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Neighborhood effects in a behavioral randomized controlled trial

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ABSTRACT

Randomized controlled trials (RCTs) of interventions intended to modify health behaviors may be influenced by neighborhood effects which can impede unbiased estimation of intervention effects. Examining a RCT designed to increase colorectal cancer (CRC) screening ($N=5628$), we found statistically significant neighborhood effects: average CRC test use among neighboring study participants was significantly and positively associated with individual patient's CRC test use. This potentially important spatially-varying covariate has not previously been considered in a RCT. Our results suggest that future RCTs of health behavior interventions should assess potential social interactions between participants, which may cause intervention arm contamination and may bias effect size estimation.

1. Introduction

Recent years have witnessed considerable growth in research on the impact of neighborhood social and physical environments on health behaviors and outcomes. However, Oakes (2004a) noted the many methodological challenges to the extant research toolkit for causal determination of neighborhood effects on health. Namely, he claimed that identifying an independent neighborhood effect on a health outcome was impossible given current methodologies (i.e. multilevel modeling of observational data). While the significance of Oakes' critique has been debated, (Diez Roux, 2004; Subramanian, 2004; Oakes, 2004b) the field has generally responded favorably with a more cautious approach to making causal claims about neighborhood effects. At the same time, while there is great interest in the design and testing of randomized controlled trials (RCTs) aimed at modifying health behaviors, scant attention has been paid to understanding how Oakes's argum ents pertain to causal inference in the context of RCTs. RCTs are considered the "gold standard" methodology for generating causal inference. Therefore, it is crucial to study the role that neighborhood effects might have on the results obtained from RCTs.

RCTs that test behavioral interventions, hereafter behavioral RCTs, differ from other types of RCTs (such as RCTs to test new drugs) in part due to the unique set of factors influencing human choices that are often outside the control (or measurement) of the RCT itself. Social dynamics that influence behaviors and that often occur within residential neighborhood contexts represent one of these key, frequently unmeasured, confounders. A recent article by Manski (2013) highlights the significant challenges social dynamics present for the estimation of intervention effects in behavioral RCTs. At the same time in the epidemiological literature, Vanderweele et al. (2012), Tchetgen and Vanderweele (2012) elucidate the challenges to causal inference in the presence of subject-to-subject *interference*. However, little is known about the likelihood and/or scope of social influences within behavioral RCTs.

We examine the case of a behavioral RCT designed to increase colorectal cancer (CRC) screening in order to further elucidate how social influences may bias behavioral RCT outcomes. While the role of social influence on cancer screening is not completely understood, significant prior research indicates spatial variation in screening behaviors (Doubeni et al., 2012; Lian et al., 2008; Mobley et al., 2010;

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Shariff-Marco et al., 2013; Vogt et al., 2014) that could, in part, be caused by interactions among neighbors. Further, the CRC intervention we examine is inherently spatial in nature because it uses mailed invitations (i.e. targeted to patient's residences) to deliver the intervention. Our contributions are two-fold: (1) we lay out an analysis framework for assessing situations in which social influences may be biasing behavioral RCT results and (2) we provide effect size estimates for the neighborhood effects occurring in our CRC screening behavioral RCT along with a discussion of how estimated neighborhood effects should be interpreted.

Our work continues the conversation began by Oakes (2004a). As such, we assess the more recent literature, across multiple disciplines, regarding the identification of neighborhood effects. This literature has much to offer health researchers interested in how neighborhoods affect health and should, therefore, be considered in the design and implementation of future behavioral RCTs. Our work also contributes to a growing body of social science research that seeks to understand the causes and consequences of geographic "spillover" effects (Anselin and Bera, 1998; Baicker, 2005; Pereira and Roca-Sagales, 2003) as well as the epidemiological literature examining the related concept of *interference* (Tchetgen and Vanderweele, 2012; Vanderweele et al., 2012).

1.1. Spatial dependence in randomized controlled trials

Spatial dependence[1] in health behaviors is not commonly assessed in the design, conduct, or evaluation of behavioral RCTs. If spatial dependence is present and unaccounted for in estimations of intervention effects, conventional standard error estimates and hypothesis tests based on the standard errors are not accurate. Moreover, depending on the underlying mechanisms that cause the spatial dependence, point estimates of intervention effects may also be biased. As a result, inference and policy recommendations arising from behavioral RCTs may be misleading, have weak support or, in extreme cases, be completely inaccurate (Anselin and Bera, 1998; Manski, 2013). Therefore, it is critical to understand the mechanisms that generate spatial dependence.

Methods developed in the fields of spatial econometrics and regional science focus on identification of mechanisms leading to spatial dependence. In these fields, mechanisms that may cause spatial dependence are divided into three categories of neighborhood effects: correlated, exogenous, and endogenous (Manski, 1993).

Correlated effects refer to the neighborhood effects that result because individuals self-select into neighborhoods—often sorting along demographic characteristics as a result of homophily, shared preferences for neighborhood amenities, and economic constraints (Tiebout, 1956). For example, if lower-socioeconomic status (SES) individuals are less likely to receive CRC screening and also sort into the same neighborhoods, spatial dependence in CRC screen ing may be an artifact of the correlation between income and screening.

Exogenous effects refer to the influence of shared neighborhood exposures or institutions. As one example, the promotion of CRC screening may vary in emphasis and outreach methods across different neighborhood clinics, in which case spatial dependence in CRC screening may be attributable to the particular clinic a patient attends.

Endogenous effects refer to a relationship between an individual's behavior and the behavior of his neighbors as a result of social interaction and social influence. For the case of CRC screening, an individual may be more likely to undergo screening if she hears about other friends and neighbors also undergoing regular screening (Manski, 1993).

1.2. Implications of spatial dependence in behavioral RCTs

Correctly attributing spatial dependence to exogenous, correlated, and endogenous effects is important because the analytic and intervention implications for RCTs vary depending upon the neighborhood effect mechanisms. Table 1 presents a summary of the implications that result when neighborhood effects exist but are unaccounted for in analysis of behavioral RCTs. In many cases traditional approaches such as adjusting for neighborhood level sociodemographic characteristics, including neighborhood fixed effects, multilevel modeling (i.e. neighborhood random effects), or incorporating spatial dependence in the model's error structure are sufficient to account for spatial dependence. However there are situations where these approaches are insufficient, as we describe below. If spatial dependence is a result of correlated or exogenous effects that are independent of treatment assignment, it may be considered a nuisance parameter and simply adjusted for in analyses. The case in which correlated or exogenous effects are correlated with treatment assignment represents a failure to randomize across neighborhoods. This is of course serious—with consequences similar to other scenarios in which randomization fails.

Endogenous effects generated by direct social interaction also have very significant implications. In the context of a behavioral RCT, not accounting for endogenous effects may result in biased intervention effect estimates through contamination of treatment and control groups (Manski, 2013). For example, if "treated" individuals influence the behavior of untreated or treated neighbors, this may augment intervention effectiveness. Failure to account for endogenous effects results in an "omitted variable" problem: endogenous effects confound the relationship between treatment and the outcome targeted by the RCT. Additional covariates that measure the endogenous effects must be added to the model to fully and accurately estimate treatment effect sizes (Greene, 1981; Hill et al., 2011).

Manski (2013) points out that traditional analysis of RCTs assumes "individualistic" treatment response, which is not the case in the presence of endogenous effects. In the presence of endogenous effects, models are needed to accurately evaluate *total* intervention effects, which would include both direct, ("individualistic") and indirect (neighbor-to-neighbor or peer-to-peer) effects (Ioannides, 2012; Durlauf and Ioannides, 2010).

To our knowledge, no studies have examined spatial dependence and neighborhood effects in the context of a behavioral RCT where participants lived close to each other. At the same time, despite a robust literature documenting spatial and geographic differences (Doubeni et al., 2012; Lian et al., 2008; Mobley et al., 2010; Shariff-Marco et al., 2013; Vogt et al., 2014), the mechanisms driving spatial variations in cancer screening behavior are poorly understood. Therefore, in a study of a geographically-based RCT designed to increase colorectal cancer (CRC) screening, we applied spatial econometric methods to test for spatial dependence and the existence of correlated, exogenous and endogenous neighborhood effects.

2. Methods

2.1. Sample

We conducted secondary analyses of data from patients in a randomized, comparative effectiveness trial (2011–2012) conducted in the John Peter Smith (JPS) urban safety-net healthcare system. JPS consists of 12 community primary-care clinics and a

[1] Spatial dependence is when the outcome of some random variable at a particular location depends on the outcomes of that same random variable at nearby locations.