SENSITIVITY ANALYSIS OF RANDOMIZED TRIALS WITH COARSENED OUTCOMES: A CASE STUDY

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In the context of a case study, we review a paradigm for analyzing randomized trials with potentially informative coarsened (missing or censored) outcomes, developed in a series papers by James Robins, Andrea Rotnitzky, Daniel Scharfstein and co-authors. Specifically, we introduce a class of models, indexed by scientifically interpretable parameters that express deviations from 'missing at random'. These parameters are not empirically verifiable from the observed data and thus we recommend drawing inference about treatment effects over a range of these parameters, especially those that are considered plausible by scientific experts. Certain values of the sensitivity analysis parameters correspond to the worst and best case inferences and the last observation carried forward inference. Graphical displays of the sensitivity analysis are used to illustrate the robustness of trial results to assumptions about the missing or censoring mechanisms. We will also discuss how these parameters can be estimated or bounded through the collection of auxiliary data.