

EVALUATIONS OPTIONS FOR COMPLEX INTERVENTIONS

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What is a complex intervention?



Some questions in studying complex Interventions

- How certain do we need to be that it works?
- What study methods can be used?
- What do we need to measure?

Quality Improvement vs. Research

Old school thoughts on what is the difference

Quality Improvement

Aim: Improve practice of health care

Methods:

- Test observable
- Stable bias
- Just enough data
- Adaptation based on data
- Many sequential tests
- **Assess by degree of belief in measured change**

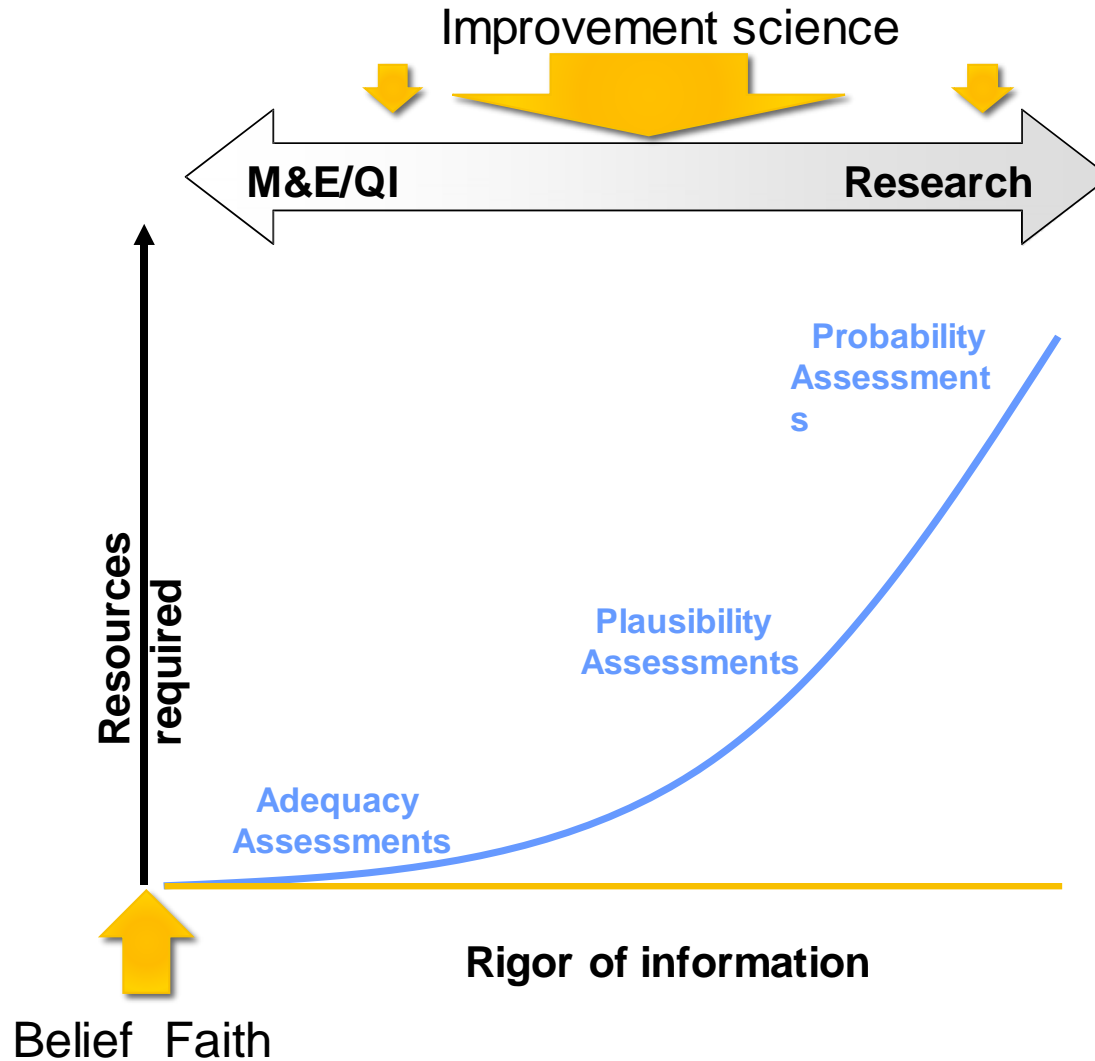
Clinical Research

Aim: Create New clinical knowledge

Methods:

- Test often blinded
- Eliminate bias (e.g. case mix, randomize)
- Just in case data (more)
- Fixed prior hypotheses
- **One fixed test/intervention**
- Assess by statistical significance

Scope and resources



2 questions to ask

- 1. Study design
 - Randomized or not
 - Controlled or not

- 2. Level of adaptation you allow during the implementation and evaluation

Study Design Options

- Randomized control trial
- Quasi experimental
- Observational

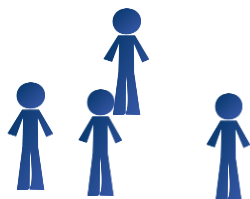
Why randomize with a control?

- Reduces bias and confounding
 - Best evidence that your intervention “caused” the change
- Adjusts for temporal trends across intervention areas
- NOTE: Having a control is more most powerful when you
 - Have large numbers being randomized
 - Are able to control your controls
 - External interventions
 - Spread (contamination) from intervention

How to randomize

- Level/unit

- Individual



- Cluster (organizational unit: clinic, district, neighborhood)

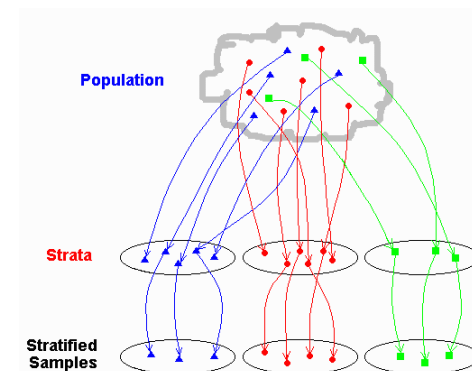
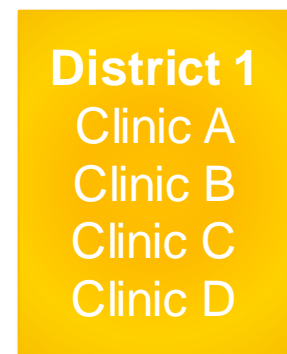
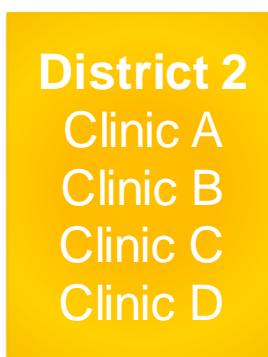
- Assume similarities of response within the unit
- Choose larger unit when changes will naturally cross smaller subunits

- Block/stratified

- Create homogenous units and randomize within them

- Depends on

- What level you are intervening
- What is the chance of spread between intervention and control
- Are there major factors shared across units randomized which will influence impact



When is a fixed RCT not the optimal design?

- No Equipoise
- Low number of randomization units
 - Your unit of intervention is the hospital only have 2 hospitals
- Can not randomize the right “unit”
 - Clustering effect outweighs intervention effect at randomization unit level
 - You want to randomize clinics, but it is more important the district policies than the individual clinic in determining quality

And a few more

- You can not “control” your controls
 - Other interventions are coming to your control sites
- You can not match intervention and control very well
 - and only have a few intervention and control sites
- Complex intervention
 - Intervention with many steps and parts
 - Can not control bias and confounding at all steps

What is stepped-wedge?

- Quasi experimental
 - Sequential, timed rollout measuring pre-intervention until every unit receives the intervention. Each one starts as a “control”

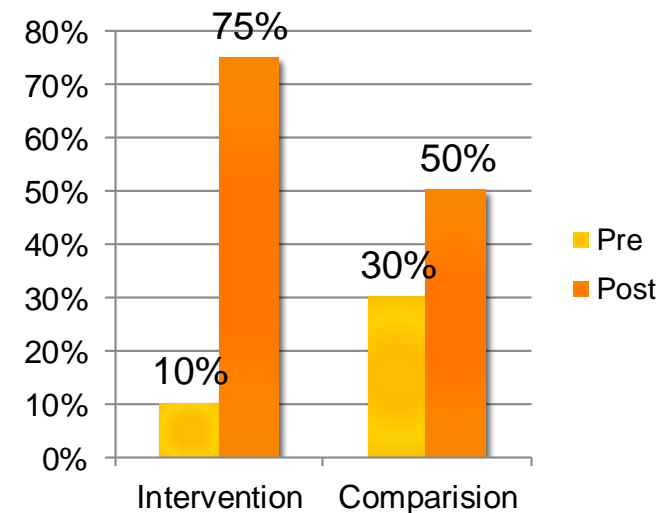
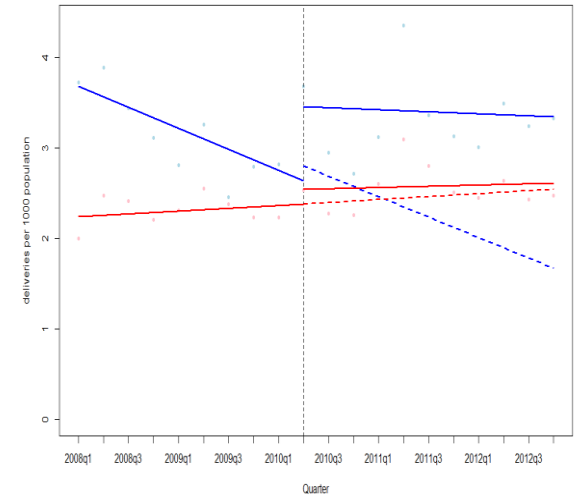
WHY use this?

- Logistical, practical or financial reasons preclude immediate scale-up or classic RCT
- Belief that implementation strategy will do more good than harm (but not completely sure)
 - No clinical equipoise

	T0	T1	T2	T3	T4	T5
Site A	C	I	I	I	I	I
Site B	C	C	I	I	I	I
Site C	C	C	C	I	I	I
Site D	C	C	C	C	I	I
Site E	C	C	C	C	C	I

Other Evaluation designs

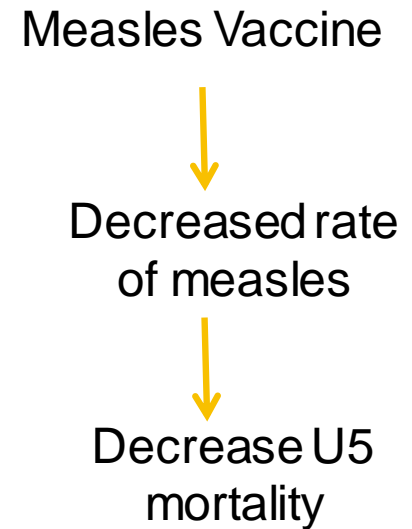
- Quasi experimental (or Observational)
 - Interrupted time series
 - Pre/post
- Observational
 - End line only



What do you choose to measure for evidence?

- Process
- Outcomes
- Impact

- Qualitative and context



So why not just do classic RCT's for complex interventions?

- Focus on HOW to implement rather than WHETHER to implement the improvement
- Context matters
- We need to change how we approach these studies/evaluations regardless of statistical or evaluation design

Need for flexibility-beyond the “pill”

- Need to better reflect real life
 - Pragmatic
- Classic methods “freeze” the intervention
 - Need adaptation
- How we measure
 - Numbers =works
 - Qualitative=explain

Pragmatic Trials

- “Designed to study real-world practice and therefore represent less-perfect experiments than efficacy trials”

Pros	Challenges
Increased generalizability	Decreased internal validity
Greater chance to understand impact of context	Less control of contextual factors (can reduce observed impact)
Designed to measure effectiveness	Can be hard to measure context

Capture Contextual variability



Applying adaptive design to studies of complex interventions

- In classic research if a group is not responding, adjust for context as a confounder at the end
- Adaptive strategy allows us to change how the intervention is being done if the strategy is not working or context changes
 - Can focus on content and/or execution
- Do up front and/or during the study

Kilbourne et al. Implementing evidence-based interventions in health care: application of the replicating effective programs framework *Implementation Science* 2013

Parry et al. Recommendations for Evaluation of Health Care Improvement Initiatives. *Acad Peds* 2013; Luce et al. Rethinking RCT for comparative effectiveness research. *Ann Intern Med* 2009

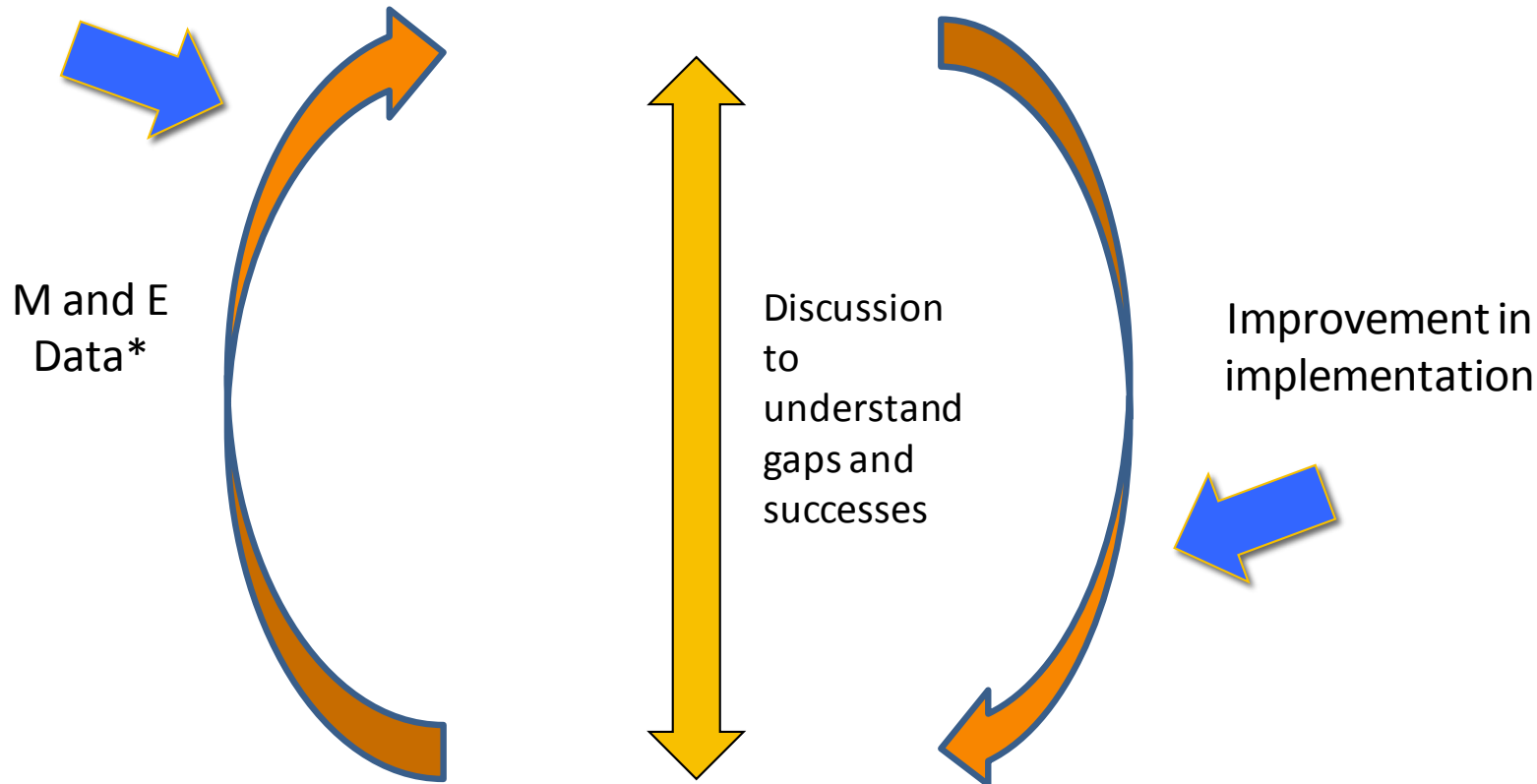
Adaptive Trial Designs

- Allow for planned adaptation of the intervention during the study (or implementation)
 - Testing a strategy
 - Fidelity-flexibility tension
- Must reflect accumulating information
 - Need feedback loop



What do you need to do an adaptive trial?

Program management



Implementation of intervention and of research activities

Summary

- Choose your evaluation design based on
 - What you are studying
 - How much evidence you have for its efficacy and effectiveness
 - Your local context
 - How many resources your have
 - Scope, time, resources

