

Guide for Authors Submitting to the Special Issue: Analysis of Randomized Controlled Trials in a Bayesian Framework

This document is a guide for authors that are preparing a manuscript for submission to the special issue of JMIR concerning the analysis of randomized controlled trials in a Bayesian framework. The call is for short papers of no more than 4,500 words. Manuscripts should describe a re-analysis of RCT data using a Bayesian framework, thus a full description of the trial does not need to be repeated here. The original publication should be referenced and only vital parts for understanding the Bayesian analysis repeated. Apart from the instructions given in this document, JMIR guidelines for manuscripts apply.

Administrative information

Title – From the title it should be clear that a Bayesian approach is to be taken, e.g. “Comparing the use of X against Y ... : a Bayesian analysis” or “Bayesian analysis of data from a randomized controlled trial comparing ...”.

Trial registration – Trial identifier and registry name.

Authors – Names and affiliations of authors.

Abstract - A structured abstract of no more than 450 words, following the normal structure: Background, Objective, Methods, Results and Conclusions.

Background

Describe briefly the rationale and aims of the trial. Depending on the results and conclusions of the analysis, it may be necessary to inform readers of certain intervention particularities or details of the trial setting. Use good judgment to include what is necessary for the reader to know about the trial to understand the analysis and results. Refer readers to the original publication for more details.

Objective

Describe which parts of the original analysis are going to be analyzed using a Bayesian framework. At this stage it is prudent to focus on two or three outcomes of the original trial (probably, but not necessarily, the primary outcomes). Describe the outcome metric (e.g. is it binary, numeric, ordinal), how was it collected and when (e.g. “Six months after randomization participants were asked to complete a questionnaire where ...”). Describe any other data collected that was used in the original analysis of these outcomes.

Methods

Due to the nature of this special issue we are asking authors to retain the same type of models that was used in the original publication. For instance, if logistic regression was used in the original analysis, then we ask authors to use logistic regression here as well, including the same regressors. Naturally, if there is interest, explorative modelling is welcomed.

In the methods section it is important that:

- The model is described clearly.
- The priors used are described and given a rationale.
- The inference method used is described (e.g. Markov chain Monte Carlo).
- The software used is mentioned.
- Thresholds that are of interest when exploring the posterior distribution are declared.

The model should be described using the traditional Bayesian method of stacking equations. For instance, for a logistic regression with one regressor X :

$$\text{outcome}_i \sim \text{Bernoulli}(q_i)$$
$$\ln\left(\frac{q_i}{1 - q_i}\right) = \beta_0 + \beta_1 X_i$$

Make sure that in the description of the model it is made clear which regressors are included and what they represent (eg, age, gender, etc.).

Describe which priors are to be used. It is interesting to do the analysis under different priors, e.g. a uniform prior, a conservative prior that a-priori believes there is no effect, and a prior that is rooted in previous research.

Describe the inference method used. If for instance using a Markov chain Monte Carlo approach, then mention the algorithm used, the number of chains, burn-in/warm-up iterations, and total number of iterations (or stopping criteria). Any other parameters of interest for the inference is welcome, and please mention which software is used.

Finally, state which thresholds that are of interest when exploring the posterior distribution. For instance, it may be interesting to know what the probability of the odds ratio being below 0.9 is, or between 1.0 and 1.1, etc. Give some rationale to the choice of thresholds considered.

Results

Begin by repeating the results of the original analysis, which usually includes the maximum likelihood estimate of relevant regression coefficients, confidence intervals, and P values.

For each relevant regression coefficient, and for each prior, include a figure that depicts the posterior distribution (histogram, density curve, etc.). Include a table that describes, for each relevant coefficient and prior, the posterior probability related to the thresholds declared in the methods section. For instance, one entry in the table might show the posterior probability that the odds ratio is less than 0.9 given a uniform prior.

Finally, if using a sampling technique for inference, then give some indication that convergence was achieved, e.g. through a trace plot of the samples drawn.

Conclusions

In this section we ask authors to contrast the original analysis with the results from the Bayesian analysis. Depending on the nature of the trial, this might include new insights gained from the Bayesian analysis, both with respect to the trial outcome and policy recommendations. Repeat any conclusions drawn from the original publication and discuss them in light of the new analysis. We ask authors to reflect on how the Bayesian posterior distribution changes their thinking of the trial outcome. Also, if there are large differences in the posterior distribution given the different priors used, this should be discussed.