



# ADVANCED TB Diagnostic Research

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



**July 9-13  
2012**

McGill University  
Montreal, Quebec  
Canada



## VENUE

McGill University, Montreal, Quebec, Canada  
Goodman Cancer Research Centre  
1160, Avenue des Pins Ouest, Karp Conference  
Room 501

## ENROLMENT

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

## TUITION

\$800 for students and applicants from low-income  
countries.  
\$1800 for industry participants.  
\$1200 for all others.  
All participants are expected to cover their travel  
and accommodation costs.

## REGISTRATION

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

## Course Coordinator

Dr. Madhukar Pai, MD, PhD  
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Department of Epidemiology & Biostatistics  
McGill University, Montreal

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

Organized with support from these partners:

## COURSE FACULTY

Dr. Andrew Ramsay, PhD  
*TDR/WHO – Geneva*

Dr. Karen Steingart, MD, MPH  
*University of Washington – Seattle*

Dr. Jessica Minion, MD, MSc  
*University of Alberta – Edmonton*

Dr. Catharina Boehme, MD  
*FIND – Geneva*

Dr. David Dowdy, MD, PhD  
*Johns Hopkins University – Baltimore*

Dr. Adithya Cattamanchi, MD, MAS  
*UCSF – San Francisco*

Dr. Nandini Dendukuri, PhD  
*McGill University – Montreal*

Dr. Dick Menzies, MD, MSc  
*McGill University – Montreal*

Mr. Gene Walther  
*Bill & Melinda Gates Foundation – Seattle*

Dr. Claudia Denkinger, MD, PhD  
*BIDMC/Harvard University – Boston*

Dr. Marcel Behr, MD, MSc  
*McGill University – Montreal*

Dr. Madhukar Pai, MD, PhD  
*McGill University – Montreal*



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diseases of poverty  
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Previous course materials available at  
[www.teachepi.org](http://www.teachepi.org)

## CONTEXT

High quality diagnostic studies are critical to evaluate new tools, 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, critical appraisal of diagnostic studies, and 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.

## OBJECTIVES

By the end of the course, participants will understand:

- the value chain for TB diagnostics development, current pipeline of TB diagnostics, and WHO policies on new diagnostics
- 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.

Materials will also be posted at:  
[www.tbevidence.org](http://www.tbevidence.org) and [www.teachepi.org](http://www.teachepi.org)

