Evaluation of a new rapid diagnostic kit (FemExam) for bacterial vaginosis in patients with vaginal discharge syndrome in the Gambia

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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
The study examined the use of the Amsel criteria plus a rapid diagnostic kit (FemExam) for the diagnosis of bacterial vaginosis (BV).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women attending a genitourinary medicine (GUM) clinic with self-reported symptoms of vaginal discharge and/or vaginal itching. Women younger than 18 years old, pregnant women and women with known advanced human immunodeficiency virus disease were excluded.

Setting
The setting was a GUM clinic. The economic study was carried out in Fajara, the Gambia.

Dates to which data relate
The effectiveness and resource use data were gathered during a 4-month period from July to October 2000. Prices for 1999 were used.

Source of effectiveness data
The prevalence and validity of the diagnostic tests were derived from a single study.

Link between effectiveness and cost data
The effectiveness and resource use (cost) data were collected prospectively from the same sample of patients.

Study sample
No power calculations were reported. Participants were sampled consecutively from those attending a GUM clinic with self-reported symptoms of vaginal discharge and/or vaginal itching. This sample appears to have been appropriate for the clinical study question since these symptoms are associated with BV. The study included 230 women who attended the clinic and were screened for BV using the Nugent score, the Amsel clinical criteria and the FemExam diagnostic test kit. Four women were subsequently excluded (three did not report symptoms and one was found to have advanced human immunodeficiency virus infection), leaving a sample of 226.
Study design
The study was a diagnostic study that was conducted in one centre (Fajara, the Gambia). After written consent was obtained and a questionnaire (to elicit background information) completed, the participants underwent a speculum examination during which swabs were taken. Treatment was given according to Gambian government syndromic management protocols, such that all women who presented were treated.

Analysis of effectiveness
The analysis of effectiveness of the diagnostic methods included only those for whom complete data were available. The performance of the Amsel criteria and FemExam cards was evaluated against the gold standard of a Nugent score between 7 and 10. Validity was assessed using the sensitivity, specificity, positive and negative predictive values, overtreatment and correct-treatment ratios. All results were presented in the paper.

Effectiveness results
The Amsel criteria had a sensitivity of 77.9 (95% confidence interval, CI: 68.7 to 85.4) and a specificity of 58.4 (95% CI: 48.8 to 67.6).

The FemExam PA (card 1) had a sensitivity of 71.4 (95% CI: 61.7 to 79.8) and a specificity of 72.8 (95% CI: 63.7 to 80.7).

The FemExam G (card 2) had a sensitivity of 70.0 (95% CI: 55.4 to 82.1) and a specificity of 80.9 (95% CI: 69.1 to 71.6).

The FemExam PAG (cards 1 and 2) had a sensitivity of 91.0 (95% CI: 83.1 to 96.0) and a specificity of 61.5 (95% CI: 50.7 to 71.6).

Clinical conclusions
The Amsel clinical criteria gave 78% sensitivity but only 58% specificity in comparison with the gold standard, and resulted in 21% overtreatment. Using FemExam card 1 or card 2 alone would detect and correctly treat around 70% of cases. Using both cards together increased the sensitivity to 91%, at the expense of more false-positives and lower specificity. Either card used singly resulted in similar overtreatment (14.2% and 10.6% for cards 1 and 2, respectively).

Measure of benefits used in the economic analysis
The measures of benefit used were the number of true cases detected and the number of individuals overtreated, relative to the Nugent score.

Direct costs
Discounting was not required because of the short time horizon. The study estimated:

the total cost (testing each patient and treating those found to be positive),

the cost per patient (total cost divided by the number of patients),

the cost per true case detected (total cost divided by the number of true cases detected), and

the cost of overtreatment (total cost of treating those falsely diagnosed).

All consumable costs were obtained from the 1999 price lists of the International Dispensary Association, except for the cost of the FemExam kit which came from the manufacturers. The costs of clinician and technician time were assumed to be $4,500 and $3,000 per year ($0.04 and $0.03 per minute), respectively.
Statistical analysis of costs
There was no statistical analysis of the costs. The analysis was purely descriptive.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

Sensitivity analysis
A one-way sensitivity analysis was carried out on the cost of the FemExam kits and the inclusion of clinician and technician time costs.

Estimated benefits used in the economic analysis
The resulting number of true cases was not reported separately.

Overtreatment occurred in 21.7% of cases with the Amsel criteria, 14.2% with FemExam card 1, 10.6% with FemExam card 2 and 19.4% with FemExam cards 1 and 2.

Cost results
The total costs were not reported. The average cost per patient was $0.74 for the Nugent Gram stain diagnosis, $1.29 for the Amsel criteria, $4.25 for FemExam card 1, $8.32 for FemExam cards 1 and 2 and $0.50 for presumptive (syndromic) treatment.

Reducing the cost of the FemExam card to $1.00 (from $4.00) reduced the cost per patient to $1.24 for card 1 and to $2.32 for cards 1 and 2.

Synthesis of costs and benefits
The simplified Amsel criteria cost $3.47 per true case and $0.11 per overtreated patient.

The FemExam card 1 cost $12.39 per true case and $0.07 per overtreated patient.

The FemExam cards 1 and 2 cost $18.49 per true case and $0.10 per overtreated patient.

Treating all women who presented with symptoms would cost $1.04 per true case and $0.26 per overtreated patient.

Reducing the cost of the FemExam card to $1.00 (from $4.00) reduced the cost per true case to $3.63 for card 1 and to $5.16 for cards 1 and 2.

The cost per overtreated patient was insensitive to the change in price.

Authors’ conclusions
This study has demonstrated that bacterial vaginosis (BV) was common in this population of women reporting vaginal discharge syndrome at an urban genitourinary medicine (GUM) clinic in the Gambia. The FemExam test compared favourably with conventional clinical diagnosis and has the advantage of being rapid, less subjective and easily performed in clinical settings of resource-poor countries. Cutting its cost would provide wider accessibility in developing countries. Presumptive treatment of BV in settings with a high prevalence of BV is at present more cost-effective than any current diagnostic method.
CRD COMMENTARY - Selection of comparators
A justification was given for the comparators used. The Nugent Gram stain is the assumed gold standard, while the Amsel clinical criteria represent a conventional clinical diagnosis. You should decide if these are widely used health technologies in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on diagnostic study, which was appropriate for the study question. In addition, the authors appear to have reported the appropriate results for a diagnostic study. The study sample was representative of the study population, although the use of a convenience sample could introduce selection bias. However, there were sufficient details to enable the reader to consider the issue of generalisability to other settings. No power calculations were reported, thus it is possible that the differences observed between the two methods were due to chance.

Validity of estimate of measure of benefit
The estimation of benefits was obtained directly from the effectiveness analysis. These choices (true cases detected and overtreatment) were justified, although they do not lend themselves easily to comparisons with other health technologies and do not capture any downstream resource use or health outcome that may occur as a result of the test.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted were included in the analysis. The costs and (some) quantities were reported separately. However, a statistical analysis of the prices was not performed. The sources of the unit cost data (the International Dispensary Association and the manufacturer) and the price year employed were appropriate. A sensitivity analysis on the cost (reduced) of the FemExam kit and the inclusion of clinician and technician time was conducted.

Other issues
The authors made appropriate comparison of their findings with those from other studies. The issue of generalisability to other settings was addressed. The authors do not appear to have presented their results selectively, although presentation of the total costs and actual outcome measures would enhance the generalisability of the study.

Implications of the study
The authors suggested that if the prevalence of BV is great then it is more cost-effective to treat those presenting with symptoms than to undertake diagnosis and treat those found to be positive. This syndromic approach is recommended by the World Health Organization. It has the additional advantage of leaving no women untreated, which represents further savings in terms of health consequences of BV or return visits. However, the consequences of overtreatment and drug resistance should not be ignored.

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