



HSR&D Center for Clinical Management Research
VA Ann Arbor Healthcare System



Session II: The Role and Selection of Theoretical Frameworks in Implementation Research

Laura J. Damschroder, MS, MPH Diabetes QUERI

Initially presented in collaboration with:

Cheryl Stetler, PhD CIPRS Consultant

Teresa Damush, PhD Stroke QUER

Christian Helfrich, PhD IHD QUERI

Audience

- ◆ Survey: What exposure have you had to the presentation for today?
 - ◆ Attended the EIS training last July in Denver
 - ◆ Listened to the presentation online
 - ◆ Reviewed only the slides online
 - ◆ This will be my first time
- ◆ *Use whatever wording you've used in the past – this is to get the gist of it.*



Outline

- ◆ Short introduction
- ◆ Using theory in hybrid & implementation studies with concrete examples

Objectives of Implementation Research

- ◆ Replicate successful implementation
 - ◆ Core components
 - ◆ Rationale
- ◆ Generalize knowledge about how to implement and sustain interventions
- ◆ Navigate complex implementations
- ◆ Improve prospects for sustainability



QUERI

Theory-driven implementation enables accomplishment of these objectives

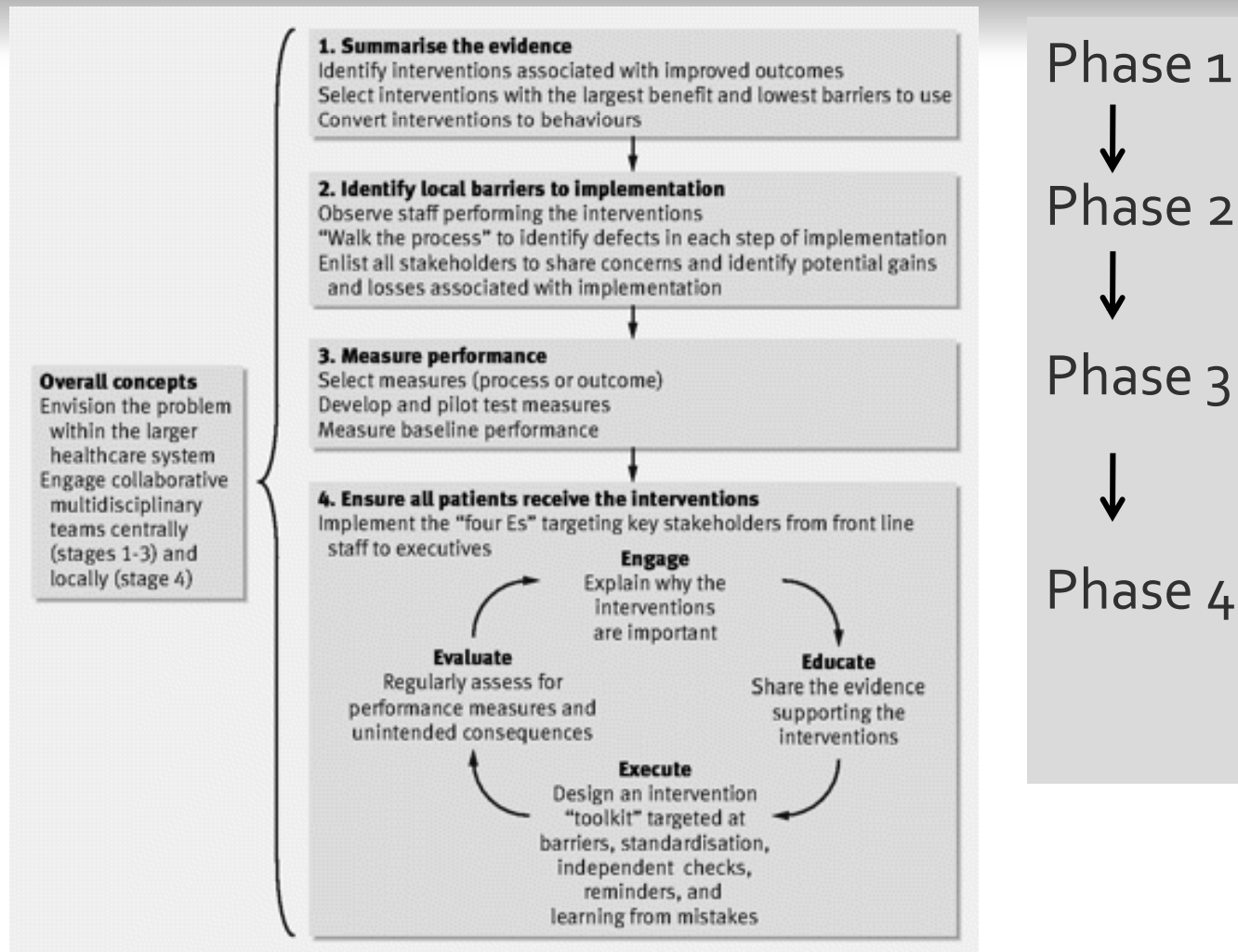
Types of Theories

- ◆ Multiple theories often needed
 - ◆ Process theories – (aka prescriptive, planned action)
 - ◆ How implementation should be planned, organized and scheduled
 - ◆ Explanatory theories (aka descriptive, impact)
 - ◆ Hypotheses and assumptions about how implementation activities will facilitate a desired change, as well as the facilitators and barriers for success
 - ◆ Mixed theories
 - ◆ Elements of both



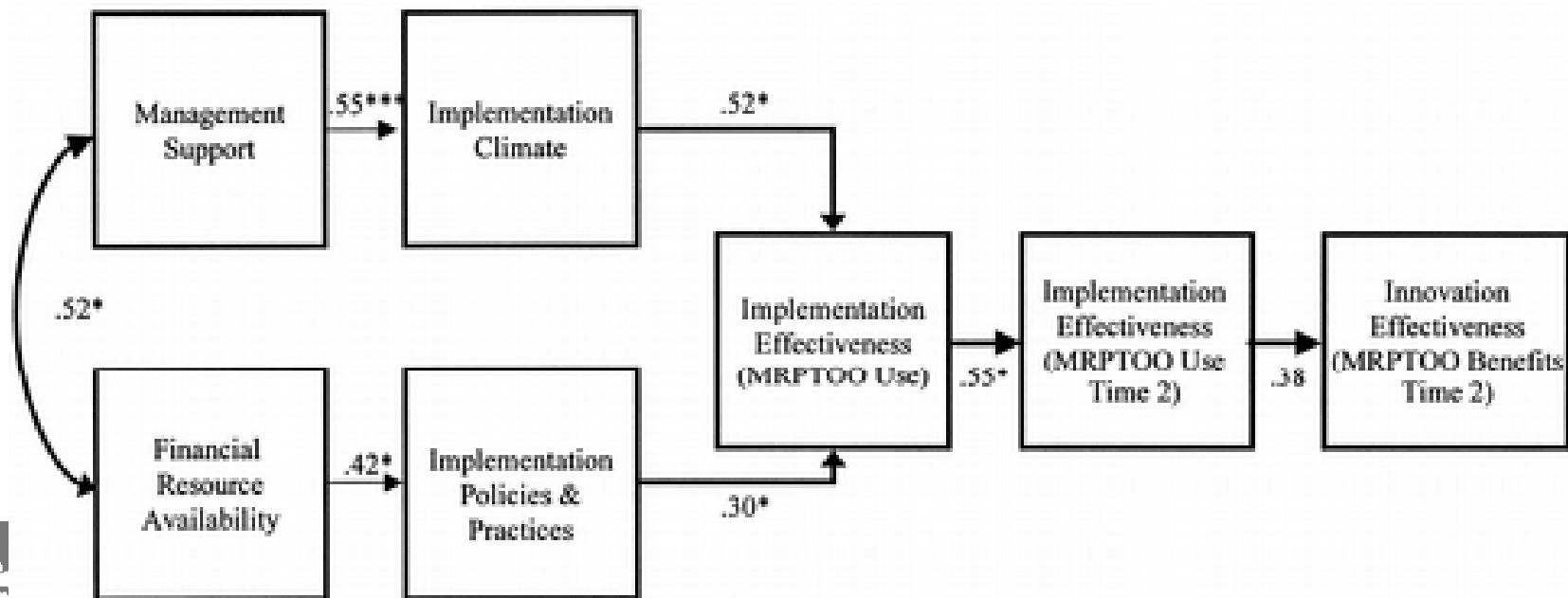
Adapted from: Grol RP, Bosch MC, Hulscher ME, Eccles MP, Wensing M. Planning and studying improvement in patient care: the use of theoretical perspectives. *Milbank Q.* 2007;85(1):93-138.

Pronovost's "4E's" Process Theory



Implementation Effectiveness Model

- ◆ Quantitative measures of predictors of implementation effectiveness
 - ◆ Strength of relationships empirically estimated



Choosing Theory

- ◆ Consider nature of the theory
 - ◆ Process v. explanatory
 - ◆ Context (e.g., policy, organization)
 - ◆ Discipline (e.g., social science, psychology)
- ◆ Consider level at which it will be applied
 - ◆ Individuals
 - ◆ Teams
 - ◆ Organization
 - ◆ System
- ◆ Previous findings, experience
- ◆ Greatest potential for adding to the knowledge-base



Audience

- ◆ Survey: How confident do you feel about conducting a theory-based implementation study?
 - ◆ *Not at all confident*
 - ◆ *Somewhat confident*
 - ◆ *Moderately Confident*
 - ◆ *Very confident*
 - ◆ *I'm ready to dive in!*



Taxonomy of Trial Designs

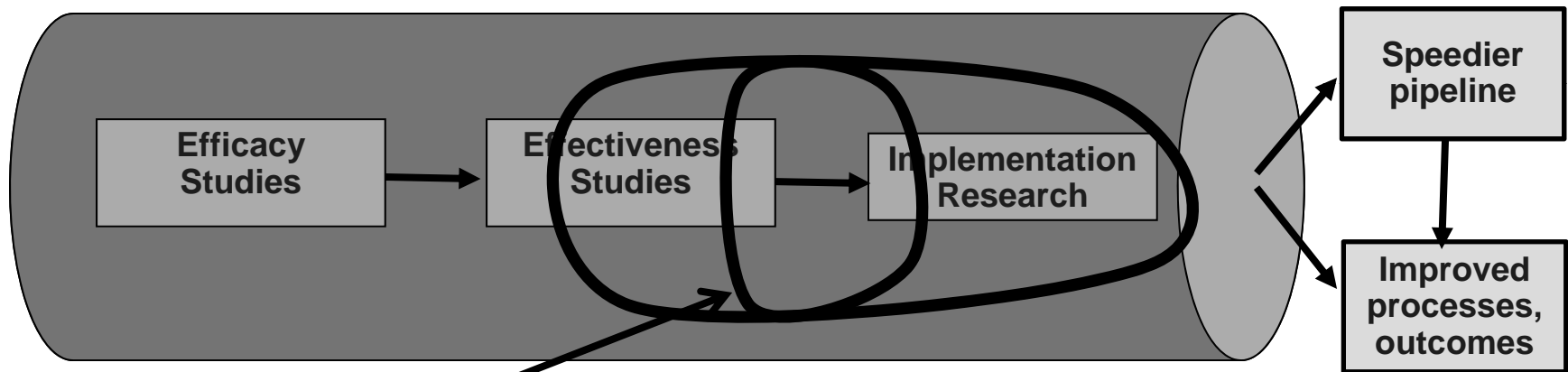
Intervention Focus		Implementation Approaches	
		YES	NO
Clinical Effectiveness	YES	Hybrid Type II: Test clinical intervention, test implementation intervention	Hybrid Type I: Test clinical intervention, observe/gather information on implementation
	NO	Hybrid Type III: Test implementation intervention, observe/gather information on clinical intervention and outcomes Implementation Study	Observational Studies



QUERI

From: Combining Elements of Clinical Effectiveness and Implementation Research Trials: Hybrid Trial Designs. Curran G., Bauer M., Mittman B., Stetler, C. Enhancing Implementation Science Series CyberSeminar. January 2011.

“Newer” Clinical Research-Implementation Pipeline



Spatially speaking, formative/process evaluations go here...



QUERI

From: Combining Elements of Clinical Effectiveness and Implementation Research Trials: Hybrid Trial Designs. Curran G., Bauer M., Mittman B., Stetler, C. Enhancing Implementation Science Series CyberSeminar. January 2011.

Traditional RCT v. Hybrid Study

Proactive Diabetes Case Management x 2 studies

- ◆ NPs / PharmD
- ◆ Medication changes & phone follow-up
- ◆ VA primary care/managed care
- ◆ RCT
- ◆ Primary Clinical Outcome A1c

Traditional RCT v. Hybrid Study

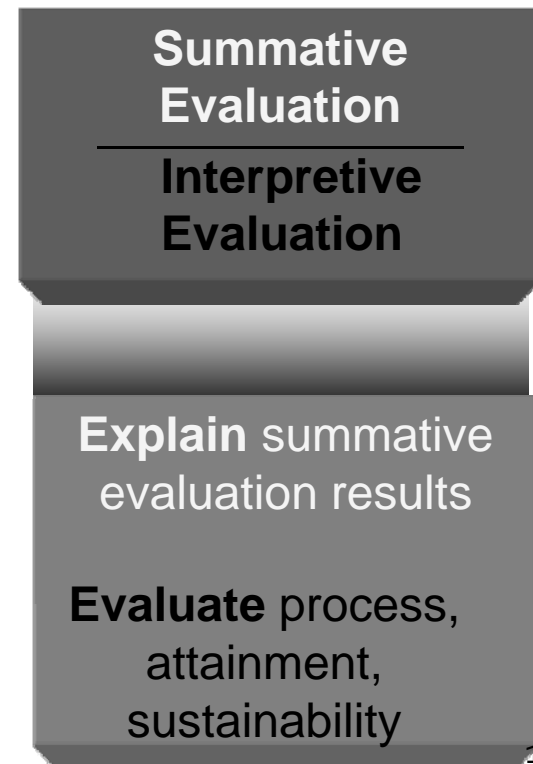
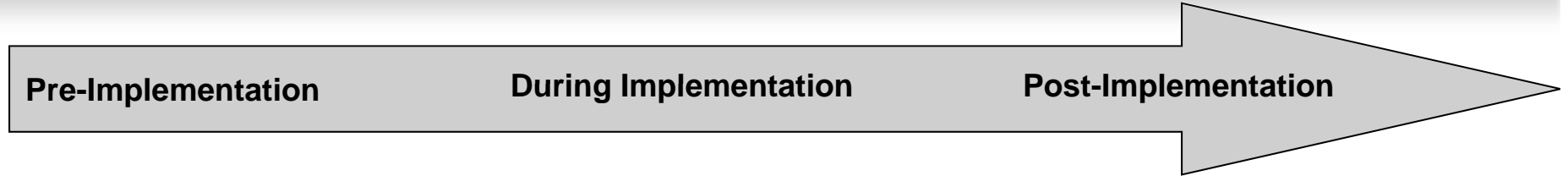
Proactive Diabetes Case Management x 2 studies

- ◆ NPs / PharmD
- ◆ Medication changes & phone follow-up
- ◆ VA primary care/managed care
- ◆ RCT
- ◆ Primary Clinical Outcome A1c

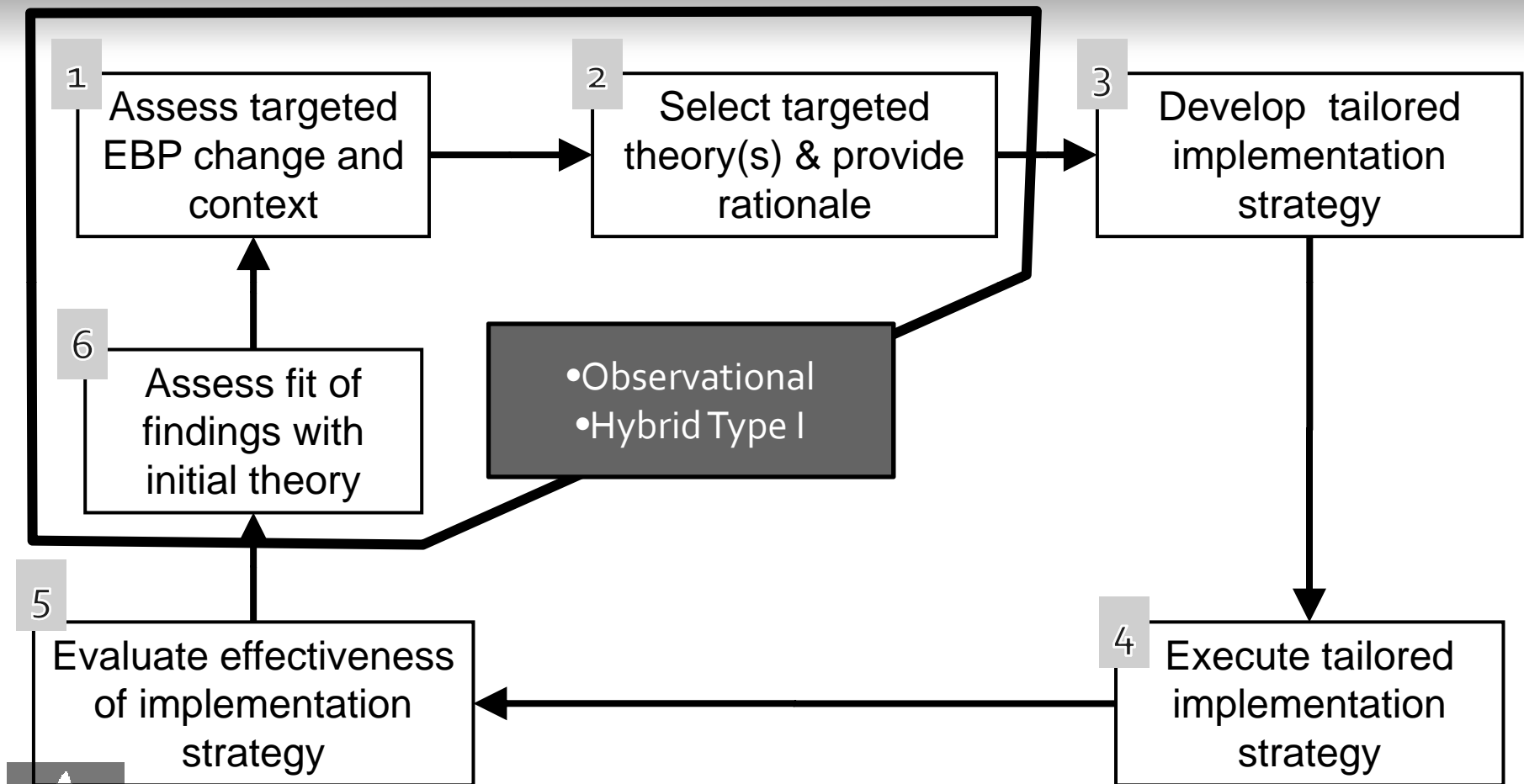
AIM

- ◆ PharmD
- ◆ Medication changes and phone follow-up
- ◆ VA primary care/managed care
- ◆ RCT
- ◆ Primary Clinical Outcome BP

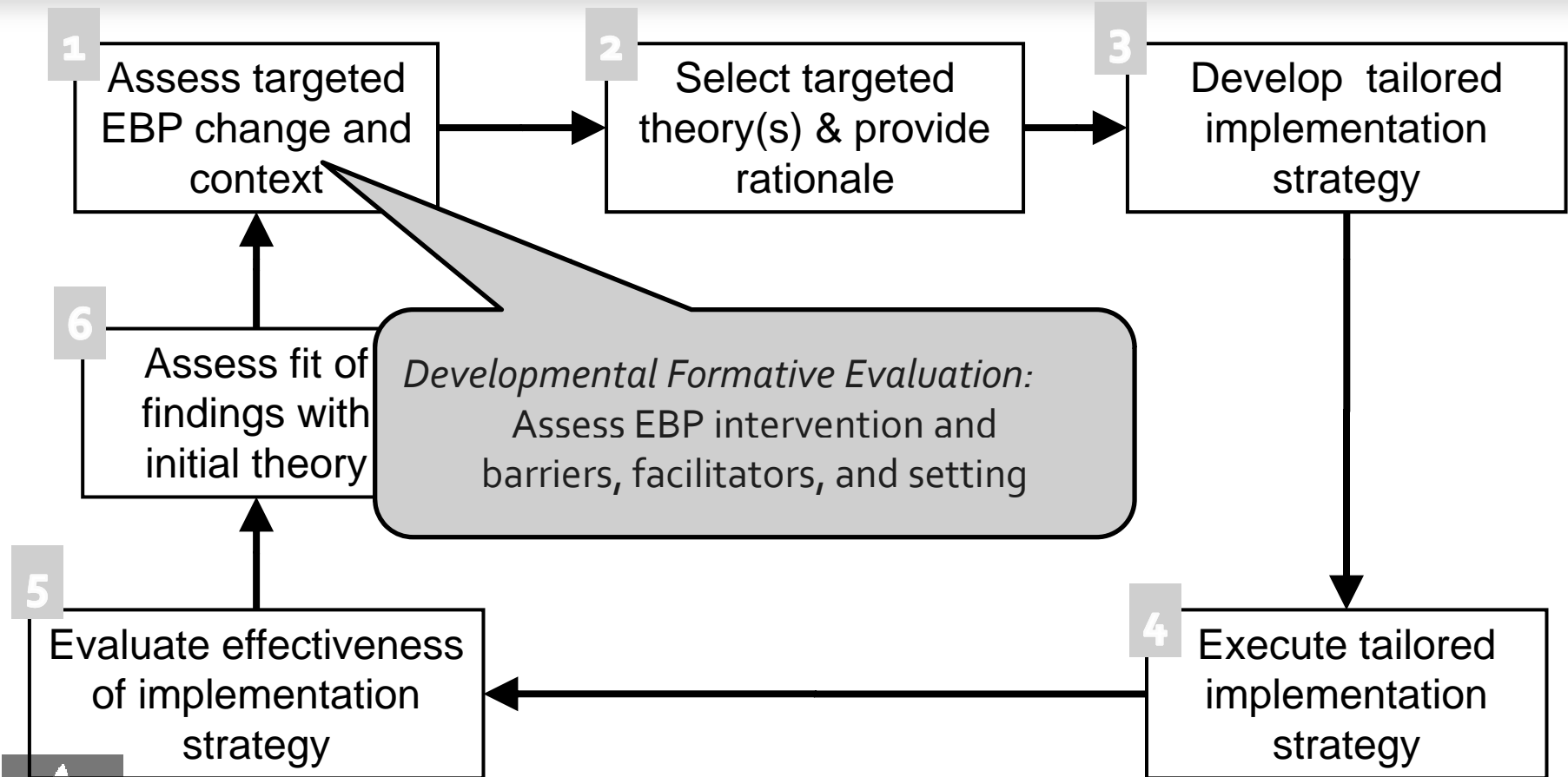
AIM Formative Evaluations



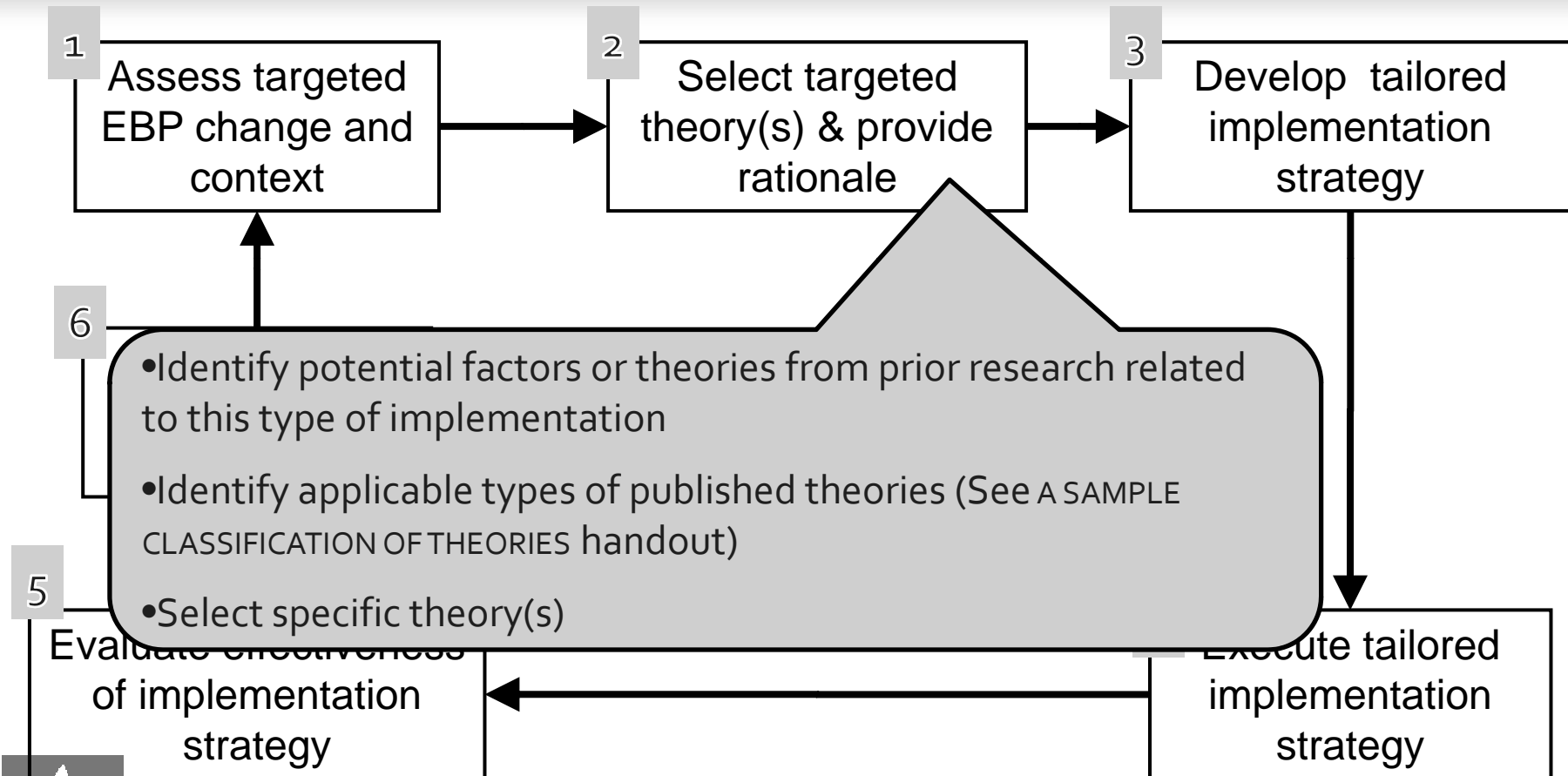
Conducting Theory-based Implementation Studies



Conducting Theory-based Implementation Studies



Conducting Theory-based Implementation Studies

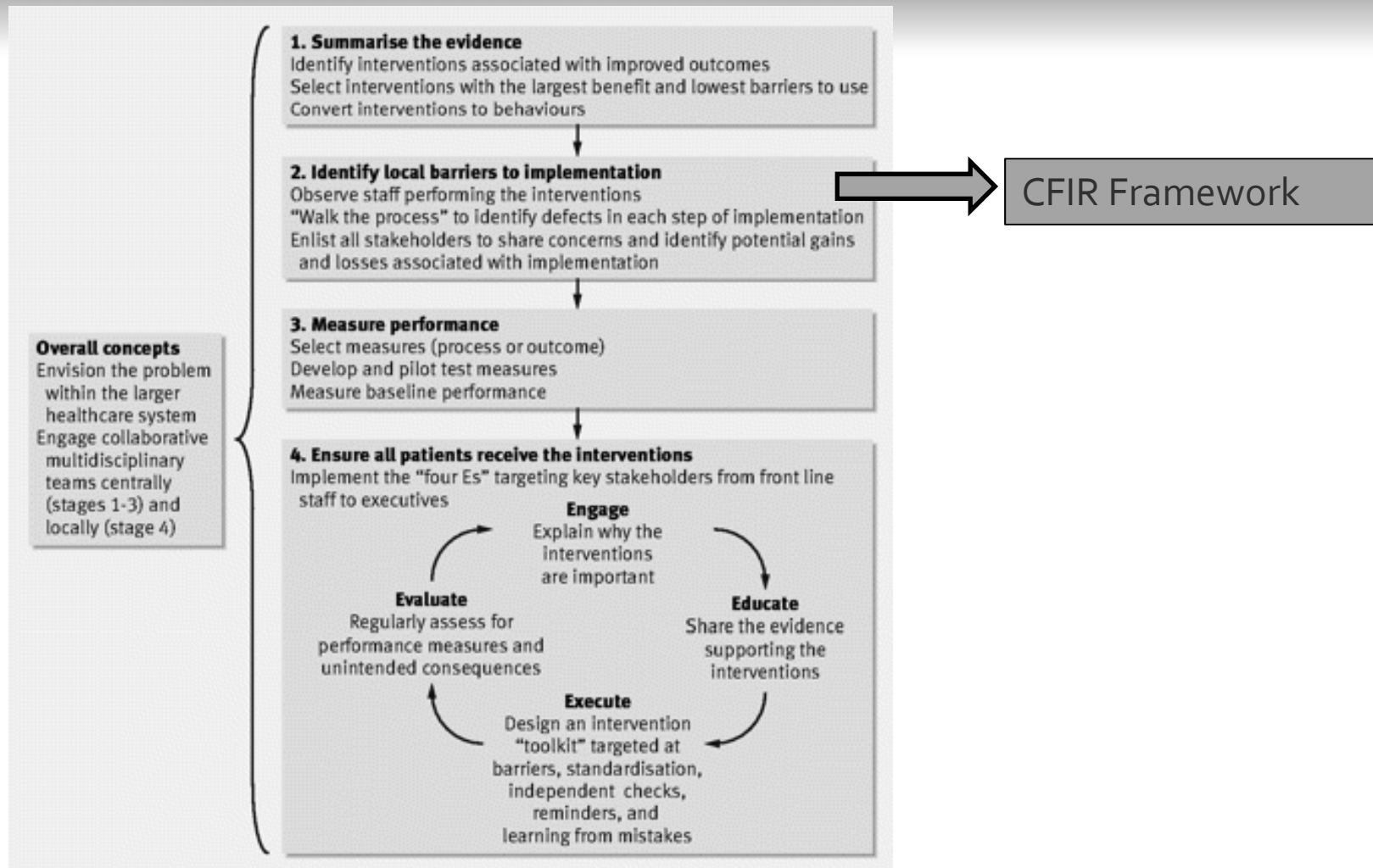


“Bladder Bundle” Study

- ◆ Study Aims
 - ◆ Describe adoption and implementation of a Catheter-associated Urinary Tract Infection Prevention Bundle (aka Bladder Bundle)
 - ◆ ID and compare barriers & facilitators of implementing the Bladder Bundle
 - ◆ **Develop and evaluate implementation strategies for the Bladder Bundle**
 - ◆ **Facilitate implementation in small sample of hospitals**



Pronovost's "4E's" Action Model



CFIR: 5 Major Domains

- ◆ **Intervention Characteristics**

- ◆ 8 Constructs (e.g., evidence strength & quality, complexity)

- ◆ **Outer Setting**

- ◆ 4 Constructs (e.g., patient needs & resources)

- ◆ **Inner Setting**

- ◆ 14 constructs (e.g., leadership engagement, available resources)

- ◆ **Individuals Involved**

- ◆ 5 Constructs (e.g., knowledge, self-efficacy)

- ◆ **Process**

- ◆ 8 Constructs (e.g., plan, engage, champions)

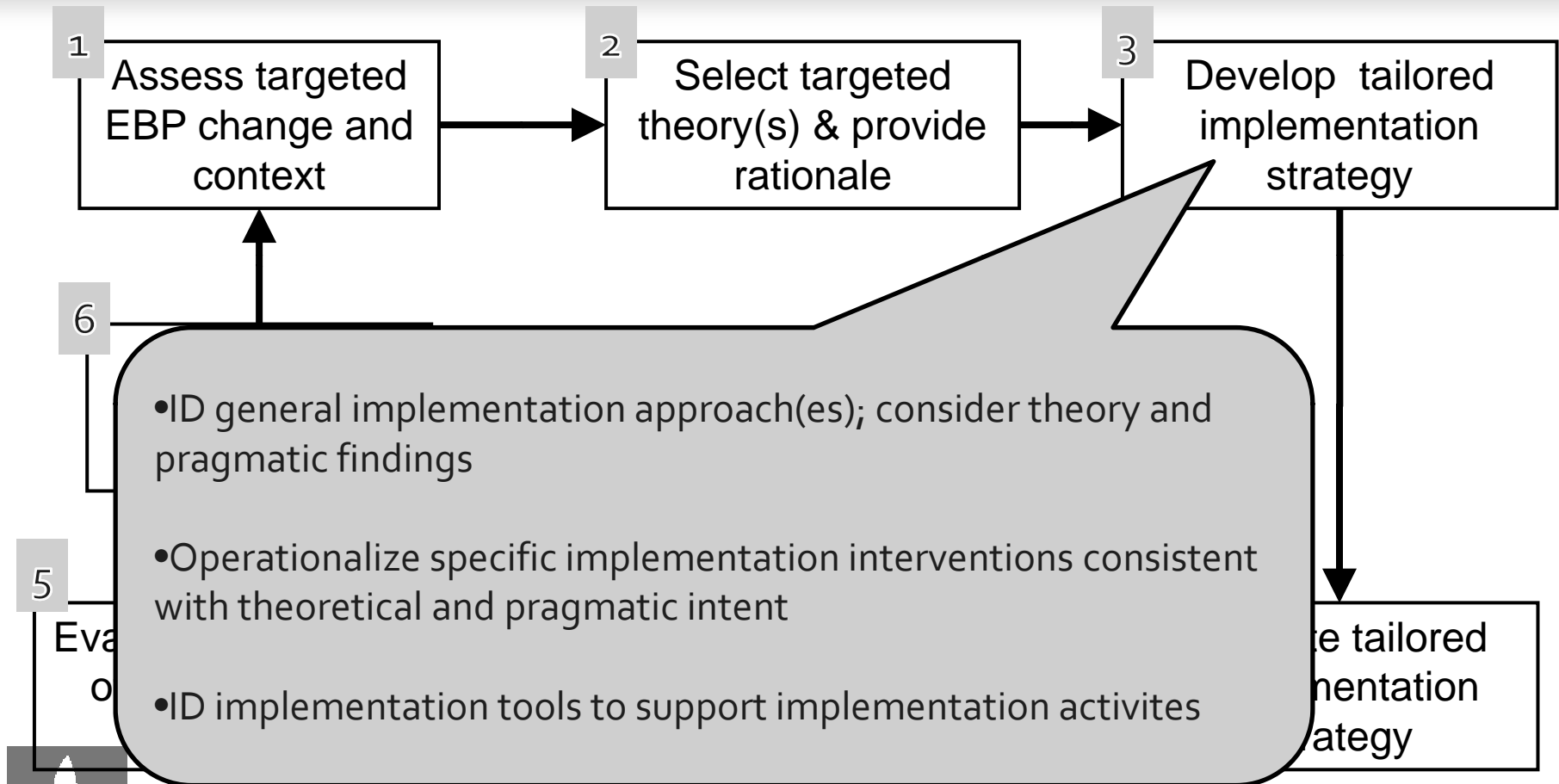


Pre-Implementation

- ◆ Selected High Priority Constructs from CFIR
 - ◆ Narrow the focus
- ◆ Data collection
 - ◆ Semi-structured phone interviews
 - ◆ On-site visits
 - ◆ Validated and customized quantitative survey items
 - ◆ Selected Organizational Readiness for Change Assessment (ORCA) items
 - ◆ Other measures



Conducting Theory-based Implementation Studies



Develop Tailored Implementation Strategy

Types of Theories	Potential Theories	Rationale	Component/Tool
Explanatory Theory	CFIR	<ul style="list-style-type: none">• Provides systematic approach for evaluating context• Barriers & facilitators	Online toolkit materials to address skepticism about supporting evidence



Develop Tailored Implementation Strategy

Types of Theories	Potential Theories	Rationale	Component/Tool
Explanatory Theory	CFIR	<ul style="list-style-type: none"> • Provides systematic approach for evaluating context • Barriers & facilitators 	Online toolkit materials to address skepticism about supporting evidence
Process theory	Pronovost's 4E's Model	<ul style="list-style-type: none"> • Used in similar setting (hospital) and practice (preventing catheter-related infections) 	Data collection tools for catheter days and indications




Develop Tailored Implementation Strategy

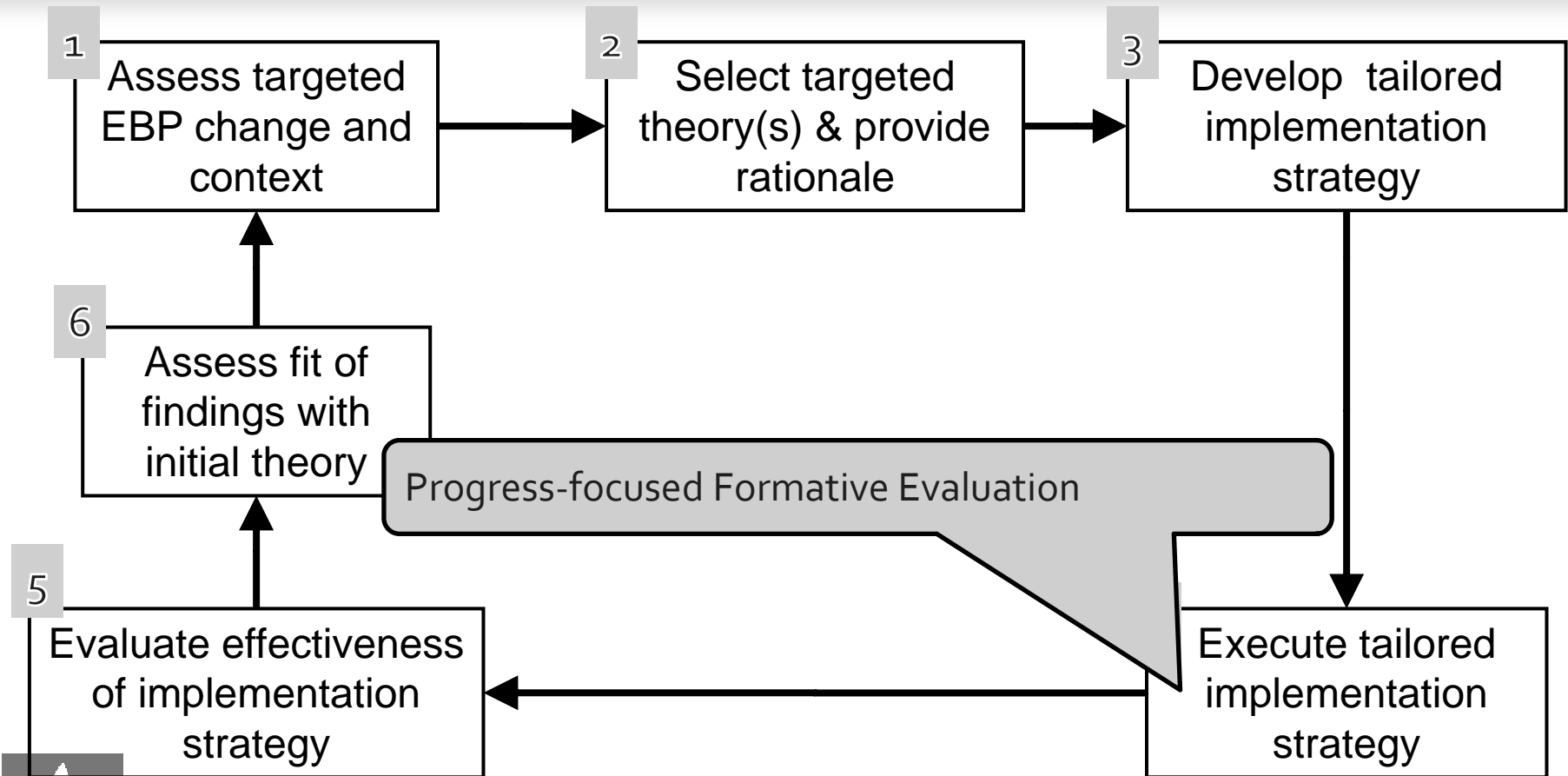
Types of Theories	Potential Theories	Rationale	Component/Tool
Explanatory Theory	CFIR	<ul style="list-style-type: none"> • Provides systematic approach for evaluating context • Barriers & facilitators 	Online toolkit materials to address skepticism about supporting evidence
Process theory	Pronovost's 4E's Model	<ul style="list-style-type: none"> • Used in similar setting (hospital) and practice (preventing catheter-related infections) 	Data collection tools for catheter days and indications
Individual-level Theory	Adult Learning Theory	Guide education approach – minimize didactic and maximize hands-on	<ul style="list-style-type: none"> • Select appropriate materials from the toolkit • Plan multi-level educational strategy



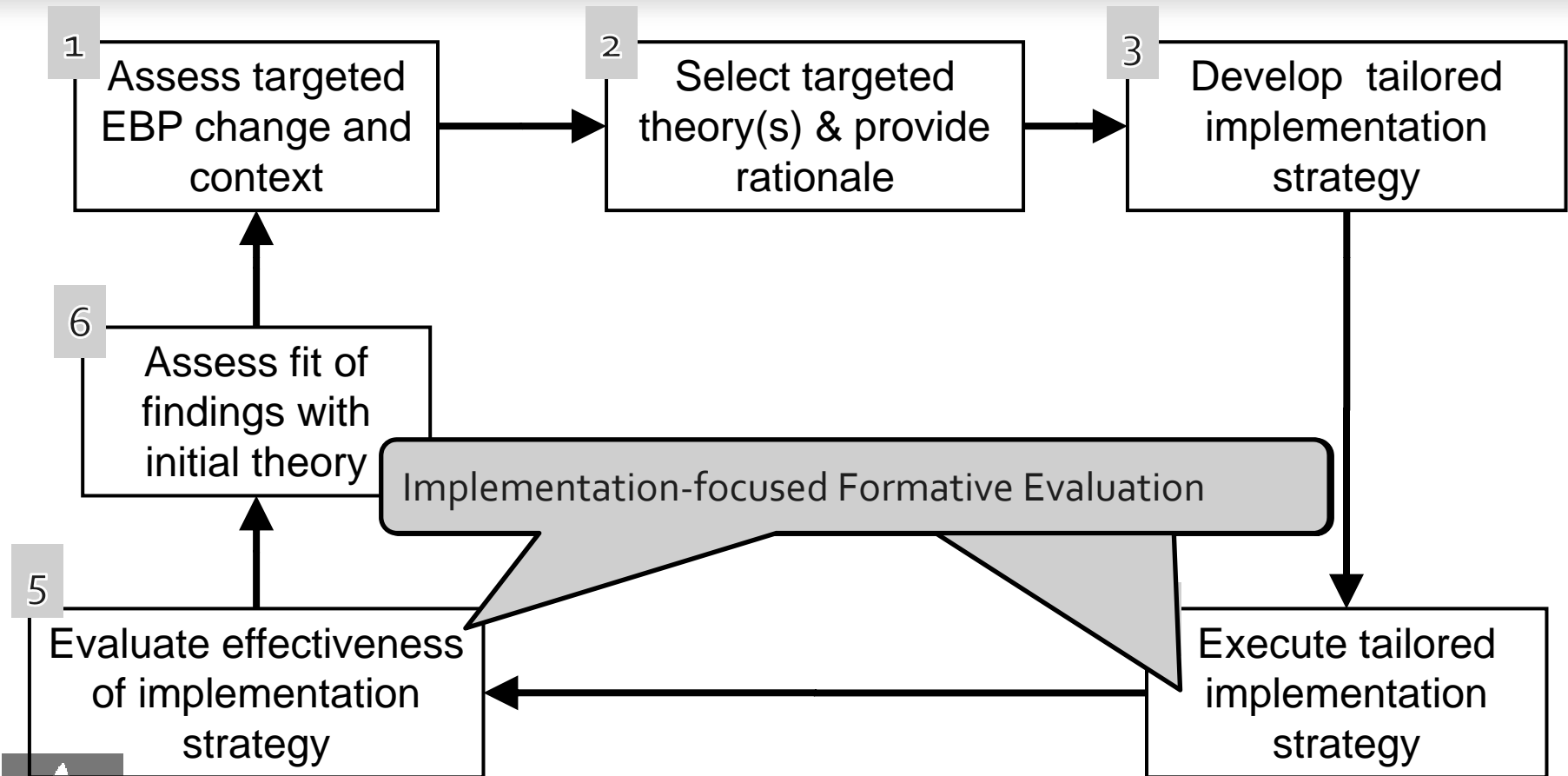
Develop Tailored Implementation Strategy

Types of Theories	Potential Theories	Rationale	Component/Tool
Explanatory Theory	CFIR	<ul style="list-style-type: none"> • Provides systematic approach for evaluating context • Barriers & facilitators 	Online toolkit materials to address skepticism about supporting evidence
Process theory	Pronovost's 4E's Model	<ul style="list-style-type: none"> • Used in similar setting (hospital) and practice (preventing catheter-related infections) 	Data collection tools for catheter days and indications
Individual-level Theory	Adult Learning Theory	Guide education approach – minimize didactic and maximize hands-on	<ul style="list-style-type: none"> • Select appropriate materials from the toolkit • Plan multi-level educational strategy
 Pragmatic	Findings	<i>What worked for others may work here</i>	<i>Nurse champion facilitate educational exercises</i>

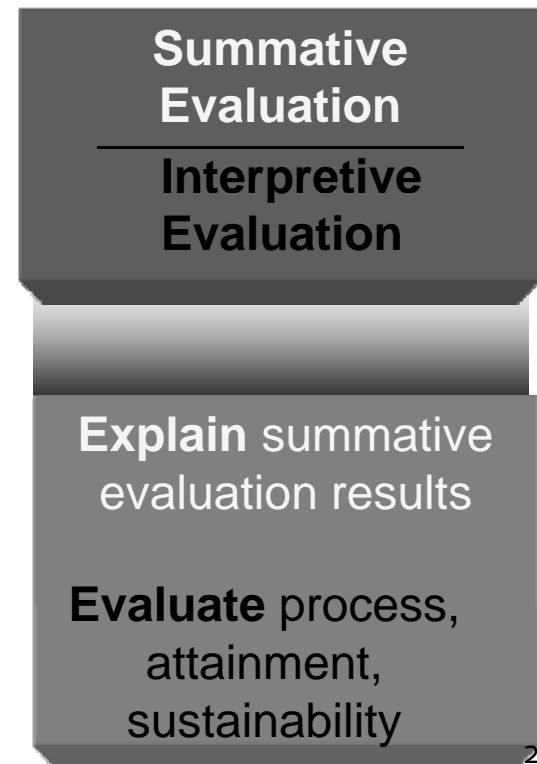
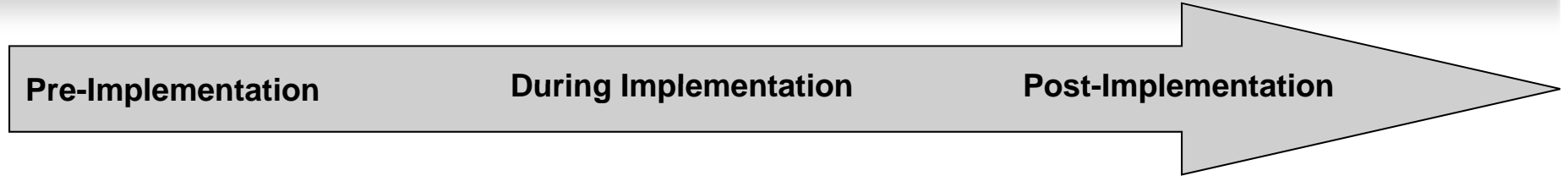
Conducting Theory-based Implementation Studies



Conducting Theory-based Implementation Studies



AIM Formative Evaluations



Pre-Implementation: Assess Sites & Tailor AIM

CFIR Construct	Potential Barrier	→	Tailor AIM
Networks & Communications	Case managers concerned about overlap between patients being case managed and those targeted by AIM	→	<ul style="list-style-type: none"> • Pre-implementation meeting with case managers to address concerns • Promote close on-going communications between AIM pharmacist and case managers
	Providers not used to working with clinical pharmacists	→	<ul style="list-style-type: none"> • Pharmacist introduced to each provider • Pharmacists participated in monthly staff meetings • Co-sign providers on all med changes within the EMR

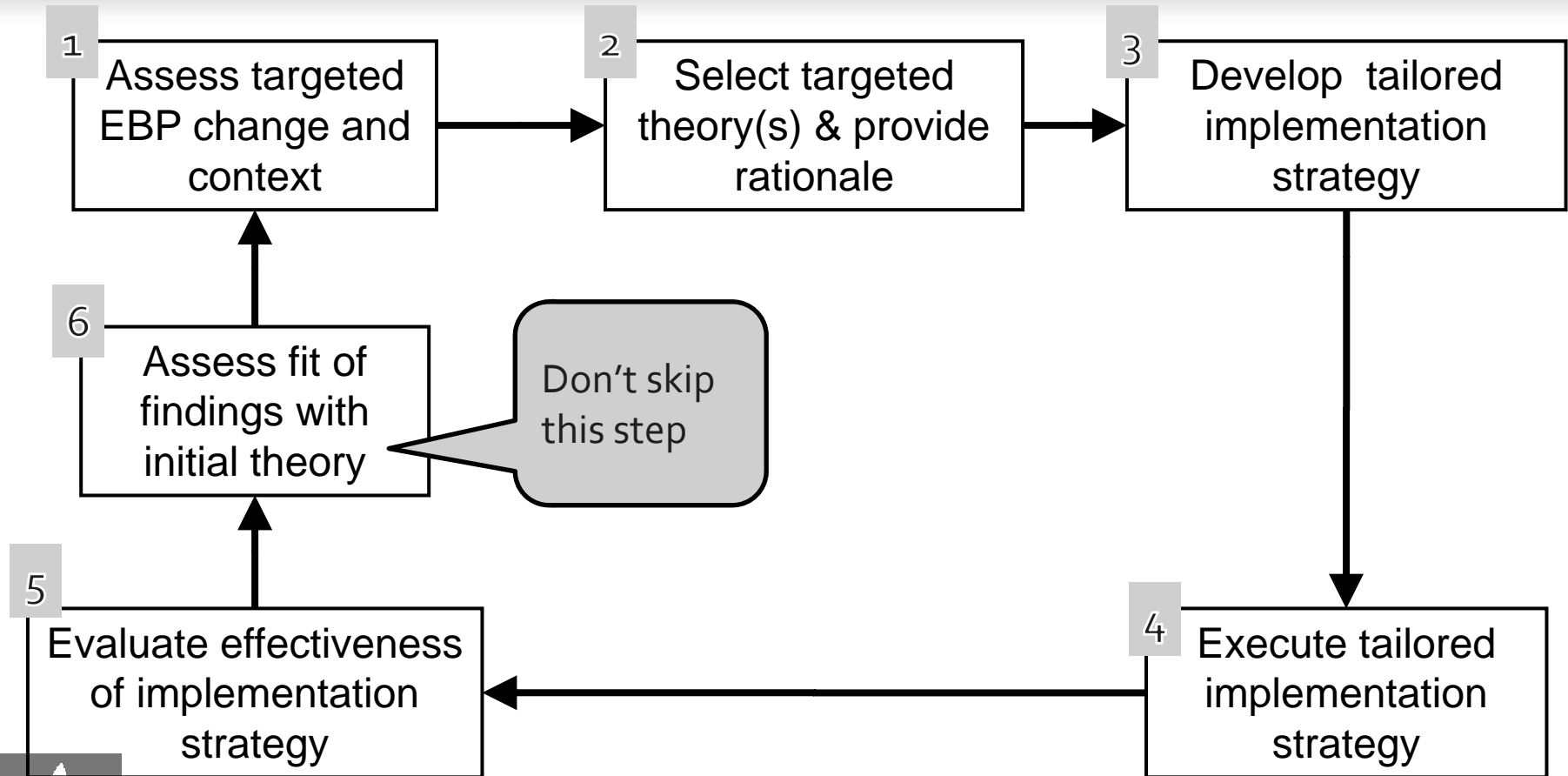


During Implementation: Refinement & Progress

CFIR Construct	Barrier	→	Adjustment
Available Resources	Inadequate space required pharmacist to negotiate for space on a daily basis	→	Unable to resolve. May help explain process or summative outcomes.
Access to Information & Knowledge	Motivational interviewing techniques were challenging to apply	→	Continued webinars where pharmacists shared their experiences and problem-solved with an MI expert
External Policy & Incentives	Pressure to treat patients who did not meet performance measure goals	→	Negotiated for a new initiative to start after the end of AIM



Conducting Theory-based Implementation

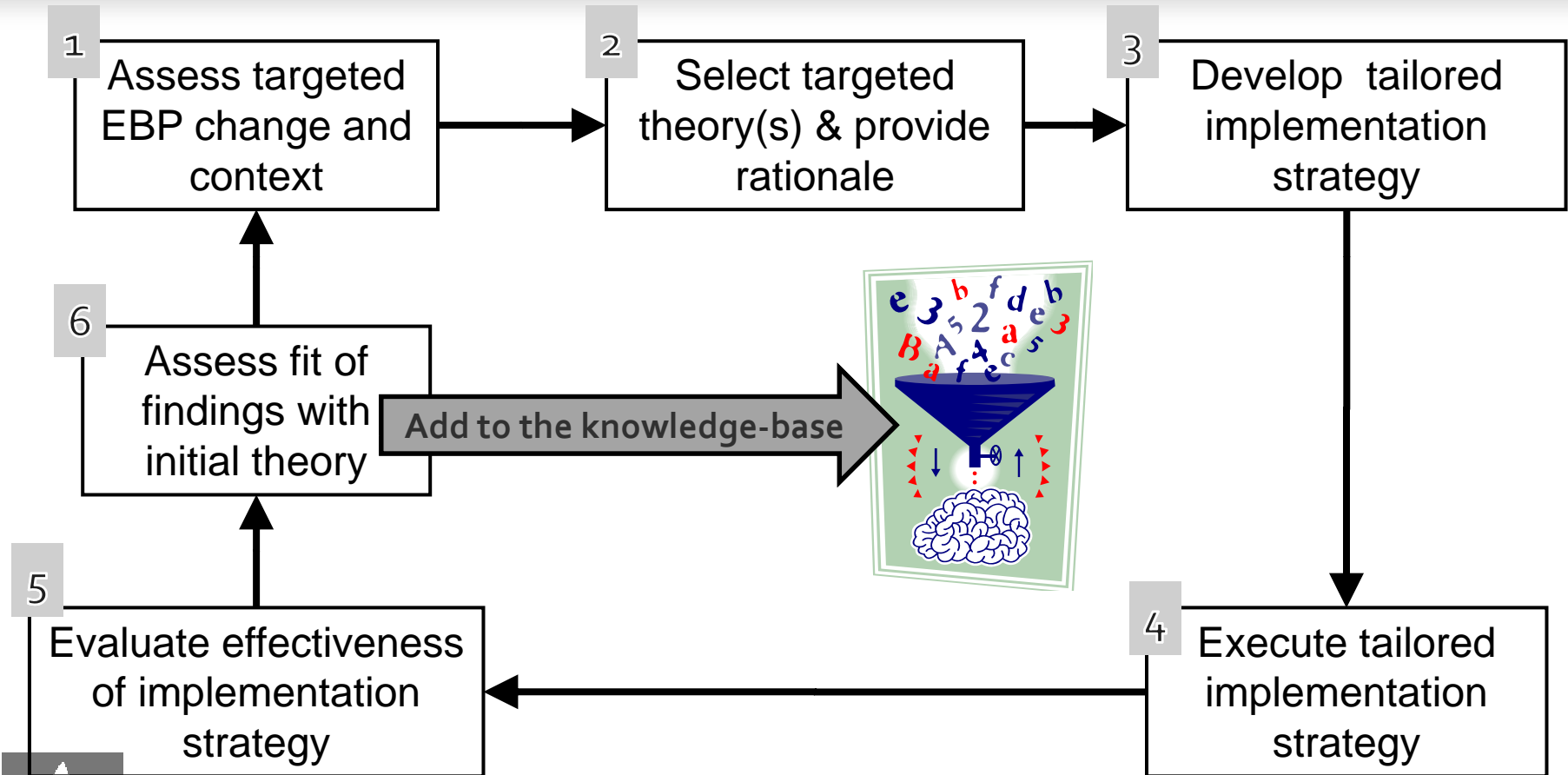


Assess Theory

- ◆ Does theory still apply?
- ◆ Modifications/refinements needed?
- ◆ Building validity
 - ◆ Quantitative theory testing
 - ◆ Test hypotheses
 - ◆ Path analyses
 - ◆ Qualitative theory testing
 - ◆ Is terminology/language coherent?
 - ◆ Does it promote comparison of results across settings and studies over time?
 - ◆ Does it stimulate new theoretical developments?



Conducting Theory-based Implementation



Using the CFIR to Promote Synthesis

- ◆ CFIR embraces, consolidates, and standardizes key constructs from other theories
- ◆ Agnostic to specific models and theories
 - ◆ Can be used to build, affirm, or evaluate them
- ◆ Provides a pragmatic structure for evaluating complex implementations
- ◆ Helps to organize findings across disparate implementations
- ◆ Paves the way for cross-study synthesis



Thank You

- ◆ Come to our workshop at HSR&D to explore more about using the CFIR to synthesize findings:

Implementation Research: An approach to promote more timely and informative synthesis for real-world implementation findings

Presented by:
Laura Damschroder
Carmen Hall
Cheryl Stetler

Thursday 4:15-5:45pm February 17th



QUERI

Audience – can we elicit after Q&A?

- ◆ Survey: Think back to the level of confidence you indicated at the beginning of this presentation. Now, how confident do you feel about conducting a theory-based implementation study?
 - ◆ *Less confident than before hearing this presentation*
 - ◆ *I'm feeling about the same*
 - ◆ *Slightly more confident*
 - ◆ *Much more confident*



Extra Slides



Observational Studies

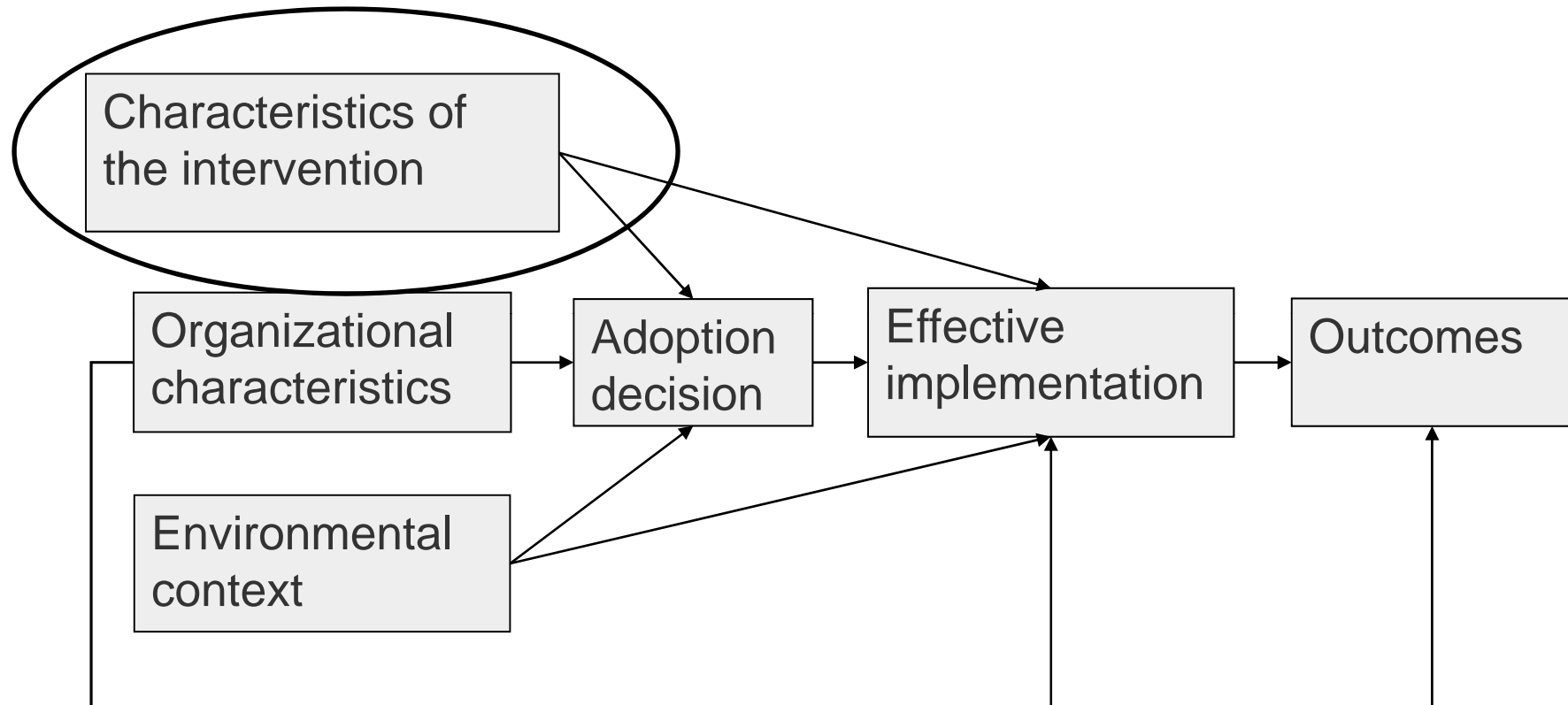
- ◆ Identify barriers and facilitators of use or implementation
- ◆ Study designs
 - ◆ Ethnographic and other qualitative approaches
 - ◆ Quantitative measures
 - ◆ Mixed methods

Example Observational Study

Aim 2:

- ◆ Identify factors that facilitate & impede adoption and implementation of evidence-based prevention practices
- ◆ Sequential mixed methods
 - ◆ Quantitative survey
 - ◆ Qualitative: semi-structured interviews, on-site observations
- ◆ Theory-guided evaluation

Roger's Theory of Diffusion



QUERI

Application to infection prevention practices

Krein SL, Olmsted RN, Hofer TP, Kowalski C, Forman J, Banaszak-Holl J, et al. Translating infection prevention evidence into practice using quantitative and qualitative research. *Am. J. Infect. Control* 2006;34(8):507-12.

Different Practices: Different Barriers

Practice 1	Practice 2
Category II evidence	Category II evidence
Evidence debated, dismissed	Evidence accepted
Mechanical issue	Challenging to change behaviors
Selective use in patients	Inconsistent implementation across units (e.g., MICU v. SICU)



Theory in Observational Studies

- ◆ Identify gaps in use and implementation
- ◆ Adds to knowledge about barriers & facilitators to use and implementation
- ◆ Tend to be single or small sample case studies
- ◆ Use theoretical framework
 - ◆ Guide evaluation
 - ◆ Organize findings
 - ◆ Evaluate the theory
- ◆ Theory allows us to build on knowledge across studies & settings

