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Designs, Variations and Examples of the Stepped Wedge Design: Supplementary Materials

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Agenda

- Welcome and introductions
- Presentations
- Instructions for obtaining your CME Certificate of Participation



Disclosures

- Presenters will not discuss off label use and/or investigational use of medications in their presentations.
- Dr. Dickinson receives some funding from the AHRQ INSTTEPP Study, but is not the PI.
- Presenters do not have any additional financial relationships to disclose.



Today's Presenters

Designs, Variations and Examples of the Stepped Wedge Design: Supplementary Materials



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Stepped Wedge Variations

- ▶ **Design A (Repeated cross-sectional)**
 - ▶ Clusters cross over but individuals are designated as either control or intervention, depending on point of entry, remaining as such throughout the study
 - ▶ Different individuals in control and intervention conditions
- ▶ **Design B (Cohort)**
 - ▶ Clusters cross over and *individuals change* from control to intervention condition at time of crossover for the cluster
 - ▶ Same individuals in control and intervention phases
- ▶ **Design variation (Region-level randomization)**
 - ▶ Crossover order randomized at region or organizational level; clusters (practices) recruited at the time of implementation for that region
 - ▶ Could be repeated cross-sectional or cohort



Select Examples

Design A	Design B	Design Variation
Dainty et al (2011) /Morrison et al (2015): Targeted temperature management in post-cardiac arrest patients	Mhurchu et al (2013): Free school breakfast and children's attendance, achievement, and hunger	Golden et al (2015): Washington State Community-Level Randomized Trial of Expedited Partner Therapy for chlamydia and gonorrhea



Targeted temperature management (TTM) after cardiac arrest

▶ Intervention

- ▶ Passive phase (identify champion, didactic presentation, standard therapeutic hypothermia protocol)
- ▶ Active phase (implement intervention – collaborative network, reminders, protocols, education, audit & feedback)

▶ Stepped wedge motivation

- ▶ Evidence-based practice for patients resuscitated from cardiac arrest: Cooling to 32-34 °C for 12-24 hrs following return of spontaneous circulation
 - ▶ Intervention will do more good than harm (unethical to keep from control hospitals)
 - ▶ Lack of adoption in clinical practice; need to study implementation
- ▶ Practical limitations to simultaneous roll-out in all hospitals
- ▶ Ability to model the effect of time

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2. Dainty KN, Scales DC, Brooks SC, et al. A knowledge translation collaborative to improve the use of therapeutic hypothermia in post-cardiac arrest patients: protocol for a stepped wedge randomized trial. *Implement Sci*. 2011;6:4.

Targeted temperature management (TTM) after cardiac arrest

▶ Design

- ▶ 8-10 hospitals randomized to one of four waves
- ▶ Wave interval 4 months
- ▶ Individuals are either intervention or control (assuming low probability of repeat event)
- ▶ Primary process outcome is % of post-cardiac arrest patients receiving appropriate TTM; Clinical outcome is survival to hospital discharge

▶ Analysis

- ▶ Generalized estimating equations (GEE)

▶ Results

- ▶ 26% of patients eligible for TTM received this treatment during passive phase, vs 9% at baseline; no incremental improvement during active phase
- ▶ No effects on survival to discharge



Free school breakfast program

▶ Intervention

- ▶ Primary schools in New Zealand offer a free daily school breakfast program (SBP), either Red Cross or private section

▶ Stepped wedge motivation

- ▶ Evidence of positive effects on nutrition, health and attendance for children from disadvantaged communities and developing nations
- ▶ Need to study effects on academic achievement, and in other populations

Free school breakfast program

▶ Design

- ▶ 14 schools randomized to one of 4 waves
- ▶ Wave interval 1 school term (4 terms per school year)
- ▶ Children enrolled at baseline, crossed over from control to intervention when their school did
- ▶ Outcomes were school attendance, academic achievement (reading, writing, numeracy), self-report hunger and eating breakfast everyday

▶ Analysis

- ▶ Linear mixed models (clustering within school and repeated measures within child)

▶ Results

- ▶ Program attendance was low
- ▶ Secular trends in school attendance (decrease throughout school year) and achievement (increase throughout school year); no effect of intervention
- ▶ Intervention reduced short-term hunger, no effect on eating breakfast daily (children replaced breakfast at home with breakfast at school)



EPT for chlamydia & gonorrhoea

▶ Intervention

- ▶ Public health program to promote medical providers' use of expedited partner therapy (EPT) for sexually transmitted infections (STI)

▶ Stepped wedge motivations

- ▶ EPT is a clinical beneficial intervention
- ▶ All areas of the state would eventually adopt the intervention
- ▶ Interested in the population-level impact

EPT for chlamydia & gonorrhea

▶ Design

- ▶ 23 local health jurisdictions (LHJ) in Washington State randomized to one of 4 waves (allocation concealed until time of implementation)
- ▶ Wave interval 6-8 months
- ▶ Practices within LHJ recruited at start of their LHJ's wave
- ▶ Outcomes measured using existing population surveillance at baseline, and in the last 3 months of each wave

▶ Analysis

- ▶ Mixed effects generalized linear model with a log link
- ▶ Random effects of LHJ and practice within LHJ

▶ Results

- ▶ STI rates decreased overall over the course of the study period
- ▶ Intervention appeared to result in 10% reduction in STI (not sig), study insufficiently powered

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