Evaluation of the ICT whole-blood antigen card test to detect infection due to Wuchereria bancrofti in Sri Lanka

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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 an immunochromatography card test (ICT, AMRAD) for the diagnosis of bancroftian filariasis was examined.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised microfilaria (mf)-positive individuals and, as controls, individuals with no history of exposure to bancroftian filariasis. The mf-positive individuals were selected from endemic localities in the Western Province of Sri Lanka, while the controls were selected from a non-endemic area in the Central Province of Sri Lanka. All individuals were aged 14 years old or older.

Setting
The setting was unclear, but it was likely to have been community care. The economic study was carried out in Sri Lanka.

Dates to which data relate
The effectiveness and resource data were collected from June 1999 to October 1999. The price year was 2001.

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

Link between effectiveness and cost data
Some cost estimations were carried out on the same sample of patients at that used in the effectiveness study. The remaining costs were based on calculation and extrapolation.

Study sample
Power calculations were not reported. A total of 242 individuals (43.3% men) were included in the study and examined by all three tests. The mean age was 34.8 years (range: 14 - 76). Of the included individuals, 213 were selected from endemic localities (intervention group) and 29 patients were selected from non-endemic localities (control group).
The selected houses were visited between 21:00 and midnight, and 2 mL venous blood was collected from each participant. TBF was carried out immediately after blood collection and was followed the next morning by NMF. An ICT for filariasis was performed on membrane filtration-positive cases and also on a minimum of 2 membrane filtration-negative cases, randomly selected from the household of each positive case. Sixty microL non-heparinised was used for TBF, 1 mL heparinised blood for NMF, and 100 microL heparinised blood for the ICT.

**Study design**
This was a prospective diagnostic study that was carried out in a single centre, designed to assess the validity of the intervention test.

**Analysis of effectiveness**
The primary health outcomes used in the study were:

- mf density by NMF,
- the number of endemic mf-positive and -negative cases, and
- the sensitivity and specificity of TBF and ICT compared with NMF.

The study sample included individuals with and without the disorder being tested for.

**Effectiveness results**
The mf counts by NMF ranged from 8 to 1,782/mL of blood (mean 343/mL).

A total of 67 (31.5%) individuals were mf positive, whereas 146 (68.5%) were mf negative.

In the endemic population, compared with NMF, the TBF had a sensitivity of 0.94 (63 out of 67) and a specificity of 1 (146 out of 146), while the ICT had a sensitivity of 1 (67 out of 67) and a specificity of 0.918 (134 out of 146).

There were no false-positive cases with the ICT among the non-endemic group.

The authors suggested that the lower specificity of ICT was probably due to the failure of the reference test (NMF) to detect all cases of infection.

The ICT test showed good reproducibility in a sub-group of 20 samples.

**Clinical conclusions**
The authors concluded that the ICT appears to be more effective (both sensitive and specific) for the diagnosis of bancroftian filariasis than the standard TBF and NMP.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic evaluation. The study was, in effect, a cost-consequences analysis.

**Direct costs**
The perspective adopted was not reported. The direct costs included the recurrent expenditure of a TBF and an ICT. Recurrent expenditure for a TBF included personnel, consumables and maintenance. Recurrent expenditure for an ICT included personnel and consumables. The unit costs and the quantities of resources used were presented separately. The source used to derive the resource use data and unit costs was not reported clearly. The capital expenditure involved in establishing a small laboratory to report on a TBF was derived from published literature. The relevant data needed to
calculate the capital costs were obtained from the Ministry of Health of Sri Lanka and local agents from AMRAD ICT. A discount rate of 10% was used to annualise the capital costs over 10 years (for a microscope) or 8 years (for a balance). The price year was 2001.

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

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

**Currency**
Sri Lanka rupees (Rs). The conversion rate was US$1 = Rs 90.37.

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

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

**Cost results**
The unit recurrent cost of TBF was Rs 27.08 (US$0.30), while the unit cost of an ICT for filariasis was Rs 248.25 (US$2.75) (10-fol difference).

The capital expenditure for the small laboratory to report on a TBF was Rs 39,156.45 (US$433.29) per year.

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

**Authors' conclusions**
The authors did not provide a general conclusion in terms of both the effectiveness and cost results. However, they reported several implications (see 'Implications of the Study' section).

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of the comparator was clear. NMF represented a conventional parasitological method for the diagnosis of bancroftian filariasis. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was based on a prospective diagnostic study. Power calculations were not carried out and, therefore, the sample size was probably too small to estimate the exact sensitivity and specificity of the ICT. The main drawback of the study was that the reference test used to estimate the sensitivity and specificity of TBF and ICT does not really appear to be appropriate for the study question. This 'gold' standard should be the most sensitive and specific test. Consequently, the lower specificity of the ICT may be questionable. In addition, the confidence intervals for sensitivity and specificity were not reported. Therefore, caution is required when transferring the results of the analysis to other centres.
Validity of estimate of measure of benefit
No summary benefit measure was derived for used in the economic analysis. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

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. Discounting was relevant for the capital costs and was carried out. Details of the unit costs, quantities of resources used and price year were reported, which enhances the transferability of the economic analysis to other settings. However, the cost estimates appear to have been derived from a single centre and were specific to the study setting. The main drawback of the cost analysis was that statistical and sensitivity analyses were not performed on the costs. Consequently, the external validity of the cost analysis may be low.

Other issues
The authors compared their results with those from other published studies, showing similar and different results in terms of effectiveness. However, they did not address the issue of the generalisability of the study results to other settings. The results were not reported selectively and the effectiveness conclusions reflected the scope of the study. The authors did not report a general conclusion in terms of both the effectiveness and cost results. In addition, they did not report any further limitations of their study. Sensitivity analyses were not performed to account for variability in the cost or effectiveness data. Hence, the robustness of the results was not examined. Consequently, caution should be exercised when extrapolating the study results to different contexts.

Implications of the study
The authors reported several implications of their study, as follows.

Because of the comparatively higher costs of the ICT, the authors suggested that the selective screening of high-risk groups in a population might be a more economical option, rather than mass screening for countries endemic for bancroftian filariasis with scarce resources.

The possibility that the ICT for filariasis is more sensitive than membrane filtration for the detection of bancroftian filariasis would have to be confirmed by the inclusion of a second test for circulating filarial antigen (e.g. Og4C3 ELISA), or the ultrasonic demonstration of the filarial dance sign.

The sensitivity of the ICT in the detection of low-density microfilaraemia needs further study.

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