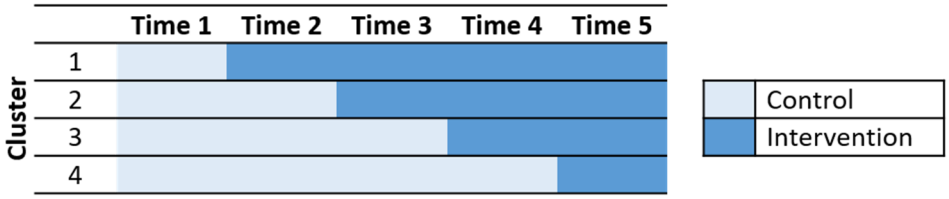
A Tour of Pragmatic Study Designs: Stepped Wedge Design

Diane Fairclough, DrPH; Erin Chaussee, MS

A **Stepped Wedge (SW)** design is a type of crossover CRT, in which the different clusters cross over (switch treatments) at different time points. A SW study extends the traditional CRT so that every cluster provides both control and intervention observations, and thus somewhat acts as its own control.

The design includes a baseline time period where none of the clusters receive the intervention of interest. Then, at regular time periods (or "steps") one cluster (which can include multiple sites) is randomized to cross from the control to the intervention of interest. This process continues until all clusters have crossed over to receive the intervention, and the study ends with a time period in which all the studies receive the intervention.



Design considerations. When designing a SW study, the number of sites, number and length of time periods, and number of sites randomized at each time period must be determined. These are often chosen based on logistical considerations. The participants expected to meet eligibility criteria determine the number of patients per cluster per time period. There are possible variations to the traditional SW design, such as transition periods during which training is implemented and the cluster cannot be considered as exposed or unexposed. Power calculations for SW trials depend on these design considerations as well as on the intracluster correlation coefficient (ICC).

Advantages	Challenges
• Eventually all the clusters receive the intervention • Allows for control of external temporal trends • Allows for within-cluster comparisons and can have smaller sample size requirements than a cluster randomized trial • Implementation is staggered across sites, thus training can also be staggered and implementation can be more carefully observed	• Contamination can bias results • Requires all sites start and stop at the same time. Site dropout is a serious threat • Requires steady recruitment over time that is consistent with respect to patient characteristics • Potential for contamination during the cross-over between control and intervention phases with extended interventions and follow-up

Statistical analysis. Since the proportion of exposed clusters increases gradually over the study period, the unexposed observations will on average be from an earlier calendar time than the exposed observations. Thus, the analysis of SW studies must not only account for clustering, as with CRTs, but also needs to control for temporal trends. This can be achieved using a **generalized linear mixed model (GLMM)** with a random effect for cluster and a fixed effect for each time period. Extensions to these models can be considered to address issues such as varying temporal trends across clusters.

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