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Advanced Methods for Primary Care Research: The Stepped Wedge Design

Presented By:

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Moderated By:

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Agenda

- Welcome and introductions
- Presentations
- Q&A session with all presenters
- Instructions for obtaining your CME Certificate of Participation

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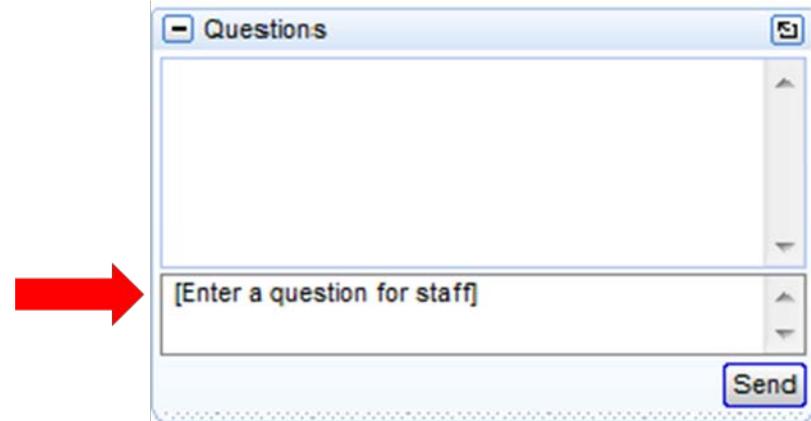
Disclosures

- 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.
- The rest of our presenters do not have financial relationships to disclose.



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Today's Presenters

The Stepped Wedge Design in Practice-Based Research



Gillian Bartlett, PhD

Associate Professor, McGill University

Research and Graduate Program Director, Department of
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Today's Presenters

The Stepped Wedge Design in Practice-Based Research



L. Miriam Dickinson, PhD

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Today's Presenters

The Stepped Wedge Design in Practice-Based Research



Christopher Meaney, MSc

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Today's Presenters

The Stepped Wedge Design in Practice-Based Research



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Denver

The Stepped Wedge Design in Practice-Based Research

Committee on the Advancement of the Science of Family
Medicine (CASFM)

Research Methods Working Group

Presenters: Gillian Bartlett, PhD; L. Miriam Dickinson, PhD; Christopher Meaney,
MSc; Bethany Kwan, PhD, MSPH

Educational Goals

- To understand:
 - The basic design of cluster randomized stepped wedge trials
 - How randomization works in stepped wedge designs
 - How enrollment and measurement are done
 - With specific implications for three design variations
 - Some basic principles of statistical analysis for the design variations
 - But one size does not fit all
 - Power and sample size in stepped wedge designs
 - How to select a stepped wedge design based on the Pros and Cons of alternative designs

Cluster Randomized Stepped Wedge Design Basics

- Stepped Wedge is a variation of the crossover design for randomized controlled trials (RCT) of different interventions
 - In practice-based research, clusters are generally a clinical practice; we use the terms clusters & practices interchangeably here
 - Practices cross over from one condition to another at different times (0=control, 1=intervention) with cross-over in one direction only

| <u>Parallel</u> | | | | <u>Crossover</u> | | | | <u>Stepped Wedge</u> | | | | | | |
|-----------------|---|------|---|------------------|------|---|---|----------------------|------|---|---|---|---|---|
| | | Time | | | Time | | | | Time | | | | | |
| | | | 1 | | | 1 | 2 | | | 1 | 2 | 3 | 4 | 5 |
| Cluster | 1 | | 1 | | | 1 | 0 | | | 1 | 1 | 1 | 1 | 1 |
| | 2 | | 1 | | | 2 | 0 | | | 2 | 0 | 1 | 1 | 1 |
| | 3 | | 0 | | | 3 | 1 | | | 3 | 0 | 0 | 1 | 1 |
| | 4 | | 0 | | | 4 | 1 | | | 4 | 0 | 0 | 0 | 1 |

Randomization and Intervention Initiation

- At the beginning of the trial, all clusters are randomized to an *order*, and assigned to a step based on that order
 - Random number generator can be used to assign order
 - Can be multiple clusters per step (e.g. groups of practices)
 - In the first time block all clusters are in the control phase
- All clusters (practices) ultimately receive the intervention
 - Randomized intervention initiation order determines *when* (not *if*) a cluster receives the intervention
 - By the last time block all clusters are in the intervention phase
- Allocation concealment (blinding) is ideal but is not always possible
 - Assessor concealment is often more feasible

Enrollment and Measurement

- Traditionally, all *clusters* are recruited and enrolled at baseline and followed for the entire duration of the study (Study 1 example: INSTEPP)
 - Alternative approach possible when retrospective data are available (Study 2 example: IDOCC)
- Outcomes measured for every cell (e.g. every time interval for every cluster)
 - Clusters (practices) “participate” in the study for the entire study period (again, study 2 shows an alternative approach)
- We will highlight and discuss distinctions between three key variations on stepped wedge designs
 - More than one can occur in the same study

Enrollment and Measurement: Design A

- Generally referred to as a *repeated cross-sectional* design (Brown and Lilford, 2006)
- *Different* individuals in control and intervention conditions
 - Patients enrolled during the control phase for that cluster are controls
 - Patients enrolled during the intervention phase for that cluster are intervention subjects
- Individuals continue to be in the same condition and are generally observed for a designated time period to observe outcomes
 - *Time in study is same for all individuals*, regardless of when they were enrolled
 - *Can be a single observation or repeated observations*
 - Individuals may participate in the study for only a *short period of time*

Enrollment and Measurement: Design B

- A ***cohort*** of individuals is identified at baseline and is the study group throughout the entire project (***cohort design***: Brown and Lilford, 2006)
- The *same individuals* are in the control and intervention phases
 - Clusters cross over and *individuals change* from control to intervention condition at time of cross-over for the cluster
 - Individuals, as well as clusters, are followed throughout the entire study period
- Must be able to identify, track and measure these individuals over a longer period of time
 - Repeated surveys or some sort of direct measurement over the entire time frame of the study is ideal
 - Longitudinal data from electronic health records can be sufficient for measuring outcomes in some cases

Enrollment and Measurement: Variation on Design B

- Larger unit of randomization, e.g. geographic region
 - *Regions* cross over from control to intervention, based on randomization order
 - Because of available existing data (e.g. EHR) to ascertain outcomes retrospectively, practices are recruited prior to implementation of the intervention within their region, *not at baseline*
- Cohort design: the *same individuals* are in the control and intervention phases
 - Individuals, as well as clusters, are followed throughout the entire study period

Example Study 1. Implementing Networks' Self-management Tools Through Engaging Patients and Practices (INSTTEPP)*

- *Overall Goal*
 - To implement the AHRQ SMS Library/Toolkit across four participating networks
- *Mechanism*
 - Use Boot Camp Translation in a stepped-wedge design to tailor and help with implementation
- *Intervention*
 - Use of AHRQ SMS Toolkit in practices
- *Evaluate* the impact of the intervention on patients and practice staff engaged in chronic care management
- *Setting*
 - Four PBRN networks (Oregon, Iowa, Wisconsin, Colorado)
 - Four practices per network (16 total)
- *Networks* randomized to intervention initiation times (order)

INSTTEPP Study Design

- Five time blocks
- T1 is a control phase for everyone
- T2 – T5 one PBRN at a time (4 practices per PBRN) cross over to the intervention phase, starting with a Bootcamp-Translation process in each network

| Stepped Wedge Design | | | | | |
|----------------------|---------|---------|--------|--------|--------|
| Network | Time | | | | |
| | T1 | T2 | T3 | T4 | T5 |
| PBRN 1 | Control | Interv. | I | I | I |
| PBRN 2 | Control | C | Interv | I | I |
| PBRN 3 | Control | C | C | Interv | I |
| PBRN 4 | Control | C | C | C | Interv |

Design A: How does this look for patients?

- Target Population
 - Patients, ages 18-70 with chronic illness who are being targeted for care management support
- Patient enrollment
 - During each time block 16 patients from each PBRN are recruited and enrolled (4 per practice)
 - Each patient completes a baseline, 1 month, and 2 month assessment, so *patient* follow up is fairly short (approximately 8 weeks)
 - Once this is complete there is no additional follow-up on the patient
 - Primary outcome is the Patient Activation Measure (PAM) (so we expect change to occur fairly quickly, an important condition of this design)
 - Patients are designated as control or intervention patients, depending on whether the practice was in the control or intervention phase at the time the patient was enrolled

Design A: How does this look for patients?

- *Different* patients in control and intervention conditions
 - Patients enrolled during the control phase receive usual care (e.g. T1-T3 for PBRN 3, 48 control patients total)
 - Patients enrolled during the intervention phase receive the intervention (AHRQ SMS Toolkit), with tailored delivery for each PBRN
- By the end of the study about half will be controls and half intervention (160 in each group)
- We want to know whether *improvement* over the *two month assessment* period is greater for intervention patients than for control patients, hence, the intervention effect is a *between-patient* effect

| Recruitment Goals | | | | | | |
|-------------------|----|----|----|----|----|-------|
| Network | T1 | T2 | T3 | T4 | T5 | Total |
| PBRN 1 | 16 | 16 | 16 | 16 | 16 | 80 |
| PBRN 2 | 16 | 16 | 16 | 16 | 16 | 80 |
| PBRN 3 | 16 | 16 | 16 | 16 | 16 | 80 |
| PBRN 4 | 16 | 16 | 16 | 16 | 16 | 80 |
| Total | 64 | 64 | 64 | 64 | 64 | 320 |

Design A: Statistical Analysis – an approach using general linear mixed (multilevel) models

Level 1 model. Repeated measures *within* each person

$$Y_{tij} = \pi_{0ij} + \pi_{1ij} (\text{time})_{tij} + \varepsilon_{tij}$$

where π_{0ij} is the individual status at time 0, π_{1ij} is the linear growth rate for person ij, and ε_{tij} is the term that represents the random deviation of observation t within person ij

Level 2 model. Individual level models include intervention status and covariates (X_j). Month of enrollment is included as a covariate to control for possible temporal trends

$$\pi_{0ij} = \beta_{00j} + \beta_{01j} (\text{Intervention}) + \beta_{02j} (\text{month}) + \Sigma \beta_{0pj} (X_i) + r_{0ij}$$

$$\pi_{1ij} = \beta_{10j} + \beta_{11j} (\text{Intervention}) + r_{1ij}$$

where β_{00j} represents the initial status of person i within practice j, β_{10j} represents the linear growth rate for control subjects in practice j, β_{11j} represents the difference in linear growth rate for intervention subjects in practice j, and the r's are person-level random effects

Level 3 model. Practice level models

$$\beta_{00j} = \gamma_{000} + u_{00j}$$

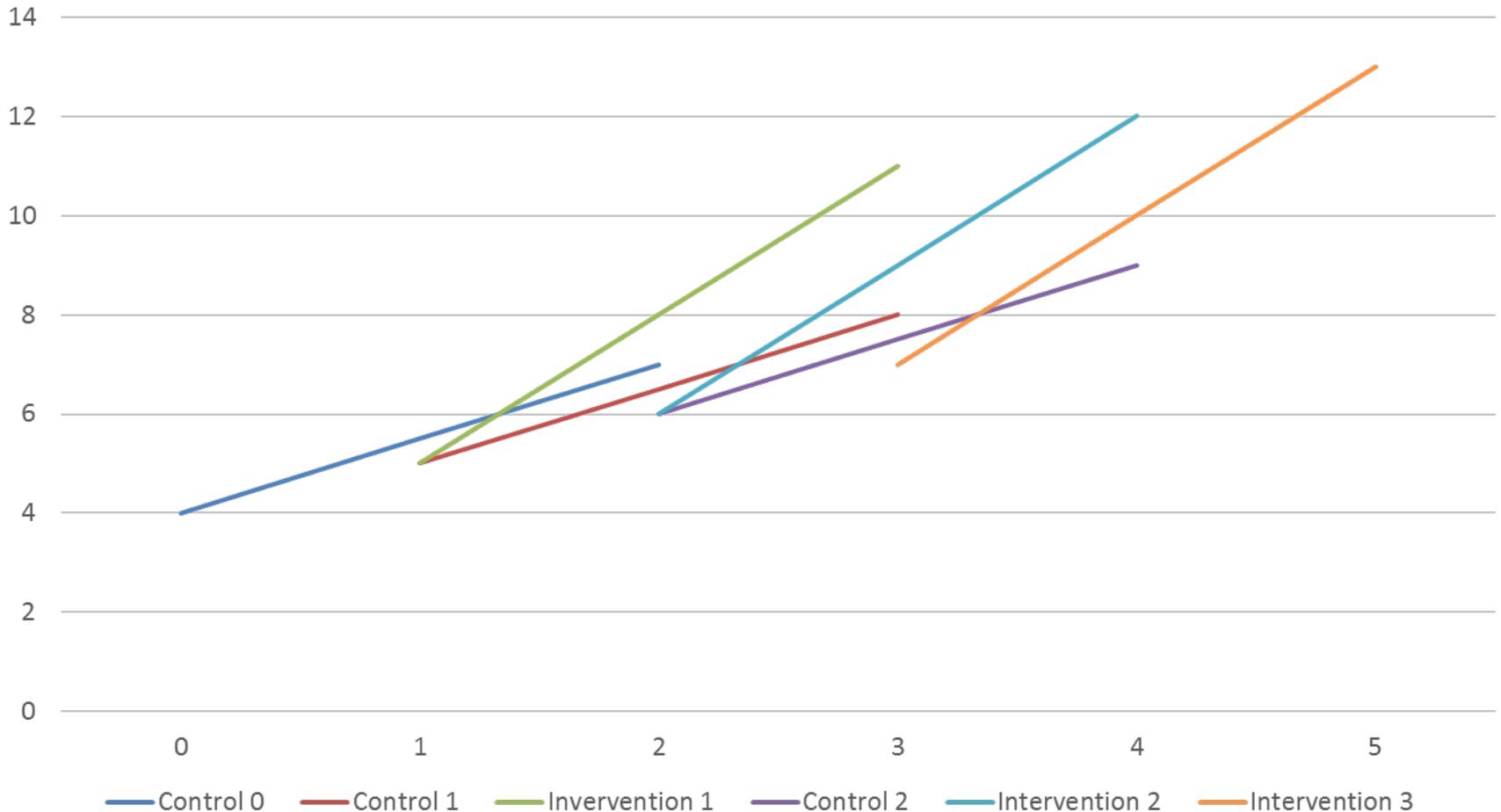
$$\beta_{01j} = \gamma_{010}$$

$$\beta_{10j} = \gamma_{100}$$

$$\beta_{11j} = \gamma_{110}$$

where γ_{000} is initial status for controls; γ_{010} represents the baseline difference between control and intervention; γ_{100} is the linear growth rate for controls, and γ_{110} **is the difference in linear growth rate for intervention subjects**. The u's are practice random effects. Thus, the primary hypothesis of intervention effectiveness can be tested as $H_0: \gamma_{110}=0$ vs $H_1: \gamma_{110} \neq 0$.

Design A example with repeated measures on patients: We hypothesize differences in slopes for intervention vs control patients



Design B: How does this look for clinicians/staff?

- A *cohort* of clinicians/staff involved in care for patients with chronic illness were recruited at baseline and followed throughout the entire study
- Each clinician/staff member completes a survey at baseline (T1), and during each subsequent time block (T2 – T5)
- Follow-up period for clinicians/staff is the entire duration of the study, approximately 12 months
- Same individuals in control and intervention periods (cohort design)
 - Clinicians/staff are in the control condition as long as the practice is in the control phase
 - Clinicians/staff cross over to the intervention condition when the practice crosses over
 - Contamination less of an issue

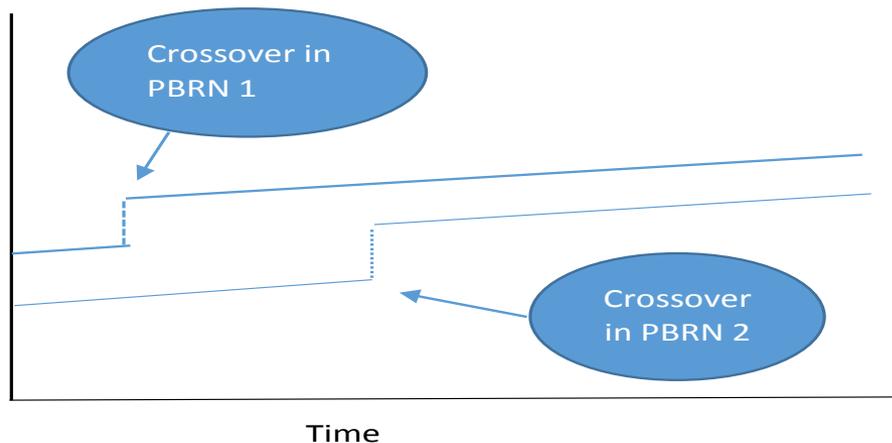
Design B: How does this look for clinicians/staff?

- Primary outcome is the Clinician Support for Patient Activation Measure (CS-PAM)
 - We hypothesized that attitudes of clinicians/staff toward patient self-management would improve after implementation of the intervention (i.e. Bootcamp and AHRQ SMS Toolkit)
- Each individual has both control and intervention periods
- The goal is to recruit 20 clinicians/staff from each PBRN (approximately 5 per practice) and each individual will complete 5 surveys over the 12 month study period
- Below: Blue= control phase, red=intervention phase

| | S1 | S2 | S3 | S4 | S5 |
|-----------------------------------|------|------|------|------|-----|
| PBRN 1 clinicians/staff (n=20) | Blue | Red | Red | Red | Red |
| PBRN 2 clinicians/staff (n=20) | Blue | Blue | Red | Red | Red |
| PBRN 3 clinicians/staff (n=20) | Blue | Blue | Blue | Red | Red |
| PBRN 4 clinicians/staff (n=20) | Blue | Blue | Blue | Blue | Red |

Design B: Statistical Analysis – a general linear mixed models approach

- **Key differences from design A model**
 - Intervention term is a within-individual effect (time-varying covariate)
 - The model, as depicted below, presumes an increment (decrement) in scores that doesn't affect slope and persists over time
 - Alternative models could include difference in slopes from pre to post-intervention, controlling for temporal trend, or both (i.e. increment/decrement and slope differences)
 - Model testing for goodness of fit will help investigators determine which is best



Example Study 2: Improved Delivery of Cardiovascular Care Through Outreach Facilitation (IDOCC)*

- Practice Outreach Facilitators work with primary care practices to optimize CVD prevention and management in high risk patients
- ***Geographic Regions*** in Eastern Ontario, Canada, are randomized to one of three intervention initiation times
 - Three regions – east, central, west
- Three phases
 - Baseline
 - Intensive intervention
 - Sustainability

*Liddy, Hogg et al, Implementation Science 2011, 6:110

IDOCC Study Design

| Step | Practices | T1 | T2 | T3 | T4 | T5 |
|------|-----------|----------|-----------------|-----------------|-----------------|----------------|
| 1 | 26 | Baseline | Intensive phase | Sustainability | | |
| 2 | 30 | Baseline | Baseline | Intensive phase | Sustainability | |
| 3 | 27 | Baseline | Baseline | Baseline | Intensive phase | Sustainability |

*Liddy, Hogg et al, Implementation Science 2011, 6:110

Example Study 2: What does this mean for enrollment and measurement?

- Differences from previous examples
 - *Practices in each region were recruited from list of all primary care practices in the region prior to intervention implementation, not at baseline*
 - This is possible because of retrospective data collection for baseline phase, so practices don't have to actually participate until they are enrolled
 - Measurement did not extend the full 5 years for all clusters
- Data collection
 - Primary outcome: Quality of Care composite score
 - Repeated chart audits of a *cohort* of the *same* randomly selected patient sample (similar to design B)
- For additional detail, including analytic approach, see Liddy et al, in Implementation Science, 2011

A General Statistical Model for A Stepped Wedge Design

- Most commonly expressed using the notation of Hussey and Hughes (2007):

$$y_{ijk} = \mu + \alpha_i + \beta_j + X_{ij}\theta + \varepsilon_{ijk}$$

- Design consists of:
 - I clusters ($i=1\dots I$)
 - T time points ($j=1\dots T$)
 - N individuals ($k=1\dots N$): n.b. sampled per cluster per time point (i.e. cross-section adaptation)
- Model parameterized in terms of:
 - Grand mean (μ)
 - Random cluster effect (α_i)
 - (Vector of)Fixed time effect (β_j)
 - A treatment indicator (X_{ij}) which equals 1 if intervention present at cluster I at time J, else it is 0.
 - A fixed treatment effect (θ)
 - Residual noise (ε_{ijk})

A General Statistical Model for a Stepped Wedge Design

- Some assumptions regarding the model of Hussey and Hughes (2007):
 - The random cluster effect is distributed as: $\alpha_i \approx N(0, \tau^2)$
 - The residual error is distributed as: $\varepsilon_{ijk} \approx N(0, \sigma^2)$
 - We assume the random cluster effects are independent of the residual error
- We can derive the variance of the responses as:
 - $V(Y_{ijk}) = \tau^2 + \sigma^2$
- We can define the intra-cluster correlation (ICC) coefficient as:
 - $\rho = \tau^2 / (\tau^2 + \sigma^2)$
 - Relates to proportion of total variance that can be explained by cluster level effects

Inference About Treatment Effects in Stepped Wedge Designs

- The primary objective of a stepped wedge trial pertains to whether the intervention has an effect on outcomes over and above that of the control
- In the model of Hussey and Hughes (2007) the treatment effect is parameterized in terms of a scalar term θ .
- $H_0: \theta=0$
- $H_A: \theta \neq 0$
- Estimation of θ is done using regression approaches. We often use a Wald statistic to perform inference on θ (which is asymptotically normally distributed):

$$Z = \frac{\theta}{\sqrt{VAR(\theta)}}$$

Inference About Treatment Effects in Stepped Wedge Designs

- In this scenario power refers to the ability to detect a true intervention effect when the intervention itself really works:

$$Power = \Phi\left(\frac{\theta}{\sqrt{VAR(\theta)}} - Z_{1-\alpha/2}\right)$$

- θ is the estimated intervention effect
- $VAR(\theta)$ is the estimated variance of the intervention effect
- $Z_{1-\alpha/2}$ refers to the $(1-\alpha/2)$ quantile of a standard normal variable
 - Related to significance level (rejection region) of the test: denoted α
- $\Phi()$ is the cumulative standard normal distribution function
 - Related to fact that Z has a limiting Normal distribution
- The variance of θ is given by the nasty equation below (Hussey and Hughes, 2007):

$$VAR(\theta) = \frac{I\sigma^2(\sigma^2 + T\tau^2)}{(IU - W)\sigma^2 + (U^2 - ITU - TW - IV)\tau^2}$$

Power in Stepped Wedge Designs

- In this design power depends on:
 - Strength of treatment effect
 - Number of clusters
 - Number of steps (time points)
 - Number of participants per cluster per step (time point)
 - Magnitude of each of the variance components (related to ICC)
- Other interesting factors
 - When does treatment effect occur (is there a lag between intervention and impact on outcome)

Analytic Options for Stepped Wedge Designs

- Two modern choices for modeling data from stepped wedge designs:
 - Generalized estimating equations (GEE)
 - Generalized linear mixed models (GLMM) a.k.a. multi-level models, random effect models, etc.
- Reasons why...
 - Data are clustered (at least have to deal with patients nested with clusters)
 - Cross sectional design variant
 - Data may be more complex:
 - Cohort designs where same individuals followed over multiple time periods
 - Hierarchical designs with multiple layers of clustering
- Other analytic approaches exist too:
 - Simple analysis adjusting estimated standard errors by design effect
 - Summary statistics at cluster level
 - Robust variance estimates
- Analysis and sample size (power) in stepped wedge designs in a novel area in statistical, epidemiological, design literature

Selecting a Stepped Wedge Design

- Typical uses:
 - Evaluation of therapies or interventions when withholding the intervention from some participants (i.e. controls) is not acceptable
 - Effectiveness (not efficacy) in real-world settings at the population level
 - Interventions shown to be effective in more controlled research settings (ready for a large scale pragmatic trial/dissemination)
 - Lack of definitive evidence of effectiveness but belief that intervention will do more good than harm

Stepped Wedge Motivations

- Practical considerations:
 - Cluster level implementation and randomization can be used
 - *Note: there is an individual-level randomization version of SWD that shares many of the features of the cluster-randomized version*
 - All must or will receive intervention
 - Outside of researcher's control but may increase acceptability to the community
 - Need for phased or sequential implementation
 - Can't be rolled out simultaneously across large groups of practices

Stepped Wedge Pros

- Addresses the following *ethical considerations* in randomized controlled trials:
 - Intervention believed likely to do more good than harm (equipoise is minimal)
 - Assumed that it would be unethical to withhold intervention (established effectiveness or gold standard)
 - Once intervention implemented, it is not removed

Stepped Wedge Cons

- Generally more difficult than traditional, parallel group, randomized clinical trials (RCT)
- Heavier data collection burden with outcomes measured for every cluster at every time point
 - Informed consent, if needed, can be complicated
- Trial duration can be long if complex implementation or prolonged time to influence outcomes
 - May not have time to observe effects on clinical outcomes (especially design A)
- Validity concerns: Greater potential for contamination (especially design A)
- Sequence generation and allocation concealment issues
 - Blinding of outcome assessors helps, but not always possible
- Impractical if comparing multiple interventions

Differentiating Stepped Wedge Design and Parallel Group Cluster RCT

- Key difference is crossover – every cluster gets the intervention in Stepped Wedge Design
- Generally longer trial duration for Stepped Wedge Design than parallel group cluster RCT
- Can do sequential implementation and rollout intervention in both, but Stepped Wedge Design allows for “stepped” implementation
- Temporal effects
 - Stepped Wedge Design can control for temporal trend analytically
 - Parallel group cluster RCT has a parallel control group to assess temporal trend

Ideal circumstances for stepped wedge

- Questions about reach, effectiveness and implementation
- Focus on shorter term outcomes (especially design A)
 - E.g., Process or intermediate outcomes (mediators)
 - Other designs (B and C) may accommodate longer times to have an intervention effect
- When there are only a few clusters available, Stepped Wedge Design may be a better option than a parallel group cluster randomized trial

Summary

- What we have learned:
 - The basics of cluster randomized stepped wedge designs and three important variations on this design
 - How randomization works in Stepped Wedge Designs
 - Enrollment and Measurement
 - Time and timing of practice, patient, clinician/staff (if applicable) “enrollment” and how this differs for the three variations
 - Measurement under the two variations of SWDs presented here
 - How power is affected by this design
 - Motivations and cautions for stepped wedge designs

Conclusions and Recommendations

- Stepped wedge is not always the best design but, when the conditions are right:
 - *Potentially beneficial interventions can eventually be offered to all participating practices or communities (greater engagement)*
 - *Particularly suited for research on evaluation of practice-based improvements where equipoise needed for traditional cluster RCT may not be present*

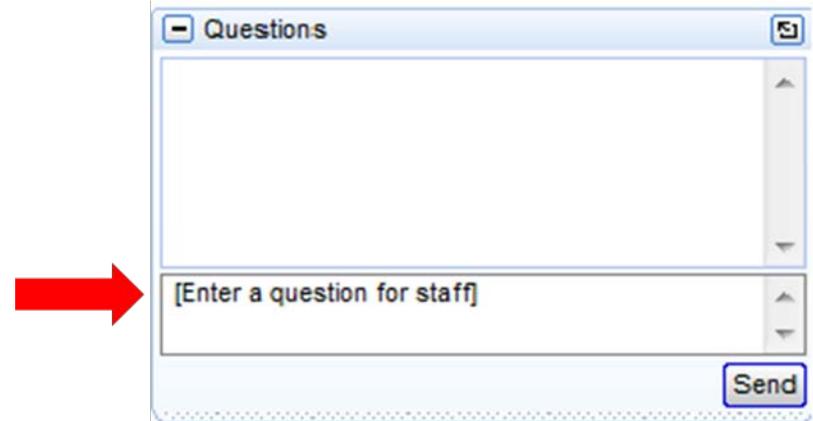
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