

Swiss Epidemiology Winter School 2021



Tools to Assess Risk of Bias in Randomized and Non-Randomized Studies: Cochrane RoB 2 and ROBINS-I

18 – 20 January 2021

Faculty	<p>Prof. Jonathan Sterne Population Health Sciences, Bristol Medical School, University of Bristol, United Kingdom</p> <p>Prof. Julian Higgins Population Health Sciences, Bristol Medical School, University of Bristol, United Kingdom</p>
Venue	<p>CH – 3823 Wengen SWITZERLAND Hotel Edelweiss (see map on http://www.epi-winterschool.org/hotels)</p>
Description	<p>Randomized controlled trials (RCTs), and systematic reviews of such trials, provide the most reliable evidence about the effects of healthcare interventions. Providing enough participants are randomized, randomization should ensure similarity of participants in the intervention and comparison groups so that differences in outcomes of interest between these groups can be ascribed to the causal effect of the intervention. Causal inferences from RCTs can, however, be undermined by flaws in design, conduct, analyses and selective reporting. Although there is good empirical evidence that flaws in RCTs may lead to bias, it is usually impossible to know the extent to which biases have affected the results of a particular trial. Therefore systematic reviews of RCTs typically include assessments of the validity of the included trials.</p> <p>Non-randomized studies of interventions (NRSI) can provide evidence additional to that available from RCTs about long-term outcomes, rare events, adverse effects and populations that are typical of real world practice. For many types of organizational or public health interventions, NRSI are the main source of evidence about the likely impact of the intervention because RCTs are difficult or impossible to conduct on an area-wide basis. Therefore systematic reviews addressing the effects of healthcare interventions often include NRSI.</p> <p>In the last decade, major developments have been made in tools to assess study validity. A shift in focus from methodological quality to risk of bias has been accompanied by a move from checklists and numeric scores towards domain-based assessments in which different types of bias are considered in turn.</p> <p>This course trains participants to use recently-developed tools for assessing risk of bias: version 2 of the Cochrane tool for assessing risk of bias in RCTs (RoB 2), and the ROBINS-I tool for assessing risk of bias in NRSI. These tools share similar approaches including the use of signalling questions to help reviewers judge the risk of bias within each domain, specification of the effect of interest, and guidance on assessing the overall risk of bias in a particular study result. However</p>

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some of the bias domains assessed differ between the tools: for NRSI but not RCTs it is necessary to assess the risk of bias due to confounding; selection bias; and bias in classification of interventions. Work extending ROBINS-I to assess studies of exposures will be described.

Objectives

By the end of this course participants will:

- understand the empirical and theoretical evidence for bias in RCTs and NRSI
 - understand the types of bias that can undermine the internal validity of RCTs and NRSI
 - be able to use version 2 of the Cochrane tool to assess risk of bias in RCTs (RoB 2)
 - be able to use the ROBINS-I tool to assess risk of bias in NRSI
 - be aware of software implementations of RoB 2 and ROBINS-I
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Target audience

The course is suitable for systematic reviewers, epidemiologists and statisticians wishing to learn about a formal framework for assessing risk of bias in studies of the effects of interventions.

Outline

The course will run over three days and consist of lectures, group work and computer practical sessions. We start early in the morning with a review of the previous day. During the extended break in the afternoon participants review course materials, catch up on emails or go skiing. We reconvene at 4:30 pm for the computer sessions.

Monday, 18 January (8:00 – 12:00 | 16:30 – 18:30)

Tuesday, 19 January (8:00 – 12:00 | 16:30 – 18:30)

Wednesday, 20 January (8:00 – 12:00 | 16:30 – 18:30)

Credits

1.0 ECTS

To bring along

Students should bring their own portable computers. A course license for Stata® will be available, to be installed before arrival. University of Bern IT staff onsite can provide help upon request per e-mail (it@ispm.unibe.ch)

Course fee

SSPH+ students: CHF 700
Academic: CHF 900
Industry: CHF 2000

Registration

You can register on the Winter School website www.epi-winterschool.org.

Accommodation

Participants must book their accommodations themselves. Please see our recommendations on www.epi-winterschool.org/hotels for special prices.

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