Report of the First Meeting of the WHO Task Force on Addressing Ethical Issues in TB Control and Care Programmes

Toronto, Canada, 8–10 December 2008
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Executive summary

The Task Force

In August 2008, the Ethics and Health Unit and the Stop TB Department of the World Health Organization (WHO) jointly established the Task Force on Addressing Ethical Issues in TB Control and Care Programmes. The objectives of the Task Force are:

- To provide a comprehensive analysis of ethical issues associated with tuberculosis (TB) control.
- To lay the groundwork for the formulation of WHO guidance to help governments and other stakeholders to implement TB control programmes in an ethical manner.
- To create a forum to exchange experiences and information on ethical issues arising in TB control and care programmes and how to deal with them.
- To promote research collaborations between the agencies/institutions working on ethical issues in TB control.
- To promote resource mobilization for research activities on ethical issues in TB control.
- To help disseminate and implement this global guidance to policy-makers and other stakeholders at international and national levels.

WHO will be looking to the Task Force for recommendations on a broad range of ethical issues related to TB care, with the ultimate goal of developing guidance for national TB control programmes.

Background

- Every year, TB causes about 9 million new cases of active disease and 1.65 million deaths. Of these 9 million cases, WHO estimates that more than half a million are multidrug-resistant TB (MDR-TB), with 130,000 deaths annually, and 50,000 are extensively drug-resistant TB (XDR-TB). Whereas the cure rate for non-resistant TB is nearly 100%, the rate for MDR-TB is only about 80%, and for XDR-TB it is only about 60% (in the best circumstances).
- Drug-resistant forms of TB are not new, but they are on the rise. Drug resistance stems from a variety of factors, including the availability and quality of drugs, the design of treatment regimens, inconsistent patient adherence to treatment, and inconsistent physician adherence to treatment standards and guidelines. While many of these factors reflect individual decisions and behaviours, they are rooted in broader social and economic problems.
- The following sections summarize four discussion papers that WHO commissioned to support the deliberations of the Task Force, as well as comments by members of the Task Force at the meeting.
Diagnosis and treatment

- Even if economic and practical barriers prevent some countries from providing comprehensive access to health care, TB treatment should receive high priority because it is inexpensive and cost effective; it prevents the spread of the disease to other persons; and the lack of proper treatment is likely to lead to the development of more dangerous, drug-resistant, strains.

- Some countries have adopted a practice of excluding patients from TB treatment when the health-care provider believes that the patient is unlikely to adhere to the prescribed regimen. In the absence of treatment, there is no drug resistance, but untreated patients may pose a risk of infection to others. Guidelines should be developed to help clinicians avoid arbitrary or discriminatory treatment denials. In addition, patients should be informed at the outset of treatment of any circumstances in which they might face limitations on access to continued care.

- Compelled isolation may be appropriate in very rare circumstances, given the danger that treatment refusals will lead to the spread of infection. Compelled isolation does not necessarily justify compelled treatment, however.

- Health-care providers need guidance on whether it is preferable to treat patients at home, if available hospitals lack basic measures to prevent disease transmission. Similarly, they need guidance on whether they should be encouraged to treat patients with drugs of unknown quality, when the alternative is not to treat these patients at all. WHO Member States should increase their efforts to make high-quality drugs available to all patients.

- The use of rapid diagnostic methods can be appropriate even when no drug treatment is available, or when the only available treatment is substandard. Diagnosis in the absence of treatment can help individuals make life plans, diminish the impact of the disease on family members and inform important behaviour regarding infection control. Moreover, evidence of a high prevalence of TB in a population can be a useful stimulus for governments to devote resources to building treatment capacity.

- There is an urgent need for developing a better evidence base for TB prevention and treatment. In addition to investigating biological questions, it is critical to explore the impact of social determinants of disease and how to address them.

- Patients should be notified, at the initiation of treatment, that they will be contacted if they do not attend their appointments, and possibly given some choice about the process by which contact will take place (e.g. by phone or letter instead of by home visit).

- It can be appropriate to use “incentives” or “enablers” to encourage TB patients to adhere to treatment, when done as part of a patient-centred programme of care.

- Even when curative treatments are limited, TB patients should be ensured access to adequate palliative care.

Obligations and rights of health-care workers, patients and communities

- In the context of TB, there may be circumstances in which health-care professionals may need to deviate from an exclusive focus on the individual patient, but any such deviations should be limited to exceptional circumstances.

- Health-care facilities should work in partnership with patients and communities, empowering all parties to play an active and responsible role in TB care.
• Patients have responsibilities to provide complete and accurate information to providers, to follow prescribed treatment regimens, to alert providers to any difficulties encountered in the treatment process, to encourage others to seek treatment and to show consideration for other TB patients and health-care providers.
• Health-care systems have obligations to identify individuals with TB infection and to provide training and protection to those who care for TB patients.
• With reasonable training, infrastructure, support and access to care and treatment, health-care professionals can legitimately be expected to care for patients with TB. These expectations may not, however, be appropriate for such professionals who are at greater danger if they are exposed to TB, for example, those who are HIV positive.

Public health measures

• Public health interventions necessary to TB control include vaccination, surveillance, screening, reporting, contact tracing, isolation, emergency detention, restricting activities, cross-border control, infection control and treatment of cases. All of these measures are relevant to individual rights, the most important of which are due process, confidentiality and privacy, freedom of movement, freedom from discrimination and religious liberty.
• In addition, a human rights approach to TB control must pay attention to the needs of special populations, such as persons in detention or indigenous groups.
• TB control programmes must consider the impact of the International Health Regulations, which require Member States to notify WHO of public health emergencies of international concern. Commentators disagree about whether XDR-TB constitutes such a condition.
• It is important to address the social determinants of TB as part of an ethics-based approach.

TB research

• Defining research and distinguishing it from other activities (e.g. public health surveillance) is an area in which further guidance may be useful. Even if an activity is not technically considered research, some of the principles of research ethics may still be relevant.
• A key element of ethical research is that all stakeholders, including local investigators (if the research comes from abroad), participate in the design and implementation and are assured access to the developed products. Participation of civil society is also crucial. WHO can play an important role in this process.
• Many of the critical issues in TB research are not related to clinical trials, but to epidemiological research with medical records and blood samples. With these types of research, a critical issue is determining how informed consent should be obtained and under what conditions it can be waived.
• It may be ethically appropriate to conduct epidemiological research on MDR-TB, such as drug-resistance surveys, even in contexts in which high-quality treatment is unavailable. The results of this research can be used for advocacy purposes, even if immediate treatment is unavailable.
• It is important to conduct international research in a manner that ultimately helps low- and middle-income countries develop the capacity to do research themselves.
Introduction

In August 2008, the Ethics and Health Unit and the Stop TB Department of the World Health Organization (WHO) jointly established the Task Force on Addressing Ethical Issues in TB Control and Care Programmes. The objectives of the Task Force are:

- To provide a comprehensive analysis of ethical issues associated with tuberculosis (TB) control.
- To lay the groundwork for the formulation of WHO guidance to help governments and other stakeholders to implement TB control programmes in an ethical manner.
- To create a forum to exchange experiences and information on ethical issues arising in TB control programmes and how to deal with them.
- To promote research collaborations between the agencies/institutions working on ethical issues in TB control.
- To promote resource mobilization for research activities on ethical issues in TB control.
- To help disseminate and implement this global guidance to policy-makers and other stakeholders at international and national levels.

WHO will be looking to the Task Force for recommendations on a broad range of ethical issues related to TB care, with the ultimate goal of developing guidance for national TB control programmes. In the short term, the Task Force’s input helped WHO staff prepare for a ministerial conference on TB held in Beijing (China) in April 2009, where multidrug-resistant (MDR) TB and extensively drug-resistant (XDR) TB were a major focus of discussion.

WHO has commissioned the following four discussion papers to support the deliberations of the Task Force:

- Diagnosis and treatment
- Obligations and rights of health-care workers, patients and communities
- Public health measures
- TB research.

WHO staff explained that the above-mentioned discussion papers prepared for this meeting should be viewed as works in progress, to be refined in light of the Task Force’s continuing deliberations. Key points from these discussion papers and the Task Force’s discussion would inform the development of a variety of WHO publications, including briefing materials prepared for the April 2009 Beijing conference. WHO staff stressed that the goal of the Task Force’s discussion was not to develop specific “recommendations”, but rather to identify key issues and general approaches for thinking about them.
The authors of the background papers would be encouraged to identify their own conclusions, which ideally would be influenced by the discussion at the meeting.

Members of the Task Force agreed that many of the cross-cutting issues raised in the discussion papers could be addressed in an introductory section of the final guidance document. This section could begin by providing an overarching ethical framework for thinking about TB control programmes. The "chapeau" section could also emphasize that the document is not intended to set formal standards of care, but rather to provide guidance to programmes for dealing with difficult issues in imperfect circumstances. Several members emphasized the importance of recognizing many countries’ need for financial and other support.
Background

General background on tuberculosis

Two billion people, or about one third of the world’s population, are currently infected with TB. While most of these infections will not lead to disease, every year TB causes about 9 million new cases of active disease and 1.65 million deaths. Asia has the highest absolute number of TB cases, but the per capita rate of TB is highest in southern Africa. Of the 9 million cases, WHO estimates that more than half a million are MDR-TB (with 130 000 deaths per year) and 50 000 are XDR-TB.

It is estimated that 8% of TB cases worldwide are associated with HIV; this percentage is expected to be higher once recently reported data are analysed. Screening for TB among HIV patients tends to yield high rates of active TB. Despite the strong link between TB and HIV, only about 12% of TB patients worldwide are tested for HIV. However, a few countries have shown dramatic improvements in HIV testing rates for TB patients. For example, in Malawi 75% of TB patients are tested for HIV.

TB treatment is usually highly effective, but treatment success rates are lower in Africa, Eastern Europe and the Americas. The past 10 years have seen a dramatic scale-up in access to TB treatment, but improvements have been stagnating. However, in recent years, there has been far more political commitment at the highest levels to a coordinated approach to TB. There has also been a particular emphasis on the “three Is”: intensified case-finding, introduction of isoniazid preventive therapy, and ensuring TB infection control in health-care and congregate settings (prisons, orphanages etc.).

WHO’s target (reflecting the Millennium Development Goals) is to halve the number of TB cases by 2015 compared with their levels in 1990 and to eliminate the disease by 2050. While prevalence and mortality rates have been declining, they must decline faster to meet these goals. WHO’s objectives are to provide universal access to diagnosis and treatment, to reduce the human suffering and socioeconomic burdens associated with the disease, to protect poor and vulnerable populations, and to support research and development of new diagnostic tools and drugs.

Background on multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis

Drug-resistant forms of TB are not new, but they are on the rise. Drug resistance stems from a variety of factors, including inconsistent patient adherence to treatment and inconsistent physician adherence to treatment standards and guidelines, the design of treatment regimens and the availability and quality of drugs. While many of these factors reflect individual decisions and behaviours, they are rooted in broader social and economic problems.

Whereas the cure rate for non-resistant TB is nearly 100%, the rate for MDR-TB is only about 80%, and for XDR-TB it is only about 60% (in the best circumstances).

Areas with the highest prevalence of drug-resistant TB are now experiencing a growing epidemic of HIV. This is particularly true in China, India and the Russian Federation, where both HIV and MDR-TB rates are increasing.
The standard of care for MDR-TB is microbiological diagnosis; a patient-centred approach to directly observed treatment (either on an in-hospital or outpatient basis); care under proper infection control conditions; use of quality-assured second-line anti-TB drugs; and recording and reporting data for monitoring and evaluation. On average, the drugs for treating MDR-TB cost about US$ 2500, which is cost effective as measured by disability-adjusted life years averted. However, in 2007, out of 490 000 cases of MDR-TB worldwide, only 46 437 patients received treatment.

WHO’s goal is to achieve universal access to diagnosis and treatment of MDR-TB by 2015.

**Task Force discussion on background issues**

One Task Force member challenged the common use of the expression “TB control” to describe strategies used to respond to the TB epidemic, and called for WHO to replace it with the expression “TB care”. He emphasized that individuals with TB do not want to be “controlled”, but instead want to be cared for like any other person with a disease. Task Force members were generally sympathetic to this comment, although some suggested that a comprehensive approach to TB would include elements of both “care” (of individuals) and “control” (of the disease).

Members discussed the uncertainty surrounding many basic epidemiological questions about TB. For example, the discussion documents prepared for the meeting indicated that there is a 10% lifetime risk that an individual infected with TB will develop the disease, but it is not known whether this risk is the same in all countries. It seems clear that factors like nutrition and other social determinants play a role in the likelihood of developing the disease, but the precise impact of these factors remains unknown.
Diagnosis and treatment

In all areas of health care, it is expected that some patients will default from treatment. However, with most diseases, non-adherence is primarily a problem for patients and their families, and any societal costs (such as increased expenses for rehabilitative care) are indirect. With TB, by contrast, patients who do not take their drugs may spread the disease to others, potentially creating a serious public health problem.

In light of the problem of drug resistance, developing new diagnostic tools, drugs, or a better vaccine is essential. However, private industry has little financial incentive to do this. Moreover, even if new drugs are developed, the problem of resistance will re-emerge unless the new drugs are administered and used properly. Thus, fixing the system in which TB care is delivered should be the top priority.

A strong ethical case can be made for ensuring universal access to high-quality TB treatment and care. First, access to TB care can be seen as part of the general human right to health, as reflected in the Universal Declaration of Human Rights and other human rights instruments. Second, even if economic and practical barriers prevent some countries from providing comprehensive access to health care, TB treatment should receive high priority because it is relatively inexpensive and cost effective; it prevents the spread of the disease to other persons; and lack of proper treatment is likely to lead to the development of more dangerous strains (for example, when poorly-trained private sector pharmacists and physicians sell patients one pill at a time, without proper diagnosis or instruction, resistance is likely to develop).

These arguments can also be made for MDR-TB and XDR-TB. However, it may be appropriate to recommend progressive realization of the right to universal access to treatment for drug-resistant forms of the disease, given the increased economic and logistical burdens that such treatment entails.

Some countries have adopted the practice of excluding patients from TB treatment when the health-care provider believes that the patient is unlikely to adhere to the prescribed regimen. This practice raises a difficult ethical dilemma. On the one hand, giving TB drugs to patients who will not use them properly contributes to the problem of drug resistance and wastes often scarce resources.

On the other hand, health-care providers are often not capable of predicting which patients are likely to stop their treatment early, and their judgements may be influenced by stereotypes about patients from particular social groups. Moreover, even if the provider has sound reasons to believe that a patient is unlikely to adhere to treatment, the risk of promoting resistance must be balanced against the impact on the individual of being denied access to care. Because untreated patients may pose risk of infection to others, an important empirical question is the extent to which treatment exclusion would, in fact, be good for public health. As a philosophical matter, the question is how great the gain to public health must be to justify limits on an individual’s right to care.

Members emphasized the importance of developing guidelines to help clinicians avoid arbitrary or inappropriately discriminatory decisions. These guidelines should incorporate legal norms prohibiting discrimination, and should emphasize the need to provide support to patients to help them adhere to
treatment regimens. Ethics advisory committees can play an important role in helping clinicians resolve difficult cases. In those exceptional cases where drug treatment is withheld, the reasons for the decision should be communicated to patients and family members in an appropriate manner. In addition, patients should be informed at the outset of treatment of any circumstances in which they might face limitations on access to continued care.

Members stressed that all TB patients deserve care, even those for whom drug treatment is inappropriate (e.g. when the strain is resistant to all available medications). In particular, palliative care should be a critical component of TB programmes.

Although rare, the provision of treatment over a patient’s objections raises difficult ethical issues. Compelled treatment conflicts with the principle of informed consent, which is generally a critical value in medical treatment and research. However, this principle consent was developed as a response to medical paternalism – i.e. the tendency of physicians to exclude patients from decision-making, on the basis of the theory that patients are incapable of understanding their own best interests. In the context of TB, calls for mandatory treatment are not based on a desire to protect patients from their own choices, but rather on the need to protect the public from the spread of infectious disease.

Yet, even if mandatory treatment cannot be criticized as paternalistic, it still infringes individuals’ freedom of choice. Any justification for mandatory treatment will have to address both empirical questions about the level of risk actually created by untreated patients, the reasons that patients refuse treatment and the measures undertaken to overcome these refusals, as well as philosophical questions about how much risk is necessary to justify infringing patient choice.

In general, Task Force members agreed that while the use of compulsion could be appropriate in some circumstances, programmes of education and community support could help in avoiding this situation. They observed that, even if it is justifiable to isolate patients who pose risks to others, that would not necessarily justify forcing the patient to accept treatment, given that forced treatment involves an infringement on bodily integrity. They also stressed that involuntary isolation should be considered a last resort, based on clear and transparent rules, and that states have an obligation to provide humane conditions of isolation and care.

Another set of ethical issues relates to mandatory defaulter tracing, i.e. tracking down patients who do not show up for appointments under directly observed treatment. Visiting these patients at home may lead to stigmatization and other harm, but failing to contact them means that they will go untreated (and possibly remain infectious). Although concerns about stigma may not be as serious with TB as they are with HIV, they are still significant.

One possible approach to this problem is to notify patients at the initiation of treatment that they will be contacted at home if they do not show up for their appointments; or to give patients some choice about the process by which contact will take place, such as by phone or letter instead of home visit, depending on the degree of urgency. (Both elements of this approach can, of course, be combined.) It is also important to address practical barriers that may lead some patients to avoid follow-up care, such as lack of money for transportation to the clinic or unfriendly behaviour by health-care professionals. As
with the issue of mandatory treatment, the underlying philosophical challenge regarding mandatory defaulter tracing is determining how much of a risk to the public is necessary to justify infringements on individual rights.

One Task Force member criticized the use of the term “informed consent” as applied to TB treatment, on the ground that the concept of consent necessarily includes the right to refuse. This member argued that, if providers intend to provide treatment or engage in defaulter tracing even over the patient’s objection, the term “informed consent” is misleading. He suggested that the term be replaced with the phrase “informed cooperation”. This language affirms the importance of treating the patient as an equal partner in the treatment process, but unlike “consent” the goal is not to protect the patient’s right to refuse but to receive treatment, which is beneficial for the patient and also the patient’s community, as easy as possible.

Another member suggested that shifting from the language of informed consent might be unwise, because it could imply a repudiation of norms central to the physician–patient relationship. In addition, he noted that traditional understandings of informed consent (including the right to refuse) play an important role in many aspects of TB care, such as in the provision of post-exposure prophylactic treatment (i.e. isoniazid preventive therapy). One member suggested that it might be useful to think about “treatment contracts” or “covenants”, which could incorporate the idea that the patient has obligations to third parties.

A similar discussion ensued regarding the language of “human rights”. One member suggested that an approach that is overly focused on rights might overlook the important societal interests at stake in TB treatment. In response, other members argued that the language of human rights plays an important rhetorical role and invokes powerful legal tools that have played a crucial role in protecting individuals and communities. Rather than abandoning this framework, these members suggested that the group interpret it in a manner consistent with public health values. This could be done by appealing to the Siracusa principles, the concept of social justice, or the idea of economic and social rights, especially the right to health. Some members, however, expressed concern about relying on the Siracusa principles, which are sometimes interpreted as applicable only in temporary crises when the very existence of society is in danger.

Task Force members discussed the problem of inadequate capacity to provide high-quality TB care. For example, hospitals in some countries lack basic capacity to prevent disease transmission, which means that caring for MDR-TB patients in hospital will place other patients at risk. Yet treating these patients at home creates risks to household members and the community. Member States need guidance on how to deal with these issues, rather than simply being told what should be done in an ideal world. At the same time, it is important to remind Member States that they have an ethical obligation to improve their capacity to deliver high-quality TB treatment, and to urge the international community to assist states that cannot fulfil this obligation on their own.

Regarding the specific question of outpatient-based or hospital-based treatment for MDR-TB patients during the intensive treatment phase, one member suggested that the focus should be on which
method will lead to less transmission. Thus, even if isolation at home will not be optimal for the patient, it may be appropriate if the alternative is that more patients will become infected. Yet he recognized that this analysis, even if ethically justifiable, may provide cover to countries that are not taking adequate steps to scale up their treatment capacity. Treating patients where minimum standards are not in place is deeply problematic.

Task Force members emphasized that, if TB patients are treated at home, states have an obligation to provide support to household members and the community.

This issue of second-best alternatives also arises with respect to drugs. Currently, the supply of quality-assured second-line drugs is insufficient to meet demand. While some countries are scaling up manufacturing capacity for these drugs, manufacturers in those countries do not always comply with basic quality standards. Should providers be encouraged to treat patients with drugs of unknown quality, when the alternative is not to treat these patients at all? Some members expressed concern that starting with low-quality treatment might hamper the establishment of high-quality treatment programmes – and that treatment with low-quality drugs may be bad for public health (given implications regarding drug resistance) as well as the patient.

Most members agreed that the use of rapid diagnostic methods can be appropriate even when no drug treatment is available, or when the only available treatment is substandard. Diagnosis in the absence of treatment can help individuals make life plans and inform important behaviour regarding infection control. Moreover, evidence of a high prevalence of TB in a population can be a useful advocacy tool for building treatment capacity.

Members agreed that cost-effectiveness is a relevant ethical consideration, given the importance of using limited resources in a manner most likely to relieve human suffering. However, cost-effectiveness analysis is not an exact science, and other values, such as equity, may sometimes override cost-effectiveness considerations. Cost-effective interventions, furthermore, are not always affordable or a high priority.

The use of incentives (monetary or other inducements, such as food coupons or dietary enhancers) or enablers (transportation to clinics, babysitting, etc.) in TB programmes was discussed at length. Members pointed out that individuals in need of TB treatment often face disabling circumstances because of their disease and the social conditions in which they live. It may therefore be necessary to give them incentives to come to treatment, including financial remuneration. One member argued that it is normal for patients to default from lengthy treatment regimens, and that all patients should therefore be given incentives to adhere to them. Members agreed that the ultimate goal should be to develop patient-centred programmes of care, which may (but need not) include incentives or enablers in some cases.

Members agreed on the need for developing a better evidence base for TB treatment. In addition to investigating biological questions, it is critical to explore the impact of social determinants of disease.
Obligations and rights of health-care workers, patients and communities

In general, health-care professionals (HCPs) have a duty to provide care to those in need, even when doing so involves some degree of risk. While HCPs cannot be expected to expose themselves or their families to unlimited risks, most HCPs who care for TB patients are not exposed to excessive risks. Therefore, with adequate training, infrastructure, support, and access to care and treatment, HCPs can legitimately be expected to care for patients with TB.

The expectation may differ, however, for certain categories of HCPs. For example, those who are infected with HIV may be at greater danger if they are exposed to TB. These HCPs may have a stronger case for opting out of treating TB patients. The final danger also depends on the strain of TB. The ultimate risks are greater in contexts involving XDR-TB. This is not because XDR-TB is any more likely to be transmitted, but because it is more difficult to treat and more likely to be fatal, even with treatment.

HCPs have a general obligation to respect patient autonomy and privacy. In the context of TB, there may be circumstances in which HCPs must deviate from an exclusive focus on the individual patient, but any such deviations should be limited to exceptional circumstances.

Many ethical issues in TB treatment can be avoided or minimized if health-care facilities work in partnership with patients, enabling them to play an active and responsible role in their care. Doing this requires the provision of complete and understandable information to patients, as well as counselling and support.

Patients also have responsibilities, as outlined in the World Care Council’s Patient Charter for Tuberculosis. These include the obligation to provide complete and accurate information to providers, to follow prescribed treatment regimens, to alert providers to any difficulties encountered in the treatment process, to encourage others to seek treatment, and to show consideration for other TB patients and care providers.

The group discussed the level of risk that HCPs actually face in caring for TB patients. Some members stated that it is very difficult for HCPs to catch TB when they take basic infection-control measures. Moreover, HCPs who are caring for persons known to have TB may be at reduced risk because they are likely to take precautions to avoid infection. The greatest risk is for those who treat undiagnosed TB patients for other conditions.

Other members suggested that the level of risk to HCPs is greater in low- and middle-income countries. For example, substantial risks to HCPs have been identified in TB programmes in the Russian Federation. One member pointed to published articles that found a substantial occupational risk to HCPs in low- and middle-income countries.

Rather than focusing on HCPs’ obligations in isolation, members stressed the importance of linking HCPs’ duties to the obligations of the health-care system overall. These systemic obligations include the duty to identify individuals with TB infection and to provide training and protection to those who care for TB patients (e.g. by improving infection control in health-care facilities). While some commentators
have referred to these responsibilities as “reciprocal obligations”, one member suggested that this terminology is misleading in so far as it suggests that the obligations are contingent. Rather, the obligations of states and health-care employers to protect HCPs should be seen as independent of HCPs’ own behaviour. At the same time, HCPs’ agreement to work may strengthen these pre-existing obligations.

One member argued that HCPs who are infected with TB have the right to receive the best proven treatment, not simply the best available treatment (as some commentators have suggested). In addition, he argued that HCPs who become infected are entitled to compensation.

Members were uncertain on how to provide guidance to HCPs who must work in inadequate conditions. For example, if a facility fails to provide HCPs with masks, can they go home, or would that constitute patient abandonment? One member noted that the Brazilian Medical Code of Ethics states that the physician should not work in a place where the conditions are inadequate for the practice of medicine.

The concept of duty to treat received significant attention. One member contrasted how this concept is understood in law in the United States of America (where such a duty must generally be voluntarily assumed) with the way it is approached in many other countries (where a duty to treat is seen as an inherent part of being an HCP). Even under this broader approach to the duty to treat, however, the duty is not absolute. Rather, it must be balanced against other duties, such as the duty to one’s family. In addition, the level of risk that an HCP can legitimately be expected to take depends on the potential efficacy of the HCP’s actions. If treatment or care is unlikely to be effective (in terms of either curative or palliative goals), the HCP should not be expected to assume significant risks to provide it.

Members also emphasized the importance of linking the discussion of HCPs’ obligations with the health-care workforce crisis that many countries are facing. In a poor country with few HCPs, it is important to consider whether insisting that HCPs take risks to their health will backfire by deterring individuals from becoming HCPs.

Several members suggested that the need for HCPs to breach patient confidentiality in order to inform patients’ contacts is often overstated. One member stated that “contact investigation in a confidential manner is an essential part of TB care for the benefit of both the source case and his or her contacts, and that it is extraordinary rare for patients to object to this process when it is done properly”. Others agreed that, if patients are treated with dignity, they are likely to become engaged in the treatment process and will inform their contacts on their own. Thus, it is crucial to emphasize the importance of having skilled professionals work with patients to identify contacts collaboratively.

Nonetheless, some members emphasized that, in exceptional cases, patients may be unwilling to participate in the process of informing their contacts, and that in these cases non-consensual notification of contacts by health-care professionals may be ethically acceptable. However, such notification should be viewed as a last resort and should be undertaken only after all reasonable efforts to secure the patient’s cooperation have failed.
Public health measures

International human rights laws oblige states to respect, protect and fulfil human rights, as defined in various human rights instruments. These instruments address both civil and political rights (e.g. freedom from torture or arbitrary detention) and economic and social rights (e.g. the right to health).

The overall human rights framework overlaps with ethics, but they are not necessarily identical. Ethics is concerned with normative issues of value – i.e. what ought to be the case. Ethics focuses on questions about what is good, right, fair and just; and philosophical questions about the nature, bases and limits of duties and human rights. Human rights specify the claims that individuals can make on the basis of their status as humans and define the parties against whom these claims can be made. Human rights also define the obligations that states and other parties have when they respect, protect and promote individual rights.

Human rights are not absolute. This is often because one right comes into conflict with another, such as the right to health versus the right to liberty of persons with communicable diseases. In these instances, competing interests must be balanced. The Siracusa principles provide a framework for this balancing process. These principles provide that limitations on human rights must respond to a pressing public or social need, must be in pursuit of a legitimate aim, and must be proportionate to that aim. While the Siracusa principles are not binding in themselves, some countries have incorporated them into national legislation. The principles of necessity, reasonableness and proportionality are also important to public health ethics. In addition, public health ethics emphasizes the values of distributive justice, solidarity, trust, transparency and social justice.

A variety of public health interventions are relevant to TB control, including vaccination, surveillance, screening, reporting, contact tracing, isolation, emergency detention, restricting activities, cross-border control, infection control, and treatment of cases. All of these measures implicate individual rights, the most important of which are due process, confidentiality and privacy, freedom of movement, freedom from discrimination, and religious liberty. In addition, a human rights approach to TB control must pay attention to the needs of special populations, such as persons in detention or indigenous groups.

In addition to human rights issues, TB control programmes must consider the impact of the newly-revised International Health Regulations, which require Member States to notify WHO of events that constitute public health emergencies of international concern. Commentators disagree about whether XDR-TB constitutes such a condition.

One member suggested that, rather than focusing on a conflict between individual rights and societal interests, a better approach would be to frame the issue in terms of an ethics of responsibility. Thus, one might talk about the responsibility of individuals with TB to avoid putting others at risk, just as one talks about the responsibility of states and health-care employers to avoid putting HCPs at risk. Coercive measures would be justified only in the exceptional cases in which individuals fail to meet their own responsibilities.
Other members supported this call for an ethics of responsibility. One member commented that this approach avoids the implication that public health ethics is all about justifying the use of coercive measures. He suggested that an ethics of responsibility could be broadly defined to include obligations of patients, HCPs, institutions, governments and the international community. This approach would give appropriate weight to values like solidarity, the common good, reciprocity and justice, rather than simply emphasizing procedural values and individual rights.

Another member suggested that the concept of responsibility could be complemented by an ethics of relationships. He emphasized that TB care involves numerous relationships, ranging from the physician–patient relationship to the relationships between governments and TB programmes. An ethical approach to TB should focus on the web of relationships and responsibilities for “sustainable human flourishing”.

One member said that the image of the uncooperative patient is misleading, as it ignores the terrible conditions under which care is sometimes provided. For example, individuals may be isolated while they are waiting for a diagnosis or drugs, and may have no indication of how long they will be confined or what will happen to them. In these circumstances, it is no wonder that some people try to escape.

Members stressed the importance of addressing the social determinants of TB as part of an ethics-based approach. If malnutrition is a risk factor for developing TB, a central goal for TB control programmes should be to ensure that people with TB infection have adequate nutrition. In this context, food can be seen as a form of preventive therapy. Members acknowledged the paucity of data on the impact of social interventions against TB and called for further research in this area.

One member observed that the importance of addressing social determinants of TB stems from the core obligation of public health – to protect communities from preventable harm. In this light, it would be negligent not to respond to factors that can be predicted to contribute to the spread of disease.
TB Research

Defining research and distinguishing it from other activities such as public health surveillance is an area in which further guidance may be useful. Even if an activity is not technically considered research, some of the principles of research ethics may still be relevant.

Guidelines for research on TB can draw on principles of research ethics already articulated in other documents, including guidelines by WHO and UNAIDS on research with HIV (UNAIDS/WHO 2007; UNAIDS/AVAC 2007). As these documents recognize, a key element of ethical research is ensuring civil society participation in the design and implementation of research plans. WHO can play an important role in this process.

Recent areas of controversy in research ethics include the use of placebos and the obligations of research sponsors to care for participants after the study is over. Some commentators believe that the Declaration of Helsinki’s provisions in these areas are overly vague. Other groups, including the Brazilian Medical Council, have taken stronger positions against placebo use when effective treatments for a condition are known to exist.

The UNAIDS guidance document on research ethics in biomedical HIV prevention trials (UNAIDS/WHO 2007) provides that trial participants who acquire HIV during the course of a prevention trial should be guaranteed access to the best proven HIV treatment. Some Task Force members suggested that a similar requirement would be appropriate in the context of TB.

Members emphasized that many of the critical issues in TB research are not related to clinical trials (in view of the scarcity of new TB drugs in the pipeline and the lack of relevant experiments in recent decades), but to epidemiological research with medical records and blood samples. With these types of research, a critical issue is determining in what circumstances informed consent should be waived. Most groups that have considered the issue have concluded that where the effort to obtain consent would make the research impossible, and there is no real risk to the subjects of the research, waiving informed consent can be authorized by the research ethics committee. Another option would be to provide an opt-out mechanism for individuals who do not want to participate, rather than requiring affirmative consent.

One member noted that, while very few clinical trials of new TB drugs are taking place, clinical research is still important with respect to new diagnostic tools, and that it is hoped that there will be more new drug trials in the future. Thus, ethical issues related to clinical trials cannot be avoided in the area of TB. In addition, intellectual property issues also need to be addressed.

One member argued that it does not make sense to introduce a new drug into a broken health-care system that cannot ensure that the drug will be prescribed and used properly, as resistance is bound to develop. Yet if a clinical trial of a drug is conducted in such a country and the drug proves to be effective, there will be strong demand in that country for access to the drug. To avoid this situation, it may be appropriate to restrict clinical trials of TB drugs to countries that have the capacity to introduce the drug.
without promoting resistance, and to aim to provide adequate care everywhere so as to have newly developed drugs available to all who need them.

In response, another member stated that, rather than denying such countries the opportunity to participate in clinical trials, such countries should be given the support necessary to help them introduce new drugs properly. He stated that research should be conducted where there is a need, not simply in ideal settings.

Similarly, some members argued that it is ethically appropriate to conduct epidemiological research on MDR-TB, such as drug resistance surveys, even in contexts in which high-quality treatment is unavailable. The results of this type of research can be used for advocacy purposes, even if immediate treatment is unavailable.

One member commented that modern principles of research ethics emerged in a context that was not focused on infectious diseases. This inattention explains why certain issues have been neglected in research ethics, including the question of protecting persons not involved in the research (e.g. third-party contacts of research subjects) from infection. The development of guidelines on TB research provides an opportunity to address these issues.

One member suggested that guidelines on TB research would present a good opportunity to emphasize the importance of conducting international collaborative research in a manner that ultimately helps low- and middle-income countries develop the capacity to do research themselves.
References

UNAIDS/AVAC. Good participatory practice: guidelines for biomedical HIV prevention trials. 

UNAIDS/WHO. Ethical considerations in biomedical HIV prevention trials. Guidance point 14, p. 48 
Annex I: List of selected questions considered by the Task Force

1. Diagnosis and treatment

Q: Should rapid diagnostic methods be deployed in the field when capacity to properly manage multidrug-resistant tuberculosis (MDR-TB), let alone quality-assured drugs, is not readily available?

Q: Should MDR-TB patients be treated at home while still infectious, when the alternative is hospitals that lack basic conditions to prevent transmission to other patients?

Q: Should people living with AIDS receive preventive therapy with isoniazid despite the probable increase in resistance to a major drug to treat TB?

Q: Should treatment, the only option for a patient to survive, be stopped after treatment failure according to guidelines and all drug treatment options have been exhausted? Problem: “Late responders”, heavy side effects, high costs.

Q: Should treatment be denied to patients in whom treatment is very likely to fail or adherence is virtually impossible (for example, refugees and migrants)? Who is starting treatment, using which guidelines? Will facilities refuse treating these patients as they: will likely threaten the ability to reach outcome targets or might squander limited drug supplies?

Q: Should treatment be offered when both patient and health services lack capacity to implement the basic measures to prevent drug resistance, such as social support to promote adherence, quality assured drugs, guidelines for management, or lack of trained staff? Which of the following options is preferable?

Option 1: Start now with whatever you have

Option 2: Wait until you have full range of services available to ensure proper treatment.

Q: What practice is ethically acceptable regarding patients who are still infectious, but do not have any treatment option, either because there is no capacity in place or because all treatments have failed and there is no further treatment option: isolation in health-care facility until death, outpatient palliative care, or other options?
Q: Should policies be promoted to stop practices and products for which there is not yet evidence of efficacy and effectiveness?

2. Public health measures

Q: Under what conditions it is acceptable from an ethics and human rights perspective to isolate and treat patients with MDR-TB and extensively drug-resistant (XDR) TB against their will? (The focus is on systematic isolation due to lack of diagnostics, as opposed to non-compliant patients.)

Q: Should research be done, such as drug resistance surveys into MDR-TB and XDR-TB, if treatment is not available?

3. Health-care workers, patients and communities

Q: Can HIV positive health-care workers be expected to work with patients with suspected TB or MDR-TB?

Q: Can family members be held responsible for delivering directly observed treatment to TB patients?

4. Research and partnerships

Q: What are the standards of care in clinical TB research, in particular with regard to MDR-TB and XDR-TB?
Annex II: List of participants

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* Invited but unable to attend.
Annex III: Agenda

Sunday, 07 December 2008

18h00-19h00 Pre-meeting of facilitators and authors of discussions papers

Monday, 08 December 2008

08h30 Registration

09h00 Welcome and introductions (JCB, WHO)
Objectives of the meeting, outline of process
Designation of the Chairs of the Task Force and the sessions

09h30 Update on the Global TB pandemic and Stop TB Strategy
Introduction to MDR-TB/XDR-TB:
Epidemiological situation and programmatic response

10h00 Presentation and discussion of Paper One: Diagnosis and treatment:
Main points to be elaborated and/or investigated through case studies for
policy and technical guidance, including the MDR-TB treatment guidelines

10:30 Refreshment break

11:00 Discussion continued

13h00 Lunch break

14h30 Presentation and discussion of Paper Two:
Obligations and rights of health-care workers, patients and communities
Main points to be elaborated and/or investigated through case studies for
policy and technical guidance, including the MDR-TB treatment guidelines

16h00 Refreshment break

16h15 Discussion continued

17h00 Conclusion of session

17h30 Reception with the Dean of the Faculty of Medicine of the
University of Toronto
Tuesday, 09 December 2008

8h30  Presentation and discussion of Paper Three: Public health measures
      Main points to be elaborated and/or investigated through case studies for policy and technical guidance, including the MDR-TB treatment guidelines

10h00  Refreshment break

10h30  Discussion continued

12h00  Lunch break

13h30  Presentation and discussion of Paper Four: Research and partnerships
      Main points to be elaborated and/or investigated through case studies for policy and technical guidance, including the MDR-TB treatment guidelines

15h00  Refreshment break

15h30  Discussion continued

17h00  Conclusion of session
      (Possibility: 1 hour presentation of potential case studies)

Wednesday, 10 December 2008

8h30  Plenary discussion:
      Review of principal conclusions/recommendations for discussion papers, case studies, and technical guidance documents

10h30  Refreshment break

11h00  Plenary discussion continued

12h30  Conclusion of the meeting