Swiss Epidemiology Winter School 2022

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

28 – 30 March 2022

Faculty

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Venue

CH – 3823 Wengen | SWITZERLAND
Hotel Edelweiss (see map on https://www.epi-winterschool.org/course-hotel-locations/)

Description

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.

Non-randomized studies of interventions 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, non-randomized studies 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 non-randomized studies. In addition, systematic reviews of studies of the effects of exposure on outcomes usually include only non-randomized (observational) studies.

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.

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	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), an updated version of the ROBINS-I tool for assessing risk of bias in non-randomized studies of interventions, and the new ROBINS-E tool for non-randomized studies of exposures. 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 some of the bias domains assessed differ between the tools: for non-randomized studies but not RCTs it is necessary to assess the risk of bias due to confounding; selection bias; and bias in classification (or measurement) of interventions or exposures.
Objectives	By the end of this course participants will: • understand the empirical and theoretical evidence for bias in RCTs and non-randomized studies • understand the types of bias that can undermine the internal validity of RCTs and non-randomized studies • be able to use version 2 of the Cochrane tool to assess risk of bias in RCTs (RoB 2) • be able to use the updated ROBINS-I tool to assess risk of bias in non-randomized studies of interventions • have experience of the new ROBINS-E tool to assess risk of bias in observational studies of the effects of exposures • be aware of software implementations of these tools
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 and exposures.
Outline	The course will run over three days and consist of lectures and group work. We start early in the morning and have an extended break in the afternoon (when participants can review course materials, catch up on emails or go skiing) before reconvening at 4:30 pm. ***Monday, 28 March (8:00 – 12:00 | 16:30 – 18:30)*** ***Tuesday, 29 March (8:00 – 12:00 | 16:30 – 18:30)*** ***Wednesday, 30 March (8:00 – 12:00 | 16:30 – 18:30)***
Credits	1.0 ECTS
To bring along	Students should bring their own portable computers. 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.
Accomodation	Participants must book their accommodations themselves. Please see our recommendations on https://www.epi-winterschool.org/course-hotel-locations/ for special prices.

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