Guidance on ethics of tuberculosis prevention, care and control

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Introduction

This is a critical time to expand access to tuberculosis prevention and care and to control the pandemic as part of a global effort. The world is on track to achieve the Millennium Development Goal target of reversing TB incidence, but the reduction is not yet outpacing population growth. Estimated global TB prevalence and mortality have dropped since 1990, but not at a rate that will meet Stop TB Partnership targets of halving them by 2015 (*1*). More disturbing, the further emergence of drug-resistant tuberculosis and HIV[1]-associated TB create well-founded concerns for the sustainable success of current efforts.

With the growing breadth and complexity of TB efforts today comes a greater range of concerns associated with the ethics of action, inaction and specific approaches to clinical, public health and research interventions. In 2006, the documented emergence of extensively drug-resistant tuberculosis (XDR-TB),[2] including a dramatic and lethal outbreak in South Africa, brought forward urgent issues of public health ethics given the imposition in some programmes of involuntary detention of persons suspected and/or confirmed of being ill with drug-resistant TB under the justification of public safety (*2*).

At its 2nd meeting in April 2008, the WHO Task Force on XDR-TB recommended the production of a guidance document on “Ethics of TB care and control”. Following this recommendation, the Ethics and Health Team of the Department of Ethics, Equity, Trade and Human Rights and the Stop TB Department jointly established a WHO Task Force on Addressing Ethical Issues in TB Care and Control Programmes in August 2008. Twenty-two members were nominated from a variety of fields, including National TB Programmes, Civil Society, Ethics, Human Rights and Health Law.

The aim was to undertake an analysis of selected priority ethical issues in TB and to support the development of WHO guidance in order to help governments and their national TB programmes, TB service providers, policy-makers and civil society and other stakeholders implement TB prevention, care and control efforts in an ethical manner.

Discussion papers on the following topics were commissioned:

1) Access to diagnosis and treatment; 2) Obligations and rights of health-care workers and patients; 3) Public health measures; and 4) Research.

The Task Force held its first meeting in December 2008 at the Joint Centre for Bioethics at the University of Toronto. Members discussed the background papers prepared for the meeting and the main points to be included in the global guidance document. The Task Force gathered again in August 2009 and drafted the outline for the guidance. In October 2009,

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[1] HIV: human immunodeficiency virus.

[2] Extensively drug-resistant tuberculosis (XDR-TB): defined as multidrug-resistant tuberculosis (MDR-TB) plus resistance to a fluoroquinolone and at least one second-line injectable agent: amikacin, kanamycin and/or capreomycin.

a consultation with additional representatives of civil society and national TB programmes enabled further valuable input.

A refined outline was endorsed by WHO's Strategic and Technical Advisory Group for Tuberculosis (STAG-TB) in November 2009, and received further input at the 40th Union World Conference on Lung Health in December 2009.

In a linked effort, the Stop TB Partnership agreed to establish a TB and Human Rights Task Force in 2010, with secretariat being provided by WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The Task Force will aim to develop a policy framework for a rights-based approach to TB prevention, care and control as joint products of WHO, the Stop TB Partnership and UNAIDS. It will also propose a strategic agenda for action. It will be composed of major stakeholders, constituencies from affected communities and risk groups, human rights and civil society organizations, health and human rights experts, United Nations agencies, and development partners. This ethics guidance and the resulting rights-based policy framework will be used as complementary and companion documents to guide further dialogue and action in these areas.

WHO will engage in a variety of follow-up activities to reach the targeted audiences, including the development of training materials and conduct of workshops on ethics and TB. As part of this process, case-studies are being developed to give concrete examples of ethical dilemmas and human rights issues that decision-makers face in defining and pursuing TB policies and programmes, and to illustrate some of the challenges and solutions proposed in the ethics and human rights guidance documents.

WHO will work closely with stakeholders to develop mechanisms for monitoring the impact of this document. An effective monitoring system should consider the extent to which, first, ethical guidelines have been incorporated into formal policies on the country and programme level; second, those policies are actually being followed in day-to-day practice; and, finally, changes in policies and practice actually improve the lives and health of individuals and communities affected by TB, with attention to social justice considerations. Specific indicators relevant to these questions should be developed and incorporated into ongoing systems of programme oversight.

Background on TB

In 2008, 9.4 million people fell ill with tuberculosis across the globe, including 1.4 million cases of HIV-associated tuberculosis. That year, WHO estimates there were 1.8 million deaths, including 0.52 million deaths in HIV-infected patients. In the same year, there were an estimated 0.5 million cases of multidrug-resistant tuberculosis (MDR-TB)[1] with at least 0.15 million associated deaths, as well as about 50 000 cases of extensively drug-resistant (XDR) tuberculosis and at least 30 000 associated deaths. Major achievements between 1995 and 2008 include 36 million patients cured, more than 6 million deaths averted compared to non-DOTS[2] treatment, reduction of case-fatality rate from 7.6% to 4%, and attainment of highest-ever cure rates of 87% in 2007–2008 (*1*). Incidence rates have been declining globally and in all sub-regions except in certain African countries since 2004.

The Stop TB Strategy (*3*), launched by WHO in 2006, builds on and enhances DOTS to address new challenges and to expand access to the most vulnerable populations. It also requires addressing TB/HIV, MDR-TB and the needs of the poor and vulnerable; contributing to strengthening health systems; engaging all health-care providers; empowering people with tuberculosis and their communities; and promoting research. The emergence of tuberculosis strains that are resistant to multiple anti-tuberculosis drugs and the synergy between tuberculosis and HIV/AIDS in coinfected persons are two major challenges to tuberculosis control. Combating the first involves pursuing the proper strategy of TB control to prevent its emergence and monitoring drug resistance and the use of available drugs. For the latter, preventing HIV/AIDS infections is one of the most important ways to prevent death from either or both diseases (*4*). For now, TB incidence and mortality in people with HIV can be reduced through early HIV testing of TB patients, high-quality TB screening in people with HIV, increased use of antiretroviral therapy (ART) and isoniazid preventive therapy (IPT), proper infection control, and scale-up of TB diagnostic capacity.

Tuberculosis is causally linked with poverty and low socioeconomic status, and deaths from the disease began declining sharply in industrializing countries long before the advent of anti-tuberculosis drugs. In modern times documented surges in tuberculosis incidence have been associated with adverse economic developments in several countries. Socioeconomic factors such as malnutrition, lack of education, and poor housing and sanitation, compounded by other risk factors such as tobacco and alcohol abuse and diabetes, affect vulnerability to TB and access to care. Furthermore, this access is often hindered by catastrophic costs associated with seeking care and lack of social security, resulting in a vicious cycle of poverty and ill-health. Given the multiple, disparate risk factors for tuberculosis, control of the disease (and the aim to achieve elimination) will require a multi-dimensional and cross-sectoral approach. Besides the core interventions against tuberculosis that are part of the Stop TB

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[1] Multidrug-resistant tuberculosis (MDR-TB): defined as TB caused by strains of *Mycobacterium tuberculosis* that are resistant to, at least, the two most important first-line drugs isoniazid and rifampicin.

[2] DOTS: Component of the Stop TB Strategy to control TB.

Strategy, bold policies across the health system, intensified research, alleviation of poverty, and action on the risk factors and the social determinants of the disease will be necessary. TB programmes should not assume that addressing social determinants is the responsibility of others. While they cannot solve all the social problems that contribute to TB, they should be designed to address social determinants to the extent possible and to promote a cross-sectoral approach to TB control. For example, they can work with poverty-reduction programmes to ensure that their impact on TB is taken into account in quality assessment measures.

Tuberculosis control and elimination also depend ultimately on establishing and enforcing policies across the health system which would benefit disease control in general. These include removing financial barriers to diagnosis and care, ensuring availability of quality treatments and regulating the use of all anti-tuberculosis drugs, establishing a network of laboratories where rapid tests are also available, ensuring well-trained and sufficient human resources, proper infection control procedures, etc.

1.

Overarching goals and ethical values

What is the overall goal of TB care and control programmes?

As outlined in WHO's Stop TB strategy (*3,5*), the goals of TB care and control programmes are to:

- achieve universal access to high-quality diagnosis and patient-centred treatment;
- reduce the human suffering and socioeconomic burden associated with TB;
- protect poor and vulnerable populations from TB, TB/HIV, and MDR-TB;
- support development of new tools and enable their timely and effective use;
- protect and promote human rights in TB prevention, care and control.

What are ethical values?

Ethical values refer to the way we ought to live our lives, including our actions, intentions, and our habitual behaviour. They can sometimes be the source of disagreement and conflict. However, through analysis and discussion, it is possible to arrive at a rough consensus as to which values ought to be seen as central. The approach taken here is to articulate the relevant ethical considerations as a complex web or network of different obligations. Such an approach allows us to accept the possibility of conflict between different values and interests both for individuals and between individuals and/or groups. This requires that situations will occur when some rights and obligations are held to be more important than others.

What is the relationship between ethical values and human rights principles?

Human rights are legal guarantees that protect individuals and groups against actions that interfere with fundamental freedoms and human dignity. They encompass what are known as civil, cultural, economic, political and social rights. Human rights are principally concerned with the relationship between the individual and the state. Governmental obligations with regard to human rights broadly fall under the principles of *respect, protect* and *fulfil*.

Human rights can be seen as a concrete legal expression of ethical values, including for instance non-discrimination, participation, and accountability. Human rights and ethical values are intimately interlinked in a dynamic way. Because human rights are legally binding, they provide an overarching ethical framework that governments and international organizations are obligated to respect. Nonetheless, the existence of this framework does not obviate the need for ongoing ethical deliberation. In many situations, multiple ethical considerations will be relevant and may point in different directions. An ethically acceptable decision depends on articulating the full range of appropriate normative considerations, ensuring that multiple perspectives are factored into the analysis, and creating a decision-making process that will be considered fair and legitimate by the stakeholders involved.

What ethical values are particularly important to TB care and control?

A comprehensive TB strategy should seek to protect individuals and communities through the proper treatment of infected individuals (active and latent) and the prevention of new infections (through the existence of an effective care and control programme as well as through measures such as infection control, vaccination, population screening, and improvement in the socioeconomic factors known to increase the risk of TB). Pursuing these goals requires coordinated action to provide the conditions for all members of the community to be protected from harm through the provision of adequate public health (*6*).

Not all of the following values will be suited to every situation, but they are all important, and ought to be protected and promoted in appropriate circumstances. Judgement must be used about which are relevant and how they can be used to articulate related obligations. The following are some key values.

- *Social justice/equity* – A focus on social justice calls attention to the underlying root causes and existence of inequalities in society and requires that we explicitly address them. In some cases, this may mean a redistribution of resources to compensate for existing inequalities and further actions to prevent their perpetuation. Given the role of socioeconomic factors, especially extreme poverty, in increasing the risk of TB infection and the progress of disease, the pursuit of social justice must now become a key component of TB control. This is also applicable to how we treat different groups – for example, all persons with TB should be treated the same way.

- *Solidarity* – Solidarity can have different definitions, but is in essence a social relation of a particular kind. It is primarily about standing together as a group, community or nation. It is often appealed to in discussion 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. Infectious diseases such as TB increase the risks of harm for whole populations. Such risks can be reduced where strong community ties result in cooperative action to enforce the conditions for flourishing, disease-free lives.

- *Common good* – An infectious disease not only threatens the health of an infected individual, but of the whole population. The removal or reduction of a threat of infection from a society is therefore something that we can all benefit from. Moreover, there is evidence that individual health is shaped by the social environment. Therefore, we *all* gain from a society with strong public health facilities to address TB control and treatment. It is important to think about how the disease is spread, how it might be prevented, and how communities can be empowered to respond to it.

- *Autonomy* – Respect for patient autonomy has often dominated discussions of ethical issues in many areas of health care. Autonomy can be defined in many ways, but is generally seen as guaranteeing individuals the right to make decisions about their own lives, including health care. While it is not the only value that is important, nor the one that always ought to take priority, it requires consideration in debates about ethical TB policy. For example, respecting autonomy means that patients generally should have the right to choose among treatment options.

- *Reciprocity* – Within societies it is common for some members to put themselves at greater risk of harm for the sake of others. A good example of this would be when individuals, either health-care workers (HCW) or members of the community, seek to treat those with TB, knowing that they themselves might be at greater risk of harm. Reciprocity seeks to express the idea that these individuals deserve benefits in exchange for running such risks. It might include an obligation to minimize the risks to individual care-givers (by providing protective equipment) as well as positive interventions to treat and compensate individuals when harm occurs as a result of providing care.

- *Effectiveness* – The idea of effectiveness includes the duty to avoid doing things that are clearly not working, as well as the positive obligation to implement proven measures that are likely to succeed. Effectiveness is linked to the concept of *efficiency*, which requires that limited resources be used in the most productive manner possible. Evidence of effectiveness (or lack of it) in TB programmes requires ongoing monitoring, surveillance and research.
- *Subsidiarity*[1] – This value promotes the idea that decisions should be made as close to the individual and communities at local level as possible. The idea is that this ought to result in decisions reflecting local interests, concerns and beliefs, and ensure the highest possible involvement by the public.
- *Participation* – This principle requires that the public be encouraged to participate in the decision-making process, and that reasons be provided for decisions.
- *Transparency and accountability* – This principle requires that decisions be made in an open manner, and that the decision-making process be fair, responsive and evidence-based.

WHO has previously articulated some of these issues in the concept of "person-centred care", an idea that builds on the concept of "patient-centred care," which has long been a part of the Stop TB strategy (*5*). Patient-centred care "involves viewing health care from the patient's perspective and then adapting care to more closely meet the needs and expectations of patients" (*7,8*). Like in the case of patient-centred care, a person-centred approach recognizes that the direct beneficiary of TB care is the individual who is sick, and that strategies must therefore be designed with this individual's rights and welfare in mind. For example, TB patients have the right to receive advice and treatment that meets international quality standards, be free of stigmatization and discrimination, establish and join peer support networks, and benefit from accountable representation (*9*). Yet, person-centred care also recognizes that patients are not the only individuals whose rights and interests must be protected (*10*). It is equally important to consider those who are sick and not receiving care (i.e., those who are not patients but should be); family members and contacts of patients, who are at heightened risk of being infected; and the community at large, which faces risks from the failure to diagnose and appropriately treat individuals with TB.

How can individuals, communities, and civil society work together to promote these ethical values?

Promoting these values requires the active cooperation of multiple individuals and entities, who together share responsibility for achieving the Stop TB goals.

Initially, the responsibility for creating, sustaining, and continually improving TB care and treatment programmes rests with governments and the international community. As explained below, all governments have a fundamental obligation to provide universal access to high-quality TB diagnosis and treatment, and to address the social determinants that are largely responsible for the spread of TB. The international community must provide financial and technical assistance to countries that lack the resources to satisfy this obligation on their own. TB has not yet been eradicated mostly because these responsibilities have been neglected.

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[1] Examples of the principle of subsidiarity include: delegating responsibility for support and care to family members, friends and neighbours; recognizing the public utility of private or not-for-profit health-care services that contribute to public health; and supporting nongovernmental organizations and faith-based organizations that provide essential health services in remote areas where public services are not accessible.

Local communities' role is also to support TB diagnosis and treatment and to monitor the equity of access to health care. Community organizations, families, and individual members should play a supportive part in TB prevention, identification, care and treatment, and provide a compassionate environment free of stigmatization and discrimination.

The web of responsibilities also embraces individual patients. It is their duty to give complete and accurate personal and clinical information to providers, to alert them to any difficulties encountered in the treatment process, to follow prescribed treatment regimens, to encourage others to seek treatment, to show consideration for other TB patients and care providers, to act in ways that do not put others at risk, and, if they can do so safely, to notify their contacts of the need to seek diagnosis.

To promote the mutual interests of individuals and the public, TB programmes should work in partnership with patients, communities, and civil society, empowering patients to play an active and responsible role in decision-making processes and in TB care.

2.

The obligation to provide access to TB services

Do governments have an ethical obligation to provide universal access to TB care?

Yes. Governments' ethical obligation to provide universal access to TB care is grounded in their duty to fulfil the human right to health. As stated in the WHO Constitution, "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition" (*11*). Similarly, the International Covenant on Economic, Social and Cultural Rights recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and specifically calls on State Parties to take steps necessary for "the prevention, treatment and control of epidemic, endemic, occupational and other diseases" (*12*). While resource constraints may prevent some countries from fulfilling these obligations completely, the principle of progressive realization requires them to "move as expeditiously and effectively as possible" towards achieving these critical goals (*13*).

Even when resources are limited, there are several reasons why governments should give high priority to providing universal access to TB care as part of their commitment to fulfilling the human right to health.

- First, its benefits to the individual patient are substantial: in most cases, proper treatment prevents significant morbidity and mortality and leads to a complete cure.
- Second, by slowing the spread of a highly infectious disease, it benefits not only the patient but also the broader community.
- Third, lack of proper TB care leads to the development of dangerous drug-resistant strains.
- Fourth, when used routinely, it is inexpensive and highly cost effective.
- Finally, TB affects large numbers of people, a disproportionate number of whom are vulnerable and marginalized, and TB can further increase people's vulnerability to poverty.

Providing universal access to TB care is important not only for drug-susceptible TB but also MDR and XDR-TB, which have had a particularly pernicious impact on vulnerable populations. As such, WHO has urged Member States "to achieve universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis as part of the transition to universal health coverage, thereby saving lives and protecting communities" (*14*).

The obligation to provide universal access to TB care implies a duty to ensure the quality of that care. Thus, governments have an ethical obligation to regulate the care that is provided to ensure that it is consistent with internationally accepted quality standards. This extends not only to TB treatment but also to diagnostic methods.

Does this obligation mean that TB care should be provided for free?

Yes. As stated in WHO's Stop TB Strategy, "anti-TB drugs should be available free of charge to all TB patients, both because many patients are poor and may find them difficult to afford, and because treatment has benefits that extend to society as a whole (cure prevents transmission to others)" (*5*). The second of these rationales reflects the ethical principle of reciprocity, which states that, when individuals undergo burdens for the benefit of the community, society has an obligation to provide "something in return" (*15*).

The obligation to provide free TB care also reflects pragmatic considerations. For many, the cost of care is a barrier to obtaining or completing a full course of TB treatment, meaning that some individuals who are infectious will never be cured, thus exposing additional people to risk. Moreover, untreated or incompletely treated TB facilitates the development of dangerous drug-resistant strains, which are also much more expensive to treat. Thus, ensuring that TB care is freely available is essential to governments' ability to protect the public's health, and likely to prove the less expensive option in the long run.

Does the obligation to provide free care include diagnosis and other services?

Yes. All aspects of TB care should be provided free of charge. Ensuring free access to diagnostic measures, including drug susceptibility testing, is critical; otherwise, patients may receive treatment with drugs to which they are resistant, which would not only fail to cure the patient but also lead to additional spread of infection and facilitate further development of drug-resistance. Free access should also be provided to preventive therapy for those who are infected, as this will minimize the overall burden of disease.

It is also important to remove non-TB-specific financial barriers to accessing the health-care system, such as user fees that prevent poor people from receiving health-care services, or charges imposed on TB patients for the care of related conditions (e.g. HIV).

Does the obligation to provide free treatment extend even to M/XDR-TB, which is more costly to treat than drug-susceptible TB?

Yes. If M/XDR-TB[1] cases are not appropriately treated, a self-sustaining and potentially devastating epidemic of drug-resistant TB will be the inevitable result. The individual and public health interest in ensuring free access to TB treatment applies even more strongly to the treatment of drug-resistant TB, given the human suffering and the significantly higher morbidity and mortality associated with these strains.

The expense of treating M/XDR-TB underscores the importance of providing adequate resources to support basic TB care and control, including infection control, DOTS, and community-based care programmes. As WHO has recognized, the root causes of drug-resistant TB are "improper treatment regimens by HCW and failure to ensure that patients complete the whole course of treatment" (*16*). Resources directed to solving these problems will enable governments to avoid the financial burdens associated with treating M/XDR-TB.

What obligations does the international community have to support governments' ability to provide universal access to TB care?

It is undeniable that the expense of providing universal access to TB care, particularly M/XDR-TB care, poses a significant burden for resource-poor countries. As noted above, these governments have an obligation to "move as expeditiously and effectively as possible" to scaling up their treatment capacity. In the meantime, the international community has an obligation to provide financial and other assistance to countries that cannot offer universal

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[1] M/XDR-TB: multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis.

access to care on their own. Such an obligation can be grounded in a number of different ethical principles. For example, an argument based on a humanitarian principle (beneficence, solidarity, etc.) might appeal to the fact that fellow human beings require relatively cheap interventions that could easily and dramatically improve their lives. Providing such basic support would not significantly impact on other people's lives. Or an argument could be grounded in the idea that justice requires a redistribution of wealth because the present actual distribution might be at least partly due to past unfairness. Even if governments find such moral arguments unconvincing, they have a strong prudential reason to be concerned about diseases such as TB, particularly given growing drug resistance. If the situation deteriorates elsewhere in the world, it is likely to be only a matter of time before it impacts upon one's own country (*17*).

In light of the obligation to provide universal access to TB care, do governments have an ethical obligation to ensure the quality of TB drugs?

Yes. It is ethically unacceptable for national TB programmes to provide drugs that are not quality-assured, as substandard drugs can both harm individual patients and contribute to the development, spread, and amplification of drug-resistant strains. Indeed, the Stop TB Partnership's Global Drug Facility has identified "infrequent and poor quality drug supplies" as "the main barrier to preventing and eliminating TB" (*18*).

The obligation to assure the quality of TB drugs is an infrastructural requirement and must be fulfilled at the governmental level. Individual providers are simply not equipped to evaluate the quality of drugs on a case-by-case basis. Governmental authorities also have an obligation to ensure the sustainability of the drug supply.

How should health-care providers make decisions about the care of individual patients when governments do not fulfil their obligation to ensure the availability of quality-assured drugs?

When governments do not satisfy their obligation to make quality-assured TB drugs available, providers making decisions for individual patients face difficult ethical dilemmas. In some cases, they may reasonably conclude that it would be ethically preferable to give a patient drugs of unknown quality rather than forego treatment entirely. In making such decisions, they should consider the risks and benefits of their decisions to both the patient and the public, in consultation with the patient and other health-care providers. There is an additional duty to notify the national government about this particular problem, and advocate for an urgent rectification.

What ethical considerations should governments and health-care providers take into account in developing strategies to promote better access to TB care and treatment?

Many of the key ethical considerations relevant to promoting access to TB prevention, care and treatment are already part of WHO's Stop TB Strategy. These include the importance of:

- *A patient-centred treatment approach* – Focusing on the patient means that treatment should be accessible, acceptable, affordable, and appropriate (*7,19*). Patients should have choices about the location of treatment and, when DOT is used, about the individuals who will be doing the observing.
- *Promoting community-based care* – which is accessible, well-accepted by patients, and promotes adherence (*16*). As WHO has recognized, "community-based care provided by trained lay and community health workers can achieve comparable results [to hospitalization] and, in theory, may result in decreased nosocomial spread of the disease" (*16*). In addition, community-based care reduces burdens on health-care facilities and is

more cost effective than facility-based treatment (*16*), thereby enabling governments with limited resources to serve the greatest proportion of those in need.

- *Focusing on patients as part of their larger communities* – Patients should be encouraged to form support groups and to work with their communities to address the social determinants of TB (*8*).
- *Promoting social justice and equity* – TB programmes should take into account the needs of all patients, and in particular, the special needs of socially vulnerable groups for whom tailored interventions should be proactively developed. Interventions should be gender-sensitive and address different types of vulnerabilities, including individuals who face increased risk of becoming infected and developing active disease, and those who face challenges of accessing and fully utilizing services. Such groups include, but are not limited to, people living in extreme poverty, indigenous populations, refugees, asylum seekers, migrants, mine workers, prisoners, substance users (including alcohol), and homeless people. In addition, the needs of women, children, and people coinfected with HIV warrant special consideration. Several resources exploring the needs of these populations have already been developed (*4,20–23*).

3.

Information, counselling and the role of consent

What is the ethical justification for giving individuals information and counselling about tests and treatments they are being asked to undergo?

There are several reasons to ensure that individuals undergoing TB testing and treatment receive complete and accurate information about the risks, benefits, and alternatives available to them. First, at the most basic level, people have a right to know what is being done to their bodies, and why it is being done. Failing to provide information about testing and treatment shows a lack of respect for this basic individual right. Second, helping patients understand TB, how it is spread, and the options for treating it makes it more likely that individuals will adhere to treatment. This is particularly true for patients who must undergo significant burdens to complete treatment, such as taking time off from work to travel to a clinic. Third, providing full information about TB treatment helps instill trust in the system, thereby enhancing a programme's status and respect in the community. It is widely acknowledged that trust is essential for public health systems to succeed.

What kind of information should individuals be given about TB tests and treatments?

Individuals who undergo TB testing should receive basic information about the nature of TB and why they are being tested. Individuals who are offered TB treatment should be given information about the risks and benefits of the proposed interventions (for both the patient and others in the community), the importance of completing the full course of treatment and of infection control measures, and available support to help patients complete the full course of treatment.

Programmes should work with peer advocates and community leaders to design mechanisms for providing information that will be appropriate for individuals from diverse linguistic, educational and cultural backgrounds (e.g. *24–26*).

What should TB patients be told about the process of contact notification?

In many countries, a diagnosis of infectious TB must be reported to public health officials. This notification sometimes triggers a public health intervention that includes an effort to determine the identity of close personal contacts, such as household members. These contacts are then notified of their risk of infection. Where such a system exists, the HCW should explain it to patients and seek to enlist the patient's cooperation in the identification and notification of contacts.

In countries that do not have case-reporting systems, or where case reporting does not lead to the identification and notification of contacts by public health authorities, patients should be encouraged to notify their contacts themselves. TB programmes should provide assistance and support to patients who undertake to notify their contacts (*27*).

When patients are unwilling to participate in the process of contact identification and notification, public health authorities and HCWs are faced with an ethical dilemma. On the one hand, the non-consensual disclosure[1] of the patient's health status to a third party interferes with the right to confidentiality, which is regarded as a cornerstone of the professional–patient relationship. The third party in this scenario, on the other hand, has rights too. The right to life is seriously threatened if the patient has infectious TB, especially if it is a drug-resistant strain. While HCWs have duties to their patients, they also have an obligation to protect the lives of others when they are in a unique position to do so.

In exceptional cases, this duty to third parties may justify disclosure of patients' TB status without their consent. The non-consensual disclosure of a patient's TB status should be viewed as a last-resort option, to be considered only after all reasonable efforts to engage the patient's cooperation have failed. Moreover, non-consensual disclosures should be made only to close contacts who would be at significant risk of infection if they remained unaware of the patient's TB status. Public health authorities and TB programmes should develop clear policies governing the non-consensual disclosure of a patient's TB status, which should specify the standards and the procedures that must be followed before a non-consensual disclosure is authorized. These standards and procedures should be aimed at protecting patients and their contacts from stigmatization and other social harms associated with TB in many settings. Patients should be notified before any non-consensual disclosure is carried out.

How does the ethical concept of "informed consent" apply to TB testing and treatment?

As an ethical concept, informed consent refers to the process of engaging patients as partners in the treatment process by giving them relevant information and an opportunity to make decisions for themselves. The ethical aspect of informed consent should not be confused with legal mechanisms, such as consent forms, that some health-care providers and researchers use to document patients' decisions. Such legal mechanisms are sometimes criticized as adding unnecessary administrative complexity, or as being threatening to patients who fear they are being asked to sign away their legal rights. Whatever the merits of these objections, they do not undercut the importance of adhering to the fundamental ethical requirement of engaging patients as partners by ensuring that their decisions are voluntary and informed.

The manner in which the patient's voluntariness should be assessed will vary depending on the type of intervention being offered. For TB testing, there is usually no need for a specific process of confirming the patient's agreement, as consent to go through necessary diagnostic testing is implicit in general agreement given to undergo a medical examination. An exception is situations where drug susceptibility testing is offered to patients when treatment for drug-resistant TB is not available (see page 19). Because patients' implicit consent to testing is premised on the assumption that treatment will be offered for any conditions that are diagnosed, it cannot reasonably be applied to tests for conditions when no treatment is available. Thus, when patients are offered drug susceptibility testing in the absence of treatment, they should be informed of the risks and benefits of testing and specifically asked if they are willing to consent even though treatment is not available to them.

When patients are offered treatment for TB, they should generally be informed and asked for their specific consent, just as they would be for other significant medical interventions. Unlike testing, patients' consent to TB treatment cannot be inferred from the mere fact that they have decided to undergo a medical examination. As noted above, the core ethical obligation is to provide relevant information and seek the patient's agreement; there is no

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[1] Non-consensual disclosure: informing a third party about a patient's status without his or her consent.

inherent ethical obligation to do this by using a written form. It is important to remember that the goal of the process is to show respect for the patient and enhance the likelihood that treatment will be completed; it should not be implemented in a manner that creates barriers to achieving these fundamental goals.

Patients who refuse to consent to TB treatment should be counselled about the risks to both themselves and the community. Providers should seek to understand the reasons the patient is reluctant about treatment, and they should work together to identify methods for overcoming these concerns. It is rare that patients persist in refusing treatment when appropriate counselling is provided. If such cases arise, patients should be informed that, while they have the right to refuse care, if they have active TB and do not complete the necessary course of therapy, it is possible that they could be subject to involuntary isolation or detention. This issue is discussed further below, on page 22.

4.

Supporting adherence to TB treatment

What is the ethical basis for promoting adherence to TB treatment?

Taking TB medications as prescribed is the most essential aspect of TB treatment, both to protect the patient's own health and to prevent the further spread of the disease and the development of drug-resistant strains. Partnership is an important key to success. While people with TB have an ethical duty to complete therapy, providers' obligations to the patient and the public create a duty to support patients' ability to adhere to treatment.

Is directly observed therapy an ethically justifiable strategy for promoting adherence?

Yes. Directly observed therapy is an effective way to ensure adherence to treatment. It is ethically justifiable when done as part of a patient-centered approach to care. Such an approach should include the following components:

- minimizing the burdens of care on patients, including the indirect costs of care, such as time lost from work;
- taking steps to avoid the stigmatization of patients (for example, through community education about TB);
- giving patients choices about who will observe them (and where); the person chosen to do the observation must assume responsibility to ensure that the therapy is completed or, if it is not, to notify the patient's health-care provider;
- clearly explaining what will happen if the patient is non-adherent (e.g. defaulter tracing);
- implementing mechanisms to promote early detection and proper management of side-effects.

Directly observed therapy should be seen as a process for providing support, motivation, and understanding to patients. It is a necessary part of TB care, but is not intended to be a method for "forcing" patients to do something against their will.

Is the use of "enablers" an ethically justifiable strategy for promoting adherence to treatment?

Yes. "Enablers" refer to mechanisms or resources that facilitate patients' ability to adhere to treatment, such as transport vouchers for patients to travel to a clinic, or food baskets that allow them to receive adequate nutrition while receiving care. Enablers are an important part of TB treatment because they help mitigate the impact of the social determinants of TB, including poverty, which can make it difficult for individuals to complete a full course of therapy. In addition, enablers empower patients to take an active role in their care, thereby promoting the ethical value of individual autonomy (*8*).

Is it ethically acceptable to give TB patients financial or other incentives in exchange for completing treatment?

Some TB programmes give patients cash or other incentives in exchange for completing treatment. There is nothing inherently inappropriate in such practices, when implemented as part of a carefully designed, respectful, person-centred approach to TB care. The process of treatment involves significant burdens that patients undergo not only for their own benefit but also for the benefit of the community. According to the ethical principle of reciprocity, when individuals accept burdens for the benefit of the community it is appropriate for society to provide something in return.

Nonetheless, there are risks with relying solely on material incentives as a means of promoting patient adherence. In some communities, such practices may be seen as inappropriate – even insulting – attempts to "buy" the patient's cooperation. In addition, a focus on financial incentives may lead programmes to overlook broader, and ultimately more valuable, efforts to address the root causes of non-adherence, including poverty and other social determinants. Further, providing financial incentives in only one area of public health may undermine important efforts in other areas.

Whether to give patients incentives to complete treatment should be based on judgements about both the expected efficacy of such practices and sensitivity to local norms. If incentives are offered, it is important to ensure that they are managed carefully. For example, mechanisms should be established to ensure that they are not provided to individuals who do not actually need TB treatment. In addition, they should not be allocated in a discriminatory or inequitable manner.

What ethical considerations apply to the management of patients who have problems with adhering to TB treatment?

Because of the importance of completing treatment to both the individual and the public, programmes have an ethical obligation to follow up with patients who are having problems with adherence. This step is an important part of the process of person-centered care, as it demonstrates both the programme's commitment to promoting the individual patient's best interests as well as the need to protect others in the community from the risks of untreated TB.

Efforts to contact patients who do not show up for treatment create a risk of intruding on individuals' privacy and autonomy. Thus, consistent with the person-centred approach, any attempts to contact patients must be carried out in a way that minimizes these intrusions. For example, if HCWs visit TB patients at home or in the community, they should not arrive in vehicles that can be identified as belonging to the TB programme.

Patients should be informed, at the initiation of treatment, that they will be contacted if they do not show up for their appointments, and, to the extent feasible, be given a choice about the process by which communication will take place (e.g. by telephone or letter instead of by a home visit), assuming the programme determines that these methods are likely to be effective.

How should programmes respond to patients who do not adhere to treatment despite repeated efforts?

When efforts to promote patients' adherence to treatment do not work, the first response should be to try a different approach – for example, scheduling treatments at a different time, relying more heavily on directly observed therapy, or addressing any possible complicating factors such as drug or alcohol use. Further research should be conducted to determine the most effective methods to promote adherence (*28*).

Programmes that frequently experience problems with adherence should reconsider their overall approach to treatment. While isolated cases of non-adherence may reflect patient-specific factors, on a larger scale it suggests that the system has failed to adequately implement a person-centred approach to care.

In rare instances, if all reasonable efforts to promote adherence have failed and the patient still remains infectious, involuntary isolation or detention may be considered. This possibility is discussed below, on page 22.

Is it ethically acceptable to refuse to initiate treatment when it appears that a particular patient is unlikely to adhere to the prescribed regimen?

No. There is no evidence that anyone can accurately predict whether an individual will adhere to treatment. Any attempt to do so is likely to be based on inappropriate stereotypes and is inherently unethical. However, if some specific reasons seem to impede adherence, they should be addressed as part of the initial discussions about treatment.

Denying treatment to individual patients based on predictions about non-adherence should be distinguished from situations in which conditions in a particular setting are inadequate to support a TB programme at all, such as settings in which basic needs of adequate water, food, shelter and sanitation cannot be met (*22*).

What are providers' ethical obligations to patients for whom treatment options are not working and who remain infectious?

TB programmes and practitioners have a fundamental ethical obligation to avoid abandoning their patients. When all available curative treatments have been attempted and the patient is still not responding, the obligation of non-abandonment requires the provision of palliative care (both chronic and terminal, as needed). The fact that curative treatment is not working does not absolve the TB programme of responsibility for optimizing the patient's comfort and well-being.

The location of care for such patients should be based on an individualized risk assessment. In many cases, care can be provided in the community, depending on the individual's degree of infectiousness, his or her willingness and ability to comply with infection-control precautions, the presence of children in the home, and the preparation and training of community care providers (*7*). Isolation or detention of such patients should only be considered as a very last resort, as discussed below on page 22.

5.

The gap between the availability of drug susceptibility testing and access to M/XDR-TB treatment

Is it ethically acceptable to offer drug susceptibility testing when treatments for drug-resistant strains are not available?

Point-of-care rapid diagnostic methods at the outset of the diagnostic process can revolutionize the treatment of M/XDR-TB by enabling the use of a tailored drug therapy. Countries should ensure that patients diagnosed through these measures are provided access to the most appropriate drugs. However, while countries are in the process of scaling up treatment, the use of drug susceptibility testing can be appropriate as an interim measure even when no second- or third-line drug treatment is available, or when the only available treatment is substandard. Among other benefits, a diagnosis even in the absence of treatment can:

- provide evidence of a high prevalence of M/XDR-TB in a particular country or region, which can be used to promote advocacy to improve management capacity (see the discussion below, page 25, on the importance of surveillance);
- ensure that individuals with M/XDR-TB are not inappropriately treated with regular TB drugs, which can harm both the patient and public health;
- guide decisions about segregating TB patients being cared for in a closed environment;
- help individuals make life plans, diminish the impact of the disease on family members, and inform important behaviour regarding infection control.

Countries that implement diagnostic testing in the absence of treatment should do so only as a temporary measure, and should establish a timetable for when treatment for M/XDR-TB will be made available. As discussed above (page 14), individuals should not be given diagnostic testing in the absence of treatment unless they have provided specific informed consent.

How can clinicians make ethically appropriate treatment decisions for patients when drug susceptibility testing is not available?

Ideally, all patients would undergo rapid drug-resistance testing, so that an appropriate treatment regimen can be provided. In addition to benefiting the individual patient, such an approach benefits the larger community by reducing the risks of further spread of the disease and of promoting drug-resistant strains. As emphasized above, countries and TB programmes should provide universal, free access to drug susceptibility testing; for resource-constrained countries that cannot meet this obligation on their own, the international community should give financial and other support.

For countries that are still scaling up their capacity to supply rapid drug susceptibility testing, decisions about how to treat patients should be made on an individualized basis, taking into account both the local epidemiology and patient-specific factors. These decisions should ideally be made in a consultative process, involving multiple practitioners and, when available, a patient advocate. Education and counselling should be offered to patients.

6.

Health-care workers' rights and obligations

What general ethical principles are relevant to the question of whether health-care workers have an obligation to care for TB patients?

HCWs have an ethical obligation to provide care to patients, even if doing so involves some degree of risk. However, there are limits to the degree of risk that they can reasonably be expected to take (*15*). Moreover, they may have multiple obligations, such as duties to family, that must be balanced against their job-related duties. Finally, HCWs should not be expected to assume risks that can be avoided by the adoption of basic infection control measures, or to assume risks when there is no reasonable possibility of benefit (curative or palliative) for those for whom they are providing care. Thus, any discussion of HCWs' obligations must also consider the reciprocal obligations of governments and health-care facilities to provide minimum standards of safety.

Are the risks associated with looking after TB patients sufficiently great to absolve health-care workers of a duty to care?

In general, no. With reasonable training, supplies, equipment, infrastructure, support, and access to proven methods of care and treatment, HWCs can legitimately be expected to look after patients with TB. Governments have an obligation to ensure that these supports are provided.

However, these expectations may not be appropriate for HCWs who run more risks of contracting a TB infection, such as those who are HIV positive, unless their working conditions adequately protect them from TB exposure (*29*). If HCWs at heightened danger cannot safely continue working, they should attempt to ensure that their patients are not abandoned by transferring their responsibilities to other providers.

What reciprocal obligations do health-care systems have to health-care workers?

The duty of care does not exist in a vacuum. Rather, it depends on the provision of goods and services by governments and health-care institutions. If these important reciprocal obligations are not fulfilled, provision of appropriate TB care may not even be possible. For example, HCWs who are not themselves in good health will not be able to properly look after their patients. For these reasons, health-care systems have an obligation to:

- provide training, equipment, and protection to those who are in charge of TB patients (*30*);
- give HCWs the skills and information necessary to assess their risks so that they can take proper precautions;
- provide access to TB diagnosis, including TB screening, for HCWs living with HIV;

- identify and treat HCWs with active TB, using the best proven treatment (including HIV counselling and testing, antiretroviral therapy, and chemoprophylaxis for TB if indicated);
- clearly articulate their expectations about the working conditions of HCWs, the specific roles they are expected to assume, and the risks inherent in those situations; and
- appropriately compensate HCWs for their services; this may include danger pay and insurance for themselves and their families, and disability pay for those who become infected.

If health systems do not fulfil their reciprocal obligations, do health-care workers still have an ethical obligation to provide care?

The duty to care is based partly on the duty of health systems to fulfill their reciprocal obligations. If these are not met and, as a result, HCWs would face significant risks from interacting with patients, they do not act unethically by deciding not to work. Under these circumstances, it is the system, not the individual worker, that is ethically responsible for any difficulties patients may face in obtaining access to care.

If HCWs believe that the system in which they are working is not as safe as it should be, they should appeal to those in a position to make changes. Governments and health-care systems have an obligation to take action accordingly (by, for example, adopting better infection control measures) in order to ensure that workers can provide care safely.

7.

Involuntary isolation and detention as last-resort measures

Is it ever ethically acceptable to resort to involuntary isolation and detention in the context of TB?

In general, TB treatment should be provided on a voluntary basis, with the patient's informed consent and cooperation. As explained above, engaging the patient in decisions about treatment shows respect, promotes autonomy, and improves the likelihood of adherence. Indeed, non-adherence is often the direct result of failure to engage the patient fully in the treatment process.

While there has been a great deal of publicity about isolated cases of TB patients unwilling to undergo treatment, it is important to remember that these cases are highly infrequent occurrences. Individuals who have been properly counselled about the risks and benefits of TB treatment rarely refuse care, and adherence is not usually a problem if appropriate support is provided. The reason many countries are struggling with high rates of TB infection is not that a few individuals refuse to take their TB medications, but rather that access to high-quality TB diagnosis and treatment is too often unavailable.

Detention should never be a routine component of TB programmes. However, in rare cases, despite all reasonable efforts, patients will not adhere to the prescribed course of treatment, or will be unwilling or unable to comply with infection control measures. In these cases, the interests of other members of the community may justify efforts to isolate or detain the patient involuntarily. As explained below, involuntary isolation and detention must be carefully limited and used only as a very last resort.

Any programme that experiences frequent refusals of care, or significant problems with adherence, should take a hard look at whether it is doing everything it can to implement the person-centred approach described in this document.

Under what circumstances can compelled isolation or detention of TB patients be ethically appropriate?

For patients who are willing to undergo treatment, isolation and detention are usually neither necessary nor appropriate. As studies have shown (*30,31*), treating TB patients at home with appropriate infection measures in place generally imposes no substantial risk to other members of the household. By the time a diagnosis is made, the household contacts have already been exposed to the patient's infection and the possibility of contact infection goes down fast as treatment is started. Even for patients with M/XDR-TB, community-based treatment models have been successfully implemented in a number of different settings. As such, community-based care should always be considered before isolation or detention is contemplated. Countries and TB programmes should put in place services and support structures to ensure that community-based care is as widely available as possible.

Isolation or detention should be limited to exceptional circumstances when an individual:

- is known to be contagious, refuses treatment, and all reasonable measures to ensure adherence have been attempted and proven unsuccessful;
- is known to be contagious, has agreed to ambulatory treatment, but lacks the capacity to institute infection control in the home;
- is highly likely to be contagious (based on symptoms and evidence of epidemiological risk factors) but refuses to undergo assessment of his/her infectious status.

Isolation or detention should never be implemented as a form of punishment.

Patients who decline treatment and who pose a risk to others should be made aware in advance that their continued refusal may result in compulsory isolation or detention.

What safeguards apply to the manner in which involuntary isolation or detention is implemented?

If, in a rare individual case, a judgement is made that involuntary isolation or detention is the only reasonable means of safeguarding the public, it is essential to ensure that the manner in which isolation or detention is implemented complies with applicable ethical and human rights principles. As set forth in the Siracusa Principles (*32*), this means that such measures must be:

- in accordance with the law;
- based on a legitimate objective;
- strictly necessary in a democratic society;
- the least restrictive and intrusive means available; and
- not arbitrary, unreasonable, or discriminatory.

These principles are not just legal obligations; they also reflect important ethical values. Other ethical values, such as reciprocity, should also be respected.

In order to make sure that these principles are followed, countries should review their public health laws to ensure that they carefully limit the scope of government authority and provide due process protections for individuals whose liberty may be restricted. In addition, in order to minimize the danger of arbitrary enforcement, countries and TB programmes should develop clear criteria and procedures for the use of non-voluntary measures, with involvement from TB patients and civil society.

In the rare event that isolation or detention is to be used, it must take place in adequate settings, with appropriate infection control measures, as specified more fully in WHO guidance (*7*). In addition, reasonable social supports should be provided to isolated patients and their dependants, taking into account the local system's capacity.

Is it ever appropriate to compel treatment of TB patients over their objection?

No. While contagious TB patients who do not adhere to treatment or who are unable or unwilling to comply with infection control measures pose significant risks to the public, those risks can be addressed by isolating the patient. Patients who are isolated should be offered the opportunity to receive treatment, but if they do not accept, their informed refusal should be respected, as the isolated patient no longer presents a public health risk. Forcing these patients to undergo treatment over their objection would require a repeated invasion of bodily integrity, and could put health-care providers at risk. Moreover, as a practical matter, it would be impossible to provide effective treatment without the patient's cooperation.

8.

Research on TB care and control

Why is research a critical component of TB care and control?

There is an urgent need to develop an enhanced evidence base for TB prevention and treatment, and to improve the standard of care. Achieving these goals will be impossible without a greater commitment to research. Further research is particularly important in the following areas:

- drugs, vaccines, treatment regimens, and diagnostic measures;
- social and structural determinants of disease and ways to prevent them;
- effectiveness of infection control measures, adherence strategies, drug delivery mechanisms, and non bio-medical interventions (social, behavioural, etc.);
- social, cultural, and anthropological studies about individuals' and communities' understanding of the disease.

The international community should cooperate to develop incentives to encourage this kind of research and development. It is also important to ensure that, as evidence is developed, it is made publicly available and integrated into practice.

What general ethical principles should govern TB research?

Guidelines for research on TB should draw on, where relevant, principles of research ethics already articulated in other documents (*33,34*). These include guidelines by WHO and UNAIDS on research on HIV (*35*), although it is important to recognize that TB and HIV do not always raise identical issues. For example, the risks to third parties may be greater in TB research because the disease can be transmitted through casual contact.

Certain considerations are particularly important in designing an ethical research strategy.

- All stakeholders, including local investigators (if the research comes from abroad) and the community must participate in the generation of research questions and the design and implementation of studies. The participation of civil society is also crucial. WHO should play a central role in facilitating links between these stakeholders.
- Participants should be kept informed of research findings and the application of these findings.
- Research should be designed so that the populations in which it is carried out stand to benefit from the results (*36*).
- Research results should lead to technology transfer, whenever applicable, for the benefit of the affected population.

- Collaborative international research should be conducted in a manner that ultimately helps low- and middle-income countries develop the capacity to do research themselves.
- As with other types of research involving human participants, research ethics committees should determine that the risks are reasonable in relation to the anticipated benefits and that there is an adequate process in place for obtaining participants' informed consent. Research ethics committees should consider how the impact of research on individuals other than the research participants (e.g. family members and other close contacts) affects the assessment of risks and benefits and the process of informed consent.
- When third-party risks are significant, appropriate infection control measures should be implemented as part of the research protocol, and the importance of informing third parties about such risks (and possibly obtaining their consent) should be considered.
- Research protocols should provide attention to how findings will be translated into public health policy, as applicable.

As much as research on the various aspects of TB care and control is necessary, there are circumstances/conditions in which biomedical research trials should not be performed. These include the following (*35*):

- when the capacity to conduct independent and adequate scientific and ethical review does not exist;
- where voluntary participation and freely decided consent cannot be obtained;
- when conditions affecting potential vulnerability or exploitation may be so severe that the risk outweighs the benefit of conducting the trial in that population;
- when agreements have not been reached among all research stakeholders on access to medical care and treatment;
- when agreements have not been reached on responsibilities and plans to make trial products (drugs, other treatments, or preventive measures) that prove to be safe and effective, available to communities and countries where they have been tested, at an affordable price.

What specific ethical issues apply to epidemiological research on TB, including research with medical records and stored blood samples?

If the records or samples retain identifying information, or if they could be linked with identifying information through the use of a code, informed consent may be necessary. However, most research ethics guidelines recognize that it can be waived if the research involves minimal risk, obtaining informed consent would be impracticable, and protections for confidentiality and other rights are provided (*34,36*). The appropriateness of waiving consent should be decided by a research ethics committee, not the researcher.

In some cases, research with records or samples for which identifying information has been permanently removed may also require review by a research ethics committee (*36*).

Do the ethical considerations related to epidemiological research also apply to routine public health surveillance activities?

Routine public health surveillance is not the same as epidemiological research. Public health surveillance refers to "the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health" (*37*). Public health surveillance is generally authorized by legislators and carried out by public health officials. Unlike research, surveillance is not intended to “generate or contribute to generalizable knowledge” (*38*). Rather, it is intended to provide the evidence basis needed for governments to monitor the prevalence of disease and measure the impact of prevention and treatment programmes. Such information is necessary for governments to carry out their basic and routine public health obligations. Surveillance is also essential to advocates’ ability to call attention to problems requiring reform.

In order for surveillance to be effective, the data must be comprehensive. For this reason, individuals are generally not given the right to “opt out” of having their information used for purposes of surveillance. Because participation in surveillance activities is not optional, it would be misleading to ask the subjects to provide informed consent. Nonetheless, it is desirable to inform individuals when information taken in clinical contexts will be used for purposes of public health surveillance. To the extent feasible, individuals and communities should be given information about the type of data being gathered and the purpose for which the data will be used, as well as the outcome of the surveillance. In addition, the confidentiality of information generated through these activities should be protected to the maximum extent possible. Individuals should be informed of any circumstances in which information obtained may be disclosed to third parties, for example for purposes of contact tracing.

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