Screening women for Chlamydia trachomatis in family planning clinics: the cost-effectiveness of DNA amplification assays

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Screening for the detection of chlamydial infections in women younger than 30 years of age and attending family planning clinics. The seven strategies considered were the use of cell culture, enzyme immunoassay (EIA), nonamplified probe assay (Pace 2), polymerase chain reaction (PCR) for cervical specimens, PCR for urine specimens, ligase chain reaction (LCR) for cervical specimens, and LCR for urine specimens.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
Women younger than 30 years of age attending family planning clinics.

Setting
Family planning clinic. The economic study was carried out in the USA.

Dates to which data relate
The data related to the prevalence of Chlamydia trachomatis and the proportion of women receiving pelvic exams were based on region-wide data collected between April 1994 and October 1995. Clinical probabilities were obtained from the literature published between 1979 and 1997. Resource use data were partly based on the region-wide data collected between April 1994 and October 1995, and partly on the published literature from 1983 to 1997. The fiscal year was 1995.

Source of effectiveness data
Effectiveness data were derived from a review of the literature.

Modelling
A decision analytic model was constructed to estimate the costs and effects associated with each alternative strategy.

Outcomes assessed in the review
The review assessed the assay sensitivity/specificity of the seven strategies; treatment effectiveness; proportion of patients experiencing side effects; probability of pelvic inflammatory disease (PID), CPP, ectopic pregnancy, and infertility; probability of transmission to male sex partner; conditional probability of neonatal conjunctivitis and
neonatal pneumonia.

**Study designs and other criteria for inclusion in the review**
Not reported.

**Sources searched to identify primary studies**
MEDLINE was searched.

**Criteria used to ensure the validity of primary studies**
Not reported.

**Methods used to judge relevance and validity, and for extracting data**
To determine the reference case sensitivities for each diagnostic assay, studies using female cervical or urine specimens and culture as a reference test, and which conducted discrepancy analyses, were included.

**Number of primary studies included**
A total of 35 studies were included.

**Methods of combining primary studies**
Modified meta-analysis.

**Investigation of differences between primary studies**
Not reported.

**Results of the review**
The results of the review were as follows:

- Assay sensitivity of cell culture was 0.85 and specificity was 1.0;
- EIA sensitivity was 0.701 and specificity was 0.946;
- Pace 2 sensitivity was 0.759 and specificity was 0.988;
- PCR-cervix sensitivity was 0.876 and specificity was 0.99;
- PCR-urine sensitivity was 0.893 and specificity was 0.99;
- LCR-cervix sensitivity was 0.933 and specificity was 0.99;
- LCR-urine sensitivity was 0.897 and specificity was 0.99.

The other probabilities were as follows:

treatment effectiveness, 0.857 (range: 0.75-0.95);
proportion of patients experiencing side effects, 0.16 (range: 0.0- 0.40);
probability of pelvic inflammatory disease (PID), 0.30 (range: 0.15-0.40);
conditional probabilities of symptomatic PID, 0.40, outpatient PID, 0.86, and inpatient PID 0.14;
probability of CPP, 0.18;
probability of ectopic pregnancy, 0.08;
probability of infertility, 0.12;
probability of transmission to male sex partner, 0.68;
conditional probability of urethritis and epididymitis, 0.40 and 0.02;
conditional probability of neonatal conjunctivitis and neonatal pneumonia, 0.20 and 0.10.

Measure of benefits used in the economic analysis
The benefit measure was cases of PID prevented over no screening for an estimated annual population of 18,000 women. Epidemiological data were mainly obtained from a region-based sample consisting of 3,794 women younger than 30 years. Of these 1,157 had no indication for pelvic examination and underwent PCR for urine specimens and 2,637 received a routine pelvic examination and underwent PCR of cervical specimens (resulting in an overall chlamydial prevalence of 9.2%).

Direct costs
Costs were discounted. Some quantities of resources were reported separately from the costs. Cost items were reported separately and were based on Medicare and Medicaid reimbursement rates or were derived from the medical literature. The cost analysis covered the costs of cervical specimen collection (materials, physician time), urine specimen collection, assay per specimen, PCR thermocycler, lab technician time and lab overhead per specimen, follow-up, treatment visit (physician time), 7-day course of Doxycycline (100 mg 2/day), adverse effects from treatment, and sequelae. The perspective adopted in the cost analysis was that of the health care system. Observed patient flow analysis in a local institution was used to estimate clinician time for pelvic examination, extra swab collection, and the treatment visit. Time-in-motion studies on technicians in a local institution were used to estimate labour costs. Medical literature was used to estimate the costs of follow-up visit for treatment and sequelae. Some of the cost data were in 1994 dollars, which were inflated to the fiscal year using the Consumer Price Index. The date of the price data was 1995.

Indirect Costs
It was reported that the inclusion of indirect costs, such as time missed from work for treatment of sequelae, in the sensitivity analysis did not change the general conclusion of the model.

Currency
US dollars ($).

Sensitivity analysis
Univariate and multivariate sensitivity analyses were conducted on most parameters of the model.

Estimated benefits used in the economic analysis
The cases of PID prevented over no screening were:

240 for EIA,
259 for Pace 2,
268 for cell culture,
299 for PCR cervix,
304 for PCR urine,
306 for LCR urine,
319 for LCR cervix.

Cost results
The discount rate was 3%. The total costs of the screening programme and sequelae for a population of 18,000 women were as follows:

$2,158,200 for the no screening strategy.
$1,316,340 for EIA,
$1,262,340 for Pace 2,
$1,610,820 for cell culture,
$1,150,560 for PCR cervix,
$1,034,100 for PCR urine,
$1,029,240 for LCR urine,
$1,068,300 for LCR cervix.

Synthesis of costs and benefits
The average cost-effectiveness ratios were calculated relative to the no screening option. The values for the cost-effectiveness ratios were as follows:

$3,508 for EIA,
$3,459 for Pace 2,
$2,042 for cell culture,
$3,370 for PCR cervix,
$3,698 for PCR urine,
$3,689 for LCR urine,
$3,417 for LCR cervix.

Incremental cost-effectiveness ratios were calculated for each strategy relative to the next most cost-effective strategy, which resulted in values of $38,720, and $3,005 for each additional case prevented for the strategies of using cell culture and LCR cervix.

Authors' conclusions
Compared with EIA screening (the strategy with the lowest programme costs), a screening strategy that combines use of
DNA amplification on cervical specimens in women receiving pelvic examinations, and DNA amplification of urine in women with no medical indications necessitating a pelvic examination, prevents the most cases of PID and provides the highest cost savings.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit
The internal validity of the estimates of benefit can not be assessed as the inclusion criteria and the methods of quality assessment of the studies identified were not reported. The authors searched one database only and this may not have identified all potentially relevant studies.

Validity of estimate of costs
Some quantities of resource use were reported separately from the costs and adequate details of methods of cost estimation were given. Costs results refer to the authors’ setting and may not be generalisable outside the USA.

Other issues
The authors’ conclusion seems to be justified given the extensive sensitivity analyses performed. The authors acknowledged that the cost-effectiveness results may not be universally generalisable.

Implications of the study
With enhanced sensitivity over the other diagnostic assays and with the use of noninvasive specimen collection, DNA amplification assays should be implemented as cost-effective components of a screening programme for Chlamydia trachomatis.

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