Cost-effectiveness of cesarean section delivery to prevent mother-to-child transmission of HIV-1

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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 use of elective Caesarean section (ECS), performed before onset of labour and before rupture of membranes, in pregnant women infected with human immunodeficiency virus (HIV).

Type of intervention
Primary prevention during delivery.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised pregnant HIV-positive women who refrained from breast-feeding.

Setting
The setting of the study appears to have been the community. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness evidence and resource use data were mainly gathered from studies published between 1996 and 1999. The price year was 1998.

Source of effectiveness data
The effectiveness evidence was derived from published studies, supported by the authors' assumptions.

Modelling
Two decision models were used to assess the costs and effectiveness of ECS in comparison with vaginal delivery. In the individual-based analysis, the per-patient costs and benefits of ECS were estimated. The population-based analysis provided information useful for the whole US population. The structure of the models was not reported, but three main scenarios were studied. These were no antiretroviral therapy (ART), zidovudine (ZDV) only, and combination ART. The models were populated with data derived from the literature and from the authors' assumptions.

Outcomes assessed in the review
The outcomes assessed from the literature, for the individual-based analysis, were the transmission rates when no ART was used, and those when ZDV prophylaxis or combination ART were used. The population-based analysis used the number of HIV-infected women delivering annually and data on population characteristics (such as HIV seroprevalence among pregnant women in the US and the percentage of women who receive ART during pregnancy).
Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not reported.

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
The effectiveness evidence was derived from five primary studies.

Methods of combining primary studies
The primary studies were combined using narrative methods.

Investigation of differences between primary studies
Not stated.

Results of the review
In the individual-based model, the transmission rates were 0.10 for ECS and 0.19 for vaginal delivery when no ART was used, 0.034 (ECS) and 0.071 (vaginal) when ZDV prophylaxis was used, and 0.01 (ECS) and 0.03 (vaginal) when combination ART was used.

In the population-based model, 4,958 HIV-infected women delivered annually, 68% of the women received ART during pregnancy, and the HIV seroprevalence among pregnant women in the USA was 1.7 per 1,000 pregnant women.

Methods used to derive estimates of effectiveness
The authors made several assumptions to support the lack of, or variability of, published data used in the decision models.

Estimates of effectiveness and key assumptions
The following assumptions were made:

- each woman received HIV counselling and testing according to current US Public Health Service recommendations;
- all women not receiving ECS delivered vaginally;
- HIV-infected women refrained from breast-feeding;
- all children received formula;
- ART had no subsequent impact on maternal health; and
ZDV was administered according to US Public Health Service recommendations.

In the population-based analysis, it was assumed that among women receiving ART, 29% received ZDV prophylaxis and the remaining 71% received combination ART. It was also assumed that 6% of the women receiving combination ART discontinued the therapy due to adverse events.

Measure of benefits used in the economic analysis
Two benefit measures were used in the economic analysis. One was the number of cases of mother-to-child transmission of HIV avoided, which was derived from the decision model only. The other was the child life-years saved, which was calculated also on the basis of the difference between the average US life expectancy of 75.8 years and the estimated life expectancy of 9.4 years for a HIV-infected child.

Direct costs
Discounting was carried out at a rate of 5%. The unit costs and the quantities of resources were not reported separately. The cost/resource boundary adopted in the analysis was that of the health care system. The costs of ART, mode of delivery (ECS or vaginal delivery), with or without morbidity, and paediatric care were estimated. Single cost items included in the analysis were not reported. The costs and the quantities were estimated from published data. The total costs of each intervention were calculated by modelling. All of the costs were inflated to 1998, which represented the price year.

Statistical analysis of costs
Statistical analyses of the costs were not carried out.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were carried out to assess the impact of some model parameters on the estimated cost-effectiveness ratios. The parameters varied were:

the vertical transmission rates, according to maternal HIV disease status and to mode of delivery;

the discounted lifetime treatment cost of paediatric HIV disease; and

the postpartum morbidity rates in the individual-based model, and the maternal HIV prevalence rates and the percentage of women receiving ART in the population-based model.

Estimated benefits used in the economic analysis
Estimated benefits were not reported in the individual-based analysis. In the population-based analysis, when comparing ECS with vaginal delivery, there was a reduction of 466 cases of HIV transmission with no ART, 198 cases with ZDV prophylaxis, and 120 cases with combination ART. Overall, regardless of the prophylaxis method, ECS resulted in a reduction of 239 HIV transmission cases in comparison with vaginal delivery.

Cost results
The cost results were not reported in the individual-based analysis. In the population-based analysis, when comparing ECS with vaginal delivery, the costs were -$27,151,509 with no ART, $224,294 with ZDV prophylaxis, and $8,875,051 with combination ART. Overall, regardless of the prophylaxis method, ECS resulted in $4,359,377 cost-savings in comparison with vaginal delivery.

**Synthesis of costs and benefits**

The costs and the outcomes were combined by an incremental cost-effectiveness analysis of ECS over vaginal delivery. This was conducted on the basis of the two benefit measures. A further cost-benefit analysis was carried out in which the economic benefit was represented by the decrease in expenditure. Thus, values greater than 1.0 indicated that the programme was cost-saving, as the costs saved were greater than the costs incurred for the intervention. In the individual-based analysis, ECS was the dominant strategy (more effective and less costly) when no ART was used. When ZDV prophylaxis was used, the extra cost per case avoided was $1,131 and the cost per life-year saved was $17 with ECS over vaginal delivery. When combination ART was used, the extra cost per case avoided was $112,693 and the cost per life-year saved was $1,697 with ECS over vaginal delivery. The incremental cost-benefit ratio of ECS over vaginal delivery was 2.23 when no ART was performed, 0.99 when ZDV prophylaxis was used, and 0.49 when combination ART was used. The decision model was mainly sensitive to vertical transmission rates according to the mode of delivery, and the costs associated with treatment for paediatric HIV disease.

**Authors’ conclusions**

Elective Caesarean section (ECS) was highly cost-effective when compared with vaginal delivery for the prevention of human immunodeficiency virus (HIV) vertical transmission among women receiving various antiretroviral therapy (ART), who refrained from breast-feeding. However, it was not always cost-saving.

**CRD COMMENTARY - Selection of comparators**

The rationale for the choice of the comparator was clear. Vaginal delivery was selected as it represented the standard delivery mode. In addition, three feasible scenarios of prophylaxis were considered. You should assess which prophylaxis therapies are currently implemented in your own setting.

**Validity of estimate of measure of effectiveness**

The effectiveness evidence was derived from published studies, although a formal review of the literature was not carried out. Details on the methods used to assess the validity of the primary studies, and combine the results, were not provided. It was unclear whether the authors considered the impact of differences between the primary studies when estimating the effectiveness. In addition, the authors made several assumptions to support the data obtained from the literature and used in the decision model. Some sensitivity analyses were carried out to take into account the uncertainty around the effectiveness estimates.

**Validity of estimate of measure of benefit**

The benefit measures used in the economic analysis were the number of cases of mother-to-child transmission of HIV avoided and the child life-years saved. These were derived using two decision models, the details of which were not provided.

**Validity of estimate of costs**

The cost analysis was carried out from the perspective of the health care system, with appropriate categories and discounting. However, details of the cost items included in the analysis were not reported. The unit costs and the quantities of resources used were not reported separately. The quantities and the costs were derived from published studies. The costs were treated deterministically, and sensitivity analyses were only carried out on the costs of paediatric HIV treatment.
Other issues
The authors made some comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not explicitly addressed. However, numerous sensitivity analyses were carried out, thus enhancing the external validity of the analysis. The authors considered pregnant HIV-infected women refraining from breast-feeding and this was reflected in their conclusions. The authors reported some limitations of their analysis. These were mainly related to the numerous assumptions made in the study, due to the lack of data published in the literature.

Implications of the study
The authors point out that ECS proved to be a cost-effective intervention under a wide range of economic and clinical scenarios. Further research should focus on different ART regimens and possible adverse events.

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