development of active social networks between community representatives and government actors.

Efforts to address the ways in which individuals and groups may be vulnerable should take into account the following:

- **Difficulty accessing services and resources** — Many of the characteristics that contribute to social vulnerability can make it difficult for individuals to access necessary services. For example, persons with physical disabilities may have mobility impairments that make travelling even short distances difficult or impossible. Other socially vulnerable persons may lack access to safe and reliable transportation or have caregiving responsibilities that make it difficult for them to leave their homes. In addition, vulnerable persons may lack access to necessary resources such as clean water or bednets to reduce the risk of contracting a mosquito-borne disease.

- ***Need for effective alternative communication strategies*** — Some types of vulnerability can impede an individual's ability to transmit or receive information. Communication barriers can stem from a wide range of factors including, but not limited to, illiteracy, unfamiliarity with the local or official language(s), vision or hearing impairments, social isolation, or lack of access to Internet and other communication services. These barriers make it difficult for individuals to receive necessary public health messages or to participate fully in community engagement activities. To overcome these barriers, messages should be delivered in multiple formats (e.g. radio, text messages, billboards, cartoons) as well as direct oral communication with key stakeholders. Health authorities should not assume that the public will search for information; instead, they should proactively reach out to the concerned population wherever they are.
- ***Impact of stigmatization and discrimination*** — Members of socially disadvantaged groups often face considerable stigma and discrimination, which can be exacerbated in public health emergencies characterized by fear and distrust. Those responsible for infectious disease outbreak response should ensure that all individuals are treated fairly and equitably regardless of their social status or perceived “worth” to society. They should also take measures to prevent stigmatization and social violence.
- ***Disproportionate burdens of outbreak response measures*** — Even when public health measures are designed with the best of intentions, they can inadvertently place a disproportionate burden on particular populations. For example, quarantine orders that require individuals to stay in their homes can have devastating consequences for persons who need to leave their homes to obtain basic necessities such as clean water or food. Similarly, social distancing measures such as school closures can place disproportionate burdens on children who depend on going to school to access regular meals, as well as on working parents who may have no one available to provide child care.
- ***Greater need for resources*** — Accommodating the needs of individuals whose situation makes them particularly vulnerable sometimes requires the use of additional resources. In some cases, additional resources are relatively minimal, such as when an interpreter is hired to make a community engagement forum accessible to members of a linguistic minority group. In other cases, they may be more substantial, such as when mobile health teams are assembled to dispatch vaccines and treatments to hard-to-reach rural areas. It is legitimate to take costs into consideration in determining whether a particular accommodation is warranted; indeed, the goal of maximizing utility demands that such assessments be made. However, despite the importance of conserving limited resources, the ethical principle of equity may sometimes justify providing greater resources to persons who have greater needs.
- ***Heightened risk of violence*** — Infectious disease outbreaks can

exacerbate social unrest, increase criminality, and induce violent behaviour, especially against vulnerable groups such as minority populations or migrants. In addition, public health measures such as home isolation, quarantine, or closure of schools and work facilities can induce violence, particularly against women and children. Officials involved in outbreak planning and response efforts should be prepared for the possibility that

specific populations may be targeted as being the cause of the outbreak or provoking transmission; strategies should be proactively designed to protect members of such groups from a heightened risk of violence.



A doctor inspects patients in an MSF supported hospital in Aweil, Northern Bar El Ghazal in South Sudan, 2011
Source: Siegfried Modola/IRIN

4. Allocating scarce resources

Questions addressed:

- What type of resource allocation decisions might need to be made during infectious disease outbreaks?
- How do the principles of utility and equity apply to decisions about allocating scarce resources during infectious disease outbreaks?
- How does the principle of reciprocity apply to decisions about allocating scarce resources during infectious disease outbreaks?
- What procedural considerations apply to decisions about resource allocation during infectious disease outbreaks?
- What obligations do health-care providers have towards persons who are not able to access life-saving resources during infectious disease outbreaks?

Infectious disease outbreaks can quickly overwhelm the capacities of governments and health-care systems, requiring them to make difficult decisions about the allocation of limited resources. Some of these decisions may arise in the context of allocating medical interventions, such as hospital beds, medications, and medical equipment. Others may relate to broader questions about how public health resources should be utilized. For example, how should limited resources be allocated between activities such as surveillance, health promotion, and community engagement? Should human resources be devoted to contact tracing at the possible expense of patient management? Should limited funds be spent improving water and

sanitation facilities or building quarantine facilities?

Infectious disease outbreaks also compete with other important public health issues for attention and resources. For example, one of the consequences of the Ebola outbreak was a reduction in access to general health-care services due to a combination of a greater number of patients and the sickness and death of health-care workers. As a result, deaths from tuberculosis, human immunodeficiency virus (HIV), and malaria increased dramatically during this period.¹⁰

Governments, health-care facilities, and others involved in response efforts should

prepare for such situations by developing guidelines on the allocation of scarce resources in outbreak situations. Such guidelines should be developed through an open and transparent process involving broad stakeholder input and, to the extent possible, should be incorporated into formal written documents that establish clear priorities and procedures. Those involved in developing these guidelines should be guided by the following considerations:

- **Balancing considerations of utility and equity** — Resource allocation decisions should be guided by the ethical principles of utility and equity. The principle of utility requires allocating resources to maximize benefits and minimize burdens, while the principle of equity requires attention to the fair distribution of benefits and burdens. In some cases, an equal distribution of benefits and burdens may be considered fair, but in others, it may be fairer to give preference to groups that are worse off, such as the poor, the sick, or the vulnerable. It is not always possible to achieve fully both utility and equity. For example, establishing treatment centres in large urban settings promotes the value of utility because it makes it possible to treat a large number of people with relatively few resources. However, such an approach may be in tension with the principle of equity if it means that fewer resources will be directed to isolated communities in remote rural areas. There is no single correct way to resolve potential tensions between utility and equity; what is important is that decisions are made through an inclusive and transparent process that takes into account local circumstances.
- **Defining utility on the basis of health-related considerations** — In order to apply the ethical principle of utility, it is first necessary to identify the type of outcomes that will be counted as improvements to welfare. In general, the focus should be on the health-related benefits of allocation mechanisms, whether defined in terms of the total number of lives saved, the total number of life years saved, or the total number of quality-adjusted life years saved. For this reason, while it might be ethical to prioritize persons who are essential to manage an outbreak, it is not appropriate to prioritize persons based on social value considerations unrelated to carrying out critical services necessary for society.
- **Paying attention to the needs of vulnerable populations** — In applying the ethical principle of equity, special attention should be given to individuals and groups that are the most vulnerable to discrimination, stigmatization, or isolation, as discussed in Guideline 3. Particular consideration must be given to individuals who are confined in institutional settings, where they are highly dependent on others and potentially exposed to much higher risks of infection than persons living in the community.
- **Fulfilling reciprocity-based obligations to those who contribute to infectious disease outbreak response efforts** — The ethical principle of reciprocity implies that society should support persons who face a disproportionate burden or risk in protecting the public good. This principle justifies giving priority access to scarce resources to persons who

assume risks to their own health or life to contribute to outbreak response efforts.

- **Providing supportive and palliative care to persons unable to access life-saving resources** — Even when it is not possible to provide life-saving medical resources to all who could benefit from them, efforts should be made to ensure that no patients are abandoned. One way to do this is to ensure that adequate resources are directed to providing supportive and palliative care.

The application of allocation principles should take into account the following considerations:

- **Consistent application** — Allocation principles should be applied in a consistent manner, both within individual institutions and, to the extent possible, across geographic areas. Decision-making tools should be developed to ensure that like cases are treated alike, and that no person receives better or worse treatment due to his or her social status or other factors not explicitly recognized in the allocation plan. Efforts should be made to avoid unintended systemic discrimination in the choice or application of allocation methods.
- **Resolution of disputes** — Mechanisms should be developed to resolve disagreements about the application of allocation principles; these mechanisms should be designed to ensure that anyone who believes that allocation principles have been applied inappropriately has access to impartial and accountable review processes, and has the opportunity to be heard.
- **Avoiding corruption** — Corruption in the health-care sector may be exacerbated during infectious disease outbreaks if large numbers of individuals are competing for access to limited resources. Efforts should be made to ensure that persons involved in the application of allocation systems do not accept or give bribes or engage in other corrupt activities.
- **Separation of responsibilities** — To the extent possible, the interpretation of allocation principles should not be entrusted to clinicians who have pre-existing professional relationships that create an ethical obligation to advocate for the interests of specific patients or groups. Instead, decisions should be made by appropriately qualified clinicians who have no personal or professional reasons to advocate for one patient or group over another.

5. Public health surveillance

Questions addressed:

- What role does surveillance play in infectious disease outbreak response efforts?
- Should surveillance activities be subject to ethical review?
- What obligations do entities conducting surveillance activities have to protect the confidentiality of information collected?
- Are there any circumstances under which individuals should be asked for consent to, or given the opportunity to opt out of, surveillance activities?
- What obligations do those conducting surveillance activities have to disclose information they collect to the affected individuals and communities?

Systematic observation and data collection are essential components of emergency response measures, both to guide the management of the current outbreak and to help prevent and respond to outbreaks in the future. Even if these activities are not characterized as research for regulatory purposes, an ethical analysis should be undertaken to ensure that personal information is protected from physical, legal, psychological, and other harm. Countries should consider organizing systems for ethical oversight of public health activities, commensurate with the activity objectives, methods, risks and benefits, as well as the extent to which the activity involves individuals or groups whose situation may make them vulnerable. Regardless of whether such systems are adopted, ethical analysis of public

health activities should be consistent with accepted norms of public health ethics and conducted by individuals or entities that can be held accountable for their decisions.

Ensuring high-quality, ethically appropriate surveillance is complicated by at least two factors. First, the law surrounding surveillance across jurisdictions may be unnecessarily complex or inconsistent. Second, surveillance activities will occur across jurisdictions with varying levels of resources, thus placing strains on the quality and reliability of the data. These issues are likely to be exacerbated during an infectious disease outbreak, creating an urgent need for careful planning and international collaboration. Specific issues that should be addressed include the following:

- **Protecting the confidentiality of personal information** — The unauthorized disclosure of personal information collected during an infectious disease outbreak (including name, address, diagnosis, family history, etc.) can expose individuals to significant risk. Countries should ensure that adequate protection exists against these risks, including laws that safeguard the confidentiality of information generated through surveillance activities, and that strictly limit the circumstances in which such information may be used or disclosed for purposes different from those for which it was initially collected. Use and sharing of non-aggregated surveillance data for research purposes must have the approval of a properly constituted and trained research ethics committee.
- **Assessing the importance of universal participation** — Public health surveillance is typically conducted on a mandatory basis, without the possibility of individual refusal. Collecting surveillance information on a mandatory basis is ethically appropriate on the grounds of public interest if an accountable governmental authority has determined that universal participation is necessary to achieve compelling public health objectives. However, it should not be assumed that surveillance activities must always be carried out on a mandatory basis. Entities responsible for designing and approving surveillance programmes should consider the appropriateness of allowing individuals to opt out of particular surveillance activities, taking into account the nature and degree of individual risks involved and the extent to which allowing opt-outs would undermine the activity's public health goals.
- **Disclosing information to individuals and communities** — Regardless of whether individuals are given the choice to opt out of surveillance activities, the process of surveillance should be conducted on a transparent basis. At a minimum, individuals and communities should be aware of the type of information that will be gathered about them, the purposes for which this information will be used, and any circumstances under which the information collected may be shared with third parties. In addition, information about the outcome of the surveillance activity should be made available as soon as reasonably possible. Careful attention should be given to the manner in which this information is communicated, in order to minimize the risk that subjects of surveillance may face stigmatization or discrimination.

6. Restrictions on freedom of movement

Questions addressed:

- Under what circumstances is it legitimate to restrict an individual's freedom of movement during an infectious disease outbreak?
- What living conditions should be assured for individuals whose freedom of movement has been restricted?
- What other obligations are owed to individuals whose freedom of movement has been restricted?
- What procedural protections must be established to ensure that restrictions on freedom of movement are carried out appropriately?
- What are the obligations of policy-makers and public health officials to inform the public about restrictions on freedom of movement?

Restrictions on freedom of movement include isolation, quarantine, travel advisories or restrictions, and community-based measures to reduce contact between people (e.g. closing schools or prohibiting large gatherings). These measures can often play an important role in controlling infectious disease outbreaks, and in these circumstances, their use is justified by the ethical value of protecting community well-being. However, the effectiveness of these measures should not be assumed; in fact, under some epidemiological circumstances, they may contribute little or nothing to outbreak control efforts, and may even be counterproductive if they engender a backlash that leads to resistance to

other control measures. Moreover, all such measures impose a significant burden on individuals and communities, including direct limitations of fundamental human rights, particularly the rights to freedom of movement and peaceful assembly.

In light of these considerations, no restrictions on freedom of movement should be implemented without careful attention to the following considerations:

- **Justifiable basis for imposing restrictions** — Decisions to impose restrictions on freedom of movement should be grounded on the best available evidence

about the outbreak pathogen, as determined in consultation with national and international public health officials. No such interventions should be implemented unless there is a reasonable basis to expect they will significantly reduce disease transmission. The rationale for relying on these measures should be made explicit, and the appropriateness of any restrictions should be continuously re-evaluated in light of emerging scientific information about the outbreak. If the original rationale for imposing a restriction no longer applies, the restriction should be lifted without delay.

- **Least restrictive means** — Any restrictions on freedom of movement should be designed and implemented in a manner that imposes the fewest constraints reasonably possible. Greater restrictions should be imposed only when there are strong grounds to believe that less restrictive measures are unlikely to achieve important public health goals. For example, requests for voluntary cooperation are generally preferable to public health mandates enforced by law or military authorities. Similarly, home-based quarantine should be considered before confining individuals in institutions. While isolation in a properly equipped health-care facility is usually recommended for individuals who are already symptomatic, especially for diseases with a high potential for contagiousness, home-based isolation may sometimes be appropriate, provided that adequate medical and logistical support can be organized and family attendants are willing and able to act under the oversight of trained public health staff. This is particularly true if the caseload overwhelms facility capacity.
- **Costs** — In some cases, a less restrictive alternative may involve greater costs. This does not, in itself, justify more restrictive approaches. However, costs and other practical constraints (e.g. logistics, distance, available workforce) may legitimately be taken into account to determine whether a less restrictive alternative is feasible under the circumstances, particularly in settings with severe resource constraints.
- **Ensuring humane conditions** — Any restrictions on freedom of movement, particularly those that are not voluntary, should be backed up with sufficient resources to ensure that those subject to the restrictions do not experience undue burdens. For example, individuals whose mobility is restricted (whether through confinement at home or in institutional settings) should be ensured access to food, drinking water, sanitary facilities, shelter, clothing, and medical care. It is also important to ensure that individuals have adequate physical space, opportunities to engage in activities, and the means to communicate with their loved ones and the outside world. Fulfilling these needs is essential to respect individual dignity and address the significant psychosocial burden of confinement on individuals and their loved ones. Mechanisms should be put in place to minimize the risk of violence (including sexual assault) and local disease transmission, especially when individuals are confined in institutional settings or when communities are under mass quarantine. At a minimum, persons who

are quarantined because they have been exposed to the pathogen responsible for the outbreak should not be put at heightened risk of infection because of the manner in which they are confined. (Decisions on the circumstances and conditions of confinement should consider the heightened needs of vulnerable populations, as discussed in Guideline 3.)

- **Addressing financial and social consequences** — Even short-term restrictions on freedom of movement can have significant — and possibly devastating — financial and social consequences for individuals, their families, and their communities. Countries should provide assistance to households that suffer financial losses as a result of inability to conduct business, loss of a job, damage to crops, or other consequences of restrictions on freedom of movement. In some cases, this support may need to continue for a period following the end of confinement. In addition, efforts should be made to support the social and professional reintegration of individuals for whom confinement is no longer necessary, including measures to reduce stigmatization and discrimination.
- **Due process protections** — Mechanisms should be in place to allow individuals whose liberty has been restricted to challenge the appropriateness of those restrictions, the way they are enforced, and the conditions under which the restrictions are carried out. If it is not feasible to provide full due process protection before the restrictions are implemented in an emergency scenario, mechanisms for review and appeal should be made

available without excessive delay. All persons involved in decisions to restrict individuals' freedom of movement should be accountable for any abuses of authority.

- **Equitable application** — Restrictions on freedom of movement should be applied in the same manner to all persons posing a comparable public health risk. Thus, individuals should not be subject to greater or lesser restrictions for reasons unrelated to the risks they may pose to others, including membership in any disfavoured or favoured social group or class (for example, groups defined by gender, ethnicity, or religion). In addition, policy-makers should seek to ensure that restrictions are not applied in a manner that imposes a disproportionate burden on vulnerable segments of society.
- **Communication and transparency** — Policy-makers and public health officials should engage communities in a dialogue about any restrictions on freedom of movement and solicit community members' views on how restrictions can be carried out with the least possible burden. They should also provide regular updates on the implementation of such measures, both to the public at large and to those whose movement has been restricted. Communication strategies should be designed to avoid the stigmatization of individuals whose liberty has been restricted and to protect their privacy and confidentiality, particularly in the media.

7. Obligations related to medical interventions for the diagnosis, treatment, and prevention of infectious disease

Questions addressed:

- What quality and safety standards should govern the administration of medical interventions offered during infectious disease outbreaks?
- What rights do patients (or their authorized proxy decision-makers) have to receive information about the risks and benefits of, and alternatives to, medical interventions during infectious disease outbreaks?
- Under what circumstances, if any, might it be appropriate to override an individual's refusal of diagnostic, therapeutic, or preventive measures during an infectious disease outbreak?
- What procedural safeguards should be provided before overriding an individual's refusal of diagnostic, therapeutic, or preventive measures during an infectious disease outbreak?

Any medical intervention for the diagnosis, treatment, or prevention of infectious disease should be provided in accord with professional medical standards, under conditions designed to ensure the highest attainable level of patient safety. Countries, with the support of international experts, should establish the minimum standards to be applied in the care and treatment of patients affected by an outbreak. These standards should apply not only to health-care institutions but also to home-based care, community activities (including health education sessions), and environmental decontamination efforts or the management of dead bodies.

Individuals offered medical interventions for the diagnosis, treatment, or prevention of an infectious pathogen should be informed about the risks, benefits, and alternatives, just as they would be for other significant medical interventions. The presumption should be that the final decision about which medical interventions to accept, if any, belongs to the patient. For patients who lack the legal capacity to make health-care decisions for themselves, decisions should generally be made by appropriately authorized proxy decision-makers, with efforts made to solicit the patient's assent whenever possible.

Health-care providers should recognize that, in some situations, the refusal of diagnostic, therapeutic, or preventive measures might be a choice that is rational from the perspective of a mentally competent individual. If an individual is unwilling to accept an intervention, providers should engage the patient in an open and respectful dialogue, paying careful attention to the patient's concerns, perceptions, and situational needs.

In exceptional situations, there may be legitimate reasons to override an individual's refusal of a diagnostic, therapeutic, or preventive measure that has proven to be safe and effective and is part of the accepted medical standard of care. Decisions on whether to override a refusal should be grounded in the following considerations:

- **Public health necessity of the proposed intervention** — A mentally competent individual's refusal of diagnostic, therapeutic, or preventive measures should only be overridden when there is substantial reason to believe that accepting the refusal would pose significant risks to public health, that the intervention is likely to ameliorate those risks, and that no other measures to protect public health — including isolating the patient — are feasible under the circumstances.
- **Existence of medical contraindications to the proposed intervention** — Some interventions that may pose low risks for the majority of the population can pose heightened risks for individuals with particular medical conditions. Individuals should not be forced to undergo interventions that would expose them to significant risks in light of their personal medical circumstances.

- **Feasibility of providing interventions to an unwilling patient** — In some cases, it may be impossible to provide an intervention to an individual who is unwilling to be an active participant in the process. For example, standard treatment for tuberculosis requires the patient to take medication on a regular basis for several months. Without the patient's cooperation, it is unrealistic to expect that such a lengthy treatment regimen could successfully be completed. In such circumstances, the only realistic way to protect public health may be to isolate the patient until he or she is no longer infectious, assuming it is feasible to do so in a humane manner.
- **Impact on community trust** — Overriding individuals' refusal of diagnostic, therapeutic, or preventive measures can backfire if it leads members of the community to become distrustful of health-care providers or the public health system. Benefits from imposing unwanted interventions should be balanced against possible harms caused by undermining trust in the health-care system.

Objections to diagnostic, therapeutic, or preventive measures should not be overridden without giving the individual notice and an opportunity to raise his or her objections before an impartial decision-maker, such as a court, interdisciplinary review panel, or other entity not involved in the initial decision. The burden should be on the proposer of the intervention to show that the expected public health benefits justify overriding the individual's choice. The process for resolving objections should be conducted in an open and transparent manner, consistent with the principles discussed in Guideline 2.

8. Research during infectious disease outbreaks

Questions addressed:

- What is the appropriate role of research during an infectious disease outbreak?
- How might the circumstances surrounding infectious disease outbreaks affect the ethical review of research proposals?
- How might the circumstances surrounding infectious disease outbreaks affect the process of informed consent to research?
- What methodological designs are appropriate for research conducted during infectious disease outbreaks?
- How should research be integrated into broader outbreak response efforts?

During an infectious disease outbreak there is a moral obligation to learn as much as possible as quickly as possible, in order to inform the ongoing public health response, and to allow for proper scientific evaluation of new interventions being tested. Such an approach will also improve preparedness for similar future outbreaks. Carrying out this obligation requires carefully designed and ethically conducted scientific research. In addition to clinical trials evaluating diagnostics, treatments or preventive measures such as vaccines, other types of research — including epidemiological, social science, and implementation studies — can play a critical role in reducing morbidity and mortality and addressing the

social and economic consequences caused by the outbreak.

Research conducted during an infectious disease outbreak should be designed and implemented in conjunction with other public health interventions. Under no circumstances should research compromise the public health response to an outbreak or the provision of appropriate clinical care. All clinical trials must be prospectively registered in an appropriate clinical trial registry.

As in non-outbreak situations, it is essential to ensure that studies are scientifically valid and add social value; that risks are reasonable in relation to anticipated

benefits; that participants are selected fairly and participate voluntarily (in most situations following an explicit process of informed consent); that participants' rights and well-being are sufficiently protected; and that studies undergo an adequate process of independent review. These internationally accepted norms and standards stem from the basic ethical principles of beneficence, respect for persons, and justice. They apply to all fields of research involving human beings, whether biomedical, epidemiological, public health or social science studies, and are explained in detail in numerous international ethics guidelines,^{11,12,13,14,15} all of which apply with full force in outbreak situations. All actors in research, including researchers, research institutions, research ethics committees, national regulators, international organizations, and commercial sponsors, have an obligation to ensure that these principles are upheld in outbreak situations. Doing this requires attention to the following considerations:

- **Role of local research institutions** — When local researchers are available, they should be involved in the design, implementation, analysis, reporting and publication of outbreak-related research. Local researchers can help ensure that studies adequately respond to local realities and needs and that they can be implemented effectively without jeopardizing the emergency response. Involving local researchers in international research collaborations also contributes to building long-term research capacity in affected countries and promoting the value of international equity in science.
- **Addressing limitations in local research ethics review and scientific**

capacity — Countries' capacity to engage in local research ethics review may be limited during outbreaks because of time constraints, lack of expertise, diversion of resources to outbreak response efforts, or pressure from public health authorities that undermines reviewers' independence. International and nongovernmental organizations should assist local research ethics committees to overcome these challenges by, for example, sponsoring collaborative reviews involving representatives from multiple countries supplemented by external experts.

- **Providing ethics review in time-sensitive circumstances** — The need for immediate action to contain an infectious disease outbreak may make it impossible to adhere to the usual timeframes for research ethics review. National research governance systems and the international community should anticipate this problem by developing mechanisms to ensure accelerated ethics review in emergency situations, without undermining any of the substantive protections that ethics review is designed to provide. One option is to authorize the advance review of generic protocols for conducting research in outbreak conditions, which can then be rapidly adapted and reviewed for particular contexts. Early discussion and collaboration with local research ethics committees can help ensure the project is viable and can facilitate local committees' effective and efficient consideration of final protocols when an outbreak actually occurs.

- ***Integrating research into broader outbreak response efforts*** — National authorities and international organizations should seek to coordinate research projects in order to set priorities that are consistent with broader outbreak response efforts, and to avoid unnecessary duplication of research effort or competition among different sites. Researchers have an obligation to share information collected as part of a study if it is important for the ongoing response efforts, such as information about hidden cases and transmission chains or resistance to response measures. Persons who share the information and those who receive it should protect the confidentiality of personal information to the maximum extent possible. As part of the informed consent process, researchers should inform potential participants about the circumstances under which their personal information might be shared with public health authorities.
- ***Ensuring that research does not drain critical health-related resources*** — Research should not be done if it will excessively take away resources, including personnel, equipment, and health-care facilities, from other critical clinical and public health efforts. To the extent possible, research protocols should anticipate provisions for local capacity-building such as involving and training local contributors or, where possible, leaving behind any potentially useful tools or resources.
- ***Confronting fear and desperation*** — The climate of fear and desperation typical of infectious disease outbreaks can make it difficult for ethics committees or prospective participants to engage in an objective assessment of the risks and benefits of research participation. In an environment where large numbers of individuals become sick and die, any potential intervention may be perceived to be better than nothing, regardless of the risks and potential benefits actually involved. Those responsible for approving research protocols should ensure that clinical trials are not initiated unless there is a reasonable scientific basis to believe that the experimental intervention is likely to be safe and efficacious, and that the risks have been minimized to the extent reasonably possible. In addition, researchers and ethics committees should recognize that, during an outbreak, prospective participants may be especially prone to the therapeutic misconception — that is, the mistaken view that the intervention is primarily designed to directly benefit the individual participants, as opposed to developing generalizable knowledge for the potential benefit of persons in the future. Indeed, researchers themselves, as well as humanitarian aid workers, may sometimes fail to distinguish between engaging in research and providing ordinary clinical care. Efforts should be made to dispel the therapeutic misconception to the extent reasonably possible. Despite such efforts, some prospective participants may still not fully appreciate the difference between research and ordinary medical care, and this should not in itself preclude their enrolment.
- ***Addressing other barriers to informed consent*** — In addition to the impact of fear and desperation,

other factors can challenge researchers' ability to obtain informed consent to research; these range from cultural and linguistic differences between foreign researchers and local participants, to the fact that prospective participants in quarantine or isolation may be cut off from their families and other support systems and feel powerless to decline an invitation to participate in research. To the extent possible, consent processes compatible with international research ethics guidelines should be developed in consultation with local communities and implemented by locally recruited personnel. In addition, researchers should be well informed about the medical, psychological and social support systems available locally so that they can guide participants in need towards these services. In some situations, it may be necessary to develop rapid mechanisms for appointing proxy decision-makers, such as during outbreaks of diseases that affect cognitive abilities, or when an outbreak leaves a large number of children as orphans.

- **Gaining and maintaining trust** — Failure to build and maintain community trust during the process of research design and implementation, or when disclosing preliminary results, will not only impede study recruitment and completion but may also undermine the uptake of any interventions proven to be efficacious. Engaging with affected communities before, during, and after a study is essential to build and maintain trust. In environments in which the public's trust in government is fragile, researchers should remain as independent as possible from official public health activities. If government workers are themselves involved in

conducting research, they should inform participants of this fact. Individuals who observe unethical practices carried out in the name of public health or emergency response efforts should promptly report them to ethics committees or other independent bodies.

- **Selecting an appropriate research methodology** — Exposing research participants to risk is ethically unacceptable if the study is not designed in a manner capable of providing valid results. It is therefore imperative that all research be designed and conducted in a methodologically rigorous manner. In clinical trials, the appropriateness of features such as randomization, placebo controls, blinding or masking should be determined on a case-by-case basis, with attention to both the scientific validity of the data and the acceptability of the methodology to the community from which participants will be drawn. In studies relying on qualitative methods, the potential benefits of using methodologies such as focus groups (in which individual confidentiality cannot be guaranteed) or of interviewing traumatized victims should be balanced against the risks and burdens to the individuals involved.
- **Rapid data sharing**: As WHO has previously recognized, every researcher who engages in generation of information related to a public health emergency or acute public health event with the potential to progress to an emergency has the fundamental moral obligation to share preliminary results once they are adequately quality controlled for release.¹⁶ Such information should be shared with

public health officials, the study participants and affected population, and groups involved in wider international response efforts, without waiting for publication in scientific journals. Journals should facilitate this process by allowing researchers to rapidly disseminate information with immediate implications for public health without losing the opportunity for subsequent consideration for publication in a journal.¹⁷

- ***Assuring equitable access to the benefits of research*** — As

recognized in existing international ethics guidelines, individuals and communities that participate in research should, where relevant, have access to any benefits that result from their participation. Research sponsors and host countries should agree in advance on mechanisms to ensure that any interventions found to be safe and effective in research will be made available to the local population without undue delay, including, when feasible, on a compassionate use basis before regulatory approval is finalized.



Staff preparing to go into the Isolation Unit at Persahabatan Hospital, East Jakarta.

Source: Jonathan Perugia

9. Emergency use of unproven interventions outside of research

Questions addressed:

- Under what circumstances is it ethically appropriate to offer patients unproven interventions outside clinical trials during infectious disease outbreaks?
- How should such interventions be identified?
- What type of ethical oversight should be conducted when unproven interventions are offered outside clinical trials during infectious disease outbreaks?
- If such interventions are provided, what should individuals be told about them?
- What obligations do persons administering unproven interventions outside clinical trials have to communicate with the community?
- What obligations do persons administering unproven interventions outside clinical trials have to share the results?

There are many pathogens for which no proven effective intervention exists. For some pathogens there may be interventions that have shown promising safety and efficacy in the laboratory and in relevant animal models but that have not yet been evaluated for safety and efficacy in humans. Under normal circumstances, such interventions undergo testing in clinical trials that are capable of generating reliable evidence about safety and efficacy. However, in the context of an outbreak characterized by high mortality, it can be ethically appropriate to offer individual patients experimental interventions on an emergency basis outside clinical trials, provided:

- 1) no proven effective treatment exists;
- 2) it is not possible to initiate clinical studies immediately;
- 3) data providing preliminary support of the intervention's efficacy and safety are available, at least from laboratory or animal studies, and use of the intervention outside clinical trials has been suggested by an appropriately qualified scientific advisory committee on the basis of a favourable risk–benefit analysis;
- 4) the relevant country authorities, as well as an appropriately qualified ethics committee, have approved such use;

5) adequate resources are available to ensure that risks can be minimized;

6) the patient's informed consent is obtained; and

7) the emergency use of the intervention is monitored and the results are documented and shared in a timely manner with the wider medical and scientific community.

As explained in prior WHO guidance, the use of experimental interventions under these circumstances is referred to as “monitored emergency use of unregistered and experimental interventions” (MEURI).¹⁸

Ethical basis for MEURI — MEURI is justified by the ethical principle of respect for patient autonomy — i.e. the right of individuals to make their own risk–benefit assessments in light of their personal values, goals and health conditions. It is also supported by the principle of beneficence — providing patients with available and reasonable opportunities to improve their condition, including measures that can plausibly mitigate extreme suffering and enhance survival.

Scientific basis for MEURI — Countries should not authorize MEURI unless it has first been recommended by an appropriately qualified scientific advisory committee especially established for this purpose. This committee should base its recommendations on a rigorous review of all data available from laboratory, animal and human studies of the intervention to assess the risk–benefit of MEURI in the context of the risks for patients who do not receive MEURI.

MEURI should be guided by the same ethical principles that guide use of

unproven compounds in clinical trials, including the following:

- **Importance of ethical oversight** — MEURI is intended to be an exceptional measure for situations in which initiating a clinical trial is not feasible, not as a means to circumvent ethical oversight of the use of unproven interventions. Thus, mechanisms should be established to ensure that MEURI is subject to ethical oversight.
- **Effective resource allocation** — MEURI should not preclude or delay the initiation of clinical research into experimental products. In addition, it should not divert attention or resources from the implementation of effective clinical care and/or public health measures that may be crucial to control an outbreak.
- **Minimizing risk** — Administering unproven interventions necessarily involves risks, some of which will not be fully understood until further testing is conducted. However, any known risks associated with an intervention should be minimized to the extent reasonably possible (e.g. administration under hygienic conditions; using the same safety precautions that would be used during a clinical trial, with close monitoring and access to emergency medication and equipment; and providing necessary supportive treatment). Only investigational products manufactured according to good manufacturing practices should be used for MEURI.
- **Collection and sharing of meaningful data** — Physicians overseeing MEURI have the same moral

obligation to collect all scientifically relevant data on the safety and efficacy of the intervention as researchers overseeing a clinical trial. Knowledge generated through MEURI should be aggregated across patients if possible and shared transparently, completely and rapidly with the MEURI scientific advisory committee, public health authorities, physicians and researchers in the country, and the international medical and scientific community. Information should be described accurately, without overstating benefits or understating uncertainties or risks.

- **Importance of informed consent** — Individuals who are offered MEURI should be made aware that the intervention might not benefit them and might even harm them. The process of obtaining informed consent to MEURI should be carried out in a culturally and linguistically sensitive manner, with an emphasis on the content and understandability of the information conveyed and the voluntariness of the patient's decision. The ultimate choice of whether to receive the unproven intervention must rest with the patient, if the patient is in a condition to make the choice. If the patient is unconscious, cognitively impaired, or too sick to understand the information, proxy consent should be obtained from a family member or other authorized decision-maker.
- **Need for community engagement** — MEURI must be sensitive to local norms and practices. One way to try to ensure such sensitivity is to use rapid "community engagement teams" to promote dialogue about the potential benefits and risks of receiving

interventions that have not yet been tested in clinical trials.

- **Fair distribution in the face of scarcity** — Compounds qualifying for MEURI may not be available in large quantities. In this situation, choices will have to be made about who receives each intervention. Countries should establish mechanisms for making these allocation decisions, taking into account the assessment of the MEURI Scientific Advisory Committee and the principles discussed in Guideline 4.

10. Rapid data sharing

Questions addressed:

- Why is rapid data sharing essential during an infectious disease outbreak?
- What are the key ethical issues related to rapid data sharing?

The collection and sharing of data are essential parts of ordinary public health practice. During an infectious disease outbreak, data sharing takes on increased urgency because of the uncertain and ever-changing scientific information; the compromised response capacity of local health systems; and the heightened role of cross-border collaboration. For these reasons, “rapid data sharing is critical during an unfolding health emergency.”¹⁹ The ethically appropriate and rapid sharing of data can help identify etiological factors, predict disease spread, evaluate existing and novel treatment, symptomatic care and preventive measures, and guide the deployment of limited resources.

Activities that generate data include public health surveillance, clinical research studies, individual patient encounters (including MEURI), and epidemiological, qualitative, and environmental studies. All individuals and entities involved in these efforts should cooperate by sharing relevant and accurate data in a timely manner. As discussed in Guideline 8, efforts should be made to ensure that rapid sharing of information

with immediate implications for public health does not preclude subsequent publication in a scientific journal.

As part of ongoing pre-epidemic preparedness efforts, countries should review their laws, policies, and practices regarding data sharing to ensure that they adequately protect the confidentiality of personal information and address other relevant ethical questions like managing incidental findings, and dealing with disputes over the ownership or control of information.

11. Long-term storage of biological specimens collected during infectious disease outbreaks

Questions addressed:

- What are the benefits and risks associated with the long-term storage of biological specimens collected during infectious disease outbreaks?
- What obligations do entities involved in the long-term storage of biological specimens collected during infectious disease outbreaks have to consult with the community?
- Are there any circumstances under which individuals should be asked for consent to, or given the opportunity to opt out of, the long-term storage of biological specimens collected during an infectious disease outbreak?
- What considerations should be taken into account in transferring biospecimens outside the institutions that collected them, whether domestically or internationally?

Biological specimens are often collected during an infectious disease outbreak in the context of diagnosis (e.g. to determine who has been infected with or exposed to a novel pathogen), surveillance (e.g. to identify the incidence of drug-resistant bacteria), or research (e.g. during clinical trials of new diagnostics, vaccines or interventions). Such samples are sent to laboratories on site or other laboratories, either domestically or internationally, for analysis.

Biospecimens collected during the management of an infectious disease outbreak offer researchers important opportunities to understand the outbreak pathogen better and to develop diagnostic, therapeutic, and preventive measures that

may mitigate the harm of similar outbreaks in the future. At the same time, long-term storage of biospecimens involves potential risks to individuals and communities. Risks to individuals primarily relate to the unwanted disclosure of personal information. This can be minimized by protecting the confidentiality of individuals' identities, but confidentiality may be difficult to protect when only a small number of people are being tested. Moreover, even when individual confidentiality can be adequately protected, some individuals or communities might still be uncomfortable making their biospecimens available for future use, especially if such use is not subject to community control. Particular concerns can arise when specimens are

transferred abroad without the originating country's prior agreement. Addressing these concerns requires time-consuming but necessary relationship-building, consultation, and education, as well as the establishment of policies, practices, and institutions capable of commanding public confidence and trust.

In addition to the general principles discussed elsewhere in this document, specific considerations relevant to the long-term storage of biological specimens collected during infectious disease outbreaks include the following:

- **Provision of information** — Before individuals are asked to provide biospecimens during an infectious disease outbreak, they should be given access to information about the purpose of the collection, whether their samples will be stored and, if so, the ways in which their specimens might be used in the future. When feasible and consistent with public health objectives, individuals should be asked to provide informed consent or be given the opportunity to opt out of the long-term storage of their specimens. Seeking informed consent is particularly important if there is any possibility that the specimens may later be used for research purposes.
- **Community engagement** — Individuals and organizations involved in the long-term storage of biospecimens collected during infectious disease outbreaks should engage representatives of the local community in a dialogue about the process. Community representatives should be involved in the development of policies regarding future use of the samples, including measures to ensure that equitable access is provided to any benefits that result from using the samples in research.
- **International sharing of biospecimens** — Sharing biospecimens internationally may sometimes be necessary to conduct critical research. If it is necessary to transfer specimens internationally, appropriate governance mechanisms and regulatory systems should be established to ensure that representatives of the country where the specimens were collected are involved in decisions about the specimens' use. The international community should make efforts to strengthen countries' capacity to maintain biospecimens within their own borders.
- **Material transfer agreements** — Biospecimens should not be transferred outside of the countries from which they are collected without formal material transfer agreements. Such agreements should specify the purpose of the transfer, certify the specimen donor's consent as appropriate, provide for adequate confidentiality protection, cover the physical security of the specimens, require that the country of origin is acknowledged in future research reporting, and guarantee that the benefits of any subsequent use of the specimens will be shared with the communities from which the samples were obtained. Material transfer agreements should be developed with the involvement of persons responsible for the care of patients and the taking of samples, representatives of affected communities and patients, and relevant government officials and ethics committees.

12. Addressing sex- and gender-based differences

Questions addressed:

- How are sex and gender relevant to infectious disease outbreaks?
- How can sex and gender be incorporated into public health and surveillance?
- How can social and cultural practices relevant to gender roles affect infectious disease outbreaks?
- How should appropriate reproductive health-care services be safely provided during an infectious disease outbreak?
- How are sex and gender relevant to communication strategies during outbreaks?

Sex (biological and physiological characteristics) and gender (socially constructed roles, behaviours, activities, and attributes)²⁰ can influence the spread, containment, course, and consequences of infectious disease outbreaks. Sex and gender differences have been associated with differences in susceptibility to infection, levels of health care received, and in the course and outcome of illness.²¹ Addressing sex and gender differences in infectious disease outbreak planning and response efforts requires attention to the following considerations:

- **Sex- and gender-inclusive surveillance programmes** — Public health surveillance should systematically collect disaggregated information on sex, gender, and pregnancy status, both to identify differential risks and

modes of transmission, and to monitor any differential impact of an infectious disease outbreak and the interventions used to control it. This information is particularly important for pregnant women and their offspring.

- **Ensuring the availability of high-quality reproductive health-care services** — Whether or not they are currently pregnant, women of childbearing age should have access to the full range of high-quality reproductive health-care services during an infectious disease outbreak. These services should be organized and delivered in a manner that does not stigmatize persons who use them or expose them to a heightened risk of infection with the outbreak pathogen. If there is evidence that an infectious

disease creates special risks for pregnant women or their fetus, both men and women should be informed of these risks and have access to safe methods to minimize them, along with reproductive counselling services.

- **Sex- and gender-inclusive research strategies** — Researchers should make efforts to ensure that studies do not disproportionately favour a particular sex or gender, and that women who are or might become pregnant are not inappropriately excluded from research participation. During an outbreak, research on experimental treatments and preventive measures should seek to identify any sex- or gender-related differences in outcomes.
- **Attention to social and cultural practices** — Gender-related roles and practices can affect all aspects of infectious disease outbreaks, including

individuals' risk of becoming infected, the consequences of infection, their use of health services and other health-seeking behaviours, and their vulnerability to interpersonal violence. Policy-makers and outbreak responders should identify and respond to these factors, drawing when possible on relevant anthropological and sociological research.

- **Sex- and gender-sensitive communication strategies** — Entities responsible for developing and implementing communication strategies should be sensitive to sex- and gender-based differences in how individuals have access to and respond to health-related information. Separate messages and communication strategies may be needed to provide relevant information to particular subgroups, such as pregnant women or nursing mothers.



Influenza in India
Source: Tom Pietrasik, WHO

13. Frontline response workers' rights and obligations

Questions addressed:

- What obligations exist to protect the health of frontline workers who participate in infectious disease outbreak response efforts?
- What obligations exist to provide material support to frontline workers who participate in infectious disease outbreak response efforts?
- To what extent do these obligations extend to the workers' family?
- What should be taken into account in determining whether individuals have an obligation to serve as frontline workers during infectious disease outbreaks?
- What special obligations do workers in the health-care sector have during infectious disease outbreaks?

An effective infectious disease outbreak response depends on the contribution of a diverse range of frontline workers, some of whom may be working on a volunteer basis. These workers often assume considerable personal risk to carry out their jobs. Within the health-care sector, frontline workers range from health-care professionals with direct patient care responsibilities to traditional healers, ambulance drivers, laboratory workers, and hospital ancillary staff. Outside the health sector, individuals such as sanitation workers, burial teams, domestic humanitarian aid workers, and persons who carry out contact-tracing also play critical roles. Some of these workers may be among the least advantaged members of society, and have little control over the type of duties they are asked to

perform. It is essential that frontline workers' rights and obligations be clearly established during the pre-outbreak planning period, in order to ensure that all actors are aware of what can reasonably be expected if an outbreak occurs.

Workers with certain professional qualifications, such as physicians, nurses, and funeral directors, may have a duty to assume a certain level of personal risk as part of their professional or employment commitments. Many frontline workers are not subject to any such obligations, and their assumption of risk must therefore be regarded as beyond the call of duty (i.e. "supererogatory"). This is particularly true for sanitation workers, burial teams, and community health workers, many of whom

may have precarious employment contracts with no social protection, or work on a volunteer basis.

Regardless of whether a particular individual has a pre-existing duty to assume heightened risks during an infectious disease outbreak, once a worker has taken on these risks, society has a reciprocal obligation to provide necessary support. At a minimum, fulfilment of society's reciprocal obligations to frontline workers requires the following actions:

- **Minimizing the risk of infection** — Individuals should not be expected to take on risky work assignments during an infectious disease outbreak unless they are provided with the training, tools, and resources necessary to minimize the risks to the extent reasonably possible. This includes complete and accurate information known about the nature of the pathogen and infection control measures, updated information on the epidemiological situation at the local level, and the provision of personal protective equipment. Regular screening of frontline workers should be put in place to detect any infection as quickly as possible, in order to initiate immediate care and minimize the risk of transmission to colleagues, patients, families, and community members.
- **Priority access to health care** — Frontline workers who become sick, as well as any immediate family members who become ill through contact with the worker, should be ensured access to the highest level of care reasonably available. In addition, countries should consider giving frontline workers and their families priority access to vaccines and other treatments as they become available.
- **Appropriate remuneration** — Frontline workers should be given fair remuneration for their work. Governments should ensure that public sector workers are paid in a timely manner, and make efforts to ensure that actors in the private and nongovernmental sectors fulfil their own obligations to pay their employees and contractors. Fair remuneration for frontline workers includes the provision of financial support during periods in which workers are unable to carry out their normal responsibilities because of an infection acquired on the job.
- **Support for reintegrating into the community** — Frontline workers may experience stigma and discrimination, particularly those involved in unpopular measures such as infection control or burials not conducted according to the traditional customs. Governments should make efforts to reduce the risk of stigmatization and discrimination and help such workers to reintegrate into the community, including by providing job placement assistance and relocation to other communities if needed.
- **Assistance to family members** — Assistance should be provided to families of frontline workers who need to remain away from home in order to carry out their responsibilities or to recuperate from illness. Death benefits should be provided to family members of frontline workers who die in the line of duty, including those who were volunteers or "casual workers."

As noted above, some workers may have a duty to work during an infectious disease outbreak. However, even for these individuals, the duty to assume risk is not unlimited. In determining the scope of workers' duties to assume personal risks, the following factors should be taken into account:

- **Reciprocal obligations** — Any professional or employment-based obligation to assume personal risk is contingent on society's fulfillment of its reciprocal obligations to workers, as outlined above. If the reciprocal obligations are not met, frontline workers cannot legitimately be expected to assume a significant risk of harm to themselves and their families.
- **Risks and benefits** — Frontline workers should not be expected to expose themselves to risks that are disproportionate to the public health benefits their efforts are likely to achieve.
- **Equity and transparency** — Entities responsible for assigning frontline workers to specific tasks should ensure that risks are distributed among individuals and occupational categories in an equitable manner, and that the process of assigning workers is as transparent as possible.
- **Consequences for non-participation** — Frontline workers should be informed of the risks they are being asked to assume. Insofar as possible, expectations should be made clear in written employment agreements. Workers who are unwilling to accept reasonable risks and work assignments may be subject to professional repercussions

(for example, loss of their job), but additional punishments, such as fines or imprisonment, are generally unwarranted. Persons responsible for assessing the consequences for non-participation should recognize that workers may sometimes need to balance other obligations, such as duty to family, against job-related responsibilities.

Additional obligations of those working in the health-care sector:

In addition to the issues addressed above, persons working in the health-care sector have obligations to the community during an infectious disease outbreak, including the following:

- **Participate in public health surveillance and reporting efforts** — Persons working in the health sector have an obligation to participate in organized measures to respond to infectious disease outbreaks, including public health surveillance and reporting. Health-care providers should protect the confidentiality of patient information to the maximum extent compatible with legitimate public health interests.
- **Provide accurate information to the public** — During an infectious disease outbreak, public health officials have the primary responsibility to communicate information about the outbreak pathogen, including how it is transmitted, how infection can be prevented, and what treatments or preventive measures may be effective. Those responsible for designing communication strategies should anticipate and respond to misinformation, exaggeration, and mistrust, and should seek (without

withholding key information) to minimize the risk that information about risk factors will lead to stigmatization and discrimination. If persons working in the health sector are asked medical questions about the outbreak by patients or the general public, they should not spread unsubstantiated rumours or suspicion and ensure that information they provide comes from reliable sources.

- **Avoiding exploitation** — In the context of a rapidly spreading life-threatening illness with no proven

treatment, desperate individuals may be willing to try any intervention offered, regardless of the expected risks or benefits. Health-care workers have a duty not to exploit individuals' vulnerability by offering treatments or preventive measures for which there is no reasonable basis to believe that the potential benefits outweigh the uncertainties and risks. This duty does not preclude the appropriate use of unproven interventions on an experimental basis, consistent with the guidelines set forth in Guideline 9.



Earthquake Haiti 2010
Source: Victor Ariscain, PAHO/WHO

14. Ethical issues in deploying foreign humanitarian aid workers

Questions addressed:

- What ethical issues arise in assigning foreign workers for deployment during infectious disease outbreaks?
- What obligations do sponsoring organizations have to prepare foreign aid workers adequately for their missions?
- What obligations do sponsoring organizations have regarding the conditions of deployment?
- What obligations do sponsoring organizations have to coordinate with local officials?
- What obligations do foreign aid workers have before, during, and after deployment?

Foreign governments and humanitarian aid organizations that deploy workers in infectious disease outbreaks have ethical obligations to both the workers themselves and the affected communities. These obligations include the following:

- **Coordination with local officials** — Foreign governments and external humanitarian aid organizations should deploy workers following discussion and agreement with local officials about their roles and responsibilities or, if this is not possible, with international organizations like WHO. Organizations working in a particular area should register their presence as a foreign Emergency Medical Team (EMT) with

the local government, and have ongoing discussions among themselves and with the local government to clarify and coordinate their roles and responsibilities and address any disparities in standards of practice. Efforts should be coordinated with local authorities and care providers to ensure that the foreign agency does not excessively draw resources away from other essential services.

- **Fairness in assigning foreign workers for deployment** — Foreign aid workers should be deployed only if they are capable of providing necessary services not sufficiently available in the local setting. Assignment of foreign

health workers should take into consideration their relevant skills and knowledge, as well as their linguistic and cultural competencies to meet mission objectives and understand and communicate with affected communities. It is inappropriate to deploy unqualified or unnecessary workers solely to satisfy their personal or professional desire to be helpful (so-called “disaster tourism”).

- **Clarity about conditions of deployment** — Prospective foreign aid workers should be given comprehensive information about the project’s expectations and risks so they can make informed decisions about whether or not they will be able to make appropriate contributions. In addition, foreign aid workers should be clearly informed of the conditions of their deployment, including the level of health care they can expect if they become ill, the circumstances under which they will be repatriated, available insurance, and whether benefits will be provided to their families in case of illness or death.
- **Provision of necessary training and resources** — Aid workers must be provided with appropriate training, preparation, and equipment to ensure that they can effectively carry out their mission with the lowest risks practicable. Training should include preparation in psychosocial and communication skills, and in understanding and respecting the local culture and traditions. Managers and organizations have an obligation to provide adequate support and guidance to the staff, both during their activity in the field and following

their mission. This should include training and resources for managing challenging ethical issues, such as resource allocation decisions, triage, and inequities.

- **Ensuring the security and safety of aid workers** — Organizations that deploy foreign aid workers have an obligation to take all necessary measures to ensure the workers’ security, particularly in situations of crisis; this obligation includes the provision of measures to reduce risks of exposure to infectious agents, contamination and violence. A clear chain of authority must be in place to provide oversight and ongoing advice. Individuals who object to assigned duties should have an opportunity for review and appeal, according to the norms of the organizations for which they work.

Aid workers also have their own ethical obligations to patients, affected communities, their sponsoring organizations, and themselves. In addition to the obligations described in other sections of this document, obligations of foreign aid workers include the following:

- **Adequate preparation** — Aid workers should take part in any training that is offered. If they believe that the training they have been given is inadequate, they should bring their concerns to the attention of their organization managers. Foreign aid workers deployed during crises and where resources are scarce should carefully consider whether they are prepared to deal with ethical issues that may lead to moral and psychological distress.

- **Adherence to assigned roles and responsibilities** — Aid workers should understand the roles and responsibilities they have been asked to assume and should not, except in the most extreme circumstances, undertake tasks they have not been authorized to perform. In addition, they should provide clear and timely information to both their sponsoring organizations and local officials and should understand that, if they go beyond the tasks they have been authorized to perform, they will be accountable not only within their

own organizations but also under applicable local standards and laws.

- **Attention to appropriate infection control practices** — Aid workers should be vigilant in adhering to infection control practices, both for their own protection and to prevent further transmission of disease. Aid workers should follow recommended protocols for monitoring symptoms and reporting their health status (including possible pregnancy), before, during and after their service.



Influenza patient, Nepal
Source: Tom Pietrasik, WHO

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Annex 1. Ethics guidance documents that contributed to the *Guidance for managing ethical issues in infectious disease outbreaks*

WHO guidance documents

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Annex 2. Participants at meetings to formulate *Guidance for managing ethical issues in infectious disease outbreaks*

Panel discussion: Ethical considerations for use of unregistered interventions for Ebola viral disease, World Health Organization, Geneva, 11 August 2014

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Consultation on potential Ebola therapies and vaccines: Pre-meeting of the Ethics Working Group, World Health Organization, Geneva, 3 September 2014

Participants

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Ms Robinah Kaitiritimba, Patient Representative (community representative, Makerere University Institutional Review Boards; Uganda National Health Consumers' Organisation), Uganda

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Ethical issues related to study design for trials on therapeutics, World Health Organization, Geneva, 20–21 October 2014

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Dr Amar Jesani, Independent Researcher and Teacher, Bioethics and Public Health; Editor, Indian Journal of Medical Ethics; Visiting Professor, Centre for Ethics, Yenepoya University, India

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Professor Ross Upshur, Chair in Primary Care Research; Professor, Department of Family and Community Medicine and Dalla Lana School of Public Health, University of Toronto, Canada

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Dr Matthew Lim, Senior Advisor, Global Health Security, Department of Health and Human Services, United States of America

Professor Ira Longini, Professor of Biostatistics, Department of Biostatistics, College of Public Health and College of Medicine, University of Florida, United States of America

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Developing ethics guidelines for public health responses during epidemics, including for the conduct of related research, Dublin, Ireland, 25–26 May 2015

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Meeting to develop WHO Guidance on ethics and epidemics. Prato, Italy, 22–24 November 2015

Participants

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Infectious disease outbreaks are frequently characterized by scientific uncertainty, social and institutional disruption, and an overall climate of fear and distrust. Invariably, the countries most affected by outbreaks have limited resources, under-developed legal and regulatory structures, and health systems that lack the resilience to deal with crisis situations. Policy-makers and public health professionals may be forced to weigh and prioritize potentially competing ethical values in the face of severe time and resource constraints . This document seeks to assist policy-makers, health care providers, researchers, and others prepare for outbreak situations by anticipating and preparing for the critical ethical issues likely to arise. In addition to setting forth ethical principles applicable to infectious disease outbreaks generally, it shows how these principles can be adapted to different epidemiological and social circumstances.



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