Evaluating Service Delivery and Patient Safety Interventions

Richard Lilford. Berwickfest
Warwick, January 2008
<table>
<thead>
<tr>
<th>Class of topic</th>
<th>Example of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>Masking</td>
</tr>
<tr>
<td>Device or procedure</td>
<td>Evolution in use</td>
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<tr>
<td>Psychological</td>
<td>Preference outcome interaction</td>
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<tr>
<td>Education</td>
<td>Contamination</td>
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<tr>
<td>Service delivery or policy</td>
<td>Context</td>
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Top-rated British business research: has the emperor got any clothes?

R J Lilford; F Dobbie; R Warren; D Braunholtz; R Boaden

*Health Services Management Research;* Aug 2003; 16,3; ABI/INFORM Global pg. 147
Two Key Evaluation Issues

• Study design
• End points
Design 1: Uncontrolled

Data-collection  Control  Intervention

Post-intervention
Design 2: Before and After

Data-collection  Control  Intervention

Post-intervention

Pre-intervention
What Would You Say About This?

Intervention

St Elsewhere Hospital Infection Rate

Time
Time Series

Infection Rate

Time
Design 3: **Controlled Cross-Sectional**

Data-collection

Control

Intervention

Post-intervention

Pre-intervention
The Concept of Terminal Event
Design 4: **Controlled Before and After**

Data-collection

Control

Intervention

Post-intervention

Pre-intervention
Advantage Controlled Before and After

1) Reduce variance (improve precision)
2) Reduce bias (especially non-randomised studies)
A Design for all Seasons

Control

Intervention

Time
Advantages of Step Wedge Design

1) Ethical, political and logistic

2) Scientific
Two Key Evaluation Issues

- Study design
- End points
Lilford’s Axiom for Evaluation of Complex Interventions

Measure distal end-points to assess effect, at the level to monitor fidelity and proximal to describe context.
Structure (Context) 

Management Processes (Fidelity) 

Clinical Processes / errors 

Outcomes and throughput 

Intervening variables 

Generic Interventions
Two Important Issues

- Triangulation
- Context
Fidelity subscore (organisation)

Treatment effect (mean days)
In the intervention (mean days)
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
### MERIT STUDY

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Met</th>
<th>p Value</th>
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</thead>
<tbody>
<tr>
<td>1) Multiple end-points</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calls: non-arrest</td>
<td>48.1</td>
<td>84.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2) Change from base-line</td>
<td></td>
<td></td>
<td></td>
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<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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## Control + MET hospitals combined

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

1) General Secular Trend

2) Study effect
   a) Mediated directly
   b) Indirect effect
<table>
<thead>
<tr>
<th></th>
<th>Parallel</th>
<th>Step-Wedge</th>
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<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>
</tr>
<tr>
<td>General</td>
<td>+</td>
<td>+ (loss of power)</td>
</tr>
<tr>
<td>Sustainability</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Time of intervention/Hawthorne</td>
<td>-</td>
<td>+</td>
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