XDR Tuberculosis, the New International Health Regulations, and Human Rights

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Extensively drug-resistant tuberculosis (XDR-TB) is the latest emerging disease recognized as a global health threat.[1] It has so far been identified in at least 27 countries covering all regions of the world except Oceania.[2] A cohort of patients was investigated in 2005-2006 in the KwaZulu-Natal province of South Africa, revealing an exceedingly high mortality rate and a rapidly fatal evolution among identified XDR-TB cases.[3] Such alarming features of this new form of tuberculosis seem to relate at least partly to HIV co-infection. We should, unfortunately, expect the initial spread of XDR-TB to affect HIV-hyperendemic countries, with the South-African subcontinent potentially confronting significant burdens from increasing cases, fatalities, and their attendant costs. The urgency of the XDR-TB threat can be sensed in some experts' calls for compulsory isolation of cases, leading if necessary to forcible detention.[4]

Importantly the XDR-TB epidemic is developing just a few months before the revised International Health Regulations, adopted by the World Health Assembly in May 2005 (IHR 2005), become legally binding on WHO Member States.[5] The IHR (2005) constitute an important legal instrument designed "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade" (Article 2). Under the IHR (2005), the WHO Director-General may, after consultation with countries affected and an Emergency Committee, declare a disease event to constitute a "public health emergency of international concern (PHEIC)" (Article 12). If the Director-General makes such a determination, then the Director-General shall issue temporary recommendations to guide WHO Member States in responding to the health threat (Article 15). The rapid expansion of the XDR-TB epidemic may give WHO and its Member States the opportunity to apply these provisions of the IHR (2005) for the first time when they enter into force in June 2007.

The exact scope of application of the IHR (2005) is still open to interpretation.[6] For example, the WHO Secretariat has been debating whether the XDR-TB epidemic qualifies as a PHEIC. The Global Task Force on XDR-TB has indicated that it does not believe that WHO should consider XDR-TB to be a PHEIC for two reasons: First, the Global Task Force asserted that "the chief risk of XDR-TB is independently created in countries[,]" and the threat from XDR-TB is not related to international spread of the resistant strain. Further epidemiological investigations may clarify whether XDR-TB poses a threat for international spread. Second, the Global Task Force argued "the IHR Emergency Committee and temporary recommendations are really intended for outbreaks of acute disease, rather than the 'acute-on-chronic' situation of MDR-TB and XDR-TB." [7]

The first reason given by the Global Task Force connects directly to a major component of the IHR (2005)'s definition of a PHEIC, the need for an extraordinary event to constitute a public health risk to other countries through the international spread of disease (Article 1.1). Although epidemiological evidence at present does not point to international spread as a major risk factor, experience with TB and MDR-TB should leave no doubt that XDR-TB could become a greater public health risk through international spread.

The Global Task Force's second reason, however, raises some interpretive questions. The Global Task Force claimed that the IHR (2005)'s rules on PHEIC are only intended for outbreaks of acute disease rather than XDR-TB's profile of "acute-on-chronic." If XDR-TB

is in fact an outbreak of an acute disease, as epidemiological evidence and public health concern about it indicate, then it falls within the intended scope of the IHR (2005), even as defined by the Global Task Force. XDR-TB's relationship with HIV/AIDS does not change the acute threat it poses to human populations, especially in countries significantly affected by HIV/AIDS. The calls for compulsory isolation of persons infected with XDR-TB suggest that the threat is acute and serious.

More broadly, the argument that the IHR (2005)'s rules on PHEIC only apply to "outbreaks of acute disease" does not reflect the content of the Regulations. The IHR (2005) never use the concept of "acute disease." One reason for this is that the IHR (2005) apply to public health risks posed by the accidental or intentional release of chemical or radiological agents, which are not "outbreaks of acute disease" but events that present serious and direct dangers to the health of human populations. The scope of the IHR (2005)'s provisions on PHEIC is thus broader than the Global Task Force suggested.

The Global Task Force raised the possibility that, under the IHR (2005), WHO should issue standing recommendations on XDR-TB as an on-going threat (Article 16) rather than temporary recommendations connected to a PHEIC determination. Any standing recommendations issued under the IHR (2005) should be informed by human rights principles if such recommendations involve compulsory measures against those infected with XDR-TB who pose a risk of spreading the disease internationally.

A fundamental principle of the IHR (2005) is that the Regulations shall be implemented "with full respect for the dignity, human rights and fundamental freedoms of persons" (Article 3.1). The IHR (2005) contain many provisions that apply human rights concepts to treatment of travellers.[8] The WHO Secretariat's guidance paper on human rights and involuntary detention for XDR-TB control constitutes an important document for the use of compulsory measures whether such measures fall inside or outside the IHR (2005).[9]

The current XDR-TB crisis has been called, with good reason, "an indicator of public-health negligence".[10] The debates about how WHO should apply the IHR (2005) to XDR-TB, including the IHR (2005)'s emphasis on the protection of human rights, is an encouraging sign that this new global health governance instrument can help WHO and its Member States transcend past negligence and address effectively the global threat XDR-TB has ominously become.

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[3] Neel R. Gandhi et al., "Extensively Drug-Resistant Tuberculosis as A Cause of Death in Patients Co-Infected with Tuberculosis and HIV in A Rural Area of South Africa," *Lancet* 368 (2006): 1575-1580.

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[7] World Health Organization, "Global XDR-TB Task Force update – February 2007," http://www.who.int/tb/xdr/globaltaskforce_update_feb07.pdf.

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[10] Annelies Van Rie and Donald A. Enarson, "XDR Tuberculosis: An Indicator of Public-Health Negligence," *Lancet* 368 (2006): 1554-1555.