Cost of bacterial vaginosis in pregnancy: decision analysis and cost evaluation of a clinical study in Germany

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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 strategies were compared for the screening and treatment of bacterial vaginosis during early pregnancy. The first strategy (A) was to screen all pregnant women and treat positive cases with clindamycin. The second strategy (B) was to screen all pregnant women and treat positive cases with Lactobacillus.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The patients were women recruited at their first antenatal visit to primary care, during early pregnancy.

Setting
The setting was primary care. The economic study was conducted in gynaecological practices in Berlin, Germany.

Dates to which data relate
The dates during which the effectiveness evidence and the resource use data were collected were not reported. The price year was 1996.

Source of effectiveness data
The effectiveness estimates were derived from a single study (see Other Publications of Related Interest).

Link between effectiveness and cost data
A single prospective study provided both the effectiveness and resource use data (see Other Publications of Related Interest).

Study sample
Three centres, each of which implemented one of the three strategies under investigation, participated in the study. The study included 300 patients in each centre (or group). Power calculations were not used to determine the sample size. Women who were to undergo Caesarean delivery and resections, indicated by breech presentation, were excluded from the analysis. The total number of women analysed was:

in group A (screening and treatment with clindamycin), 293;
in group B (screening and treatment with Lactobacillus), 288; and
in group C (no screening and no treatment), 289.

No baseline characteristics of the women were given.

**Study design**
This was a non-blinded, non-randomised study carried out at three gynaecological practices. The women were allocated to the treatment according to the strategy adopted by the practice at which they sought antenatal care. The women were followed-up until the birth outcome could be assessed.

**Analysis of effectiveness**
The primary health outcome used in the analysis was the number of pre-term births at different gestational ages (less than 37 weeks’ gestation) and at low birth weight (less than 2,500 g). The method of analysis was not stated. Health outcomes were not valued in this analysis. The authors did not report the degree to which the groups were comparable in terms of key demographic parameters. In addition, they did not adjust for confounding factors.

**Effectiveness results**
There were 16 pre-term deliveries in the first centre, 36 in the second centre, and 41 in the third centre.

The proportion of pre-term deliveries was presented for each group, according to the gestational age. At 28 weeks’ gestation, the proportion of pre-term births was 5.9% in group A, 0% in group B, and 0% in group C. At 36 weeks’ gestation, these figures were 52.9% (group A), 63.9% (group B), and 38.1% (group C).

The proportion of pre-term deliveries was also reported by birth weight (g). For a birth weight of 1,000 - 1,500g, the proportion of pre-term births was 5.9% in group A, 0% in group B, and 4.8% in group C. For a birth weight of 3,001 - 3,500 g, these figures were 11.7% (group A), 25.0% (group B), and 7.1% (group C).

There were more than twice as many premature infants with a birth weight of less than 2,500 g in the third practice (C), than in the first practice (A).

There were 7.1% more infants weighing less than 2,500 g in the third practice (C) than in the first practice (A). Also, there were 25% more infants weighing less than 2,500 g in the third practice (C) than in the second practice (B).

No p-values or results of statistical tests were provided.

**Clinical conclusions**
There appeared to be more pre-term babies in the no screening and no treatment group. The comparison between the two screening groups was unclear.

**Modelling**
A decision-analytic model was used to synthesise the resource use information from the trial.

**Measure of benefits used in the economic analysis**
This was a cost-consequence analysis and, therefore, a summary measure of benefit was not expressed.

**Direct costs**
The perspective of the study was that of the health service. The analysis included the costs of screening, treatment of bacterial vaginosis, and deliveries. The resource quantities (only in terms of the number of deliveries) were derived...
from the trial. The unit cost data were taken from charges applicable to the hospital where most of the deliveries were conducted. The unit costs and quantities were not reported separately. The costs were divided, according to the decision model, into those for greater and those for less than 37 weeks' gestation, and whether delivery was vaginal or abdominal. The average cost of the screening and treatment per delivery was assessed for each practice, then expressed as a mean cost per delivery. The charges and the prices of the drugs were from 1996. Discounting was irrelevant due to the short timeframe of the study, and was therefore not carried out.

Statistical analysis of costs
A statistical analysis of costs was not carried out.

Indirect Costs
No indirect costs were included.

Currency
German marks (DM). These were converted into US dollars ($). The conversion rate was that of 18 May 1998 viz., US$1 = 1.79DM.

Sensitivity analysis
The authors conducted a one-way sensitivity analysis on the costs of two estimates: the proportion of pre-term deliveries (+/-20%), and the charges for pre-term deliveries (+/-20%).

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

Cost results
The total cost for screening 300 women in the first practice (A) was $3,084. The screening and treatment costs were not reported for the second practice (B). When taking the cost of deliveries into account, the total cost was $493,159 for the first practice (A), $497,619 for the second practice (B), and $534,926 for the third practice (C). The average cost per patient was $1,683 in the first practice (A), $1,728 in the second practice (B), and $1,851 in the third practice (C). The savings associated with screening and treatment were therefore $37,307 to $41,767, compared with no screening and no treatment. The presence of savings was not altered by the sensitivity analysis.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The authors concluded that it was likely that the screening and treatment of bacterial vaginosis reduced the rate of premature births. Further, they commented that money could be saved from reducing the number of pre-term deliveries.

CRD COMMENTARY - Selection of comparators
Screening was compared with no screening. The comparison to no screening appears to have been appropriate, as this is the most common process in the setting of the study. However, the rationale for the choice of the drug interventions (clindamycin and Lactobacillus) to treat bacterial vaginosis was not provided. Decision-makers should therefore judge whether these treatments are relevant in their own setting.
Validity of estimate of measure of effectiveness
The estimate of effectiveness was derived from a prospective study in which patients were allocated to the treatment according to the study centre. Such a study design may have been efficient, but the authors did not provide any demographic data on the study centres or the participating women. Thus, it was not possible to assess whether the study groups were comparable. It was also difficult to assess whether the association between the screening and treatment for bacterial vaginosis and the birth outcome was valid. The study may have benefited from an attempt to adjust for potential confounding factors due to the non-randomised design. The authors acknowledged this problem but stated that the women coming from a similar location would reduce this bias. They also noted that there was no screening in practice C, which would have shown the extent to which one could attribute the difference between practices to the treatment of infection.

Validity of estimate of measure of benefit
Not applicable.

Validity of estimate of costs
There were several problems with the cost analysis. As the authors acknowledged, the cost was varied according to the gynaecological practice and the method of delivery. The latter was not controlled for, practice C having the highest rate of Caesarean section. Also, it was assumed that the costs were only variable by the measure of prematurity (gestational age), in two categories: less than 37 weeks and 37 weeks or more. No account was taken of the actual resource use or the variability by birth weight. Since the resource quantities and the unit costs were not given, it is impossible to validate these results or consider their generalisability. Also, the sensitivity analysis used only an arbitrary range.

Other issues
The authors compared their results with studies conducted elsewhere, and commented that their findings support other studies. However, they did not address the issue of generalisability of their findings. Also, there was a lack of presentation of the cost results. The authors’ conclusions relating to the savings due to screening and treatment are questionable due to the problems highlighted.

Implications of the study
The authors recommend that the current practice of not screening pregnant women for bacterial vaginosis should be re-evaluated.

Source of funding
None stated.

Bibliographic details

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Administration, Intravaginal; Anti-Bacterial Agents /administration & dosage /therapeutic use; Clindamycin /administration & dosage /therapeutic use; Costs and Cost Analysis; Female; Germany; Gestational Age; Humans; Infant, Low Birth Weight; Infant, Newborn; Infant, Premature; Lactobacillus; Obstetric Labor, Premature /etiology /prevention & control; Pregnancy; Pregnancy Complications, Infectious /economics /diagnosis /therapy; Vaginosis, Bacterial /economics /complications /therapy

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