What Are the Arguments For and Against the Stepped-Wedge Design?

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Choosing the right kind of cluster randomized trials, CRT. Arguments for a stepped wedge design could mean it may have been difficult to immediately implement the intervention in half of the clusters were we to do a parallel design.

In pragmatic research, we may be in a system where an intervention's going to be rolled out to all clusters, say all clinics, but we'd like to adopt a randomized trial design in order to obtain the most rigorous evidence possible as the treatment effect, so then the stepped wedge design is really appealing in that setting. Interestingly, if you have very few clusters, it may be possible to gain power.

Arguments against the stepped wedge cluster randomized trial. Well, you actually are intentionally confounding the treatment effect with the time effect. Why is that? Well, on average the intervention, or the treatment, is implemented later in calendar time than the usual care or the control period. That's just a design feature of the stepped wedge design.

Similarly, the risk of interruption or external events with these stepped wedge trials which have confounding of treatment effects with time, can just throw in a whole host of issues and challenges. Recommendations, we would all tend to say if possible, use a parallel cluster randomized trial design, if you can. But if you go with a stepped wedge design, please do plan for time effects in both design and analysis, and of course plan for clustering effects in design analysis of all cluster randomized trial designs.