The 'real-world' impact of improved diagnostic techniques for Chlamydia trachomatis infection in Glasgow

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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
Two techniques for diagnosing Chlamydia trachomatis (chlamydia) infection were studied. The techniques were enzyme-linked immunoassay (EIA) and ligase chain reaction (LCR).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients from Glasgow city's general practitioners (GPs) and two main sexual health care providers (Genitourinary Medicine (GUM) and Family Planning services (FP)) who submitted genital specimens to Glasgow's main chlamydia testing laboratory. No inclusion or exclusion criteria were reported.

Setting
The setting was a laboratory. The economic study was carried out in Glasgow, UK.

Dates to which data relate
The effectiveness data were collected between April 1996 and March 2000. The authors did not specify the years during which the resource use data were collected. The costs were for the year 1999-2000.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

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

Study sample
The sample size was not determined in the planning phase of the study and power calculations were not carried out retrospectively. It would appear that the study sample was appropriate for the clinical study question. The patient sample consisted of all patients who were tested for chlamydia at the main chlamydia testing laboratory in Glasgow between April 1996 and March 2000. The numbers of samples (and their origin) were as follows:

in the control group, male patients provided 102 (GP), 2,301 (GUM), 5 (FP) and 235 (other health care settings)
samples; and
female patients provided 2,829 (GP), 1,485 (GUM), 2,675 (FP) and 2,653 (other) samples;
in the comparator group, male patients provided 633 (GP), 7,801 (GUM), 68 (FP) and 2,203 (other) samples; and
female patients provided 15,797 (GP), 5,170 (GUM), 12,242 (FP) and 11,232 (other) samples.

In the control group, 8.8% (GP), 8.7% (GUM), 8.8% (FP) and 7.5% (other) of the samples were from patients aged younger than 20 years of age. The corresponding percentages in the comparator group were 9.3% (GP), 12.9% (GUM), 9.7% (FP) and 9.2% (other).

No details of any patients refusing to participate or being excluded were reported.

Study design
This was a before-and-after study that was conducted retrospectively. The study was carried out in a single centre (the main chlamydia testing laboratory in Glasgow). The study design did not require follow-up of the groups, or a blinded method for the outcome assessment. The data were collected from April 1996 to March 2000.

Analysis of effectiveness
Although not stated explicitly, it would appear that the analysis of the study included all participants. The primary health outcome used was the number of cases of chlamydia detected. The authors did not state whether any patients were excluded for incomplete data. At analysis, the control group was very much smaller than the comparator group.

Effectiveness results
During the course of the study, 3,993 (5.9%) specimens tested positive.

The detection rate of chlamydia rose substantially in both genders during the review period, by 63% in women (chi-squared test for trend = 72.5, p<0.001) and 64% in men (chi-squared test for trend = 186.4, p<0.001).

There was a 44% rise in detection rate in patients under 20 years old (chi-squared test for trend = 5.77, p<0.01) and a 29% rise in those aged 20 or above (chi-squared 5.73, p<0.01).

The rise in detection rate was particularly marked in the GUM clinic population, rising from 6.4 to 8.6% (chi-squared test for trend = 7.7, p<0.01).

By 1999-2000, the majority of samples from male patients were urine specimens. The overall detection rate LCR from male urine was 10.2%, compared with 7.8% from urethral swabs.

Clinical conclusions
There was an increase in chlamydia detection rates during the study period. This increase was observed in both genders, in patients aged younger than 20 years, and in those aged 20 and older.

Modelling
An unspecified model was used to estimate the costs of the diagnostic tests.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. In effect, a cost-consequences analysis was performed.
Direct costs
The resource quantities and the costs were not reported separately. Hospital costs (staff, reagents, consumables and laboratory overheads, based on the amount of space used) were included in the analysis. The source of the direct costs was not reported. It would appear that the costs were derived using modelling techniques. Discounting was not relevant as the costs were assigned retrospectively using 1999-2000 values. The paper seems to indicate that average prices have been used.

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
The indirect costs were not reported.

Currency
UK pounds sterling (Ł).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total intervention costs and total comparator costs were not included. In addition, a statistical analysis of the costs was not reported. However, the authors reported that following the introduction of LCR testing, an additional 53,525 on testing men and 222,105 on testing women was spent in comparison with the predicted cost of using EIA.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The authors estimated that the improved detection rates of ligase chain reaction (LCR) testing resulted in an additional 331 men and 844 women being diagnosed during the study period. The cost per additional diagnosis was estimated to be 162 for men and 263 for women.

CRD COMMENTARY - Selection of comparators
The comparator chosen represented current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a retrospective before-and-after study, which was appropriate for the study question. The study sample included all samples sent to one laboratory. Demographics and other characteristics were not reported for either the study population or the study sample (except for the percentage under 20 years old). Thus, it is not possible to say with certainty whether or not the patient groups were comparable at analysis. The authors stated that the demographic profile of family planning clinic attendees in the city showed no significant change during the study.
period. However, they also suggested that changes in population and health care provider characteristics might have influenced the observations found. The analysis of effectiveness appears to have been handled credibly.

**Validity of estimate of measure of benefit**
The analysis of benefits was based upon the therapeutic equivalence of treatment alternatives. Therefore, the economic analysis included only costs.

**Validity of estimate of costs**
Full details of the costs were not included in this paper, but it appears that all the categories of cost relevant to the perspective adopted have been included in the analysis. The costs were not reported separately from the quantities and the resource use quantities were not reported. A statistical analysis of the prices was not performed. Charges were not used to proxy prices. The authors reported that 1999-2000 laboratory costs were used.

**Other issues**
The authors made appropriate comparisons of their results with findings from other studies. The issue of generalisability to other settings was not addressed. The authors reported only a selection of their results. The authors' conclusions reflected the scope of the analysis.

The authors recognised that the study was limited by its retrospective, laboratory-based design. They also reported that changes in population and health care provider characteristics, including age, sexual behaviour, health-seeking behaviour and the selection of patients for testing, might have influenced the observations found. The authors acknowledged that the relative quantitative effects of the implementation of LCR testing, the lower threshold for testing, and the growing number of younger patients attending GUM services are impossible to differentiate within the methodology of this study.

**Implications of the study**
The authors suggested that the difference in the cost per case detected and the cost per additional case detected might relate to the populations being tested. More work is required to study this in detail. They recommended that a full economic evaluation of the costs and health consequences of false-positive and false-negative tests for chlamydial infection should be carried out. Also, further studies are required to resolve the issue of which type of specimen produces optimal detection rates in both high- and low-prevalence populations.

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