Poolling urine samples for ligase chain reaction screening for genital Chlamydia trachomatis infection in asymptomatic women

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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
Pooling urine samples for ligase chain reaction (LCR) for the detection of genital Chlamydia trachomatis.

Type of intervention
Screening; diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Asymptomatic women undergoing a LCR test to ascertain genital C. trachomatis infection.

Setting
Laboratory. The economic analysis was conducted in the USA.

Dates to which data relate
No information was given about the date of the effectiveness or cost data. The price year was not stated.

Source of effectiveness data
Effectiveness data were derived from a single study, and a previously published study.

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
There was no evidence of the use of power calculations to determine the sample size. 1,088 urine samples were processed from US army females with a mean age of 22 (SD: 4). A sample of 568 specimens was pooled by 4 into 142 pools (sample 1), and 520 specimens were pooled by 10 into 52 pools (sample 2), these samples were also used as a comparator.

Study design
Prospective cohort study.
Analysis of effectiveness
Effectiveness data were analysed according to the intention to treat principle. The primary outcomes of the study were the sensitivity and specificity of the LCR test. A small pilot study consisting of 148 specimens, out of the total urine study samples, was conducted to determine an appropriate sample to cut-off ratio (S/CO).

Effectiveness results
It was estimated that by lowering the S/CO from 1.00 to 0.2 all of the positive pools were detected. Considering such S/CO the estimated sensitivity and specificity in sample 1 were 100% and 98%, respectively. Similarly, sensitivity and specificity in sample 2 were 97.4% and 92.9%.

Clinical conclusions
The high sensitivity and specificity of LCR was not affected by pooling up to 10 samples when the S/CO was adjusted from 1.0 to 0.2.

Modelling
A model using the binomial distribution was developed to determine the pool size that yielded the highest cost savings.

Outcomes assessed in the review
The review estimated the population prevalence of C. trachomatis infection with pooled data.

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

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
One study was included.

Methods of combining primary studies
Not applicable.

Investigation of differences between primary studies
Not applicable.

Results of the review
The estimated population prevalence and 95% confidence intervals for the pooled data were 9.1% (95% CI: 6.5 - 11.6)
for sample 1 and 12.9% (95% CI: 8.8 - 17) for sample 2.

Measure of benefits used in the economic analysis
The authors did not produce any measure of benefit.

Direct costs
Costs/quantities were reported separately. Costs were not discounted as they occurred within a one year period. The price year was not stated. Only health services costs were considered. The cost items included were: laboratory consumables (gloves and supplies used for handling samples), technician costs (annual salary, benefits, and laboratory or university overhead) and LCR assay used (cost per unit).

Statistical analysis of costs
Costs were not treated in a stochastic way.

Indirect Costs
Not stated.

Currency
US dollars ($).

Sensitivity analysis
One-way and multi-way sensitivity analyses were performed on costs and effectiveness estimators.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
A baseline total cost of $12.76 per individual sample was estimated. Sensitivity analysis revealed that the optimal number of specimens to be pooled strongly depended on the prevalence of C. trachomatis in the population. Assuming an 8.5% prevalence, pooling by four would reduce costs by 39%, whereas with a 2% prevalence, pooling eight samples would reduce the cost per sample by 59%.

Synthesis of costs and benefits
Costs and benefits were not combined by the authors as the pooling algorithm was the dominant strategy.

Authors’ conclusions
The use of pooling processed urine samples for LCR testing of C. trachomatis will decrease the cost of screening compared to individual testing.

CRD COMMENTARY - Selection of comparators
The reason for the selection of comparators was clearly stated and justified.

Validity of estimate of measure of benefit
Population prevalence with pooled data was estimated based on calculations from a previously published study, the
selection of which was not clearly justified. Furthermore, as population prevalence was found to be a key variable in the analysis, without a clearer justification of the validity and accuracy of its estimation, results should be treated with caution.

**Validity of estimate of costs**

The costs and quantities were reported separately. Sensitivity analyses were performed on various parameters, though no justification for the alternative values chosen was provided.

**Other issues**

The generalisability of the results to other settings was investigated and potential benefits from the pooling algorithm were identified by the authors.

**Source of funding**

None stated.

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