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Tuberculosis, ethics and human rights

Report of a regional workshop

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ABSTRACT

The *Consolidated action plan to prevent and combat multidrug- and extensively drug-resistant tuberculosis in the WHO European Region, 2011-2015* raises important ethical, human-rights and legal issues that need to be addressed. In 2010, WHO developed guidance on the ethics of tuberculosis prevention, care and control and, more recently, the Global Fund to Fight AIDS, Tuberculosis and Malaria published a strategic plan on the promotion and protection of human rights. The objectives of the Regional workshop on tuberculosis, ethics and human rights held at the WHO Regional Office for Europe on 16 October 2013 were to afford the countries the opportunity of sharing best practices and discuss ways of solving the human-rights and ethical problems related to the involuntary isolation and/or involuntary treatment of people with TB and M/XDR-TB and the compassionate use of new drugs. The workshop concluded that: involuntary treatment is not acceptable for any TB and M/XDR-TB patient; the involuntary isolation of TB patients should be considered as a last resort and only when other measures, such as decentralized treatment and adequate patient support, have failed; during the assessment of a patient in connection with possible involuntary isolation, consideration should be given to related country-specific requirements; WHO assistance would be required in a number of areas related to involuntary isolation; the compassionate use of new anti-TB drugs should be considered an urgent need in WHO European countries with a high burden of MDR-TB and XDR-TB; and that WHO assistance would be requested in a number of areas pertaining to the compassionate use of these drugs.

KEYWORDS

ETHICS
HUMAN RIGHTS
TUBERCULOSIS, MULTI-DRUG RESISTANT
TUBERCULOSIS, EXTENSIVELY DRUG-RESISTANT
PREVENTION & CONTROL

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Abbreviations

CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CHRB	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine
CRC	Convention on the Rights of the Child
ECHR	European Convention for the protection of Human Rights and Fundamental Freedoms
ECPT	European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment
ESC	European Social Charter
ICCCPR	International Covenant on Civil and Political Rights
ICERD	International Convention on the Elemination of All Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social and Cultural Rights
IHR	International Health Regulations
MDR-TB	multidrug resistant tuberculosis
MSF	Médecins Sans Frontières
TB	tuberculosis
UDHR	Universal Declaration of Human Rights
UNMD	United Nations Millennium Declaration
XDR-TB	extensively drug resistant tuberculosis

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Background

The *Consolidated action plan to prevent and combat multidrug and extensively drug-resistant tuberculosis in the WHO European Region 2011–2015 (1)* adopted by the WHO Regional Committee for Europe in September 2011 *(2)* foresees a set of activities for implementation by Member States, WHO and partners towards the achievement of universal access to the prevention, diagnosis, treatment and care of multidrug and extensively drug-resistant tuberculosis (M/XDR-TB). Providing unversal access provokes important issues ethical, human-rights and legal issues that need to be addressed, also in the light of the Health 2020 policy framework *(3)*, which aims to improve the health and well-being of populations, reduce health inequalities and ensure sustainable, people-centred health systems in the WHO European Region.

In 2010, the Global Tuberculosis Programme and the Department of Ethics and Social Determinants of WHO developed guidance on the ethics of tuberculosis prevention, care and control *(4)*. More recently, the Global Fund to Fight AIDS, Tuberculosis and Malaria published a strategic plan, one of the five objectives of which is to promote and protect human rights *(5)*. As the voices of the most vulnerable and affected are being heard much more widely, countries are improving their ethical standards and upholding human rights. It is essential that these experiences be documented and shared so that national tuberculosis (TB) programmes may learn from them and address the social determinants and downstream risk factors of TB more adequately.

Introduction

The main purpose of the workshop was to assist national TB programmes in priority countries of the Region in further promoting human rights and practices based on sound ethical standards in the management of M/XDR-TB.

The objectives of the workshop were:

- to share best practices in designing and implementing the involuntary isolation and/or involuntary treatment of TB and M/XDR-TB and the compassionate use of new drugs; and
- to discuss solutions to human-rights and ethical problems related to TB- and MDR-TB prevention, diagnosis, treatment and care.

The expected outcomes of the workshop were:

- an improved awareness of the human-rights and ethical dimensions of M/XDR-TB prevention and care;
- the identification of strengths and weaknesses in current national laws/regulations and practices related to involuntary isolation, involuntary treatment and the compassionate use of new drugs for TB and MDR-TB; and

- the identification of opportunities for aligning TB and MDR-TB prevention, diagnosis, treatment and care with international standards based on sound ethics and human rights.

In opening the workshop, Dr Guénäel Rodier, Director, Division of Communicable Diseases, Health Security and Environment, WHO Regional Office for Europe, welcomed the participants (Annex 2), mentioning that this was the first meeting of its kind to be organized by and held at the WHO Regional Office for Europe. Dr Rodier emphasized that, apart from the technical and operational issues related to the prevention and treatment of tuberculosis (TB) and M/XDR-TB, there were important human-rights and ethical issues to be considered. He informed the participants that the outcome of the meeting could also have implications for the prevention and treatment of other diseases, such as HIV.

Dr Masoud Dara, Programme Manager, Tuberculosis and Multidrug-Resistant Tuberculosis, WHO Regional Office for Europe, also welcomed the participants and invited them to introduce themselves. He pointed out that only 7[1] of the 18 high-priority countries[2] were represented at the workshop in order to ensure that all participants would have the opportunity to contribute to the discussions. The meeting was also attended by three experts who held presentations, two observers, and staff of the WHO Regional Office for Europe and WHO headquarters.

Dr Dara stated that challenges in the area of TB and M/XDR-TB prevention and control differ from country to country but that it was nonetheless important that each country found the balance between patients' rights and public health requirements. He encouraged the participants to share their experiences and offer any suggestions that could be of inspiration to other countries.

Dr Pierpaolo de Colombani, Medical Officer, Tuberculosis and Multidrug-Resistant Tuberculosis, WHO Regional Office for Europe, presented the objectives and the provisional programme of the workshop (Annex 1).

WHO perspective on ethics and human rights in the management of MDR-TB

Following the emergence of MDR-TB, and as an aid to protecting public health and the individual, WHO published *Guidance on ethics of tuberculosis prevention, care and control (4)* in December 2010. The document is based on the work of the WHO Task Force on Addressing Ethical Issues in TB Care and Control Programmes[3] and broad consultations with experts and stakeholders. It is not set up like a treatment guideline but defines generic principles for each

[1] Armenia, Azerbaijan, Belarus, Estonia, Georgia, Republic of Moldova and Ukraine.
[2] Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, the Republic of Moldova, Romania, the Russian Federation, Tajikistan, Turkey, Turkmenistan, Ukraine and Uzbekistan.
[3] The WHO Task Force on Addressing Ethical Issues in TB Care and Control Programmes was established jointly by the Ethics and Health Team of the Department of Ethics, Equity, Trade and Human Rights and the Stop TB Department of WHO in 2008.

country to consider in deciding policy. Ethical issues are complicated: a decision taken in one country may not be applicable in others.

Despite these diversities, there is agreement on the principles of equity, solidarity, authonomy of the patient and reciprocity as listedin the above-mentioned WHO guidance document *(4)*, among others.

During the workshop, the major ethical issues discussed included: the obligation to provide care, including social support in adhering to treatment; the obligation not to abandon patients, also when treatment fails; the gap between the diagnosis and treatment of MDR/XDR-TB; and the exposure of health-care workers to TB infection and their rights to adequate protection.

WHO's position on the involuntary isolation and treatment of TB patients is that it is rarely justified and should always be seen as the very last resort when all other options have been exhausted. WHO recommends providing different treatment and care options before considering involuntary isolation. Moreover, isolation settings must be adequate and human-rights and ethical norms respected. The decision for involuntary isolation must be reviewed periodically (e.g. at monthly intervals) to consider any new factors.

A human-rights-based approach to TB should: put the individual at the centre of any health policy; identify and support the most marginalized and vulnerable; address the related socioeconomic determinants and their implications for human rights; overcome institutional constraints and capacity gaps preventing individuals and groups from fulfilling their rights; support an integrated response to TB; provide accountability mechanisms; and create a platform for documenting and sharing best practices.

International treaties, conventions and declarations

An overview of Member States' obligations under international law on human rights was presented based on: international treaties, conventions and declarations; national constitutions; and the interpretation of case law by courts and human-rights treaty bodies. Annex 2 to this report provides more details.

The specific international treaties, conventions and declarations of reference are the following:

- *The Universal Declaration of Human Rights* (UDHR) (1948), the preamble of which states: "… the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women …" *(6)*;
- *Convention for the protection of Human Rights and Fundamental Freedoms* (1950)/*European Convention on Human Rights* (ECHR) (2010) *(7)*;
- *European Social Charter* (ESC) (1961, revised 1996) *(8)*;
- *International Convention on the Elimination of All Forms of Racial Discrimination* (ICERD) (1965) *(9)*;
- *International Covenant on Civil and Political Rights* (ICCPR) (1966) *(10)*;
- *International Covenant on Economic, Social and Cultural Rights* (ICESCR) (1966) *(11)*;

- *Convention on the Elimination of All Forms of Discrimination against Women* (CEDAW) (1979) *(12)*;
- *European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment* (ECPT) (1987) *(13)*;
- *Convention on the Rights of the Child* (CRC) (1989) *(14)*;
- *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (CHRB) (1997) *(15)*.

Human rights at stake in the management of MDR-TB are: the right to life,[4] the right to liberty and security of person,[5] the right not to be subjected to torture or to cruel, inhumane or degrading treatment,[6] the right to respect for private and family life,[7] and the right to health.[8] Moreover, human rights are universal, as evidenced by the following documents and other enforceable human-rights treaties at the international and regional levels.

- *United Nations Millenium Declaration* (Resolution A/Res/55/2) (2000) *(16)*:

> *24. … spare no effort to promote democracy and strengthen the rule of law, as well as respect for all internationally recognised human rights and fundamental freedoms, …;*
>
> *25. … resolve therefore to respect fully and uphold the universal declaration of human rights ... [and] ...to strive for the full protection and promotion in all our countries of civil, political, economic, social and cultural rights for all.*

- *International Health Regulations (2005)* (IHR), Article 3 *(17)*:

> *(1) The implementation of these regulations shall be with full respect for the dignity, human rights and fundamental freedom of persons. (2) The implementation of these regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization. (3) The implementation of these regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease.*

Table 1 gives an overview of the treaties and conventions ratified by the countries represented at the workshop. Most are Member States of the Council of Europe. The human rights included in their national constitutions are listed in Table 2.

[4] UDHR, Article 3 *(6);* ECHR, Article 2 *(7)*; ICCPR, Article 6 *(10)*.
[5] UDHR, Article 3 *(6)*; ECHR, Article 5 *(7)*; ICCPR, Article 9 *(10)*.
[6] Universal Declaration of Human Rights (UDHR), Article 5 *(6);* ECHR, Article 5 *(7)*; ICCPR, Article 7 *(10)*; CEDAW, Article 12 *(12)*.
[7] ECHR, Article 8 *(7)*; ICCPR, Article 17 *(10)*.
[8] UDHR, Article 25(1) *(6)*; ICESCR, Article 12 *(11)*; CRC, Article 24 *(14)*; ICERD, Article 5 *(9)*; CEDAW, Article 12 *(12)*.

Table 1. Countries (relevant to workshop) party to international treaties and conventions on human rights

International law on human rights	Country							
	Armenia	Azerbaijan	Belarus	Estonia	Georgia	Republic of Moldova	Russian Federation	Ukraine
CEDAW	yes	yes	yes	yes	yes	yes	yes	yes
CHRB[a]	no	no	no	yes	yes	yes	no	no
CRC	yes	yes	yes	yes	yes	yes	yes	yes
ECHR[a]	yes	yes	no	yes	yes	yes	yes	yes
ESC[a]	no	no	no	no	no	no	no	no
ECPT[a]	yes	yes	no	yes	yes	yes	yes	yes
ICCPR	yes	yes	yes	yes	yes	yes	yes	yes
ICERD	yes	yes	yes	yes	yes	yes	yes	yes
ICESCR	yes	yes	yes	yes	yes	yes	yes	yes

[a] Treaties under the Council of Europe.

Table 2. Human rights included in constitutions of countries relevant to workshop

National constitutions	Country							
	Armenia	Azerbaijan	Belarus	Estonia	Georgia	Republic of Moldova	Russian Federation	Ukraine
Right to life	Art. 15	Art. 27 I	Art. 24	§16	Art. 15, No. 1	Art. 24	Art. 20 No. 1	Art. 3 I
Freedom from torture	Art. 17	Art. 46	Art. 25 III	§18	Art. 17, No.2	Art. 24 II	Art. 21	Art. 28
Right to individual liberty/security	Art. 16	Art. 28 I	Art. 25 I	§20	Art. 18, No. 1 Art. 22	Art. 25 I Art. 27	Art. 22	Art. 29, 33
Right to private/family life	Art. 23	Art. 17 Art. 31	Art. 32	§26	Art. 20, No. 1 Art. 36, No.2	Art. 28	Art. 23	Art. 32 I
Reference to IHR treaties	Art. 3 Art. 14	Art.1 Art. 12 Art. 24	Art. 8 Art. 21	§3 §123	Art. 6 II Art. 7	Art. 4 Art. 8	Art. 2 Art. 17, No.1 Art. 45 Art. 55	Art. 9, No.1, Art. 21 Art. 22
Right to health	_	Art. 41 I	Art. 21 Art. 45 I	§28	_	Art. 36, No. 1	Art. 7, Art. 41, No. 1 Art. 38	Art. 3 Art. 49
Access to health care	Art. 38	Art. 41 I, II	Art. 45 II	§28	Art. 37 No. 1 Art. 51 No. 1	Art. 36 Art. 47	Art. 41, No. 1	Art. 49
Health care security system	Art. 37 Art. 48, Nos 1, 4, 7, 12	Arts 38, 41 II	Art. 45 I	§28	Art. 37, No. 1, Art. 50, No. 1	Art. 36 Art. 47	Art. 39	Art. 46 Art. 49

Involuntary isolation and treatment

Detention, i.e. quarantine and isolation, is interpreted as the deprivation of liberty but is not necessarily a violation of the right to liberty because this right is not absolute. ICCPR, Article 9, states: "No one shall be deprived of his liberty except on such grounds and in accordance with such procedure as are established by law" *(10)*; hence, reasons for arrest and detention must be

prescribed by law. It also states: "Anyone who is deprived of his liberty by arrest or detention shall be entitled to take proceedings before a court, in order that that court may decide without delay on the lawfulness of his detention…" *(10).*

Furthermore, according to the *The Siracusa principles on the limitation and derogation provisions in the International Covenant on Civil and Political Rights*:

> *Public health may be invoked as a ground for limiting certain rights in order to allow a state to take measures dealing with a serious threat to the health of the population or individual members of the population. These measures must be specifically aimed at preventing disease or injury or providing care for the sick and injured (18).*

These provisions are accepted in practice as permissible reasons for detention.

Decisions on the involuntary isolation of patients must be reviewed by a court. The Siracusa principles *(18)* summarize the conditions required for doing so as follows.

> *The decision must be strictly necessary (to respond to a pressing public or social need) in a democratic society (a society which recognizes and protect human rights), pursue a legitimate aim (protection of health of the individual and the society), and be proportionate to that aim (the least restrictive and intrusive means available).*

The conditions under which involuntary isolation may be invoked have been confirmed by the European Court of Human Rights and the Human Rights Committee, which is in charge of monitoring the implementation of the rights guaranteed by ICCPR *(10).*

In one case, *Enhorn vs Sweden* (2005) *(19)*, the European Court of Human Rights had to decide whether detention of the patient was a violation of ECHR, Article 5 (on the right to liberty and security) *(7).* The national court had ruled that detention of the patient was not in violation of the right to liberty but that it was justified in that it was relevant to public health (namely, to prevent the spread of infectious diseases, in this case HIV) and proportionate to the aim (other measures taken having been insufficient). The Court did not agree with this interpretation and concluded that involuntary isolation had not been the last resort and had violated the liberty of the applicant as the public authorities had not offered any alternative.

As regards involuntary treatment, which relates mainly to human-rights issues in the context of involuntary isolation, very exceptional circumstances are required to deviate from the general principle of not initiating medical treatment without consent. The general rule of patient consent is enshrined in many provisions of human rights law, including ECHR, Article 8 *(7)* and ICCPR, Articles 1, 7, 9 and 17 *(10).*

Compassionate use of new drugs

In connection with the human-rights aspect of the compassionate use of (and extended access to) non-marketed drugs, so far, no human-rights guarantee has been interpreted as an obligation imposed on government authorities to ensure access to unauthorized medicinal products (i.e. products that have not been tested for their quality, efficacy and safety) for terminally ill patients. In a recent case, *Hristozov and others vs Bulgaria* (2012) *(20)*, the European Court of Human Rights decided that the refusal of the Bulgarian authorities to authorize access to a product, the safety and efficacy of which were still doubtful for terminally ill patients, did not violate the right to life (ECHR, Article 2 *(7)*) or the right to private and family life (ECHR, Article 8 *(7)*). The Court also concluded that ECHR, Article 3 *(7)* had not been violated; the consequences of the authorities' refusal to authorize access to the product had not been severe enough to characterize their decision as inhuman treatment. However, the Court recalled that the positive obligations under ECHR, Article 2 *(7)* may includethe duty to establish an appropriate legal framework in the field of health care *(20)*.[9]

Discussion on involuntary isolation and treatment

Involuntary isolation and treatment: best practice in Estonia

The Estonian experience in the area of involuntary isolation and treatment presented below is also documented in the compendium, *Best practices in prevention, control and care for drug-resistant tuberculosis (21)*, recently published by the WHO Regional Office for Europe.

In Estonia, involuntary isolation and treatment are only permitted in the management of mentally ill persons who are dangereus to themselves or others. During the period 1998–2003, the annual number of MDR-TB cases diagnosed in Estonia was around 100 out of a total of 700–800 registered cases of TB. In 2012, 47 of the 290 registered cases were MDR-TB. For the first time, the incidence rate had fallen to below 20 new TB cases per 100 000 people.

Involuntary isolation was introduced in 2004, particularly for the management of patients with alcohol or drug addictions who represent more than 80% of the cases where it is applied. It took many years for the Parliament to accept the need for legislation on involuntary isolation, which was the only option available for the management of patients repeatedly defaulting TB treatment and thus creating a risk for themselves and others.

Before the introduction of involuntary isolation in Estonia, the National TB Programme offered flexible, patient-friendly TB-treatment options free of charge through ambulatory or home care and, since 1999, has provided incentives and social support in connection with TB treatment. A "treatment contract" is used and patients are advised on the consequences of non-adherence. A documented history of non-adherent behaviour (e.g., treatment default, alcohol/drug abuse) is

[9] Hristozov and others vs Bulgaria: Judgment (Merits and Just Satisfaction) § 108 *(20).*

important in providing sufficient evidence and establishing grounds for issuing a court order on treatment and involuntary isolation. The decision to seek a court order for involuntary isolation must be made by a physician on the basis of a medical examination and initial laboratory and x-ray analyses. According to chapter 2, paragraphs 4 and 5, of the Estonian Act on the Prevention of Communicable Diseases (2003) *(22)*, the involuntary isolation of infectious TB patients must be backed by a court order and can last for up to 182 days. A court order can only be issued on the basis of a written statement from a physician indicating that the person poses a threat to public health. For practical reasons, the physician may wish to ensure that the patient remains in hospital for up to 48 hours to allow time for the documents to be signed and sent to the court.

In Estonia, the facilities for involuntary isolation are located in the TB Department of the Psychiatric Clinic at Viljandi Hospital. The Department is financed from the Estonian Health Insurance Fund and the state budget. The rooms are of a high standard, accommodating one or two patients, and each has separate sanitary facilities. The Department is divided into three zones according to infectiousness status (smear+/culture+, susceptible TB and MDR-TB) to avoid hospital reinfection. Patients can walk about freely in the ward and the other rooms in their zone. At same time, all doors between zones and to exit the Department are operated by an electronic-card sytem. Patients are allowed to walk outdoors in a fenced garden area three times a day. Some patients are even willing to stay in this ward when involuntary isolation is no longer required. On rare occasions patients manage to escape, in which case a new court order is issued and a police search initiated.

The system of involuntary isolation also works as a prophylactic measure as it is common knowledge among TB patients that they will be isolated if they fail to follow the rules. Since 2004, 140 TB patients have been involuntarily isolated in the hospital; currently there are 7. Treatment results for these patients are as follows:

- drug-susceptible TB: 98.2% success rate; only one death;
- MDR/XDR-TB and other drug-resistant foms of TB: 66.7% success rate; 8.3% defaults; 23.6% deaths (from TB or other causes); 11 patients still on treatment; all treatment interruptions and majority of deaths occurred after discharge.

In conclusion, the legislation on involuntary isolation *(22)* is a help in the treatment of TB in Estonia. The overarching principle is to show the patients respect. In applying involuntary isolation, human rights and ethical principles must be adhered to, and this encompasses all possible treatment options for TB and co-morbidities. Involuntary isolation for 182 days is sufficient to achieve recovery for patients with drug-susceptible TB and in most cases helps achieve smear/culture conversion for MDR-TB patients. For patients with problems relating to alcohol and drug abuse, psychiatric and medical treatment and methadone substitutional therapy are provided simultaneously in the institution in question. Involuntary isolation and the consequent TB treatment have been positive for the following reasons: all of the treatment options are available; the legal basis has been established; there are excellent measures for

controlling infection;, staff receive training on an ongoing basis; and last, but not least, staff show respect for the patients' dignity.

In Estonia, the option of involuntary isolation is only used when it is possible to treat the patients, the purpose being to treat them not isolate them from the rest of the society. In the case of patients with XDR-TB, and in other special circumstances, it is possible to ask the court to extend the isolation period beyond 182 days.

One of the participants raised a question concerning the management of patients in involuntary isolation who refuse to be treated. The response was that almost all patients do accept treatment (to end their involuntary isolation); in cases where patients do not, the court would normally rule that they be discharged. Also, patients undergoing treatment who wish to be treated at home can do so as ambulant patients. Those without homes may stay in hospital. Patients are aware that if they do not adhere to treatment and remain infectious, they will be involuntarily isolated again.

In response to a question about patient rights, it was explained that patients are entitled to a lawyer if they have complaints. However, it can be difficult to persuade lawyers to visit the hospital because of the risk of infection. Furthermore, patients are allowed to leave the hospital accompanied by a nurse, for instance, to go to the bank. Alcohol is not allowed on hospital premises.

The procedure and criteria for involuntary isolation in Estonia were also discussed. There are no specific criteria for recommending involuntary isolation to the court. The decision is taken by the treating physician and sometimes the case is referred to a council established by the Ministry of Health comprising 5–6 members. The council often consults the hospital administration regarding approval of involuntary isolation. There is no automatic procedure for approving involuntary isolation for medical reasons and each case is decided individually.

Conditions in Estonia are much the same as in the other countries represented at the workshop: many of the patients defaulting from treatment can be characterized as "difficult" and there are complex cases involving alcohol or drug addiction, HIV infection or other comorbidities. However, involuntary isolation requires the hospital to have efficient infection control measures and some countries were challenged in this respect. It was recommended that involuntary isolation only be used when proper infection-control measures are in place. The alternative is home care with daily visits by medical staff.

Presentation of the working group on involuntary isolation and treatment

Some countries have legislation on involuntary isolation, others do not. Some of those countries with legislation do not put it into practice. The working group agreed that even if other options for outpatient treatment are lacking, involuntary isolation should never be a substitute for them. Providing patients with psychological and social support is necessary to prevent the spread of TB

and avoid high rates of non-adherence and isolation. Tailored programmes on the provision of social support to TB patients with alcohol and drug problems and to sex workers should also be available but many countries lack the necessary financial resources.

Armenia

Legislation on involuntary isolation has been adopted but enforcement procedures have not been established and Armenia has no special facilities for involuntary isolation due to a lack of financial resources. In addition, involuntary isolation is not seen as the right approach. Currently home treatment is offered but some patients discontinue it. An investigation needs to be carried out into whether public rights are being violated in such cases. As there is no mechanism for compelling patients continue treatment, it would be beneficial if Armenia could receive support in introducing and implementing the legislation on involuntary isolation.

Azerbaijan

Azerbaijan has no specific legislation on involuntary isolation but clinical guidelines exist, specifying grounds for hospitalization. It is considered that involuntary isolation is a necessity and should be supported by law. TB patients are hospitalized but some do not adhere to treatment and are difficult to manage. These patients are seen as bad role models for other TB patients and they spread the disease; therefore, a separate hospital department is needed for them. The TB clinic in Baku had 56 new cases of TB last year, 86% of which were treated successfully; 5–6% were MDR-TB cases and the percentage is increasing.

Belarus

Involuntary isolation is used in Belarus, which has special legislation and experience in using it. There are, however, some weak points. Belarus does not have enough preventive measures and outpatient treatment mechanisms are not properly developed. Guidelines on the coordination of treatment exist and the Ministry of Health is developing treatment algorithms. One important aspect is that patients in involuntary isolation feel victimized; they do not understand that it is necessary. Although the number of TB and MDR-TB patients in the country is decreasing, it is still quite high. Since many of these patients default treatment, they are concentrated in special facilities for involuntary isolation and treatment. Physicians need training in how to educate patients about their disease and motivate them to adhere to treatment. An external review of the National TB Programme in 2012 resulted in specific recommendations on how to improve adherence to treatment and decrease involuntary isolation.

Georgia

Current legislation in Georgia does not envisage involuntary isolation for TB patients. The Parliamentary Committee for Health and Social Issues has recently initiated the development of the legislative amendments aimed at strengthening TB control. The legislation, if enacted, will ensure a balance between the rights of the patient and the rights of the population and consider involuntary isolation as the last resort for TB patients who refuse or fail to adhere to treatment.

Republic of Moldova
The Republic of Moldova has legislation on involuntary isolation, which was revised in 2012 and is considered to be respectful of human rights. It encompasses a schedule for providing TB patients with information about their disease; reasons for refusing to comply with treatment must be discussed with a social worker and the patient referred to outpatient care centres to ensure TB management. Detaining the patient for treatment is the last resort. However, due to lack of financial resources, not all of the options available are used to motivate patients to adhere to treatment. There are no dedicated facilities for the involuntary isolation of TB patients, when this is necessary in addition to social support.

Ukraine
In Ukraine, the legislation on involuntary isolation was revised in March 2012. In 2011, 600 TB patients were placed in involuntary isolation; in 2012, the number was 2000. Involuntary isolation is not practised in all regions of the country. Where it is used, there are special hospital units for this purpose but, because of the present economic crisis, the number of these facilities cannot be expanded. More mechanisms are needed for determining how and when to use involuntary isolation. Ukraine would appreciate support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (similar to that afforded for the treatment of people with HIV). In addition to financial support, Ukraine needs assistance in establishing algorithms for treatment at the different stages of the disease, and for psychological and social pateint support.

Conclusions of the working group on involuntary isolation

Ways and means of preventing, diagnosing and treating TB and M/XDR-TB and the level of psychological and social support available to patients vary greatly between countries, each of which has different needs. The countries would appreciate WHO support in: developing guidelines on psychological and social support, staff training, and diagnosis and treatment algorithms for specific groups of patients; accessing information about best practices, such as that in Estonia; organizing country missions to assess and revise existing legislation; establishing a checklist of measures to be taken before deciding to isolate TB patients; and conducting cost-effectiveness studies on the different approaches to managing the disease (ambulatory care with patient support, hospital care, involuntary isolation).

Discussion on the compassionate use of new anti-TB drugs

Compassionate use of new anti-TB drugs: best practice in Armenia

Armenia's experience in the compassionate use of new anti-TB drugs presented below is also documented in the compendium, *Best practices in prevention, control and care for drug-resistant tuberculosis*, recently published by the WHO Regional Office for Europe *(21)*.

TB morbidity and mortality rates are decreasing in Armenia. The treatment success rate among new smear patients was 77% in 2011, an increase from 72% in 2010. The use of new anti-TB drugs for compassionate treatment is recommended by WHO.

A pilot project was started in 2012 involving the use of new drugs (Bedaquiline, Linezolid and Imipenem) made available through support from Médecins Sans Frontières (MSF). A confidentiality agreement between the National TB Programme and Janssen Research & Development (USA) was signed in October 2012 for Bedaquiline. By February 2013, 23 patients were enrolled in the project and 16 started treatment in April; currently, 7 patients are still waiting for drugs to become available. The enrolment criteria were: (i) that the patient was suffering from either XDR-TB or pre-XDR-TB, i.e., the patient could not be treated so the condition was life-threatening; (ii) that the patient's clinical condition was deteriorating; (iii) that the patient was 18 years of age or older; and (iv) that female patients were not pregnant and using adequate contraceptive measures. The selection criteria for treatment were decided by the National TB Programme in consultation with MSF, other partners, and the Medical Health Committee of the Ministry of Health, which included TB experts. The patients were required to give their written consent to participating in the project; the final selection of patients was approved by Janssen Research & Development.

Bedaquiline and Linezolid are administered orally, whereas Imipenem is administered through an in-dwelling intravenous (IV) line, such as a port-a-cath. IV administration raises some operational challenges: staff working hours need to be adapted to accomodate a twice-daily drug intake at 10-hour intervals. In additon, some patients receive ambulatory treatment. Progress is followed through daily clinical assessments over the first two weeks, followed by weekly assessments for a period of two months.

It is hoped that this project will contribute to increasing Armenia's success rate in the treatment of XDR-TB patients, and provide the relevant staff with the skills necessary for following the new treatment approaches and training in monitoring and reporting on adverse drug events. Although it is too early to drawn any conclusions, the project results look promising.

The new drug, Bedaquiline is used in association with all available drugs without a resistance pattern and patients receive the second daily injection of the drug at home after discharge from hospital. Adverse reactions to the drug are monitored through completion of a designated form and entry of the information in a specific database.

In Armenia, the rate of MDR-TB among new patients is 9.5% while that among previously treated patients is 43%. In comparison, the same rates in, for example, Georgia, are 9.2% and 31%, respectively.

The question of marketing authorization was raised. It was explained that the ethical issues related to the use of Bedaquiline had been considered thoroughly, initial discussions having started a year before the study began, and the Armenian Ministry of Health had issued relevant guidelines. The use of Bedaquiline is an interim measure but it is hoped that by obtaining marketing authorization it may be included in the Armenian list of drugs approved for the treatment of XDR-TB. Data on the use of bedaquiline in treating patients over a 6-month period are available and more will be available for presentation/publication in the future. These data may be the evidence required to obtain marketing authorization.

Presentation of the working group on the compassionate use of new drugs

Whether potentially life-saving drugs should be administered to XDR-TB and potential XDR-TB patients without evidence that they are safe is an ethical and a clinical dilemma. Each country must create its own legal framework. WHO could provide support to countries wishing to introduce the compassionate use of new anti-TB drugs.

Besides Armenia, two more of the countries participating in the workshop (Belarus and Georgia) have programmes on the compassionate use of new anti-TB drugs.

Armenia

Initiating the compassionate use of drugs was a challenge in the beginning because of the differences in opinion of the stakeholders. A study protocol was presented to the Ethics Committee of the Ministry of Health. MSF was a key partner in facilitating the process and this, along with the fact that bedaquiline had been approved by the United States Federal Drug Administration, meant that obtaining drug authorization was not a problem. Drugs can be used during a clinical study without country registration. This was the first project on compassionate use to be undertaken in Armenia.

Azerbaijan

Azerbaijan would like to develop a protocol on the compassionate use of new anti-TB drugs and would need WHO support.

Belarus

A workshop was held in August 2013 with WHO assistance to assess the current capacity for and needs in diagnosing and treating XDR-TB patients, as well as conducting pharmacovigilance. As a result, the National TB Programme submitted an application to the manufacturer of Bedaquiline (Janssen Research & Develæopment) along with a study protocol. Approval is pending.

Georgia

Since 2011, twelve patients have benefitted from the compassionate use of drugs. Bedaquiline is imported and used in accordance with the relevant Georgian legislation, and taking into account the individual needs of patients and upon their informed consent.

Republic of Moldova

There is no programme on the compassionate use of drugs in the Republic of Moldova. The legislation does not allow for the use of drugs, which are still in the research phase; unapproved drugs may only be used in clinical trials. The first step towards introducing compassionate use in the Republic of Moldova would be to negotiate a modification of the current legal framework with the stakeholders. WHO could assist in presenting the case by designing an operational framework and organizing a workshop involving the stakeholders.

Ukraine

The many MDR-TB and XDR-TB patients in Ukraine constitute a huge problem.There is no legal framework for the compassionate use of drugs and the introduction of one new drug will not solve the problem; more are needed. The first issues to be addressed in connection with the compassionate use of drugs would be, for example, the criteria for the selection of patients and ways of expanding access to new drugs from an ongoing clinical study. A workshop organized by the Ministry of Health and WHO to discuss these and other related issues could facilitate progress in the compassionate use of new drugs in Ukraine.

Conclusions of the working group on compassionate use of drugs

The WHO European Region has very high rates of MDR-TB and XDR-TB and, considering the prospective availability of additional new drugs over the next 5–10 years, there is a need in some countries to introduce legislation on the compassionate use of new anti-TB drugs. Patients are already seeking treatment outside their own countries. In the European Union, the basis for the compassionate use of drugs needs to be developed within 4–5 years. Currently, national regulatory authorities have to provide conditional approvals within interim operational frameworks.

The experience gained in Armenia was seen as an example of best practice to be followed by other countries. A workshop on pharmacovigilance will be organized in Copenhagen in 2014 along the lines of that held in Belarus. This will provide a very good opportunity for sharing experiences. Moreover, Azerbaijan, the Republic of Moldova and Ukraine consider it important that, as a next step, WHO organize similar workshops in their countries.

General conclusions and recommendations

The workshop proved to be very interactive and much appreciated and it was agreed that similar workshops of this kind are needed in the future. The following were the conclusions and recommendations of the workshop.

1. Involuntary treatment is not acceptable for any TB or M/XDR-TB patient. Involuntary isolation could be considered for selected patients.

2. The involuntary isolation of TB patients should be considered as a last resort and only when other measures, such as decentralized treatment and adequate patient support, have failed. Countries are encouraged to assess their legislation and bring it into line with international human-rights law adopted by most of the countries. This also applies to operational decrees enabling the implementation of legislation.

3. Countries have different ways and means of providing services for the prevention, diagnosis and treatment of TB and M/XDR-TB, and psychological and social support to TB patients. When assessing the need to isolate patients involuntarily, countries need to take their own specific requirements into account.

4. WHO assistance is requested in a number of areas related to involuntary isolation, namely in connection with: developing guidelines on psychological and social support, staff training, and algorithms for the diagnosis and treatment of specific groups of patients; sharing examples of best practices; organizing country missions to assess and revise existing legislation; establishing a checklist of measures to be taken before the involuntary isolation of a TB patient is decided; and conducting cost-effectiveness studies to produce evidence for policy-makers on ambulatory care with patient support vs hospital care vs involuntary isolation.

5. The compassionate use of new anti-TB drugs should be considered as being an urgent need in countries of the WHO European Region with a high burden of MDR-TB and XDR-TB. Operational legal frameworks and operational protocols for the safe use of new anti-TB drugs, which avoid the development of further drug resistance, should be developed and approved in each country.

6. WHO assistance would be appreciated in organizing intercountry workshops for sharing experiences and practices related to the compassionate use of new anti-TB drugs, as well as national workshops to indentify ways and means of applying to the manufacturers of new anti-TB drugs, and in preparing technical advice on intervention protocols and pharmacovigilance.

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Annex 1. Programme

Time	Topic	Facilitator/speaker
09:00 – 09:15	Welcome and introduction	Dr Guenael Rodier Director, Division of Communicable Diseases, Health Security and Environment, WHO Regional Office for Europe Dr Masoud Dara, Programme Manager, Tuberculosis & M/XDR-TB, WHO Regional Office for Europe
09:15 – 09:30	WHO's perspective on ethics and human rights in the management of MDR-TB	Dr Ernesto Jaramillo, Medical Officer, Global TB Programme, WHO headquarters Dr Andreas Reis, Technical Officer, Ethics and Social Determinants, WHO headquarters
09:30 – 09:45	Management of MDR-TB from a human rights perspective: obligations of states under international human rights law	Professor Stéphanie Dagron, Professor of Public Health Law, Institute of Law, Zurich, Switzerland
09:45 – 10:15	Discussion	Dr Pierpaolo de Colombani, Medical Officer, Tuberculosis & M/XDR-TB, WHO Regional Office for Europe
10:15 – 10:30	Involuntary isolation and treatment in Estonia	Dr Manfred Danilovits, Head, TB Department, Tartu University Clinics, Estonia
11:00 – 11:15	Compassionate use of new TB drugs in Armenia	Dr Armen Hayrapetyan, National TB Programme, Yerevan, Armenia
11:15 – 12:00	Discussion	Dr Pierpaolo de Colombani
13:00 – 13:15	Introduction to the working groups	Dr Pierpaolo de Colombani
13:15 – 15:00	Working groups: - Involuntary isolation - Compassionate use	 Dr Andreas Reis, Professor Stephanie Dagron Dr Ernesto Jaramillo, Dr Pierpaolo de Colombani
15:30 – 16:00	Reports of the working groups	
16:00 – 16:45	Discussion	Dr Pierpaolo de Colombani
16:45	Conclusions	Dr Masoud Dara, Dr Pierpaolo de Colombani

Annex 2. Participants

Country representatives

Armenia

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Invited speakers

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Rapporteur

Ms Karenlise Nielsen
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Annex 3. Management of MDR-TB from a human-rights perspective: obligations of states under international human-rights law

Professor Stéphanie Dagron, Faculty of Law, University of Zurich, Switzerland

1. Introduction

Public health ethics and human rights share common goals, namely, the protection of individual rights and the protection of the public, which constitute a collective benefit. These values have to be safeguarded, which implies the necessity of balancing individual rights on one hand and protecting the public on the other.

Guarantees of human rights may sometimes conflict with the mechanisms used and decisions taken in connection with diagnosing, treating and controlling MDR and XDR-TB. One example of such a conflict is when the detection of cases of MDR and XDR-TB occasions the implementation of extraordinary control measures, such as detention, quarantine or forced treatment, which usually constitute an infringement of a person's right to liberty and security.

The human rights most relevant to this discussion are: the right to life; the right to liberty and security; the right not to be subjected to torture or to inhuman or degrading treatment or punishment; the right to respect for private life and physical integrity; and the right to health.

2. International human-rights law

Each of these rights is enshrined in international and regional treaties. One of the most significant sources of international human-rights law is the Universal Declaration of Human Rights (UDHR) adopted in 1948 by the General Assembly of the United Nations *(a)*. This declaration has inspired the content of many other treaties adopted within the framework of the United Nations or at the regional level within the framework of other organizations, such as the Council of Europe. The most relevant human-rights treaties are: the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) *(b)*, the International Covenant on Civil and Political Rights (ICCPR) *(c)*, the International Covenant on Economic Social and Cultural Rights (ICESCR) *(d)*, the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) *(e)*, the Convention on the Rights of the Child (CRC) *(f)*, the Convention on the Rights of Persons with Disabilities *(g)*; and, at the regional level, the European Convention on Human Rights (ECHR) *(h)*.

Armenia, Azerbaijan, Belarus, Estonia, Georgia, the Republic of Moldova, the Russian Federation and Ukraine, are among the countries the States Parties to the above-mentioned international treaties. With the exception of Belarus, these countries are Member States of the Council of Europe and, as such, party to ECHR *(h)* and the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment *(i)*.

The obligations[10] of states parties take different forms, which are:

(i) to respect rights by desisting from passing laws that are, for example, discriminatory;
(ii) to protect the individuals in their territory and subject to their jurisdiction from violations perpetrated by third parties; and
(iii) to fulfil rights by taking active steps to deliver their obligations *(j)*.

3. Detention

The detention of patients for the management and control of infectious diseases implies quarantine, isolation and other well known public health tools.

Isolation is defined in IHR, Article 1 as the "separation of ill or contaminated persons or affected baggage etc. (…) in such a manner as to prevent the spread of infection or contamination" *(k)*. In the same article, quarantine is defined as the "restriction of activities and/or separation from others of suspect persons who are not ill, or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination" *(k)*.

Detention is a violation of ICCPR, Article 9 *(c)*, which guarantees everyone's right to liberty and security of person, as well as of ECHR, Article 5 *(h)*.

However, although the right to liberty is of profound importance, it is not absolute. ICCPR, Article 9 *(c)*, and ECHR, Article 5 *(h)*, do not exclude arrest or detention. They do, however, require that deprivation of liberty is non-arbitrary and carried out in accordance with the rule of law.

Although ICCPR, Article 9 *(c)*, does not enumerate reasons to justify the deprivation of a person's liberty, involuntary hospitalization in the case of infectious diseases is interpreted in ICCPR as a deprivation of liberty *(l)*.

ECHR *(h)* however, does list reasons permitting the deprivation of liberty; Article 5, paragraph 1 (e) states:

> *Everyone has the right to liberty and security of person. No one shall be deprived of his liberty save in the following cases and in accordance with a procedure prescribed by law: (...) (e) the lawful detention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drug addicts or vagrants.*

Article 9 of ICCPR *(ref)*, lists the following conditions to be fulfilled regarding detention in order not to violate human rights.

[10] All branches of government and other public or governmental authorities, at whatever level, are in a position to engage the responsibility of the state.

1. **Detention should be non-arbitrary**, otherwise it will constitute a violation.

   This notion is really broad and includes elements of inappropriateness, injustice, lack of predictability and violation of the due process of law. For a detention to be non-arbitrary, all of the circumstances relating to it must be reasonable and necessary. Any decision to keep a person in detention should be open to periodic review, and the length of detention should not exceed that for which the state can provide appropriate justification.

2. **Detention should be prescribed by law**. Unlawful detention is also a violation.

   The substantive and procedural grounds for arrest and detention must be prescribed by law and should be clearly and unambiguously defined. Regulations should also provide for the possibility of a judicial review of decisions on cases involving the forcible detention of patients.

In 2005, in the case of *Enhorn v. Sweden (m),* the European Court of Human Rights decided that a limitation of ECHR, Article 5 *(h)*, would not result in a violation of the Convention *(h)* if the limitation were necessary in a democratic society and, at the same time, proportionate *(m)*. The Court explained that executing the deprivation of liberty in conformity with national law does not suffice alone. The circumstances must be such that deprivation of liberty is necessary for the protection of society and the individual. The Court insists on balancing the rights of society with those of the individual. According to the Convention *(h)*, the predominant reason for depriving a person of his/her liberty is not only the fact that the person is a danger to public safety but also the fact that detention may be necessary in the person's own interest.

4. Compulsory treatment

According to international human-rights law, medical treatment should bot be administered without consent. This principle is enshrined in different human rights guaranteed under ICCPR *(c)*, ICESCR *(d)* and ECHR *(h)*, such as the right to self-determination and autonomy (ICCPR, Article 1 *(c)*); the right not to be subjected to torture or to inhuman or degrading treatment (ICCPR, Article 7 *(c)*); ECHR, Article 3 *(h)*); the right to the security of the person (ICCPR, Article 9 *(c)*); the right to physical integrity (ICCPR, Article 17 *(c)*; ECHR, Article 8 *(h)*; and the right to health (ICESCR. Article 12 *(d)*).

ICESCR, Article 12 *(d)* interprets the right to health to include freedom and entitlements and defines freedom as having "the right to control one's health and body (…) and the right to be free from interference, such as the right to be free from (…) nonconsensual treatment (…) *(j)*."

However, this principle is not absolute. Two exceptions are recognized: (1) "... for the treatment of mental illness, or (2) "the prevention and control of communicable diseases" *(j)*. The Committee reiterated that compulsory treatment is acceptable on an exceptional basis.

The European Court of Human Rights confirmed this interpretation, for example, in connection with the case of *Acmanne and others v. Belgium in 1984 (n).* Interference with an individual's

freedom of choice within the sphere of health care must be prescribed by law and can only be justified if it is "necessary in a democratic society" and proportionate.

5. Compassionate use

According to European legislation: "compassionate use" shall mean "making an unauthorized medicinal product (...) available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who can not be treated satisfactorily by an authorised medicinal product" *(o)*.

National legislation on compassionate use is extremely varied around the world. Some countries do not foresee the possibility of accessing unauthorized drugs while others have a more or less restrictive system. Member States of the European Union are under no obligation to adopt legislative acts enabling compassionate use.

From a human-rights perspective, it is relevant to question:: (1) whether access to drugs, which are not on the market for terminally ill patients, is a human-rights requirement; and (2) whether it would be positive to oblige countries to enable access to drugs, which have not been fully tested for safety and efficacy, in certain circumstances.

So far, the European Court of Human Rights has dealt with one case on compassionate use, namely that of *Hristozov and others vs. Bulgaria (p).* The applicants, who were suffering from various types of terminal cancer, wished to be treated by means of the compassionate use of an anti-cancer drug that a Canadian developing company would provide free of charge. The Bulgarian authorities, in accordance with the national legislation, refused to grant access to this drug. Bearing in mind that matters of health-care policy are normally dealt with by the national authorities *(p)*,[11] the Court was very cautious in its deliberations and concluded that the Convention had not been violated. More specifically, the Court, while acknowledging that "acts and omissions of the authorities in the field of health care policy may in some circumstances engage the state's responsibility under ECHR, Article 2" *(p)*, [12] refused to derive from this that the State was under any obligation to regulate in a certain way to allow access to unauthorized drugs. Moreover, the Court considered that the balance between the competing interests of the public to access safe medicinal products on one hand, and the interest of terminally ill patients in obtaining access to experimental products on the other, was acceptable with respect to the wide margin of appreciation in this field afforded to national authorities *(p)*.[13]

[11] *Judgment Hristozov and others vs. Bulgaria*, § 119. *(p).*
[12] *Judgment Hristozov and others vs. Bulgaria*, §§ 106-109 *(p).*
[13] *Judgment Hristozov and others vs. Bulgaria*, §§ 121-126 *(p).*

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(g) Convention on the Rights of Persons with Disabilities. New York: United Nations; 2006 (http://www.un.org/disabilities/convention/conventionfull.shtml, accessed 25 January 2014).

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