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Title **Systematic Review of the Clinical Effectiveness and Cost Effectiveness of Rapid Point-Of-Care Tests for the Detection of Genital Chlamydia Infection in Women and Men**

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Aim

To assess whether or not the point-of-care Chlamydia Rapid Test (CRT) could improve detection of genital chlamydia, and whether it, or any other point-of-care test, is more effective than current practice using nucleic acid amplification tests (NAATs) in terms of the number of cases of chlamydia detected and treated and the proportion of partners identified and treated.

Conclusions and results

Limited evidence suggests that NAATs remain the most accurate and cost-effective way to diagnose chlamydia infection. In some circumstances point-of-care tests could be provided in addition to existing NAAT services, but there is little evidence on point-of-care methods in such settings. Robust evidence of the diagnostic accuracy of point-of-care tests for different types of samples is required, as are studies evaluating clinical effectiveness outcomes for these tests in comparison with NAATs. The analysis included 13 studies enrolling 8817 participants. In the pooled estimates for CRT, sensitivity (95% CI) was 80% (73%-85%) for vaginal swab specimens and 77% (59%-89%) for first void urine (FVU) specimens. Specificity was 99% (99%-100%) for vaginal swab specimens and 99% (98%-99%) for FVU specimens. In the pooled estimates for a comparator point-of-care test (Clearview Chlamydia), sensitivity (95% CI) was 52% (39%-65%) for vaginal, cervical, and urethral swab specimens combined, and 64% (47%-77%) for cervical specimens alone. Specificity was 97% (94%-100%) for vaginal, cervical, and urethral swab specimens combined, and 97% (88%-99%) for cervical specimens alone. Results of the economic evaluation showed that for a hypothetical cohort of 1000 people, the current practice of NAAT testing (using polymerase chain reaction) would result in 12.63 people who were offered testing being correctly treated and having their sexual partners contacted, at a cost of 7070 pounds sterling (GBP) (for the whole cohort). For the CRT, the number being correctly treated would be 10.98, at a cost of GBP 7180. For the Clearview Chlamydia test, the number correctly treated would be 7.14, at a cost of GBP 7170. Hence, both point-of-care tests were more costly and less effective than current practice.

Recommendations

See Executive Summary link www.hta.ac.uk/project/1795.asp.

Methods

Electronic searches, eg, in MEDLINE, EMBASE, BIOSIS, and CENTRAL, identified published and unpublished reports. The most recent search was conducted in November 2008. The types of studies considered were randomized controlled trials (RCTs) for the reviews of diagnostic accuracy and effectiveness, direct head-to-head studies for the review of diagnostic accuracy, and nonrandomized comparative studies if an insufficient number of RCTs were identified to review effectiveness. Participants were sexually active adolescents and adults being tested for or suspected of having genital chlamydia infection. The tests considered were the CRT and other comparator point-of-care tests using a NAAT as a reference standard. One reviewer screened the titles and abstracts of reports identified by the search strategy. Two reviewers independently assessed full-text reports of potentially relevant studies. One reviewer extracted data from the included full-text studies, which were checked by the second reviewer. For the diagnostic accuracy review, two reviewers independently assessed the quality of all included studies using a modified version of the QUADAS (Quality Assessment of Diagnostic Accuracy Studies) instrument.

Further research/reviews required

See Executive Summary link www.hta.ac.uk/project/1795.asp.

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