ADVANCED TB DIAGNOSTIC RESEARCH

An intensive, high-level course on TB diagnostic research methods

Previous course materials
available at
www.teachepi.org

VENUE

McGill University
Goodman Cancer Research Centre
Karp Conference Room
1160, Avenue des Pins Ouest
Montreal, QC, Canada
H3A 1A3

ENROLMENT

Maximum of 40 participants.
Only participants with prior TB
diagnostic research experience or
advanced training will be eligible.

TUITION

$800 for students
$800 for applicants from low-income countries
$2000 for industry participants
$1400 for all others
All participants are expected to cover their
travel and accommodation costs.

COURSE FACULTY

Niaz Banaei, MD
Stanford University, Palo Alto

Catharina Boehme, MD
FIND, Geneva

David Boyle, PhD
PATH, Seattle

Lucian Davis, MD, MAS
UCSF, San Francisco

Nandini Dendukuri, PhD
McGill University, Montreal

Claudia Denkinger, MD, PhD
BIDMC, Boston & McGill University, Montreal

David Dowdy, MD, PhD
Johns Hopkins University, Baltimore

Nora Engel, PhD
Maastricht University, Amsterdam

Janet Ginnard, PhD
UNITAID, Geneva

Michael Kimerling, MD, MPH
Bill & Melinda Gates Foundation, Seattle

Dick Menzies, MD, MSc
McGill University, Montreal

Kara Palamountain, MBA
Kellogg School of Management, Illinois

Andrew Ramsay, PhD
TDR, Geneva

Karen Steingart, MD, MPH
University of Washington, Seattle

Gene Walther, MBA
Bill & Melinda Gates Foundation, Seattle

REGISTRATION

To apply, please request a registration form:
Ms. Danielle Bastien
RECRU, Montreal Chest Institute
Email: danielle.bastien@mcgill.ca

Registration deadline: 1 February 2013

COURSE COORDINATOR

Madhukar Pai, MD, PhD
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McGill University, Montreal

Respiratory Epidemiology & Clinical Research Unit (RECRU)
Montreal Chest Institute, Montreal

McGill University
Montreal, Quebec, Canada

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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 the principles behind diagnostic research, 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 latent class analysis, mathematical modeling, costing 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 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.

Materials will also be posted at:
www.teachepi.org
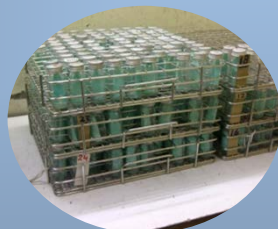
Organized with support from these partners:

www.tbevidence.org