Misspecifying within-cluster correlation structure in stepped wedge trials

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What is a "stepped wedge trial"?

Multiple-period cluster randomised trials randomise *clusters* of subjects to different treatment sequences. An example of such a trial is the *stepped wedge*:

	Period 1	Period 2	Period 3	Period 4
Cluster 1	Control	Control	Control	Intervention
Cluster 2	Control	Control	Intervention	Intervention
Cluster 3	Control	Intervention	Intervention	Intervention

The key feature is that all clusters start off administering the Control treatment and sequentially transition to the Intervention. This can be extended to have more clusters and more periods: just retain the "stepped wedge" structure! We want to estimate the effect of the intervention on an outcome: but to do so it is necessary to say something about how *correlated* the observations on subjects from the same cluster are.

Correlation structure?

The *within-cluster correlation structure* describes the degree of correlation between observations made on subjects within the same cluster.

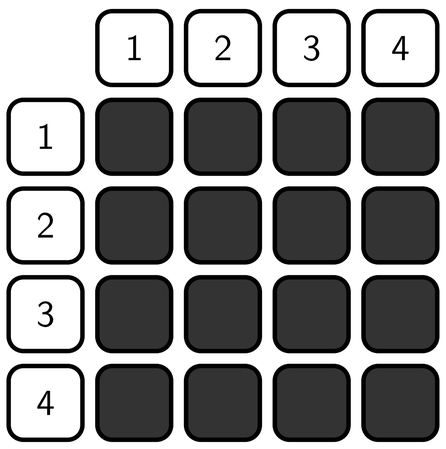
Need to consider subjects measured in the same cluster:

- *in the same period*;
- and *in different periods.*

Three different correlation structures for the four-period stepped wedge are displayed below.

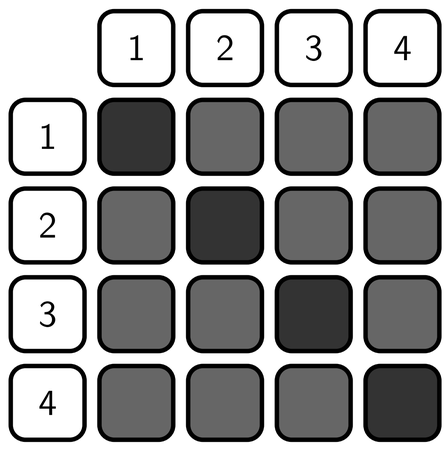
What happens if we get the correlation structure wrong?

Model 1: equal correlations



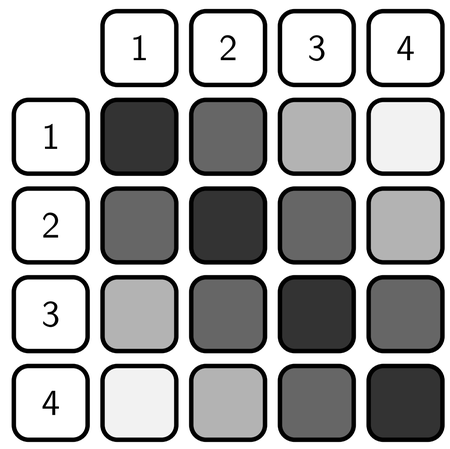
In this model, the correlation between any pair of subjects in the same cluster is *identical*, no matter when they were measured.

Model 2: correlations differ



The correlation between any pair of subjects in the same cluster differs, depending on whether they are measured in the *same or different periods*.

Model 3: correlations decay



The correlation between any pair of subjects in the same cluster *decays the further apart in time they are measured*.

What if Model 3 is correct, but Model 1 or Model 2 is assumed?

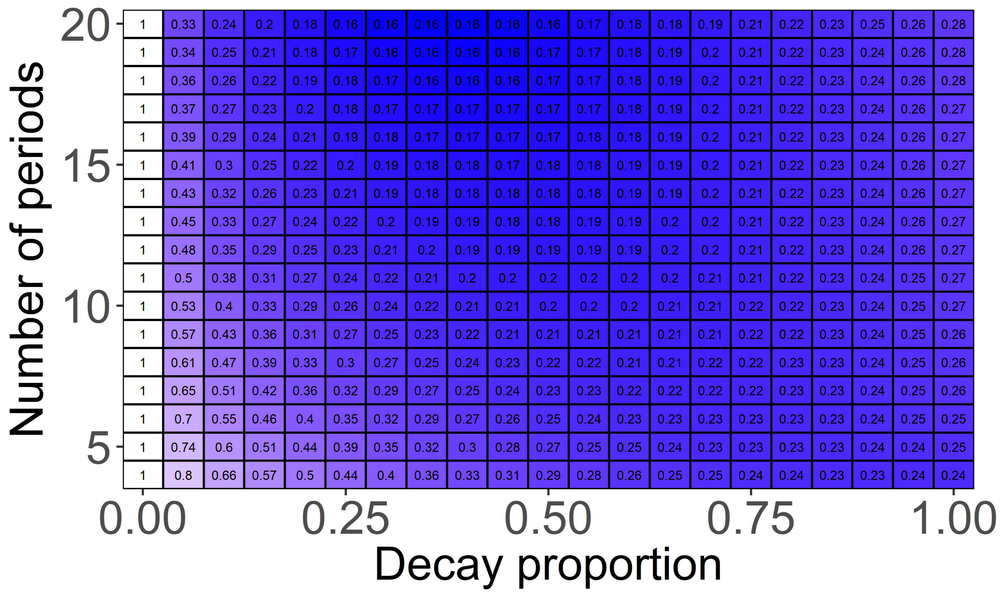
Interest is in estimating the effect of the Intervention. Studies usually assume the correlation structure is given by Model 1, or sometimes Model 2, but never Model 3: **even if it is the most appropriate model!**

- Even if a decay in correlation is incorrectly omitted, the estimate for treatment effect is unbiased (for a continuous outcome)!
- **BUT** the width of the confidence interval around the estimate depends on the assumed within-cluster correlation structure.

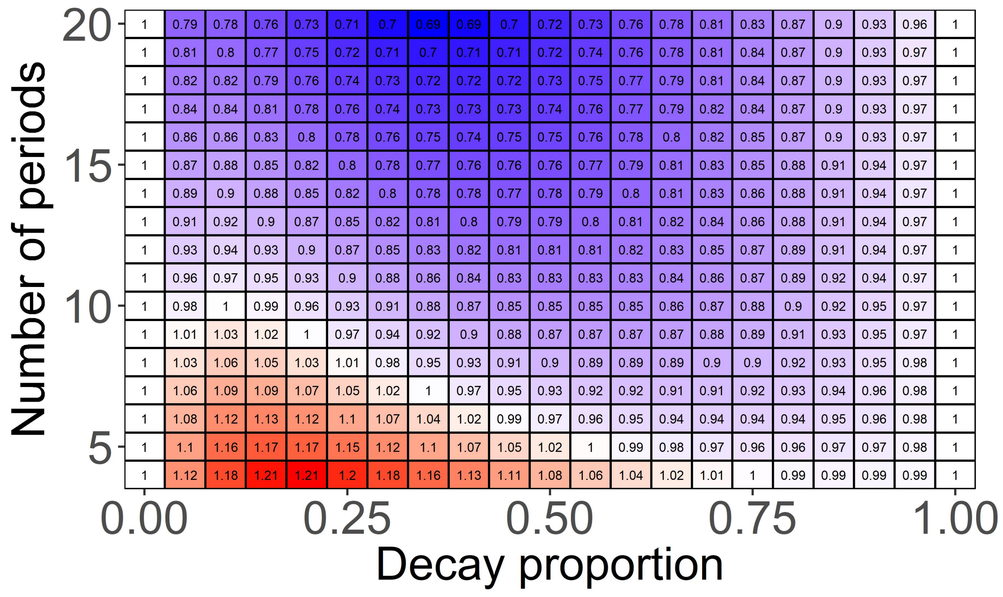
What happens to the confidence interval for the treatment effect if Model 3 should be used but Model 1 or 2 is used instead?

Answer depends on the amount of decay, and the number of periods. We display the impact on confidence interval width for several combinations of the number of periods and the proportion that the correlation decays by in each period in the figures below. A decay proportion equal to 0 means that there is no decay at all (and all three models are equivalent).

Model 1 instead of Model 3



Model 2 instead of Model 3



Confidence interval width: Too narrow | Just right! | Too wide

If we incorrectly say all correlations are the same, confidence interval will be too narrow.

If we say correlations differ but don't allow for a decay, confidence interval could be too narrow OR too wide!

Want to know more? Then check out our Shiny app, or get in touch!

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