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A note about the identifiability of causal effect estimates in randomized trials with non-compliance

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ABSTRACT

We show that assumptions that are sufficient for estimating an average treatment effect in randomized trials with non-compliance restrict the subgroup means for always takers, compliers, defiers and never takers to a two-dimensional linear subspace of a four-dimensional space. Implications and special cases are exemplified. © 2013 Elsevier B.V. All rights reserved.

1. Introduction

Making causal estimations for randomized clinical trials with non-compliance is important in practice but their validity relies on certain assumptions. Estimations of two causal parameters, namely the complier average causal effect (CACE) and the average causal effect (ACE), require slightly different assumptions. Apart from common assumptions such as exclusion restriction, the estimation of CACE requires a monotonicity assumption and the estimation of ACE requires a no-interaction assumption, which will be discussed in detail in Section 2. The two assumptions do not imply one another but their relationships are unclear. We discuss implications of the no-interaction assumption and connections to the estimation of CACE and ACE in Section 3. In Section 4, we show that under a plausible partial ranking between causal treatment effects among always takers, compliers and never takers, the hyperplane restriction implies that causal treatment effects among always takers, compliers, defiers

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Table 1			
Compliance classes defined	l by ci	oss-classifying T	T(1) and $T(0)$.
- ()		T (1)	

	T(1) = 1	T(1) = 0
T(0) = 1	Always taker (A)	Defiers (D)
T(0) = 0	Compliers (C)	Never taker (N)

and never takers are all equal. Therefore, CACE and ACE are the same and can be consistently estimated by an instrumental variable estimator.

2. Notation and assumptions

Let *R* be a binary treatment assignment indicator, where $R_i = 1$ when a subject is assigned to the treatment arm, and $R_i = 0$ when a subject is assigned to the control arm. Also, let n_1 and n_0 be the sample sizes of the treatment and control arms respectively and $n = n_1 + n_0$. In the presence of non-compliance, the actual treatment received, *T*, may not be the same as the treatment assignment *R*. To define compliance classes among the subjects, we follow the potential outcome framework of [1]. Let $(T_i(1), T_i(0))$ be the potential treatment that would be received if subject *i* was assigned to treatment and control respectively. Compliance classes are defined by cross-classifying T(1) and T(0), as shown in Table 1.

For each subject, we can only observe $T_i = T_i(R_i)$, where R_i is the assigned treatment. Similarly, we can define potential outcomes $Y_i(R, T)$ to be the responses from subject *i* given the treatment assignment *R* and the actual treatment received *T*. We denote as $Y_i = Y_i(R_i, T_i)$ the observed outcome, with $\mathbf{Y} = (Y_1, \dots, Y_n)^T$, $\mathbf{T} = (T_1, \dots, T_n)^T$ and $\mathbf{R} = (R_1, \dots, R_n)^T$.

To estimate the complier average causal effect (CACE), the following assumptions has been made in [1].

Assumption A. Stable Unit Treatment Value Assumption: If $R_i = R'_i$, then $T_i(\mathbf{R}) = T_i(\mathbf{R}')$. If $T_i = T'_i$ and $R_i = R'_i$, then $Y_i(\mathbf{R}, \mathbf{T}) = Y_i(\mathbf{R}', \mathbf{T}')$.

Assumption B. Random Assignment: $P(\mathbf{R} = \mathbf{r}) = P(\mathbf{R} = \mathbf{r}')$ for all \mathbf{r} and \mathbf{r}' such that $\mathbf{e}^T \mathbf{r} = \mathbf{e}^T \mathbf{r}'$ where \mathbf{e} is the *n*-dimensional column vector with all elements equal to 1.

Assumption C. Exclusion Restriction: $Y(\mathbf{R}, \mathbf{T}) = Y(\mathbf{R}', \mathbf{T})$ for all \mathbf{R}, \mathbf{R}' and for all \mathbf{T} .

Assumption D. Nonzero Average Causal Effect of *R* on *T*: $E(T(1) - T(0)) \neq 0$.

Assumption E. Monotonicity: $T_i(1) \ge T_i(0)$ for all i = 1, ..., n.

Assumption C guarantees that we can write Y(T) = Y(R, T). Assumption E rules out defiers. [2] commented that Assumption E is very strong because it does not hold even when there is just one defier in the sample. Also, the subgroup of compliers are defined on the basis of counterfactual outcomes and individual membership cannot be exactly identified from data. As a result, some researchers (see for example [3]) prefer estimation of the average causal effect (ACE) $\eta = m_A \pi_A + m_C \pi_C + m_D \pi_D + m_N \pi_N$, where $m_A, m_C, m_D, m_N (\pi_A, \pi_C, \pi_D, \pi_N)$ are the expected values of Y(1) - Y(0)(or population proportions) among always takers, compliers, defiers and never takers. Note that the definition of ACE involves the counterfactual effects of a treatment that is not taken. Whether this makes sense will depend on the context.

The estimation of ACE requires slightly different assumptions. The Monotonicity Assumption, Assumption E, is replaced by the following collections of assumptions [3]:

$$E(Y(0) | R = 1) = E(Y(0) | R = 0)$$
(1)

$$E(Y(1) | R = 1) = E(Y(1) | R = 0)$$
(2)

E(Y(1) - Y(0) | T = 0, R = 1) = E(Y(1) - Y(0) | T = 0, R = 0)(3)

E(Y(1) - Y(0) | T = 1, R = 1) = E(Y(1) - Y(0) | T = 1, R = 0).(4)

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