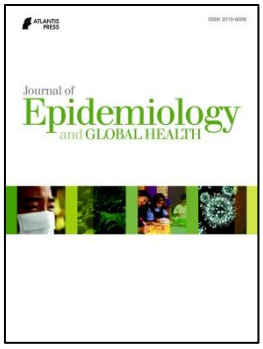

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EDITORIAL FOR WORLD TB DAY (24TH MARCH 2013)

New tuberculosis tools are here: Can we deliver them for maximal impact?

24th March is World TB Day, and a good time to take stock of progress in global tuberculosis (TB) control. In 2013, TB continues to be major public health threat, with an estimated 8.7 million new cases per year, and an estimated 1.4 million deaths from TB [1]. Early case detection and rapid treatment continues to remain the most important TB control strategy. With the incidence of TB declining very slowly, it is now obvious that TB cannot be eliminated by 2050, at least not with the kind of TB tests, drugs and vaccine used in most high TB burden countries [2,3]. Currently, TB patients are not diagnosed and cured quickly enough, and this ensures high levels of transmission [2].

TB elimination will require substantially better tools, and, finally, there is some light at the end of the tunnel. New, accurate diagnostics for TB are finally here and steadily being scaled up. For the first time, a rapid, cartridge-based, automated molecular test, the Xpert MTB/RIF test (Cepheid Inc., Sunnyvale, CA), is being scaled up for TB diagnosis and drug-resistance detection in more than 20 countries. The Xpert® MTB/RIF technology was endorsed by the WHO in 2010 [4]. Since then, over 1,900,000 Xpert® MTB/RIF cartridges have been procured worldwide in the public sector in 77 of the 145 countries eligible for concessional pricing [4].

Several published studies, summarized in a recent Cochrane systematic review [5], have confirmed the high accuracy of this test and its superior performance vis-à-vis the conventional sputum smear microscopy. In June 2012, UNITAID, the Bill and Melinda Gates Foundation, the US Agency for International Development (USAID), and US President's Emergency Plan for AIDS Relief (PEPFAR) announced an agreement with Cepheid Inc. to reduce the cost of the test to $9.98 per cartridge (from the original price of $16.86). As part of the agreement, UNITAID is also supporting scale-up through an accelerated roll-out of the test in high-burden countries via the WHO Stop TB Department and the Stop TB Partnership secretariat. The three-year TBXpert project will support the implementation of over 200 GeneXpert instruments and 1.4 million Xpert cartridges in 21 countries, starting in 2013 [4].

Already, fast-follower, next-generation molecular TB tests have emerged, after the Xpert® MTB/RIF technology [6]. In many ways, the Xpert® MTB/RIF technology has become the pathfinder for wider use of rapid, accurate molecular tests for TB, and for showing that it is possible for healthcare programs to go beyond the century-old microscopy. These next-generation NAATs will help further scale-up molecular testing in resource-limited settings and eventually replace sputum smears in peripheral laboratories.

Progress has also been made on the TB drug front. Recently, the US Food and Drug Administration approved a drug called bedaquiline, as part of combination therapy to treat adults with MDR-TB when other alternatives are not available [7]. This is the first new TB drug approved in over 40 years. Other new TB drugs or combinations are expected within the next 2—3 years. For example, moxifloxacin has the potential to be first new drug to treat drug-sensitive TB in nearly 50 years, and a moxifloxacin-containing regimen could shorten treatment duration by a third. A recent trial showed that a novel drug combination treatment (called PaMZ) containing PA-824, moxifloxacin and

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pyrazinamide was highly effective [8]. Although further trials are needed, this drug combination has the potential to treat patients with drug sensitive as well as drug resistant TB. Shortening TB treatment to 2 or even 4 months should greatly increase cure rates, improve patient adherence, and reduce the likelihood of drug resistance.

In contrast to diagnostics and drugs, progress has been relatively slower with new TB vaccine development, although major investments have been made in this area. Among the various candidate vaccines being evaluated, results from the trial on the MVA85A vaccine were published recently [9]. Although not efficacious, this first TB vaccine efficacy trial in almost a century has offered useful insights for subsequent vaccine candidates entering trials.

As we welcome the emergence of new tools for TB, it is critical to remember that new tools, by themselves, cannot make an impact, unless they are successfully delivered to the millions who need them. The availability of new tools does not mean they will be adopted, used correctly, scaled-up, or have public health impact.

Experience to date with new diagnostics suggests that many national TB programmes (NTPs) in high-burden countries struggle to adopt and scale-up new tools, even when these are backed by evidence and global policy recommendations. As reviewed recently [10], there are several common barriers to effective national adoption and scale-up of new technologies: global policy recommendations that do not provide sufficient information for scale-up; complex decision-making processes and weak political commitment at country-level; limited engagement of and support to NTP managers; high cost of tools and poor fit with user needs; unregulated markets and inadequate business models; limited capacity for laboratory strengthening and implementation research; and insufficient advocacy and donor support. Overcoming these barriers will require enhanced country-level advocacy, resources, technical assistance and political commitment.

The challenge for TB control in future will be less about technology and more about finding innovative business models for delivering technologies in a manner that ensures impact, and at a scale where impact is substantial.

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