Cost-effectiveness of the polymerase chain reaction versus smear examination for the diagnosis of tuberculosis in Kenya: a theoretical model


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
Using polymerase chain reaction (PCR) for the diagnosis of tuberculosis.

Type of intervention
Screening and diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients suspects of having tuberculosis (TB).

Setting
Outpatient clinic. The economic study was carried out in Nairobi, Kenya.

Dates to which data relate
Effectiveness data on the comparator, which were obtained from the study clinic, referred to 1995. Effectiveness data related to sensitivity and specificity of PCR were obtained from the published literature in 1995. Resource use data were not reported. The price year was not explicitly specified.

Source of effectiveness data
Effectiveness data were derived from a single study, a review of the literature, and assumptions made by the authors.

Link between effectiveness and cost data
Costing was not conducted on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. Approximately 4,100 TB suspects underwent the routine screening procedure (the comparator).

Study design
This was a cohort study, carried out in a single centre. No follow-up period or loss to follow-up were reported.
Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The health outcome measures used were percentage of patients diagnosed as having TB, and percentage of patients diagnosed as having TB who were smear positive and smear negative. The percentage of patients with negative smear who received antibiotics was obtained by interviewing the patients.

Effectiveness results
The percentage of patients diagnosed as having TB was 36%. The percentage of patients diagnosed as having TB who were smear positive and smear negative were 65%, and 35%, respectively. The percentage of patients with negative smear who received antibiotics was 30%.

Clinical conclusions
Direct smear microscopy is a specific procedure, but it only detects TB patients excreting high numbers of mycobacteria.

Outcomes assessed in the review
Sensitivity and specificity of the PCR kit was assessed through a review of the literature.

Study designs and other criteria for inclusion in the review
Not 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
A total of 4 studies were included.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
The overall sensitivity of the PCR kit was 80% with a 96% sensitivity in smear-positive and 53% in smear-negative TB. The specificity of the PCR kit was more than 99%.
Methods used to derive estimates of effectiveness
Assumptions were also made by the authors.

Estimates of effectiveness and key assumptions
The proportion of false positive patients with smear microscopy screening procedure was assumed to be 10% versus 0% with PCR. Acid fast bacilli (AFB) microscopy was 50%. It was assumed that one PCR test is sufficient to diagnose TB.

Measure of benefits used in the economic analysis
The total number of TB cases correctly (falsely) diagnosed per 1,000 patients examined was regarded as the main benefit measure.

Direct costs
Costs were not required to be discounted as the follow-up period of the study was less than one year. Resource utilisation was not systematically reported (some components of resource utilisation were assumed to be common for both techniques) separately from the costs. The cost items were reported separately. The cost analysis covered health service costs (including labour and equipment costs of the clinic, operative and invest costs of laboratory and X-ray), patient costs (including costs of travel, other expenditures, and antibiotics), and costs related to treatment of false positive patients (labour, drug, and patient costs). The cost analysis was performed from the perspective of a health care system and a patient. The source of resource use data (materials and equipment) for the comparator was the National Leprosy and TB Programme. The sources of cost data were the clinic, the International Dispensary Association (IDA), and the manufacturers of the Roche PCR kit. The source of patient cost data was structured interviews with patients. The date to which the price data related was not explicitly specified. The cost calculation did not cover the costs of running the clinic and the laboratory, or the costs of missed patients.

Indirect Costs
Costs were not required to be discounted as the follow-up period of the study was less than one year. The cost analysis covered the costs to patients related to loss of earning, travel costs and other expenses (not specified). The cost data were obtained from 100 patients via interviews. The date to which the price data related was not explicitly specified.

Currency
Kenyan shillings (Ksh). A conversion to US dollars was carried out on the basis of an exchange rate of US$1 = Dfl1.66 (Dutch guilders) or Ksh 0.54 (Kenyan Shilling).

Sensitivity analysis
One-way sensitivity analysis was performed on almost all important parameters.

Estimated benefits used in the economic analysis
Total number of TB cases correctly (falsely) diagnosed per 1,000 patients examined was estimated to be 347 (13) for the routine smear microscopy and 374 (0) for the PCR diagnosis procedure.

Cost results
The total cost per 1,000 TB suspects was $13,985 for the routine procedure versus $26,697 for the PCR procedure.

Synthesis of costs and benefits
The cost-effectiveness measure adopted was cost per correctly diagnosed TB patient, which amounted to $40 for the routine procedure versus $71 for the PCR procedure. The sensitivity analysis established the relative robustness of the
results to reasonable changes in the parameters involved in the calculation of the cost-effectiveness measure.

Authors’ conclusions
The authors concluded that the PCR method can potentially be a cost-effective screening procedure for tuberculosis, provided that the largest contributing cost component, the cost of the PCR-kit, can be reduced substantially.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator. It was regarded as the routine diagnostic test in the context in question in Kenya. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the effectiveness results for the smear microscopy seems to be reasonably assured due to the large sample size. It is not clear how comprehensive the literature review was when estimating the sensitivity and specificity of PCR.

Validity of estimate of costs
Resource utilisation was not systematically reported separately from the costs. However, adequate details of methods of cost estimation were given. Cost results may not be generalisable to other settings or countries.

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