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Review

Point-of-care tests for infection control: should rapid testing be in the laboratory or at the front line?

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SUMMARY

Background: A point-of-care test (POCT) offers a rapid result to manage a patient immediately. The presumed simplicity of such tests belies observed variation between personnel in performing and interpreting results when not appropriately trained. The number of point-of-care devices being developed for the diagnosis of infectious diseases is increasing; by understanding the limitations associated with their use, such tests for infection control purposes may be possible.

Aim: To review the expanding repertoire of POCTs for the diagnosis of infectious diseases and to assess their utility as tools to aid in the reduction of hospital-acquired infection and outbreak management.

Methods: A systematic review using PubMed and Scopus of published literature on the subject of POCTs for the diagnosis of infectious diseases.

Findings: Although the number of publications describing POCTs is increasing, there remains a paucity of literature describing their use in a clinical setting. Of the literature reviewed, POCTs for the diagnosis of respiratory syncytial virus and norovirus have the greatest utility in an infection control setting, although the data suggest that sensitivity and training issues might be a problem. The future generation of POCT devices is likely to be molecular-based, improving sensitivity but at a significant cost to the user.

Conclusions: POCTs have a role in infection control but currently the lack of good, consistent clinical data surrounding their use outside of the laboratory is a limiting factor in their implementation.

Introduction

The term 'point-of-care test' (POCT) has been previously defined as a rapid diagnostic assay that can be performed close to a patient, with the results used to facilitate management of that patient.[1] The term has now been expanded to include any test that can be performed rapidly outside of a central laboratory environment (including home testing) even when the result might not directly impact on patient outcome.

In the USA, many POCT assays are waived by the Clinical Laboratory Improvement Amendments (CLIA) legislation, being defined as:

> simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.[2]

The CLIA-waived derogation is often highlighted by commercial companies to demonstrate to markets outside of the USA the simplicity of a POCT. In reality, there have been serious incidents involving CLIA-waived assays including a series of

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outbreaks of hepatitis B in the USA and Europe associated with blood glucose measurement assays. Although these were the results of inappropriate use of the sample collection device rather than the test itself, the outbreaks demonstrate that even with the simplest tests there can be failures in the testing process resulting in patient harm.[3–6]

Today, POCTs that have been designed to detect biochemical and haematological analytes are used widely and successfully by all grades of healthcare professional outside of the laboratory environment. In most developed countries POCT use in healthcare settings is co-ordinated through a central laboratory or committee. Evidence is required to ensure clinical need for the POCT being introduced and that all healthcare personnel performing the assay are trained and competent in all quality aspects including appropriate documentation of tests performed, sample collection as well as performing and interpreting the test result.[7–9] Previous studies have shown that failure to train staff in each of these aspects can have adverse outcomes in terms of assay performance.[10,11]

The development of POCT assays for the diagnosis of infectious diseases has been largely driven by the need to diagnose high-burden diseases in low-resource settings where laboratory facilities might not be available. Early data from regions where POCT was widely used for human immunodeficiency virus (HIV) diagnosis demonstrated that diagnostic accuracy was equivalent to a laboratory test when two POCTs were used together. This finding led to the Centers for Disease Control and Prevention (CDC) approving the use of HIV POCT for screening high-risk groups in 1998.[12] POCT has consistently been used to great effect in resource-limited countries, particularly for blood-borne viruses and malaria.[13–16] Subsequently, HIV testing in outreach clinics and emergency departments in other regions is becoming more acceptable and with good links to a centralized laboratory the quality of such services is high.[17–19]

The role of POCT for diagnosing infectious diseases outside of HIV is more contentious in areas where good laboratory facilities exist. One argument runs that, with greater laboratory centralization, many smaller hospitals will lose access to rapid microbiology testing and that POCT may be appropriate in these circumstances.[20,21] POCT may also be used for infection control purposes either by testing patients with symptoms on entry into the healthcare setting or to rapidly determine the causative agent of an outbreak. In either situation, the rapid results afforded by a POCT can greatly facilitate patient management and reduce the burden associated with hospital-acquired infection.

By analysing the data from published studies this review aims to determine how POCTs developed for the diagnosis of infectious disease might specifically and rapidly aid infection control procedures and outbreak management. The review will take into account the current assays available and also look to the future and to the role of new technologies in enhancing the sensitivity and specificity of POCTs.

Methods

Search strategy and selection criteria

A literature search was undertaken to include data published up to and including December 2012 using PubMed and Scopus. The search terms applied were 'point-of-care test', 'near-patient test' and 'rapid diagnostic test'. Further search terms were then applied – 'microbiology', 'infectious diseases' and 'infection control' – to the original search results. Laboratory evaluation data; clinical evaluations and articles describing the use of POCTs in clinical settings were included.

Smaller laboratory-based retrospective evaluations using <50 stored clinical samples were excluded from the final review unless the assay was novel and not previously described in earlier publications. Articles describing POCTs where rapid infection control intervention would not affect patient management such as HSV IgG testing and other antibody assays, group B streptococcal screening, and procalcitonin testing in sepsis were excluded from the final discussion but were included for background purposes.

Results

Using the initial search criteria 2267 articles on the topic of POCT were found. Using the secondary search terms, 71 articles were finally selected, of which 37 described POCT for the diagnosis of infectious diseases (other than HIV). Of the 37 infectious disease-specific articles, 15 included data collected from clinical settings, of which eight detailed studies about the rapid diagnosis of malaria or HIV in resource-poor countries. Excluded studies included those repeating studies previously published and small scale laboratory evaluations which provided few further data.

Current POCT devices

The literature revealed that for infectious diseases most currently available POCTs are based on the most recognizable lateral flow immunochromatography (LFI) devices.[15,22–32] The format of the assay may vary from a simple strip, which is dipped into the sample, to a cassette on to which the sample is applied, but the overall principle is the same. The patient sample needs to be a liquid that soaks into and reacts with dried reagents incorporated into a solid matrix such as nitrocellulose. A positive result is indicated by a colour change that can be visually read by the user within 10–15 min. The most difficult aspect of these types of POCT is in the interpretation of the results. Generally any colour change at the sample line or spot should be interpreted as positive, but this can be subjective with very faint reactions often missed by the user or misinterpreted as being false positive and thus reported as negative.[32,33]

Numerous studies have shown that the sensitivity of LFI POCT devices directly correlates with pathogen load in the sample and that samples from adults have a poorer overall sensitivity than samples from children.[34,35] Samples for POCT should therefore always be taken as soon after symptom onset as possible and a negative result should be interpreted with caution when there is a high clinical suspicion.

The sensitivity, specificity, positive and negative predictive values (PPV and NPV) of any POCT are greatly affected by the overall prevalence of an infection in a population and are major limiting factors that should always be considered when setting up a POCT-based service in a low-prevalence population.[32] The success of POCT for the detection of HIV in high-disease burden settings highlights this fact and suggests that

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