An incremental cost-effectiveness analysis of the first, second and third sputum examination in the 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.

Health technology
The examination of three, consecutive sputum smears for the diagnosis of pulmonary tuberculosis (TB).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised persons suspected of being AFB positive. It was not stated whether the chosen guidelines, which stated that patients had to have had a cough for more than 3 weeks and/or haemoptysis, were followed.

Setting
The setting was a rural district hospital. The economic analysis was carried out in Zambia.

Dates to which data relate
The effectiveness, resource use, and cost data were collected during 1997 and 1998. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study using patient questionnaires.

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

Study sample
A total of 1,423 suspected AFB cases were examined during the study period. At least three smears were examined for each of these patients. No power calculations were performed to determine the sample size. No baseline characteristics were reported.

Study design
This study was a diagnostic test evaluation carried out at a single centre. The patients were not followed-up beyond the results of the third smear. No patient was lost to follow-up.
Analysis of effectiveness
The analysis was performed on an intention to treat basis. The primary health outcome was the number of TB cases identified. A positive smear was defined by the Ziehl-Neelsen test as one in which at least 3 AFB are seen in 100 oil-immersion fields of the smear.

Effectiveness results
There was a total of 166 suspected cases that were found to be AFB positive, who had had three sputum smears examined sequentially. Of these, 128 (77.1%) were identified on the first smear, a further 25 (15%) were identified on the second smear, and 13 (7.9%) additional cases were identified on the third smear.

Clinical conclusions
The use of repeated testing produced incremental gains in the number of AFB cases detected, which became smaller with each successive test.

Measure of benefits used in the economic analysis
The measure of health benefit used was the number of TB cases identified.

Direct costs
The capital costs were annualised using a 3% discount rate. Other direct costs were not discounted. The quantities and unit costs were not reported separately. The direct costs were for the buildings, equipment, staff, and diagnostic supplies only. The quantity/cost boundary adopted was that of the hospital. The resource use data were obtained from administrative records, interviews, and by direct observation. The labour costs were obtained from salary scales issued by the Ministry of Health. The cost of supplies was taken from a Central Board of Health Publication. The price year was not reported.

Statistical analysis of costs
The costs were presented as an "average". There was no statistical analysis of any differences.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($). The exchange rate was $1 = 2,700 Zambian Kwacha.

Sensitivity analysis
No sensitivity analyses were reported.

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

Cost results
The total costs amounted to $576 for the first sputum examination, $587 for the second, and $580 for the third.
Synthesis of costs and benefits
The average cost per case detected was $4.5 for the first sputum examination, $7.6 for the second, and $10.5 for the third.

The incremental cost per case detected was $4.5 for the first sputum examination, $23.3 for the second, and $44.8 for the third.

Authors' conclusions
The authors argued that a policy of examining two samples should be considered in resource-poor settings, providing the remaining steps of the national diagnostic algorithm were adhered to with respect to smear-negative suspects. In other words, any smear-negative patients detected should only be assumed to be uninfected following antibiotic treatment, further smear testing and an X-ray examination.

CRD COMMENTARY - Selection of comparators
The comparators used were justified on the grounds that they represented commonly employed strategies requiring investigation. You should decide if these health technologies are relevant to your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a diagnostic test evaluation, which was appropriate for the study question. The authors did not show whether the study sample was representative of the study population, because they did not report baseline characteristics. The number of cases detected is clearly an important consequence of a diagnostic technology. However, the authors may have missed important consequences by focusing on these true positives. They should have also identified false positives, false negatives or true negatives by a 'gold' standard test, for example, by following the guidelines reported. Also, as the authors stated, the value of detecting cases depends on how quickly they can be treated.

Validity of estimate of measure of benefit
The measures of health benefit were obtained directly from the effectiveness analysis (see the commentary above).

Validity of estimate of costs
The cost analysis seems to have included all the direct cost categories relevant to diagnosis in the hospital. However, as with the effectiveness consequences, those in terms of treatment resource use were neglected. For example, by detecting costs earlier, future treatment costs might be reduced. Also, no sensitivity or statistical analyses were conducted on the cost data, the price year, and resource quantities. The unit costs were not reported, which made it difficult to replicate the cost results in other settings. In addition, the cost data were taken from local sources, and were thus unlikely to be generalisable to other settings.

Other issues
The authors did not compare their findings with those from other studies, and did not address the issue of generalisability to other settings. In addition, they do not appear to have presented their results selectively. The authors' conclusions about TB suspects are threatened by a lack of information on the nature of the population or the sample. The authors noted that, if a two-smear policy were adopted, the quality of the smear examinations might improve, thus enabling the correct diagnosis of more patients. However, if, as a result of recommending two smears instead of three, some infectious patients are not identified at an early stage, the eventual costs could be high. The authors also acknowledged that they did not consider the effects of alleviating the burden on existing staff, by reducing the number of smears from three to two.

Implications of the study
The authors argued that a policy of examining two samples should be considered in resource-poor settings, if the
remaining steps of the national diagnostic algorithm can be adhered to with respect to smear-negative suspects. Such a policy could result in savings that may be re-deployed to improve other aspects of TB control. However, although the authors have shown an incremental gain in the number of cases detected and the cost to achieve this, there was insufficient information to make a decision on the number smear examinations required.

The decision on whether to pay for this gain in effectiveness should be taken in view of: the value of the consequences discussed; the incremental gain for alternative uses of the resources, for example on other aspects of TB control; and the size of the budget. Further work is required to examine the effect of a two-smear policy on AFB detection, and any policy on dealing with smear-negative results.

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