

Drug regulation in the age of AMR – what is known from experience with tuberculosis

October 26 2016, by Bev Stringer

The World Health Organization's [Global Tuberculosis \(TB\) Report 2016](#), released last week, is a sobering read. TB remains one of the world's biggest killers, and cases of multidrug-resistant tuberculosis (MDR-TB) are increasing.

With this in mind, the theme of this week's [47th Union World Conference on Lung Health](#) "confronting resistance: fundamentals to innovation" is welcome to the many patients and practitioners dealing with the agonising challenges of MDR-TB.

Alongside low quality TB medications, poor treatment adherence, ineffective regimens, and poor hospital infection control practices, direct access to TB drugs through the private market is a driver of the resistance epidemic. A key component of the WHO Stop TB Strategy is effective drug management and supply. However, this topic needs urgent attention on the global agenda, particularly as new and improved TB treatments are becoming available and they need to be used in a way that does not select for resistance.

Uzbekistan has some of the highest reported rates of MDR-TB in the world, with resistance seen in 23% of new and 62% of retreatment cases. Médecins Sans Frontières (MSF) treats MDR-TB in collaboration with the Ministry of Health (MoH) in the autonomous region of Karakalpakstan. Despite national drug policies prohibiting the sale or use of anti-TB drugs without a prescription, we found pharmacies selling anti-TB drugs over the counter, and anecdotal evidence suggested the

misuse of anti-TB drugs was prolific through self-medication and regimen mismanagement.

Uzbekistan is in the process of improving drug regulation processes but little was known about how anti-TB drugs were being used outside of the MSF/MoH programme, so MSF/MoH conducted a [qualitative study](#) to explore patient and practitioner perceptions of this issue.

We found that that stigma and shame were driving patients to seek treatment elsewhere, but once enrolled in the programme patients appeared less likely to self-medicate. In addition, incorrect advice about treatment passed on through friends and family also influenced decisions to medicate outside of the MSF/MoH programme. Key to tackling this issue is early case finding, alongside community education strategies to reduce stigma and improve knowledge of the disease. Trust between patient and practitioners was also found to prevent drug misuse. Practical solutions to regulate the sale of drugs, such as monthly audits in all pharmacies are also needed.

Elsewhere, other suggestions to improve drug regulation have been proposed, such as [an accreditation system](#) for private providers involved in TB management, to increase practitioner knowledge about the disease and correct regimens.

The issue of drug regulation needs international and national commitment and engagement across the public and private sectors. The challenges of drug resistance are not exclusive to TB; the political momentum to address wider antimicrobial resistance (AMR), ratified last month with a [United Nations declaration](#), demonstrates that many countries around the world are trying to find the delicate balance between ensuring access to antibiotics, while promoting their stewardship. However, it is crucial not to lose sight of the fact that in curtailing the epidemic of MDR-TB, the key gap is provision of

effective treatment programmes. One of the most sobering facts in the WHO reports was that only 22% of MDR-TB patients globally who are eligible for treatment actually receive it. Without attention to this issue the market for unregulated TB drugs will continue to thrive.

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