

## Laboratory Diagnosis of Sexually Transmitted Infections in Belarus

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Following the collapse of the Soviet Union, the management of sexually transmitted infections (STIs) became fragmented, with a consequent increase in STI morbidity. In Belarus, reliable data are generally lacking as a result of poor access to effective diagnostic facilities, while the quality of laboratory testing for STIs in recognised centres is questionable. As part of the Belarusian-Swedish project "Optimization of the prevention and control of STI/HIV in Belarus" (1) we surveyed STI diagnostic facilities for the methods they used (including their range, availability and quality) and their adherence to international evidence-based guidelines.

### MATERIALS AND METHODS

During the period September 2006 to December 2007, all state-owned laboratories and other facilities that performed laboratory diagnostics for STIs in Belarus were invited to complete a questionnaire similar to that used and validated in our earlier studies (2). To evaluate the quality of the diagnostic assays and algorithms/strategies used in the surveyed laboratories, international evidence-based recommendations for STI diagnostics and definitions of STI surveillance cases (3–5) were used for comparison.

### RESULTS

Of the 316 state medical facilities that provided STI services, 44% performed testing for syphilis, 82% for gonorrhoea, 80% for trichomoniasis, 55% for genital chlamydial infections, 24% for genital *Ureaplasma* and *Mycoplasma* infections, 51% for *Candida* infections, 61% for bacterial vaginosis (BV), 16% for genital herpes, and 4% for human papillomavirus. On average, each laboratory provided STI diagnostic services for approximately 30,000 inhabitants.

Screening for syphilis was performed in 140 of the 316 laboratories surveyed (44%). Of these, 130 (93%) used locally-manufactured microprecipitation reaction (MPR) tests employing cardiolipin antigen and treponemal enzyme-linked immunoassays (ELISAs). Confirmatory treponemal ELISAs were used in only 56% of these laboratories. The *Treponema pallidum* haemagglutination (TPHA) test was used by 1.3% of the laboratories, while fluorescent treponemal antibody absorbed (FTA-abs) and *T. pallidum* immobilisation (TPI) tests were performed at seven (5%) central regional serology laboratories. Thirteen percent of the

laboratories performed dark-field microscopy for the direct detection of *T. pallidum*.

More than 80% of the surveyed laboratories tested for *Neisseria gonorrhoeae* and *Trichomonas vaginalis* infections. Microscopic analysis of methylene blue- and/or Gram-stained smears was the main diagnostic method employed for the diagnosis and screening of both males and females (used by 76% of laboratories). Culture for *N. gonorrhoeae* was performed in 54 laboratories (17%). Persons suspected of having gonorrhoea, sexual contacts of persons with diagnosed gonorrhoea, and persons being tested to determine whether or not they had been cured were extensively exposed to provocation methods (biological, chemical, mechanical, alimentary and physiological) before culture was performed (6). Only five laboratories (1.6%) utilised polymerase chain reaction (PCR) testing for the diagnosis of gonorrhoea, while six (1.9%) used this technique for the detection of *T. vaginalis* (using reagents and equipment manufactured in the Russian Federation). Culture of *T. vaginalis* was employed in three (1%) of the surveyed laboratories.

More than half (55%) of the laboratories provided diagnostic testing for genital *C. trachomatis* infections. Of these, 45% used microscopic analysis of smears stained by the Romanovsky-Giemsa method, while 37% used antibody detection by ELISA. Direct fluorescent antibody (DFA) tests were utilised by 24%, PCR by only 7.4%, and culture by 1% of the laboratories surveyed. All these test systems were manufactured in Russia.

Approximately a quarter (77%) of the laboratories surveyed provided STI diagnostic services for *Ureaplasma* spp. and *Mycoplasma hominis*. Of these, 38 (49%) used culture methods, 30 (39%) DFA tests, 13 (17%) PCR, and 3 (4%) ELISA for the detection of antibodies to *U. urealyticum*, *M. hominis* and *M. genitalium*.

### DISCUSSION

It is clear that reliable data regarding STI morbidity in Belarus are limited due to diversity in the methods used for the diagnosis of individual infections and the quality of the testing that is routinely available. The majority of the diagnostic tests used in the country are not validated against any Western quality-assured analogues. Of the 316 participating laboratories in

the present study, only 73 (23%) were able to provide comprehensive diagnostic services for the four main treatable non-viral STIs, namely *T. pallidum*, *N. gonorrhoeae*, *T. vaginalis* and *C. trachomatis*. Many tests used in STI diagnostics in Belarus are manufactured in Russia. Clinical evaluation of these tests should prove valuable when choosing the most appropriate test systems for use in Belarus (7–10).

The findings of the present study clearly emphasise that many of the tests used in laboratory diagnosis are inadequate, resulting in poor case-reporting of STIs in Belarus. Representatives from Belarus have actively taken part in the European Network for Sexual and Reproductive Health (EE SRH)'s (11) development of regional consensus guidelines for the diagnosis of several STIs. These guidelines have subsequently been adapted to local conditions and adopted by the Ministry of Health of Belarus as the national standard for diagnosis of these infections. The need for quality testing has been recognised and the International Organization for Standardization (ISO) 15189 (international laboratory quality management standard) has been adopted nationally. Recommendations regarding preparation for laboratory accreditation have been accepted and published, and a training programme for laboratory professionals has been designed in collaboration with the Belarus Medical Academy for Postgraduate Education (BelMAPS). The formation of a Belarus national STI reference laboratory is currently under consideration. Studies to determine the performance characteristics of tests manufactured in Belarus are currently in progress.

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