A comparison study of different methods used in the detection of Giardia lamblia
Aziz H, Beck C E, Lux M F, Hudson M J

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
Five diagnostic procedures for the detection of Giardia lamblia (G. lamblia) were examined:

the ova and parasite (O&P) approach;

the direct immunofluorescent assay (DFA; Meridian Diagnostic);

two enzyme-linked immunosorbent assays (ELISA; Seradyn or Trend Scientific); and

an enzyme immunoassay (EIA; Alexon).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with a suspected G. lamblia infection.

Setting
The setting was a hospital laboratory. The economic study was carried out at the Medical Technology Department of the University of Southern Mississippi, USA.

Dates to which data relate
The dates when the effectiveness and resource use data were collected were not provided. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

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

Study sample
Power calculations to determine the sample size were not reported. Faecal specimens from 68 individuals with a suspected G. lamblia infection were used. The method used to select the sample was not described. A single group of
patient specimens was used for all of the diagnostic tools.

**Study design**
This was a prospective within-group comparison study, which was carried out in a single centre. No follow-up was carried out. To reduce the possibility of observer bias, a researcher blind to the reference laboratory results coded the specimens. The method used for each diagnostic approach was accurately described.

**Analysis of effectiveness**
All the specimens included in the initial study sample were accounted for in the effectiveness study. The outcomes estimated in the analysis were the results of the diagnostic assessment and the sensitivity and specificity of each immunodiagnostic test. The sensitivity and specificity were determined in accordance with the agreement obtained by the two reference methods (O&P and DFA). The specimens were counted as true-positive if the O&P and/or DFA were positive. Any specimen that was negative by all methods was counted as a true-negative.

**Effectiveness results**
Of the 68 specimens, 21 were positive with all techniques, 31 were negative with all techniques, 8 (12%) were negative with all but O&P, and disagreement was observed for the remaining specimens (12%). Therefore, all methods were in agreement in 76% of the specimens.

The sensitivity for the detection of G. lamblia infection was 94% with ELISA (Trend Scientific), 91% with ELISA (Seradyn) and 100% with EIA. The specificities were 89% (ELISA, Trend Scientific), 89% (ELISA, Seradyn) and 100% (EIA), respectively.

**Clinical conclusions**
The effectiveness study suggested that all diagnostic tools provided high values of both specificity and sensitivity for the detection of G. lamblia infection.

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

**Direct costs**
Discounting was irrelevant since the costs were incurred during a short time. The unit costs were not provided separately from the quantities of resources used, but the hourly cost of personnel was reported. The health services in the economic analysis were personnel (technician or technologist time), commercial assay kits, and expendable supplies. Large equipment costs, such as microscopes, centrifuges, incubators and incubation times were not considered. The cost/resource boundary adopted was unclear. The resource use data were estimated using data coming from the sample of specimens considered in the effectiveness study. The average technician or technologist's salary was based on the wages of medical laboratory personnel in the USA. The source of the other costs was not reported. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not considered in the economic evaluation.
Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not carried out.

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

Cost results
The estimated cost per specimen was:

$32.54 with O&P;

$26.15 (technologist salary) and $24.60 (technician salary) with ELISA, Trend Scientific;

$26.62 (technologist salary) and $25.07 (technician salary) with ELISA Seradyn;

$30.13 (technologist salary) and $28.58 (technician salary) with EIA; and

$11.26 with DFA.

Synthesis of costs and benefits
The costs and benefits were not combined because the analysis was classified as a cost-consequences analysis.

Authors' conclusions
All techniques performed with high levels of specificity and sensitivity. The study showed the advantages and disadvantages of each diagnostic approach for the detection of Giardia lamblia (G. lamblia) infection. The standard ova and parasite (O&P) tool was labour-intensive and this was reflected in the high cost per specimen. Its main advantage, however, was its broad screening for a variety of pathogens. On the other hand, the immunodiagnostic techniques were less labour-intensive, and therefore less costly, and had a shorter turnaround time. The direct immunofluorescent assay (DFA) was the most cost-effective technique in comparison with the other immunodiagnostic methods.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. All diagnostic techniques were selected because they represented valid approaches for the detection of G. lamblia infection. You should decide whether they represent currently used tools in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a prospective within-group comparison study. This was appropriate for the study question as no external comparison group was required. In fact, the same specimens were used for all of the diagnostic techniques. Partial blinding was performed during the outcome assessment. However, the method of sample selection was not reported and it was unclear whether the study sample was representative of the study population. All the specimens came from a single centre and this could reduce the transferability of the results to other settings. The sample size was small.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The authors did not state the perspective adopted in the study. It was unclear whether all the relevant categories of costs were considered. Some items were not included in the analysis and no justification was provided for their exclusion. A breakdown of the costs was reported, but details of the unit costs and the quantities of resources used were not given separately. The price year was not stated, thus making reflation exercises in other settings difficult. The cost estimates were specific to the study setting and sensitivity analyses were not performed. Statistical tests were not carried out and the costs were treated deterministically.

**Other issues**
The authors did not compare their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not carried out, which further limits the external validity of the study. The analysis referred to patients with a suspected G. lamblia infection and this was reflected in the conclusions of the study.

**Implications of the study**
Each laboratory should evaluate the best approach for the identification of G. lamblia infection on the basis of laboratory needs, the equipment available and cost issues.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
11517624

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Animals; Costs and Cost Analysis; Enzyme-Linked Immunosorbent Assay /economics; Feces /parasitology; Fluorescent Antibody Technique, Direct /economics; Giardia lamblia /isolation & purification; Giardiasis /diagnosis; Humans; Immunoenzyme Techniques /economics; Immunologic Tests /economics; Sensitivity and Specificity

**AccessionNumber**
22001007790

**Date bibliographic record published**
31/08/2004

**Date abstract record published**
31/08/2004