The Extended Family of Randomized Roll-Out Designs, Including Stepped Wedge and Dynamic Wait Listed Designs

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Randomized Roll-Out Designs and their Cousins

1. Concept and Appeal of Roll-Out Designs
   Examples
2. Advantages of a Rollout Design
   Community
   Researcher
3. Roll-Out Design and Analysis Choices
4. Summary and References
1. Concept and Appeal of Roll-Out Designs

- **Location/Policy Maker/Community/organization/agency**
  Very committed to wide-scale delivery of a particular intervention
  Ultimately desire scale out or have everyone to get this intervention
  Unwilling to or uncomfortable withholding the intervention by using “controls”

- **Intervention**
  Little or no information available on its benefit or potential harm
  Cannot provide to everyone at once because of logistics/resources

- **Subregions**
  Community can be divided into subregions or areas where intervention can be implemented independently
  Outcomes can be assessed in a relatively short period of time

It is possible to construct a rigorous randomized trial to evaluate this intervention by randomizing the timing of when the intervention in introduced.

Units are randomized to \textit{when} they get the intervention (roll-out)


## Examples

<table>
<thead>
<tr>
<th>Location</th>
<th>Intervention</th>
<th>Subregions</th>
<th>Name</th>
<th>Year</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gambia</td>
<td>Hepatitis B Vaccination</td>
<td>17 Vaccination Areas</td>
<td>Stepped Wedge</td>
<td>1987</td>
<td>Gambia Hepatitis Study Group, Cancer Research</td>
</tr>
<tr>
<td>Eugene OR &amp; Santa Barbara CA</td>
<td>Mpowerment HIV Prevention for MSM</td>
<td>2 Cities</td>
<td>(Pairwise enrollment) wait-listed design</td>
<td>1996</td>
<td>Kegeles et al., AJPH</td>
</tr>
<tr>
<td>Cobb County School District, GA</td>
<td>QPR Youth Suicide Prevention</td>
<td>32 Secondary Schools</td>
<td>Dynamic Wait-Listed Design</td>
<td>2006</td>
<td>Brown et al., Clin Trials</td>
</tr>
<tr>
<td>CA and OH Counties</td>
<td>Compare 2 Implementation Strategies for Multidimensional Treatment Foster Care</td>
<td>51 Counties</td>
<td>Head-to-Head Randomized Roll-out Design</td>
<td>2010</td>
<td>Chamberlain et al.</td>
</tr>
</tbody>
</table>
Randomized Roll-Out Designs as a Categorical Name

- More functional and appealing to communities than jargon like Stepped-Wedge and Dynamic Wait-Listed Designs
- Misuse of the term Stepped-Wedge
  - Standard Condition → Single Active Intervention

  Standard Condition → Randomize to Intervention A or B
- There are many examples of roll-out designs
2. Advantages of Roll-Out Designs
From a Policy Maker or Community Perspective

Ethical Issues
No one should be denied a potentially useful program, as long as it can be delivered with fidelity – Roll-out trials

Traditional research designs like RCTs are unacceptable or foreign in some minority communities and for many policy makers
Allows for programs to improve over time

Decision on which subregion gets the intervention first is fair.
   Go First: Immediate access to a potentially beneficial program
   Go Later: Program potentially improved through experience
2. Advantages of Roll-Out Designs
   From a Researcher’s Perspective

Ethical Issues
When communities don’t hold equipoise about a prevention program
   Roll-out designs minimize withholding of a potential beneficial intervention

Statistical Advantages
Improvement over alternative designs
   Avoids “readiness bias” of non-randomized community studies
   Statistically efficient compared to wait-listed designs – Brown et al. Clinical Trials

This is a True experiment producing strong causal inferences
   Even with modest numbers of subregions – Brown et al., Clin Trials 2006
   Allows for modeling time and subregion effects – Wyman et al., Prev Sci 2015

Wide range of design choices
   Adoption of a New Intervention
   Head-to-head Comparisons of two interventions or implementation strategies Brown et al., Ann Rev PH (in press)
### 3. Roll-Out Design and Analysis Choices

- More Efficient allocation of 32 Schools than a Standard Wait-Listed Design

<table>
<thead>
<tr>
<th>Year</th>
<th>Time Block</th>
<th>Wait-Listed Design</th>
<th>Dynamic Wait-Listed Design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time</td>
<td>Intervention</td>
<td>Wait-Listed</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
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<tr>
<td></td>
<td>8</td>
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Schools Blocked Into 8 Equivalent Groups of 4 who are trained in the same Quarter year.
Power increases with even a few subregions

Figure 6  Statistical power for estimating intervention effect on increasing referrals for suicidality with a dynamic wait-listed design begun in the second phase of the Georgia gatekeeper project
Analyses

Model time as a systematic + random effect
Model Sub as a random effect
Model Intervention as fixed, potentially varying in duration

Advantages Even with a Few Units to Randomize

N = 2

Mpowerment Young MSM (Kegeles AJPH 1987)
Rollout of Repeated Pairs of Randomized Communities: Cumulative Trials (Brown et al., Ann Rev PH 2009)

Single Selection Roll-Out of Randomly Selected Communities

Head-to-Head Roll-Out Designs (Brown et al., in press Ann Rev PH)

<table>
<thead>
<tr>
<th>Time</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort A</td>
<td>0</td>
<td>X*</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>Y*</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Cohort B</td>
<td>0</td>
<td>0</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>Y*</td>
<td>Y</td>
</tr>
<tr>
<td>Cohort C</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>X*</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Y*</td>
</tr>
</tbody>
</table>
Randomizing 40 CA Counties for Head-to-Head Comparison of Community Development Team (CDT) or Independent (Ind) Implementation Strategies (Brown et al., Imp Sci 2014)
4. Summary and References

1. With our limited set of evidence-based community and preventive interventions, especially to address health disparities, **we need to emphasize rigorous evaluation of home-grown programs.**

2. Roll-Out Designs are often appropriate
   - Policy Maker or Community Leaders: Ethically get out potentially valuable program
   - Researcher: Rigorous and efficient design allowing strong causal inferences

3. A Bestiary of Roll-Out Designs possible


