Economic analysis of the diagnosis of smear-negative pulmonary tuberculosis in South Africa: incorporation of a new rapid test, FASTPlaqueTB, into the diagnostic algorithm

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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
Four algorithms for the diagnosis of smear-negative pulmonary tuberculosis (PTB) were examined. These were:

- the National Tuberculosis Control Programme (NTCP) algorithm (algorithm 1);
- a new rapid test, FASTPlaqueTB (Biotec laboratories Ltd., Ipswich) and culture of all smear-negative suspects (both tests performed on a single specimen) (algorithm 2);
- FASTPlaqueTB of all smear-negative suspects, with culture performed on those specimens with a negative FASTPlaqueTB result (algorithm 3); and
- FASTPlaqueTB only of all smear-negative suspects (algorithm 4).

Type of intervention
Diagnosis and screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with suspected smear-negative PTB. A hypothetical cohort of 1,000 patients was used for modelling purposes, based on the outcomes of 1,618 sputum specimens from 853 new TB suspects.

Setting
The setting was primary care. The economic study was carried out in Cape Town, South Africa.

Dates to which data relate
The effectiveness data were derived from studies published between 1996 and 2002. In terms of resource use, data for some test items were from two studies published in 1997 and 2001, while the dates of others were not reported. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a review of the literature and authors' estimates or assumptions.

Modelling
A decision analytic model was used to assess the costs and benefits of the four diagnostic algorithms. Modelling details
for the algorithms were not described.

**Outcomes assessed in the review**
The outcomes estimated from the published study were the sensitivity, specificity, and positive and negative predictive values of the four algorithms. These were based on test accuracy data for chest X-ray, acid-fast bacilli (AFB) smear, FASTPlaqueTB and culture. TB prevalence data were also derived for the model.

**Study designs and other criteria for inclusion in the review**
The design of the primary study was not stated. No inclusion criteria were reported.

**Sources searched to identify primary studies**
Not reported.

**Criteria used to ensure the validity of primary studies**
Not reported.

**Methods used to judge relevance and validity, and for extracting data**
Not reported.

**Number of primary studies included**
To derive the effectiveness data, five studies were included in the review.

**Methods of combining primary studies**
Not reported.

**Investigation of differences between primary studies**
Not reported.

**Results of the review**
The sensitivity of FASTPlaqueTB was taken to be 50 to 68% and its specificity was 98%.

The test performance of chest X-ray was not stated.

The sensitivity was 72.9% for algorithm 1, 100% for algorithm 2, 100% for algorithm 3 and 48.7% for algorithm 4.

The specificity was 100% for algorithm 1, 100% for algorithm 2, 99.5% for algorithm 3 and 99.5% for algorithm 4.

The positive predictive value was 1.00 for algorithm 1, 1.00 for algorithm 2, 0.93 for algorithm 3 and 0.84 for algorithm 4.

The negative predictive value was 0.98 for algorithm 1, 1.00 for algorithm 2, 1.00 for algorithm 3 and 0.97 for algorithm 4.

**Methods used to derive estimates of effectiveness**
The authors made assumptions to derive some of the model parameters.
Estimates of effectiveness and key assumptions
The sensitivity and specificity of the culture test were both assumed to be 100%. It was assumed that all patients would complete the entire diagnostic process for each algorithm. It was also assumed that the culture result would supersede previous test results, owing to its higher test performance.

Measure of benefits used in the economic analysis
The summary benefit measure used was the number of smear-negative TB suspects diagnosed. The benefit was derived from the model. Discounting was not relevant because of the short time horizon.

Direct costs
The cost/resource boundary adopted was that of a health care provider. The economic evaluation included the costs associated with the diagnosis of PTB. The costs for some diagnostic tests were derived from the review of published studies, while those for other tests were taken from the National Health Laboratory Service (Johannesburg and Cape Town). The costs associated with the diagnosis of other diseases were not included, nor were the potential costs for the increased morbidity and mortality related to a delay in diagnosis. The costs associated with the transmission of TB from undiagnosed cases were also excluded.

The unit costs were reported separately from the quantities of resources used. Resource use was derived from the published study, and was extrapolated to a hypothetical cohort of 1,000 patients for each of the four algorithms. Discounting was not relevant because of the short time horizon of the study. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($). The conversion rate from US dollars to South Africa rands (R) was $1 = R10.

Sensitivity analysis
Sensitivity analyses were conducted to investigate uncertainty in the estimates used in the decision model. The parameters varied were the costs of each component. Of the five components, the ranges of costs for two individual components (AFB smear microscopy and clinic visit ($1.00 to $3.90)) were derived from the review of published studies. The author did not report the source of the ranges for other components.

The ranges of costs explored were $1.80 to $2.90 for AFB smear microscopy, $1.00 to $3.90 for clinic visit, $6.60 to $12.80 for chest X-ray, $6.32 to $7.57 for FASTPlaqueTB when performed on a separate specimen, and $4.98 to $6.23 for FASTPlaqueTB when performed on the same specimen at culture.

Estimated benefits used in the economic analysis
Of 1,000 smear-negative TB suspects, the number of patients diagnosed was 39 with algorithm 1, 54 with algorithms 2 and 3, and 26 with algorithm 4. Algorithms 2 to 4 enabled rapid and specific diagnosis of 26 patients within 2 days.

Cost results
The total costs per 1,000 suspects tested were $20,079 with algorithm 1, $18,581 with algorithm 2, $18,312 with algorithm 3 and $14,740 with algorithm 4.
Synthesis of costs and benefits
An incremental cost-effectiveness analysis was conducted to combine the costs and benefit of the four diagnostic algorithms, but cost-effectiveness ratios were not reported. Compared with algorithm 1, algorithm 2 enabled 28% more patients to be diagnosed with significantly less implement costs. Algorithm 3 was cheaper than algorithm 2. Algorithm 4 was the cheapest overall, but had lower overall sensitivity than algorithm 1.

The sensitivity analysis revealed that FASTPlaqueTB algorithms remained cost-effective in comparison with the NTCP algorithm, even when the estimated cost per clinic visit was reduced by 50%, the cost of FASTPlaqueTB was increased by up to 125% of the baseline cost of the kit, or the cost of chest X-ray test was increased to $12.80.

Authors' conclusions
Incorporating the FASTPlaqueTB test into the diagnostic algorithm for pulmonary tuberculosis (PTB) could offer patients more rapid and reliable diagnosis whilst reducing the overall cost.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The NTCP represented the commonly used approach in South Africa for the diagnosis of smear-negative PTB. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on data derived from a review of the literature. Only five studies were chosen to derive effectiveness data according to the parameter of interest. Sources searched and other details of the methodology and conduct of the review were not given. The author assumed that the sensitivity of culture was 100%, although she stated it was accepted that culture-negative PTB did occur. Appropriate sensitivity analyses were performed to investigate the robustness of the study findings to variations in the cost components but not effectiveness estimates.

Validity of estimate of measure of benefit
The number of smear-negative TB suspects diagnosed was selected as the measure of benefit in the economics analysis. This benefit measure was specific to the intervention/patient domain. The impact of the algorithms was not investigated for long-term health benefits such as life-years gained or quality-adjusted life-years. Given the short timeframe of the analysis, discounting was not necessary and was not applied.

Validity of estimate of costs
The cost analysis was conducted from the perspective of the health care provider. As such, only those costs related to the diagnostic tests were included in the analysis. The costs were treated deterministically in the base-case, but sensitivity analyses were conducted on the cost data. Data for the unit costs were derived from published studies and obtained from organisations, while the resource use quantities were taken from a published study. The cost estimates were quite specific to the study setting. Discounting was not carried out because the costs were incurred during less than two years. The price year was not reported, which will hinder the reflation of costs to other time periods.

Other issues
The author compared the findings with those from other studies. Since some discrepancies between the current study and the published literature were observed, possible reasons for these differences were discussed. A possible explanation was the difference in the samples of patients enrolled in the studies. The author also noted the advantages and disadvantages of induced sputum testing, and concluded that the favourable aspects outweighed the negative ones. The issue of the generalisability of the study results to other settings was addressed in relation to its likely benefit dependent on the prevalence of TB/HIV in a given population. Sensitivity analyses on the costs were conducted, which
enhance the external validity of the results. Finally, the use of incremental rather than average cost-effectiveness ratios would have been technically more appropriate.

Implications of the study
The findings of the study suggested that the use of new tools such as FASTPlaqueTB can assist in improving existing case detection strategies, and can be cost-effectively implemented into the current TB diagnostic infrastructure. The author indicated that more comprehensive country-wide studies should be performed because of epidemiological variations from one geographical location to another.

Source of funding
None stated.

Bibliographic details

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Other publications of related interest


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