or the model fitting procedure differs from the model generating procedure. For example, this could be useful if the model generating procedure was a three-level linear mixed model with 5 clusters at level three. In these situations, a three-level model may not be feasible in the model fitting stage due to fewer level three units, therefore two-level models could be fitted or a generalized estimating equations (GEE) approach could be specified instead to understand how this may impact the power estimate. Users can also specify the alpha value, type of test statistic, and vary terms. For example, users can specify a variety of sample sizes, in which case a factorial design is used for all varied terms and all varied conditions are explored.

Additional Resources

Additional resources for the simglm package can be found on my website, brandonlebeau.org. In addition, package vignettes can be found on the CRAN page for the package, developmental versions and issues can be submitted on the simglm package GitHub page, and a pkgdown site is available.

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STRengthening Analytical Thinking for Observational Studies (STRATOS)

Introducing the Simulation Panel (SP)

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Previous issues of this Bulletin introduced the nine Topic Groups (TGs) of the STRATOS initiative.

Soon after the formal launch of the initiative at the 34th annual meeting of the International Society for Clinical Biostatistics (ISCB) in August 2013, we realized the need for several cross-cutting panels. The first panels were created to deal with 'internal' issues such as applications for STRATOS membership (Membership Panel), 'rules' for talks and papers on behalf of the STRATOS initiative or one of its TGs (Publication Panel), and the need for TGs and panels to employ common terminology (Glossary Panel). See the STRATOS newsletter from May 2018 for more details. Meanwhile STRATOS has eleven panels and this BB report is the first of several, each of which will introduce one of them.

It is obvious that simulation studies, and the more complex concept of 'neutral comparison studies' (Boulesteix et al 2017), are and will remain a key instrument to systematically assess and/or compare competing statistical methods and to create solid evidence to support STRATOS guidance. Consequently, in 2015 the STRATOS steering group decided to start a Simulation Panel (SP).

The two co-chairs of the SP are Michal Abrahamowicz and Anne-Laure Boulesteix. Further members are Harald Binder, Rolf Groenwold, Victor Kipnis, Jessica Myers Franklin, Tim Morris, Willi Sauerbrei, Pamela Shaw, Ewout Steyerberg, and Ingeborg Waernbaum.

The aim of the Simulation Panel is to provide guidance for the design, implementation, interpretation and reporting of simulation studies for different types of audience (from data analysts with limited statistical background to experts). More generally, the panel is interested in methodological aspects of the empirical assessment of the performance of statistical methods in simulated and/or real-life data. One of the basic principles adopted by the initiative is that the guidance to be formulated in documents written by STRATOS TGs is based on solid evidence, including both theoretical considerations and evidence from empirical studies comparing and validating the relevant methods (Sauerbrei et al 2014). Independently of STRATOS, reliable empirical evidence is frequently needed everyday by data analysts facing choices regarding the use of one or more of the alternative existing methods in their analysis. Systematic evidence of the behavior and performance of methods can be obtained through simulations, but how can we ensure such evidence is robust and reliable? This is the general question addressed by the Simulation Panel.

Data analysts, knowingly or unknowingly, choose methods based on recommendations that were often derived from simulation studies. Yet, for researchers with limited staistical background interpreting published simulation studies is challenging, not to speak of running their own ones. On the other hand, methodological statisticians frequently need to conduct complex simulation studies to assess the methods under investigation in realistic settings. However, they may face a lack of guidance on the design, implementation and reporting of such studies. A recent tutorial paper offers first guidance for design, execution, analysis, reporting, and presentation (Morris et al 2019). The authors provide a structured approach for planning and reporting simulation studies, which involves defining aims, data-generating mechanisms, estimands, methods, and performance measures ("ADEMP").

The Simulation Panel published a letter to the Editors of Biometrical Journal entitled „On the necessity and design of studies comparing statistical methods" (Boulesteix et al, 2018). The first goal of this letter was to point out the importance of neutral comparison studies, such as those intended by STRATOS Topic Groups, which assess methods without intention to show the superiority of a particular method; see also Boulesteix et al. (2017) for more insights on the concept of neutral study. The second goal was to stress the necessity to study the methodology of such comparison studies, in particular the design and the assumptions underlying simulation studies. Ideas related to the content of this letter and more general issues of simulation studies have been presented at various conferences including the CEN-ISBS in Vienna (2017) and DAGSTAT in Munich (2019). Another talk was accepted for the invited session at IBC 30 in Seoul in 2020.

The panel has a forthcoming paper on simulation studies aimed at a level I audience (Boulesteix et al, 2020). The paper offers a gentle introduction to simulation studies for data analysts and researchers who have little or no hands-on experience in this area but (i) may rely on previously published simulation studies to choose their statistical methods and/or (ii) wish to perform own simulation studies and need to understand the basic principles of designing and conducting such studies.

Led by Tim Morris and Willi Sauerbrei, several SP members have started a project to extend the ADEMP structure from Morris et al (2019) to a 'profile' to improve and standardise the reporting in simulation studies, with an emphasis on analyses of simulated datasets. Basic ideas are shown in Table 1 of De Bin et al (2020). Further, several members of SP are also involved in a paper of TG9 on simulation studies for high-dimensional data.

The Simulation Panel regards simulation studies as a useful 'generic' methodological tool for a broad range of researchers, and attempts to promote their more frequent and more accurate use. On the one hand, applied analysts could be empowered by better understanding the concepts regarding interpretation of simulation results. On the other hand, methodological researchers would do well to pay better attention to neutral and clinically plausible design, sensitivity analyses with variation of crucial assumptions and parameters, and clear reporting. We aim to target both with the aim of enabling researchers to make more informed decisions about the methods they use, based on better evidence.

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