Study Designs and Analysis for D&I Research

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Outline

Considerations for study design choice

- Research question
- Type of evidence required
- Levels at which D&I strategies, EBI operate

Types of designs

- Within-site
- Between-site
- Within- and Between-site
- Hybrid

Resources available

Maximizing the impact of the research



What would you do?

You are working on a team focused on healthy aging for older adults. Your colleagues have developed an evidence-based intervention to reduce inappropriate prescribing in nursing homes, which was shown to reduce hospitalizations. Your funders are looking for a cost-efficient way to implement the intervention to maximize potential reach. Your team is interested in testing two implementation strategies: 1) a training model for nursing home physicians, nurses, and pharmacists (initial training + 4 monthly sessions), and 2) creating clinical care teams to review medications for nursing home residents.

How would you go about deciding a study design? What factors would you consider?

Considerations for study design choice



D&I research questions



What D or I strategy is most relevant to the population and the EBI?

What factors impact the decision to disseminate or implement?

Does D or I of the EBI work with the chosen strategies?

What strategies are needed to maintain or extend use of the EBI?

Internal vs. external validity



Threats to internal validity

Threats	Study Design Feature to Minimize Treat	
Ambiguous temporality	Manipulate the causal factor, multiple repeat observations over time	
Selection	Randomization	
History	Select groups from the same general location & ensuring that similar measurement schedules in each group	
Maturation	Select groups \sim the same age or the same general location & multiple pre-test measures	
Regression to the mean	Stratify based on scores and randomize extreme scores to both conditions, select participants based on multiple measures	
Attrition	Use strategies to reduce dropout rates	
Testing	Use similar instruments for all individuals or groups	
Instrumentation	Avoid switching instruments or items on a measure during the study, multiple repeat measures over time	

Threats to external validity

Causal Relationships do not hold true over:	Study Design Features to Minimize Threat	
People	Reduce restrictions on the eligibility criteria	
Treatment variations	Use theory to hypothesize/study key components of the intervention or factors that influence implementation. Test min. intervention required	
Outcomes	Use multiple outcome measures	
Settings	Conduct studies in multiple settings. Use theory to describe/measure the characteristics of settings that influence generalizability of findings	

Comparisons

Your research question should state a comparison

• Typically by D&I strategy/group or time



BY GROUP





Types of evidence



Engage stakeholders



Levels of D&I strategies and EBIs



D&I is inherently multi-level!

Consistency of design components



Keep the levels of assignment, strategy, and measurement consistent!

Types of study designs

Categories of D&I research designs

- 1. Within-site
 - Evaluate implementation successes or failures by examining changes inside an organization, community, or system
 - Evaluate changes over time within one or more sites exposed to the same D&I strategy
- 2. Between-site
 - Compare processes and output among sites that have different exposures
- 3. Within- and between-site

Within-site: Interrupted time series

Multiple data collection points, with a dissemination or implementation effort in between

 $O_1 O_2 O_3 O_4 X O_5 O_6 O_7 O_8$

- O = observation (data collection time point), numbered by subscript
- X = EBI dissemination or implementation



Between-site: Factorial designs

Investigates combination of ≥ 2 ISs at a time

Each experimental factor has ≥ 2 levels

2×2 factorial design

- Assigns units randomly to 1 of 4 conditions
- Provides estimates of each factor by itself and of their interactions

Incomplete factorial designs: \geq 1 arms are excluded

2x2 Factorial Design					
	IS-B Level 1	IS-B Level 2			
IS-A Level 1	1	2			
IS-A Level 2	3				

3x3 Factorial Design						
	IS-B Level 1	IS-B Level 2	IS-B Level 3			
IS-A Level 1	1	2	3			
IS-A Level 2	4	5	6			
IS-A Level 3	7	8	9			

Between-site: SMART designs

Sequential multiple assignment randomized implementation design (SMART)

Special case of the factorial experiment

Multistage randomization (adaptive)

- Site-level implementation process can be modified if unsuccessful
- Can optimize allocation of available resources and change its approach if a strategy is failing



Within- and Between-sites: Stepped wedge

Stepped wedge is one type of rollout design

Time that sites receive D/I strategy is assigned by the researcher

All sites receive the D/I strategy and EBI at some point

Measurement as each group transitions allows within- and between-site comparisons



Hybrid designs



Putting it all together



Summary points

Many factors play into the choice of a study design

Main considerations

- Research question
- Type of evidence needed
- Levels of your D&I strategies and EBI

Many study designs available for D&I research that fit nuances of D&I research, individual phases of D&I research

As you develop research plans, make close friends with a biostatistician and/or design expert

Resources

DIRC Design toolkit (and consultants!)

 Lewis, E., Baumann, A., Gerke, D., Tabak, R., Ramsey, A., Small, S. & Proctor, E. D&I Research Designs. [Internet]. St. Louis, MO: Washington University; 2017 July. Eight toolkits related to Dissemination and Implementation. Available from <u>https://sites.wustl.edu/wudandi</u>

Penn State Methodology Center

- Support for SMART, MOST, factorial designs
- <u>https://methodology.psu.edu/</u>

Implementation Science Webinar Series

- National Cancer Institute (NCI) Division of Cancer Control & Population Sciences Implementation Science Team
- <u>https://cyberseminar.cancercontrolplanet.org/implementationscience/</u>

2014 Training Institute for Dissemination and Implementation Research in Health (TIDIRH) presentations

- <u>http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2014/agenda.html</u>
- Designs for D&I Research, Dr. David Marrero
 - <u>http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2014/Presentations/July%2021/4_Marrero_DesignsforD&IResearch.pdf</u>

References

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Curran GM et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care*. 2012 Mar; 50(3): 217-26.

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Questions?

