Practical bench comparison of BBL CHROMagar Orientation and standard two-plate media for urine cultures

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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
A chromogenic agar, BBL CHROMagar Orientation (CO), developed for urine cultures, was studied.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
No details of the patient population were given. However, the urine samples used in the study were those consecutively received for routine culture by the authors’ laboratory, attached to Stanford University Medical Center (CA), USA.

Setting
The setting was secondary care. The economic study was carried out in California, USA.

Dates to which data relate
The dates to which the effectiveness and resource use data referred were not reported. The price year was also not reported

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

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

Study sample
The method of sample selection was convenience; 1,023 consecutive urine samples received for culture were included. Of these, 53% were clean catch voided, 37% were obtained via straight catheter, 9% were collected through the port of an indwelling Foley catheter and the remaining 1% were suprapubic taps.

Study design
The study was a diagnostic study. Each urine sample was plated 3 times using the three different agars under review.
always with the same streaking technique. The study took place in a single centre.

**Analysis of effectiveness**
The analysis of the clinical study was based on the full sample. The diagnostic outcomes used in the analysis were the correct detection and identification of growths of clinically significant pathogens and agreement in susceptibility results. Standard protocol at the laboratory required that up to 2 potential pathogens detected at levels in excess of 10,000 CFU/mL was considered clinically significant. Three or more were usually reported as "mixed culture". Rapid methods including spot indole, pyrrolidonyl-beta-naphthylamide aminopeptidase, oxidase, coagulase and smell, as described by the National Committee for Clinical Laboratory Standards (NCCLS M35-A), were used for identification alongside "conventional" methods. A Vitek 2 was used for identification where necessary and for susceptibility testing. A MicroScan Walkway was also used for susceptibility testing. The plates were incubated in air at 35 degrees C overnight and read after 10 to 24 hours.

**Effectiveness results**
Two hundred and fifty (24.4%) of 1,203 urine samples yielded clinically significant results.

For 199 urine cultures (80% of all positive results) the interpretation of growth on CO and standard media was identical.

The remaining 51 cultures, 40 of which produced a pure culture, yielded different interpretations on the two types of media.

Eleven clinically significant organisms were not detected on conventional media, but were on the CO plate. Six organisms detected on standard plates were missing on CO.

The CO plate was correct for 69% of the urine samples for which results did not match. Organisms named on the basis of colony colour and morphologies on CO were in 100% agreement with these organisms as identified from colonies on conventional media.

A total of 2,268 drug-organism combinations were compared during susceptibility testing. Most errors occurred with Klebsiella species, nitrofurantoin and P. aeruginosa, with other errors distributed randomly across species and drugs.

Testing from routine media yielded 14 resistant results (25% of all discordant results) that showed intermediate results from the CO plate.

**Clinical conclusions**
The authors concluded that CO was easy to use and reliable in the identification of cultures.

**Measure of benefits used in the economic analysis**
No summary measure of benefits was used. In effect, a cost-consequences analysis was performed.

**Direct costs**
Discounting was not carried out and was not relevant given the timeframe of the study. The costs were estimated concurrently with effectiveness, but the dates pertaining to resource use and prices were not reported. The costs and the quantities were analysed separately. Resource use included the time spent streaking and labelling one urine culture plate, the time required to perform a complete bench workup on the routine two-plate setup and on the single-plate CO system, the CO, BAP and MacConkey plates and spot test reagents, and the time spent on spot testing. All other setup activities, such as accessioning, removing urine samples from a refrigerator, organising the work area, flaming loops and putting items away, were equal for either conventional or CO urine inoculation and were excluded from the analysis. The quantities were estimated using actual data recorded during the study. Average hourly salaries plus 25% overhead were used to determine the labour costs associated with setup and culture workshop. The costs of materials
Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

Sensitivity analysis
As the authors expected salaries in the laboratory to be above average, an additional cost analysis was performed for laboratories where staff salaries were lower. The source of the range used was not given.

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

Cost results
Annualised to 20,000 urine samples, the authors found that the cost-savings accrued through the inoculation and examination of one plate only, with savings in spot test reagent and labour, totalled $35,680.

In laboratories with lower staff salaries, this corresponded to $28,142.

The authors' laboratory could make the change from two conventional plates to CO and remain cost neutral at a CO plate price of $1.78 ($1.41 for lower-salaried laboratories).

If a laboratory wished to continue with a BAP plate alongside a CO plate, urine cultures would remain cost neutral at a CO plate price of $1.53 in California ($1.16 in lower-salaried areas of the country).

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The benefits of BBL CHROMagar Orientation (CO) included a more rapid turnaround time for result reporting, decreased labour in interpretation, cost-savings on reagents and labour that could be significant over time, and ease of use.

CRD COMMENTARY - Selection of comparators
The comparators selected represented standard practice in the authors' laboratory setting. You should decide whether they are widely used health technologies in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on an appropriate study design for the study question. The authors could have gone further and produced sensitivity and specificity results to assist in comparing the different media.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. The analysis was, in effect, a cost-consequences study.

Validity of estimate of costs
All the categories of costs relevant to the hospital perspective were included in the analysis. Some relevant costs were omitted from the analysis as they were common to both health interventions. However, these omitted costs are unlikely to have affected the authors' conclusions. The costs and the quantities were reported separately, as were collection methods, thus enhancing the generalisability of the study to another setting. The resource use quantities were taken from a single study and no statistical analysis was performed (mean quantities were applied). The prices were taken from the authors' setting and no statistical analysis was performed. The price year was not reported.

Other issues
The authors compared their results with those from other studies and found agreement. They also stated that their study contributed to the evaluation of the utility of performing susceptibility tests directly from CO. The issue of generalisability to other settings in the USA was addressed via a cost analysis based on lower salaries for technical staff. The authors appear to have presented their results comprehensively and their conclusions reflected the scope of the analysis. It would have been useful had the study investigated and included the potential knock-on benefits of faster turnaround time in result reporting. Finally, combining the costs and benefits in a single measure could add considerable confidence to the cost-effectiveness of CO plates.

Implications of the study
The authors expected that the benefits of CO infer clinical and financial gains from the rapid reporting of clinically significant results. They accepted that CO interpretation requires practice, but that regular use of CO would reduce errors. They recommended that laboratories phase in CO use gradually, possibly in conjunction with a BAP.

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