Causal Inference for Intervention Spillover in a Cluster-randomized Stepped Wedge Trial: Lessons from Physician Networks

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Extended Abstract

Often motivated by concerns about contamination of control subjects, cluster-randomized stepped wedge designs assign interventions to distinct clusters (e.g., hospitals) and protect against confounding by randomizing the timing of intervention delivery [1]. However, when trial units are embedded in professional networks that span clusters, such designs cannot prevent spillover. In this study, we use longitudinal cluster-randomized trial data and contemporaneous physician networks [2] to estimate the direct, indirect, and interaction effects of an advance care planning (ACP) intervention. The direct effect reflects the intervention's impact absent contamination, the indirect effect captures spillover to control subjects, and the interaction term assesses whether spillover modifies the intervention's effect - allowing us to test if contamination compromised the trial, recover the uncontaminated effect, and test whether spillover reinforces or attenuates the intervention.

We combined data on patient-physician encounters with potential ACP conversations and physician networks constructed from health insurance billing records. In these networks, nodes represent physicians and edges denote shared patients, capturing professional ties within and across hospitals (Figure 1). Assuming the network is exogenous to the intervention, we analyzed time-varying networks updated at each trial step to reflect evolving professional interactions. For each patient in each network, we quantified:

- Direct exposure: whether the hospital received the intervention (enabling physicians to participate in it) or, in a dose-response specification, the number of treating physicians during hospitalization who had received the intervention.
- Spillover exposure: the extent to which physicians were connected to peers who had already been exposed.

Using potential outcomes notation, we define:

1. The direct effect of receiving care from an intervened physician under the counterfactual of no spillover;
2. The spillover effect of receiving care from a physician not yet intervened on who is connected to (and potentially influenced by) treated peers;
3. An interaction effect reflecting the modification of the direct effect of the intervention by spillover exposure at the time of intervention.

Assuming network exogeneity, we fit a generalized linear mixed-effects model (GLMM) including the standard treatment indicator for effect 1, predictors for effects 2 and 3, fixed effects for trial step, hospital random intercepts, and optionally, patient and hospital covariates. This model yields causal estimates of effects 1–3, with results shown in Table 1.

Without adjusting for network structure, the intervention showed no significant effect on ACP billing (OR = 0.96, p = 0.42). In the network adjusted analyses, the direct effect reversed sign (OR 1.08, p = 0.07), the spillover effect prior to the intervention being received was null (OR = 0.99, p < 0.88), and the interaction term representing contamination was positive (OR = 1.09, p = 0.009). Therefore, the network adjusted results imply that the network effects may have reinforced the intervention leading to an accentuated effect that the standard analysis fails to capture. In ongoing work, we are exploring methods to extend the model to assess whether post-intervention changes in spillover exposure support intervention reinforcement.

References

[1] Hemming K, Taljaard M (2020) Reflection on modern methods: when is a stepped-wedge cluster randomized trial a good study design choice? International Journal of Epidemiology 49(3):1043–1052
[2] Barnett ML, Landon BE, O'Malley AJ, et al (2011) Mapping Physician Networks with Self-Reported and Administrative Data. Health Services Research 46(5):1592–1609.

Table 1. Estimated Effects of Intervention and Spillover on ACP Billing

Model	Variable	Odds Ratio (95% CI)	p-value
Traditional SW-CRT	Direct Intervention	0.96 (0.88, 1.06)	0.42
Network-Adjusted Accounting for Possible Spillover	Direct Intervention	1.08 (0.99, 1.17)	0.07
	Physician Spillover	0.99 (0.86, 1.13)	0.88
	Intervention × Spillover Interaction	1.09 (1.02, 1.16)	0.009

Figure 1. Physician-patient sharing network across 35 hospitals in the intervention trial. Edges represent shared patients between physicians during the baseline observation period. Nodes are colored by hospital intervention step; white nodes indicate physicians not directly assigned to the intervention.