JUNE 20-24, 2016

ADVANCED TB DIAGNOSTICS RESEARCH COURSE

"This course was very useful in prioritizing the research and advocacy needed in order to get to the next step in product development."

– ADVANCE TB DIAGNOSTICS PARTICIPANT FROM 2015

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This advanced course will cover advanced topics in TB diagnostics research and implementation, including 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. The 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 meta-analysis, mathematical modeling, and cost-effectiveness studies. Panel discussions will cover topics such as value chain for TB diagnostics development, market analyses, market dynamics, target product profiles, and barriers to scale-up of new diagnostics. Participants will include product manufacturers, donors, product development partnerships, policy makers, academics, clinicians, community advocates, public health implementers and National TB Program managers. Previous course materials are available at: http://mcgill-idgh.ca/previous-course-materials/

COURSE DIRECTOR

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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.

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 and practice 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

ENROLMENT

Maximum of 100 participants. Only participants with prior TB diagnostic research experience or advanced training will be eligible.

2016 COURSES To Register: http://mcgill-idgh.ca/

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