A prospective study of a serum-pooling strategy in screening blood donors for antibody to hepatitis C virus

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 serum-pooling strategy in screening blood donors for antibodies to hepatitis C virus.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of blood donors.

Setting
The study setting was a hospital. The economic study was carried out in China.

Dates to which data relate
Effectiveness, resource use, and cost data were collected from March to May 1995. The price year was 1995.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
1,875 blood donors from the Blood Transfusion Service were screened for anti-HCV. There were 771 men and 1,104 women, aged 18 to 52 years. They had donated blood for 1 to 14 years. No power calculations were reported.

Study design
The study took the form of a screening test evaluation carried out at a single centre.

Analysis of effectiveness
The primary health outcomes were seroprevalence, false negative and false positive rates, sensitivity and specificity of
the pooling protocol. The sensitivity and specificity of the individual tests were assumed to be 100%.

**Effectiveness results**
The tests on 1,875 individual serum samples revealed 42 positive samples, with the seroprevalence being 2.24% (95% Cl: 1.57 - 2.91%).

Among the 375 serum pools, 40 were positive.

The rate of false negativity was 0 (95% CI: 0 - 8.4%).

The sensitivity of the serum pooling protocol was 100% (95% CI: 91.6 - 100%).

The false positive rate was 0.8% (95% CI: 0 - 1.8%) and the specificity of the pooling protocol was 99.2% (95% CI: 98.2 - 100%).

**Clinical conclusions**
The pool EIA did not perform worse than individual EIAs.

**Modelling**
By applying probability theory, the expected percentage reduction in the number of tests performed (L value) when the serum-pooling strategy was used was calculated for the seroprevalences (P) and size of pool (k). The empirical reduction was used to validate the reduction, L, predicted. The maximum predicted values of L were also used to produce a table for different values of P at optimal k.

**Measure of benefits used in the economic analysis**
There was no summary measure of benefit and this was, therefore, a cost-consequences analysis (CCA).

**Direct costs**
Direct costs were not discounted due to the short time horizon of the study (less than one year). Quantities and costs were not reported separately. Direct costs related to the costs of the test. The quantity/cost boundary adopted was that of the hospital. The source of cost estimates was not reported. The price year was 1995.

**Statistical analysis of costs**
The authors reported total costs of tests.

**Indirect Costs**
Indirect costs were not included.

**Currency**
Chinese currency (RMB yuan) with US$1 = 8.3 yuan.

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
Please refer to the effectiveness results above.

**Cost results**
Total costs of tests were 7,875 yuan in the individual strategy and 2,415 yuan in the pooling strategy. Hence, 69% of costs could have been saved if the serum-pooling strategy had been used.

**Synthesis of costs and benefits**
Not applicable.

**Authors’ conclusions**
"The pool EIA did not perform worse than individual EIAs, and the pooling strategy was markedly less expensive. The pooling protocol was recommended for screening of anti-HCV-positive subjects from large populations with low seroprevalence.”

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparator used, namely that it was established practice. You, as a user of the database, should decide if these health technologies are relevant to your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a diagnostic test evaluation, which was appropriate for the study question. The authors did not report whether the study sample was representative of the study population. The analysis of effectiveness was handled credibly. The measure of outcome was appropriate, although its validity rests on the assumption that individual tests have 100% accuracy.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
The authors considered the costs of the tests, although it is not clear which costs this includes. The price year was reported, which would make reflation exercises in other settings possible. No sensitivity or statistical analyses were conducted on costs. Quantities and costs were not reported separately, which limits the generalisability of the results. The source of cost estimates was not reported.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies and the issue of generalisability to other settings was addressed. The authors did not present their results selectively. The study considered blood donors and this was reflected in the authors’ conclusions. The authors noted that the application of the serum-pooling strategy for anti-HCV detection is restricted by the seroprevalence as well as the test methods and reagents. The authors produced a table of the expected percentage reduction in the number of tests performed when the serum-pooling strategy is used. This table can be used by serologists to determine the optimum size of the pool to use if estimates of the seroprevalence are available. The table can also apply to the screening of a wide variety of antibodies and/or antigens. This does depend on the accuracy remaining the same as k changes.

**Implications of the study**
"The pool EIA did not perform worse than individual EIAs, and the pooling strategy was markedly less expensive. The
pooling protocol was recommended for screening of anti-HCV-positive subjects from large populations with low seroprevalence.” In fact, as long as the accuracy of the pooled strategy does not diminish, the authors’ calculations show that there is still a saving up to about $P = 30\%$.

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