

Simulation Studies for Good Practice in Biostatistics: The STRATOS Perspective

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Motivation

The primary aim of the STRATOS initiative (STREngthening Analytical Thinking for Observational Studies) is to promote appropriate methods and accurate interpretations in statistical analyses of observational studies. Simulation studies are absolutely essential for achieving this goal. We propose to give an overview of the thoughts on simulation studies and their applications within the STRATOS initiative with:

- An introduction to the typical four phases of methodological research in biostatistics in analogy to the well-known phases of clinical research in drug development, and the different roles of simulation in each phase.
- A discussion about simulation strategies in missing data research. When evaluating analytic approaches for handling missing data, one must first generate complete data and then simulate missing values. Different simulation approaches will be discussed with the pros and cons outlined, and some guidance will be given on when one approach may be favored over another.
- Two examples of simulation studies designed to illustrate potential biases induced by measurement and classification errors and provide recommendations for epidemiological studies: (1) concerning the inclusion of time-varying covariates measured at sparse times with error in survival models; (2) concerning the use of predetermined latent classes in secondary statistical analyses.
- A discussion of the concept of neutral simulations from the open science perspective. When comparing the performance of a newly proposed method to existing alternatives in a simulation study, there are several factors that may bias the results in favor of the former: besides the apparent wish to present the proposed method in a favorable light, the authors will, in general, have more expertise with the method they propose and they may naturally imagine a data generating mechanism that is in accordance with this method. Open science practices can address the resulting lack of neutrality in simulation studies.
- The presentation of a novel design of collaborative simulations exemplified through the comparison of three methods for estimating non-linear relationships between an outcome and a covariate measured with error. The design involves a data generation team who is in charge of generating the simulation data, and one separate team per method who estimates at best the outcome-covariate relationship and returns the results to the generation team for an impartial evaluation of the results.

Proposed Speakers

Georg Heinze, Medical University of Vienna (Austria): Phases of methodological research in biostatistics—Simulation as a tool to build the evidence base for new methods

Cécile Proust-Lima, Bordeaux Population Health Research Center, Inserm, (France): Promoting good practice in handling measurement error and misclassification using simulations: two case examples

Sabine Hoffmann, Ludwig Maximilian University of Munich (Germany): Improving the neutrality of simulation studies through open science practices

Laurence Freedman, Gertner Institute for Epidemiology and Health Policy Research (Israel): A simulation study to compare methods of estimating non-linear relationships between an outcome and a covariate measured with error