Transportability and beyond: challenges and opportunities in the context of (registry-based) randomised clinical trials and Swedish health registries

While the day is primarily focused on cardiovascular research, the tools are applicable across other areas of health. The event will be of interest to doctoral students, junior and senior researchers, and clinicians from diverse research fields.

Register by September 8 here: https://survey.ki.se/Survey/43700

Abstract

Randomised controlled trials (RCTs) are widely regarded as the gold standard for evaluating causal effects of interventions in medicine and public health. However, participants in randomised trials may differ from individuals in the target population that will receive the interventions. Consequently, the magnitude and direction of causal effects estimated in trials may not accurately reflect those in the target population, leading to suboptimal or inequitable policy and clinical decisions. To address this critical gap, a growing body of methodological research focuses on transportability methods — approaches that integrate data from both randomised trials and observational sources to extend inferences beyond the trial population. It is anticipated that transportability studies will become standard as they will be increasingly required by decision makers, including policymakers and healthcare payers.

The Swedish national register data structure with extensive and high-quality administrative and quality registers offers an ideal setting for the implementation of transportability methods. Swedish researchers have pioneered registry-based randomised clinical trials (R-RCTs) — a more cost-effective trial approach because embedding the trial in an existing registry allows to use its established infrastructure to identify and follow eligible individuals. Additionally, data collection on baseline and follow-up information is harmonised for all eligible individuals.

The TASTE trial (Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia) was the first R-RCT, enrolling individuals undergoing percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI). A recent large-scale R-RCT is the REDUCE-AMI trial (Randomized Evaluation of Decreased Usage of Beta-Blockers after Acute Myocardial Infarction). All elements of these trials were integrated within the SWEDEHEART registry (the Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies), which continuously provides real-time data on the quality and content of patient care, treatments, and outcomes for cardiac diseases, which is itself linked to several population registers.

Recent developments in transportability methods for extending randomised trial findings to broader populations will be presented, alongside with novel trial augmentation methods for using observational data to improve the efficiency of randomised trials (e.g., using the non-randomised registry data to improve efficiency for the R-RCT analysis). A key focus will be on the identifiability conditions that underpin the validity of transportability methods as well as ways to ensure the robustness of augmentation methods. To demonstrate and evaluate the applicability of these methods, we will consider both nested trial designs, in which trials are embedded within a registry or cohort (e.g., R-RCTs such as the TASTE trial within SWEDEHEART) and non-nested trial designs, in which trials are combined with a separately obtained sample from the target population.

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Speakers

Issa Dahabreh, MD, ScD, Associate Professor of Epidemiology, CAUSALab, Department of Epidemiology, Department of Biostatistics, Harvard T.H. Chan School of Public Health, Boston, MA. Section Head for Data Science and Epidemiology, Richard A. and Susan F. Smith Center for Outcomes Research, Beth Israel Deaconess Medical Center, Boston, MA. Statistical Editor JAMA.
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Ole Fröbert, MD, PhD, Professor of Cardiology, Department of Clinical Medicine, Faculty of Health, Aarhus University, Aarhus, Denmark and Örebro University Hospital, Örebro. PI TASTE trial, Chair RRCT Council SWEDEHEART.
Website: Ole Frøbert - Aarhus University

Tomas Jernberg, MD, PhD, Professor of Cardiology, Head Department of Clinical Sciences, Danderyd Hospital (KI DS), Stockholm. Chairman of the National Program Group (Nationella programområdet) for cardiovascular diseases. Previously, Chairman of the SWEDEHEART registry. PI REDUCE-AMI trial.
Website: Tomas Jernberg | Karolinska Institutet

References (selected)

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Jernberg T, Attebring MF, Hambraeus K, et al. The Swedish web-system for enhancement and development of evidence-based care in heart disease evaluated according to recommended therapies (SWEDEHEART). Heart 2010;96:1617–21.

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Yndigegn T, Lindahl B, Mars K, et al, for the REDUCE-AMI Investigators. Beta-blockers after myocardial infarction and preserved ejection fraction. New England Journal of Medicine 2024;390:1372–1381.

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Schedule

Venue: Hall Vesalius, Berzelius väg 3, Karolinska Institutet Solna

Date/time: Monday September 15, 2025, at 08:45-17:00

08:45 – 09:00	Welcome and introduction to the day (Anita Berglund and Camila Olarte Parra)
09:00 – 10:00	The SWEDEHEART registry (Tomas Jernberg)
10:00 – 10:20	Coffee break
10:20 – 11:20	TASTE and pragmatic randomised trials using existing infrastructure (Ole Fröbert)
11:20 – 12:00	The REDUCE-AMI R-RCT (Tomas Jernberg)
12:00 – 13:30	Lunch break (on your own)
13:30 – 15:00	Transportability methods and their applications (Issa Dahabreh)
15:00 – 15:20	Coffee break
15:20 – 16.30	Novel trial augmentation methods for using observational data to improve the efficiency of randomised trials (Issa Dahabreh)
16:30 – 17:00	General discussion and concluding remarks

Organisers: Anita Berglund and Camila Olarte Parra, CAUSALab, IMM, KI
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