

Evidence-based Tuberculosis Diagnosis

One-page plain language summaries of systematic reviews - #10

Title: Light emitting diode (LED) fluorescence microscopy for the diagnosis of tuberculosis

This *systematic review* presents *evidence* from a collection of studies evaluating tests or strategies for the diagnosis of tuberculosis (TB). Terms in *italics* are defined in the TB Evidence Glossary.

Why this review is important: Most of the world's TB cases occur in low-income and middle-income countries, where sputum microscopy with a conventional light microscope is the primary method for diagnosing pulmonary TB. The development of fluorescence microscopy (FM) using auramine staining has been a significant improvement over conventional microscopy using Ziehl-Neelsen (ZN) staining. FM has been shown to have approximately 10% higher *sensitivity* compared with conventional microscopy, with no significant compromise in *specificity*. Light emitting diode (LED) microscopy is a novel diagnostic tool. Compared with conventional mercury vapour fluorescence microscopes, LED microscopes are less expensive, require less power, can run on batteries, and reportedly perform well without a darkroom, qualities making LED microscopes suitable for resource-constrained areas and enabling the benefits of FM to reach areas where they are needed most.

Objective: to determine the sensitivity and specificity of LED microscopy for the diagnosis of TB. To combine results from individual studies in a *meta-analysis* to obtain summary (pooled) estimates for sensitivity and specificity.

Main findings: 12 studies were included in the review. Using culture as the reference (8 studies), LED sensitivity estimates ranged from 67% to 96% and specificity estimates from 89% to 100%. In the meta-analysis, pooled sensitivity was 84% (95% CI 76, 89) and pooled specificity 98% (95% CI 97, 99). LED microscopy was 6% more sensitive (95% CI, 0.1,13), with no appreciable loss in specificity, when compared with direct ZN microscopy. In comparison with ZN microscopy, LED microscopy showed similar gains in time for reading as conventional FM, with about half the time required for microscopic smear examination.

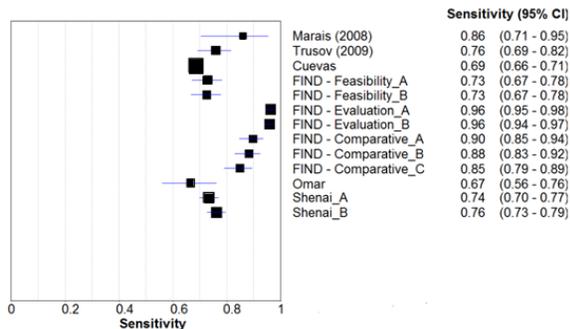


Figure. Forest plot of LED microscopy sensitivity; squares show point estimates of sensitivity from each study; 95% CIs are shown by the horizontal lines.

Authors' conclusions: The benefits associated with using FM have been previously established (see plain-language summary #1), and current LED studies are consistent with the improved sensitivity and efficiency of FM compared with conventional ZN microscopy. The barriers to widespread implementation of FM in many low-income settings have been largely practical and several may be overcome with the introduction of LED fluorescence microscopy.

Policy implications: In 2009, WHO recommended that conventional FM be replaced by LED microscopy in all settings and that LED microscopy be phased in as an alternative for conventional ZN microscopy in both high-volume and low-volume laboratories. The switch to LED microscopy should be carried out through a carefully phased implementation plan, using LED technologies that meet WHO specifications.

Comments: The *GRADE* approach confirmed that there is sufficient generalizable evidence to recommend strongly the use of LED microscopy.

Systematic review: Minion J et al. Fluorescent Light Emitting Diode (LED) Microscopy for the Detection of Mycobacterium tuberculosis: a Systematic Review & Meta-analysis, WHO expert group meeting on approaches to improve sputum smear microscopy for tuberculosis diagnosis; Sept 7, 2009, Geneva

Publications and other resources of related interest

1. Minion J, Sohn H, Pai M. Light-emitting diode technologies for TB diagnosis: what is on the market? *Expert Rev Med Devices*. 2009 Jul;6(4):341-5.
2. Toman K. What are the advantages and disadvantages of fluorescence microscopy? In: Frieden T, ed. *Toman's tuberculosis: case detection, treatment and monitoring—questions and answers*. 2nd ed. Geneva; WHO 2004.

Contact: Karen R Steingart, MD, MPH karenst@uw.edu, Evidence Synthesis & Policy Subgroup, NDWG, Stop TB Partnership