

ADVANCED **TB** Diagnostic Research

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



VENUE

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

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 \$1800 for industry participants \$1300 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

Registration deadline: 1 March 2012

Course Coordinator

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Department of Epidemiology & Biostatistics McGill University, Montreal

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

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COURSE FACULTY

Dr. Andrew Ramsay, PhD

Dr. Karen Steingart, MD, MPH University of Washington - Seattle

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

Dr. Catharina Boehme, MD

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



Montreal, Quebec Canada

Previous course materials available at 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. 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 decisionmaking, therapeutic choices, and patientimportant outcomes
- principles of implementation research, collecting evidence for scale-up, costeffectiveness 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 and www.teachepi.org



www.tbevidence.org