Evaluating Service Delivery and Patient Safety Interventions

Two Key Evaluation Issues

- Study design
- End points
Before and After

Data-collection  Control  Intervention

Post-intervention

Pre-intervention

Example: Blood stream infections in ICU. Pronovost et al, 2006
Controlled Cross-Sectional

Data-collection | Control | Intervention

Post-intervention

Pre-intervention

Impact of dedicated medication nurses. Greengold et al 2003
The Concept of Terminal Event
Advantage Controlled Before and After

1) Reduce variance (improve precision)
2) Reduce bias (especially non-randomised studies)
Two Key Evaluation Issues

• Study design

• End points
Structure → Management Processes (Fidelity) → Clinical Processes / errors → Outcomes and throughput

Intervening variables
Structure

Management Processes (Fidelity)

Intervening variables

Clinical Processes /errors

Outcomes and throughput

Specific interventions
Corollaries for Service Interventions

1) Multiple end-points

2) a) Controlled before and after
   b) Compare change in outcomes
      from base-line to post-intervention
## CASE STUDY: MERIT TRIAL

<table>
<thead>
<tr>
<th>1) Multiple end-points Calls: non-arrest</th>
<th>Control</th>
<th>Met</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>48.1</td>
<td>84.1</td>
<td>&lt;0.001</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>2) Change from base-line</th>
<th>Control</th>
<th>Met</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest</td>
<td>-0.98</td>
<td>-0.44</td>
<td>0.2</td>
</tr>
<tr>
<td>Unexpected death</td>
<td>-0.68</td>
<td>-0.31</td>
<td>0.2</td>
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</table>
Control + MET hospitals combined

<table>
<thead>
<tr>
<th></th>
<th>Base-line</th>
<th>Post</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest</td>
<td>2.08</td>
<td>1.47</td>
<td>0.003</td>
</tr>
<tr>
<td>Unexpected death</td>
<td>1.63</td>
<td>1.11</td>
<td>0.01</td>
</tr>
</tbody>
</table>
Possible Reasons for Combined Pre-Post Effect

1) General Secular Trend

2) Study effect
   a) Mediated directly
   b) Indirect effect
A Design for all Seasons

Control

Intervention

Time
Advantages of Step Wedge Design

1) Ethical, political and logistic

2) Scientific
A Design for all Seasons

Control

Intervention

Time
## Scientific Arguments for Step Wedge Cluster Designs

<table>
<thead>
<tr>
<th></th>
<th>Parallel</th>
<th>Step-Wedge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention effect</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Sub-groups</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Time-effects</td>
<td></td>
<td></td>
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<tr>
<td>General</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Sustainability</td>
<td>+</td>
<td>+ (loss of power)</td>
</tr>
<tr>
<td>Time of intervention/Hawthorne</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>
Design 1: Uncontrolled

Data-collection Control Intervention

Post-intervention