

GLOBAL HEALTH ETHICS

KEY ISSUES



Global Network of WHO Collaborating Centres for Bioethics



World Health Organization

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Introduction

Ethical questions related to health, health care, and public health cover topics as diverse as moral issues around reproduction, state obligations in the provision of health care services, and appropriate measures to control infectious disease. Scholars and health care professionals have debated ethical questions related to health and health care since the earliest days of medicine. Recent formal efforts to articulate international standards of ethics applicable to health and health care can be traced to the Nuremberg trials of 1947, during which the horrors of Nazi medical experiments came to light. The principles that emerged from those trials, known as the Nuremberg Code¹, are broadly applicable to many types of health-related research involving human participants, including clinical trials. The growing breadth and complexity of contemporary health challenges have produced a range of difficult questions that cannot always be adequately addressed by relying exclusively on existing policies, guidelines or codes of conduct. Debates over access to new and expensive pharmaceuticals and medical technologies, as well as increasing awareness of the gross health disparities that exist both within and between countries, have called attention to the need for an ethics of health policy and practice.

In the face of limited resources and competing priorities, health care service providers, biomedical and public health investigators, and policy-makers are often forced to make difficult choices about how best to secure optimal health

outcomes for individuals and populations. Demands for rapid action may leave little time for adequate consideration of ethical issues. However, a failure to give explicit attention to ethics may result in various wrongs, such as harm and injustice, the consequences of which are often borne disproportionately by the most vulnerable groups. Thus, it is critical that ethics remains central to decision-making in health and health care.

This document aims to assist policy-makers, health care providers and researchers to understand key concepts in health ethics and to identify basic ethical questions surrounding health and health care. It illustrates the challenges of applying ethical principles to global public health and outlines practical strategies for dealing with those challenges. The document is divided into four main parts. The first part explores key concepts in health ethics and explains common terms, theories and principles. The second part examines the main challenges in the practice of health ethics from the perspective of global public health. These issues provide the reader with a concrete understanding of the various ethical obstacles that may arise in public health, health research, and the provision of health care services. The third part describes practical strategies for dealing with these challenges and the key actors involved in developing ethical frameworks. Finally, the fourth part explains why health ethics is important to WHO, and how WHO supports Member States in building capacity in health ethics.

A. Introduction to health ethics: key concepts

1. What is health ethics?

Ethics, derived from the Greek *ethos*, or “behaviour”, is concerned with questions about right versus wrong conduct and what constitutes a good or bad life, as well as the justificatory basis for such questions, the situations in which values conflict (e.g. ethical dilemmas), and the systematic analysis and resolution of these conflicts. Health ethics is the interdisciplinary field of study and practice that seeks specifically to understand the values undergirding decisions and actions in health care, health research and health policy, and to provide guidance for action when these values conflict. It is distinguishable from the narrower medical ethics, which is concerned with ethical issues that arise in the clinical context related to the care of specific patients, as well as the broader bioethics, which refers to ethical issues arising from the creation and maintenance of the health of all living things.²

Health ethics has a broad focus, taking in ethical issues faced by health professionals, health policy-makers and health researchers, as well as by patients, families, and communities in a range of contexts related to health, including clinical care, health services and systems, public health, epidemiology, information technology and the use of animals in research. Health ethics is built on a sound appreciation of the empirical realities of particular health issues. For example, if authorities have a limited supply of vaccine, an ethical analysis of the situation is likely to take into account clinical concerns about vaccine side-effects, epidemiological concerns about herd immunity and population risk, and logistic concerns about maintaining an effective and efficient delivery system. What health ethics adds to the analysis is the incorporation of value-oriented questions, such as the equity of the vaccine distribution system and its impact on vulnerable groups. Health ethics is increasingly on the curriculum in health professional and bioscience training, as well as programmes in health administration, health economics, public health, law, biotechnology (e.g. genomics) and environmental health. Though it is a comparatively young field, there is an extensive and growing international literature in the area, and many research efforts are devoted to understanding it.

2. What is the difference between ethical, social and personal values in health?

If ethics is concerned with the values underlying decisions and action, what values and whose values are relevant? Values describe what is important to an individual, a group, or a society. Values that are commonly invoked

include autonomy, fairness, equity, compassion, honesty, freedom, solidarity, trust and respect. Some of these values might be specified as principles, e.g. “health inequities in a population ought to be minimized” or “patients should give free and informed consent to treatment”, in which case they provide guidance for concrete decisions and actions. Sometimes a situation may give rise to a conflict between different values, such as when achieving greater equity may involve some reduction in individual autonomy, or between values at the universal, group, or individual levels. Moreover, different societies may have different values and practices. Most people would agree that tolerance of such differences is important, and we must, generally, respect values that differ from our own. However, it is also important to realize that not all personal or societal values have equivalent moral status. For example, slavery violates ideas of equal respect for all human beings. Even if an individual or group wishes to support slavery, others in society are not bound to respect such a view. Where apparent disagreement exists, it is worth taking time to understand and discuss divergent points of view. Often, a resolution can be found, but sometimes respectful disagreement will be the only option.

3. What is the relationship between health ethics and the law?

Both ethics and law are normative frameworks, i.e. they define how people ought to act. Ethics and law are often complementary; for example, a legal decree might require a person to do what is ethically required (such as refrain from harming others). However, something can be legal and yet conflict with ethical standards. For instance, there are no laws prohibiting countries from investing vast public resources in the development of medical interventions of minor public health significance, such as a cure for male-pattern baldness. But one might wonder whether, ethically speaking, countries should not instead devote their resources to reducing the burden of life-threatening disease. Similarly, ethics is concerned with a broader set of relationships and behaviours than most forms of legal regulation. For example, speaking disrespectfully to one’s parents may be considered unethical, even though it is not against the law. It is also possible that individual laws may themselves violate important ethical principles, e.g. laws that discriminate against certain groups in a population. Ethical analysis of the law can stimulate important reform efforts or acts of civil disobedience.

Even when ethics and law are consistent, important differences between the fields remain. For example, laws



Judges of Military Tribunal No. 1, Nuremberg, Germany, 1946–1947.

Source: United States National Archives and Records Administration.

sometimes provide general standards, the interpretation of which requires further ethical analysis, e.g. a law prohibiting public health authorities from imposing “unreasonable” restrictions on individual liberty. In addition, the violation of an ethical norm entails different sanctions than the breaking of a legal code. In the former case, the violator might suffer rejection and disapproval by society; in the latter, a concrete punishment, such as a fine or imprisonment, might be imposed. In sum, while ethics and law are different in certain ways, ethics remains a foundation for law, and often provides a justificatory basis for legal norms.

4. What is the relationship between health ethics and human rights?

Human rights are “those rights which are inherent to the human being.”³ The modern human rights movement developed after the Second World War and the adoption of the Universal Declaration of Human Rights in 1948,⁴ and led to the adoption of treaties and other sources of law “protecting individuals and groups against actions which interfere with fundamental freedoms and human dignity”. Human rights encompass what are known as civil, cultural, economic, political and social rights. Governments have an affirmative obligation to respect, protect, and fulfil human rights. The obligation to respect human rights means that government must not interfere, directly or indirectly, with individuals’ enjoyment of human

rights. The obligation to protect human rights means that government has a duty to prevent third parties from interfering with individuals’ enjoyment of human rights. And the obligation to fulfil human rights requires government to adopt appropriate legal, budgetary, and other measures to ensure that individuals’ human rights are fully realized.⁵

Ethical questions about the duties and responsibilities of individuals and institutions include questions about the actions required to ensure the protection and promotion of human rights. Additional ethical questions related to human rights include questions about what should be done in cases where there is a conflict between different human rights, such as when protecting the community’s right to health may require limiting the liberty of people with contagious disease. In addition, when limited resources make it impossible to satisfy everyone’s human right to health care, ethical analysis is necessary to establish priorities. While concerns about ethics and human rights are closely related—human rights, after all, are ultimately grounded in overarching ethical principles, such as liberty and equality—there are also important distinctions between the two. What human beings have a right to as a matter of ethics is not necessarily the same as what they have a right to as a matter of law. It might be argued that there are human rights that people should have that have not yet been enshrined in legally binding human rights instruments.

B. Health ethics in practice: key issues and challenges

5. What are key ethical issues in public health?

Both public health practice and policy raise diverse ethical considerations. An important set of issues concerns the relationship between the liberty of the individual and broader societal concerns. Other important issues include such things as equity, solidarity, social justice, reciprocity, and trust. Underlying all approaches to public health ethics is a strong commitment to collective action as a means of protecting individuals and the public from harm and promoting the highest attainable standard of health.

Harm prevention, public good and individual liberty

Individuals have a right to privacy and to freedom of movement. However, because infectious disease threatens the health and welfare of others, it may be legitimate to restrict people's privacy and liberty in order to protect others in the community. How far may governments go in limiting privacy and freedom of movement in the name of infectious disease control? With the outbreak of severe acute respiratory syndrome (SARS) in 2002–2003, health officials in both Asia and North America relied on strategies such as closing schools, cancelling social gatherings, and quarantining people suspected of being infected. In retrospect, it became clear that some of these strategies were more extensive than necessary to address the public health crisis. Yet, where outcomes are uncertain and potentially catastrophic, liberty-restricting actions may well be justified by values such as solidarity and reciprocity, provided that the restrictions are informed by evidence, proportionate to the threat (see "Proportionality" in the glossary of terms), carried out humanely and limited to the immediate crisis at hand (see Siracusa Principles in Human Rights).⁶

Treatment and prevention

Much public health practice and policy is founded on the idea that prevention is better than waiting for harm to develop and then focusing on treatment. The argument in favour of prevention can be a financial one (it is cheaper), a practical one (when prevention is possible, why wait to intervene until the disease actually develops?) or a moral one (a focus on prevention may reduce overall suffering). At the same time, when resources are limited, devoting greater attention to prevention may take away needed resources from treatment. Determining how to allocate scarce resources between prevention and treatment can therefore raise difficult ethical issues related to distributive justice.

For example, scientists working in disease prevention have recently determined that providing antiretroviral therapy to people infected with HIV may significantly lower the risk that they will transmit the virus to uninfected sexual and needle-sharing partners. However, this approach may lead to the use of antiretroviral therapy in persons who do not need it for their own clinical benefit. Should the provision of antiretroviral therapy to those who would get sicker or even die without it take priority over the provision of medication for the purpose of reducing the risk of transmission? What are the global obligations to meet the needs of nations facing these difficult trade-offs?

Health promotion and equity

Ill-health related to chronic disease is rising across the world. A large part of this disease burden is caused by so-called lifestyle choices, such as smoking tobacco, drinking alcohol, overeating, and not exercising enough. What ethical obligations do governments have to try to change such behaviour? For example, we know that smoking is harmful and linked to the death and suffering of millions of people each year. It is also a deeply entrenched, often addictive, behaviour. At the same time, autonomous adults generally have the right to engage in risky behaviour, as long as their actions do not put other people directly at risk. In this context, to what extent do governments have an ethical obligation to adopt policies that reduce the harm resulting from smoking? Should governments use the tax system to deter individuals from starting or continuing to smoke? Is it acceptable to place limits on the advertising of



WHO provides vaccinations against diphtheria and tetanus at Port-au-Prince's National Stadium, where many Haitians displaced by the earthquake have set up temporary shelters.

Source: UN Photo/Sophia Paris.



A health worker performs an antenatal examination on Mema Kiahon in the maternal and child health section of the UNICEF-supported clinic in Senjeh, a town in Cape Mount County, Liberia.

Source: UNICEF/Giacomo Pirozzi.

tobacco products? Is it appropriate for governments to seek to influence the cultural and social factors that may lead some people to take up smoking? Similar issues arise in other contexts, such as the use of alcohol and the excessive consumption of unhealthy foods.

Public health surveillance

Public health activity requires robust data on the level of disease and threats to health within a population. Such data allow threats to individual and population health to be assessed, and priorities set and resources allocated on the basis of risk. How should the need for accurate disease surveillance data be balanced against the principle of individual autonomy? For example, in the mid-1980s, blood samples that had been taken for clinical purposes were stripped of identifying information and tested for HIV, in an attempt to estimate the prevalence of HIV infection in the population. Supporters of this practice maintained that it was ethical to perform HIV tests without patient consent because the samples did not carry any identifying information, and the results of the tests could provide important information about the prevalence of HIV in the community. Critics expressed concerns about the fact that patients who tested positive for HIV would not be informed of the results of their tests.⁷ In the early years of the HIV pandemic, when no treatment was available, there was a consensus that, given the population-level benefit of gathering accurate data on the prevalence of HIV infection, this mode of surveillance was ethical and, in fact, might be obligatory for states confronting the emerging epidemic. Over the past decade,



Source: WHO.

however, as prospects of treating HIV have improved, the argument has shifted. Today, anonymous testing of blood samples for HIV would probably not be approved by an ethics committee, as it would be considered ethically inappropriate to identify individuals as HIV-positive without being able to follow up with treatment. This example shows how ethical policy-making is a dynamic process that must be adapted to the evolving situation.

6. What are key ethical issues in health research?

The goal of biomedical research is the creation of knowledge to improve the health of populations. Ethical questions in research include:

- Does the research have social value for the communities that take part or from which the participants are drawn?
- Who benefits from the research?

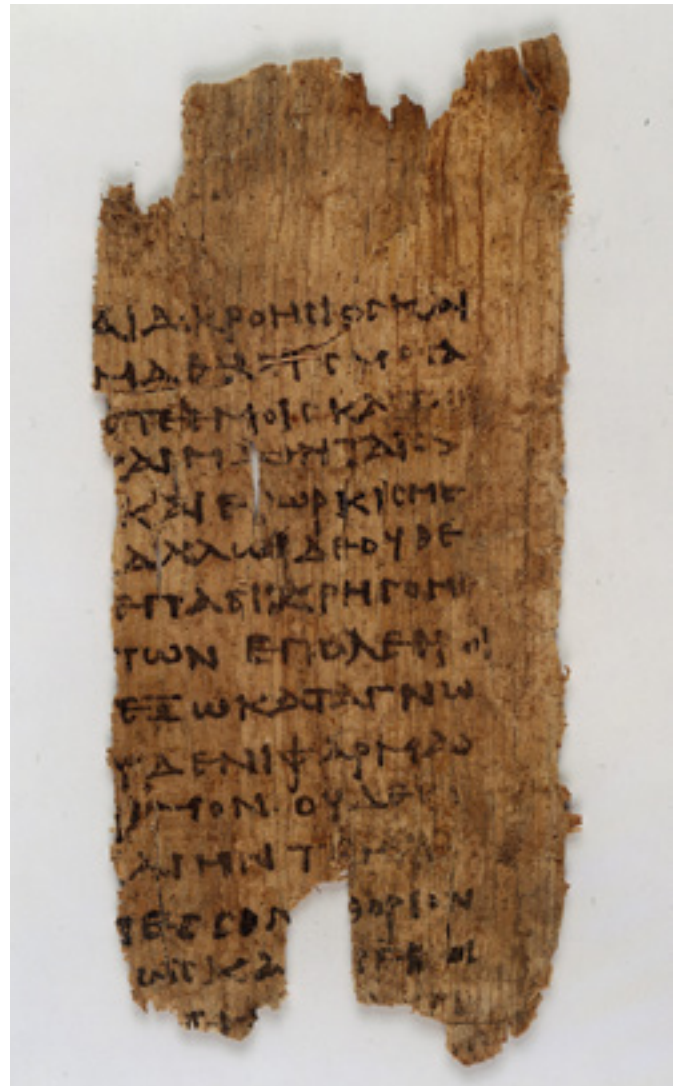
- Are subgroups of the population treated fairly?
- Are the rights and well-being of individual research participants protected?

These issues are explored in detail in international ethical guidelines on research, including the World Medical Association's *Declaration of Helsinki*,⁸ the Council on International Organizations of Medical Sciences' *International ethical guidelines on biomedical research involving human subjects*,⁹ and various research ethics guidelines issued by WHO.¹⁰ The discussion below highlights some of the major points covered in these guidelines; readers are encouraged to consult the guidelines themselves for additional detail.

Research aims to improve all of our lives by testing existing and new treatments, preventive measures, and systems and procedures. Health care research has undoubtedly produced great public health benefits. However, research also brings to the fore several ethical concerns for the groups and individuals that contribute to or take part in research, as described below.

Ethical issues regarding groups

- Social and economic disparities at national, regional and global levels magnify concerns that efforts to improve the health of some populations might have the unintentional consequence of making things worse for others. When studies are carried out in disadvantaged societies, the members of those societies who take part are being put at risk, while – because of their economic or social disadvantages – they may not be able to benefit from the knowledge gained by the study. Unfairness can be reduced or eliminated by ensuring that study populations enjoy the benefits of the research. At the same time, great caution is required when the only chance for medical care is linked to participation in biomedical research studies. This is a problem in resource-poor countries, as well as for people of low socioeconomic status in wealthy nations.
- Ethical questions also emerge in the selection of topics for research. The health concerns of affluent populations often drive the research agenda, leading to the development of new drugs and devices for which there is a large (and profitable) market. The health problems of resource-poor populations offer fewer opportunities for commercial success and therefore tend to receive less attention from investigators, exacerbating disparities between rich and poor.



A fragment of the Hippocratic Oath on papyrus (verso showing oath), circa 3rd century

Source: Wellcome Library, London.

- Another ethical challenge arises when businesses or individuals patent new drugs or devices to help ensure that product sales recoup investments and generate profits. While laws that protect intellectual property can provide valuable incentives for research and development, they also increase the price of new drugs and devices, and can thereby severely restrict or prevent access to life-saving therapies for resource-limited populations. This issue has generated intense debate within the HIV/AIDS community, and in some cases has led to the development of proposals for or implementation of alternative financing mechanisms designed to reduce economic barriers to essential treatments. (See also question 9.)
- Research in public health and epidemiology presents a number of distinctive challenges, including: the question of whether it is always necessary to obtain individ-

ual informed consent from participants in large observational studies; issues of privacy and confidentiality in the collection and storage of personal health information; and how best to communicate study results to participants and the public. Public health workers and epidemiologists continue to debate the differences between research and disease surveillance, and the question of whether or not they have – or should have – different ethical requirements.

Ethical issues regarding individuals

International standards tend to focus on the rights of individuals who may participate in research, and prescribe procedures meant to ensure that potential research subjects have the freedom to choose to participate or not. In order to do this, prospective participants must be able to understand and appreciate the information they are given, the information about risks, potential benefits, and alternatives must be clear and comprehensive, and individuals must understand that they are free to decline to participate or to withdraw from the study at any time.

Managing ethical dilemmas

The human research enterprise will always be subject to an array of influences generated by investigators' interests, sponsors' requirements, subjects' motivations (altruism, hope, desperation) and the prevailing social conditions. These influences create the potential for systemic problems that cannot be solved solely by following guidelines, but require ethical integrity on the part of researchers and research organizations if they are to proceed with fairness and prudence. However, the history of research has demonstrated that this is not enough. Researchers and research organizations are often too involved in the research to remain disinterested in the outcome, and are often unable to view the research project dispassionately. Therefore, several mechanisms have been established to ensure that research projects are designed and conducted in an ethical manner.

- Research ethics committees perform the important role of assessing the potential risks and benefits involved in research. In some cases, such committees may decide that the risks of the study are not justified by the potential benefits and decide not to allow the research to go ahead.
- In the case of clinical trials and other large community-based trials, data safety monitoring boards (DSMBs)

or their equivalent are established to ensure, among other things, that the safety concerns – as they arise in research – are addressed promptly and adequately.

- In many clinical trials, clinical monitors are appointed to independently monitor the conduct of the research, including whether it is conducted as approved by the ethics committee.

7. What are key ethical issues in clinical care?

Most health practitioners want to do what is best for their patients. Non-maleficence (“first do no harm”), beneficence (doing good) and trust are fundamental ethical principles at the heart of clinical care. Health practitioners also seek to ensure that patients are given adequate information, are consenting to treatments and procedures voluntarily, and have the capacity to understand and appreciate the potential benefits and risks of the care they receive. Health practitioners seeking to provide the best possible care to their patients in the most ethical manner may find it difficult to balance the right to information with the need to avoid information overload. Some common challenges in clinical ethics are outlined below.

- How much information is adequate? How should complex medical information be communicated to patients who may be frightened or feeling ill, and may have trouble assessing risks, benefits and alternatives? Do all patients even want a great deal of information? Some may prefer to trust their health provider to do what is best for them. When, if ever, is it permissible for a provider to withhold information from a patient because the patient does not appear to want it?
- When, if ever, should a clinician's professional opinion or treatment recommendation take precedence over a patient's right to make a voluntary and free decision to accept or reject treatment? Is paternalism (i.e. acting to bring about something for another individual's own good) ever permissible?
- What criteria should be used to assess whether a patient has the capacity to make his or her own decisions about treatment? How much preparation and information should a surrogate or proxy have before making a health decision for someone else?

Other important ethical issues in clinical care relate to privacy and confidentiality. These are longstanding values in



Guatemalan children living in refugee camps in the State of Campeche wait to get their food ration.

Source: UN Photo/Pat Goudvis.

many cultures. Privacy and confidentiality should be protected, first because there is wide agreement that people have the right to control who has access to their person or to information about them. Secondly, the ability to provide high quality medical care depends on patients feeling free to communicate fully and truthfully with their caregivers. Furthermore, individuals could face stigmatization and discrimination if certain medical information, such as about sexually transmitted diseases or mental illness, is not carefully protected. Respecting privacy and confidentiality carries special importance in an era of electronic medical records.

However, not every issue in clinical ethics is about individuals. For example, the way that people access health care, what services are provided, how they are funded, and how much patients have to pay at the point of delivery, all raise important ethical questions about how health care systems are set up. In this way, ethical issues in clinical care are often linked to larger ethical questions related to health care organizations and systems.

8. What are key ethical issues of health organizations and systems?

Ethical issues arise in the governance and management of health institutions and systems, particularly where there are competing stakeholder needs and values. Some examples are given below.

- **Resource allocation across health services and programmes.** How should priorities be set to ensure that resources are allocated fairly and appropriately to meet the community's health needs? How much priority should be given to disease prevention as opposed to treatment? In a public health crisis, such as an influenza pandemic, who should have priority access to vaccines, drugs, and hospital services? Because normal health care systems may cease to function during a severe public health crisis, efforts should be made to achieve consensus on these questions in advance.
- **Corporate partnerships and philanthropic fundraising.** In the face of scarce resources, are there restrictions on the kinds of funding sources from which a health institution may accept support? What if there is a conflict of interest between the values of the potential funder and the health institution?
- **Workplace ethics.** What obligations do health institutions have to their staff to ensure that the workplace is safe, respectful, and just? What supports ought to be in place to assist staff at all levels in dealing with ethical issues in their daily practice?
- **Equitable access.** What obligations do health institutions or systems have to care for the uninsured, patients beyond their catchment area or jurisdictional borders, or future patients?
- **Individual versus population health.** How much priority ought to be given to population health needs versus individual patient needs, if not all needs can be met? This question overlaps with the issues discussed above regarding the appropriate allocation of resources between prevention and treatment.
- **Public accountability.** What obligations do health institutions and systems have to the communities they serve to be transparent about how health resources are used and to reflect community values in their decisions?

In some cases, these issues may highlight the challenge of resolving tensions between different ethical values, such as efficiency, equity and choice. The decisions made may have significant implications for patients, families, clinicians, and other key stakeholders.

Organizational and health system ethics are also concerned with the institutional environment within which decisions are made and the conditions that contribute to the development of a culture that supports and reinforces ethical decision-making. Experience shows that the insti-



Local health staff work with experts from Médecins Sans Frontières to disinfect the house of a patient who died of Ebola. Democratic Republic of the Congo, 2007.

Source: WHO

tutional decision-making culture and context are often shaped by the behaviour of local leaders. Accreditation bodies are increasingly emphasizing the importance of ethical accountability at the highest level of health organizations, are giving increasing attention to defining the moral attributes and competencies of ethical leadership, and are developing standards to monitor and evaluate ethical performance of health organizations.

9. What are key ethical issues in global health?

Considerations of justice are central to global health. While access to good health may be thought to be a vitally important ethical principle, it remains unavailable to most people. Health in low-resource countries is often compromised by social determinants, such as poverty, malnutrition, poor education, unhealthy living conditions, and lack of access

to health care, as well as by corruption in the public and private sectors. The global health care status quo reflects a collective failure of the international community to meet the most basic needs of most of the world's population. An urgent challenge in global health ethics is to specify the actions that wealthier countries should take, as a matter of global justice and solidarity, to promote global health equity.

The problem of limited access to health care in resource-poor countries has been exacerbated by a "brain drain".¹¹ Health professionals trained in resource-poor countries are commonly recruited to work in wealthier countries, resulting in a severe shortage of health care workers in the former. This raises questions about the ethical acceptability of such recruitment and the incentives that might be used to discourage emigration. This is another case of a moral conflict – between the freedom to relocate and associate freely and the need to improve the health of some of the most vulnerable people.

Another set of ethical issues in global health is related to cultural relativity. It is sometimes asked whether ethical standards are universal, given that different people in different countries may hold different values or place different weights on common values. For example, some practices that are widely condemned by the international community, such as female genital mutilation, may still be carried out by certain social groups in accordance with specific religious or cultural beliefs. While some people may argue that condemning such practices as human rights violations constitutes a form of ethical imperialism, others strongly argue that we must stand up for the women and children who are at risk of being harmed.

A third challenge in global health ethics concerns international research, especially where investigators from wealthy countries conduct research in impoverished settings where participants are especially vulnerable or where language and cultural barriers make informed consent difficult. One of the most hotly debated issues regarding international research ethics during the past two decades has been about standards of care: what level of care should be provided to participants in the control arm of a clinical trial in settings where the usual standard of care is especially low? And what level of care or other benefits should be provided to participants or participating communities at the conclusion of a trial?

C. Health ethics in practice: key strategies

10. What role can ethical theories and principles play in addressing ethical issues?

Ethical theories and principles are helpful in addressing ethical issues in two key ways: (1) they explain why the issue at hand is an ethical issue, and (2) they justify why one course of action ought to be preferred over another. Ethical theories provide a coherent system of thought about what constitutes ethical action and tend to be abstract; ethical principles are more narrowly focused and provide the basis for specific rules or norms that can be more readily applied in practice. Some ethical theories focus on the consequences of decisions to determine what the right course of action should be. For example, utilitarianism is a consequentialist theory, which holds that resources should be allocated to achieve the best overall outcomes, e.g. improved population health. Other ethical theories hold that certain types of action are categorically wrong, regardless of their consequences. For example, some people maintain that it is inherently unethical for physicians to actively hasten a patient's death, regardless of the patient's wishes or how much the patient may be suffering. Some theories are primarily concerned with how decisions are made (are decisions made rightly?), rather than what decisions are made (what is the right decision?). Some ethical theories aim to achieve greater social justice by considering the social and institutional conditions that shape the health of individuals and populations.

In practice, different theories may overlap regarding judgments about what to do within health ethics. For example, both utilitarian and egalitarian approaches to ethics may suggest a redistribution of health resources in response to socioeconomic constraints on health. Moreover, how different ethical principles are applied will necessarily depend on the specific context. For example, while respect for individual autonomy can be seen as operative in the emphasis on informed consent for both treatment and research, in a public health context, autonomy may be constrained when doing so is the only means of protecting the public good. In health policy more generally, respect for autonomy may be expressed in efforts to engage affected stakeholders in shaping the policies that will affect their lives.

11. What is the role of ethical decision-making frameworks?

Ethical decision-making frameworks provide systematic and practical approaches to the analysis of ethical issues

and questions. They aid decision-making by framing the ethical issue at hand (what type of ethical issue is this?), making relevant values and ethical principles explicit (what is at stake, and for whom?), providing a structure for determining how to address or resolve the ethical issue (what actions ought to be taken?), and ensuring consistency in similar situations and across decision-makers. Ethical frameworks may consist of a set of procedures to be followed in addressing an ethical issue or a set of criteria to be factored into a decision, or both.

A procedural ethical framework provides guidance on how decisions ought to be made and by whom. For example, when faced with a complex ethical challenge involving multiple stakeholder interests, values, and needs – e.g. how to prioritize access to antiretroviral drugs – a procedural justice framework emphasizing principles of transparency, inclusiveness, and revisability may be necessary to establish the ethical legitimacy of the policy. A substantive ethical framework specifies what decisions ought to be made with reference to pre-agreed criteria. For example, in deciding where to invest resources in primary care services, the principle of equity – in terms of reducing preventable health inequalities or addressing socioeconomic factors influencing health – may be an overarching ethical consideration.

Ethical frameworks must generally be tailored to the ethical issues and challenges at hand. Hence, although they may appeal to similar ethical principles, there are likely to be different ethical frameworks for questions related to public health surveillance and for individual treatment decisions.

12. What are the roles of ethics committees in addressing ethical issues in health?

Ethics committees are institutional structures that provide a deliberative forum in which ethical issues can be analysed and addressed. They are generally comprised of multiple stakeholders and relevant content experts, to ensure a robust assessment of the ethical issues and an ethically justified and empirically informed identification of solutions. There are three common types of ethics committee: national ethics committees, research ethics committees, and clinical ethics committees.

- **National ethics committees (NECs).** A number of countries have created official bodies to advise their executive and legislative branches, and often the general public, about ethics of health and health care. They may be appointed by the chief executive, min-



Source: WHO/Christopher Black.

ister of health or legislature to analyse ethical issues and offer conclusions and policy recommendations. In some countries, the bodies that serve this function are appointed outside formal governmental structures, and may comprise several advisory groups. Since 1996, NECs have met every two years at the Global Summit of National Bioethics Advisory Bodies, the purpose of which is to facilitate international dialogue and to foster consensus on ethical issues of global concern. WHO serves as the Secretariat of these Global Summits.

- **Research ethics committees (RECs).** RECs review proposed human research studies to ensure that they conform to internationally and locally accepted ethical standards. The main responsibility of RECs is to evaluate research protocols with the aim of safeguarding participants' rights and well-being, by ensuring that the risks of the research are minimized, that they are reasonable in relation to anticipated benefits, and that the researchers have made adequate plans for obtaining participants' informed consent. Other responsibilities of RECs include: assessing the recruitment process and any incentives that will be given to participants; evaluating risks to participants' confidentiality (and the related risk of potential discrimination) and the adequacy of measures to protect it; and ensuring that the participants and their communities are not exploited. Some RECs operate within research institutions, where they may be referred to as institutional review boards, while others operate at the regional or national level. The advan-

tages of an institutional committee are that it is familiar with the local context and can closely monitor ongoing studies. On the other hand, an external committee may provide greater consistency and carry greater legitimacy in the eyes of the research community and the broader public.

- **Clinical ethics committees.** Clinical ethics committees are an important instrument of clinical decision-making on ethical issues arising from the provision of care in health care institutions. Clinical ethics committees are usually multidisciplinary and may include ethicists, health care professionals, patient advocates, and religious representatives. They provide guidance to clinicians, patients, and families in clinical dilemmas and may also contribute to the development of institutional policies and procedures.

13. What role should citizens, community members, and other stakeholders play in addressing ethical issues?

Health policy decisions can be ethically challenging as a result of multiple health system or institutional goals (e.g. health promotion vs health care), competing stakeholder interests (e.g. funder vs health provider), conflicting values (e.g. equity vs utility), or incomplete information, for which there is no obvious or "rationally" correct policy

answer. Although ethical theories and principles provide insight into the nature of the ethical issues, they cannot in themselves address the empirical and ethical uncertainty in policy decisions that have wide-reaching implications for patient groups, communities, and populations. Expert opinion is often a valuable resource to inform such decisions; however, many ethicists believe that the ethical legitimacy of health policies also depends on the appropriate engagement of affected stakeholders, including citizens, patient populations, communities and nongovernmental organizations (NGOs). For example, the “accountability for reasonableness” framework (see glossary of terms) requires that rationales for decision-making be publicly available. Stakeholder engagement is especially important in pluralistic societies, where different people may have different ideas about how much weight should be placed on various values or how a balance should be struck between competing values in cases of conflict. There are three common reasons for engaging affected stakeholders: (1) to

improve the quality of decisions by examining ethical issues from diverse perspectives and bringing relevant experience and expertise, both lay and professional, to the table; (2) to provide input on values, to inform policy decisions and guide the application of available evidence; and (3) to provide a mechanism for improving public accountability for these decisions. Stakeholders can be engaged in a number of ways, including through surveys, interviews, and focus groups to elicit relevant stakeholder values, public meetings to discuss policy issues, citizens’ councils or community advisory panels to provide direct input into policy deliberations, referenda and other shared decision-making processes. Civic deliberation and public participation in the policy process require that those involved understand the facts, the areas of uncertainty and risk, the reasons used to justify public health interventions, the goals of such interventions, and the steps that will be taken to safeguard individual rights.

D. Health ethics and the World Health Organization

14. Why is health ethics important for the work of WHO?

One of WHO's six core functions is to develop "ethical and evidence-based policy options."¹² This requires a clear understanding of the nature of ethical analysis in health care decision-making. WHO, as a member of the United Nations family, is bound by internationally accepted principles of human rights, which provide an important -- and non-negotiable -- ethical framework for work and research in health and health care. However, the existence of an overall ethical framework for decision-making in health does not eliminate the need for ongoing ethical analysis. In many situations in public health policy, multiple ethical considerations will be relevant. While principles of human rights must guide the analysis of these issues, those principles often do not point to a single, objectively correct answer. Rather, an ethically acceptable decision can only be reached by articulating the full range of relevant normative considerations, ensuring that multiple perspectives are factored into the analysis, and creating a decision-making process that is considered fair and legitimate by the relevant stakeholders. At the same time, it is essential to remember that ethical decision-making is not simply a matter of determining the majority's point of view. Ultimately, any decision that is reached must be consistent with fundamental human rights norms.

In 2002, WHO established a dedicated ethics team, which is now called the Global Health Ethics Unit. Through this

team, WHO works in close collaboration with other international organizations and NGOs, and the UN Interagency Committee for Bioethics. The mandate of the Unit is to provide a focal point for the examination of ethical issues raised by activities throughout the Organization, including the regional and country offices, and to foster discussion and debate on a wide range of topics in global health ethics.

15. How does WHO support health ethics capacity-building in Member States?

One of the most important objectives of the Global Health Ethics Unit is to build and strengthen capacity in WHO Member States in relation to a wide range of global health ethics topics.¹³ This is done initially through the elaboration of guidance at global level. The publication of WHO guidance documents is usually followed by implementation activities at regional and country levels, aimed at ensuring that the guidance is used and adapted to the local setting. Workshops and training with key stakeholders, such as Ministry of Health officials, public health experts, and patient groups, are organized. For example, the Global Health Ethics Unit led the process of developing guidance for Member States regarding the fair distribution of antiretroviral treatment in response to the HIV epidemic.¹⁴ With regard to preparedness and response to pandemic influenza, the Unit developed advice for planners on how to confront ethical issues of isolation and quarantine, and fair access to services during pandemics.¹⁵ It also collaborated with WHO's Stop TB Programme in developing guidance on ethical issues related to tuberculosis care and control.¹⁶ In 2010, the World Health Assembly adopted guiding principles on organ and tissue transplantation to support Member States in developing an ethical framework for transplantation.¹⁷

WHO has an ethics focal point in each of its six regional offices; they are responsible for building ethics capacity and addressing issues at regional level in coordination with WHO's country offices. For example, the Regional Program on Bioethics of the Pan-American Health Organization/WHO Regional Office for the Americas was already established in 1994. Their proximity to the countries helps them to tailor the global guidance to the local context and to ensure that questions with local relevance for Member States are addressed at the global level. Support for ethics capacity-building among WHO Member States is further strengthened through collaboration with ethics experts affiliated with the WHO collaborating centres for bioethics.



The 60th World Health Assembly opens in Geneva, Switzerland on Monday, 14 May 2007.

Source: WHO

16. What is the Global Network of WHO Collaborating Centres for Bioethics doing to build health ethics capacity in Member States?

WHO collaborating centres for bioethics are academic centres specializing in health ethics, located in universities around the world. They represent an essential resource for WHO in implementing its ethics mandate. The scientific validity of WHO's ethics work is enhanced by collaboration and dialogue with these academic centres. WHO also encourages connections and synergies between its collaborating centres to achieve better results, facilitate resource mobilization, and strengthen Member States' capacity, in particular at the regional level. WHO is committed to

the development of collaborating centres for bioethics in low- and middle-income countries and encourages active partnership between centres in high- and low-resource settings. The University of Toronto Joint Centre for Bioethics, Canada, was designated as the first WHO collaborating centre for bioethics in 2002. In the following years, several other centres were designated in the regions of the Americas, Europe and the Western Pacific. In 2009, the Global Network of WHO Collaborating Centres for Bioethics was created, to advance WHO's ethics mandate through enhanced collaboration and synergies across the collaborating centres. At present, the Network has six members, and undertakes a wide variety of capacity-building, technical, and training activities in collaboration with WHO, on ethics issues related to, for example, public health surveillance, research ethics, pandemic preparedness and response, and tuberculosis.

Glossary of terms

This glossary provides definitions for common concepts, principles, and values in health ethics. For many of the terms, a number of definitions are available. This glossary is therefore not intended to be definitive, but to aid understanding of common terminology, in particular as used in this document.

Concept, principle or value	Definition
Accountability for reasonableness	Framework that requires that the rationale or reasons underlying health-care-limiting decisions be made publicly available. Moreover, “fair-minded” individuals – those who seek cooperation with others on mutually justifiable terms – must agree on the applicability of these reasons to health care delivery in resource-constrained settings (18).
Autonomy	Most often taken to refer to the ability of an individual to be his or her own person, to make his/her own choices on the basis of his/her own motivations, without manipulation by external forces. However, others in a more Kantian tradition see autonomy as being firmly related to accepting and acting on the basis of one’s obligations, i.e. acting morally, the precise opposite of doing what one wants (19, 20).
Beneficence	Principle requiring that governments, health care providers, and researchers do good for, provide benefit to, or make a positive contribution to the welfare of populations, patients and study participants (21).
Bioethics	The field of enquiry that examines ethical issues arising from the “creation and maintenance of the health of living things”. Bioethics is much broader than medical ethics, and includes all ethical issues in medicine, the life sciences and biomedical research (2).
Confidentiality	The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities (15).
Dignity	A term used to suggest the idea of human worth or value. It is often used to link to the idea of persons as being of value. “The notion of dignity is used to mark a threshold, a kind of respect and care beneath which the treatment of any human being should never fall” (22).
Distributive justice (see also <i>Equity</i>)	A set of principles that provide “moral guidance for political processes and structures that affect the distribution of economic benefits and burdens within societies”. It is generally thought to be difficult, if not impossible, to distribute health. However, there are a number of factors that may be considered relevant to the just distribution of health (including income, wealth, utility), the number of possible persons involved (individuals or groups), and differences in how the distribution should be made (equality, maximization, etc.). Egalitarianism is one example of a distributive justice principle (23).

Egalitarianism	A belief in equality. However, egalitarians disagree about what it is that should be equal, for example whether people are entitled to equal opportunities, an equal share of resources, or whatever level of opportunities and resources are necessary to generate equal results (24).
Equity (see also <i>Distributive Justice</i>)	Equity focuses on equal outcomes and this may require an unequal distribution of some good to bring about the equal outcome. Health equity requires responding to “differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust” (25).
Ethics	Branch of knowledge concerned with questions about right versus wrong conduct and what constitutes a good or bad life, as well as the justificatory basis for such questions (26).
Human rights	Fundamental freedoms and rights enshrined in a set of universal legal statements. Some of the most important characteristics of human rights are that: they are acknowledged in international declarations; states and state actors are obliged to respect them; they cannot be waived or taken away (although the enjoyment of particular human rights may be limited in exceptional circumstances); they are interdependent and inter-related; and they are universal (27).
Informed consent	Agreement to a certain course of action, such as treatment or participation in research, on the basis of complete and relevant information by a competent individual without coercion (28).
Justice	A highly contested concept that can, roughly, be thought of as giving people what they deserve (29). See also: Equity and Distributive justice.
Liberty	A highly contested and complex concept that is often presented as freedom from such things as the interference, influence, or control of others. However, other accounts of liberty focus on authenticity, self-realization, or even appropriate relations with others (30).
Non-maleficence	A principle requiring that health care providers and researchers do not inflict undue harm, either intentionally or through negligence (21).
Principle	A broad but fundamental norm which can provide justification for more specific rules or standards. For example, it is often claimed that informed consent (a standard) is necessary because of the need to respect autonomy (a principle) (31).
Privacy	Privacy seeks to protect a person from scrutiny by others. Respect for privacy implies that a person should not be expected to share personal information unless they so choose. Any violation of privacy requires ethical justification although it might be outweighed by other considerations in some cases (i.e. for the protection of the common good) (32).
Procedural justice	Discussion of the values and processes necessary to bring about a just outcome. For example, where resources are scarce and rationing is needed, a procedurally just outcome would provide clear and justifiable reasons for the decisions made (18).
Proportionality	The balancing of the positive features and benefits of a particular intervention, policy, or research study against its negative features and effects, when deciding whether or not to implement it (33).

Public good	A commodity or service that meets the following two criteria: it is practically non-excludable (i.e. no one can be excluded from consumption, irrespective of individual contributions to provision) and non-rival (i.e. consumption by some does not reduce the benefits of consumption accrued by others). For example, the eradication of smallpox counts as a public good because it meets these criteria (34).
Public health ethics	The field of enquiry that examines ethical issues and dilemmas relevant to the protection and promotion of population health and the collective actions necessary to achieve these aims (35).
Reciprocity	A principle that focuses on “providing something in return for contributions that people have made”. In some cases this can be a strict matching between an action, such as participation in research, and compensation for any harm caused. In other cases, reciprocity may be less direct and involve more general contributions for the benefit of others or society in general (36).
Social justice	A concept focused on the root causes and existence of inequalities in society and the need to explicitly address them. In some cases, this may require a redistribution of resources to compensate for existing inequalities and further actions to prevent their perpetuation (37).
Solidarity	A social relation in which a group, community, or nation stands together. It is often appealed to in discussions about justifications for the welfare state or shared risks through insurance pooling, and in thinking about how states might defend the interests of vulnerable groups within their population (37).
Utilitarianism	A set of theories centred on the principle of utility which is often taken to require that any action should maximize benefits for the greatest number of people (38).
Value	Concept that is “used to explain how and why things matter. Values are involved wherever we distinguish between things as good and bad, better or worse.” Values are central to ethical judgements. Often, the place to start in a discussion about what ought to be done is to make clear what values are most relevant and what weight should be attached to them (39).

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Health care service providers, biomedical and public health investigators, and policy-makers are often forced to make difficult choices about how best to secure optimal health outcomes for individuals and populations. While such decisions have to take into account a number of logistic and practical factors, it is increasingly recognized that ethical considerations must also be given explicit consideration. Failure to do so may result in various wrongs, such as harm and injustice, the consequences of which are often borne disproportionately by the most vulnerable groups in society.

This document aims to help policy-makers, health care providers and researchers to understand key concepts in global health ethics and to identify basic ethical questions related to health and health care. Through responses to 16 questions, it explains common terms and theories, examines the challenges of applying ethical principles to global public health, and outlines practical strategies for dealing with those challenges. Finally, it explains how health ethics is incorporated into WHO's work and what WHO is doing to strengthen health ethics capacity in its Member States.

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