Cost-effectiveness analysis of PCR for the rapid diagnosis of pulmonary tuberculosis

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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.

**CRD summary**
This study examined the cost-effectiveness of two diagnostic strategies for pulmonary tuberculosis (TB) in patients with suspected human immunodeficiency virus (HIV). The acid-fast bacilli (AFB) smear microscopy by Ziehl-Neelsen staining plus colourimetric test by polymerase chain reaction dot blot was potentially cost-effective, in settings with a high prevalence of HIV and TB, compared with AFB smear plus culture. The study was well presented, but some limitations in the synthesis of costs and benefits might affect the validity of the conclusions.

**Type of economic evaluation**
Cost-effectiveness analysis

**Study objective**
This study examined the cost-effectiveness of two diagnostic strategies for pulmonary tuberculosis (TB) in patients with suspected human immunodeficiency virus (HIV) infection.

**Interventions**
The two strategies for the diagnosis of pulmonary TB, using sputum specimens, were acid-fast bacilli (AFB) smear microscopy, by Ziehl-Neelsen staining, plus culture versus the same AFB smear microscopy plus a colourimetric test, using a polymerase chain reaction (PCR) dot blot. A detailed description of both options was given.

**Location/setting**
Brazil/out-patient setting.

**Methods**

Analytical approach:
The analysis was based on a decision analytic model that simulated the two diagnostic strategies, using data from one study. A short-term analysis was conducted covering the period of the diagnosis and treatment of TB. The authors stated that the perspective of the health care system and the patient was considered.

Effectiveness data:
The clinical evidence came from a diagnostic study, in which patients underwent the two options. A cohort of 277 consecutive adults, who were suspected of having pulmonary TB and referred to the TB and HIV Reference Center at the study hospital in Brazil, were prospectively studied between May 2003 and May 2004. These patients were followed-up until they had completed the diagnostic process. Laboratory technicians and respiratory specialists were blinded to the results of cultures and PCR dot blots or chest radiograph results and clinical predictors. The accuracy of the diagnostic tools was the key endpoint.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
The benefit measures were the number of accurately diagnosed cases of pulmonary TB and the number of accurately diagnosed and treated cases, including the treatment of falsely diagnosed cases.

Cost data:
The economic analysis included those costs incurred by the patient (travel, food, and income loss) and the laboratory.
drug, consumables, equipment, and treatment (in-patient and out-patient) costs. Staff costs were based on the base salary in the hospital setting. In general, the costs were those of procedures from the Brazilian Public Health System. The capital costs for PCR were considered. The resource use data were based on conventional treatment patterns and authors’ opinions. All costs were presented in US dollars ($).

Analysis of uncertainty:
A deterministic sensitivity analysis was undertaken and considered variations in the TB prevalence, the sensitivity and specificity of PCR dot blot, and the PCR dot blot running costs. Alternative values were based on authors’ opinions.

Results
In a cohort of 1,000 patients, the total costs were $5,635,760 ($190,800 patient costs and $5,444,960 health service costs) with AFB smear plus culture and $1,498,660 ($34,000 patient costs and $1,464,660 health service costs) with AFB smear plus PCR dot blot.

The average cost per accurately diagnosed case of TB was $50,773 ($49,053 health service costs only) with culture and $13,749 ($13,437 health service costs only) with PCR dot blot. The average cost per case accurately diagnosed and treated, including the treatment of falsely diagnosed cases was $55,501 and $15,190.

The sensitivity analysis did not substantially alter the base-case findings and disease prevalence was the most influential parameter.

Authors’ conclusions
The authors concluded that the AFB smear plus PCR dot blot was potentially cost-effective in the diagnosis of pulmonary TB, in settings with a high prevalence of HIV with TB co-infection.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear. The authors compared the conventional approach (based on culture) with the novel and rapid diagnostic strategy (based on PCR assessment). A description of the two diagnostic options was provided and these strategies are likely to be generalisable to other health care settings, but the accuracy of the PCR dot blot might vary between settings.

Effectiveness/benefits:
A prospective diagnostic study was an appropriate source of evidence that allowed the assessment of the diagnostic accuracy of the two strategies. The inclusion of consecutive patients reinforces the validity of the comparison, but the enrolment took place at only one institution, which might not be representative of other health care centres. The blinded assessment was a further strength of the analysis. The benefit measures were restricted to the accuracy of the two options, and these were intermediate outcomes for the impact of the interventions on a patient's health, which will be of clear relevance for clinicians, but not comparable with the benefits of other interventions.

Costs:
The economic analysis was consistent with the perspective of the patient and the health care system. A breakdown of cost items was provided, and most of the unit costs and resource quantities were reported separately, enhancing both the transparency of the analysis and the possibility of replicating it for other settings. The data sources were reported and, in general, the economic analysis was satisfactorily presented, but the lack of information on the reference year limits the ability to perform reflation exercises for other time periods.

Analysis and results:
The results were extensively presented and the costs and benefits were synthesised in an average analysis. An incremental approach would have been helpful to directly compare the two strategies. The issue of uncertainty was only partly investigated, using a deterministic approach that focused exclusively on selected parameters. The authors acknowledged some limitations of their analysis, such as the exclusion of some costs (e.g. adverse events of TB drugs) and the fact that mortality was not considered.
Concluding remarks:
The study was well presented, but some methodological limitations in the synthesis of costs and benefits might affect the validity of the authors’ conclusions.

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