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Evaluating diagnostics: STIs

This supplement on evaluating diagnostics for bacterial sexually transmitted infections is the second in a series of user-friendly operational guides explaining how to conduct evaluations of diagnostic tests for infectious diseases that are of public health importance in the developing world. Here, Rosanna Peeling, head of the WHO/TDR Sexually Transmitted Diseases Diagnostics Initiative, introduces the supplement.

Diagnostic tests are needed for the control of sexually transmitted infections (STIs), as many infected individuals are asymptomatic. It is particularly important that tests for STIs should be both sensitive and specific. False-negative test results are a public health disaster, giving rise to a false sense of security that results in continuing transmission of the infection to sexual partners. False-positive results are a personal disaster, leading to stigmatisation, marital discord and the breakdown of relationships. In many societies, women diagnosed with STIs are at risk of violence from their sexual partners.

Syphilis, gonorrhoea and chlamydia can all be cured with a single dose of antibiotics. Yet they remain out of control, especially in the developing world. Between them, they account for almost 500,000 new infections every day. Syphilis in pregnant women causes 500,000 stillbirths or neonatal deaths every year in Africa alone. Gonorrhoea and chlamydial infection cause pelvic inflammatory disease, infertility and ectopic pregnancy in women, and potentially blinding eye infections in infants.

For more than a century, since Wasserman first described an agglutination assay for the serological diagnosis of syphilis and Neisser showed that gonorrhoea could be diagnosed reliably in males by microscopy using Gram's stain, diagnostic tests for these infections have benefited from the latest technological developments. In recent years, chlamydial diagnostics have led the way in nucleic acid amplification technology, and several tests, using a variety of amplification techniques, are now commercially available. However, these state-of-the-art tests require sophisticated laboratory facilities and technical expertise, neither of which are widely available in the developing world. Microscopy for the diagnosis of gonorrhoea and the rapid plasma reagin test for syphilis can both be performed rapidly, but require electricity, equipment and trained laboratory staff. Under field conditions in developing countries, their performance is often less than optimal.

Rapid diagnostic tests that can be performed at the point of care are ideal for increasing access to STI diagnosis in the developed world as they do not require laboratory facilities and enable treatment to be given immediately,

preventing complications and further transmission. They also allow healthcare providers to provide early treatment for the sexual partners of infected patients. Such tests for STIs are now commercially available. They are simple to perform and easy to read, require no equipment, and give a result in less than one hour. Rapid HIV tests, with sensitivities and specificities exceeding 99% compared with laboratory tests, have revolutionised voluntary counselling and testing, as well as prevention of mother-to-child transmission programmes in both developing and developed countries.

In 2000, representatives from 189 countries committed to the attainment of a set of Millennium Development Goals. The fourth goal calls for a 75% reduction in mortality in children under 5 years of age and the fifth goal calls for the improvement of maternal health, both by 2015. Most countries are still struggling to sustain a course of action that will achieve these goals. It is hoped that increased access to quality-assured STI diagnostic tests will go a long way towards helping countries to do so. Unfortunately, in many developing countries, clinical care is often critically compromised by the lack of regulatory controls on the quality of these tests and independent evaluations suggest that these tests do not always perform as well as the manufacturers claim. As a result, diagnostic tests are sold and used in much of the developing world without evidence of effectiveness.

The WHO/TDR Sexually Transmitted Diseases Diagnostics Initiative has coordinated international evaluations of tests for syphilis, gonorrhoea and chlamydia in recent years and the results of their evaluations are due to be published in a special supplement with a forthcoming issue of the journal *Sexually Transmitted Infections*.

The aim of this supplement with *Nature Reviews Microbiology* is to provide standards for the evaluation of diagnostic tests for STIs, and enable STI programme managers, health service providers, regulatory bodies and national and regional health authorities to assess the rigor of the evaluations that are published in the peer-reviewed literature or submitted as dossiers for regulatory approval and, when necessary, to conduct such evaluations themselves.