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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
A two-test approach (alanine aminotransferase assay (ALT) and tests for antibodies to hepatitis B core antigen (anti-HBc)) versus a three-test approach (ALT, anti-HBc, and testing for anti-hepatitis C virus antibodies (anti-HCV) through enzyme immunoassay (EIA)) in screening blood donors in order to discard infected donations.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
Blood donors.

Setting
Tertiary care (blood transfusion centres). The economic study was carried out in France.

Dates to which data relate
The data related to the percentage of discarded blood donations (and its distribution in terms of source of detection of infection) and cost data (not resource use data) were collected in 1993, and covered the period between January and December 1992. The data related to the sensitivity of the approaches, and the prevalence of hepatitis C and non-A, non-B, non-C hepatitis virus in blood donors were extracted from literature published between 1984 and 1994. The price year was 1992.

Source of effectiveness data
Effectiveness data were derived from a single study, a review of published studies, and assumptions made by the authors.

Link between effectiveness and cost data
The costing was retrospectively performed on the same sample as that used in the estimation of the percentage of discarded blood donations (and its distribution in terms of source of detection of infection).

Study sample
Power calculations were not used to determine the sample size. A questionnaire was sent to 26 blood transfusion centres.
centres and 15 centres responded. Four types of centre were included in the study: non-profit centres (6), public health centres (3), private foundations (1), and hospital centres (4). One respondent centre was excluded from the study.

**Study design**
A prospective cohort study was carried out in 14 centres. A one-day visit to 11 centres was carried out to control for the quality of data provided.

**Analysis of effectiveness**
The primary health outcome was the percentage of discarded blood donations (and its distribution in terms of source of detection of infection). The centres included in the study were comparable in terms of the percentage of new donors, demographic features, and the percentage of donations collected inside and outside the centres.

**Effectiveness results**
10% of the donations tested were discarded. 2.22% of donations were discarded because of abnormal ALT values, 0.38% because of positive anti-HBc antibody screening, 0.41% because of positive anti-HBc antibody testing, 1.14% because of positive results in other test, clotting and 5.55% were discarded because of technical accident.

**Clinical conclusions**
The 14 centres in the study were centres with the highest activity rate since there was an average of 75,600 donations collected per year, while the average number of donations collected in all the centres with the same type of activity was 46,610 per year.

**Outcomes assessed in the review**
The sensitivity of the approaches, and the prevalence of hepatitis C and non-A, non-B, non-C hepatitis virus in French blood donors were among the outcomes assessed in the review.

**Study designs and other criteria for inclusion in the review**
The article included in the study satisfied the following criteria: containment of "measure of sensitivity and specificity, existence of gold standard, large spectrum of patients, setting of study, reproducibility and precision of the tests, definition of normality, and contribution to the validity of a sequence of tests".

**Sources searched to identify primary studies**
Not reported.

**Criteria used to ensure the validity of primary studies**
Not reported specifically but may be included in the inclusion criteria.

**Methods used to judge relevance and validity, and for extracting data**
Not reported specifically but may be included in the inclusion criteria.

**Number of primary studies included**
A total of 22 studies were included in the review.

**Methods of combining primary studies**
Investigation of differences between primary studies
Not reported.

Results of the review
The three-test approach had a sensitivity of 95% (based on a range of sensitivity values from 68 to 100% for anti-HCV, a range of 63 to 99% being considered in the sensitivity analysis) versus 35% for the two-test approach (based on a range from 9 to 36%, a range of 18 to 38% being considered in the sensitivity analysis). The prevalence of hepatitis C and non-A, non-B, non-C hepatitis virus in French blood donors was 0.3%, a range of 0.05 to 1% being considered in the sensitivity analysis.

Methods used to derive estimates of effectiveness
Authors’ assumptions were also used to derive estimates of effectiveness.

Estimates of effectiveness and key assumptions
It was assumed that "the sensitivity of a series of tests was equal to the sensitivity of the most sensitive test used".

Measure of benefits used in the economic analysis
The number of infected donations detected was used as the main measure of benefit.

Direct costs
The quantities were not reported separately from the costs. The cost items were broadly reported separately. The cost analysis covered the costs of medical supplies, equipment, staff, and administration, the cost per blood product and cost per donation. The cost analysis was performed from the perspective of transfusion centres. The cost data were provided by the 14 centres included in the study. The price date was 1992.

Indirect Costs
Not considered.

Currency
French francs (Ffr).

Sensitivity analysis
A set of one-way simple sensitivity analyses was performed on the prevalence of infection, the sensitivity of both approaches, and average costs.

Estimated benefits used in the economic analysis
The number of infected donations detected was 105 for the two-test approach versus 285 for the three-test approach per 100,000 donors.

Cost results
The cost per blood product for the three-test approach was Ffr30.30 versus Ffr7.34 for the two-test approach. The cost per donation for the three-test approach was Ffr34.06 versus Ffr8.40.
Synthesis of costs and benefits
An incremental analysis was performed. The incremental costs per additional donor detected were calculated as the measure of cost-effectiveness. The incremental cost-effectiveness ratio (three-test compared to two-test approach) was FrF14,256. The range of the cost-effectiveness ratio in the sensitivity analysis was from FrF9,292 to FrF85,537.

Authors' conclusions
The results of this study suggest that screening is undeniably useful in avoiding the transfusion of infected donations. Indeed, the currently used approach detected 180 additional infected donors in a total of 100,000 donors at a cost of FrF14,256 per additional infected donor detected. Transfusion centres may change their screening approach in areas of high or low prevalence of hepatitis C in France.

CRD COMMENTARY - Selection of comparators
A justification was provided for the choice of the comparator. It represented the former strategy adopted in France in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the estimate of the benefit can not be objectively assessed due to lack of information regarding the design and quality of the primary studies included in the review.

Validity of estimate of costs
Resource utilisation was not reported separately from the costs, although adequate details of the methods of cost estimation were given.

Other issues
The issue of generalisability to other settings or countries was not fully addressed. It was only mentioned that the results of the study can be applied to centres with high activity rate. The cost-effectiveness did not include "patients at risk, such as patients transfused before mandatory screening for hepatitis C was implemented, transplant recipients, hemodialyzed patients, or intravenous drug users".

Implications of the study
Further studies of a randomised design are needed to assess the cost-effectiveness of the approaches in screening for hepatitis C and non-A, non-B, non-C hepatitis.

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