Mycobacterial growth and bacterial contamination in the mycobacteria growth indicator tube and BACTEC 460 culture systems

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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
Using mycobacterial growth indicator tube (MGIT) versus the BACTEC 460 TB system for detection of mycobacterial growth.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Specimens submitted to a microbiology laboratory for acid-fast bacillus (AFB) culture.

Setting
Hospital. The economic study was carried out in Philadelphia, USA.

Dates to which data relate
Not reported.

Source of effectiveness data
Two studies were used to derive the effectiveness data.

Link between effectiveness and cost data
The cost per system was calculated retrospectively based on the number of tests performed per year.

Study sample
No power calculations were reported. A total of 510 specimens (excluding blood and bone marrow) was included in the analysis. 270 of these were sputum-bronchial aspirate, 8 were from urine, 20 from stool, and 212 were from sterile body sites. All of the specimens (direct and concentrated) were inoculated into three media: a BACTEC 12B bottle, an MGIT tube and a Lowenstein-Jensen (LJ) slant. The specimens were inoculated in two different studies (n=238 from 137 patients for the first, and n=272 from 182 patients for the second), which differed from one another in terms of the concentration of NaOH used in the decontamination process (4% in the first study, and 6% in the second study).

Study design
This was a cohort study. The studies were carried out in a single centre.

**Analysis of effectiveness**
The analysis was based on the intention to treat principle. The primary health outcomes used in the analysis were the number of isolates grown in the media for each positive complex found in the specimens, average time to AFB detection and identification to the species level.

**Effectiveness results**
For the first study (with a 4% concentration of NaOH), the 4 specimens positive for M. tuberculosis complex grew isolates in both media; of the 25 specimens positive for M. avium- M. intracellulare complex, the isolates grown in MGIT medium only, BACTEC 460 medium only, and both, were 5, 8 and 12 (p>0.05). The analysis in terms of mean time to detection of AFB (for those commonly detected cases), yielded, for M. Tuberculosis complex, 20.75 days in MGIT and 14.5 days in BACTEC 460; M. Avium-M. intracellulare complex, 19.3 days in MGIT and 12.6 days in BACTEC 460 (p<0.05). The contamination rates in MGITs and BACTEC bottles were 29.8% and 5%, respectively. In the second study (6% NaOH concentration), the figures for isolates grown in MGIT only, BACTEC only, and both media, were respectively: of the 23 positive specimens for M. avium-M. intracellulare complex, 6, 5, and 11 (p>0.05); of the 10 positives for M. Gordonae, 2, 6, and 2; five out of 5 specimens positive for M. kansasii, M. fortuitum, M. marinum, and M. chelonae, were grown in both media. The mean times to detection of AFB in the 10 M. avium- M. intracellulare complex positive specimens were 13.7 and 10.7 days with MGIT and BACTEC, respectively (p<0.01). The corresponding figures for identification to the species level of these specimens were 18.9 and 14 days (p>0.05). The contamination rates for the MGIT and the BACTEC 460 systems were, respectively, 12.1% and 5.5% (p<0.001). Some comparisons could not be tested statistically due to low numbers.

**Clinical conclusions**
Overall bacterial contamination is less in BACTEC 460 than in MGIT, but contamination rates vary with the contaminating organisms in the specimens tested.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

**Direct costs**
Quantities of resource use were reported separately from the costs. Cost items were reported separately. The costs measured were those associated with capital (equipment), labour, and reagents. The perspective adopted in the cost analysis was not explicitly reported. The cost calculation was carried out assuming 4,500 specimens analysed per year. The labour cost estimation was based on guidelines from the College of American Pathologists. The price year was not reported. The costs associated with laboratory, time, effort, and maintenance of a BACTEC 460 system, reprocessing of contaminated specimens and patient care when discarding rather than reprocessing takes place, and Wood's lamp or transilluminator, were omitted from the analysis.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The total cost per year for the BACTEC 460 was reported as $30,465.85, whereas for MGIT it was $33,906.00.

**Synthesis of costs and benefits**
Not combined.

**Authors' conclusions**
BACTEC can be used for all specimen types and for susceptibility testing of first-line anti-tuberculosis drugs. On the other hand, the need for needle inoculation of the BACTEC 460 bottles poses a real hazard that is not present in the MGIT system. For laboratories which do not receive many blood specimens and do not perform susceptibility testing, MGIT is a good alternative to the BACTEC system.

**CRD COMMENTARY - Selection of comparators**
The choice of comparator was justified by the authors. It was regarded as being the most rapid detector of mycobacterial growth then in current use.

**Validity of estimate of measure of benefit**
The internal validity of the study results was undermined by the problem of low numbers. No power calculations were reported. No dates were reported. Nevertheless, the data were not used selectively to prove a particular point.

**Validity of estimate of costs**
The scope of the cost analysis was limited. Adequate details of cost estimation were given as well as quantities of resource use, although both the price year and certain important cost items were omitted in the analysis.

**Other issues**
The authors noted the limitations of their study. The generalisability of the study was not discussed nor were adequate comparisons with previous studies. The results, however, were not presented selectively.

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None stated.

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