Value and cost-effectiveness of screening blood donors for antibody to hepatitis B core antigen as a way of detecting window-phase human immunodeficiency virus type 1 infections


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
Screening blood donors for antibody to hepatitis B core antigen (anti-HBc) as a way of detecting window-phase (WP) human immunodeficiency virus type 1 (HIV-1) infections.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
There were two partially overlapping study populations: male and female repeat donors (after the implementation of anti-HBc screening, 1987) seroconverted to HIV-1 positivity made before December 1990 and male and female (white, black, Hispanic and other) HIV-1 seropositive persons at least 18 years of age giving routine or directed donations.

Setting
Blood centres. The economic study was carried out in the USA (California, Georgia and New Hampshire).

Dates to which data relate
The main effectiveness data were mostly obtained from a single trial and previously completed studies published between 1993 and 1996. Resource and cost data were obtained from 1993-94 sources. The price year was 1995.

Source of effectiveness data
The sensitivity of anti-HBc in identifying HIV-1 WP infections, correlations between anti-HIV-1 and anti-HBc positivity among donors, long term survival for patients with and without transfusion-related complications, survival of patients infected with HIV-1 and yield of anti-HBc for HIV-1 prevention were derived from a single trial. The estimates for the rate of HIV-1 WP donations after the introduction of p24 antigen screening and health states (asymptomatic HIV-1 infection, symptomatic infection or reduced T-cell counts and AIDS) were derived from a review of previously completed studies.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
225 repeat donors (after the implementation of anti-HBc screening, 1987) seroconverted to HIV-1 positivity made before December 1990 (104 had given their pre-seroconversion donations in 1987, 75 in 1988, 37 in 1989 and 9 in 1990) and 1,654 (1,254 male) HIV-1 infected donors (871 first-time donation, 398 were less than 25 years old, 818 were between 26 and 35 years old, 317 between 36 and 45 and 121 older than 45 years). Only 1,014 donors were enrolled in the interview component of the study - 460 primary risk factor, 211 secondary risk factor and 343 no identified risk (NIR). Power calculations to determine the sample size were not given.

Study design
Cohort study. The duration of follow-up and the loss to follow-up were not given.

Analysis of effectiveness
The analysis of effectiveness was based on screening completers only. The primary health outcomes were sensitivity of anti-HBc in identifying HIV-1 WP infections, correlations between anti-HIV-1 and anti-HBc positivity among donors, long term survival for patients with and without transfusion-related complications and survival of patients infected with HIV-1.

Effectiveness results
Of the 225 HIV-1 seroconverting donors, 17.7% had reactive anti-HBc results on their preceding anti-HIV-1 negative donation. Overall, 36% of HIV-1 infected donors (43% male, 26% <25 years, 40% between 26-35 years, 46% between 36-45 years and 37% > 45 years, 36% first-time donation and 37% repeat donation) tested anti-HBc reactive on their anti-HIV-1 positive donation. Of the 1,014 donors, 34% tested anti-HBc positive: 49% primary risk factor, 16% secondary risk factor and 24% NIR (17% female and 28% male). The anti-HBc reactivity by risk factor was estimated to be 44% in first time donors in the primary risk factor and 9% in the secondary risk factor group. The corresponding figures for repeat donors were 52% and 23%. In the NIR group, the figures were 17% (male) and 29% (female) for first time donors and 16% (male) and 29% (female) for repeat donors. The estimates of 18% and 34% sensitivity for anti-HBc in detecting HIV-1 WP donations and a current rate of 1 in 676,000 HIV-1 WP donations could result in the transfusion of 5 to 12 fewer HIV-1 infected units per year in the USA to the 3.5 million annual transfusion recipients.

Clinical conclusions
The identification rate for the seroconverting donors was significantly less than the rate of anti-HBc positivity among anti-HIV-1 seropositive donations. Anti-HBc rates were significantly higher among seropositive male donors, black donors and donors over 26 years of age than they are among female donors, white donors and donors less than 25 years of age, respectively. The rate of anti-HBc reactivity was similar among first-time and repeat donors. Among repeat donors in all risk categories, anti-HBc rates were lower among those who had given an HIV-1 negative donation within the year preceding their seropositive donation than among those who had done so more than 1 year previously.

Modelling
A Markov model was used to represent post-transfusion HIV-1-related outcomes in patients undergoing transfusion, to estimate long-term survival for patients with and without transfusion-related complications and survival of patients infected with HIV-1 (four-stage Markov-model).

Outcomes assessed in the review
The outcomes assessed from the review were estimates for the rate of HIV-1 WP donations after the introduction of p24 antigen screening and health states (asymptomatic HIV-1 infection, symptomatic infection or reduced T-cell counts and AIDS).

Study designs and other criteria for inclusion in the review
No specific study design were stipulated by the authors as inclusion criteria.
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
3 primary studies were included.

Methods of combining primary studies
Narrative method.

Investigation of differences between primary studies
Not stated.

Results of the review
The frequency of HIV-1 WP donations with current anti-HIV-1 screening was estimated to range from 1 in 450,000 to 1 in 660,000 in a study published in 1995. In a study published in 1996 the risk associated with anti-HIV-1 screened blood was estimated to be 1 in 493,000 and the addition of p24 antigen screening assays was estimated to reduce this risk to 1 in 676,000. Asymptomatic HIV-1 infection was estimated to be 4.6 years. The symptomatic infection or reduced T-cell counts was 5.2 years and AIDS was 2 years.

Measure of benefits used in the economic analysis
The benefit measure was quality-adjusted life years (QALYs). The basic method of valuation of health status was asymptomatic HIV-1 infection, symptomatic infection or reduced T-cell counts and AIDS.

Direct costs
Costs associated with anti-HBc testing (reagents, equipment, technologists, loss of units and donor deferral due to positive test results) and costs of treating patients with complications of HIV-1 infection were included in the analysis. A discounting rate of 5% was applied. Quantities were reported separately from the prices. The quantity/cost boundary adopted was the provider perspective. The price year was 1995.

Statistical analysis of costs
Not undertaken.

Indirect Costs
Not considered.

Currency
US dollars ($).
Sensitivity analysis
Not undertaken.

Estimated benefits used in the economic analysis
As a result of the interdiction of HIV-1 infected WP units by anti-HBc testing applied to 3.5 million annual transfusion recipients, 19 to 48 QALYs were estimated to be saved.

Cost results
The annual cost of performing anti-HBc testing was $36,650,000. The cost of additional care with no anti-HBc testing was $791,000 and $981,000 with low effect and high effect, respectively.

Synthesis of costs and benefits
The cost-effectiveness of testing was estimated to be $992,000 per QALY with low effect and $2,343,000 per QALY with high effect.

Authors' conclusions
The study shows poor sensitivity, yield and cost-effectiveness of anti-HBc as a surrogate test for detection of HIV-1 WP infection. However, continued inclusion of anti-HBc testing in the battery of tests performed on donated blood may slightly increase the safety of the allogeneic blood supply although its value is limited by other safety measures.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear. As the HIV-1 and HB viruses share a number of modes of transmission, anti-HBc screening may be useful as a surrogate marker for the WP of HIV-1 infection. You, as a user of this database, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis is likely to be internally valid. The data have not been used selectively. However, as no sensitivity analysis was conducted the results need to be treated with some caution.

Validity of estimate of costs
Resource quantities were reported separately from the prices. Adequate details of methods of quantity/cost were given and important cost items do not appear to have been omitted. However, no statistical analysis was conducted. As the study was conducted retrospectively the costs need to be treated with a degree of caution.

Other issues
The authors’ conclusions are likely to be justified given the uncertainties in the data. However, in employing a model, the study suffers from the well-accepted limitations of using hypothetical patients. The issue of generalisability to other settings and countries was not addressed. However, appropriate comparisons with other studies, supporting the clinical results from the present investigation, were reported in the study. The results do not appear to have been presented selectively. A synthesis of benefits and costs was provided.

Implications of the study
Further research is required to assess the effect of recently available HIV drug regimes that include protease inhibitors or the effect of the additional testing of plasma derivatives. Moreover, other infectious agents that may be transmitted by transfusion and surrogate effects on their transmission frequency through discontinuation of anti-HBc testing need to
be considered as well as the possible effect of higher viral risk among the 120,000 new donors that are required annually to replace deferred anti-HBc-reactive donors.

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