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| Title | A Systematic Review of the Clinical, Public Health and Cost Effectiveness of Rapid Diagnostic Tests for the Detection and Identification of Bacterial Intestinal Pathogens in Feces and Food |
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Aim

1. To identify studies on rapid diagnostic methods for food poisoning due to *Salmonella* spp., *Campylobacter*, *Escherichia coli* O157, *Clostridium perfringens*, *Staphylococcus aureus*, and *Bacillus cereus* relevant to both the food chain and clinical samples
2. To assess and summarize the sensitivity and specificity each diagnostic test for each organism compared to a gold standard
3. To assess usefulness for transfer to clinical testing of tests designed and/or currently applied only to food samples
4. To assess the time for full laboratory analysis and reporting for each diagnostic test
5. To develop a decision analytic model to assess the cost and cost effectiveness of each diagnostic test in a clinical setting and in managing outbreaks
6. To make recommendations for future research based on this systematic review of evidence.

Conclusions and results

Good test performance levels are observed with rapid test methods, especially for polymerase chain reaction (PCR) assays. The estimated levels of diagnostic accuracy using the area under the curve (the summary receiver operating characteristic curve) were high. Although traditional culture is the natural reference test to use for comparative statistical analyses, in many instances the rapid test outperforms culture, detecting additional potentially true positive cases of foodborne illness. The economic model suggests that adoption of rapid tests in combination with routine culture is unlikely to be cost effective. Nominal group analysis identified priorities as: the exclusion of infection due to organisms causing severe disease; and meticulous organization to reduce the interval between sample collection and reporting of results to the clinician.

Recommendations

Despite the relatively poor-quality reporting of studies evaluating rapid detection methods, the reviewed evidence shows that PCR for *Campylobacter*, *Salmonella*, and *E.coli*O157 is potentially very successful in identifying pathogens, possibly more than the number currently detected through culture. Less is known about the benefits of testing for *B. cereus*, *C. perfringens*, and *S. aureus*. It is unclear how clinical outcomes may change if test results are available more quickly and with greater precision than the current practice of bacterial culture.

Methods

See Executive Summary link at www.hta.ac.uk/project/1445.asp.

Further research/reviews required

Further research is needed on the effectiveness and cost effectiveness of emerging tests for more than one organism at a time, eg, multiplex PCR and DNA microarray technologies.