Roles

Paper: The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting (Hemming et. al, 2015)

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Summary
**General Context**

- **Objective**: Evaluate service delivery interventions with rigor of drug trials
- Stepped wedge study design reconciles logistical/political constraints with the need for rigorous scientific evaluations
- Study applications include HIV, cancers, healthcare associated infections, social policy, and criminal justice

**Approach**

- Conventional randomized trial assigns clusters to intervention or control arm before the trial
- Stepped wedge design sequentially exposes every cluster to the intervention
- Compares results across unexposed and exposed observation periods
Illustration

Schematic illustration of conventional parallel cluster study (with variations) and stepped wedge study
## Advantages/Disadvantages

### Advantages
- Practical for service delivery interventions
- Investigators can examine how the impact of the intervention develops over time
- For larger intra-cluster correlations, a stepped wedge study tends to deliver more statistical power

### Disadvantages
- Requires cooperation from the clusters to stay on schedule
- Sample size calculation needs to account for confounding effect of calendar time
- When the intra-cluster correlation is small, a parallel design tends to deliver more statistical power
## Sample Size

<table>
<thead>
<tr>
<th></th>
<th>Intra-cluster correlation 0.01</th>
<th></th>
<th>Intra-cluster correlation 0.1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Simple parallel trial</td>
<td>Parallel trial w/ baseline period</td>
<td>Stepped wedge trial</td>
<td>Simple parallel trial</td>
</tr>
<tr>
<td>Number of clusters</td>
<td>20</td>
<td>20</td>
<td>20</td>
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<tr>
<td>Cluster size</td>
<td>50</td>
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<tr>
<td>Total sample size</td>
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<tr>
<td>Number of steps</td>
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<td>Number of clusters per step</td>
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<tr>
<td>Power</td>
<td>0.97</td>
<td>0.87</td>
<td>0.88</td>
<td>0.5</td>
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</tbody>
</table>
Example

**EPOCH Trial**

- Intervention to improve emergency laparotomy care
- Rolled out to 90 hospitals, 6 clusters of 15 hospitals
- Switch to intervention every 5 weeks with 5 week transition period
- Expected total sample size \( \approx 27,500 \) patients
- Detect 90 day mortality change from 25% to 22% (90% power, 5% significance)

*Schematic representation of the EPOCH stepped wedge study*
Discussion
Discussion Questions

1) What are advantages and disadvantages of stepped wedge design compared to standard parallel cluster study?

2) What are possible application areas? When would you use this method? What are possible challenges in applying the method to a similar problem?

3) If this was applied in an HSyE project, how would you approach the problem?

4) Do you see any similarities in the paper examples with past or current HSyE projects? Would this method apply?

5) What is good or bad about the way the method is presented in the paper? Is it easy to follow/understand?

6) Identify any other strengths and weaknesses in the paper
Thank You