Study Designs in Implementation Science

Gregory A. Aarons, PhD
Department of Psychiatry
UC San Diego, La Jolla, CA

Child and Adolescent Services Research Center
San Diego, CA

UC San Diego
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Overview

- Study Design Considerations
- Observational Designs
- Experimental Designs
- Quasi-Experimental Designs
- Effectiveness-Implementation Hybrid Designs
- Mixed Methods Designs

Brown, C.H., Curran, G., Palinkas, L.A., Aarons, G.A., Wells, K.B., Jones, L., Collins, L.M., Duan, N., Mittman, B.S., Wallace, A. and Tabak, R.G., 2017. An overview of research and evaluation designs for dissemination and implementation. *Annual Review of Public Health*, *38*, pp.1-22.

Study Design Considerations

- What is the *best* study design to use in implementation research?
  - Depends on your research question
- Many study designs used in implementation research
- Observational, experimental, quasi-experimental, etc.
- Most designs are pulled from other disciplines
- A few (e.g., effectiveness-implementation hybrid designs) are unique to implementation research

Selecting a Study Design

- Research Question(s)
- Feasibility
- Cost/Personnel
- Setting
- Funding Opportunity
- Stakeholders
- Type of Intervention
- Logistics
- Target Population(s)
- Timeline
- Ethics
- Data

Observational Study Designs

- Studying or assessing phenomena as it occurs naturally
- No randomization, no manipulation
- Cohort study
- Cross-sectional study

Experimental Study Designs

- Randomization *and* manipulation
- Randomized controlled trial (RCT)
- Cluster RCT
- Pragmatic RCT
- Stepped-wedge cluster RCT

Pragmatic RCTs

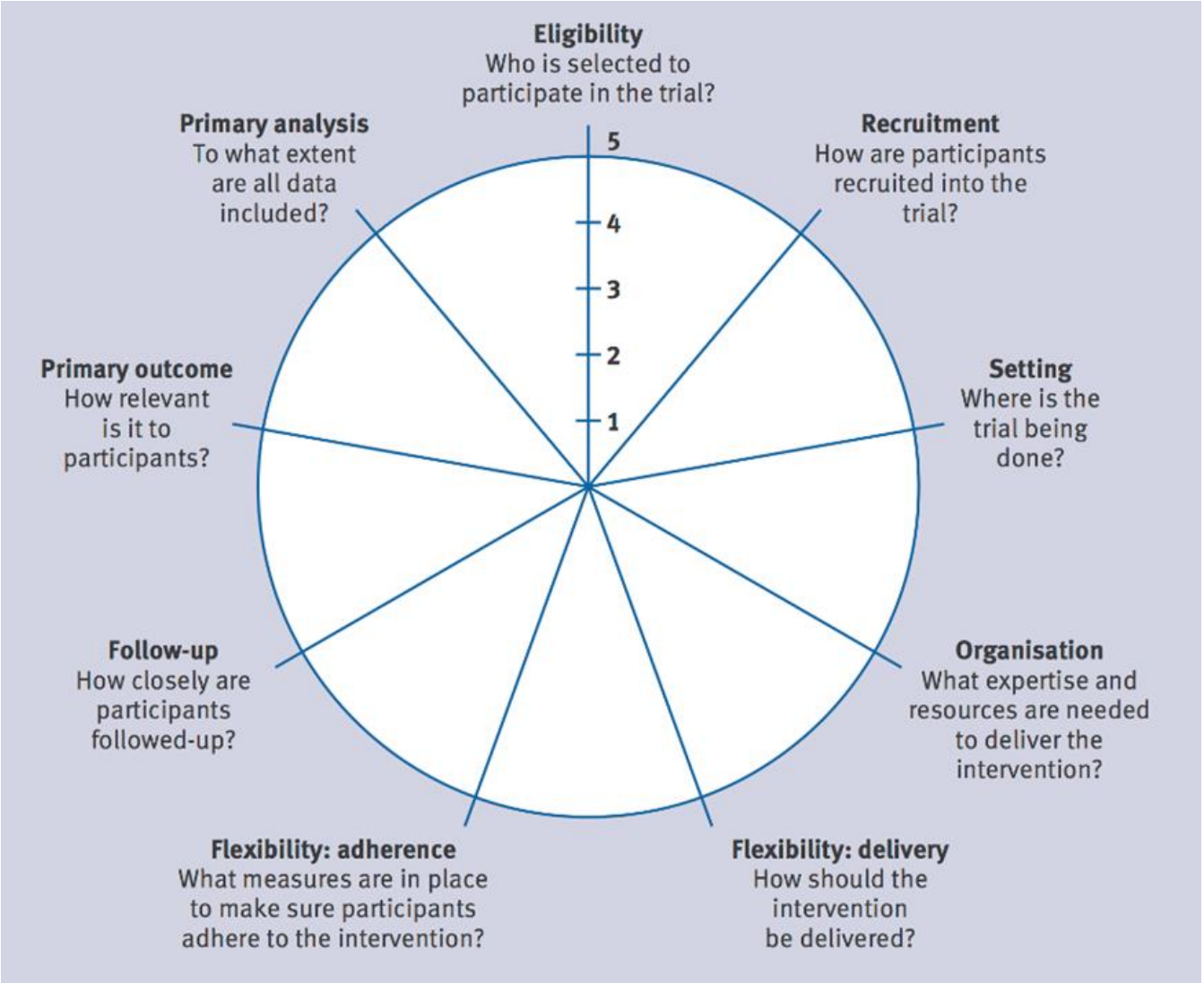
- A pragmatic trial can be broadly defined as a randomized controlled trial whose purpose is to inform decisions about practice (Zwarenstein et al., 2008)
- Explanatory trials measure efficacy—the benefit of a treatment produced under idea conditions.
- Pragmatic trials measure effectiveness—the benefit the treatment produces in routine clinical practice (Roland et al., 1998)
- Explanatory trials maximize internal validity while pragmatic trials prioritize external validity but maintain rigor of RCT

PRECIS

- Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) to help trialists design trials that match their intended use and can be pragmatic across multiple domains (Thorpe et al., 2009)

- PRECIS-2 is second version with 9 constructs and guidance for coding

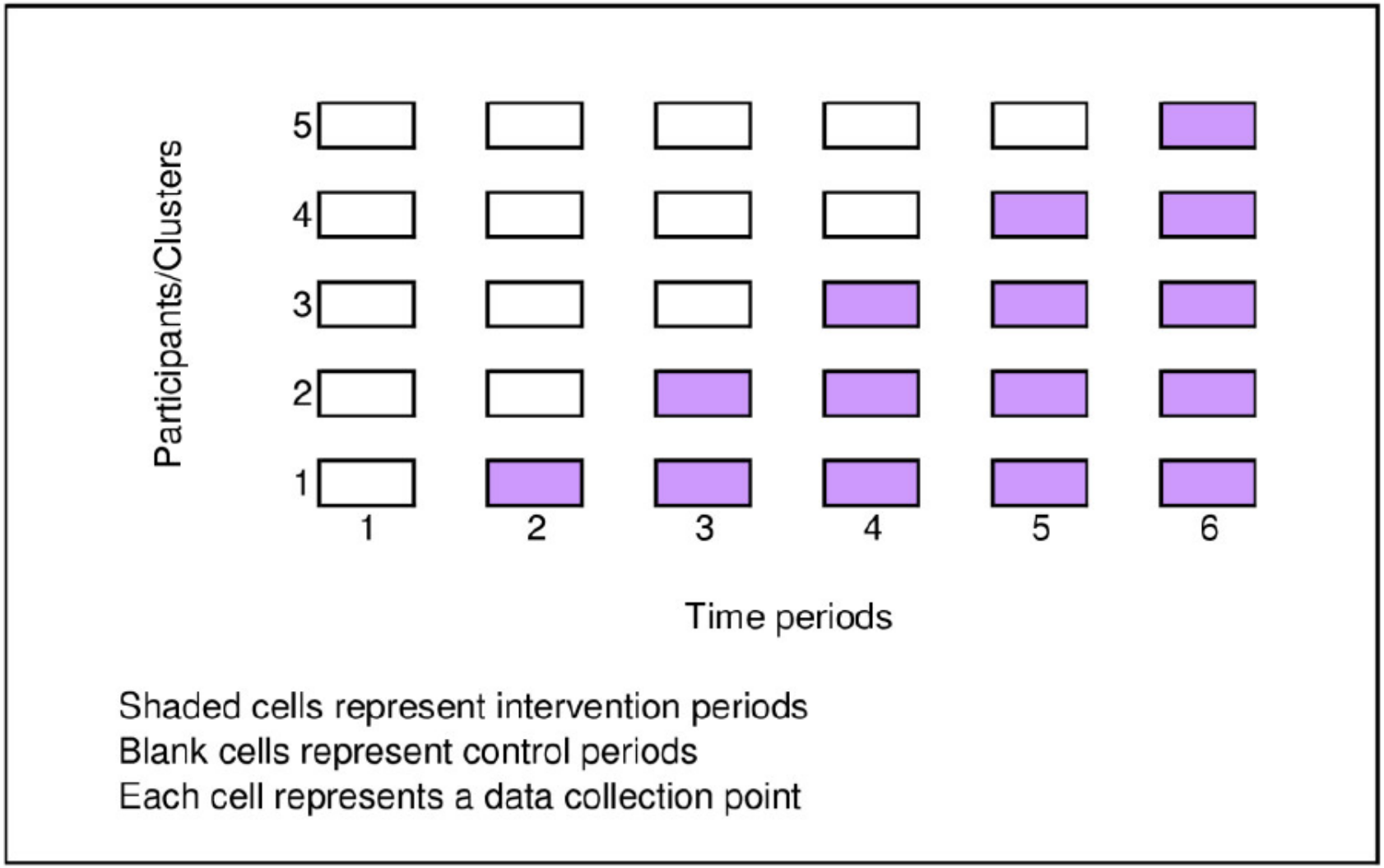
Thorpe, K.E., Zwarenstein, M., Oxman, A.D., Treweek, S., Furberg, C.D., Altman, D.G., Tunis, S., Bergel, E., Harvey, I., Magid, D.J. and Chalkidou, K., 2009. A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *Journal of clinical epidemiology*, *62*(5), pp.464-475.



1 = Very explanatory, 5 = Very pragmatic

Loudon, K., Treweek, S., Sullivan, F., Donnan, P., Thorpe, K.E. and Zwarenstein, M., 2015. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*, *350*, p.h2147.

Stepped-Wedge Cluster RCTs



Brown & Lilford (2006). The stepped wedge trial design: A systematic review. *BMC Med Res Method*.

Quasi-Experimental Study Designs

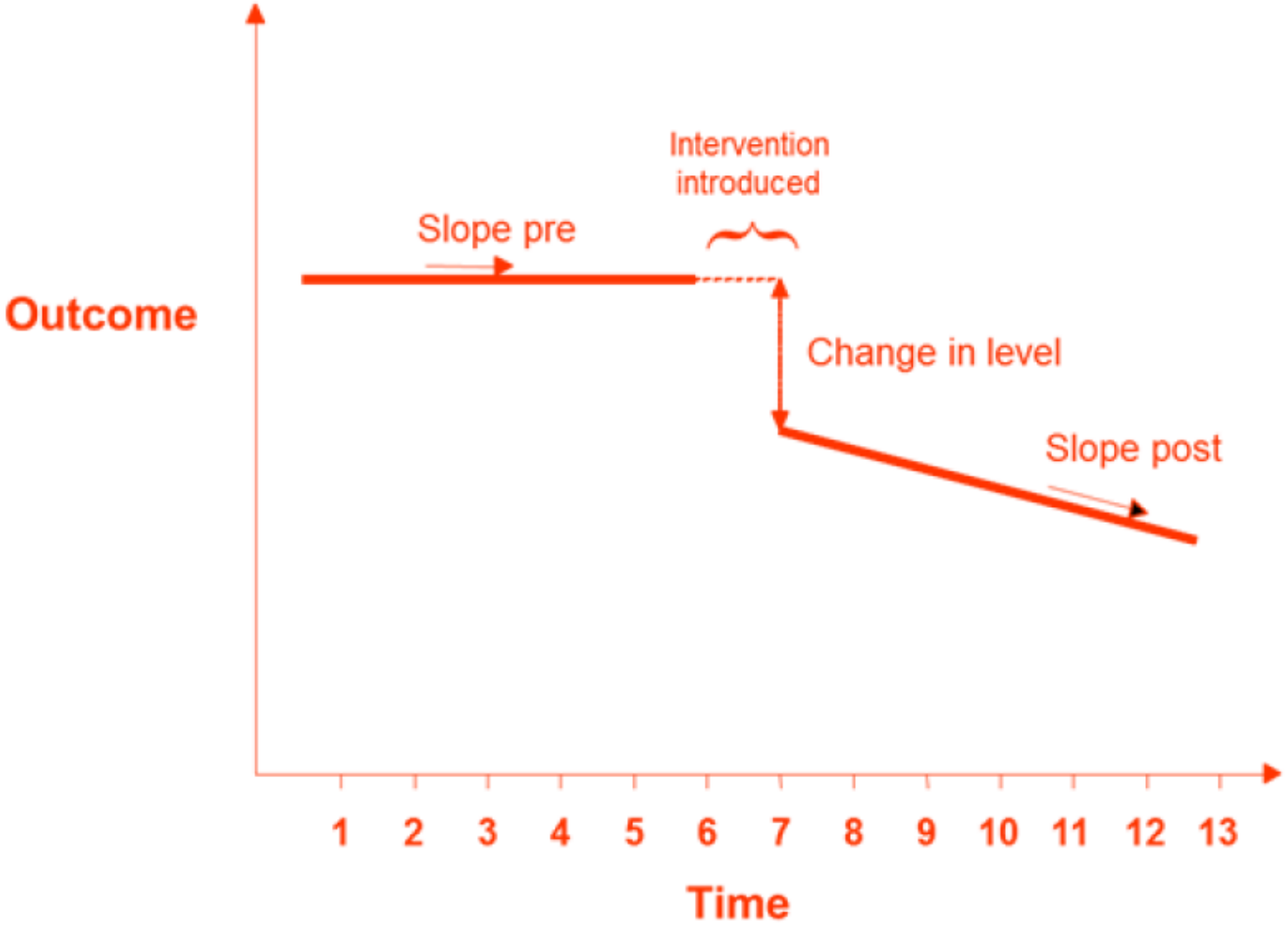
- Regression Discontinuity Design
  - Individuals/groups assigned to intervention or control based on *a priori* score or metric

- Non-Equivalent Control Group Design
  - One group receives intervention, one group is control
  - Can compare groups at baseline (but can't control for unmeasured differences)

- Interrupted Time Series (ITS)
  - Multiple assessments prior to and following introduction of intervention
  - More accurate assessment of outcomes or behavior than single pre-post assessments

William R. Shadish, Cook, T.D. and Campbell, D.T., 2002. *Experimental and quasi-experimental designs for generalized causal inference*. Wadsworth Cengage learning.

Interrupted Time Series



Flodgren & Oddgard-Jensen for Effective Practice and Organization of Care (2013).

Adaptive Designs

- …planned modification of characteristics of the trial based on information for the data already accumulated.” (Brown et al., 2009, p. 4)

- As data are collected, they are used to make anticipated choices about pre-specified alternatives

- Three types of adaptation
  - Relating to specific elements of study design of an ongoing trial
  - Relating to the design of the next trial
  - Relate to intervention or its delivery

Brown, C.H., Ten Have, T.R., Jo, B., Dagne, G., Wyman, P.A., Muthén, B. and Gibbons, R.D., 2009. Adaptive designs for randomized trials in public health. *Annual review of public health*, *30*, pp.1-25.

Sequential Multiple Assignment Randomized Trial (SMART) Designs: Adaptive Interventions for Implementation Research

- Heterogeneity of practices/providers
- Not all barriers/facilitators observable
- Deliver implementation strategies where needed
- React to non-responsiveness/limited uptake
- Reduce implementation burden; use only what is necessary
- Sift through available implementation strategies
- ⇒ More site-specific attention over time
- ⇒ Improving sustainability

Naar-King, S., Ellis, D.A., Idalski Carcone, A., Templin, T., Jacques-Tiura, A.J., Brogan Hartlieb, K., Cunningham, P. and Jen, K.L.C., 2016. Sequential multiple assignment randomized trial (SMART) to construct weight loss interventions for African American adolescents. Journal of Clinical Child & Adolescent Psychology, 45(4), pp.428-441.

SMART Trial: Adaptive Implementation of Effective Programs Trial (ADEPT)

Primary Aim: Among sites not initially responding to REP to implement collaborative care program, sites receiving External and Internal Facilitator (REP+EF/IF) vs External Facilitator alone (REP+EF):

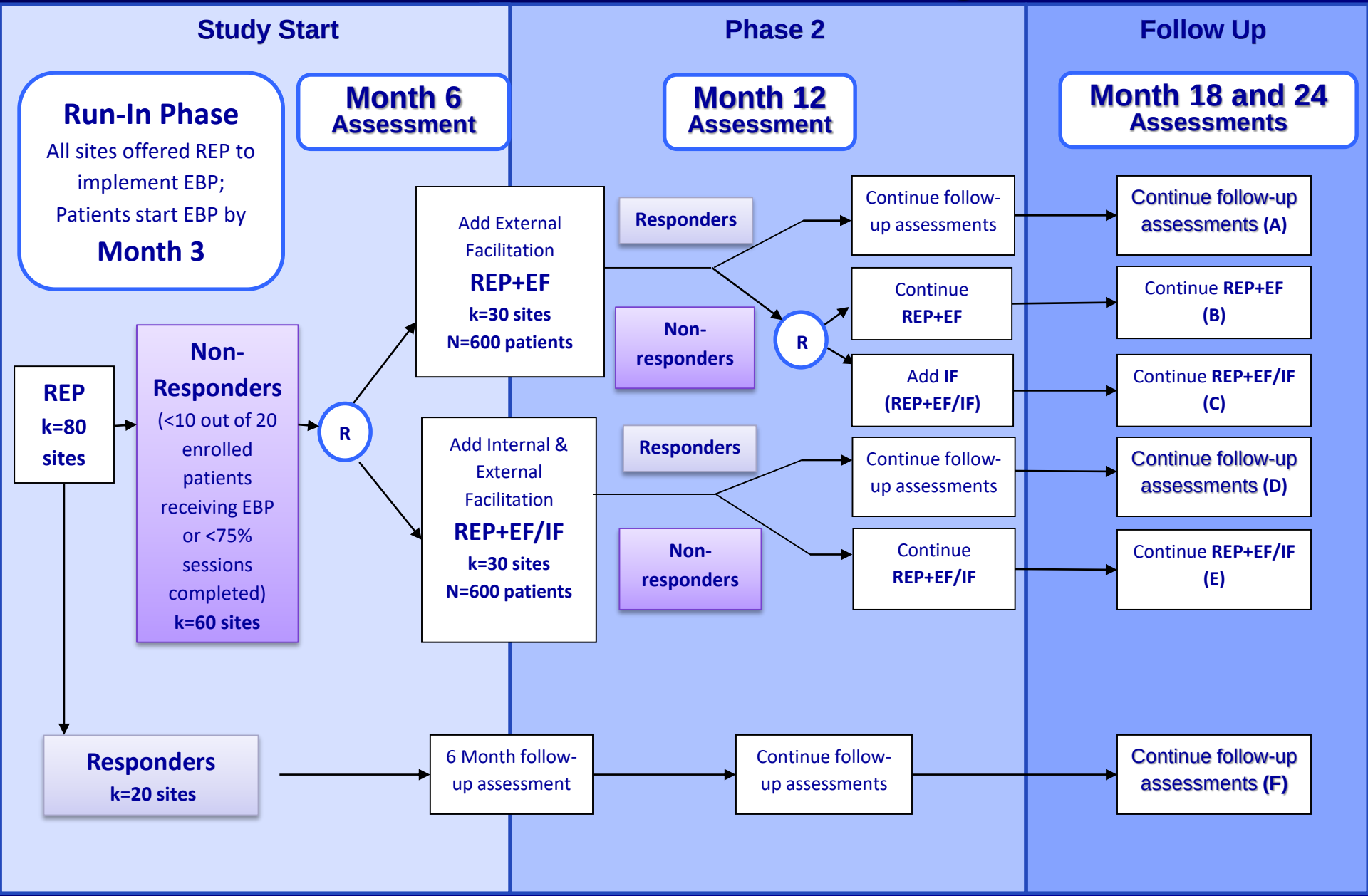
1. Improved 12-month patient outcomes (QOL, sx)
2. Improved uptake (# collaborative care visits)

Secondary Aims:

- Effect of continuing REP+EF versus adding IF
- Effect of continuing with REP+ EF/IF for longer time period

Kilbourne, A. M., Almirall, D., Eisenberg, D., Waxmonsky, J., Goodrich, D. E., Fortney, J. C., ... & Thomas, M. R. (2014). Protocol: Adaptive Implementation of Effective Programs Trial (ADEPT): cluster randomized SMART trial comparing a standard versus enhanced implementation strategy to improve outcomes of a mood disorders program. *Implementation Science*, *9*(1), 132.

SMART TRIAL: ADEPT Design



Kilbourne, A. M., Almirall, D., Eisenberg, D., Waxmonsky, J., Goodrich, D. E., Fortney, J. C., ... & Thomas, M. R. (2014). Protocol: Adaptive Implementation of Effective Programs Trial (ADEPT): cluster randomized SMART trial comparing a standard versus enhanced implementation strategy to improve outcomes of a mood disorders program. *Implementation Science*, *9*(1), 132.

Effectiveness-Implementation Hybrid Designs

- Dual focus *a priori* on assessing intervention effectiveness and implementation
- Type 1, Type 2, Type 3
- Overall goal is to accelerate transition from effectiveness trials to implementation trials
- Unlike other designs, the hybrid designs are unique to implementation research

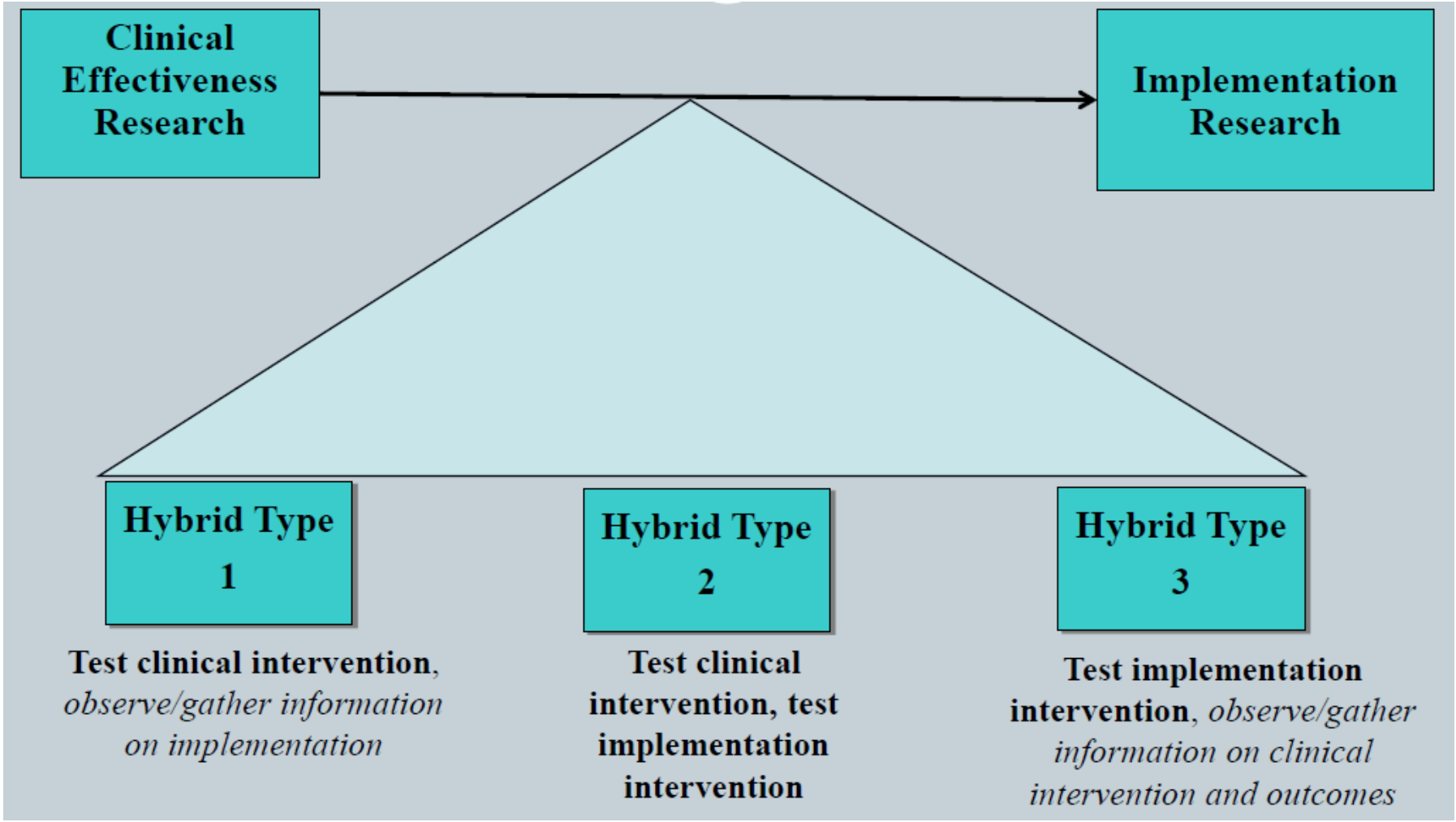
Curran, G.M., Bauer, M., Mittman, B., Pyne, J.M. and Stetler, C., 2012. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, *50*(3), p.217.

Effectiveness *vs.* Implementation Trials

Design Characteristic	Effectiveness Trial	Implementation Trial
Test	Intervention (e.g., practice, program, drug, etc.)	Implementation strategy (e.g., facilitation, training, reminders, etc.)
Unit of Randomization	Individual or patient	Provider, clinic, system
Unit of Analysis	Patient	Provider, clinic, system
Outcomes	Health outcomes (e.g., behavior, functional status, survival, etc.)	Adoption and appropriate use of intervention

Curran et. al. (2012). Effectiveness-Implementation Hybrid Designs. *Med Care.*

Hybrid Designs: 1, 2, 3



Curran et al. (2013). Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*.

Hybrid Trial *Type 1*

- Primary Aim: Test effectiveness of intervention
- Secondary Aim: Collect information on implementation process
- *Example*: You want to test whether an intervention to increase physical activity and delivered by peers among works in the ‘real-world.’ The intervention was shown to be efficacious in an RCT, but in that study, research staff delivered the intervention to participants. You also want to collect information on how the intervention is being delivered by peers.

Hybrid Trial *Type 2*

- Co-primary Aim: Test effectiveness of intervention
- Co-primary Aim: Develop and pilot implementation strategy
- *Example*: You want to assess the feasibility and acceptability of a two-day training plus follow-up technical assistance (i.e., implementation strategies) on community health workers' ability to deliver an evidence-based intervention to increase breast cancer screening among women.

Hybrid Trial *Type 3*

- Primary Aim: Test implementation strategy
- Secondary Aim: Assess effectiveness of intervention
- *Example*: You want to conduct an RCT to test different strategies (e.g., implementation as usual vs. external facilitation/coaching) for integration an HPV vaccine delivery program into 20 primary care clinics. You will collect data on how well the delivery program is integrated and delivered in clinic as well as how many women receive the vaccine.

Mixed Methods Designs

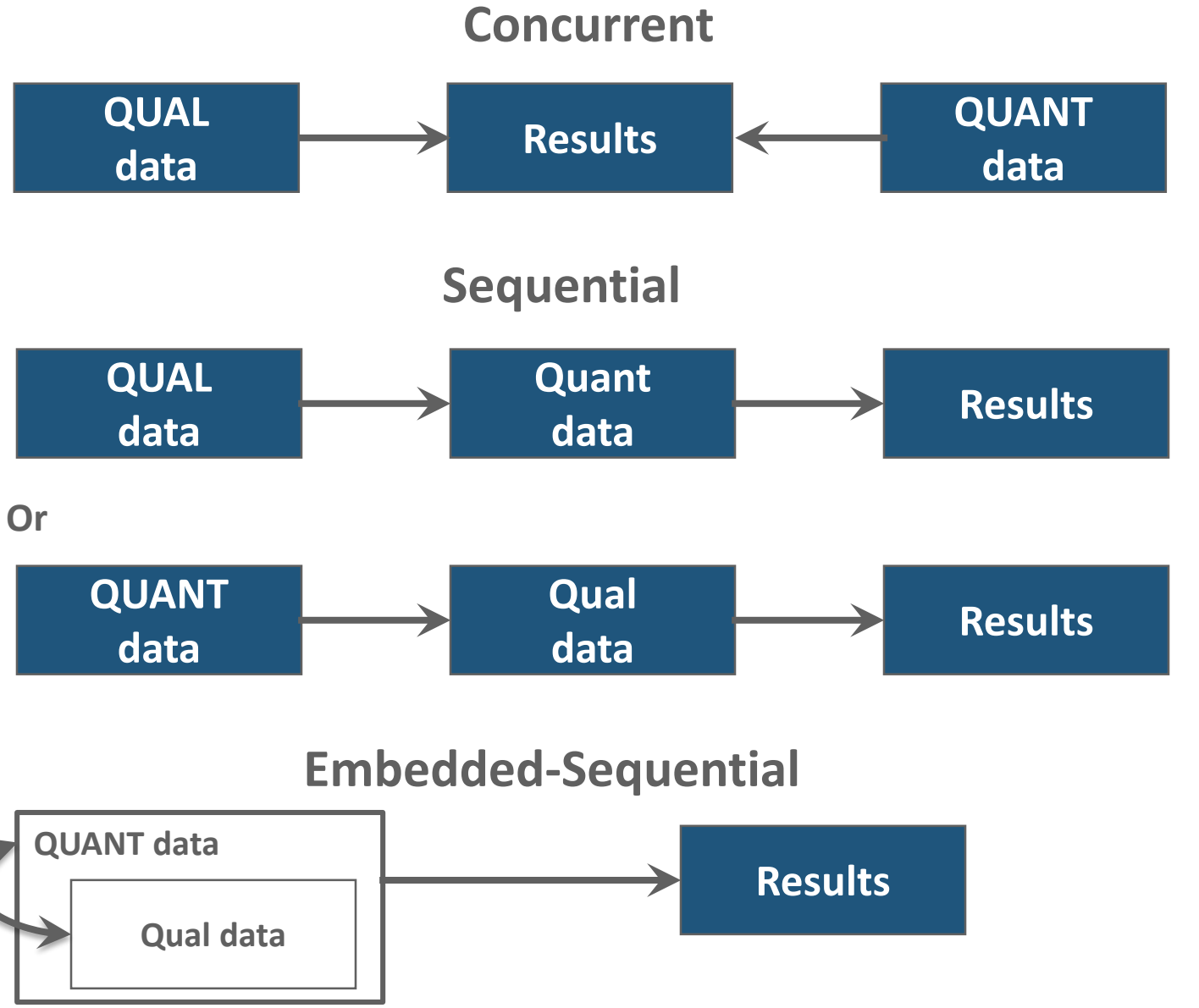
Mixed Methods Designs

- Collection and integration of qualitative and quantitative data
- Good approach for understanding processes, context and complexity
- Can embed within other types of study designs
- Qualitative Data: Interviews, focus groups, etc.
- Quantitative Data: Surveys, number-based data, etc.

Creswell, J.W. and Clark, V.L.P., 2007. Designing and conducting mixed methods research. Thousand Oaks, CA. SAGE Publications, Inc.

Palinkas, L.A., Aarons, G.A., Horwitz, S., Chamberlain, P., Hurlburt, M. and Landsverk, J., 2011. Mixed method designs in implementation research. *Administration and Policy in Mental Health and Mental Health Services Research*, *38*(1), pp.44-53.

Mixed Methods Design Typology



Palinkas, L.A., Aarons, G.A., Horwitz, S., Chamberlain, P., Hurlburt, M. and Landsverk, J., 2011. Mixed method designs in implementation research. *Administration and Policy in Mental Health and Mental Health Services Research*, *38*(1), pp.44-53.

Mixed Methods Designs: *Embedded*

- Collect qualitative and quantitative data to obtain broader and more comprehensive understanding of context and processes

- Conduct one study within the other type of study design (e.g., qualitative within quantitative study design or quantitative within qualitative study design)

- Qualitative + Quantitative

- Concurrent data collection

Embedded Example

You are conducting a randomized controlled trial (RCT) to test different strategies for training community health workers to deliver a smoking cessation intervention.

- Why would you want to use an embedded design?
- What type of quantitative data would you want to collect, how often, and from whom?
- What type of qualitative data would you want to collect, how often, and from whom?

Mixed Methods Designs: *Explanatory*

- Qualitative data helps explain or build on initial quantitative results
- Use qualitative to explain atypical quantitative results
- Use quantitative participant characteristics to guide sampling for qualitative data collection
- Quantitative  Qualitative
- Sequential data collection

Explanatory Example

You administered a survey to health practitioners to understand their attitudes (+/-) about the HPV vaccine. Responses ranged across the spectrum from very positive to very negative, and you want to better understand why.

- Why would you want to use an explanatory design?
- How would you use the quantitative data to inform your sampling approach?
- What type of qualitative data would you want to collect, how often, and from whom?

Mixed Methods Designs: *Exploratory*

- Quantitative data help explain or build on initial qualitative results
- Exploration is needed due to lack of available data, limited understanding of context, and/or few available measures/instruments
- Qualitative → Quantitative
- Sequential data collection

Exploratory Example

HPV self-sampling is available in a community but very few women use it. You want to understand barriers towards correct use of self-sampling and to develop an instrument (measure) to assess readiness for use.

- Why would you want to use an exploratory design?
- What type of qualitative data would you want to collect, how often, and from whom?
- What type of quantitative data would you want to collect, how often, and from whom?

Mixed Methods Design Typology

Design Type	Purpose	Data Collection Timing	Integration Timing or "Mixing"	Implementation Order
Convergence	Corroboration: analyze data from different sources regarding the same phenomenon	Concurrent	Interpretation	QUAL + QUAN
Complementarity	Understand a phenomenon more completely	Sequential	Analysis and Interpretation	QUAN → qual
Exploratory/ Development	Instrument or taxonomy/ typology development	Sequential	Analysis and Interpretation	QUAL → quan
Expansion	Assess different phenomenon using different methods	Embedded-Sequential	Analysis and Interpretation	QUAN(qual) or QUAL(quan)

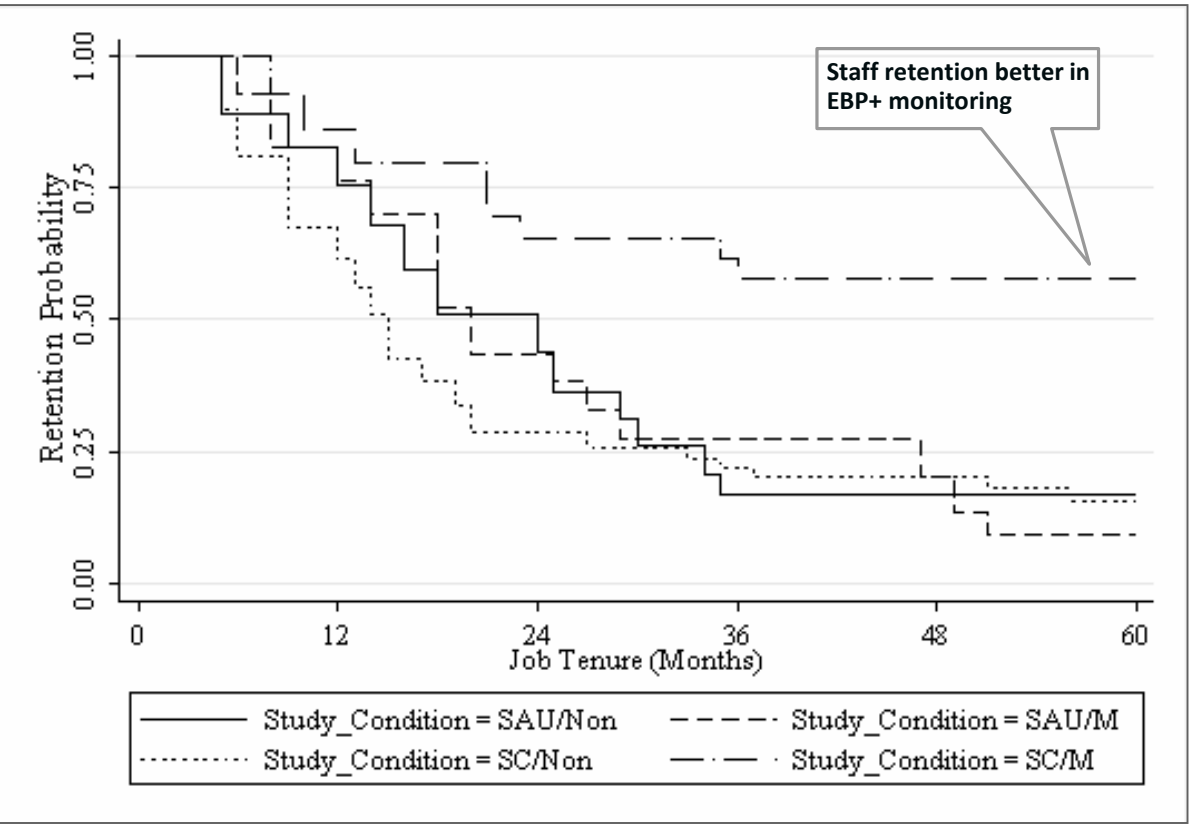
Mixed-Methods Study of Statewide EBP Implementation

(NIMH R01MH072961 PI: Aarons)

- Implementation of an EBP (SafeCare®) Statewide Public Sector Children's Services System
  - EBP assigned at region level
  - Teams within region randomized to coaching/no coaching
- Combines exploratory and confirmatory approaches
- Longitudinal at organization/team level
- Examines reciprocal effects of EBP implementation on service system and organizations and service system and organization impacts on EBP implementation

Aarons, G.A., Sommerfeld, D.H., Hecht, D.B., Silovsky, J.F. and Chaffin, M.J., 2009. The impact of evidence-based practice implementation and fidelity monitoring on staff turnover: evidence for a protective effect. *Journal of Consulting and Clinical Psychology*, *77*(2), p.270.

Implementation Outcomes: Effect of EBP Implementation on Staff Retention



Annualized Turnover by Condition		
	Consultation	
	Yes	No
SafeCare® Yes	**14.9%**	33.4%
SafeCare® No	41.5%	37.6%

Figure 1. Kaplan-Meier Survival Function Estimates (Retention Probability) by Study Condition.

- Lowest turnover in EBP+Fidelity Monitoring Condition ($p<.05$)
- Lower perceived job autonomy associated with higher turnover ($p<.05$)
- Higher turnover intentions associated with higher turnover ($p<.05$)

Aarons, G.A., Sommerfeld, D.H., Hecht, D.B., Silovsky, J.F. and Chaffin, M.J., 2009. The impact of evidence-based practice implementation and fidelity monitoring on staff turnover: evidence for a protective effect. *Journal of Consulting and Clinical Psychology*, *77*(2), p.270.

Table 1: Mixed method Results Demonstrating Convergence of Findings Source: Aarons, Fettes, Sommerfeld, & Palinkas (2012)

Method	Quantitative	Qualitative
Question	*Does SC implementation increase risk of turnover?*	*Does SC implementation increase risk of turnover?*
Answer	No: Home based providers in the SC/M condition had a greater likelihood of staying with their agencies for a longer period of time.	No: Many of the providers reported satisfaction with the structure provided by the EBP. No: None of the providers interviewed reported leaving primarily because of their involvement in the EBP effectiveness trial.
Question	*Does fidelity monitoring increase risk of turnover?*	*Does fidelity monitoring increase risk of turnover?*
Answer	No: Home based providers in the SC/M condition and UC/M condition had a greater likelihood of staying with their agencies for a longer period of time. (See figure at right)	No: Many of the providers reported satisfaction with the support they received from monitors.
Question	*Is SC implementation + fidelity monitoring associated with greatest risk of turnover?*	*Is SC implementation + fidelity monitoring associated with greatest risk of turnover?*
Answer	No: Home based providers in the SC/M condition had a greater likelihood of staying with their agencies for a longer period of time.	No: Many of the providers reported satisfaction with the support they received from monitors/consultants.
Question	*Does lower perceived job autonomy increase risk of turnover?*	*Does lower perceived job autonomy increase risk of turnover?*
Answer	Yes: Lower perceived job autonomy was associated with turnover.	Yes: Some providers reported intentions to leave due to supervisor micromanagement but this was unrelated to the EBP.
Question	*Does higher turnover intention increase risk of turnover?*	*Does higher turnover intention increase risk of turnover?*
Answer	Yes: Higher turnover intention was associated with turnover.	Yes: Some providers who reported intentions to leave during focus groups resigned from their positions within the following year because they felt unsupported by their supervisor.

Expansion

Table 3: Mixed method Results Demonstrating Expansion of Findings		
Method	**Quantitative**	**Qualitative**
Question	*Does SC Implementation and/or monitoring lead to increased turnover?*	*Why are they more likely to stay?*
Answer	Home based providers in the SC/M condition had a greater likelihood of staying with their agencies for a longer period of time.	Providers like the structure that SC provides to services. Providers like the support they receive from monitors. They view it as "free" supervision. EBP providers supported one another in application of the EBP and developed a distinct identity. SAU providers reported decline in morale due to factors unrelated to the EBP (e.g., conflicts with supervisor, change in leadership, few opportunities for promotion or pay raise, lack of distinct team identity).
Question	*Does lower perceived job autonomy increase risk of turnover?*	*Is job autonomy threatened by SC or other work conditions?*
Answer	Yes: Lower perceived job autonomy was associated with turnover.	Yes: Some providers reported intentions to leave due to supervisor micromanagement however this may be more related to work activities rather than the EBP.

Aarons, G.A., Fettes, D.L., Sommerfeld, D.H. and Palinkas, L.A., 2012. Mixed methods for implementation research: application to evidence-based practice implementation and staff turnover in community-based organizations providing child welfare services. *Child maltreatment*, *17*(1), pp.67-79.

Summary

- Best study design to use is the one that is able to best answer your research question(s)
- Selection of study design also influenced by key factors (e.g., feasibility, cost, resources, timing, researcher expertise, etc.)
- Variety of study designs to choose from in implementation science

Contact Information

Gregory A. Aarons, PhD
Professor
Department of Psychiatry
University of California San Diego

Director
Child and Adolescent Services Research Center

Email: gaarons@ucsd.edu

Web:
http://profiles.ucsd.edu/gregory.aarons

http://implementationleadership.com/