EVANS CENTER FOR IMPLEMENTATION AND IMPROVEMENT SCIENCES

BOSTON UNIVERSITY

Bringing Science to Quality

Transforming Implementation & Improvement Into Science: *A skills building series*

February 28, 2018

Engage with CIIS

Guide & Innovate

- Provide guidance, support & innovation to design projects that rigorously evaluate the effectiveness of efforts to implement change

Accelerate & Promote Sustainability

- Identify strategies that accelerate the adoption & promote sustainability of effective healthcare interventions

Educate

- Provide implementation & improvement sciences education to faculty, trainees, students

Overview: Implementation & Improvement Sciences

Implementation Science
Focuses on optimal strategies to promote evidence uptake in real-world settings

Addresses
Did stakeholders perform the desired endeavor?
Why or why not?
How well?

Improvement Science
Focuses on rigorously measuring outcomes associated with efforts to improve care delivery

Addresses
Did the new endeavor measurably improve desired outcomes?

Aims

Translate research intro practice

Systematically implement evidence-based practices

Improve the quality of healthcare

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Identifying High-Quality Projects

Main NIH Criteria

- Overall impact
- Significance
- Innovation
- Approach
- Investigator team
- Research environment

Issues Applying NIH Criteria to Implementation & Improvement (IIS)

- Broad, non-specific to IIS
- Criteria could be operationalized to better describe high-quality IIS

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Proctor's 10 Key Ingredients	NIH Criteria
1. Quality/care gap	Impact; Significance
2. Evidence-based treatment	Significance; Innovation
3. Conceptual model, theoretical justification	Approach; Innovation
4. Stakeholder priorities, engagement in change	Impact; Approach; Research Environment
5. Setting's readiness to adopt new services	Impact; Approach; Environment
6. Implementation strategy/process	Impact; Significance; Innovation
7. Team experience with the setting, treatment, processes	Approach; Investigator Team
8. Feasibility of proposed research design	**Approach; Investigator Team**
9. Measurement & analysis section	Approach; Investigator Team
10. Policy/funding environment; support for sustaining change	Impact; Significance

Source: Writing Implementation Research Grant Proposals: Ten Key Ingredients. Proctor EK, Powell BJ, Baumann AA, Hamilton AM, Santerns RL. *Implementation Science.* 2012;7:96.

Upcoming Sessions

Tentative Date	Session Title	Proposal Areas Addressed
10/25/2017	Identifying Your Implementation & Improvement Sciences Research Question	Quality/Care Gap, Evidence-Based Practice
12/6/2017	Using & Discussing Implementation Science Models	Conceptual Model
1/25/2018	Implementation Strategies Versus Study Interventions	Implementation Strategy
2/28/2018	**Designing an Implementation & Improvement Sciences Study**	**Study Design, Measurement, Analytic Methods**
3/22/2018	**Designing Your Implementation & Improvement Sciences Study**	**Measurement, Analytic Methods**
4/18/2018	Mixed Methods for Implementation & Improvement Sciences	Measurement, Analytic Methods
5/10/2018	Engaging with Stakeholders to Conduct Feasible & Meaningful Research	Stakeholder Engagement, Feasibility, Team, Policy Environment

Series Goal


Proctor's 10 Key Ingredients
CIIS Educational Series
High-Quality Implementation & Improvement Sciences
Significant Contributions to Improve Care, Advance Fields

Designing an Implementation & Improvement Sciences Study

Allan Walkey, MD
Co-Director, CIIS

Study Designs – What, Why & How?

- Identify key considerations for selecting the best study design for implementation & improvement sciences (IIS) questions

- Discuss the strengths & weaknesses of different study designs

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What Do You Mean, Design?

- **Qualitative vs. Quantitative Methods?**
  - No, these are analytic approaches
  - Can be applied to almost any design
  - Not a topic for today
- **Efficacy vs. effectiveness vs. implementation vs. hybrid?**
  - A little…We'll discuss

We mostly mean:

*How will you set up the project to **gain knowledge?***

What Can IIS Designs Address?

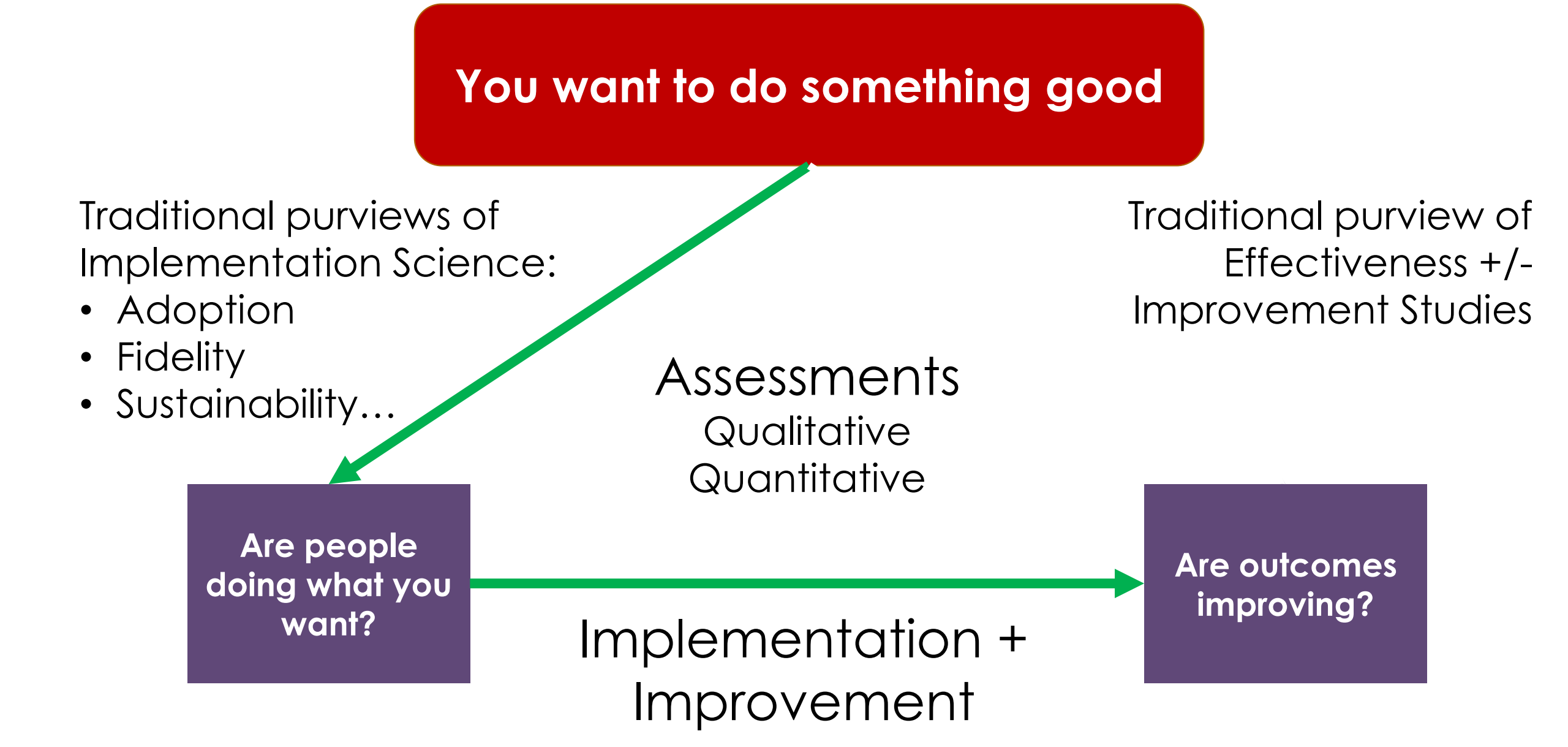
Any or multiple aspects of implementation, including:

- **Factors** affecting implementation

- **Process** of the implementation
- Studying the strategies, not the interventions

- **Outcomes** of the implementation
- e.g. comparative effectiveness of different strategies

- **End-Products** of the implementation
- Effectiveness


You want to do something good
Traditional purviews of Implementation Science:
• Adoption
• Fidelity
• Sustainability…
Traditional purview of Effectiveness +/- Improvement Studies
Assessments
Qualitative
Quantitative
Are people doing what you want?
Are outcomes improving?
Implementation + Improvement

Hybrid Studies

- Evaluate both effectiveness & implementation strategies
  - Do not assume real world effectiveness of efficacious interventions
  - Can use most of the designs we will discuss

Type 1

- **Testing effectiveness**
- Also gather some data to inform future implementation

Type 2

- **Effectiveness & implementation strategies are tested simultaneously**, with equal weight

Type 3

- **Testing implementation strategies**
- Also gather some measures of effectiveness

Source: Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50(3):217-226.

Hybrid Type 1: Primarily Testing Effectiveness

- Examine **patient function/symptoms as primary outcomes** in response to the intervention while also examining some implementation outcomes (often feasibility and acceptability of the implementation strategy)

- Implementation outcomes typically measured through qualitative or mixed methods

- Recommended use when **there is some efficacy data available but effectiveness (real world) of intervention not fully demonstrated**
  - Some quality work can fall here: Evidence-informed, but not strongly evidence-based interventions
  - ***It may or may not help, and if it does, we're not sure how to get people to do it***

Hybrid Type 2: Equally Testing Implementation & Effectiveness

- Equal focus on testing effectiveness of clinical intervention (clinical data at patient-, clinic-, population-level) & implementation strategy (process data at provider-, clinic-, site-level)

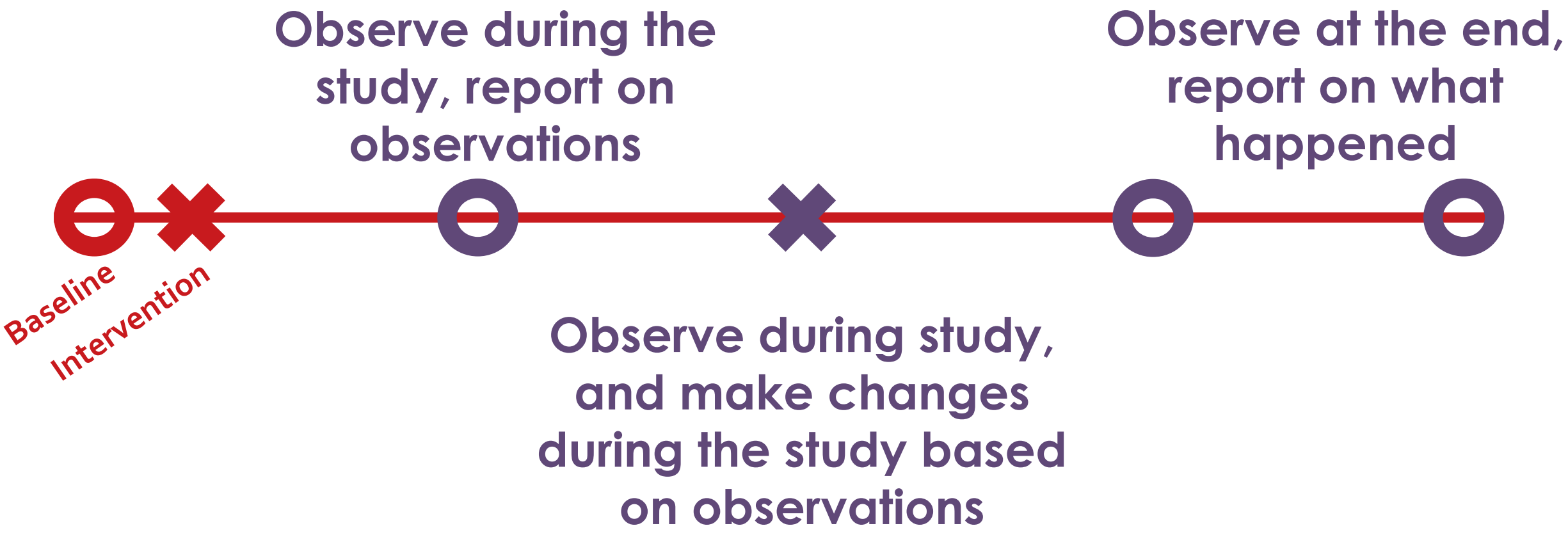
- Implementation outcomes typically measured through qualitative or mixed methods (survey, interviews, EMR)

- Recommended use when **there is robust clinical intervention data available & the implementation research is preliminary**
  - ***It probably works, but may not in my patients because they're different than those in trials, & I'm not sure how to get people to do it***

Hybrid Type 3: Primarily Testing Implementation

- Focus is testing implementation strategy while gathering information on the intervention's impact on patient outcomes
- Focus of implementation strategies tends to go beyond feasibility & acceptability to **adoption, penetration, fidelity**
- Implementation outcomes measured through qualitative or mix methods (survey interviews, EMR, fidelity checks)
  - *Patient outcomes examined quantitatively, but far less focus*
- Recommended use when **robust clinical intervention data available but effects suspected to be "vulnerable" to implementation**
  - ***What is the best way to get people to do this thing with strong evidence?***
  - ***Will the way that we implement affect improvement in patient outcomes?***

When Should We Evaluate Change?



Process Evaluation

- What influences the conduct & quality of implementation?
  - Prior to, during, after the study?
- Results do not change the study processes, but describe them
- May be used more in Hybrid Type 1
  - What happened?
  - How might it inform future implementation?

Formative Evaluation

- Measures take during the study influence later processes in the study

- What's happening? Is it what we want or expected? Can we perturb the strategy to get what we want?
  - Plan Do Study Act is one formative evaluation strategy

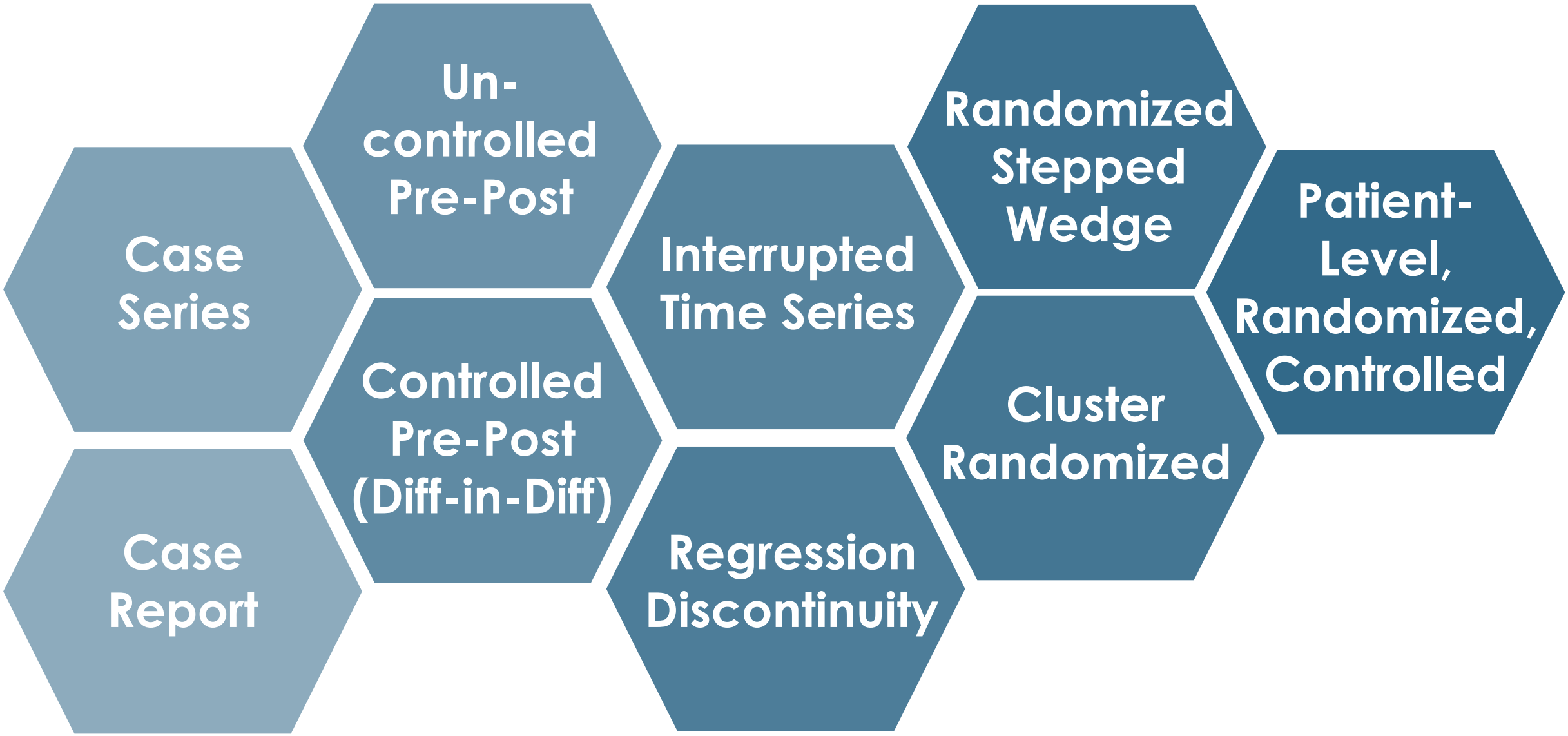
- More in Hybrid Type 2 or Type 3

Summative Evaluation

- What happened at the end of the study?

- What were the measure of success or failure?

Study Design Examples



Causal Inference Theory 101

- There was an intervention
  - For our purposes today, an implementation strategy
- We measured some outcomes of interest
  - Could be qual- or quant-itative measures
  - Depends on your question
- Did the intervention **change** the process and/or outcome?
  - We want to know: Did the intervention **WORK?**

Physics 101

- Work is ONLY done when a force that is applied to an object moves that object

$$W = \text{Force} * \text{Distance}$$

Physics & Causal Inference

- Did our force (strategy) move the outcome?
- We can identify individuals to whom we gave an intervention
- We can measure individuals' outcomes
- We cannot measure that would have happened if we did not give the intervention to the individual
  - The counter-factual, or potential outcomes
- We can only measure pseudo-counterfactuals between individuals, some who got the intervention and some who didn't

The Fundamental Challenge

Implementing something is hard

- How do we know if our strategy worked?

We need to know…

- What would have happened if we did not implement something?
- Who are the "counterfactuals" to our intervention/implementation strategy?

Design = Counterfactual-Building (often)

- The study design you choose is the method you use to build your counterfactuals
- Who is like my intervention group, but did not get the intervention?

Good counterfactuals → **Internally valid design**

- Are these people similar to the ones who I'll end up using this on?

Risk-benefits in study sample = Risk-benefits in target population → **External validity**

Back to Study Designs

Uncontrolled pre-post

Cluster randomization
Step wedge RCT

Level of Causal Inference (Internal Validity)

Case report
Case series

(Quasi-experimental)
Controlled pre-post
Interrupted time series
Regression discontinuity

Individual RCT without contamination

Level of External Validity, Resources, Ease, Ethics

Case Studies

- No counterfactuals
  - So not used for estimating causal effects
  - But valuable!
- Pre-intervention case study
  - Evaluate readiness to change
  - Facilitators/barriers
  - Plan theoretical models, develop strategies
- Similar for post-intervention
  - What went wrong or right?

Uncontrolled Pre-Post

- Probably the most common study design

PRO:

- Simple
- Measure/do/measure (OXO)
- Can adjust for measured confounders

CON:

- Anything that has changed over time breaks the counterfactual
- Unmeasured confounding by time

- Commonly "confounding by secular trends"

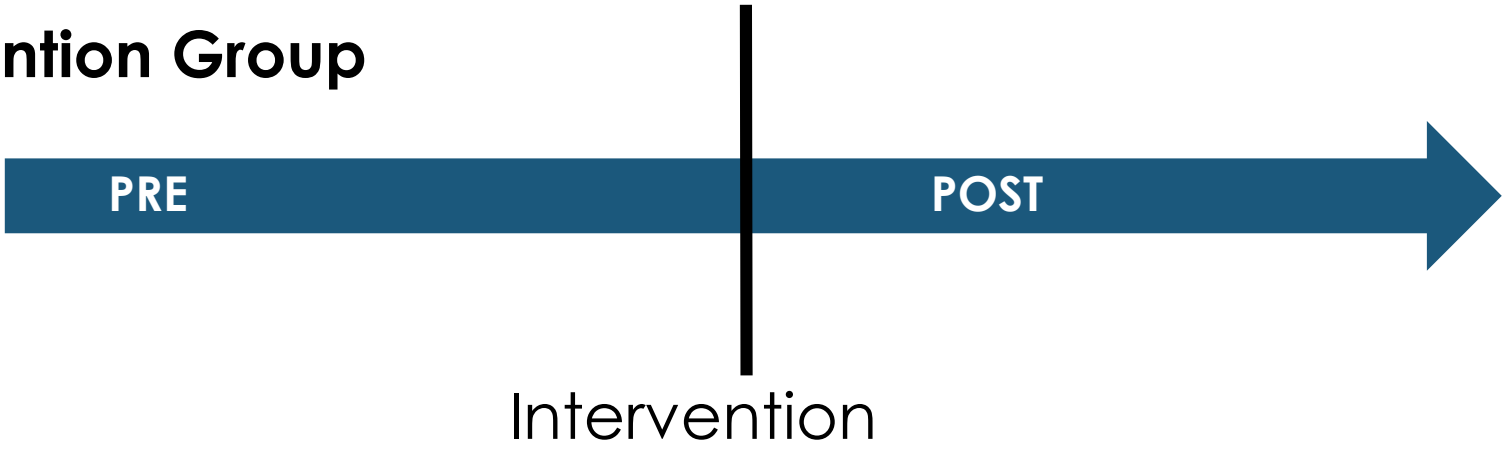
Quasi-Experimental Designs

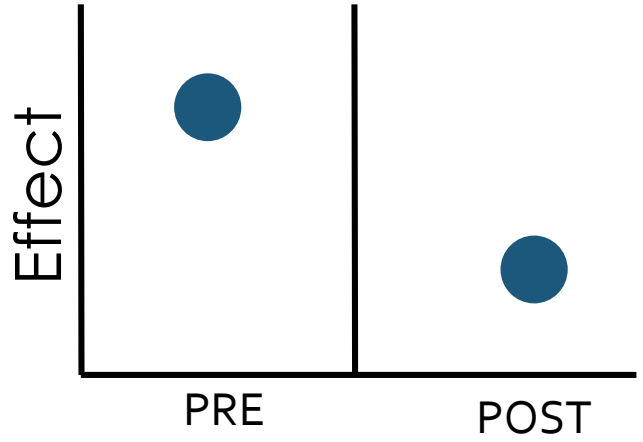
- Intervene in a way that offers a minimally confounded control group
  - Create a better counterfactual

- The econometrics designs
  - Difference-in-Difference
  - Interrupted Time Series
  - Regression Discontinuity Design

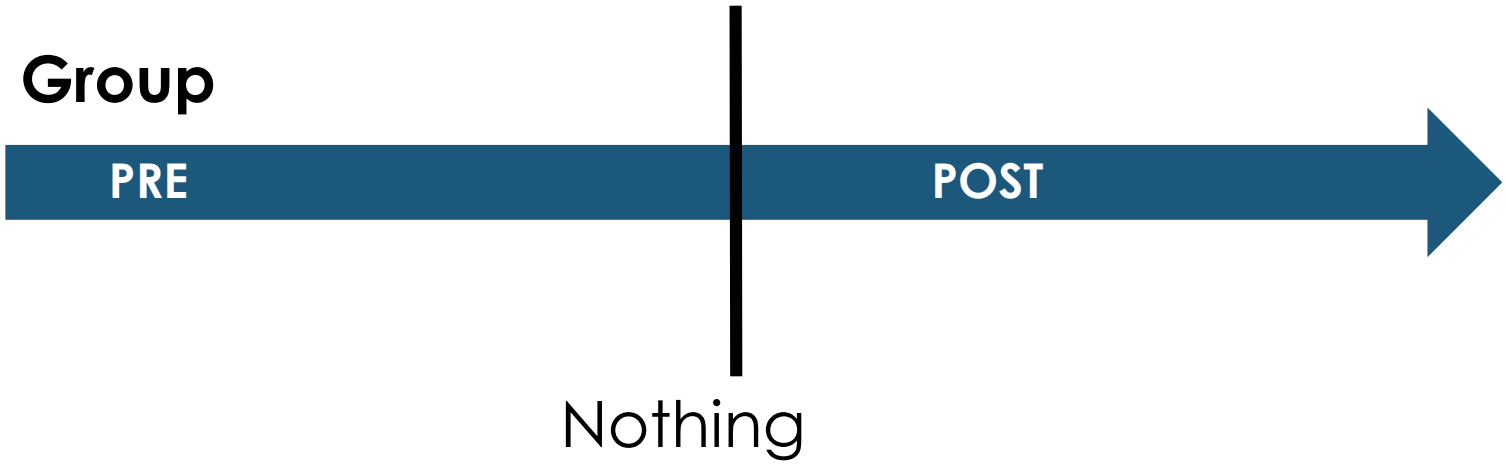
Controlled Pre-Post/Difference-in-Difference

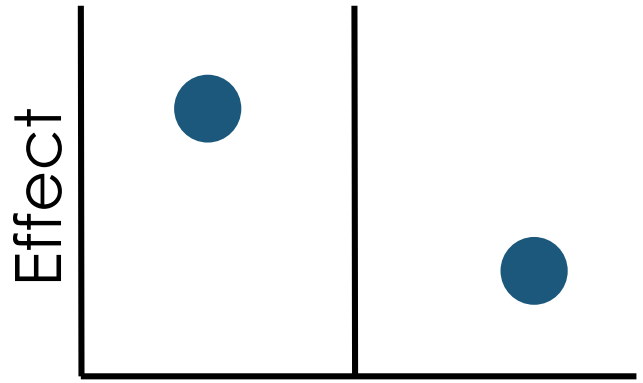
Intervention Group





Control Group





Interrupted Time Series (ITS)

- For interventions implemented at a specific time
- An improvement over simple pre-post design because it takes into account confounding by secular trends

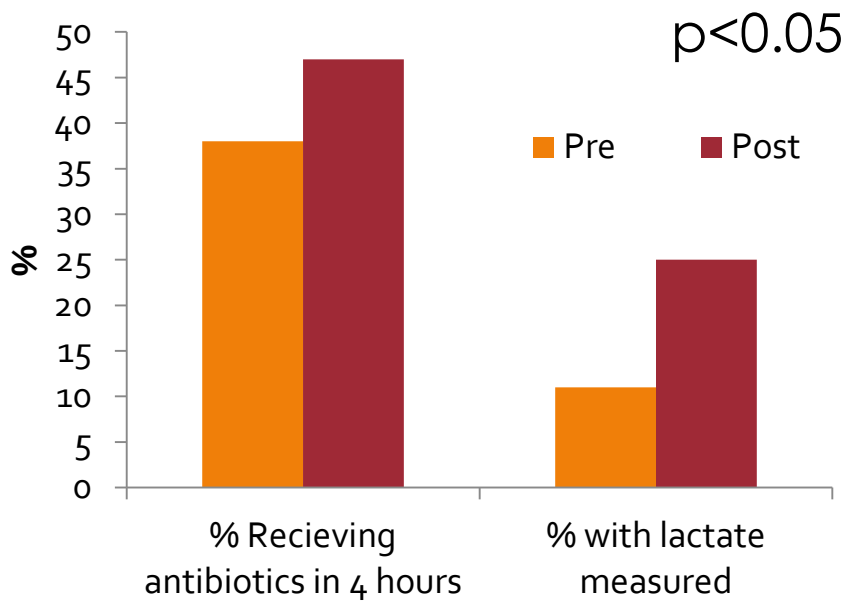
Outcome = exposure + other variables + time

Pre-Post ITS

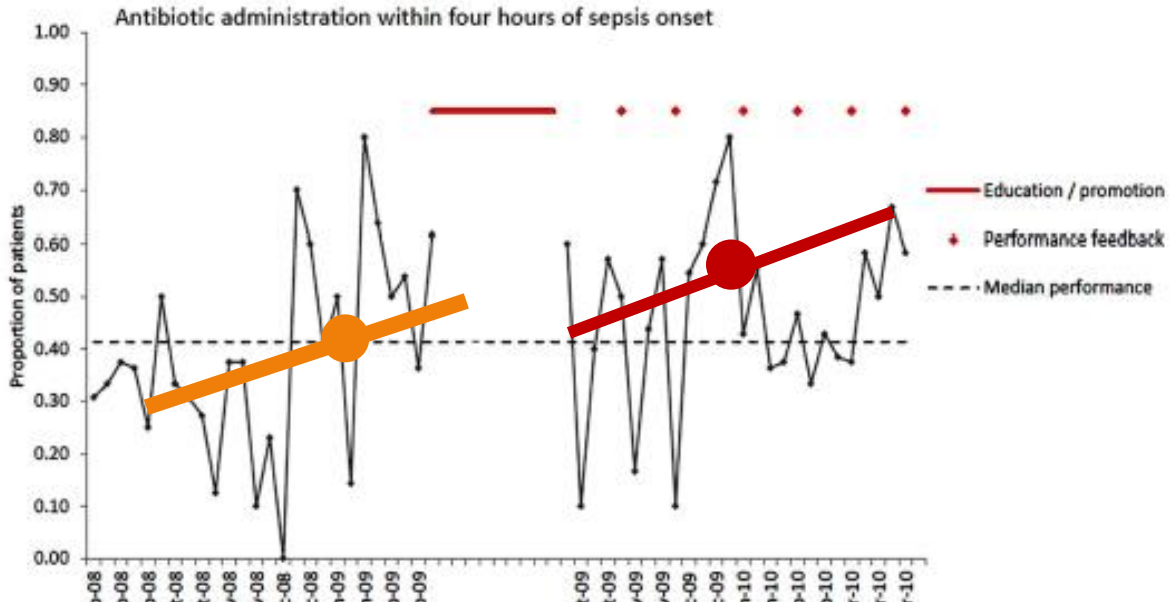
- CON: Need ~6M pre-post, sharp cut-off in intervention (no continuous Plan Do Study Act)

A multifaceted intervention to improve sepsis management in general hospital wards with evaluation using segmented regression of interrupted time series

Simple Pre- Post- Analysis



Interrupted Time Series Analysis



No difference!

Source: Marwick C, Guthrie B, Pringle JE, Evans JMM, Nathwani D, Donnan PT, Davey PG. A multifaceted intervention to improve sepsis management in general hospital wards with evaluation using segmented regression of interrupted time series. *BMJ Quality & Safety*. 2013;23(12):e2.

Regression Discontinuity Design (RDD)

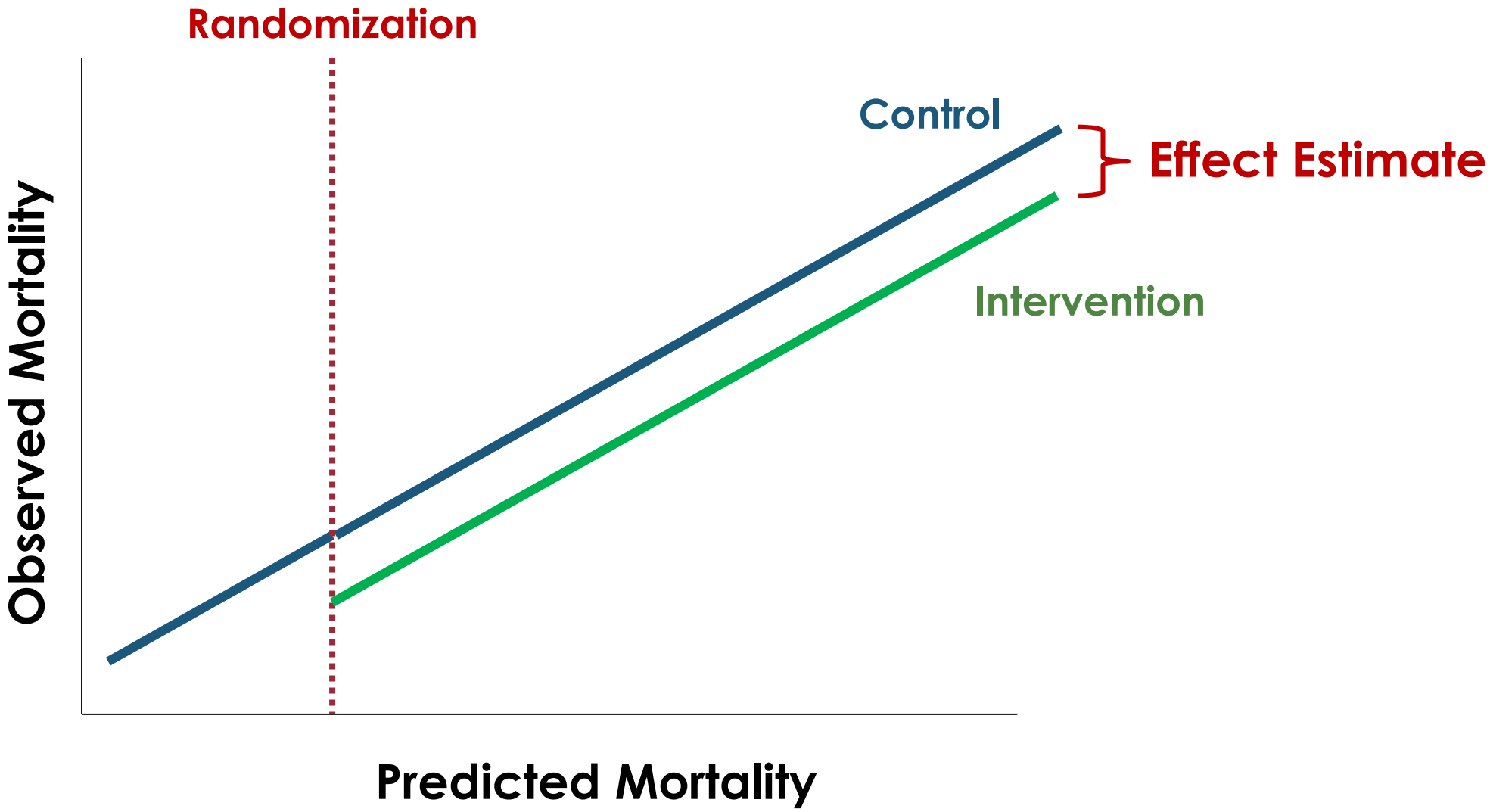
- For interventions planned to be implemented at a **threshold** of a continuous value

- Like ITS, but you choose a value to implement on that may have clinical meaning
  - E.g., only do intervention for highest risk

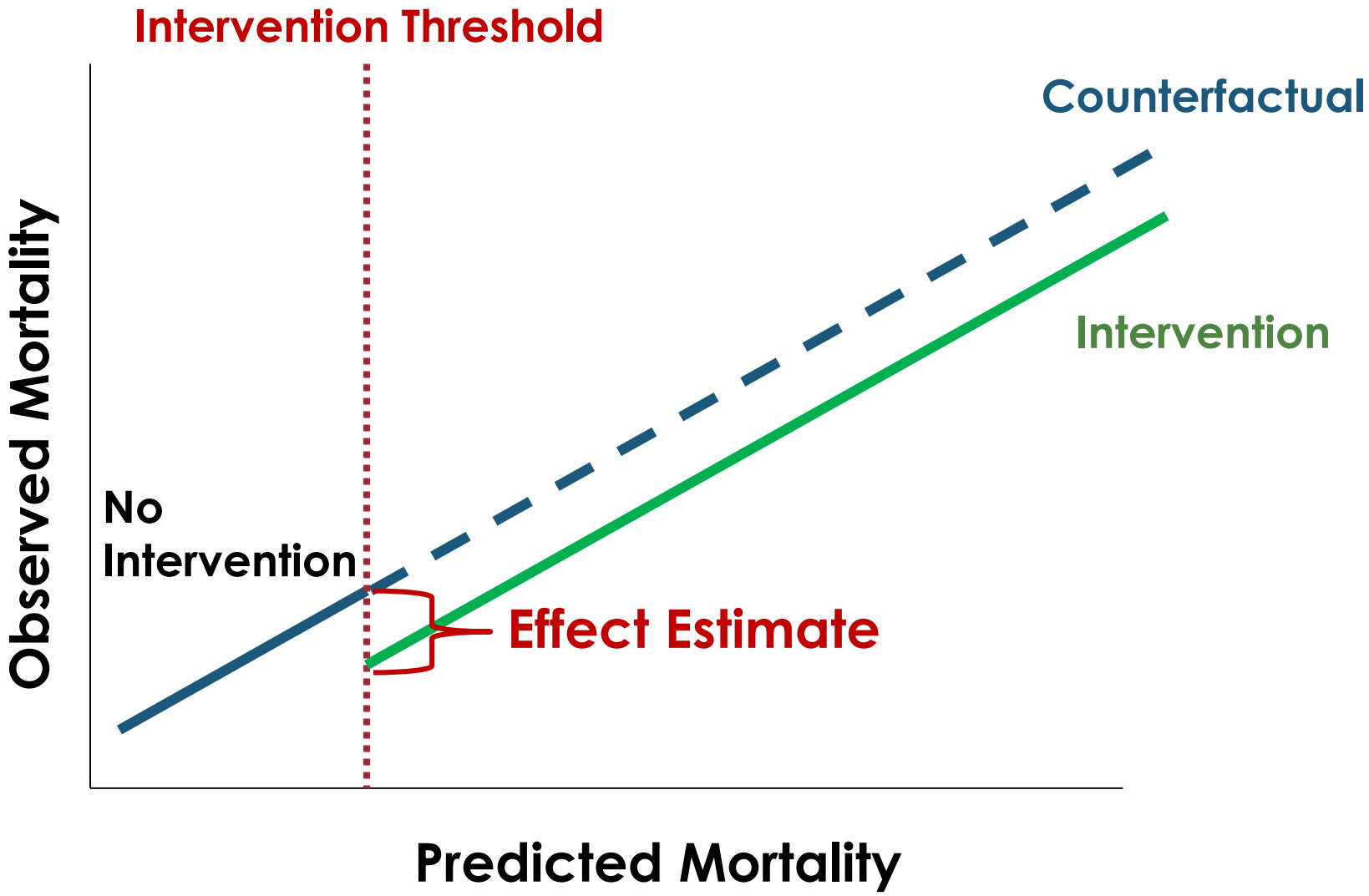
- Noise in intervention assignment at implementation threshold → randomization
  - People assigned just above and below the threshold are counterfactuals

- CONs:
  - Need threshold
  - Correct functional form
  - No manipulation of score
  - Requires large N (4x RCT)

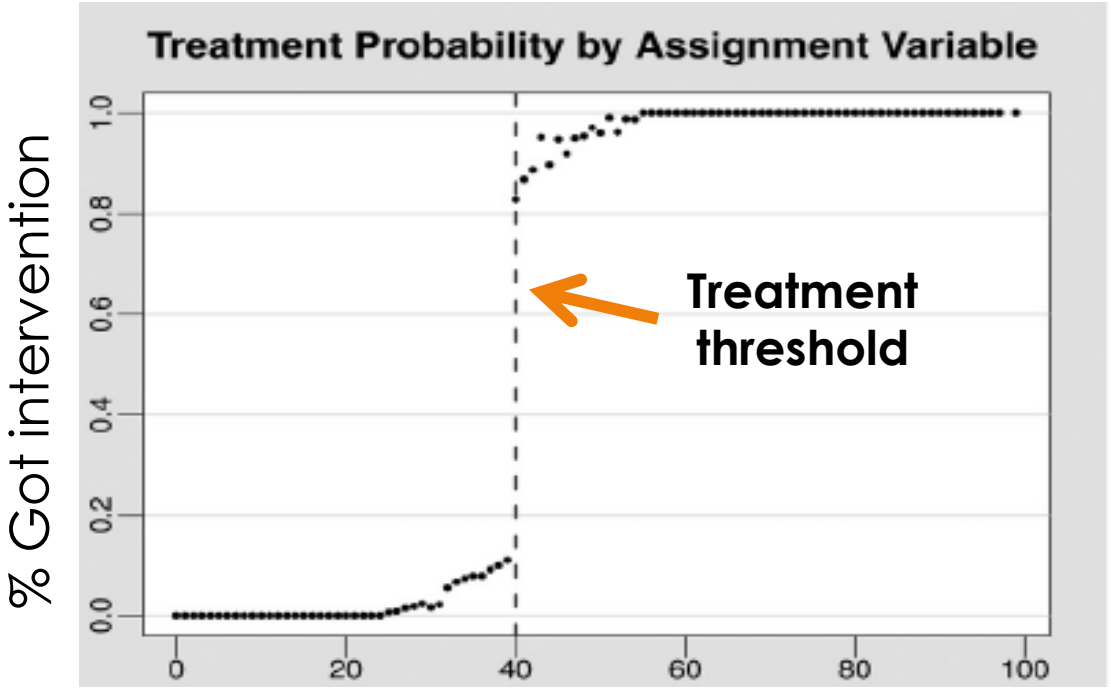
A Randomized Controlled Trial



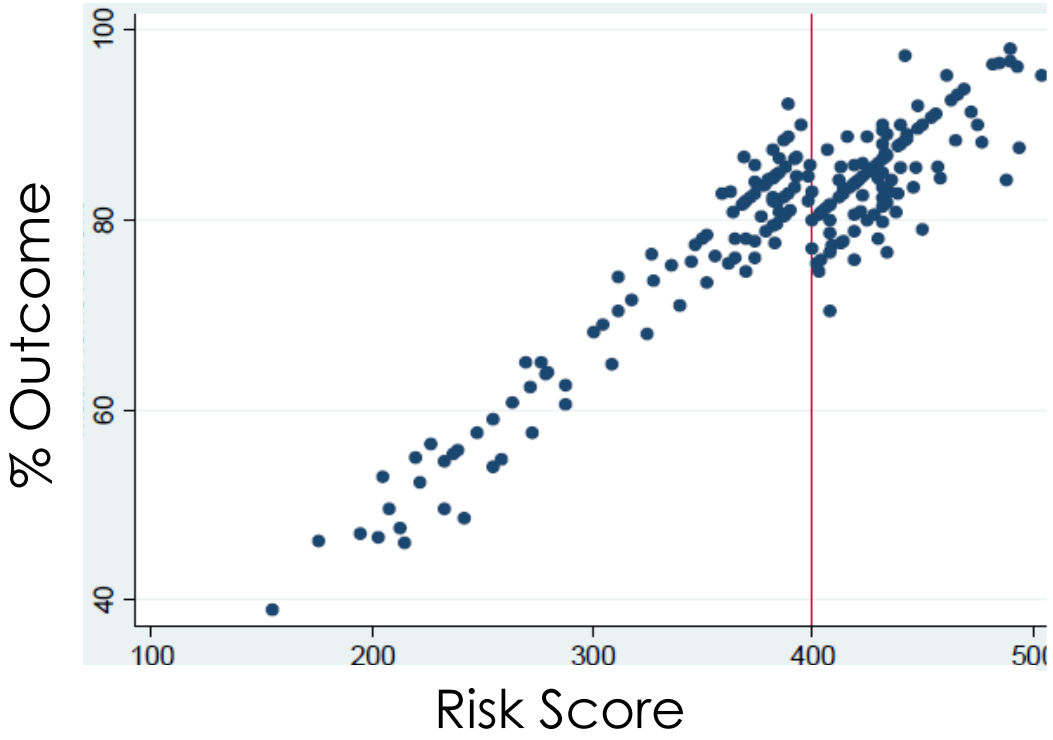
A Regression Discontinuity Design



RDD As Continuous Evaluation of Implementation & Improvement

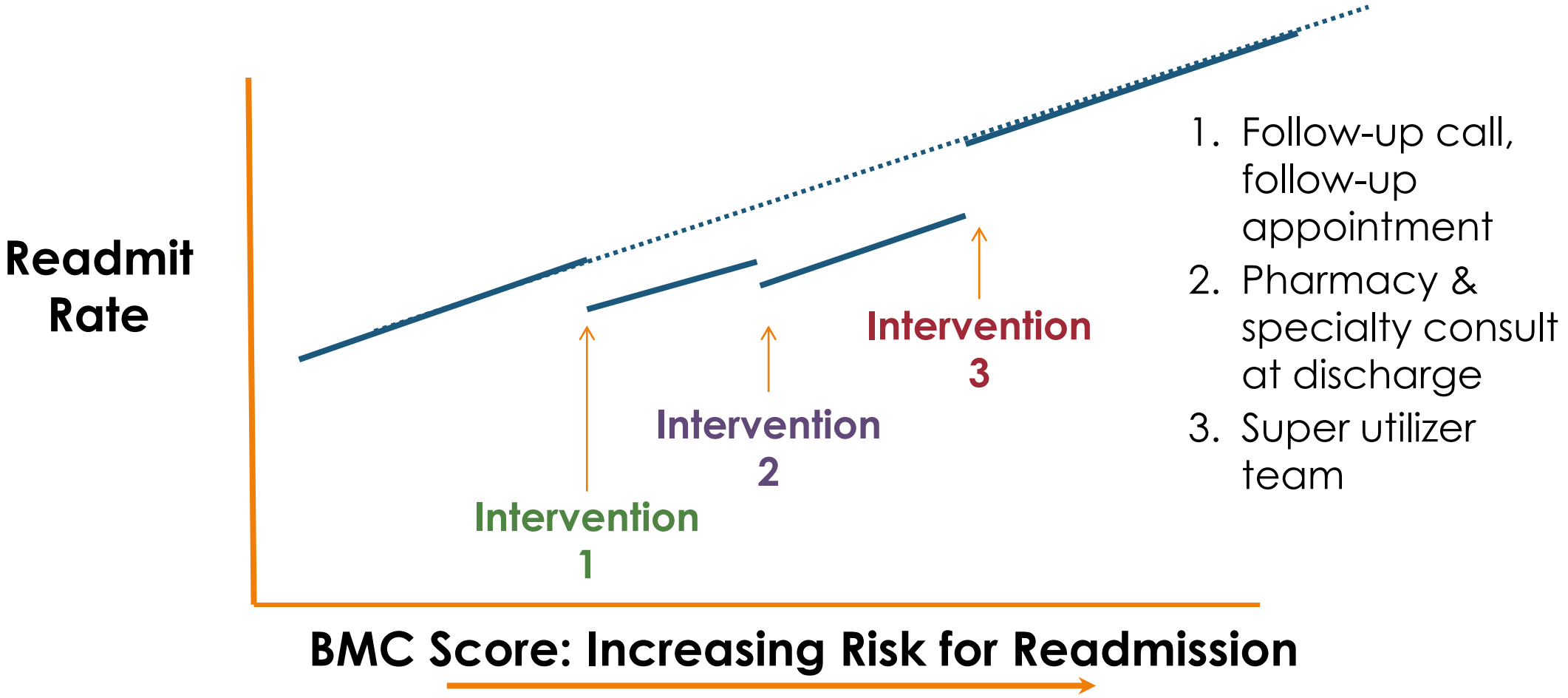


Did Implementation Occur?
Why, why not?



Did Improvement Occur?
Why, why not?

Theoretical Model for Evaluating Readmission-Reduction with RDD – 3 at same time



1. Follow-up call, follow-up appointment
2. Pharmacy & specialty consult at discharge
3. Super utilizer team

Stepped Wedge Cluster RCT

- Start intervention sequentially at randomly chosen sites
- A controlled pre-post, but at many sites, at different times

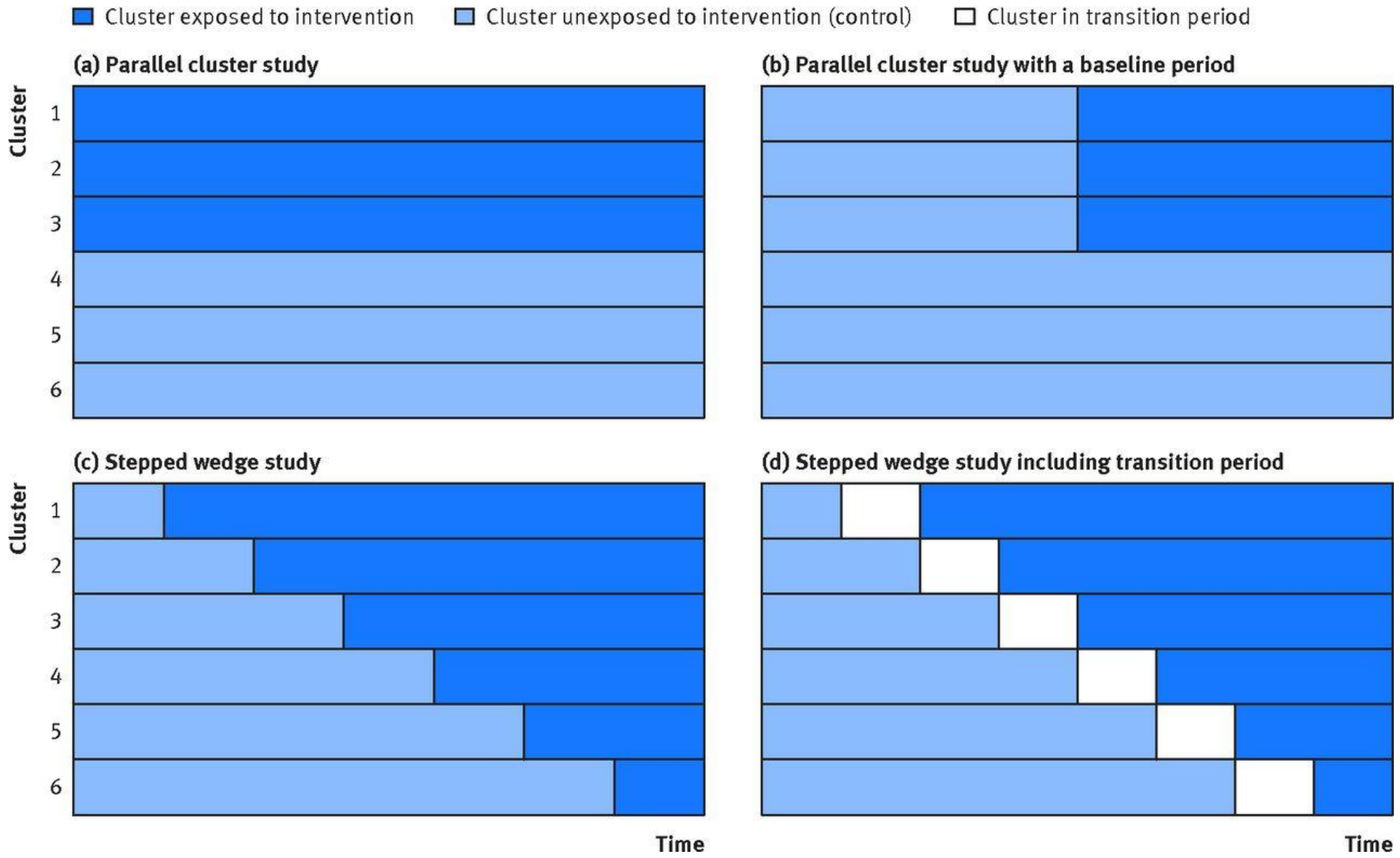
PRO:

- Every site gets the intervention, eventually!
- Limit contamination of individual RCT
- Cluster randomization → waived consent

CON:

- Need many sites
- Power calculations are difficult (site & time correlations)
- Blinding
- Secular trends can confound

Conventional Parallel Cluster Study (with Variations) & the Stepped Wedge Study



Source: Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomized trail: Rationale, design, analysis, and reporting. *BMJ*. 2015;350:h391

Power

	Intra-cluster correlation 0.01		Intra-cluster correlation 0.1	
	Simple parallel cluster RCT	Stepped wedge trial	Simple parallel cluster RCT	Stepped wedge trial
Number of clusters	20	20	20	20
Cluster size	50	50	50	50
Total sample size	1000	1000	1000	1000
Number of steps	0	4	0	4
Number of clusters per step		5		5
Power*	0.97	0.88	0.50	0.82

Source: Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomized trail: Rationale, design, analysis, and reporting. *BMJ*. 2015;350:h391

Parallel Cluster Randomization

PRO:

- Similar to stepped wedge
- No contamination, waived consent
- Avoid confounding by secular time trend

CON:

- Similar to stepped wedge
- Not all sites get the intervention in the end

Individual Patient RCT

PRO:

- Most efficient statistically
- Blinding

CON:

- Contamination for most implementation & improvement initiative across individual patients
- Infrastructure for consent & individual data collection
- Ethics of randomizing individuals to strategies meant to improve evidence-based interventions

Factorial Designs

Test multiple different intervention components simultaneously

Group	Factor A: Information Display	Factor B: Presentation of Statistics	Factor C: Risk Presentation	Factor D: Order of Presentation	Factor E: Health Risk Context
1	Pictograph	100	Incremental	Benefits first	Present
2	Pictograph	100	Incremental	Risks first	Absent
3	Pictograph	100	Total	Benefits first	Absent
4	Pictograph	100	Total	Risks first	Present
5	Pictograph	1000	Incremental	Benefits first	Absent
6	Pictograph	1000	Incremental	Risks first	Present
7	Pictograph	1000	Total	Benefits first	Present
8	Pictograph	1000	Total	Risks first	Absent
9	Prose only	100	Incremental	Benefits first	Absent
10	Prose only	100	Incremental	Risks first	Present
11	Prose only	100	Total	Benefits first	Present
12	Prose only	100	Total	Risks first	Absent
13	Prose only	1000	Incremental	Benefits first	Present
14	Prose only	1000	Incremental	Risks first	Absent
15	Prose only	1000	Total	Benefits first	Absent
16	Prose only	1000	Total	Risks first	Present

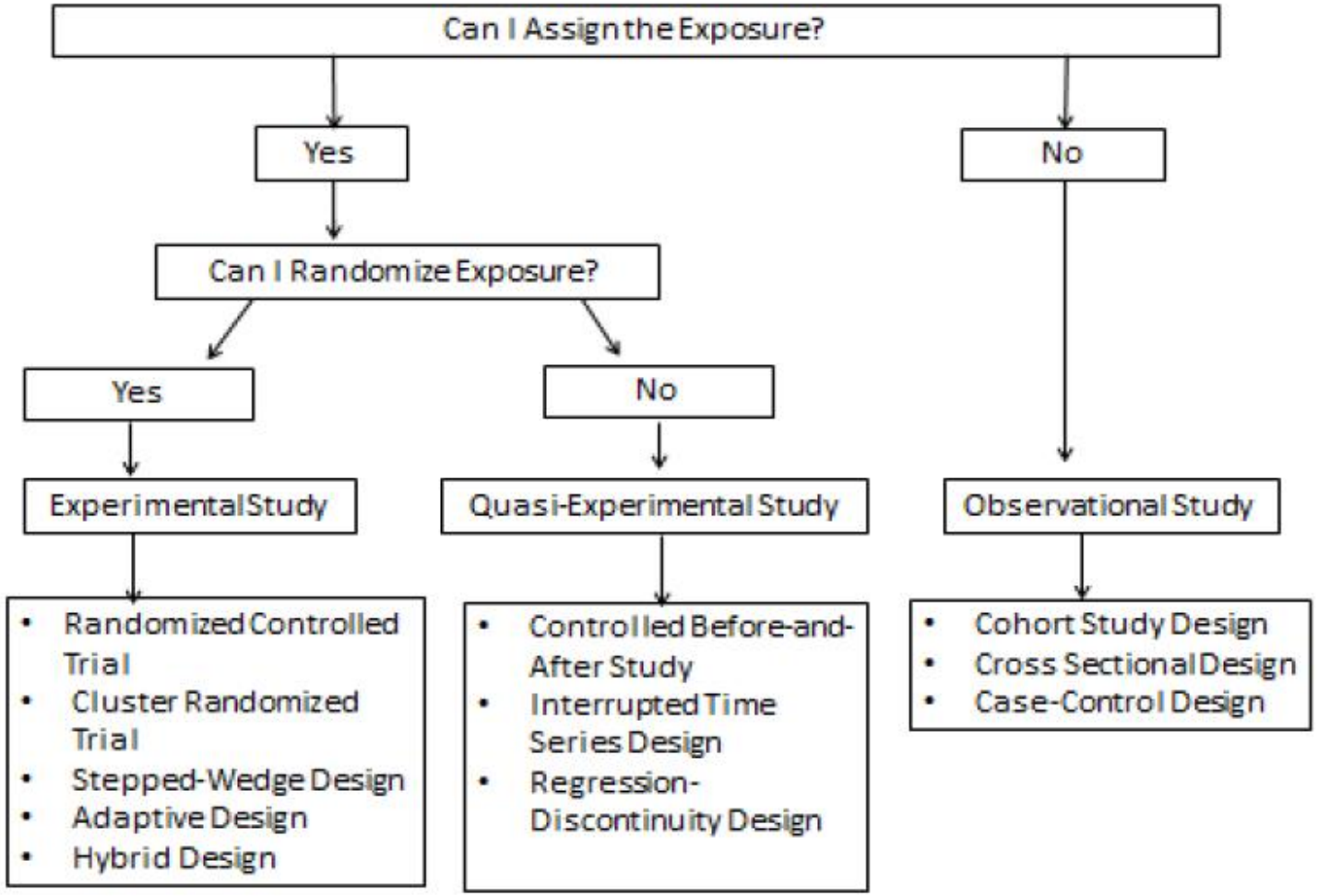
Source: Nair V, Strecher V, Fagerlin A, Ubel P, Resnicow, K…Zhang A. Screening Experiments and the use of fractional factorial designs in behavioral intervention research. *Am J Public Health*. 2008;98(8):1354-1359.

What's the Worst Study Design?

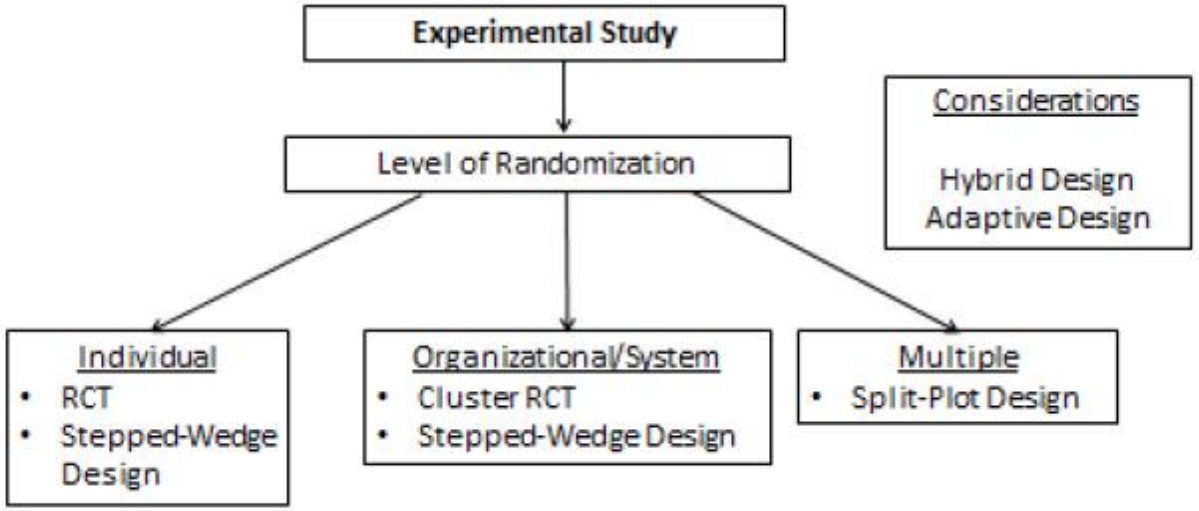
- INCONCLUSIVE

- How to avoid:
  - Clearly defined intervention, strategy, outcomes
  - Methods match goals
  - Adequate sample size for realistic effect estimate
  - Mixed methods

Putting It All Together



Source: Lewis E, Baumann A, Gerke D, Tabak R, Ramsey A, Small S & Proctor E. D&I Research Designs. St. Louis, MO: Washington University; 2017 July. Eight toolkits related to Dissemination and Implementation.



Quasi-Experimental Study

Group by Appropriate Control Site	Group by Specific Qualifying Characteristics	Group by Time
Controlled Before-and- After Study Design	Regression-Discontinuity Design	Interrupted Time Series Design

Randomization Plan

Randomized by Intervention	Randomized by Time
RCT	Stepped-Wedge Design
Cluster RCT	

Source: Lewis E, Baumann A, Gerke D, Tabak R, Ramsey A, Small S & Proctor E. D&I Research Designs. St. Louis, MO: Washington University; 2017 July. Eight toolkits related to Dissemination and Implementation.

An Intervention to Prevent Bad Outcomes in Your Favorite Disease

	Efficacy	Effectiveness	Implementation
Hypothesis	RCT, randomize at patient level, quantitative methods	RCT or quasi-experimental at patient level, quantitative methods	RCT, quasi-experimental, observational, at provider or organizational level, mixed methods
Population	Clinical outcomes, primary stressed	Small number of clinical outcomes, risk-harm balance	Emphasize implementation outcomes – adoption, penetration, coverage, fidelity, etc.
Intervention clinicians	Make it consistent at all costs	Work within typical conditions of clinic	Local conditions
Intervention fidelity	Lots of support, not part of usual care	Research support, but separate from regular clinic activities	Research support for training only

Key Takeaways

- Study designs abound, but not all are equal
  - Need to understand strengths/weaknesses of each design
- **Study designs need to match YOUR questions**
  - Efficacy, effectiveness, implementation, Hybrid
- Can perform qualitative or quantitative within any design

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Tell Us About Your Projects

- What is your research question?
- Which of the study designs we discussed work for your research?
- Where do you get stuck? What is a puzzle here that is hard to sort out and solve?

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2018 CIIS Pilot Grant Funding

Intent to Submit Form 3/18/18

Receive CIIS Feedback

Study Proposal Application 6/15/18

Thank You!

Contact CIIS

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