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
Mandatory compared with voluntary screening for human immunodeficiency virus in pregnancy.

Type of intervention
Health care policies for the prevention of perinatal transmission of HIV.

Economic study type
Cost-effectiveness analysis.

Study population
Pregnant women.

Setting
Hospital. The study was the result of the collaboration between specialists from Boston, Massachusetts, Washington DC and North Carolina, USA.

Dates to which data relate
The authors used, as the main source of effectiveness data, the AIDS Clinical Trial Group protocol 076, published in February 1994, but baseline probabilities were also derived from studies published between 1991 and 1996. Costs were derived from studies published between 1994 and 1996 and from personal communications. All monetary values were expressed in 1995 US dollars.

Source of effectiveness data
Effectiveness data were derived from a synthesis of previously published studies.

Modelling
Using a health care system perspective, a decision-analysis model was constructed to estimate the outcomes and costs of two strategies:

(1) Voluntary testing of those pregnant women who agreed to be screened after counselling (universal counselling and voluntary testing), and

(2) Mandatory screening of all pregnant women after counselling about the implications of a positive HIV test in pregnancy, including the option of zidovudine treatment (universal counselling and mandatory testing).

The number of cases of paediatric infection prevented was the main outcome measure considered. Key assumptions
included:

(1) The authors considered only the testing and treatment of previously unidentified HIV-infected women for whom ZDV would not be recommended as therapy on the basis of indications other than vertical transmission;

(3) The authors assumed the following counselling policies. For voluntary testing all pregnant women received pre-test counselling and those who agreed to be tested received post-test counselling. For mandatory testing all pregnant women received pre and post-test counselling;

(3) Post-test counselling was assumed to be more intensive and therefore more expensive for women with positive test results;

(4) The authors assumed that women who become aware of their HIV-positive status would not be more likely to terminate their pregnancy than seronegative women;

(5) The authors assumed that women identified as HIV positive after 34 weeks would also be treated, with lower efficacy and medication costs;

(6) The authors also assumed that zidovudine treatment was not associated with increased risk of adverse pregnancy outcomes.

Outcomes assessed in the review
Baseline probabilities were derived from the literature for: prevalence of HIV, proportion of women agreeing to testing after counselling, relative risk of HIV infection in women refusing testing, proportion of women presenting for prenatal care before 34 weeks, proportion of women presenting with no prenatal care, relative risk of HIV infection in women with late or no prenatal care, sensitivity and specificity of ELISA (enzyme-linked immunosorbent assay), sensitivity and specificity of Western blot, proportion of HIV positive women accepting ZDV (zidovudine) under voluntary screening, vertical transmission rate of HIV from mother to infant, efficacy of ZDV in reducing vertical transmission.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Various public health reports from different Centers for Disease Control and Prevention, BMJ, Lancet, JAMA, AIDS Public Policy, National Center for Statistics reports, American Journal of Obstetrics and Gynaecology, New England Journal of Medicine, and AIDS Journal were mentioned as sources for primary studies.

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
14 studies were considered.

Methods of combining primary studies
Most studies had separate inputs and only few outcomes were estimated based on findings of two or more studies.
Investigation of differences between primary studies
Not detailed.

Results of the review
The following baseline probabilities were reported:

- Prevalence of HIV, 0.0017;
- Proportion of women agreeing to testing after counselling, 0.8;
- Relative risk of HIV infection in women refusing testing, 2;
- Proportion of women presenting for prenatal care before 34 weeks, 0.96;
- Proportion of women presenting with no prenatal care, 0.015;
- Relative risk of HIV infection in women with late or no prenatal care, 3;
- Sensitivity and specificity of ELISA (enzyme-linked immunosorbent assay), 0.98 and 0.995 respectively;
- Sensitivity and specificity of Western blot, 0.97 and 0.994 respectively;
- Proportion of HIV positive women accepting ZDV (zidovudine) under voluntary screening, 0.8;
- Vertical transmission rate of HIV from mother to infant, 0.25;
- Efficacy of ZDV in reducing vertical transmission, 0.66.

Methods used to derive estimates of effectiveness
Effectiveness estimates were also based on the authors' assumptions.

Estimates of effectiveness and key assumptions
Estimates were made for the relative risk of no prenatal care in response to mandatory screening, the relative risk of acceptance/compliance with ZDV in women identified through mandatory screening and relative efficacy of ZDV after 34 weeks used and these were based on the following assumptions:

1. The authors considered only the testing and treatment of previously unidentified HIV-infected women for whom ZDV would not be recommended as therapy on the basis of indications other than vertical transmission;
2. The authors assumed the counselling policies described above;
3. Post-test counselling was assumed to be more intensive and therefore more expensive for women with positive test results;
4. The authors assumed that women who become aware of their HIV-positive status would not be more likely to terminate their pregnancy than seronegative women;
5. The authors assumed that women identified as HIV positive after 34 weeks would also be treated, with lower efficacy and medication costs;
6. The authors also assumed that zidovudine treatment is not associated with increased risk of adverse pregnancy outcomes.
Measure of benefits used in the economic analysis
The number of cases of paediatric infection prevented was the benefit measure considered.

Direct costs
The authors adopted a US health care system perspective and limited costs to direct and indirect costs associated with the prevention and treatment of paediatric HIV infection, namely: cost of maternal screening, counselling and treatment costs in pregnancy and paediatric HIV costs. Sources for costs were the literature and personal communication with staff at the Centers for Disease Control and Prevention and the New York City and New York State Health Departments. The time frame and analytic horizon for maternal costs were limited to the duration of pregnancy. Cost variables were reported separately. Future costs for paediatric HIV medical care were distributed over the median reported life expectancy (6 years). Costs were discounted at a base rate of 5% per year.

Statistical analysis of costs
Not performed.

Indirect Costs
Indirect costs were not considered (such as loss of productivity due to AIDS, etc).

Currency
US dollars ($).

Sensitivity analysis
All calculations and analyses were performed using DATA 3.0, a decision-analysis software program. No details were given regarding the type of analyses performed. The following variables were reported to have been tested: baseline probabilities, costs, and discount rate.

Estimated benefits used in the economic analysis
The numbers of cases of paediatric infection prevented were 12.3 for the voluntary and 18.4 for the mandatory screening strategy.

Cost results
At a prevalence of 170 per 100,000, the costs of the voluntary screening strategy were pediatric HIV costs of $3,020,000, and maternal screening and treatment costs of $5,737,000. The corresponding costs for the mandatory screening strategy were $2,410,000 and $6,531,000.

Synthesis of costs and benefits
At a prevalence of 170 per 100,000, the average costs per case prevented were $255,158 for mandatory screening and $367,998 for voluntary screening. The incremental cost-effectiveness of mandatory compared with voluntary screening was $29,478. These values decreased as prevalence of HIV increased; above an estimated cost for paediatric HIV of $129,250, mandatory screening was less expensive and more effective than voluntary screening. Assumptions about patient behaviour affected the results: a 40% reduction in zidovudine acceptance in women identified only through mandatory screening increased the incremental cost-effectiveness to $112,434. The impact of behaviour increased as the prevalence of HIV increased.

Authors’ conclusions
Mandatory screening will prevent more cases of paediatric AIDS, but at somewhat higher cost than voluntary screening.
under baseline assumptions. The cost-effectiveness of mandatory screening will be influenced by patient behaviour, especially acceptance of zidovudine treatment among women who would have refused voluntary screening.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparators (mandatory versus voluntary screening for HIV) is clear, as both are possible screening strategies. You, as a database user, should consider whether this applies to your own setting.

**Validity of estimate of measure of benefit**
It is difficult to judge the validity of the estimates of measure of benefit as it is not clear whether the baseline probabilities were derived using a systematic literature review. The authors chose not to include quality of life in the analysis as they considered it to be inappropriate.

**Validity of estimate of costs**
Costs appear to be valid and no important direct items appear to have been omitted. The cost analysis is detailed and the authors provide sufficient details relating to cost estimation. Cost results may not, however, be generalisable to other settings or countries.

**Other issues**
The uncertainties around the data were explored in a set of sensitivity analyses, although further details would have been helpful. The authors presented an extensive comparison of their study with other similar published papers.

**Implications of the study**
Mandatory screening will prevent more cases of paediatric AIDS, but at somewhat higher cost than voluntary screening under baseline assumptions.

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