4th Advanced TB Diagnostic Research Course

AN INTENSIVE, HIGH-LEVEL COURSE ON TB DIAGNOSTIC RESEARCH METHODS

McGill University, Montreal, Quebec, Canada - **July 7–11, 2014**

Previous course materials available at:
www.teachepi.org

COORDINATOR

Madhukar Pai, MD, PhD
Associate Director
McGill International TB Centre
madhukar.pai@mcgill.ca

VENUE

McGill University, Montreal, Canada

ENROLMENT

Maximum of 50 participants. Only participants with prior TB diagnostic research experience or advanced training will be eligible.

TUITION

$800 for students, fellows, and applicants from low-income countries. $2000 for industry participants. $1600 for all others. All participants are expected to cover their travel and accommodation costs.

REGISTRATION

To apply, please request a registration form:
montreal.course@gmail.com

Registration deadline: January 31st, 2014

COURSE FACULTY

Niaz Banaei, MD, Stanford University
David Boyle, PhD, PATH
Adithya Cattamanchi, MD, UCSF
Harkesh Dabas, MBA, CHAI
Claudia Denkinger, MD, PhD, FIND
Keertan Dheda, MD, PhD, Univ. of Cape Town
David Dowdy, MD, PhD, Johns Hopkins Univ.
Nora Engel, PhD, Maastricht University
Jim Gallarda, PhD, MBA, Gates Foundation
Janet Ginnard, PhD, UNITAID
Glenn Johns, PhD, Alere Inc.
Sandra Kik, PhD, McGill University
Michael Kimerling, MD, BMGF
Dick Menzies, MD, MSc, McGill University
Kara Palamountain, MBA, Northwestern Univ.
Andy Ramsay, PhD, TDR/WHO
Karen Steingart, MD, MPH, Cochrane ID Group
Grant Theron, PhD, Univ. of Cape Town

ORGANIZED WITH SUPPORT FROM THESE PARTNERS:

McGill · Centre universitaire de santé McGill McGill University Health Centre · Centre international de TB McGill · McGill International TB Centre · TB NEAT · TDR For research on diseases of poverty · FIND Foundation for innovative new diagnostics · Stanford Pathology Global Health Diagnostics Fellowship · Kellogg School of Management · PATH · Stop TB Partnership

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CONTEXT

High quality diagnostic studies are critical to evaluate new tools, and to develop evidence-based policies on TB diagnostics. There is evidence that TB diagnostic trials are poorly conducted and poorly reported. Lack of methodologic rigour in TB trials is a cause for concern as it may prove to be a major hurdle for effective application of diagnostics in TB care and control. Furthermore, there is evidence that a majority of TB diagnostic studies are focused on test accuracy. There are limited data on outcomes such as accuracy of diagnostic algorithms (rather than single tests) and their relative contributions to the health care system, incremental value of new tests, impact of new tests on clinical decision-making and therapeutic choices, cost-effectiveness in routine programmatic settings, and impact on patient-important outcomes. This poses problems because research on test accuracy, while necessary, is not sufficient for policy and guideline development. Test accuracy data are surrogates for patient-important outcomes and cannot provide high quality evidence for policy making. Therefore, accuracy studies must be considered along with impact of the test on patient-important outcomes, and other factors such as quality of the evidence, the uncertainty about values and preferences associated with the tests and presumed impact on patient-important outcomes, and cost and feasibility. Translation of policy into impact requires collecting evidence for scale-up, country-level data on cost-effectiveness and feasibility, implementation research, and local decisions on scale-up, delivery and impact assessment.

COURSE CONTENT

This advanced course will cover advanced diagnostic study designs, sources of bias, and value chain for TB diagnostics development. Also, conventional and advanced methods for systematic reviews (meta-analyses) of diagnostic tests will be presented, along with the GRADE approach to diagnostic policies. More recently, there is growing appreciation that “test accuracy research” focused on sensitivity and specificity is not necessarily the same as “diagnostic research.” There is also a clearly felt need to go beyond test accuracy and evaluate accuracy of diagnostic algorithms (rather than single tests) and their relative contributions to the health care system, incremental value of new tests, impact of new tests on clinical decision-making and therapeutic choices, cost-effectiveness in routine programmatic settings, and impact on patient-important outcomes. This course will introduce multivariable approaches to diagnostic research, and cover alternative designs which evaluate patient outcomes, including the diagnostic RCT, and implementation research. The course will also cover mathematical modeling and cost-effectiveness studies. Panel discussions will cover topics such as market analyses, market dynamics, regulatory issues, target product profiles, and industry engagement in TB diagnostics development.

OBJECTIVES

By the end of the course, participants will understand:

- the value chain for TB diagnostics development, current pipeline of diagnostics, market dynamics, WHO policies on new diagnostics, and challenges for scale-up
- principles and practice of diagnostic research focused on accuracy of tests
- principles of multivariable approaches to diagnostic research, and adjustment for imperfect reference standards
- principles of meta-analyses of diagnostic accuracy studies and GRADE approach to diagnostic policies
- principles of alternative designs to evaluate impact of new tests on clinical decision-making, therapeutic choices, and patient-important outcomes
- principles of implementation research, collecting evidence for scale-up, cost-effectiveness analyses and modeling studies in TB diagnostics

READINGS

USB drives will be provided to all participants; they will contain PDF articles and course materials.

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