Cost-effectiveness of additional hepatitis B virus nucleic acid testing of individual donations or minipools of six donations in the Netherlands

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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.

CRD summary
This study examined the cost-effectiveness of triple nucleic acid testing, to reduce hepatitis B virus (HBV) infection by blood transfusion, in small pools of six donations and in individual donations, compared with pools of 24 donations. The authors concluded that reducing the pool size from 24 to six or to individual donations led to relatively effective prevention of HBV transmission, but at a very high cost. The study was well conducted and the authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The objective was to examine the cost-effectiveness of a triple nucleic acid test, to reduce the risk of hepatitis B virus (HBV) by blood transfusion, in small pools of six donations, in individual donations, or in pools of 24 donations, in a low-prevalence country.

Interventions
The three strategies were nucleic acid testing in pools of six donations, in individual donations, or in pools of 24 donations.

Location/setting
Netherlands/laboratory setting.

Methods
Analytical approach:
The analysis was based on a mathematical model of the transfusion from donors to recipients and on a Markov model to determine the economic impact of the three strategies. A lifetime horizon was adopted. The authors did not explicitly state the perspective adopted.

Effectiveness data:
The clinical data came from a selection of known, relevant studies, which were not described, except for a pilot study performed in 1997 in the Netherlands, which included a random sample of 1,000 whole blood donations and was used to obtain the age distributions of donors and their survival rate. Other country-specific sources were used for HBV incidence and other epidemiological values. The key inputs were the probabilities of transition between health conditions in the model and these were mainly from a published cost-effectiveness analysis.

Monetary benefit and utility valuations:
The utility valuations were from published studies, including a cost-effectiveness analysis, but their methods were not reported.

Measure of benefit:
The number of HBV cases prevented and quality-adjusted life-years (QALYs) were the summary benefit measures and these were discounted at an annual rate of 1.5%.
Cost data:
The economic analysis included the additional cost of nucleic acid testing for pools of six donations and individual donations (compared with 24 donations) and the costs of HBV infections (both medical and indirect due to inability to work). The cost of testing (reagents, disposables, personnel, and investments) was derived from a Dutch blood supply foundation for the formal annual budget proposal to the Ministry of Health. The costs of HBV infections included outpatient and in-patient treatment of various health states associated with HBV and transplantation. These costs were derived from a previous Dutch study. All costs were in Euros (EUR) and the price year was 2005. A 4% annual discount rate was applied to future costs.

Analysis of uncertainty:
The issue of uncertainty was investigated in regression analyses of output variables that allowed the identification of the most influential model inputs. Arbitrary ranges of values were used for the costs of each disease state, while published ranges of values were used for the clinical inputs. Confidence intervals (CIs) around the cost-utility ratios were calculated. A hypothetical scenario was considered where the proportion of immigrants from endemic countries among donors was identical to the proportion in the general Dutch population.

Results
In comparison with the reference strategy (testing 24 donations pooled), the number of HBV cases prevented was 3.12 with six donations and 3.57 with individual donations. The incremental cost per case prevented was EUR 308,001 with six donations and EUR 526,383 with individual donations.

Each HBV infection prevented saved 1.01 QALYs. The incremental cost per QALY gained was EUR 303,218 (95% CI 233,001 to 408,388) with six donations and EUR 518,995 (95% CI 399,359 to 699,120) with individual donations. In the alternative scenario for the proportion of immigrant donors, the incremental cost per QALY gained was EUR 280,835 with six donations and EUR 480,742 with individual donations.

The sensitivity analyses showed that the incremental cost-effectiveness ratios were most sensitive to changes in the incidence rate, recipient age, and discount rate. In general, the testing of 24 pooled donations remained the most cost-effective option at standard thresholds.

Authors' conclusions
The authors concluded that reducing the pool size for triplex nucleic acid testing from 24 to six or to individual donations led to relatively effective prevention of HBV transmission, but at a very high cost.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear as the conventional strategy in the authors' setting was compared with the two potential strategies. The authors justified their exclusion of testing for antibodies to hepatitis B core antigen as it was not available in the Netherlands.

Effectiveness/benefits:
Limited information on the derivation and the characteristics of data sources was provided, which limits the possibility of judging the validity of the clinical data. It was unclear whether a selective approach was used to derive these estimates. Except for some country-specific sources, no information on the other studies was given. Issues related to the use of data from multiple sources were not explicitly discussed. This was due to the fact that most of the clinical data were from a published economic model. The authors justified their use of QALYs rather than unadjusted survival as the summary benefit measure, given the relevance of the quality of life associated with avoided HBV infections. Conventional discounting was applied.

Costs:
The analysis of costs was valid and a wide perspective was adopted. The perspective was not explicitly stated, but appeared, from the categories of costs, to be societal. The costs were presented as macro-categories and were not broken down into individual items, which reduces the transparency of the economic approach. The sources of data reflected the Dutch setting, but were not fully described. Some key items were appropriately varied in the sensitivity
Analysis and results:
The analysis was based on a valid approach and the costs and benefits were reported and synthesised in an incremental analysis. The issue of uncertainty was appropriately investigated and was well discussed. The authors acknowledged some limitations of their study, which mainly related to assumptions, but these do not appear to have biased the results. They compared their results with those of other published studies and highlighted the reasons for any differences.

Concluding remarks:
The study was well conducted and, despite some limited reporting of both the clinical and economic data, the authors’ conclusions appear to be valid.

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