HLA antibody screening: comparison of a solid phase enzyme-linked immunoassay with antiglobulin-augmented lymphocytotoxicity

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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
Using a solid phase enzyme-linked method (EIA) as a prescreen or antihuman globulin-augmented lymphocytotoxicity (AHG-CDC) for regular determination of HLA class I alloimmunization.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
Sera presenting for monthly antibody screening from multiparous blood donors and from patients on solid organ waiting lists.

Setting
Hospital. The economic study was carried out in Rochester, the USA.

Dates to which data relate
No dates were mentioned.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
No information was given regarding the link between costing and effectiveness data.

Study sample
Power calculations were not used to determine the sample size. A total of 215 sera submitted for monthly antibody screening was included in the study sample. The two alternative screening methods were applied in parallel to the study sample and the results were compared.

Study design
The study was a cohort study carried out in one institution.
Analysis of effectiveness
The principle used (intention to treat or treatment completers only) was not explicitly specified. The main clinical outcome measures were the rate of concordance between the two methods and the rate of positive and negative sera by EIA alone.

Effectiveness results
The rate of concordance between the two methods was 96.2% with a rate of 78.6% negative and 17.6% positive results for both methods. The rate of positive and negative results by EIA alone was 3.25% (as false positive) and 0.46% (as false negative), respectively.

Clinical conclusions
The study revealed that EIA, with high sensitivity and acceptable specificity, could be regarded as an effective prescreen method for regular determination of HLA class I alloimmunization.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic study and only separate clinical outcomes were reported.

Direct costs
Costs/quantities were not reported separately. The alternative methods were compared only in terms of cost per serum. The sources of the resource utilisation and cost data were not specified. It was not explicitly specified from whose point of view the cost analysis was performed. The date to which the price data referred was not specified.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The cost per serum screened by EIA was $15 versus $105 for the AHG-CDC method.

Synthesis of costs and benefits
A synthesis was not performed since EIA was regarded as the weakly dominant strategy.

Authors' conclusions
The authors concluded that "this EIA method is simple, sensitive, objective, and cost-effective as a prescreen for HIA class I antibodies".
CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator. The AHG-CDC was considered as the gold standard method. You should consider whether this is a widely used screening technology in your own setting.

Validity of estimate of measure of benefit
The clinical results seem to be internally valid.

Validity of estimate of costs
Resource quantities were not reported separately from the costs. Adequate details of the methods of cost estimation were not given. As mentioned by the authors, a comprehensive cost analysis would involve the inclusion of the frequency of screening of sera.

Other issues
Given the lack of sensitivity analysis, and statistical analysis of the costs, the results need to be treated with some caution. The issue of generalisability to other settings or countries was not addressed.

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