Empiric immunization versus serologic screening: developing a cost-effective strategy for the use of hepatitis A immunization in travellers
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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
The use of serologic screening versus empiric immunisation for hepatitis A in a traveller population was under evaluation.

Type of intervention
Primary and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were candidates for hepatitis A immunisation and who had undergone total hepatitis A antibody testing. Specific inclusion criteria were not reported. Patients were excluded if the testing was part of a diagnostic evaluation.

Setting
The setting was secondary care (clinics). The economic study was carried out in Honolulu (HI), USA.

Dates to which data relate
The effectiveness data were collected retrospectively from November 1997 to October 1998. The dates to which the resource data related were not reported, nor was the price year.

Source of effectiveness data
The effectiveness data were derived from a single retrospective study.

Link between effectiveness and cost data
The costing was not carried out on the same sample of patients used in the effectiveness study, but was derived from mathematical formulae.

Study sample
Power calculations were not reported.

A total of 219 patients with hepatitis A total antibody results, performed from November 1997 to October 1998, were identified. Of these patients, 137 (62.6%) were available to complete an interview retrospectively. The interview covered information on the country of birth, countries travelled to for either business or leisure (<=30 days), countries
of residence (>30 day stay), history of jaundice or prior diagnosis of hepatitis A, and indication for testing. As a result, 22 patients were excluded because testing had been undertaken as part of a diagnostic evaluation. A total of 115 patients were included in the study, of which 90 were seen in the travel clinic and the remaining 25 in other clinics.

**Study design**
This was a within-group comparison study that was carried out in a single centre. The duration of follow-up was not reported. No loss to follow-up was reported.

**Analysis of effectiveness**
All patients who completed the treatment were considered at analysis. The primary health outcomes used in the study were the prevalence of antibodies to hepatitis A and risk factor data for hepatitis A acquisition. Using these data, statistical analyses were performed to determine the predictive factors of seropositivity to hepatitis A.

**Effectiveness results**
Previous visits overseas (<=30 days), history of jaundice or hepatitis, and age did not predict seropositivity to hepatitis A.

Country of birth (foreign-born patients 80% versus US-born patients 35.6%) was a statistically significant predictor of seropositivity for hepatitis A (odds ratio, OR=7.25, 95% confidence interval, CI: 2.31 - 26.64; p<0.001).

Living outside of the USA was also correlated with a higher prevalence of hepatitis A positive serology (OR 3.61, 95% CI: 1.48 - 9.15).

A lower prevalence was noted in the group of US-born patients aged 30 to 60 years (24.3% versus 85.7%; p<0.001) and in the group of US-born patients aged older than 60 (42.9% versus 85.7%; p<0.05).

Travel and prior history of jaundice failed to demonstrate significance.

**Clinical conclusions**
The authors did not report any clinical conclusions.

**Modelling**
Mathematical formulae were developed to evaluate the costs of empirical immunisation and serologic strategies. Formulae for the total cost of each of the two strategies and for their comparison were given. The formulae were based on the number of patients, the prevalence of antibodies to hepatitis A in the sample, the number of patients who were seronegative, the cost of serology and the cost of vaccination.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic evaluation. It seems that the authors implicitly hypothesised that the two strategies have similar benefits (e.g. in terms of the number of hepatitis A cases averted). Only the costs were considered in the economic analysis.

**Direct costs**
The perspective adopted in the study was not reported. The categories of costs included in the analysis were serology testing and vaccination. Several costs associated with screening patients were not included. For example, the costs of obtaining test results, contacting patients with results, patients' return to the clinic for immunisation, and potential delay in immunisation prior to travel. Other costs that were not included were the syringes, alcohol pads, gauze pads and nursing time for vaccine administration, and revaccination costs. The cost of serology was determined by contract
agreement between the authors' institution and laboratories. The cost of vaccination was based on two doses of the Merck vaccine and was derived from Department of Pharmacy procurement procedures. Although the quantities of resources used and the price year were not reported, the unit costs of serology and vaccination were reported. Discounting was not relevant as all the costs were incurred during less than one year. The total costs for each preventive strategy were not calculated. Only the ratio of the unit costs of serology and vaccination was estimated.

**Statistical analysis of costs**
A statistical analysis of the costs was not carried out.

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

**Currency**
US dollars ($)

**Sensitivity analysis**
Sensitivity analyses were not performed.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The ratio of the unit costs of serology and vaccination was 0.457 ($16/$35).

Thus, a prevalence of greater than 45.7% would make screening before immunisation less costly than empirical immunisation.

If the initial lower cost of serology remained in effect (the cost of antibodies hepatitis A serology before December 1997 was $11), a prevalence of greater than 31% would make screening before immunisation less costly than empirical immunisation.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant.

**Authors' conclusions**
It was cost-effective to screen all foreign-born individuals and those who had lived outside the USA before immunisation for hepatitis A.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of the comparator (empirical immunisation against hepatitis A) was clear. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
A within-group comparison study was used, which was appropriate for the study question. Power calculations were not carried out. All patients with hepatitis A total antibody results were included in the study, except those for whom testing
was part of a diagnostic evaluation. The main drawback of the study was that intermediate outcome measures rather than real health outcomes were estimated. Statistical analyses were undertaken to determine the predictive factors of seropositivity to hepatitis A, but neither the performance characteristics of serologic testing nor the efficacy of empirical immunisation was investigated. A more appropriate measure of effectiveness would have been the number of hepatitis-A-immunised individuals.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis. The authors reported that they conducted a cost-effectiveness analysis. However, they did not provide a measure of health benefits. It seems that the authors considered the two strategies to have similar benefits. In effect, a cost-minimisation analysis was conducted.

Validity of estimate of costs
The perspective of the study was not stated. Thus, it was not possible to assess whether all the relevant categories of costs were included in the analysis. However, it would appear that some relevant costs were omitted from the analysis. For example, the analysis did not include the cost of obtaining test results, or the cost of syringes and nursing time for vaccination. The cost-effectiveness of the intervention therapy might, therefore, have been overestimated. Though details of the unit costs were reported, which ease transferability of the economic analysis to other settings, the price year was not reported and this limits reflation exercises. The cost estimates seem specific to the authors’ setting. Discounting was not relevant and was not reported. The main drawbacks of the cost analysis were that the total costs were not reported and statistical and sensitivity analyses were not performed on the costs. Consequently, the external validity of the study might be low.

Other issues
The authors compared their results with other published studies and found either similar or different effectiveness results. The issue of the generalisability of the study results to other settings was not addressed. The results were not reported selectively. However, before addressing the results in terms of whether the strategy was cost-effective, a more relevant effectiveness analysis should be conducted. The authors reported several further limitations. For example, the small sample size, the inclusion of non-travel clinic patients, and the use of serum immunoglobulin as pre-deployment prophylaxis in active duty soldiers. Sensitivity analyses were not performed to account for variability in the cost. Consequently, caution should be exercised when extrapolating the study results to different contexts.

Implications of the study
The authors did not make any recommendations concerning policy or practice as a result of their study.

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None stated.

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Other publications of related interest

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MeSH
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