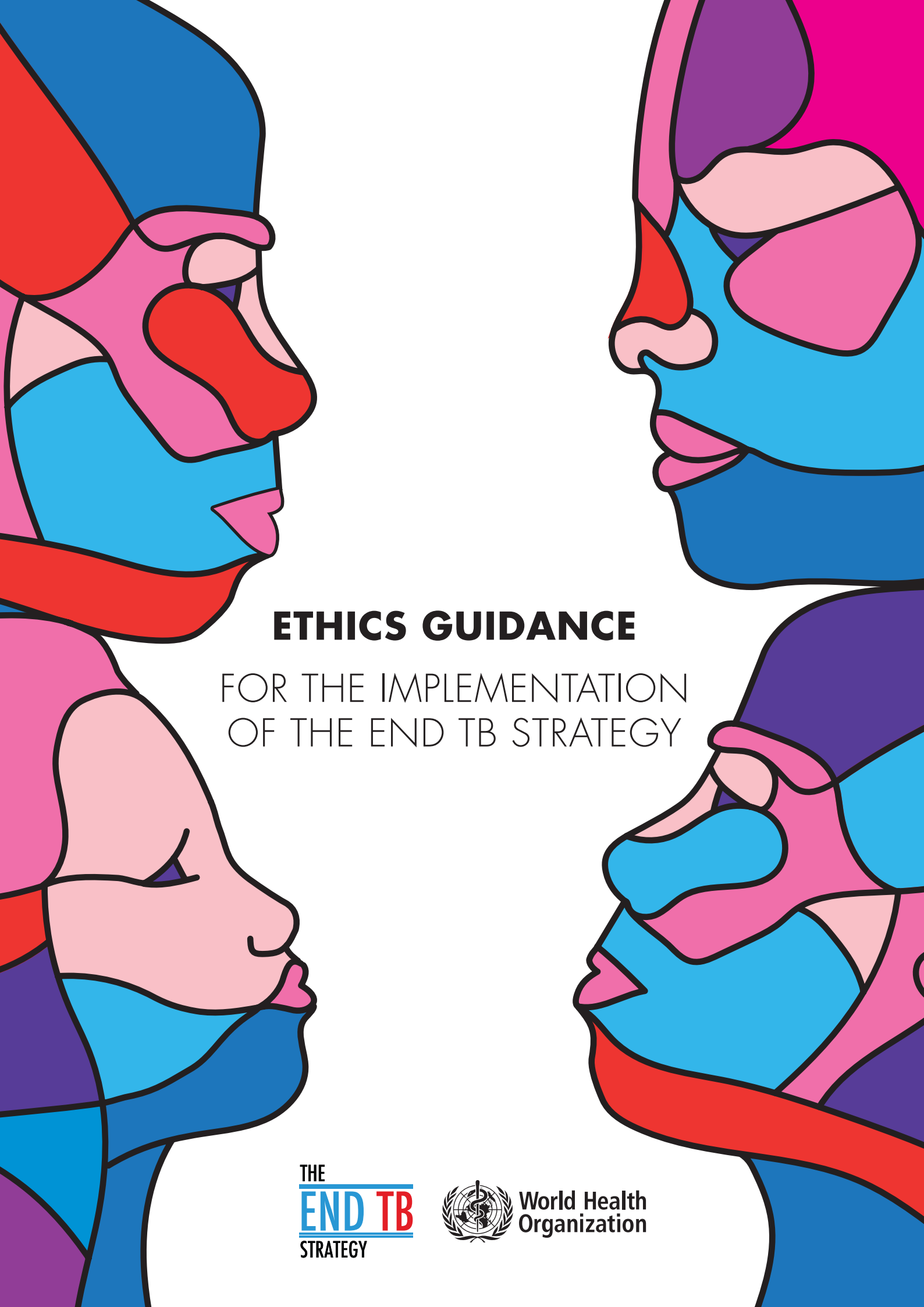

ETHICS GUIDANCE

FOR THE IMPLEMENTATION OF THE END TB STRATEGY

THE END TB STRATEGY

World Health Organization

Ethics guidance for the implementation of the End TB strategy

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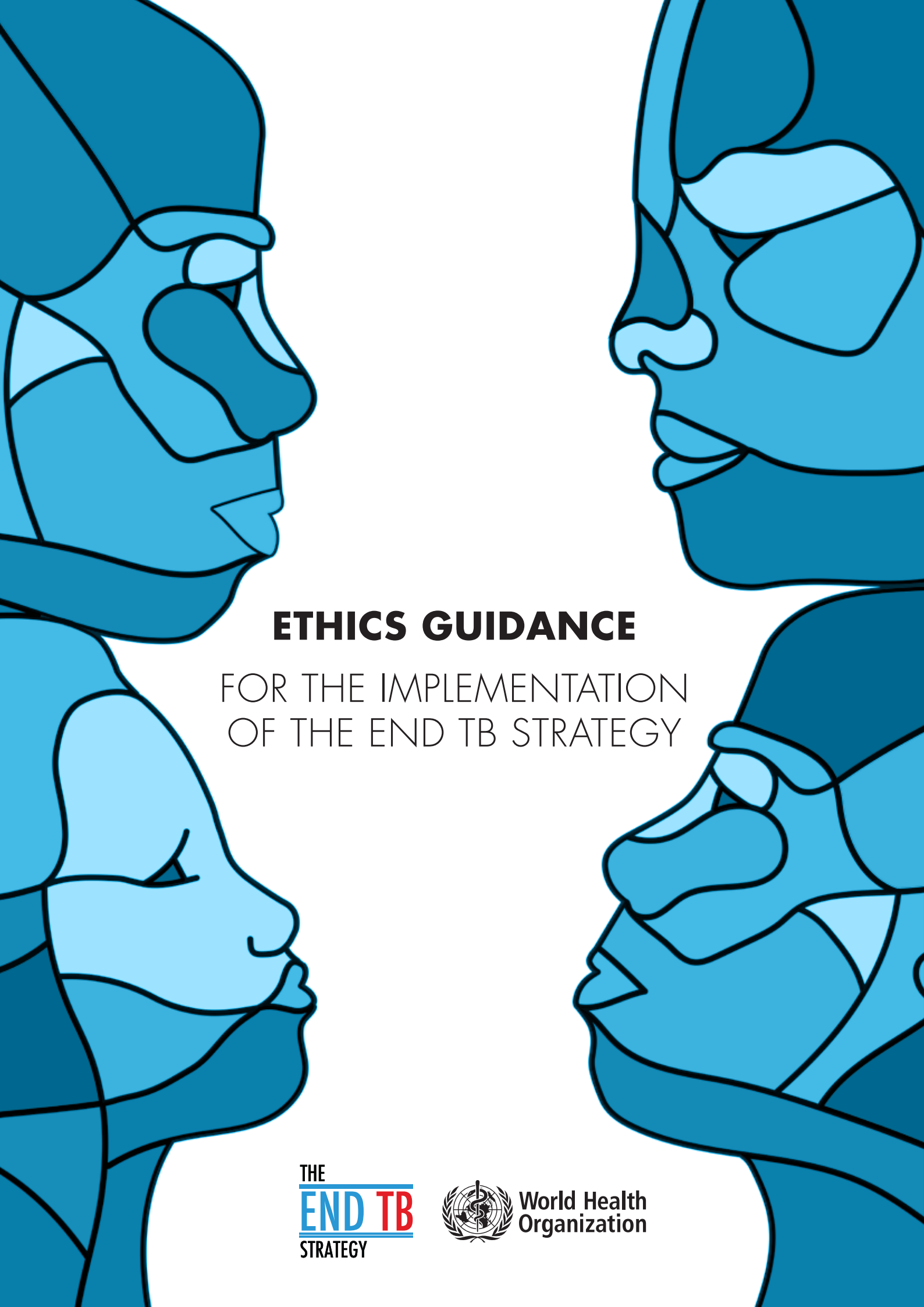

ETHICS GUIDANCE

FOR THE IMPLEMENTATION OF THE END TB STRATEGY

THE END TB STRATEGY

World Health Organization

Contents

Foreword

The World Health Organization (WHO) End TB Strategy is fully aligned with the framework of the Sustainable Development Goals (SDGs). Both require due attention to equity, human rights and ethics. In fact, "protecting human rights, ethics and equity" is one of the four key principles of the WHO End TB Strategy. The SDG agenda itself is inspired by a simple motto: "Leave no one behind". Ensuring that these essential principles guide the implementation of the *End TB Strategy* is a must, especially when tuberculosis (TB) is rampant among the most vulnerable and marginalized populations everywhere in the world.

Applying these principles in the field is not always easy, as patients, communities, health workers, and other TB stakeholders face conflicts and even ethical dilemmas when implementing the Strategy. This guidance aims at addressing that very challenge, and represents the work of people and experts belonging to many constituencies: from national TB programmes to civil society, affected individuals and communities as well as experts in public health, ethics, health law and human rights. We are grateful for their essential contributions and for their engagement in supporting the development of this document. We hope that there is rapid and wide uptake of this guidance, which is designed to help ensure that the implementation of the End TB Strategy is in line with sound ethical standards.

In this new millennium, it is widely recognized that science and ethics need to work together very closely to guide our action. Only when evidence-based, effective interventions are informed by a sound ethical framework, and respect and protect human rights, will we be successful in reaching our ambitious goals of ending the TB epidemic and the associated human suffering, "leaving no one behind".

Dr Mario Raviglione

Director, Global TB Programme
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Abbreviations and acronyms

AIDS	acquired immunodeficiency syndrome
DOT	directly observed therapy
GPP-TB	Good Participatory Practice Guidelines for TB Drug Trials
HIV	human immunodeficiency virus
MDR/RR-TB	multidrug/rifampicin-resistant TB
PHEIC	public health emergency of international concern
SDGs	sustainable development goals
SMS	short message service
TB	tuberculosis
TB/HIV	HIV-related tuberculosis
UN	United Nations
UNICEF	United Nations Children's Fund
VOT	video-observed therapy
WHA	World Health Assembly
WHO	World Health Organization
XDR-TB	extensively drug-resistant TB

Introduction

The World Health Organization (WHO) *End TB Strategy* – adopted by the World Health Assembly in May 2014, with targets linked to the Sustainable Development Goals (SDGs) – serves as a blueprint for countries to reduce the number of tuberculosis (TB) deaths by 95% by 2030 and cut new cases by 90% between 2015 and 2035. The End TB Strategy builds on three essential pillars:

1. Integrated, patient-centred TB care and prevention.
2. Bold policies and supportive systems.
3. Intensified research and innovation.

These pillars are underpinned by four key principles:

1. Government stewardship and accountability, with monitoring and evaluation.
2. Strong coalition with civil society organizations and communities.
3. Protection and promotion of human rights, ethics and equity.
4. Adaptation of the strategy and targets at country level, with global collaboration.

Building on the original *Guidance on ethics of tuberculosis prevention, care and control* in 2010, this guidance updates and broadens its scope to address the most critical challenges being faced by health care workers and decision-makers to ensure that sound ethics underpins the implementation of the End TB Strategy. This document's structure will therefore follow the pillars and ideas as presented in the End TB Strategy itself, for clarity and ease-of-use.

In the near future, those working in TB will have to address traditional challenges (such as promoting health seeking behaviours, enabling adherence to treatment, preventing and mitigating stigma and discrimination) alongside new ones, including the use of new tools for diagnosis, treatment, prevention, care and management and the uptake of digital health tools. New tools are required to sustain and accelerate progress, in particular a new vaccine that is effective pre- and post-exposure, better diagnostics, shorter drug regimens, and more effective targeted treatment for latent TB infection. Immediate investment in research and development is thus needed to ensure that these tools become available in time to meet the targets set by the End TB Strategy and the SDGs.

Thus, the goal of this guidance document is to assist those working towards ending TB in the 21st century by proposing practical answers to key ethical questions and enabling patients, families, civil society, health workers and policy makers to move forward and address current challenges. This TB ethics guidance can then inform difficult decision-making processes by providing recommendations and serving as a basis for further analysis of complex ethical challenges.

Methods

To develop this guidance, a prospective table of contents with the main topical challenges being faced by patients, health care workers and TB programme managers implementing WHO policies on TB was developed by the chief editors, based on feedback and inputs provided by a variety of TB stakeholders. The topics listed in this table where discussed in two guideline development group (GDG) meetings held on 12–13 November 2015 and 14–15 July 2016, in Geneva, Switzerland. The participants in these two meetings reflected the perspectives of key TB stakeholders (former TB patients, civil society, health care providers, TB programme managers, scientists, donors and academics).

For each specific chapter of the guidance, a leading international expert in that field was assigned to produce the first draft, drawing on the literature and his or her professional experience. The corresponding draft chapters were subsequently discussed by at least two external experts in the respective field at the in-person meetings held in Geneva. External experts reviewed the final draft of the guidance and brought together the perspective of former TB patients, ethicists, health care workers and TB programme managers. This approach facilitated the achievement of a broad consensus when contributors to the guidance expressed different values and interests. The chief editors of the guidance were responsible for the technical editing of the document, taking into account the feedback received from the reviewers and existing WHO policies. This document updates several of the recommendations released by WHO in 2010 in the *Guidance on ethics of tuberculosis care, prevention and control (1).*

The scope of the guidance, and the composition of the GDG, including their biographies, were made public for comments ahead of the meetings in line with WHO's conflict of interest policy. All GDG members completed the WHO Declaration of Interest (DOI) forms, and none of them declared any interest to be considered as a conflict with the role to be played in the GDG.

OVERARCHING GOALS AND VALUES

1. Ending TB as a matter of social justice

Social inequalities drive TB, and TB drives many people deeper into poverty. Ending TB and addressing social determinants of health are interdependent. This chapter describes the meaning of social justice and its important role in the implementation of WHO's End TB Strategy.

What is social justice?

As defined in the United Nations' *Social justice in an open world,* justice is generally concerned with understanding the rights and obligations of persons as members of societies and communities; the fairness of social and political structures and processes; and the relationships between persons and between persons and the state. Social justice, with regard to health, is commonly understood as being concerned with inequalities and with the fair distribution of advantages and burdens among people *(2)*. Despite the general agreement regarding the aims of social justice, there are reasonable disagreements about how social justice should function in practice; however, there will often be a great deal of overlapping ideas and conclusions among these different beliefs. This document will direct the reader in instances where there is general agreement, while pointing out challenges that remain unresolved and require a closer understanding of the context for a better answer.

Why is social justice important to public health?

Social justice may be conceived of as capturing "…the twin moral impulses that animate public health: to advance human well-being by improving health and to do so by focusing on the needs of the most disadvantaged" *(3)*. Social justice is a hallmark of other WHO work and guidance documents, where it is referred to, for example, as a key guiding principle for addressing social determinants of health *(4)*. In order to improve health, particularly the health of marginalized or disadvantaged persons and communities, it is imperative to acknowledge the intertwined, complex and reinforcing nature of social, economic and political forces. To incorporate social justice as a pillar of public health means not only aiming to improve the immediate health outcomes of persons and communities at the clinical and population levels, but also to target and ameliorate precisely those social, economic and political factors that lead to the ill health of marginalized persons.

How does social justice impact how we should go about ending TB?

TB overwhelmingly affects marginalized persons of lower socioeconomic status. As such, ending TB requires more than just biomedical interventions. Tackling TB requires addressing the underlying social, economic and political conditions that lead to infection and disease, and that prevent those affected from fully benefitting from existing effective measures, including current diagnostics and drugs. The three pillars of the End TB Strategy aim at providing patient-centred prevention, diagnosis, treatment and care (pillar one); instituting robust supportive systems, including poverty alleviation through prevention of catastrophic costs (pillar two); and increasing the quality, quantity and relevance of research (pillar three). Moreover, "protection and promotion of human rights, ethics, and equity" is one of the key principles of the End TB Strategy *(5)*. Social justice speaks to all three of these pillars and thus can be a focus of attention when addressing the complex ethical challenges posed by TB care and control.

2. Ethics and human rights: key foundations of the End TB Strategy

Ethical principles and values underpin the End TB Strategy. It is thus important to ensure that ethical issues posed by TB care and control are properly examined and addressed. The first step is to articulate the nature of ethics, its relation to human rights, and the ways to incorporate this guidance into the operations of national TB programmes and other stakeholders implementing the End TB Strategy.

What is ethics?

Ethics is concerned with what should, or ought to, be done. It includes consideration of the way we ought to live our lives (including our actions, intentions and habits). Due to cultural or religious differences, ethics can sometimes be a source of disagreement and conflict between people. However, through careful analysis and debate between all relevant stakeholders, it is often possible to arrive at a meaningful consensus regarding which actions or policies should be pursued *(6–10)*.

What are rights? What are human rights? Is the right to health a human right?

A right is a claim that one person can make against another person or group, including legal persons (such as corporations), governments or states. The claim a person makes against another party can be positive (i.e. require action) or negative (i.e. requiring inaction). The action of another party that corresponds with a given right is often referred to as a "responsibility" or "obligation". People have or obtain rights in virtue of different actions or states of being (such as by virtue of being a citizen of a state or entering into contracts).

Human rights are a special type of rights that people have simply by virtue of being human. Human rights are legal guarantees that protect individuals and groups

against actions that interfere with fundamental freedom and human dignity, while establishing entitlements requiring positive actions *(11)*. They encompass civil, cultural, economic, political and social rights and are enshrined in international treaties, such as the International Covenant on Economic, Social and Cultural Rights *(17)*, and the constitutions of nearly all countries *(12–14)*.

Human rights are principally concerned with the relationship between the individual and the state but also include responsibilities for private, non-state actors. Governmental obligations with regard to human rights broadly fall under the principles of respect, protect and fulfil.

In particular, the right to health, articulated as the highest attainable standard of physical and mental health, is a fundamental right of every human being. The right is enshrined in the WHO Constitution, article 25 of the Universal Declaration of Human Rights and article 12 of the International Covenant on Economic, Social and Cultural Rights *(11,14,15)*. The right of individuals to receive treatment for TB and the obligation of Member States to take steps to prevent the spread of TB is a component of the right to health.

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

Human rights are a concrete legal expression of a certain set of ethical values, including human dignity, equality, non-discrimination, participation, solidarity and accountability. Human rights and ethical values are intimately interlinked; because human rights are legally binding, they provide an overarching framework by which governments, international organizations and private actors are obligated to abide. Nonetheless, the existence of this framework does not obviate the need for ongoing ethical deliberation. Indeed, much of ethics falls beyond the scope of human rights. In many situations, multiple ethical considerations would be relevant and may point in different directions. An ethically acceptable decision depends on articulating the full range of appropriate ethical considerations, ensuring that multiple perspectives are factored into the analysis, and creating a decision-making process that stakeholders will consider fair and legitimate.

Who is responsible to protect and promote ethics and human rights when implementing the End TB Strategy?

The managers of national TB programmes, and those responsible at the subnational level, have the primary duty to promote, support and monitor the implementation of the End TB Strategy in line with sound ethics and due protection of human rights law as established in conventions, such as the International Covenant on Economic, Social and Cultural Rights, since the vast majority of Member States are signatories and have ratified the said covenant *(17)*. This responsibility, however, is not limited to leaders of TB programmes: everyone who participates in TB management, care and research has a responsibility to do so in a manner that is ethical and in keeping with international human rights.

How can individuals, civil society, private sector, donors and governments work together to promote ethical values?

The responsibility for creating, sustaining and continually improving services to end TB rests with governments with the support of the international community. Governments have a legal obligation to ensure universal access to TB diagnosis, treatment and care, according to international standards, to protect against discrimination, and to address the social determinants of health that are largely responsible for TB. The international community must provide financial and technical assistance to countries that lack the resources to satisfy this obligation on their own. Furthermore, some argue that private companies, including pharmaceutical companies, also have an ethical responsibility to contribute in the fight to end TB.

Community organizations, families and persons with TB should play a supportive part in TB prevention, diagnosis, care and treatment, and provide a compassionate environment free of stigmatization and discrimination. Furthermore, they should demand accountability of private and public sectors in the fulfilment of their responsibilities in funding, supporting and implementing the End TB Strategy.

Responsibility also falls upon individual patients given that those with active disease can infect and thereby harm others. Patients have an ethical duty to: give complete and accurate personal and clinical information to health providers; alert health providers to any difficulties encountered in the treatment process; follow prescribed treatment regimens; encourage others to seek treatment; show consideration for other TB patients and care providers; (where relevant) comply with isolation orders and act in ways that do not put others at risk; and, if they can do so safely, notify their contacts of the need to seek diagnosis. However, some of the key responsibilities of TB patients can be properly met only if the responsibilities of governments, the international community and local communities are met first.

Leaders of national TB programmes, technical agencies, donors, civil society, health care workers and other TB stakeholders are responsible for actively disseminating this guidance, or the equivalent national adaptation, and for promoting debates necessary to address the ethical challenges emerging both locally, regionally and globally.

3. Guiding principles and values to help end TB

What ethical principles and 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 measures *(18)*.

Not all of the following principles and values will be suited to every situation, but they all are important, and ought to be protected and promoted in appropriate circumstances *(19)*. Judgement must be used about which are relevant and how they can be used to articulate related obligations.

- **Equity**: All persons should have equal protections of their rights, interests and welfare. Ensuring equity requires that the resources necessary to tackle TB should be distributed on the basis of need and with the goal of not only addressing the disease but also attempting to address as many as possible of the underlying social and economic factors that cause TB.
- **Common good**: TB not only threatens the health of an affected individual, but of the whole population. The removal or reduction of the threat of TB from a society is therefore something from which all benefit. Everybody benefits, globally and locally, from countries with strong public health facilities that effectively address TB.
- **Solidarity**: This represents a social relation between persons. It is about standing together as a group or community, either nationally or internationally, particularly for those persons who are socially, politically or economically marginalized. Solidarity is often used in discussions about how Member States may defend the interests of marginalized groups within their population. TB increases the risks of harm for the whole population, but particularly for marginalized populations. Part of these risks can be reduced where strong community ties result in cooperative action to implement the End TB Strategy and tackle the TB social determinants.
- **Reciprocity**: It is the idea of returning good to those from whom we, as individuals or society, receive a good, and to lessen the burdens on those persons who have been harmed or disadvantaged, even if the disadvantage is justified. For TB, ensuring that health care workers who place themselves at risk by treating those with the disease are properly protected, and supporting patients who take on greater burdens for the sake of the community (such as patients who remain in respiratory isolation) are two prominent examples of reciprocity in the context of TB.

- **Harm Principle**: This states that persons are free to act as they choose, including undertaking harmful activities on themselves, so long as they do not harm another non-consenting person. It is the Harm Principle that ultimately justifies isolation and involuntary isolation in TB care, since the TB patient can, unfortunately, spread the infection to the broader public. When deploying the Harm Principle in the context of TB, it is imperative to note that other values, notably reciprocity and solidarity, ought to be utilized to support the TB patient (see Chapter 15 "Isolation and involuntary isolation" for more discussion on these points).

- **Trust and transparency**: These two interrelated values require that communications and decisions at all levels be made in an open manner, through a fair process, and that the said decisions are responsive, factual and evidence-based whenever evidence exists, so as to engender trust by all relevant stakeholders.

- **Duty to care**: All health care workers have a duty to care for persons with TB, as well as to care for the well-being of the family of the patient. However, health care workers must feel safe in their work environments and their well-being must be protected. This means that it is the responsibility of public health authorities to provide them with the appropriate safe environment, including legal protections, adequate training and support, adequately equipped facilities and access to quality and regular supplies.

- **Effectiveness**: This means to avoid doing things that are clearly not working or have negative unintended consequences, as well as the positive obligation to implement measures that are proven, or reasonably likely to succeed.

- **Efficiency**: This requires that limited resources be used in the most productive manner possible. TB programmes require ongoing monitoring, surveillance and research to ensure efficiency.

- **Proportionality**: Any responses to potentially harmful actions from patients or the health system (such as patient's refusal to adhere to treatment, or to an isolation request, government's withdrawal of non-essential social support to patients) must be in proportion to the threat of harm itself. The response should not be more than necessary to accomplish the result desired by patients and the health system.

- **Participation and community engagement**: Local resources are critical to end TB. TB care must be sensitive to local customs and norms of communities in order to respect the individuals within those communities and (via fostering of trust) to ensure the greatest likelihood of success. The general public should have knowledge about how TB care is provided within their own communities in order to attempt to cohere with local customs and values. As such, national TB programmes and the broader TB community must prioritize engagement with communities and those suffering from TB in the deployment of a national TB policy.

- **Respect and dignity**: These intertwined terms refer to the idea that all persons are worthy of being treated with equal care and attention throughout the full course of their lives. It also means that persons should be treated as ends in themselves and not instrumentally or for the good of others. Treating people equally or as an end in themselves does not mean that everyone must receive the same share of resources. Resources may be distributed based on

varied and ethically relevant criteria (such as need, utility etc.). What it does mean is that people should not be subject to prejudice, discrimination and stigma on the basis of their beliefs or life choices or circumstances (including, but not limited to, disease status, religion, race, gender or sexual orientation).

- **Autonomy**: This can be defined in the context of the End TB Strategy as guaranteeing individuals the right to make decisions about their own lives, including with regards to their health. While it is not the only value that is important, nor the one that always ought to take priority, it requires careful consideration in debates about ethical TB policy. For example, respecting autonomy means that patients generally should have the right to choose the place where to receive TB services.
- **Privacy and confidentiality**: It is important to keep confidential all private information of persons with, or being investigated for TB, in keeping with the necessary public health functioning of a TB programme or unit. Keeping people's TB status private will also help combat the stigma that is still associated with TB and help ensure the trust of patients and their communities.

Pillar one of the End TB Strategy explicitly adopts a patient-centred approach, which puts "patients at the heart of service delivery". A patient-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 and best practices, be free of stigmatization and discrimination, have access to peer support networks, and benefit from accountable representation *(20)*. A patient-centred approach should be interpreted and understood as compatible with other public health values and principles. It is equally important to consider those who are sick and not receiving care (such as those who are not yet diagnosed); family members and contacts of patients who are at heightened risk of being infected and socially harmed by TB (such as children whose parents can no longer earn an income); and the community at large, which faces risks from the failure to diagnose and appropriately treat individuals with TB.

4. The obligation to provide access to TB services

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

Yes. Governments have an ethical obligation to provide universal access to TB care according to international standards, including the provision of social support as a critical part of that care. This is grounded in their duty to promote the common good and 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" *(15)*. Similarly, the International Covenant on Economic, Social and Cultural Rights establishes "the right of everyone to the enjoyment of the highest attainable

standard of physical and mental health" (i.e., the right to health), and specifically calls on State Parties to take steps necessary for "the prevention, treatment and control of epidemic, endemic, occupational and other diseases" *(16)*. Additionally, the Declaration of Lisbon on the Rights of the Patients from the World Medical Association *(21)* states the principle on how this health care should be delivered.

Do governments have an ethical obligation to provide access to essential medicines and care?

Yes. States have a core obligation under the right to health "to provide essential drugs" as defined under the WHO Action Programme on Essential Drugs *(22)*. In addition, the UN Committee on Economic, Social and Cultural Rights while acknowledging availability as one of the main elements of the right to health, has declared that "functioning healthcare facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party." *(23)*. The Committee further establishes that a State Party "cannot, under any circumstances whatsoever, justify its noncompliance with the core obligations [. . .] which are non-derogable." *(24)*. All State Parties to the International Covenant on Economic, Social and Cultural Rights therefore have a non-derogable obligation to ensure universal access to TB medicines.

Do above obligations mean that TB care should be provided for free?

Yes. Diagnosis, treatment, care and prevention of TB, including TB drugs, should be available free of charge to all persons with TB and populations at risk. There is a two-fold benefit to this: (i) many people are poor and may find it difficult to afford the medicines; and (ii) the treatment has benefits that extend to whole of society, as cure prevents transmission to others *(25)*. The second of these rationales reflects the ethical principle of reciprocity, which states that, when individuals undergo burdens for the benefit of the community, the society has an obligation to provide "something in return" *(26)*.

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, inadequately treated TB facilitates the development of drug-resistant strains, which are also much more costly and difficult to treat. Thus, ensuring that TB care is freely available is essential to a government's ability to protect the public's health, and likely to prove the less costly option in the long run.

Does the obligation to provide free treatment extend even to multidrug/rifampicin-resistant TB (MDR/RR-TB), which is costlier to treat than drug-susceptible TB?

Yes. If MDR/RR-TB cases are not appropriately treated, high rates of death occur. 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 MDR/RR-TB underscores the importance of providing adequate resources to support basic TB services, including infection control, patient-centred DOT, and community-based care programmes.

What obligation does the international community have to support a government's ability to provide universal access to TB care?

It is undeniable that the expense of providing universal access to TB care, particularly MDR/RR-TB care, poses a significant burden for resource-poor countries. As noted above, these governments have an obligation under international human rights law to "move as expeditiously and effectively as possible" to scaling up their treatment capacity *(27)*. In the meantime, the international community has an obligation to provide financial and other assistance to countries that cannot offer universal access to care on their own. Such an obligation can be grounded in a number of different ethical principles. An argument based on a humanitarian argument may appeal to the fact that human beings require relatively cheap interventions that could easily and dramatically improve their lives. Or an argument could be grounded in the idea that justice may require the sharing of wealth among nations because of the unfairness of gross global inequalities. Even if governments find such moral arguments unconvincing, they have a strong prudential and instrumental reason, and an obligation to their own citizens, to be concerned about diseases such as TB, particularly given the growing drug resistance. TB is a highly infectious disease that does not respect borders. Drug-resistant strains can challenge even the most advanced medicine and therefore truly pose a global risk *(28)*.

Does the obligation to provide universal access to TB care mean that 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 of drug-resistant strains *(29)*.

The obligation to assure the quality of TB drugs 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 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 who have to make decisions for individual patients face difficult ethical dilemmas. In some cases, they may reasonably conclude that it would be ethically preferable to give patients 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 End TB Strategy. These include the importance of:

- *A patient-centred care approach* means that treatment is accessible, acceptable, affordable and appropriate *(30)*. Patients should have choices about the location of treatment, when patient-centred DOT is used, and about the individuals who will be doing the observing.
- *Promoting community-based care* that is accessible, well accepted by patients, and promotes adherence *(31)*. 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" *(31)*. Community-based care may also be provided at primary care facilities by workers with proper training, under the supervision of qualified health workers (such as nurses). Community-based care reduces burdens on health care facilities and is more cost-effective than facility-based treatment *(31)*, thereby enabling governments with limited resources to serve the greatest proportion of those in need.
- *Focusing on patients as part of their larger communities* encourages the formation of support groups and working with their communities to address the social determinants of TB *(32)*.
- *Promoting social justice and equity* in 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), those with physical or cognitive disabilities and homeless people. In addition, the needs of women, children and people coinfected with HIV warrant special consideration depending on the various national contexts. Several resources exploring the needs of these populations have already been developed *(33–37)*.

SECTION ONE – INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

5. Education, counselling and the role of consent

Persons with TB and their communities are at the centre of the End TB Strategy. Their critical role requires their access to all information about TB that would be needed to inform their free participation in the End TB Strategy as patients and as members of the civil society.

Why is there a duty to give individuals information and counselling about TB prevention, diagnostics, treatment and care services?

There are several reasons to ensure that individuals have access to complete and accurate information about their rights and responsibilities, risks and benefits and the alternatives available to them when dealing with TB.

First, in order to uphold the idea of autonomy, people have a right to access information about TB, its causes, its implications on their health, and the internationally recommended standards for prevention, diagnosis and treatment. The right to information is established in the International Covenant on Civil and Political Rights *(38)* and as a component of the human right to health in the International Covenant on Economic, Social and Cultural Rights *(39)*. People also have the right to know and participate actively in the decision related to what is being done to their bodies and to the samples obtained from their bodies, and why it is being done. Failing to provide this information shows a lack of respect and disregard for people's autonomy, and prevents their involvement in the political debates conducive to full implementation of the End TB strategy.

Second, helping people to understand TB and its management makes it more likely that individuals will adhere to protocols established for TB screening, diagnosis, treatment, care and infection control. This is particularly true for patients who must undergo significant financial and social burdens to follow screening, diagnostic procedures, adherence to treatment and infection control protocols.

Third, providing complete information about TB policies and services may help to instil trust in the health system, thereby enhancing a programme's status and respect in the community, which is essential for the End TB Strategy to succeed.

What kind of information should individuals be given about TB tests, treatment, infection control and social support services?

Individuals who undergo TB testing should receive adequate information about the nature of TB, i.e. how TB is transmitted, why is testing required, what are the implications of not being tested, and what are the implications of the results of the test for the individual and his or her family. Individuals who are diagnosed with TB must be given information about the risks and benefits of the treatment (for both the patient and others in the community), the importance of adhering to treatment, and to the infection control measures. Providing social support to prevent or mitigate stigma and discrimination helps enable adherence to treatment and to infection control norms.

Programmes should work with peer advocates and community leaders to design mechanisms for providing information and education that respond to the specific needs of the patient and is sensitive to the gender, linguistic, educational, economic, cultural and legal backgrounds.

Is there a justification for systematic contact investigation as part of routine TB care?

Yes, the practice of contact investigation is obligated on the grounds of protecting the patients' community and the broader public from contracting TB by screening and testing of people who, being recently exposed to a person with confirmed TB, are more likely to have TB. Thus, contact investigation can provide early diagnosis and treatment for affected contacts.

What ethical issues arise, and what principles need to be balanced, as persons with TB are told about the process of contact investigation?

WHO recommends that health care providers notify all people diagnosed with TB to the local public health surveillance system *(40)*. The health care worker should inform and counsel patients about the process and seek to enlist the patients' cooperation in the identification of contacts for the corresponding follow up.

In the investigation of TB by public health authorities, health care workers have to balance the need to persuade persons with TB to notify their contacts as per protocol, with the potential negative unintended effects on contacts and patients, such as stigma and discrimination. In some settings, a person with TB may feel that their TB status cannot be revealed to their partner, relatives or employer for fear of abandonment, community shaming or being fired from their job. TB programmes have the ethical duty to provide persons with all assistance and support needed to prevent and mitigate stigma and discrimination that may result from a contact investigation *(41)*.

When people are unwilling to cooperate in the process of contact investigation consistent with the laws and policies of the country, public health authorities and health care workers are faced with an ethical dilemma. The non-consensual disclosure[1] of the patient's health status to a third party interferes with their privacy and confidentiality, which is regarded as a cornerstone of the health care worker–patient relationship. The third party in this scenario has rights too. Others may be threatened if the patient is infectious. While health care workers have duties to their patients, they also have an obligation to protect the lives of others. At times, the privacy and well-being of patients has to be balanced against preventing harm to others, while adhering to the principle of proportionality. Any national TB programme has to balance "the need to maintain confidentiality" and "protect the patient from stigma" all the while protecting and promoting the common good through routine public health activities. The ways to achieve this balance can only be determined in the context of an actual scenario.

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. Even then, it may be possible to maintain the patient's anonymity (such as sending anonymous short message service text messages to contacts whenever appropriate for them to get tested, leaving a brochure or letter at the home of potential contacts). Non-consensual disclosures should be made only to close contacts who would be at a significantly higher risk of having acquired infection or of developing disease. Public health authorities and TB programmes should develop clear guidelines 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 aim to protect patients and their contacts from stigmatization and other social harms associated with TB. Person with TB should be notified when all options are exhausted and a non-consensual disclosure has to be carried out. Where and when appropriate, it may be important to activate social or community support systems to mitigate any potential fallout for the patient, such as stigma and discrimination, while deploying mechanisms to prevent loss to follow up.

What is informed consent and why is it relevant to the End TB Strategy?

Informed consent refers to the process of engaging patients as partners in the delivery of health services by giving them sufficient and relevant information to enable them to make decisions for themselves. It is a basic right and an important means of upholding a patient's autonomy. It is an ongoing, dynamic process that must be continually monitored and renewed during the whole time a patient is receiving health care services.

A patient-centred approach in the End TB Strategy requires, among other things, engaging patients as partners by ensuring that their decisions are voluntary and informed. Where culturally appropriate, information should ideally be provided in writing, but this should not replace proper counselling, especially in situations of greater risk or uncertainty. Special care should be taken whenever fear and desperation, poor health literacy and distrust of public institutions may affect patients' choice to give or withhold consent. Similarly, patient counselling has to be culturally sensitive to ensure that consent or its withdrawal are well-informed and autonomous

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

and should be conducted throughout the course of care and not only at the moment of diagnosis. Signing an informed consent form at the beginning of treatment or research without providing information is insufficient to protect autonomy throughout the course of therapy or a research project, as the informed consent should be seen as a continuous process. The ethical aspect of informed consent in TB should not be confused with legal mechanisms, such as consent forms, that some health care providers and researchers use to document patients' decisions.

When and how should informed consent be sought from persons with TB?

The manner in which the patient's consent is sought and obtained 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 the consent to go through necessary diagnostic testing is an implicit agreement to undergo a medical examination. An exception would be situations where drug susceptibility testing is offered to patients when treatment for drug-resistant TB is not available or difficult to access. 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 to testing even though treatment is not yet available to them. In situations where a potential person with TB refuses testing in the absence of treatment, and the treating health care workers suspect that the patient is a source of transmission (such as school teachers), other preventative public health measures should be considered in a sensitive manner similar to when a patient is known to be infectious but does not want his or her status to be disclosed.

When patients are offered treatment for TB, for either latent TB infection or active disease, they should be informed about and asked for their specific consent, just as they would be for any 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 to seek the patient's agreement; there is no inherent ethical obligation to do this by using a written form. It is important to remember that the goal of the process is to ensure a patient-centred approach in which the patient and his or her values and interests are respected. This will also likely enhance the chance that a patient completes treatment, reports adverse reactions in a timely fashion, helps track down contacts, and actively engages in supporting the End TB Strategy. The informed consent process should not be implemented in a manner that creates barriers to achieving these fundamental goals.

Patients who refuse to consent to TB treatment, either for latent TB infection or active disease, should be counselled about the risks to both themselves and the community. Providers should seek to understand the reasons why 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, however, 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. It should be made clear to the patient that none of these measures are intended as punishment but only for the protection of public health interests. For details about the management of refusal of TB treatment see page 38; for more details about measures for refusal of treatment for latent TB infection see pages 16–18.

6. Diagnosis in the absence of treatment services

Novel diagnostic methods are modernizing the diagnosis and treatment of TB. Countries should ensure that all patients have access to WHO recommended TB care tools as per national policy. However, in many settings the capacity to uptake TB innovations in diagnosis is not always matched by the capacity to treat.

Is it ethically correct to offer a test that detects drug-resistant TB when the corresponding treatment is not available?

Yes, it is ethically permissible. While countries are in the process of scaling up capacity to provide MDR/RR-TB treatment, the use of tests that provide information on drug susceptibility can be appropriate even when no effective treatment is available, as it can provide benefits to the patient and the community by:

- ensuring that individuals with MDR/RR-TB are not inappropriately treated, which can harm both the patient and public health, and waste resources;
- helping individuals to make life plans, diminish the impact of the disease on family members, and inform behaviour regarding infection control processes;
- preventing patients and their families incurring catastrophic costs by choosing ineffective treatment options when standard treatments have failed due to drug-resistance;
- guiding decisions on infection control in the setting where the person with TB lives;
- guiding the management of contacts proven to have TB; and
- strengthening advocacy efforts with evidence of presence of MDR/RR-TB in a particular country or region. Having an evidence-based argument can help supporters and policymakers to advocate for making treatment available (see the discussion below, page 49, on the importance of surveillance).

Any setting implementing diagnostic testing in the absence of treatment should do so only as a temporary measure and should establish a timetable for when treatment for MDR/RR-TB will be made available. As discussed above, 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 should undergo drug susceptibility 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 transmission of drug-resistant strains. Countries should provide universal, free access to patients for drug susceptibility testing; and the international community should

provide the required support to resource-constrained countries that cannot meet this obligation on their own.

For countries that are still scaling up their capacity to supply rapid drug susceptibility testing, decisions on 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, and the patients' responses and wishes should be taken into consideration.

7. Addressing latent TB infection

Latent TB infection is defined as a state of persistent immune response to prior acquired infection without evidence of clinically manifested active TB. WHO estimates that one quarter of the world population lives with latent TB infection. People with latent TB infection may develop active disease and become infectious, but most do not. The public health policy for latent TB infection, like that for TB, is not only about protecting the individual but also about protecting public health. Diagnostic tests for latent TB infection have several limitations, including poor predictive value for identifying those who will progress to active disease. Latent TB infection treatment carries risks of adverse effects, including isoniazid-associated hepatotoxicity. Fatal isoniazid-associated hepatotoxicity is rare, but does occur. Thus, the benefits of screening and treating for latent TB infection should be weighed against potential harms on a case-by-case basis. Newer latent TB infection regimens such as three months of rifapentine and isoniazid taken once weekly for 12 doses, or four months of daily or twice weekly rifampin may offer far less toxicity and may be more acceptable.

What are the main ethical issues in the management of latent TB infection?

Diagnosis and treatment of latent TB infection is characterized by uncertainty. Current diagnostic tests have poor predictive value for identifying individuals who will develop active disease. It is therefore uncertain whether a given patient will benefit from preventive treatment. A patient with latent TB infection does not pose a current risk for TB transmission but has a potential risk in the future, should she or he develop active TB. Meanwhile testing and treatment for the uncertain future risk posed by latent TB infection may impose harm in the form of adverse effects of medication, stigma, psychological burden and inconvenience. Proportionality therefore has to be a key consideration.

In assessing proportionality, there are several risk–benefit calculations that ought to be considered in the context of managing latent TB infection. The risk of progression from latent TB infection to active TB is increased by certain medical conditions compromising the immune system (e.g. HIV, diabetes, malnutrition). Existing diagnostic and follow-up tests are not highly predictive of progression to TB disease and cannot establish that treatment for latent TB infection has been successful for an individual. For high-risk populations (i.e. people living with HIV/AIDS, prisoners or health care workers) additional tests for concomitant diseases, such as HIV, reduce

the uncertainty about the risk–benefit ratio and predict greater expected benefits of diagnosis and treatment. The adverse effects of preventive treatment (such as hepatotoxicity) should be carefully weighted when evaluating policy. Systematic testing and treatment should be limited to those groups with demonstrated risk of progression from latent TB infection to active TB disease.

How should latent TB infection be managed in vulnerable groups?

Equity is a key value for managing latent TB infection, especially since both prevalence and risk for developing active disease is higher among already marginalized groups – prisoners, homeless persons, illicit drug-users and persons living with HIV/AIDS. High-risk groups are also more likely to reside in places with poor infection control and crowded conditions, with additional medical risk factors and public health risks for potential transmission or outbreaks if TB disease develops. Access to screenings and treatment for these groups has to be ensured as a matter of equity, human rights and solidarity. This may include providing social support to cover the social and economic costs associated with screening and treatment and designing interventions in a way that minimizes the burden on patients, for example by requiring only one visit and/or access to short treatment schemes. Any intervention targeting vulnerable groups has to pay special attention to minimizing the risks of stigmatization, such as by treating the nature of screening and treatment confidentially or by providing community education on latent TB infection and the low risks associated with it.

Is it ethical to enforce mandatory TB screening at borders and in high-risk groups?

When migrants are screened for active TB, they may also be automatically screened for latent TB infection. Screening for either condition should always be done with the intention to provide appropriate medical care, and never to exclude or preclude entry. Since latent TB infection does not present an immediate risk, but merely a potential future risk to individuals and others, excluding or deferring immigrants on the basis of latent TB infection is particularly disproportionate to the actual present risk of population-level harm and thus all the more unjustified and unethical. For more information refer to Chapter 13, "Migrants".

When is it ethical, if ever at all, to enforce testing and treatment for latent TB infection among health care workers?

Health care workers are at increased risk for acquiring TB infection and/or disease. As with other groups, the focus should be on maximizing benefits and protecting the rights of those directly targeted for screening and treatment, rather than on secondary benefits such as limiting potential future transmission to others.

Health care workers also have professional obligations to act in a way that minimizes the risk of harm to patients. Periodic screening for TB infection and/or disease should always be based on genuine evidence of the risk of transmission, to benefit both health care workers and others potentially affected and it should never impose unreasonable risks or burdens on health care workers. Any consideration of mandatory screenings should take into account both the burden imposed on health

care workers and the potential risks for others. Policies should take into account the likelihood of transmission (i.e. if health care workers are located in a clinical or ambulatory setting with heightened exposure to them or their patients), and how likely patients are to suffer harm by developing active disease (i.e. immunosuppressed patients). If health care workers are exposed to a higher risk of acquiring TB due to their work or even undergo screening and treatment for the sake of their patients, then there is a reciprocal obligation on the health system to alleviate as much as possible the burdens imposed on them by infection, through screening and treatment.

Should informed consent be sought for the diagnosis and treatment of latent TB infection?

For latent TB infection, explicit consent (see Chapter 5) is generally required since the subject does not pose a present risk to others and because of possible uncertainty concerning diagnostic and follow-up tests. Informed consent requires effective and adequate communication of the possible uncertainty surrounding latent TB infection testing, the safety of treatment, as well as the prospects of risk reduction (often uncertain due to the additionality of reinfection). In addition to individual benefits and risks, the risks for communities, as well as the professional obligations of persons involved, should be clarified. Affected communities often do not understand or have a poor understanding of the nature and implications of latent TB infection. Community engagement and health education therefore play an important role in ascertaining that individuals and communities can autonomously make informed choices regarding latent TB infection. Special attention should be paid to communicating risk and uncertainty in culturally and linguistically appropriate forms and obtaining feedback when screening programmes are implemented.

8. Supporting patients to adhere to treatment and other health care recommendations

TB diagnosis, treatment, care, patient support and prevention should be free, though there are still many costs that the vast majority of those affected need to pay for. One of the targets of the End TB Strategy is to eliminate catastrophic costs for patients and their families. TB programmes must strive to enable patients to have access and adhere to all recommended measures to protect public and personal health, including treatment.

Why is there an ethical duty to provide social support to people with TB?

Social support includes (i) information and education, (ii) psychological and (iii) material support. The ethical duty to provide social support to people with TB rests on at least three principles described earlier: (i) solidarity, (ii) reciprocity, and (iii) autonomy. Any argument as to how one principle applies in this case is sufficient to justify social support to persons with TB.

Persons with TB and their families need to be protected from economic destitution and social isolation becoming a barrier to access diagnosis, treatment, care and prevention. Solidarity requires communities and countries to stand with its most marginalized members, which describes many, if not most, persons with TB. The End TB Strategy endorses a "health-in-all-policies" approach to poverty reduction strategies and the expansion of social protection. Solidarity requires addressing the social determinants of TB by improving the lives and working conditions of the most marginalized and increasing access to medical care for diseases that increase the risk of TB, such as diabetes and HIV.

Reciprocity means, in part, returning good for good received and supporting those who sacrifice on behalf of others. Public health benefits from the hardships that people with TB may endure while seeking diagnosis, adhering to treatment, disclosing their status to others, or even undergoing respiratory isolation (a person with TB wearing a mask when in public). Society therefore has an obligation to provide patients with social support as a matter of reciprocity and compensate patients for lost income or lost employment as a result of TB treatment and care received.

Social support may also help persons with TB to retain their autonomy and lead more self-directed lives. Preventing families from becoming destitute or family members from abandoning people with TB enables the latter to continue their lives in their social environment. This may also help them retain more autonomy regarding other health-related choices.

Finally, social support is instrumental for enabling adherence to TB treatment to protect the health of the patient and the community. Taking TB medications as prescribed is the most essential aspect of TB treatment, both to protect the patient's own health and to prevent further spread of the disease and the development of drug-resistant strains.

Is there an ethical duty of health care providers to support patients to adhere to treatment and all other recommendations?

Yes, there is. While people with TB have an ethical duty to adhere to and complete treatment, and observe the recommended infection prevention and control practices, social and health care systems and care providers have the duty to support patients' ability to adhere to recommendations. Communities and civil society too can play a crucial role by supporting both patients and health systems in fulfilling their respective duties.

In which context can DOT be an ethically justifiable strategy for ensuring adherence?

Adherence to long-term therapy, such as TB treatment, is very complex and cannot be accurately predicted in most patients. Lack of adherence to TB treatment has serious consequences for patients and to public health, such as the development of resistant strains, further transmission, and death. DOT is an effective way to ensure adherence to treatment by direct monitoring of intake of medicines. However, it is also onerous and restrictive in many contexts, and may impose additional burdens on those with the disease. Therefore, it is ethically justifiable only when done as part of a patient-centred approach to care. Such an approach should include the following components:

- Educating (properly informing) patients about TB including the risks poor adherence poses for themselves, their families and the community, and justifying the benefit of having such adherence monitored by patient-centred DOT.
- Identification by the health care workers of main barriers to completion of treatment in conjunction with the patient.
- Development and implementation of a consensual plan by health care workers and patients to address all identified hurdles to adhere to treatment, and to offer all possibilities to make patient-centred DOT a feasible option. These options may include community-based DOT, and digital tools (such as video-observed therapy (VOT)). Patients must be given the right to choose the place and person responsible for having their adherence monitored via DOT. Moreover, the person chosen to monitor adherence must assume the responsibility to identify and report all barriers that may emerge during treatment. The patient and the care provider need to be reassured that their interactions, both in person and virtual (over telephone or the Internet), are protected from inadvertent disclosure of clinical details to unintended parties. Digital technologies can minimize such risk through measures such as data encryption (see also Chapter 20).
- Social support is the core element of a patient-centred approach, which enables adherence to treatment and monitoring through DOT. Social support consists of information and education, psychological support and material support in kind or as services (such as food baskets, transport, cash transfers). Its purpose is to minimize the burden of care on patients, including the indirect costs of adherence monitoring (such as money and time lost from work), while enhancing the autonomy of the patient in the handling of treatment issues and respective social challenges like stigma and discrimination.
- Educating the patient about the consequences of non-adherence.

Every meeting between the patient and whoever has the responsibility to monitor their adherence should be used not only for supervising treatment, but also to provide support through information, education, motivation and identification of emerging barriers to treatment adherence.

What ethical considerations apply to the management of patients who are unable to adhere to TB treatment or other medical recommendations?

Because of the importance of treatment adherence and infection control to both the individual and the public, all health care providers 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 patient-centred care, as it demonstrates both the health provider's commitment to promoting the individual patient's best interest as well as the need to protect others in the community from the risks of TB transmission.

Efforts to contact patients who are lost to follow up sometimes risk intruding on individuals' privacy and autonomy. Patients should be informed, at the initiation of treatment, that they may be contacted if they do not attend their appointments and for the agreed upon method to monitor their adherence to treatment. To the extent feasible, patients should be given a choice about the process by which communication will take place (i.e. by telephone, text messaging or an intermediator instead of by a home visit), assuming the programme determines that these methods are feasible and likely to be effective.

Thus, consistent with the patient-centred approach, any attempts to contact patients must be carried out in a way that minimizes these intrusions. For example, if health care workers visit patients at home or in the community, they should not arrive in vehicles that can be identified as belonging to the TB programme or provide contact details that can be easily associated with the TB programme.

What would be an ethical response by programmes to patients who do not adhere to treatment or infection control recommendations?

Treatment monitored under a patient-centred DOT may be an effective way to ensure adherence to treatment but it is an option that should not be enforced on patients. Similarly, adherence to proper TB infection control practices, especially in patients in whom all treatment options have been exhausted, should not be enforced without a due process. Programmes that frequently experience problems with patients' adherence should review their overall patient-centred care strategy. While isolated cases of non-adherence may reflect patient-specific factors, on a larger scale it suggests that the health system has failed to adequately implement a patient-centred approach to care. For example, difficulties in accessing care in the face of adverse events may be a reason for stopping treatment. Thus, a careful assessment of all potential hurdles should be conducted. All feasible methods for a patient-centred approach to DOT, including home-based DOT or VOT, and the social support needed should be offered to the patients. Patients in whom application of proper TB infection control measures is critical to protect public health because there are no effective therapeutic options to pursue should also be part of a similar evaluation, followed by corresponding support.

In rare instances, if all efforts to perform patient-centred DOT fail and the patient still remains infectious, involuntary isolation may be considered once it is confirmed that the regimen prescribed is effective (drug resistance has been ruled out) and there are reasons to suspect non-adherence (patient does not show up to collect the medicines; there is no weight gain; symptoms do not improve; all this occurs in the absence of medical reasons other than active TB to explain these signs). Involuntary isolation may need to be considered as well for persons with TB who have no effective treatment options and refuse to adopt the recommended infection control measures despite all support provided. The ethical issues in relation to involuntary isolation are discussed in Chapter 15.

Is it ethically acceptable to refuse to provide 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 properly addressed as part of the initial patient counselling about TB treatment.

Can TB treatment and care be provided in the absence of social support?

Yes. TB treatment can be provided in the absence of comprehensive social support, if a patient does not require it or while resources needed are mobilized. Providing effective TB treatment still ultimately provides benefits to the patient and protection to the broader community should the patient adhere to therapy. However, failing to provide social support to those in need means that an important responsibility of government and society goes unfulfilled. In other words, providing TB treatment in the absence of social support when needed means wronging the person with TB, but less so than providing no treatment and thereby placing the patient in danger and the broader community at risk of TB transmission.

How can "enablers" be considered an ethically justifiable strategy for promoting adherence to treatment and other medical recommendations?

"Enablers" are mechanisms or resources that facilitate and very often ensure patients' ability to receive treatment with patient-centred DOT. Common enablers are transport vouchers for patients to travel to the patient-centred DOT site, or food baskets that allow them to secure food and compensate for loss of income while receiving care. Enablers are a crucial part of TB treatment for most patients because they help mitigate the social and economic impact of long-term therapy. In addition, enablers help patients to take an active role in their care, thereby promoting the ethical value of autonomy *(32)*.

It is critical to ensure the sustainability of enablers within countries. The various enabling mechanisms or resources are often funded through international aid organizations at the behest of the national TB programmes. As such, the local governments and national TB programmes have a responsibility to ensure the sustainability of enablers by explicitly requesting international aid organizations for as many resources as necessary to ensure a steady and sustainable level of enablers. Moreover, it is the responsibility of the international community and aid organizations to work with local governments and national TB programmes to ensure that funds are available for all necessary parts of the programme beyond that of merely providing TB drugs.

Under which conditions is it ethically acceptable to provide persons with incentives in exchange for adherence to TB treatment and other medical recommendations?

Incentives are goods or services delivered for free, which are nevertheless deemed not to be essential for the patient to adhere to health recommendations (such as free tickets for a sport event; free registration to a gym; a pack of candies). These practices per se may not be inherently inappropriate, provided they are implemented as part of a carefully designed, respectful, patient-centred approach to TB care. The process of TB diagnosis, treatment, care and prevention 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, or even insulting, i.e. attempting to "buy" the patient's cooperation. More importantly, a focus on 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. The decision to use incentives to promote treatment completion and adherence to infection control measures should be based on judgements about both the expected efficacy of such practices, the competing priorities for resources available, and sensitivity to local norms. If incentives are offered, it is important to ensure that they are managed carefully and evaluated critically. 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.

9. Patient treatment and care when recommended TB treatment regimens are not feasible

People with MDR/RR-TB who are not eligible for the currently recommended shorter treatment regimen should receive a regimen consisting of at least four drugs, that are considered to be effective, plus pyrazinamide *(42)*. Among these patients, those with severe drug resistance patterns, poor tolerance to medications, or without access to the prescribed medicines are usually found ineligible for treatment as a regimen fulfilling the WHO recommended criteria for MDR/RR-TB treatment (i.e. the use of at least four effective drugs plus pyrazinamide) cannot be designed.

What ethical dilemma do health care providers face when an effective treatment regimen for MDR/RR-TB cannot be designed?

In case of patients for whom a treatment regimen cannot be designed according to current recommendations, health care providers face the dilemma of either not providing any treatment at all or providing a substandard treatment regimen composed of less than five medicines, which would be less effective but not necessarily ineffective in all cases.

The practice of treating MDR/RR-TB patients only with an optimal drug regimen safeguards the broader public by protecting the efficacy of anti-TB medicines, which are essential for the treatment and cure of patients in the future.

Treating patients with suboptimal regimens, such as using drugs that are under development or repurposed medicines, may alleviate symptoms, produce sputum smear/culture conversion, and even cure some patients. Yet, this practice has proven to create additional drug resistance, limiting further the availability of efficacious anti-TB medicines and the impact of TB programmes *(43,44)*.

Thus, the case of functionally untreatable TB poses a serious ethical dilemma to national TB programmes and treating physicians in deciding whether to provide

suboptimal therapy to cure some, or refrain from treating at all, and cure none. Ultimately, this is a choice between the immediate best interests of the patient (to alleviate suffering and potentially save his/her life), and the public health interest (of protecting the efficacy of existing anti-TB medicines, a public health good).

Under what conditions would the use of suboptimal therapy in functionally untreatable MDR/RR-TB be ethically justified?

Health care providers have the ethical duty to ensure individual access to potentially life-saving treatment, and also the ethical duty to protect the public good of efficacious TB medicines. The use of suboptimal therapy in functionally untreatable TB for the patient's individual benefit may be ethically defensible, but only when certain essential conditions are met. Those conditions include:

- Availability of qualified TB experts to confirm the absence of an optimal treatment regimen according to WHO standards that is suitable to the needs of the patient, and able to manage treatment and care of the patient according to international standards.
- Proper education and counselling is provided to the patient with regard to the expectations of suboptimal treatment, TB transmission mechanisms and her or his rights and responsibilities during the course of treatment, including the potential need for respiratory isolation during the treatment and afterwards if treatment fails.
- Patient's written informed consent to abide with medical instructions, including infection control measures, and to accept potential respiratory isolation during the treatment and afterwards should treatment fail.
- Availability of sufficient resources in the health system to guarantee access to all commodities and services to deliver proper care. Those include uninterrupted supply of quality assured medicines, patient-centred care for DOT, social support, palliative/end-of-life care services; and to protect public health, the availability of health facilities with proper infection control in place, to guarantee respiratory isolation during the course of treatment, and afterwards if treatment fails.
- Considering that more often than not, this treatment will be done with drugs under development, or repurposed medicines, it is strongly advisable to provide this treatment and care in the context of research under an institutional-based model of care, with corresponding approval by appropriate national research ethics committees and/or public health authorities.

This guidance should not be taken as a recommendation for actively promoting systematic use of substandard regimens, even among patients in whom treatment options are limited or have been exhausted. All efforts should be made to ensure that resorting to a suboptimal treatment becomes the exception; the resources needed to plan and deliver adequate treatment for the expected caseload should be a core function of the national authorities responsible for TB care and prevention.

10. Palliative and end-of-life care

Zero suffering is one of the goals of the End TB Strategy. Palliative care is defined as an approach to improve the quality of life of patients facing a "life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual" *(45)*. TB is a life-threatening disease in which the vast majority of patients can be cured, though a significant share of people still suffers and dies due to either lack of access to treatment or because of inadequate treatment and care. Thus, the relevance of palliative care in TB is mostly, if not exclusively, limited to patients with MDR/RR-TB, and especially those with XDR-TB, in whom cure rates are very low with existing treatment tools.

Access to palliative care is a core component of the human right to health. The UN Committee on Economic, Social and Cultural Rights has declared that State Parties are under obligation to respect the right to health by "refraining from denying or limiting equal access for all persons . . . to … palliative health services" *(46)*. State Parties also have a core obligation under the right to health "to provide essential drugs" as defined under the WHO Action Programme on Essential Drugs. Sections 1 and 2 of the 19th edition of WHO Model List of Essential Medicines include more than 25 palliative care medicines *(47)*.

What ethical obligations exist to address suffering in addition to the delivery of TB treatment?

People with TB suffer as a result of the disease, its treatment, the costs associated with the diagnosis and treatment, and subsequent stigma and discrimination. There is an ethical duty to address all forms of suffering associated with TB, through proper access to care and to the management of adverse drugs reactions, management of psychological stress, prevention and mitigation of stigma and discrimination, and access to social protection mechanisms to reduce indirect costs.

Which person with TB should be prioritized for palliative care?

Ensuring timely access to life-saving treatment of all people with TB is the top priority to relieve their suffering. Care that relieves suffering is an integral part of the care of all persons with TB at all times during the course of illness. National TB programmes and all health care providers should note that suffering is more severe in XDR-TB patients due to the usual chronicity and the limited options for effective treatment; and this is a group to be prioritized for delivery of palliative care until highly effective regimens are developed.

Why is there an ethical obligation to deliver palliative care to persons with MDR/RR-TB in need?

There is a fundamental ethical obligation not to abandon patients when most or all the available treatments have been attempted and have been unsuccessful. Non-abandonment requires the provision of palliative and end-of-life care. Failure of curative treatment does not absolve the TB programme of responsibility for optimizing

the patient's comfort and well-being that is in line with the patient-centred approach of the End TB Strategy. Besides the management of physical symptoms (such as dyspnoea, fatigue, pain) the social, spiritual and emotional challenges that impact the quality of this last phase of life should be addressed. Palliative care is not aimed at replacing treatment but is a necessary additional treatment that should be made available whenever there is suffering and poor prognosis. It is not intended to be an exclusive specialty taking over the care of patients; it is meant as a specific competence offered, on a generalist level, by all health professionals involved in the care of all patients with TB. For patients with high symptom load and complex needs, specialist palliative care should be provided, if available. The locations of care for such patients should be based on an individualized risk assessment and availability of relevant services.

What is the right time for delivering palliative care?

Measures to relieve the suffering caused to a person with MDR/RR-TB disease and its treatment must be provided according to patient needs rather than the prognosis *(48)*. To the greatest extent possible, patients and their families should be educated and counselled about their options for palliative care should the prognosis in the course of treatment become ominous. Clear communication about what palliative care can and cannot accomplish is required.

What are the public health responsibilities when delivering end-of-life care in TB?

To combine the goals of TB care with care of the dying, and matching rights and responsibilities of health care providers with the needs of patients and their families can be challenging, especially when the person with TB remains infectious. Respiratory isolation measures are in conflict with social inclusion as a basic goal in end-of-life care. However, to protect family members, staff and the public, infection control measures should be continued while trying to comfort the patient as best as possible. Bereavement follow-up is essential and may help minimize the risk of complicated grief, such as due to involuntary isolation *(49)*.

When is it ethical to stop TB medication?

TB medication with no proven prospects of success has to be stopped and pharmacological treatment should be restricted to symptom management. Additionally, when side effects outweigh possible benefits (disease or infection control) a cessation of medication should be considered. The costs to the health system of a treatment that is not serving the needs of the patient should also be taken into account.

How should palliative care resources be balanced against the need to provide TB medicines and other resources for persons with TB?

The approach of palliative care should be integrated with existing services, delivered at the point of care (i.e. home, hospital, outpatient service) and is neither a substitute nor a counterpart to curative treatment. Where specialized services are available, cooperative models should be developed. This cooperation may even facilitate infection control by improving patient adherence to treatment *(48)*. Similarly, families

and friends of patients, where possible, can and should play an important role in alleviating the patient's suffering. Empowering them to provide non-medical palliative care to patients can be a highly effective way to address physical and psychological pain while putting relatively little strain on health systems. Moreover, evidence from other diseases suggests that timely integration of palliative care may have a cost saving effect *(50,51)*. Educational efforts to qualify health workers in palliative and end-of-life care are necessary. It is misleading to think of palliative care and curative treatment as competitors.

Is it ethical to ask terminal patients to participate in research studies?

Yes. Research is essential to advance palliative and end-of-life care for a person with TB. From many studies in other settings it is well known that patients in a palliative care situation can opt in to participate in research, although recruitment and attrition in particular in studies regarding end-of-life care may be challenging.

The physical, psychological, social and cultural burdens borne by patients with MDR/RR-TB and their families are not well understood. Better knowledge would help to tailor services to needs. It is unclear whether the lessons learned from palliative care in cancer or other respiratory diseases fit the requirements in MDR/RR-TB. Interventions with the potential to increase quality of life and quality of dying in this population are not well known and require more research. Evidence based criteria for the integration of specialized palliative care for patients with XDR-TB have to be developed.

11. Children

Around one million children worldwide suffer from TB, and more than 136,000 die from TB each year *(52)*. The low priority given to TB in children over the recent decades has contributed to the current limitations in TB diagnostics, treatment and care. The End TB Strategy gives the same priority to children with TB as to any other group. It is imperative to provide the best TB tools and training to health care workers, so that childhood TB burdens are recognized and proper care delivered. The UN Convention on the Rights of the Child *(53)* establishes that "best interests of the child shall be the primary consideration" in all actions concerning children. The UN Committee on the Rights of the Child has explained that this means children's best interests must be the "basis of all decision-making with regard to providing, withholding or terminating treatment" and should "[a]id the resolution of conflict of interest between parents and health workers" *(54)*. These principles should be upheld in the case of children with TB.

Which ethical duties exist with respect to diagnosing and reporting childhood TB?

There is a duty to care for children with TB even if they are not a major source of transmission, and therefore no major impact on public health is expected. Lack of ideal diagnostic tools is no good reason to withhold treatment and care. Moreover, the family of children with TB should also be supported so as to help them in their care of their child.

Affected children need to be registered with their national TB programme in order to be counted, which is essential for development of policies and planning and implementation of End TB Strategy activities. Although acknowledged increasingly, more often underreporting of childhood TB remains a common problem in too many settings.

What services should be considered part of the ethical duty to care for children with TB?

Apart from screening, diagnostics and treatment, children and their parents are in need of counselling and other forms of social support, such as health education, psychological and material support. The psychological and social needs of adolescents should be especially addressed in coordination with other actors of the health system, while capacity for the best standards of care is being built. Particular care is required for adolescents transitioning from paediatric to adult models of care. Further, childhood groups with special needs include orphans, street children, children of migrant populations, and also child-headed households; these children are particularly vulnerable and their vulnerability needs to be taken into consideration when making decisions regarding their care.

Is it ethical to hospitalize children for the delivery of TB treatment, in the absence of medical justification?

No, it is not. Hospitalization of children with TB should be limited to those cases in which the needs for treatment and care can only be provided in the premises of an institution, either hospital or hospice. The significant harms caused from institutionalization, hospitalization, confinement or isolation of infectious and non-infectious children do not compensate for the potential benefits. Their confinement impacts their education, family and personal relationships. Children may also experience stigmatization if and when they return to their communities and schools. For the sake of non-maleficence, children should thus not be institutionalized without sound medical or public health reasons. All efforts should be pursued to prevent unintended negative effects of hospitalization and treatment, such as support to continue and complete the school year uninterrupted.

Is it ethical to neglect children when developing innovations in TB diagnosis, treatment and care?

No, it is not. As it stands, adjustments and uptake strategies are too often adopted on the basis of learning by doing. The lack of adequate diagnostics and child-friendly medication is mostly due to insufficient inclusion of children into the TB research agenda. This has two primary reasons. Firstly, perceptions of additional risk and limited returns have deterred companies from conducting trials on children *(55)*. Secondly, ethical and legal issues are generally seen as barriers to the inclusion of children into trials. For example, children are not normally taken to be able to give informed consent *(56)*.

Regulators, researchers and stakeholders need to collaborate closely in order to design frameworks and oversight mechanisms that both protect children and facilitate the development of better diagnostics, treatments and vaccines. One step in this direction is to understand research on children as a natural and necessary part of a

health care system, and, if age permits, seeing children not as passive subjects but as individuals who play a part in determining their lives *(57)*. For pharmaceutical companies and manufacturers, incentives such as subsidies, waivers of registration fees, cost-sharing mechanisms, and the streamlining of regulatory approvals should be considered *(58)*.

It is a matter of equity to ensure that research should be planned and performed specifically for children and adolescents addressing all age-related aspects of TB diagnosis, treatment and care. Once available, national programmes should facilitate uptake of new and existing guidelines, insights and products, such that the most effective prevention and response efforts are provided. This includes the provision of training and awareness-raising among health care workers to take note of new developments and adhere to updated guidelines with regard to children.

12. Prisoners

In most prisons[2] inmates are faced with elevated risk factors for acquiring TB, such as crowded and poorly ventilated spaces, inadequate prevention, medical care and treatment, stress and malnutrition. An additional risk factor is also denial of harm reduction services *(59)*. Further, prisoners disproportionately come from disadvantaged backgrounds, including with histories of substance abuse, homelessness, poverty or mental illness. They can, therefore, be at a higher risk of acquiring TB infection even before they arrive in prison, as well as of suffering from comorbidities, such as HIV infection, hepatitis and diabetes. Thus, prisoners are a key population to be covered by the End TB Strategy.

Which ethical principles should govern TB prevention, screening, diagnosis and care for prisoners?

It is ethically impermissible to provide inadequate health care as part of prisoners' punishment. The right to health applies to people inside and outside of a prison equally. Prisoners should thus have access to the same levels of prevention, screening, diagnostics and care as in their communities and they should be treated according to the same ethical principles that apply to the general population. Health care providers and governments have a duty to care in a manner that satisfies the requirements of respect, dignity and equity. Patients' autonomy, consent, privacy and confidentiality should be respected and protected and reassurance should be provided to these individuals that adherence to TB care will in no way negatively affect their sentences. Trust should be established between patients and health care workers and transparency should be maintained regarding available prevention and care. Moreover, taking equity concerns seriously would mean taking into account the often impoverished socioeconomic backgrounds of most prisoners and the power imbalance all inmates face while in prison with regard to health care and other goods; health care workers should be aware that particular attention must be given to these factors when treating prisoners with TB.

2 "Prison" here means any government institution designed for compulsory detention, including pre-trial detention facilities.

How should refusals for TB screening, treatment or isolation be ethically dealt with in prison?

All forms of forced screening, diagnostics or treatments are not only ethically wrong, but also counterproductive in terms of effectiveness as they damage patients' and communities' trust in health systems, making it less likely that others will seek diagnosis and care or that they will adhere to treatment and infection control measures. Isolation without consent should only take place as a last resort and only if the patient is at a particularly high risk of infecting others. Isolation should take place in a hospital or health care unit and all efforts should be undertaken to obtain the patient's freely given consent through dissemination of information and counselling before considering involuntary isolation (see Chapter 15 "Isolation and involuntary isolation" for more information). Involuntary isolation of prisoners suspected to suffer from TB should be done in a way that protects their privacy, in line with those provisions used in the general community (outside the prison).

Do governments have an obligation to ensure continued access to treatment for prisoners upon release?

Yes, this falls under the obligation to provide access to TB services. Arrangements should be made in advance for released prisoners to continue treatment and mechanisms should be in place to ensure that this occurs. This includes, but is not limited to, identifying a facility for continued treatment, provision of patient records to that facility, and mechanisms for follow-up to ensure proper access and retention to care.

13. Migrants

Some groups of migrants[3] are at increased risk for acquiring TB and remaining undiagnosed, and their TB status threatens to hinder their movement and status. These increased risks are of ethical relevance with regard to social justice and equity. Efforts to end the TB epidemic are further complicated because migration and legal status of migrants may interrupt ongoing treatments or increase barriers to access diagnostics and treatment due to the many challenges certain types of migration can entail, such as lack of citizen rights and privileges; linguistic and cultural challenges; increased risk of exploitation; inadequate access to food, water, housing, material goods and education; and having to stay in overcrowded camps/detention centres.

What values should be guiding policies and services for TB diagnosis, treatment and care in migrants?

First, because certain migrant groups and mobile populations are frequently marginalized, they may lack political power and may be stigmatized. For such groups, solidarity should be practiced, regardless of citizenship or legal status, to

3 The International Organization for Migration considers a migrant to be any person who is moving or had moved across an international border or within a state away from his/her habitual place of residence, and his/her children, regardless of: (i) a person's legal status, (ii) whether the movement is voluntary or involuntary, (iii) what the causes of movement are, (iv) or what the length of stay is.

advocate that they receive the requisite TB care and other needed forms of health care. Second, doing so is in keeping with the principles of equity and justice, by providing care to those in greatest need. Finally, caring for persons with TB who are migrants is one way of ensuring that they can continue on their journey and act on their life choices, as is their right by appealing to the principle of autonomy and in keeping with their dignity as human beings. Like all other persons with TB, their privacy and confidentiality should be protected at all times, especially due to the increased risk of stigma they may face.

Is it ethically justified to use TB screening as an instrument to allow or deny immigration in case of forced migration?

No. In the case of forced migration immigration decisions should be made independent of the health status of a person. There should be firm legal principles in place that ensure that the enforcement of migration law on the one hand and the protection of human rights, including the right to health on the other, are separated from one another *(60–63)*. Otherwise migrants may not fully disclose essential information or be driven to alternative irregular migration routes, resulting in the health of both migrants and the public being put at risk. The ethical value of solidarity should thus prevail so that immigration decisions are made independently of TB status (or any other health indicator); and access to services of the national health system is provided in the receiving country *(64)*. It is essential to ensure that there is continuity of care and support to complete treatment on arrival in the new host country, thus ultimately controlling the spread of disease. TB screening can create a moral dilemma for health care workers who are concerned with individual patient care, but who are also required to abide with the law and follow government migration policies. For these reasons, TB screening is not justified as an instrument to decide the permissibility of a person to immigrate.

Is deportation or repatriation ethically justified if treatment options for TB are not in place in the new country?

As with other diseases or conditions, repatriation should only occur if adequate treatment options are not available and accessible in the new country *(65)* and if the original country allows entry to the migrant. In situations where repatriation programmes for migrants are being implemented, the health care structures in the new country should be involved from the beginning of the transfer process to ensure that TB treatment is appropriately continued *(65)*.

Unlike deportation, assisted voluntary return and repatriation – if and when not exploited – can be a humane alternative when a migrant ends up destitute, without any social protection from the new host country, and does not have the means to return on his own. Although migrants are most often left with only a few alternative options, assisted voluntary return and repatriation must be firmly based on the personal will of the migrant, and autonomy should be respected through the process of informed consent. This assistance can also be tailored towards the needs of migrants at increased risk, such as victims of trafficking, unaccompanied minors and migrants with health-related needs. Prior to the transfer, potential returnees will first be deemed fit to travel and be competent to make an informed decision regarding

their return. If the returnee is identified as having a significant medical condition, such as a communicable disease of public health concern like TB, a medical escort or other special travel arrangements may be arranged to assist the travel. The access to adequate medical services and medical treatment on a permanent basis in the country of origin should also be determined to ensure that health needs are addressed. This is often best realized through referrals to existing health and social services.

Is it ethically justified to provide migrants with TB care inferior to the one offered to citizens?

No. Keeping with the principles of equity and justice, it is required to provide access to adequate health care for migrants too *(63,66–70)*. Migrants should receive equal access to quality TB prevention, diagnosis, care and treatment as their host country's citizens. In practice, this may mean that health systems have to allocate additional access to migrant-specific TB care. For example, training staff and stakeholders in cultural competency and ensuring that language resources are adequate to overcome cultural and linguistic barriers to care faced by some groups of migrants *(71)*.

Is it ethically justified to withhold TB treatment for migrants due to lack of financial guarantee or coverage for the costs?

No. Doing so would go against the very idea of social justice, equity, common good and solidarity. It moreover is against the public's best interest of infection control and conflicts with the End TB Strategy's goal of ending TB. Withholding financial coverage for treatment costs also does not align with the goal of universal health coverage, in that no one should suffer from financial hardship or impoverishment paying for needed health services *(72)* and is against the End TB Strategy's goal of zero households affected by catastrophic costs specifically due to TB.

Is it ethically justified to deny entry or work permits to migrants suspected or known to have latent TB infection?

No. According to the WHO's guidelines on the management of latent TB infection, migrants from high TB burden countries are recognized as an at-risk population that should be considered for systematic screening. However, the threat of latent TB infection is not a present risk but a potential future risk, whereas denying entry and work to migrants produces real hardship in the present moment for the migrants and their families. A person's status – tested positive for latent TB infection or receiving latent TB infection treatment – should not affect the process, procedure and status of immigration, entry or work permit. Testing and voluntary treatment for an at-risk migrant population may be a cost-effective public health measure, but the result of testing during migration should never be used to justify denial of entry, residence or work permit. Instead, a positive test-result may be used to provide migrants with counselling and to offer voluntary preventive treatment *(73)*. Screening and testing of migrants may only be justified with the objective to provide adequate medical care, and never with the idea to discriminate.

Is it ethically justified to withhold TB diagnosis, initiation or treatment from migrants in transition or on the migratory route until they reach their final destination?

No. This is because there is a health risk both to the individual patient and the population in delaying the diagnosis and initiation of treatment. It also is against the ethical principles of beneficence and non-malevolence. Delaying the diagnosis or treatment keeps individual patients longer without the needed medicines and potentially exposes others to the infection on the route and in the destination where they are likely to stay in crowded residences. Additionally, with no guarantee that the receiving authorities will diagnose or treat TB, there is little justification in such a delay.

SECTION TWO – BOLD POLICIES AND SUPPORTIVE SYSTEMS

14. Infection prevention and control

The ethical issues of certain aspects of infection control, such as maintaining infectious persons in isolation and providing appropriate clinical measures, are dealt with in greater detail elsewhere in the document (see chapters 5, 8, 10, 15 and 19). Other issues that deserve particular attention are: segregation of people in whom TB is suspected or confirmed, the application of infection prevention and control measures to patients receiving end-of-life care, and maintaining confidential private information of persons with TB, including their health status.

What ethical considerations should inform the use of personal protective measures (such as surgical masks and respirators)?

Patients and relatives should receive complete and accurate information on the rationale, rights and responsibilities related with the use of masks and respirators. This information should be provided to the community as well. Public banners and health education posters related to TB should be carefully designed to prevent the creation of stigma. While preventing and relieving stigma is a challenge throughout most aspects of caring for a person with TB, special considerations can arise in the context of infection prevention and control. Part of good infection control is to ensure the early separation of those presumed to have active TB from those who do not; doing so however may be difficult without revealing that TB is suspected in a patient. Thus, all measures should be pursued to protect patients' right to confidentiality, which is critical to prevent stigma.

Should the patient's right to confidentiality override the responsibility of health care workers to perform duties that would disclose the TB status of the patient?

Preserving confidentiality during routine infection control procedures is challenging, particularly when a person with TB asks not to notify specific members of their social network that otherwise need to get tested for TB. Non-consensual disclosure should

always be done respectfully and discreetly by members of the health care team and information that is vital to protect the public from harm only should be shared. For a more detailed discussion on disclosure, please see Chapter 5.

15. Isolation and involuntary isolation

Respiratory isolation in TB management can take the form of physical isolation in hospital or household, or the use of masks worn by patients, and it is almost always voluntary. Involuntary isolation, except in narrowly defined circumstances (as described below), is unethical and infringes an individual's rights to liberty of movement, freedom of association, and to be free from arbitrary detention. Immediate enrolment on an effective treatment regimen is the most effective way to cut transmission in a short period of time, and no respiratory isolation measures other than use of masks are recommended when such a regimen is feasible and the patient adheres to it. Generally, those with active TB want to protect their loved ones and the broader community from infection. In some instances, patients may be initially reluctant to accept isolation if needed to protect public health. This situation can usually be solved by listening to the patients to understand what they need, and by providing social support. In very rare circumstances, all efforts to persuade patients to accept voluntary isolation may fail. In such instances, involuntary isolation may be deemed ethically acceptable given certain conditions are met, as explained below. However, involuntary isolation must always be a last resort to be considered only after all else fails. It is important to know that among the reasons many countries are struggling with high rates of TB is not that individuals refuse to take their TB medications but rather that there are deeper systemic issues at play, e.g. poverty, lack of access to primary care, etc.

Why is isolation an ethically acceptable part of TB management?

It is ethical to ask persons with active TB to voluntarily isolate themselves while they are deemed to be contagious in order to protect others from acquiring the bacteria. Isolation is justified on the basis of protecting others from harm, an idea commonly referred to as the Harm Principle, which is a pillar of public health and justifies restrictive measures on persons' freedom of movement and freedom of association during many airborne infectious disease outbreaks. Moreover, the idea of protecting others from harm through restrictive measures like isolation is also found in human rights law, including the International Covenant on Civil and Political Rights, and expert-guidance documents, such as the Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights *(74)*.

It is important to note that the least restrictive isolation measures should be taken at all times. For example, if basic respiratory isolation measures suffice (i.e. a person with TB wearing a mask), then a patient should not be subjected to physical isolation too. Doing so ensures that the interests and well-being of a person with TB are minimally affected and only to the extent that is absolutely necessary.

When is it unethical to isolate persons with TB?

It is unethical to isolate persons with TB if the person is not contagious or if isolation holds no clear public health benefit to the community. Given the gravity of isolation and its negative effects on a person's rights, interests and well-being, including potentially resulting in stigma, isolation cannot be justified if other ways of protecting the public from infection exist, such as enrolment on effective treatment and use of masks. Isolation, voluntary and involuntary, is also unethical if isolated individuals are not offered treatment when treatment exists, efficient infection control measures and humane living conditions, such as adequate shelter, sanitation, food, water and access to communication with the outside world.

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

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. 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 some cases of persons with TB 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 necessarily a problem with a patient-centred approach.

Involuntary isolation should never be a routine component of TB programmes. However, there are rare situations where, despite all reasonable efforts, patients do not adhere to the prescribed course of treatment, or are unwilling or unable to comply with infection prevention and control measures. For such cases, the interests of other members of the community may justify efforts to isolate the patient involuntarily. As explained below, involuntary isolation must be carefully limited, in accordance with a pre-existing law or policy, and used only as a very last resort, since doing so directly restricts the patients' autonomy and affects many human rights (such as freedom of movement, employment). Involuntary detention in a non-medical prison setting, such as in a prison cell or in the general prison population, is always unethical because it provides no clinical benefit. In human rights terminology, involuntary isolation interferes with the patient's right to liberty while severely limiting the patient's autonomy and possibly resulting in stigma or insecurity of individuals, and may expose the prison population to infection.

All programmes should develop laws and policies in line with this guidance that clearly explains when and how involuntary isolation of patients is allowable. Involuntary isolation decisions should be made in a transparent fashion with appropriate opportunities for external review and appeal, and be made by public health authorities rather than the treating clinicians *(75)*. Any programme that experiences frequent refusals of care, or significant problems with adherence, should carefully evaluate its work and assess whether it is doing everything it can to implement the patient-centred approach described in this document. Civil society should also be involved in this evaluation process.

Under what circumstances can involuntary isolation of persons with TB be ethically appropriate?

For patients who are willing to undergo effective treatment, isolation is usually neither necessary nor appropriate. Studies have shown that treating persons with TB at home with appropriate infection measures in place generally imposes no substantial risk to other members of the household *(76,77)*. By the time a diagnosis is made, it is often the case that the household contacts have already been exposed to the patient's disease and the possibility of contracting infection goes down quickly once effective treatment is started. Even for patients with MDR/RR-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 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 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.

Involuntary isolation should be limited to exceptional circumstances when an individual:

- is known to be contagious, refuses effective treatment, and all reasonable measures to ensure adherence have been attempted and proven unsuccessful; OR
- is known to be contagious, has agreed to ambulatory treatment, but lacks the capacity to institute infection control in the home, and refuses inpatient care; OR
- is highly likely to be contagious (based on laboratory evidence) but refuses to undergo assessment of his/her infectious status, while every effort is made to work with the patient to establish a treatment plan that meets his needs.

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

If, in a rare individual case, a judgement is made that involuntary isolation is the only reasonable means of safeguarding the public, it is essential to ensure that the manner in which isolation is implemented is ethical and non-discriminatory. Involuntary isolation should be a last resort in accordance with a pre-existing law or policy, as least restrictive as possible, and occur in an appropriate medical setting.[4] When it is determined that an individual case requires involuntary isolation, the individual concerned should have the right to appeal the decision in an appropriate judicatory setting, including before an administrative, judicial or quasi-judicial body. A patient in involuntary isolation maintains all other rights except those necessary to restrict for the protection of the broader community and must be offered treatment and all necessary social support.

It is imperative that involuntary isolation is only seen as a drastic measure to be used in very rare cases for the benefit of the public's health when a patient, after

4 For a more in-depth list of all the conditions required to justify involuntary isolation in the case of infectious diseases, it is recommended that the reader consult the Siracusa Principles. United Nations, Economic and Social Council, Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, U.N. Doc. E/CN.4/1985/4, Annex (1985). University of Minnesota (http://hrlibrary.umn.edu/instree/siracusaprinciples.html, accessed 10 February 2017).

adequate information about his or her status, refuses to cooperate, and never as a means of convenience or as a form of punishment. The table 1 sets out all conditions that should be met to justify involuntary isolation.

Table 1. Conditions necessary to justify involuntary isolation
Isolation is necessary to prevent the spread of TB, AND
Evidence that isolation is likely to be effective in this case, AND
Patient refuses to remain in isolation despite being adequately informed of the risks, the meaning of being isolated and the reasons for isolation, AND
Patient's refusal puts others at risk, AND
All less restrictive measures have been attempted prior to forcing isolation, AND
All other rights and freedoms (such as basic civil liberties) besides that of movement are protected, AND
Due process and all relevant appeal mechanisms are in place, AND
Patient has, at least, basic needs met, AND
The isolation time given is the minimum necessary to achieve its goals.

What do we owe persons with TB who are subject to voluntary or involuntary isolation?

Persons who are subjected to isolation, even if involuntary, must be protected from encroachments and abuses of other rights and interests beyond the limitations necessary for the protection of the public. This includes a right to appeal the decision to involuntarily isolate or detain them, as mentioned above. The ethical principles of dignity and respect should be ensured. Thus persons who are in isolation should receive all the necessary clinical and social support so as to minimize the associated burden of isolation in their lives to the greatest extent possible. Doing so is in keeping with the principles of reciprocity (by supporting those who do good for others) and solidarity (by standing with those persons during a period of acute vulnerability), as described above, as well as the protection of their human rights.

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

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

16. Screening

Why is screening an ethically relevant component of TB programmes?

Screening consists of systematic identification of people with suspected active or latent TB, in a predetermined target group by the use of tests, examinations or other procedures, which can be rapidly applied. The goal of screening is to identify individuals who have TB in order to treat them and to provide data for epidemiological purposes. All testing done during screening must be voluntary and with the informed consent of each participant.

Screening of people in whom active TB is suspected is a key public health measure used to curb the spread of infection, and the screening of people suspected of latent TB infection is a key component in the elimination of TB. Ethically, screening contributes to the common good, since whole communities and regions benefit from it. Moreover, screening upholds the ethical principle of accountability, since it is the responsibility of national TB programmes to devise not only clinical interventions but also public health interventions in order to promote the common good.

Screening should ideally be implemented when good quality diagnosis, treatment and support are available in a given community. Screening should occur in those groups of people deemed to be at high risk of infection or disease (such as household contacts of those infected, those living with HIV/AIDS, people who are exposed to silica in their workplaces, patients seeking health care for other complaints in very high burden settings).

What potential ethical conflicts exist when implementing TB screening programmes?

A person may choose not to participate in screening, thereby exercising his/her autonomous choice to not abide by recommended public health edicts. In such cases, to ensure that a person is acting autonomously and with complete information, it is important that public health officials communicate why screening is important and what exactly will be needed of the person. If the decision not to participate in screening is based on incomplete or false information, it diminishes the person's autonomy and potentially places the family and community at greater risk of transmission.

What obligations do TB programmes have towards those that are screened?

TB programmes must ensure that persons are screened voluntarily with their informed consent, and that all information about the risks and benefits of screening is provided before they make their choices. In addition, TB programmes must ensure that proper diagnosis, treatment and support are available to those who test positive, and that in rare instances in which false positive results are detected, patients are properly counselled and supported.

Given the stigma associated with TB, it is important to take all measures to reduce stigma and subsequent discrimination of those who partake in screening, particularly those who are already marginalized (such as migrants, prisoners). Screening should always be done with the intent to provide care to those who need it, and never to discriminate them. For example, border screenings must not be used to refuse entry to migrants (see Chapter 13 "Migrants" and Chapter 7 "Addressing latent TB infection"). To prevent and ensure that screening is done in a culturally sensitive manner, it is imperative that local communities are consulted and provided with a meaningful opportunity to help shape how screening will be performed and what it means for them.

Finally, if during screening for TB, health care workers learn that a person is not suffering from TB, but rather another illness, it is incumbent on the health care workers to ensure that appropriate care is provided for the other illness (e.g. by referral).

17. Surveillance

What is the role of TB surveillance?

Surveillance is one of the oldest and most essential public health activities. TB surveillance systems should be concerned with the production of valid data to assist health system planning and adequate responses to epidemics. Effective surveillance activities are crucial to promote public health as valid and reliable data can save human lives. Accurate surveillance indirectly promotes equity, as individuals from disadvantaged groups are at higher risk of TB, suffer greater harm when affected, and are less able to make their condition visible and determinant for health policy. Thus surveillance can help to direct scarce resources to those who need it the most, as well as to monitor that individuals with TB are receiving the treatment they need, so as to reduce the risk of drug-resistant TB.

Adequate TB surveillance and MDR/RR-TB management will contribute to the global common good of public health. Countries have an obligation to develop comprehensive and sustainable TB surveillance systems that can collect high-quality data. Surveillance systems should have a clear purpose and plan for data collection, analysis, use and dissemination. As a matter of solidarity, the global community has an obligation to support countries that lack adequate resources in their efforts to improve surveillance systems and establish routine drug susceptibility testing, to monitor and prevent the spread of drug-resistant strains.

Why is data protection important in TB surveillance?

Knowledge of an individual's TB status can lead to discrimination and stigmatization, and discourage honest reporting. This is why National TB programmes and others who hold surveillance data must ensure that they are appropriately secured. Confidentiality in treating sensitive personal information should be guaranteed to the greatest possible extent, except when it may interfere with vital public health goals. For example, it may not be necessary to keep personal identifiers, except at the local level, where confidentiality should be very stringently respected. Health care providers which are not included in national TB control programmes, both

public and private, should be involved in surveillance, without compromising on data quality. In contexts where data are produced in great quantities, it has become increasingly difficult to strip data of personal identifiers. In the light of these risks, data sharing initiatives should never be undertaken lightly. The sharing of anonymized or aggregate data with the broader public may increase awareness but also cause excessive alarm and place groups who face heightened susceptibility to harm or injustice at additional risk of stigmatization. Even in the face of such risks, in some specific circumstances, it may still be ethical to publish data about these groups aiming at addressing their specific problems, as silence about their health needs may harm them more than stigma would in the long term.

Does TB surveillance require informed consent?

Informed consent is not the default in public health surveillance. When critical public health objectives require complete data (and/or personal identifiers) and relevant protections are in place, individuals have an obligation to contribute to routine surveillance programmes. In addition, obtaining informed consent is often not feasible in practice. However, even when informed consent is not required, patients should be informed about the surveillance activities taking place, where possible. The communities concerned should be consulted, and their values and concerns should be taken into account in the planning, implementation, and utilization of surveillance.

Nevertheless, there are some specific surveillance activities where consent may be considered when there is potentially a risk to participants. Some examples are household surveys on HIV/AIDS, the conduct of anti-TB drug surveys or TB prevalence surveys, and surveillance of drug sensitive and MDR/RR-TB in settings where there is no capacity to treat patients identified as having drug-resistant strains. While doing surveillance under these circumstances is ethically permissible, individuals should not be tested in the absence of treatment unless they have provided specific informed consent (see also Chapter 6). It is the obligation of the public health authority accountable for surveillance to assess the importance of seeking informed consent. If in doubt, they should seek the advice of an ethics committee.

18. Compassionate use and expanded access to TB drugs

Although sometimes used interchangeably, "compassionate use" refers to doctors or health care workers appealing directly to pharmaceutical companies on behalf of their patients for the use of an investigational agent that has some evidence of safety and efficacy. "Expanded access" or "expanded access programme" "…is a means by which manufacturers make investigational new drugs available, under certain circumstances, to treat a patient(s) with a serious disease or condition who cannot participate in a controlled clinical trial" *(78)*. For research and development in TB drugs, it is imperative to think through the ethical issues related to compassionate use and expanded access and for governments to institute clear compassionate use and expanded access policies if they do not currently exist.

Why should people with MDR/RR-TB have access to investigational agents through compassionate use or expanded access programmes?

There may be risks associated with using drugs where the safety and efficacy profiles are not well understood. However, in MDR/RR-TB the potential benefits of compassionate use and expanded access may sufficiently balance the risks associated with taking drugs with incomplete information. As such, given the extreme danger and circumstances surrounding the treatment of MDR/RR-TB, it is appropriate to support compassionate use and expanded access programmes.

What ethical values and principles should guide thinking with regards to the compassionate use of, and expanded access to, new anti-TB drugs?

First, a key goal in compassionate use and the establishment of all expanded access programmes (even those beyond the context of TB), is to minimize the risk of harm to patients. Appropriate conditions, such as ensuring proper patient inclusion, setting up rigorous pharmacovigilance, and promoting informed consent, are all ways to protect the patient from harm as best as possible given the uncertain nature of new anti-TB drugs.

Second, allowing for compassionate use and creating expanded access programmes is a way of ensuring that patients have access to all possible recourses in treating their TB, and exhausting all possible avenues. Doing so helps promote the dignity of patients by viewing their lives as worthy of protection and promotion to the greatest extent possible.

Third, informed consent points to the importance of upholding a person's autonomy and autonomous choices with regard to their health and health care. Autonomy includes the right to choose how best to interpret the risks and benefits of using, or not using, drugs available via compassionate use and expanded access.

Finally, the requirement for pharmacovigilance and the close monitoring of the drugs used in compassionate use and expanded access is imperative to protect patients and build trust and transparency in such programmes.

19. Health care workers' rights and responsibilities

Health care workers 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 *(26)*. Moreover, they may have multiple obligations, such as duties to family, which must be balanced against their job-related duties. Finally, health care workers should not be expected to assume risks that can be avoided by the adoption of basic infection prevention and control measures, or to assume risks when there is no reasonable possibility of benefit (curative or palliative) to those for whom they are providing care. Thus, any discussion of health care

workers' obligations must also consider the reciprocal obligations of governments and health care facilities to provide adequate standards of safety.

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

No. With reasonable training, supplies, equipment, infrastructure, support and access to proven methods of care and treatment, health care workers can legitimately be expected to look after patients with TB. Governments have an obligation to ensure that adequate support is provided. However, these expectations may not be appropriate for health care workers who are at more risk of contracting a TB infection, such as those who are living with HIV/AIDS, unless their working conditions adequately protect them from TB exposure *(79)*. If health care workers at heightened danger cannot continue working safely, 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, health care workers who are not in good health will not be able to properly care for their patients. For these reasons, health care systems have an obligation to:

- provide training, equipment and protection to those who are in charge of a person with TB *(76)*;
- give health care workers the skills and information necessary to assess their risks so that they can take proper precautions;
- provide access to TB diagnosis and treatment (for both antiretroviral therapy and isoniazid preventive therapy), including TB screening, for health care workers living with HIV;
- identify and treat health care workers 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 health care workers, the specific roles they are expected to assume, and the risks inherent in those situations;
- appropriately compensate health care workers for their services, which may include danger pay and insurance for themselves and their families, and disability pay for those who become infected;
- ensure that immunocompromised health care workers are not exposed to persons with TB, but rather given a safer working environment, while preventing stigma and negative consequences for their career; and
- have a mechanism in place for health care workers to raise concerns about safety and working conditions without fear of reprisal.

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 fulfil their reciprocal obligations. If these are not met health care workers would face significant risks from interacting with patients, and in such a situation they would not be acting unethically if they decide not to work. Under these circumstances, it is the system and not the individual worker, which is ethically responsible for any difficulties that the patients may face in obtaining access to care. If health care workers 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, without being subject to any kind of reprisal. Governments and health care systems have an obligation to take action accordingly (such as adopting better infection control measures) to ensure that workers can provide care safely.

SECTION THREE – RESEARCH AND EMERGING TECHNOLOGIES

20. TB and health information technology

Digital health technologies are poised to be a key tool in the implementation of the End TB Strategy, especially in areas such as TB surveillance, data sharing, monitoring of adherence to treatment, advocacy, eLearning and programme management. It is fundamental that digital health technologies are deployed in line with sound ethics standards *(80)*.

What new challenges do the use of digital technologies raise for TB surveillance and data sharing?

Digital technologies are hugely efficient at storing and communicating large volumes of data, very often over the Internet. Because TB is often associated with poverty, homelessness and suboptimal health system resources, the use of these technologies in TB surveillance, care and research contexts can indirectly accentuate bias and stigma if inadvertent disclosure of confidential information occur. TB surveillance has always been risky in this regard. The duty to monitor the incidence and prevalence of TB often entails that some populations and subpopulations will become associated with a disease that is often stigmatizing. Inappropriate use of the information arising from the tools of digital surveillance has the potential to magnify or amplify these risks. Beyond the reporting from infectious disease laboratories, clinical institutions are increasingly using electronic health records, which may also increase the risk of information disclosure.

Such traditional and contemporary risks demand the adoption of practices to minimize and mitigate the risks and should not be used as supporting arguments for not conducting surveillance, in the same way that the reason to isolate infectious and non-adherent or non-compliant persons with TB is not to shame or stigmatize them, but to protect those they would otherwise come in contact with. The duty to conduct robust TB surveillance is in part to understand the situation and risk for TB in any given setting in a comprehensive, timely and accurate manner. It is also essential to establish a foundation for decision making and action regarding where resources should be directed and prioritized. Because the misuse of digital technology may be

a more efficient "stigmatizer" it follows that special precautions must be adopted to address the risk. These precautions include:

- applying policies and procedures to ensure that any data collection, storage, analysis and management will not harm, but on the contrary, benefit the patient;
- seeking consent in data collection and storage and use;
- using robust security technologies and protocols to enhance privacy and confidentiality, minimizing the likelihood that any individual patient would be inappropriately identified (a reliable unique identifier may help to reduce the likelihood of misclassification or mistaken treatment); and
- strengthening ethics committees to inform and guide decision-making. In the same way that the principle of proportionality is essential for the management of isolation, a principle of "digital proportionality" will help ensure that no "more than needed" information will be collected, and that data stewards will have access to such committees.

What is the role of social media in ending TB?

There are at least three overarching issues to consider regarding the role of social media: (i) the use of social media by health care services to inform and educate people with TB; (ii) the use of social media by people with TB; and (iii) the surveillance or monitoring of social media by public health authorities. All these may bring great opportunities to the successful implementation of the End TB Strategy, but they may pose some challenges as well.

Digital communication tools and eLearning technologies can be a powerful means to inform, empower and educate the general population and people with TB about their disease, and the roles and responsibilities of different actors in the prevention, treatment and cure of affected populations through the End TB Strategy.

Patients' use of social media may contribute to improving awareness and understanding of the disease whether in peer groups or in the general public. It may improve treatment adherence and social support as well. It may also result, however, in unintended self-inflicted public disclosure of their disease states or risks, with negative personal and social consequences in settings where stigma attached to the disease is common. Though individual tolerance of such disclosure will vary, patients should be supported to make use of social media in ways that would contribute to their personal well-being and to the wider engagement of the population in implementing the End TB Strategy.

Health authorities may adopt strategies for monitoring of social media sites to provide focused warnings and education. Whether, when and under what circumstances authorities may conduct such monitoring entails the need for evidence-based guidance and governance plans and strategies. Such monitoring may constitute a form of surveillance and this in turn means authorities must have in place standards for informing affected populations and others about the existence of any such techniques and how it uses them.

Is it ethically permissible to share TB data internationally or among Member States?

Yes. The duty to protect the health of populations, especially perhaps from a communicable disease as TB, points to a number of obligations for health authorities.

One reason that data sharing is permissible, if not obligatory, is related to conducting surveillance. The United Nations and other organizations have identified a "right to benefit from scientific progress and its applications," *(81)* and the WHO, through its collaboration with Healthcare Information for All, promotes the "right to health and the right to receive safe, effective healthcare" and the correlate right to access information *(82)*.

Public health is data-intensive, and so sharing of data becomes an essential component of a competent and robust global health mission. It follows that data made inaccessible or secret is useless to that mission. Perhaps the most important ethical justification for data sharing is that countries, communities and individuals have long benefited and are currently benefitting from the use of data from other countries, communities and individuals *(83)*.

A wide variety of informatics tools have been developed to monitor the incidence and prevalence of TB, the spread of the disease and the success of treatments, including treatments for drug-resistant TB. These tools will be ineffective if data and information are not shared. Any data-sharing scheme must have in place adequate safeguards to protect privacy and confidentiality, to minimize, mitigate or eliminate the risks of bias and stigma and to ensure correct use by appropriate users. For more information on rapid data sharing, see Chapter 22.

How can the safety and reliability of data, and the security of information systems used to share and analyse data be ensured?

The growth of biomedical informatics has engendered debate over system reliability and this is a major empirical and ethical issue.

Having made the case for data sharing, it is morally disturbing if the systems for collecting and transmitting data are flawed, or if the data are of low quality and reliability, or if the software and systems for securing and sharing data are inadequate. There are a number of solutions for and approaches to this challenge. One is the adoption of data and software standards to ensure reliability, quality and traceability. Database structure and software code often embody a number of assumptions, and these may be misguided, embed bias or otherwise not be up to the task.

TB "data warehouses" – including those created (even temporarily) by linking local, regional or national data repositories – must be able to rely on comprehensive and iterative evaluations and assessments. Fostering a culture of ongoing review should be made a responsibility of all stewards of such data. In other words, the privilege of and the responsibility to share data should be matched by a suite of obligations, i.e. transparency, responsibility and accountability. In this way, surveillance, data sharing and system reliability are better able to earn the trust of the populations they are meant to serve.

21. New frontiers in TB care and control

The WHO's End TB Strategy recognizes the close connection between TB research and human rights and ethics. The End TB Strategy highlights "protecting and promoting human rights, ethics and equity" as one of the foundational principles upholding the Strategy's three pillars, including intensified research and innovation. Experts estimate that the world must spend US$ 2 billion on TB research each year to eliminate TB. Despite the urgent need for research, funding for TB research and development has stagnated since 2009, never exceeding US$ 700 million per year, and leaving a shortfall of US$ 1.3 billion. Underfunding in TB research, and the consequently slow progress in the development of improved ways to prevent, diagnose and treat TB, raise a number of ethical and human rights concerns on which policymakers and governments should act.

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 address them.
- Effectiveness of infection control measures, adherence strategies, drug delivery mechanisms and non-biomedical interventions (such as social, behavioural).
- Social, cultural and anthropological studies about the understanding of the disease by individuals and communities.

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 public health practice.

Why is developing TB research ethically important?

Research itself must respect ethical principles, and the design, conduct, financing and distribution of TB research and its results (whether tangible products such as drugs or vaccines or more generalizable knowledge) can serve to either advance or undermine the realization of ethical values. In addition, shortcomings in research and development give rise to many of the ethical challenges that TB programmes face. Few drug companies develop such research due to lack of incentive of business. For example, the slow pace of TB drug research, with only two new drugs from novel classes approved to treat TB in the past 40 years, has left people with TB and their caregivers reliant on lengthy treatment regimens with high pill burdens, poor tolerability and side effects that complicate adherence. Medical technologies developed through research can also transform how a disease is culturally perceived. Improvements to TB prevention, diagnosis and treatment may lessen the stigma associated with TB, catalyze advocacy to address TB, or help shift public perceptions about TB.

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 *(84,85)*. These include guidelines by WHO and the Joint United Nations Programme on HIV/AIDS on HIV research *(86)*, 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.

Considerations that are particularly important in designing an ethical research strategy include the following:

- 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.
- 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 (such as 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 specify how findings would be translated into public health policy, as applicable. Possible negative consequences for participants (such as stigmatization, discrimination) should be taken into account. Attention should also be paid to avoid misinterpretation of statistical results.

Are there situations in which TB research should not be conducted?

As much as research on the various aspects of TB care and control is necessary, there are circumstances/conditions that make TB research very challenging. These include the following *(86)*:

- When the capacity to conduct independent and adequate scientific and ethical review does not exist;
- Where voluntary participation and provision of informed, free and uncoerced 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, and/or preventive measures) that prove to be safe and effective, available to communities and countries where they have been tested, at an affordable price.

In these circumstances, it is essential that proper support is sought and obtained in advance in such a way that TB research can be conducted according to international ethical standards.

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 is 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 *(84, 85)*. The appropriateness of waiving consent should be decided by a research ethics committee, and not by the researcher.

In some cases research records/samples for which identifying information has been permanently removed, should be reviewed by a research ethics committee *(85)*.

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" *(87)*. 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" *(88)*. Rather, it is intended to provide the evidence base 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 so that advocates can call to attention 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 (see also Chapter 17).

What obligations do researchers have to engage and dialogue with communities?

Recent research ethics frameworks extend researchers' ethical obligations beyond protecting trial participants to engaging a broader community of stakeholders who may be affected by the research. The Good Participatory Practice Guidelines for TB Drug Trials (GPP-TB) offers an ethical framework for engaging a wide range of stakeholders – including people with TB, the civil society and representatives from TB-affected communities – in each step of the research process *(89)*. Although written for TB drug developers, the ethical principles of the GPP-TB guidelines apply to TB clinical research more broadly. In line with GPP-TB, certain considerations are particularly important in designing an ethical TB research strategy.

Community members should have the opportunity to participate in research beyond their role as potential trial participants. This participation should extend throughout each stage of the research process, from the design and conduct of studies to the dissemination of results. Building on the definition in Chapter 3 (Guiding principles and values to help end TB), "community engagement" can take a number of forms and many researchers choose to work with community advisory boards – groups of non-scientists that help to facilitate effective communication between study teams and communities where research is conducted.

Research should be designed so that the community in which it is carried out stands to benefit from the results. This accords with the ethical requirement that studies carry the potential to generate social value (i.e. the research has the potential to improve health or increase knowledge).

The ability to access the benefits of research is a key component of social value, not only for communities where research takes place, but also for others that stand to benefit from the results. Early on in the research process, researchers and their sponsors should begin making plans to ensure that results will be made available to

participants. For all types of studies, this should include the dissemination of results beyond the minimum expectation of publication in scholarly journals. For research that produces a tangible medical product (such as a new drug or vaccine), sponsors and developers must make plans to ensure equitable access to the product if it is judged safe and effective at later stages of research. In the early stages, wherever possible, access plans should include agreements enabling the non-restrictive licensing of intellectual property, arrangements for technology transfer and platforms for knowledge sharing for the benefit of TB-affected communities. At later stages, developers should devise plans for compassionate use, widespread registration of products with regulatory authorities and affordable fair pricing.

Much of TB research is global in orientation. Over half of funding for TB research and development comes from the United States of America and Europe, but most clinical studies are conducted in low- and middle-income countries where the burden of TB is greatest. Collaborative international research should be conducted in a manner that helps low- and middle-income countries develop research capacity, including capacities for local independent scientific and ethical review. Good collaborative research approaches scientists in these countries as equal partners; and makes efforts to avoid diverting financial and human resources from primary health systems.

How can governments promote ethics in TB research?

Governments should recognize the close connection between TB research and the ethical and human rights dilemmas faced by TB programmes. Governments can take the following four actions steps to promote ethics, human rights and equity through support for TB research:

i. Support the purposive development of TB research and development within larger national research agendas. This support could take the form of creating national strategic plans for TB research and backing the plans with financial resources and initiatives to build local scientific and ethics review capacities.

ii. Promote community engagement in TB research. Create provisions to ensure that research conducted in a country meaningfully engages a wide range of stakeholders in each step of the research process in line with guidelines such as the GPP-TB. National TB programmes are key stakeholders in TB research and development and must involve themselves in the design, conduct and dissemination of research.

iii. Create policies and systems to equitably disseminate and create access to research results. Governments should demand that research sponsors and product developers create plans to make products of research equitably available. National TB programmes should anticipate the introduction of new tools and plan for the swift registration and rollout of safe and effective technologies.

iv. Strengthen capacity to evaluate the safety and efficacy of technologies developed through research conducted elsewhere. This could include regulatory harmonization regionally, or national reforms to strengthen the ability of regulatory authorities to review and, when warranted, approve new technologies without undue delay.

22. Rapid sharing of data

The development and introduction of new TB tools, the corresponding operational research, and the conduct of systematic TB surveillance contribute to the production of new evidence that may result in updated policies and guidelines. The collection and sharing of data in a timely fashion are essential to inform policy updates and guidelines related to the End TB Strategy.

What key ethical issues are related to rapid data sharing?

At least since the recent Ebola epidemic, it is now widely accepted that during epidemic outbreaks and emergencies, rapid data sharing is of utmost importance for an expedient response. This is due to: the urgency of the situation (which is uncertain and ever-changing scientific information); the compromised response capacity of local health systems; and the heightened role of cross-border collaboration *(90)*. For these reasons, "rapid data sharing is critical during an unfolding health emergency" *(91)*. This is not only constitutive of good scientific practice, but an ethical obligation. The ethically appropriate and rapid sharing of data can help identify etiological factors, predict disease spread, evaluate existing and novel treatment, offer symptomatic care and preventive measures, and guide the deployment of scarce resources. Clinical and research data, which are crucial for emergency response efforts, should also be shared, taking into account the need for respecting confidentiality and avoiding any possible related discrimination of already vulnerable individuals.

Although TB is not formally classified as a public health emergency of international concern (PHEIC), it can be argued that since TB ranks among the top 10 causes of death in the world *(92)* there is a sense of great urgency and that a similar need for rapid data sharing exists. Withholding data from relevant shareholders of the End TB Strategy that could use the collected data to offer better policies as soon as possible to serve patients and public health would be ethically unsound. The high lethality reported among those affected by MDR/RR-TB, and especially those affected by XDR-TB, explains why some countries decide to manage the epidemic as a public health emergency.

In addition, there is an ethical obligation to responsibly share research data because participants in research often have put themselves at risk. While the informed consent process makes it clear that participants in trials should not necessarily expect a benefit to themselves as a result of their participation, the social contract for taking these risks and experiencing these harms imposes an ethical obligation that the results lead to the greatest possible benefit to future patients and society *(93)*.

For the End TB Strategy to be effective, fair and enhance the common good, it is essential to receive, link and share data from various public agencies and researchers responsible for questions related to TB in a timely fashion. Rapid sharing of data speeds up the process of learning about and understanding TB and hence allows national TB programmes to better serve communities and patients affected by TB. Beyond that it may help reduce the duplication of research projects that may or may not be successful. Promising trials can be carried further while others can be abandoned at an earlier stage so that similar mistakes are not repeated.

For example, because of stringent data security that has surrounded HIV surveillance, there have been situations where data about HIV was not shared with those responsible for TB surveillance, preventing identification of cases with comorbidity. Such conditions may have caused an intolerable delay in patients not receiving lifesaving treatment. Public health actors can neither forcefully respond to swiftly moving infectious diseases in real time, nor take all necessary action in the case of chronic conditions without access to all relevant data.

Countries should establish frameworks to enable secure sharing of data with all the relevant stakeholders, in particular health care workers, researchers, public health officials and policy makers involved in carrying out the End TB Strategy. The frameworks should protect patients' rights to privacy by ensuring that data are not shared more broadly than necessary. Data should normally not be subsequently re-shared with and by other agencies *(94)*.

When is there an ethical obligation for researchers to share data before publishing in peer-reviewed publications?

As WHO has previously recognized, every researcher who engages in generation of data related to a public health crisis like the rapidly increasing number of MDR/RR-TB cases, has a fundamental moral obligation to share preliminary results once they are adequately quality controlled for release. In cases where many lives depend on the new data, the onus is on the researcher, and the sponsors, to disseminate information through pre-publication mechanisms, unless publication can occur immediately using post-publication peer review processes *(95)*. In situations of public health crises, such data should be shared with public health officials, the study participants, the affected population, and groups involved in wider international response efforts, without waiting for publication in scientific journals. Journals should facilitate this process by allowing researchers to rapidly disseminate data with immediate implications for public health, as is currently supported by the International Committee of Medical Journal Editors *(96)*. Moreover, granting agencies and organizations in which TB researchers reside (such as universities, public health units, pharmaceutical companies) should also strive to make such publicly valuable data easily accessible and not be limited by the norms of recognition through peer review. Scientists willing to share data prior to publication should not be reprimanded for doing so.

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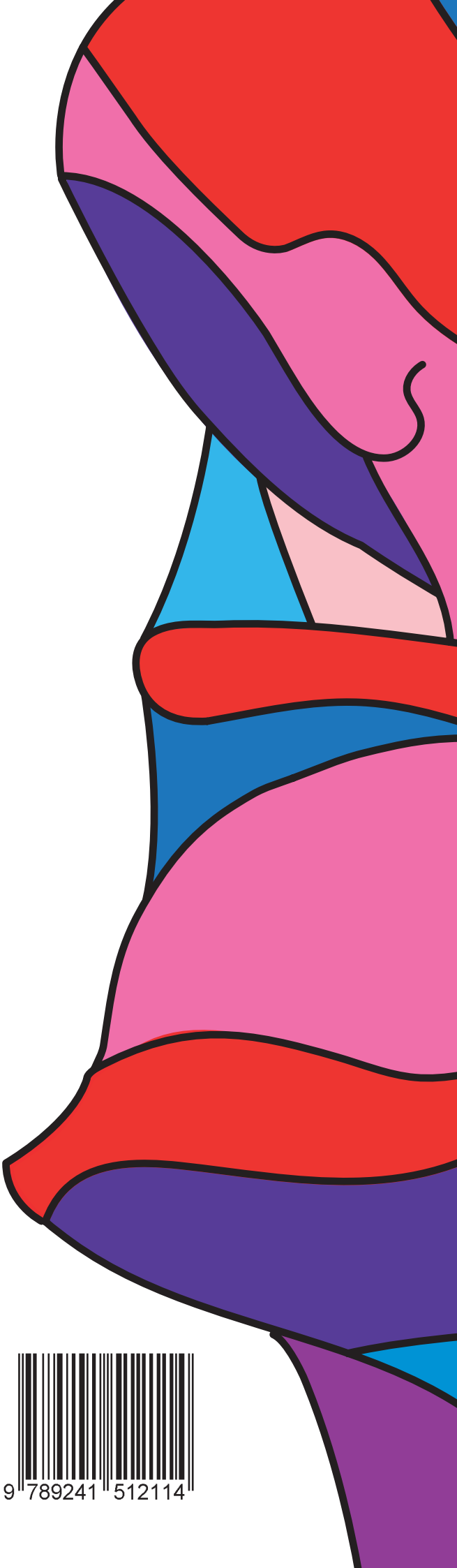

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