STEPPED WEDGE WORKSHOP

PRACTICE BASED RESEARCH NETWORK, JUN 2017

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AGENDA

Start	Activity
900	Introductions/self assessment
910	Ontario primary care context
920	Overview of stepped wedge trials
930	PICO
940	Small group discussion
1010	Compile collective wisdom
1025	Closure

SELF ASSESSMENT: STEPPED WEDGE TRIAL DESIGN -- SLIDO

- What is your most advanced experience with stepped wedge trials to date? (rank)
  - I have (or least pretend to have) heard of stepped wedge trials
  - I have participated in a stepped wedge trial
  - I have helped design a stepped wedge trial
  - I have led the design/implementation of a stepped wedge trial
  - Having stepped on all the wedges, I teach/coach/support others in the same
- What did you see as an advantage of this design? (open ended)

ONTARIO CONTEXT

- AFHTO
  - 186 interdisciplinary primary care teams (FHTs, NPLCs) -- 25% of sector
  - Committed to Starfield principles in measuring and improving quality of primary care
  - Momentum for measurement: D2D, a voluntary performance report – 5 iterations & counting
  - Composite measure of Quality reflecting patient, provider and system perspectives
  - Demonstrated relationship between high primary care quality and lower healthcare system costs
- Ontario
  - Other primary care delivery models: fee-for-service, group practice, other team models – 75% of sector
  - Embarking on Patients First healthcare system transformation agenda
  - Priority is to increase access to team-based primary care, not necessarily increase number of teams
  - Considerable interest in Patient Medical Home and associated concept of quality improvement
  - Generally, not well-organized or supported administratively

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THE CHALLENGE: SPREADING MEASUREMENT MOMENTUM

DATA
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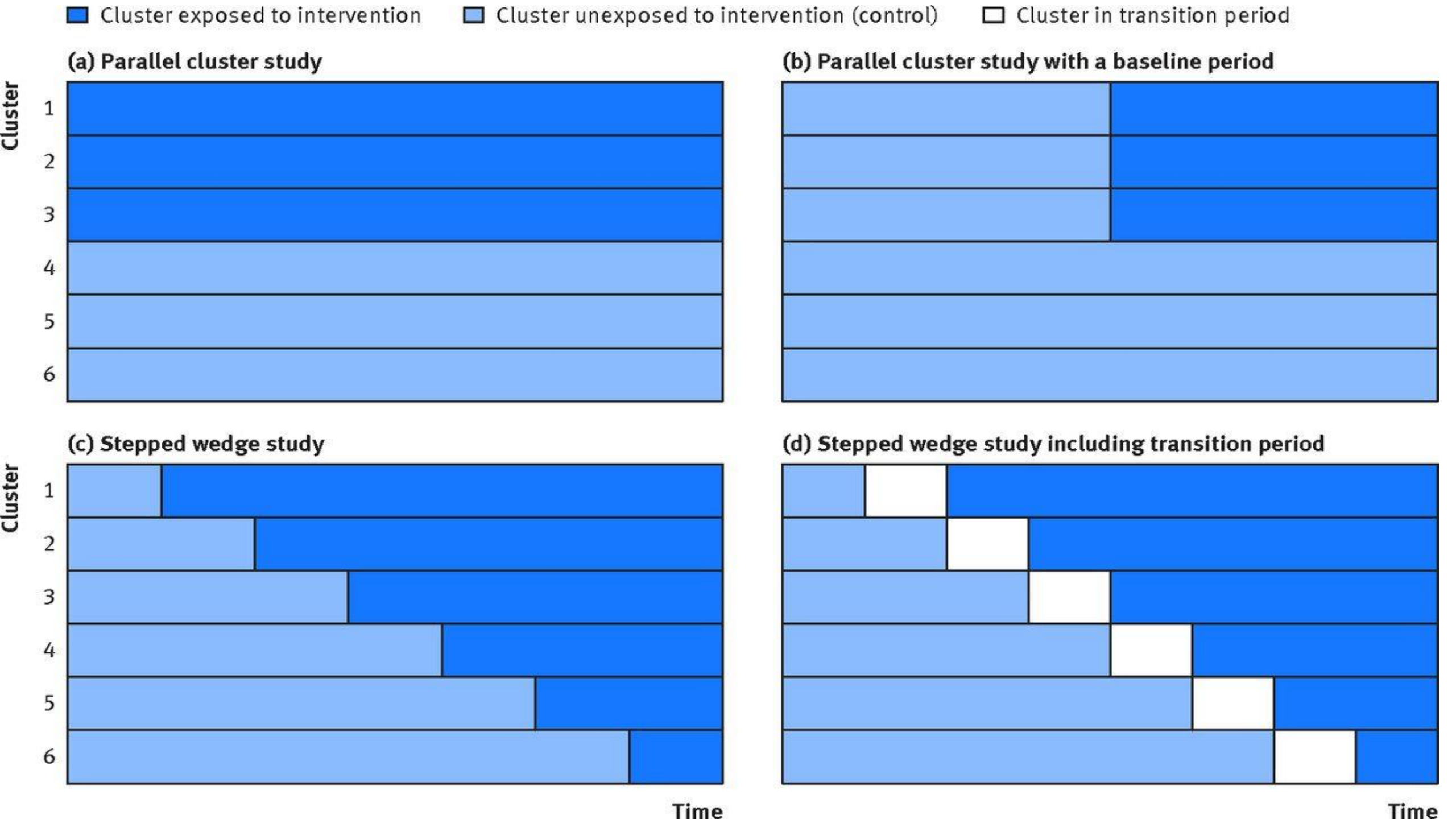
WHAT IS A STEPPED WEDGE RANDOMIZED TRIAL?

- Alternative to parallel RCT
- Commonly uses Clusters:
  - A group (rather than an individual) is randomized to intervention or placebo
  - Outcome may be measured at individual level
  - Individuals within groups may be more alike than individuals across groups
- Initial period: no intervention
- Clusters are randomly picked at regular intervals to receive intervention
- This continues until all clusters have received intervention


Cluster exposed to intervention
Cluster unexposed to intervention (control)
Cluster in transition period
(a) Parallel cluster study
(b) Parallel cluster study with a baseline period
(c) Stepped wedge study
(d) Stepped wedge study including transition period
Cluster
1
2
3
4
5
6
Time

STEPPED WEDGE RANDOMIZED TRIALS: OVERVIEW

- Rationale: why use a Stepped Wedge design?
  - Belief/evidence that **intervention will do more good than harm** (parallel, placebo-controlled arm may be unethical)
    - Example: all participants would want to receive intervention
  - Cannot **deliver intervention simultaneously** to everyone
- Advantages
  - Appropriate for **sequential implementation** of interventions (example, a team travels to sites to deliver intervention)
  - Random allocation is possible
- Challenges
  - Complicated statistical analyses
  - Blinding may not be possible – therefore risk of selection bias.
  - More clusters are exposed to the intervention towards the end of the study than in its early stages – the effects may be due to positive underlying temporal trends.

K Hemming, T P Haines, P J Chilton et al.

The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ 2015*

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PICO: STEPPED WEDGE TRIAL OF QI SUPPORT IN ONTARIO

?

- **Population:**
  - Primary care providers
- **Intervention:**
  - Access to a local, embedded Quality Improvement Decision Support specialist (QIDSS)
- **Control group:**
  - No Access to QIDSS
- **Outcomes:**
  - measures extracted from routinely collected data
  - show if/how QIDSS "make a difference"

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POPULATION: SOME OPTIONS

- Interdisciplinary teams without QIDS Specialists
- Physician group practices (ie without administrative or QI supports)
- Solo physician practices
- Non-physician practices or groups (eg Nurse Practitioner Led Clinics, Community Health Centres)

OUTCOMES: DEFINITIONS AND EXAMPLES

- Manageable
  - Data are readily accessible during ***and beyond*** the study
  - People ***take action*** in response to these measures eg local QI activity or systemic QI-supportive policy
- Meaningful
  - Progress on measures is accepted as evidence that QIDSS "made a difference"
- Example: contribution to D2D:
  - Manageable: Easy to measure during & after the trial – D2D is an ongoing operational process
  - Meaningful: Perceived as a commitment to measurement and QI
- NON-example: submission of a QIP
  - NOT manageable: Requires a policy decision to force the behaviour
  - NOT meaningful: Perceived as *compliance*, not *interest* in QI

SMALL GROUP DISCUSSION FOCUS

- **P:** Who should the population be for this stepped wedge trial?
- **O:** What are some manageable meaningful outcomes of this trial of QIDSS support?
- **Stepped wedge:** How is it appropriate (or not) for this question and context?

COMPILE COLLECTIVE WISDOM

- Compile recommendations from small groups
- Reflect on feasibility in participants' home settings

THANK YOU!

- To offer more suggestions or participate further:
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