The economics of HIV vaccines: projecting the impact of HIV vaccination of infants in sub-Saharan Africa
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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 health technology studied was the vaccination of infants in sub-Saharan Africa against HIV (specifically the HIV-1 type) through the Expanded Program on Immunisation (EPI).

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised infants in sub-Saharan Africa.

Setting
The vaccination programme would be administered as part of the EPI, which is presumably delivered in primary or community care. The economic study pertained to 27 countries in sub-Saharan Africa.

Dates to which data relate
Data published between 1996 and 2001 inclusive were used to estimate the effectiveness using a model. 1998 and 2000 unit cost data were used. The costs were reported in 1998 dollars.

Source of effectiveness data
The effectiveness data were derived from a synthesis of various published sources.

Modelling
A static decision analysis model was used to incorporate the epidemiological, effectiveness and cost data. Its purpose was to estimate the cost-effectiveness and market size associated with the infant vaccination programme.

Outcomes assessed in the review
The following outcomes were assessed in the review:
percentage of infants with perinatally acquired HIV;
length of asymptomatic HIV and duration from AIDS to death;
average age at time of infection;
life expectancy at birth (without AIDS);
lifetime chance of acquiring HIV infection;
vaccine coverage rate;
the number of surviving newborns in 1998 in the region;
mean infant mortality in sub-Saharan Africa.

**Study designs and other criteria for inclusion in the review**
The data were derived from the Joint United Nations Programme on HIV/AIDS, the World Health Organisation (WHO), journals, and other sources as needed to populate the model.

**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**
Eight primary studies were included.

**Methods of combining primary studies**
Each model parameter was derived from one source. Most were subjected to sensitivity analysis (see below).

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
The percentage of infants with perinatally acquired HIV was 10%.

The length of asymptomatic HIV was 8 years and duration from AIDS to death was 1 year.

The average age at time of infection was 25 years.

The life expectancy at birth without AIDS was 54.8 years.

The lifetime chance of acquiring HIV infection was 35%.

The vaccine coverage rate was 48%.

The number of surviving newborns in 1998 in the region was 18,559,222.
The mean infant mortality in sub-Saharan Africa was 9.2%.

**Methods used to derive estimates of effectiveness**
The authors made some assumptions in the construction of the model.

**Estimates of effectiveness and key assumptions**
In the base case, it was assumed that the lifetime chance at birth of acquiring HIV was the same as the lifetime chance at age 15.

The vaccination coverage rates were assumed to apply to all infants, including those with perinatally acquired HIV.

No benefits were assumed to occur from the vaccination of children with perinatally acquired HIV.

The effectiveness of the vaccine was assumed to be 60%.

**Measure of benefits used in the economic analysis**
The health benefits were measured in disability-adjusted life years (DALYs) gained. Disability weightings of 0.123 for HIV and 0.505 for AIDS were used, these being derived from a report published in 1996. Discounting of future benefits was carried out at a base case rate of 3% per year.

**Direct costs**
The following direct costs were included in the analysis: administering the extra vaccine as part of EPI, counselling the mothers of the infants, and the cost of the vaccine itself. The medical costs of managing HIV/AIDS were not included. The administration and counselling cost data were derived from two sources published in 1998 and 2000. The vaccine costs were estimated based on a World Health Organisation report published in 2000. The costs were reported in 1998 US Dollars. The resource use quantities were not reported separately but could be inferred.

**Statistical analysis of costs**
No statistical analysis of costs was carried out.

**Indirect Costs**
Indirect costs were not included in the analysis.

**Currency**
US dollars ($)

**Sensitivity analysis**
Sensitivity analyses were carried out on several model parameters to assess the robustness of the findings to variability in the data, changes in the model's assumptions and changes in analytical methods (specifically, the discount rate). These parameters included: the vaccine efficacy, the discount rate, the impact of multiple doses of the vaccine and vaccine prices, the lifetime probability of acquiring HIV and the average age of infection. One-way and multi-way sensitivity analyses were carried out. Parameter values were varied over a wide range though no rationale was provided for the ranges adopted. However, the authors did provide their arguments for the choice of parameters included in the sensitivity analysis.

**Estimated benefits used in the economic analysis**
In the base case, the vaccination programme in the countries analysed was estimated to reach 8,717,122 infants per year and prevent 1,839,355 HIV infections per year. This translates to 16,461,800 DALYs gained per year. Potential adverse reactions to the vaccine were not considered.

Cost results
At a vaccine price of $5, the size of the market in these countries was estimated at $44,536,111 annually in 1998 US dollars.

Synthesis of costs and benefits
In the base case, the cost-effectiveness ratio was estimated to be $3.4 per DALY gained. Under all scenarios tested, the ratio remained within the threshold value suggested by the World Bank for health care interventions in the developing world. The cost-effectiveness of the vaccination programme was, however, sensitive to the number of doses required, the vaccine effectiveness and the lifetime chance of acquiring HIV.

Authors' conclusions
This analysis suggests that an HIV vaccine could be very cost-effective and possibly profitable to the manufacturer.

CRD COMMENTARY - Selection of comparators
The implicit comparator was no HIV vaccination programme for infants in sub-Saharan Africa. This is the current situation.

Validity of estimate of measure of effectiveness
The authors did not describe the methods they use to identify and extract effectiveness evidence. The model was clearly described and sensitivity analyses were carried out on the model parameters.

Validity of estimate of measure of benefit
The health benefits of vaccination were valued in DALYs gained, a system which is commonly used to evaluate health programmes for the developing world. Thus, these findings should be comparable with the estimated cost-effectiveness of other such programmes.

Validity of estimate of costs
The unit cost data were taken from reliable sources. No statistical analysis was performed but some of the cost parameters were subjected to sensitivity analysis. The authors claimed to have taken a societal perspective but included in their analysis only the direct costs of delivering the vaccine. Savings of indirect costs and medical costs were excluded. Thus, the societal cost-effectiveness was likely to be better than that estimated in this study. Moreover, to the extent that this study was an attempt to inform manufacturers of the potential size of the market, the wider societal costs and benefits were of little relevance.

Other issues
Due to the uncertainty surrounding many of the parameters, the authors used a simple static model to estimate the costs and benefits of a vaccination programme. Thus the benefits reported in the study are probably an underestimate, as they did not take into account any subsequent reduction in secondary transmission of HIV. On the other hand, they acknowledged the possibility of an adverse effect to vaccination whereby vaccinated people engaged in more risky behaviour believing that they were protected against HIV. This could result in an increase in HIV infections if the vaccine was not fully effective and could lead to a higher incidence of HIV types that are not covered by the vaccine, as well as to other infectious diseases. This effect was not built into the model. The authors acknowledged these points.
Approximately 16 countries were excluded from the analysis due to a lack of appropriate data. Thus, the cost-effectiveness ratios were not directly generalisable to sub-Saharan Africa as a whole. However, the robustness of the overall finding to sensitivity analysis suggests that vaccination is likely to be cost-effective in the other countries. The size of the market in this region is therefore underestimated by this study.

The authors cited three model parameters as being important in the multi-way sensitivity analyses though they appeared to subject only four parameters to this analysis. It is not clear whether they have presented only a selection of the multi-way sensitivity analysis results or whether the analysis was of limited use in distinguishing the most sensitive parameters.

**Implications of the study**

Having described why they believe the EPI to be the most effective way to deliver HIV vaccination, the authors recommend that more research is needed to test the safety and efficacy of the vaccines in infants. They also acknowledge that this delivery system does not target the highest-risk groups.

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None given.

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