



Diagnosing Tuberculosis (TB) in the Developing World - A Primer

The Issue

Tuberculosis (TB) is challenging to diagnose and difficult to treat, especially in the developing world which bears 95% of the global disease burden. Inaccurate diagnosis has spurred the rapid spread of TB and drug resistance especially in HIV/AIDS patients.

The Impact

According to The World Health Organization (WHO) there are an estimated nine million new cases of active TB reported each year. TB results in approximately two million deaths each year and is the leading cause of death among HIV/AIDS patients. Strains of TB that are resistant to both first-line and second-line drugs threaten the success of not only tuberculosis programs, but also HIV treatment programs worldwide.

The Challenge

Access to effective TB diagnostics in the developing world lags far behind the rest of the globe. The acid-fast bacillus sputum smear, the test most commonly used in these remote locations, is more than 115 years old. The test has poor sensitivity, particularly in HIV patients who do not have enough TB bacteria to easily detect, even though they are very sick. As a result, the test is not accurate or reliable and false negative results are very common. A more sensitive and accurate testing method that utilizes liquid-based culture was developed 25 years ago and can also detect drug resistance. Unfortunately, developing countries have not been able to widely employ this technology because it is more expensive, requires a more sophisticated laboratory setting and until recently, has not been recommended by leading global health organizations like WHO.

The Goal

While the ultimate goal of providing a more up-to-date TB diagnostic tool for the 21st century is the focus of ongoing research and development, steps can and have been taken to introduce the developed world standard of liquid TB culture and drug susceptibility testing to the developing world. To ensure this testing is widely accessible requires investment in training personnel, instrumentation and laboratories which can only happen with the collaboration of government and non-government agencies, international aid organizations, health ministries of developing countries and manufacturers. In turn, investment in these critical areas makes adoption of future diagnostic tools easier, including those being specifically designed for developing countries.

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Recent Progress

One solution to the TB diagnostic issue in the developing world has been realized with the collaboration between The Foundation for Innovative New Diagnostics (FIND) and BD (Becton, Dickinson and Company). In 2004, with funding from the Bill and Melinda Gates Foundation and in cooperation with WHO's Stop TB Partnership and the Johns Hopkins Center for TB Research, BD and FIND partnered to conduct a series of demonstration projects designed to show that liquid culture would improve TB diagnosis in the developing world. In 2007, based on the results of these studies, WHO endorsed the use of liquid culture and drug susceptibility testing in low and middle-income countries with resource-limited settings. Realizing that insufficient laboratory services in developing countries would be an obstacle to rapid adoption of this TB diagnostic, FIND and BD expanded their collaboration to strengthen lab settings in targeted regions. The partners then announced a pricing agreement to make liquid culture testing available to 39 countries defined by WHO as highly burdened with TB and defined by the World Bank as low income. The agreement is designed to make this technology available in areas that currently do not have access to it, and where it can have an immediate impact on the crisis of drug-resistant TB.