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Point-of-Care Diagnostics for Tuberculosis: Are we there?

Amani Mansour Mohmad Alnimr*

College of Medicine, University of Dammam, Saudi Arabia

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Introduction

With the increasing incidence of tuberculosis including its drug-resistant forms, point-of-care-diagnostics for tuberculosis (POCT-TB) are desirable. Smear-microscopy was the first point-of-care test for tuberculosis. It can be performed on un-centrifuged specimens at the point of care. The introduction of the low cost light-emitting diode (LED) microscopy with the benefit of fluorescence microscopy without the associated operational requirements, has offered a new tool for POCT-TB [1]. More recently, the processing of serial sputum specimen examinations in the front-loaded microscopy approach focuses on collecting several specimens during one visit [2]. Although this may lead to a reduced diagnostic sensitivity for the individual patient but is expected to improve rate of active case finding by reducing dropout rates [3,4].

Nucleic acid amplification tests (NAATs) offered a new platform for POCT-TB. Although the Xpert MTB/RIF assay was not evaluated specifically as a POCT-TB in primary care settings, its suitability for point of care use is suggested by its fully automated nature and totally closed environment to detects *M. tuberculosis* complex and identify Multi-drug resistant (MDR) form. Another advantage of performing Xpert MTB/RIF as a POCT-TB is to be able to identify highly infectious patients since the cycle threshold (Ct) values generated correlate with the bacillary load [5,6]. The available evidence shows that cross-contamination and error rates are minimal, and the assay performance was shown to be equivalent when performed at primary care versus reference laboratories [5]. There is a growing body of evidence that up to 8 log reduction in colony forming units occurs in the clinical samples following their treatment with the buffer provided with the system [7,8]. Thus the cartridge waste generated by the procedure may not represent a great hazard. Of note aerosolized viable bacilli are not encountered unless the specimens were incorrectly processed [8] which were still less than those generated by microscopy, thus Xpert MTB/RIF is likely to provide a safer procedure than smear microscopy in the absence of a biosafety cabinet. An area of concern is the higher cost of Xpert MTB/RIF compared to smear microscopy although a study by Vassal et al showed its cost-effectiveness [9]. One approach suggested to reduce cost is to perform the assay only in smear-negative cases in high prevalence countries. This may not be the optimum in low-intermediate prevalence settings or in patients with risk factors for infections by non-tuberculous mycobacterial. Another concern is to provide an effective algorithm to deal with cases that are detected as MDR tuberculosis by Xpert MTB/RIF at the point of care. Other novel approaches for POCT-TB include antigen- and serology-based assays but these are still investigational. Of clinical interest also is monitoring treatment compliance, which is another, evolving area of POCT-TB [10].

A future point-of-care-diagnostic needs to have a reliable performance, ability to test different types of clinical specimens in different patient populations including HIV cases, and be cost-effective and user friendly. Besides, ability to fit the primary care infrastructure with minimal safety impact is a major requirement for a future POCT-TB. Nevertheless, training, competency assessment and proficiency testing will be a cornerstone for the performance of such assays. The launching of POCT-TB will provide a flexible alternative to the current complex diagnostics, which aids in the global control of TB. Research that compares the performance of the candidate assays in the primary care versus the reference laboratories is highly desirable.

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***Corresponding author:** Amani Mansour Mohmad Alnimr, Assistant Professor & Consultant Clinical Microbiologist, King Fahad Hospital of the University College of Medicine, University of Dammam, Saudi Arabia, Tel: +9668966666; E-mail: amalnimr@ud.edu.sa

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