



# TB RESEARCH METHODS

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
Mon • June 5	Tues • June 6	Wed • June 7	Thurs • June 8	Fri • June 9
8:30AM – 5:00PM	9:00AM – 5:00PM	9:00AM – 5:00PM	9:00AM – 5:00PM	9:00AM – 4:30PM
Introductions and overview Big picture stuff	Randomized trials	Operational Research	Systematic reviews and, Controversies	Modeling and economic analysis

HOSTS



GLOBAL HEALTH PROGRAMS



McGill

**M[i]**<sup>4</sup>

Interdisciplinary Initiative in Infection and Immunity



Research Institute McGill University Health Centre

Infectious Diseases and Immunity in Global Health Program  
Programme en maladies infectieuses et immunité en santé mondiale

# OVERVIEW OF SMALL GROUPS

GROUP 1	Randomized trials	<p>Bill Burman &amp; Anna Mandalakas</p> <p>(Biostatistician: Andrea Benedetti)</p>	<p>Randomized controlled trials remain a critical way to advance TB control and program activities. Fortunately, there has been a substantial increase in randomized controlled trials in TB over the past 20 years. Deciding which clinical trial results to incorporate into TB control programs and the management of individual patients is a key skill for program leaders. This group will do the initial design work on a randomized controlled trial of TB treatment as a way of learning to be critical reviewers of this methodology. Participants should prepare for this small group in advance by performing an (informal and small scale) assessment of the needs of their local TB control program/clinic (What aspects of TB treatment are the highest priority for improvements?)..</p>
GROUP 2	Systematic reviews	<p>James Johnston &amp; Mayara Bastos</p>	<p>A choice is offered:</p> <ol style="list-style-type: none"> <li>1. Practical aspects. Searches, file management, data entry, quality assessment, and meta-analysis. This group will have hands on experience with searches – matching search strategies to the PICO, performing searches in different data bases. Saving searches and using different software to manage title selection. Data entry and meta-analysis using R.</li> <li>2. Protocol development. If interest - a sub-group will work on developing a systematic review protocol – from PICO to Prospero registration.</li> </ol>
GROUP 3	<p>Operational Research</p> <p>Quantitative &amp; Qualitative</p>	<p>Quantitative: Gonzalo Alvarez, Thu Anh Nguyen Dick Menzies</p> <p>Qualitative: Stephanie Law (with Amrita Daftary on-line)</p>	<p>This group will split into multiple sub-groups for the week, to develop protocols for operational research. Questions will be proposed by participants and shaped into feasible operational research projects by all members of each sub-group, with the help of the facilitators, who will work with the groups – providing different perspectives and experiences. This year we will have ‘quantitative’ OR and qualitative OR sub-groups, lead by facilitators with particular expertise in these methods.</p>
GROUP 4	<p>Costing in Operational Research</p>	<p>Jonathon Campbell, Alice Zwerling &amp; Kevin Schwartzman</p>	<p>This group (which may also split into sub-groups) will work on developing a protocol for operational TB research projects with a focus on the economic or costing aspects. The final protocol will describe the methods used to derive estimates of the true costs of novel programmatic interventions for TB. With the assistance of the facilitators, groups will examine various costs, such as those associated with implementation, capital costs and recurrent or ongoing costs, with the option of examining costs from societal vs health system perspectives. The small group will be guided by a toolkit for estimating costs associated with TB interventions.</p>

# DAY 1: MONDAY, JUNE 5

8:30AM	<i>Registration</i>
9:00-9:30AM	<b>Introductions, Course objectives and overview</b> Dick Menzies
9:30-10:00AM	<b>How will research End TB? The “big” questions in TB Research</b> Bill Burman
10:00-10:30AM	<b>How will research End TB? Bridging basic science and Clinical research.</b> Marcel Behr
10:30 - 11:00	<b>How will research end TB? Engaging people affected by TB for an inclusive research agenda.</b> Amrita Daftary (ZOOM)
11:00-11:15AM	<i>Coffee Break</i>
11:15-11:45AM	<b>How will research End TB? What about kids?</b> Anna Mandalakas
11:45-12:15PM	<b>How will research end TB? “Bridging The Know-Do Gap in Tuberculosis”</b> Madhu Pai
12:15-1:00PM	<b>Lunch</b>
1:00-1:30PM	<b>A smorgasbord of TB Research methods: 1. Disability post TB – a new outcome</b> Mayara Bastos
1:30-1:45PM	<b>Late Breaker 1:</b> Stephanie Law
1:45 -2:00PM	<b>Small groups: Organization – who, where, what?</b> Dick Menzies
2:00-5:00PM (Includes Coffee Break)	<b>Small groups:</b> Overview of each topic by group leaders Forming sub-groups and selecting objectives
5:00 – 7:00 PM	<b>5 a 7 Social hour</b> – this is an informal get together of TBRM and Tropical Medicine course participants. Cash bar - sorry) Thomson House, 3650 McTavish St. <i>All TBRM participants and faculty with a passion for TB Research invited!</i>

# DAY 2: TUESDAY, JUNE 6

Time	
9:00-9:30AM	<b>DPSICO-TB: Developing study objectives. From a clinical problem to study questions</b> Dick Menzies
9:30-10:10AM	<b>Trial design and selecting study populations—minimizing bias, maximizing generalizability</b> Bill Burman
10:10-10:55AM	<b>Clustered trial designs: DOBS vs DOTS</b> Greg Fox (ZOOM)
10:55- 11:15 AM	<i>Coffee Break</i>
11:15 – 11:45AM	<b>Including Children, pregnant women, vulnerable populations in trials - how, and when</b> Anna Mandalakas
11:45-12:15PM	<b>Applying RCT results to practice – clinical and public health</b> Bill Burman
12:15-12:45 PM	<b>“After the researchers pack up and go home” - sustaining/scaling up - example from ACT4</b> Thu Anh Nguyen
12:45 - 1:45PM	<i>Lunch</i>
1:45-2:15PM	<b>A smorgasbord of TB Research methods: 2. Qualitative methods - a complementary approach to researching TB</b> Amrita Daftary (ZOOM)
2:15-2:30PM	<b>Late Breaker 2:</b> Thu Anh Nguyen
2:30-5:00PM (Includes Coffee)	<b>Small groups:</b> Work on projects

# DAY 3 WEDNESDAY, JUNE 7

Time	
9:00-9:30AM	<b>Lecture 1: Operational research – what- why and how.</b> Gonzalo Alvarez
9:30-10:00AM	<b>Lecture 2: Capacity building for operational research in low- and middle-income countries.</b> Priya Shete (ZOOM)
10:00-10:30AM	<b>Lecture 3: Principles and structure of a research protocol</b> Dick Menzies
10:30-10:45AM	<i>Coffee break</i>
10:45-11:15AM	<b>Lecture 4: Examples of operations research changing policy and practice</b> Thu Anh Nguyen
11:15-11:50PM	<b>Examples of Operational research in Canada - that worked!</b> Gonzalo Alvarez
11:50-12:30PM	<b>A Smorgasbord of TB research methods: 3. Using Big data. New lessons learned using Canadian data from many sources. Can this be applied in LMIC?</b> Jay Johnston
12:30-12:40PM	<b>Group photo</b>
12:40-1:30PM	<i>Lunch</i>
1:30-2:00PM	<b>All about sample sizes—what, how, how many</b> Andrea Benedetti
2:00-2:15PM	<b>Late Breaker 3:</b> Jonathon Campbell
2:15-5:00PM (Includes Coffee break)	<b>Small groups: Work on projects</b>

# DAY 4 THURSDAY, JUNE 8

Time	
9:00-9:30AM	<b>Systematic reviews</b> Jay Johnston
9:30-10:00AM	<b>Individual patient data meta-analyses</b> Mayara Bastos
10:00-10:30AM	<b>The nuts and bolts of Research: Publishing your results (or, getting past those #\$\$@! Reviewers)</b> Jonathon Campbell
10:30-11:00AM	<i>Coffee Break</i>
11:00-12:00PM	<b>Controversies in TB Research: Shorter vs safer</b> The top priority for TB trials is safety and tolerability. (Safety first) Bill Burman The top priority for TB trials is shortening duration (The shorter the better). Susan Dorman <i>Perspectives from the course participants</i> <b>Discussion</b>
12:00-1:00PM	<i>Lunch</i>
1:00-1:30PM	<b>Data Analysis 101</b> Andrea Benedetti
1:30-1:45PM	<b>A smorgasbord of TB Research methods: 4. Genomic epidemiology of TB</b> Marcel Behr
1:45-2:00PM	<b>Late Breaker 4:</b> Mayara Bastos
2:00-5:00PM (Includes Coffee break)	<b>Small groups:</b> Finalizing protocols Preparing presentations

# DAY 5 FRIDAY, JUNE 9

Time	
9:00 - 9:30 AM	<b>Economic analysis—cost effectiveness, cost minimization, cost-outcome descriptions—what’s the difference?</b> Kevin Schwartzman
9:30 - 10:00 AM	<b>All about the money: how to accurately assess the true costs of a new public health/TB program intervention</b> Jonathon Campbell
10:00 - 10:30 AM	<b>Introduction to modeling—what it can do, what it can’t</b> Alice Zwerling
10:30 - 11:00 AM	<b>Coffee break</b>
11:00 - 11:30 PM	<b>Decision analysis for economic evaluation—methods, applications, and key studies in TB</b> Alice Zwerling
11:30 - 12:00 PM	<b>Dynamic transmission modeling for TB—principles and applications in endemic settings</b> Juan Vesga (ZOOM)
12:00 – 12:30	<b>A smorgasbord of TB Research methods: 5. Demystifying Pharmacokinetics – How, why, what PK can tell us</b> Fajri Gafar
12:30 - 1:30 PM	<i>Lunch</i>
1:30 - 4:00PM (Includes Coffee)	<b>Small groups:</b> Presentation of study protocols by small groups Comments on study protocols Moderated by: TBC
4:00 - 4:30PM	<b>Course evaluations and closure</b> Dick Menzies

*This program meets the accreditation criteria as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada and has been accredited by the Office of Continuing Professional Development, Faculty of Medicine and Health Sciences, McGill University for up to 32 Section 1 credits/hours.*

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