

## Augmented Designs to Assess Principal Strata Causal Effects

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### Abstract

Many research questions involving causal inference are often concerned with understanding the causal pathways by which a treatment affects an outcome. The use of the concept of ‘direct’ versus ‘indirect’ effects is common not only in statistics, but also in many area of social, economic and political sciences as well as in biomedical and pharmacological sciences, where there are the closely related concepts of ‘biomarkers’ and ‘surrogate outcomes’.

Disentangling direct and indirect effects may be a difficult task, because the intermediate outcome is generally not under experimental control. Within the potential causal framework for causal inference, we will use the concept of principal stratification for addressing the issues of direct and indirect causal relationships.

In order to address complications due to the presence of endogenous selection into groups defined by the joint potential values of an intermediate variable (principal strata), we will investigate new augmented designs, where the treatment is randomized, and the mediating variable is not forced, but only randomly encouraged. We argue that this source of exogenous variation may help to identify and estimate direct and indirect effects. These designs will be feasible in some clinical and social experiments, when partial control of the intermediate variable can be conceived. Using non parametric identification strategies, we will investigate alternative sets of assumptions, which allow us to either reduce the number of strata or state the equivalence of the distribution of the primary outcome across some strata.