Cost-effectiveness of different strategies for amplified Mycobacterium tuberculosis direct testing for cases of pulmonary tuberculosis


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
The objective was to examine the cost-effectiveness of various specimen dilution strategies for the diagnosis of pulmonary tuberculosis using the amplified Mycobacterium tuberculosis direct test. The authors concluded that, in their laboratory, a strategy of testing that incorporated the dilution of smear-positive, but not smear-negative, respiratory specimens was the most cost-effective option. Although the study had some methodological limitations, it seems to have been appropriate for the authors’ objective and their conclusions are valid, but specific to their institution.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to examine the cost-effectiveness of various specimen dilution strategies for the diagnosis of pulmonary tuberculosis using the amplified Mycobacterium tuberculosis direct (MTD) test.

Interventions
The four comparators were the conventional, simultaneous, smear-positive, and sequential strategies as follows.

The conventional strategy was a conventional MTD test, regardless of the specimen smear result, with smear-positive and MTD test-negative specimens re-tested using an internal amplification positive control to assess for the presence of inhibitors.
In the simultaneous strategy, both conventional and dilution methods were performed simultaneously for each specimen.
In the smear-positive strategy, the dilution method was used for smear-positive specimens, and the conventional method was used for smear-negative specimens.
In the sequential strategy, the conventional test was performed on all specimens, and those with negative or equivocal results were re-tested using the dilution method.

The dilution method consisted of adding 450μl of sterile distilled water to 50μl of the processed specimen, which was used in the conventional MTD test.

Location/setting
USA/laboratory.

Methods
Analytical approach:
This economic evaluation was based on a decision tree. The time horizon was not stated, but it appears to have been that of the diagnostic results. The authors stated that the laboratory perspective was adopted.

Effectiveness data:
Most of the clinical data came from a published retrospective study by the authors of this evaluation. The published study was a two-year retrospective review of MTD test data from the Maryland Department of Health and Mental Hygiene (DHMH) Laboratory. This included 491 respiratory specimens from 401 people, who were tested using both
the conventional and dilution methods. The key clinical input was the MTD test sensitivity with or without dilution for smear-positive and smear-negative specimens.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
The summary benefit measure was the rate of correct pulmonary tuberculosis diagnoses.

Cost data:
The economic analysis included MTD testing and the performance of controls. This included test kits, laboratory supplies (gloves, pipette tips, tubes, etc.), and technician time. All the economic data were derived from the authors’ institution. The unit costs were reported for most items. They were in US dollars ($) and the price year was not reported.

Analysis of uncertainty:
A threshold analysis was carried out on the following model inputs: the proportion of tested specimens that were smear-positive, the proportion of smear-positive specimens that were culture positive for *Mycobacterium tuberculosis*, and MTD test sensitivity for both conventional and dilution methods for smear-positive specimens.

Results
The total costs were, $27,759 for the conventional strategy, $46,518 for the simultaneous strategy, $23,259 for the smear-positive strategy, and $41,070 for the sequential strategy. The probabilities of correct diagnoses (491 cases) were 0.91 for the conventional strategy, 0.96 for the simultaneous strategy, 0.94 for the smear-positive strategy, and 0.96 for the sequential strategy.

The expected costs per correct pulmonary tuberculosis diagnosis were $68.29 for the conventional strategy, $102.69 for the simultaneous strategy, $53.40 for the smear-positive strategy, and $90.96 for the sequential strategy.

The key finding from the sensitivity analysis was that the smear-positive strategy remained more cost-effective than the conventional strategy when the proportion of smear-positive specimens decreased to values as low as 0.10, and when tuberculosis prevalence among smear-positive specimens decreased to values as low as 0.10.

Authors’ conclusions
The authors concluded that, in their laboratory, the strategy of MTD testing that incorporated the dilution of smear-positive, but not smear-negative, respiratory specimens was the most cost-effective option.

CRD commentary
Interventions:
The selection of the comparators was appropriate, as all possible strategies seem to have been considered. The gold standard for correct diagnosis was the final culture result.

Effectiveness/benefits:
The clinical data were based on a retrospective review of data from the authors’ institution. The use of a database is generally considered to be a weak source of evidence, not only because of the retrospective nature of the data, but also because administrative data are usually not gathered for the purpose of the study. Except for the number of patients included in the database, no other information was reported. The benefit measure was disease-specific, but it appears to have been appropriate for the objective.

Costs:
The cost categories were appropriate to the perspective. Some unit costs were reported, which improves the transparency of the economic study. In general, the economic analysis reflected the experience in the authors’ institution. The price year was not reported, which limits the possibility of making reflation exercises for other time periods.
Analysis and results:
The costs and benefits were reported and they were combined using average cost-effectiveness ratios. The use of an incremental analysis could have been more useful, but it might have been difficult to interpret the final results. The study was based on clinical and economic data gathered at a single laboratory, which might not be representative of other health care institutions. The authors noted some limitations of their analysis, such as the use of retrospective data and the exclusion of costs associated with delayed or missed diagnoses.

Concluding remarks:
Although the study had some methodological limitations, it appears to have been appropriate for the authors’ objective. Their conclusions are valid, but specific to their institution.

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