

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

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Diabetes QUERI
Stroke QUERI

Outline

- ◆ Why use theory?
- ◆ What is implementation research?
- ◆ Observational study example using theory
- ◆ Framework to guide your use of theory
- ◆ Implementation study example
- ◆ Key points

Session Objectives

- ◆ Understand the role & value of theory in implementation research
- ◆ Equip you with a guide for applying theory in your work

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A word on THEORY

- ◆ A generalized definition of theory in science will be used today
 - ◆ A set of statements or principles devised to explain a group of facts or phenomena¹
 - ◆ May be embodied by frameworks, models, specific theory

1. The American Heritage Science Dictionary. <http://dictionary.reference.com/browse/theory>

WE'RE GOING TO USE OMMI. IT'S A MODEL FOR DEVELOPING A PROCESS TO CREATE A FRAMEWORK.



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OR IT MIGHT BE A PROCESS FOR CREATING A FRAMEWORK TO MAKE A MODEL.



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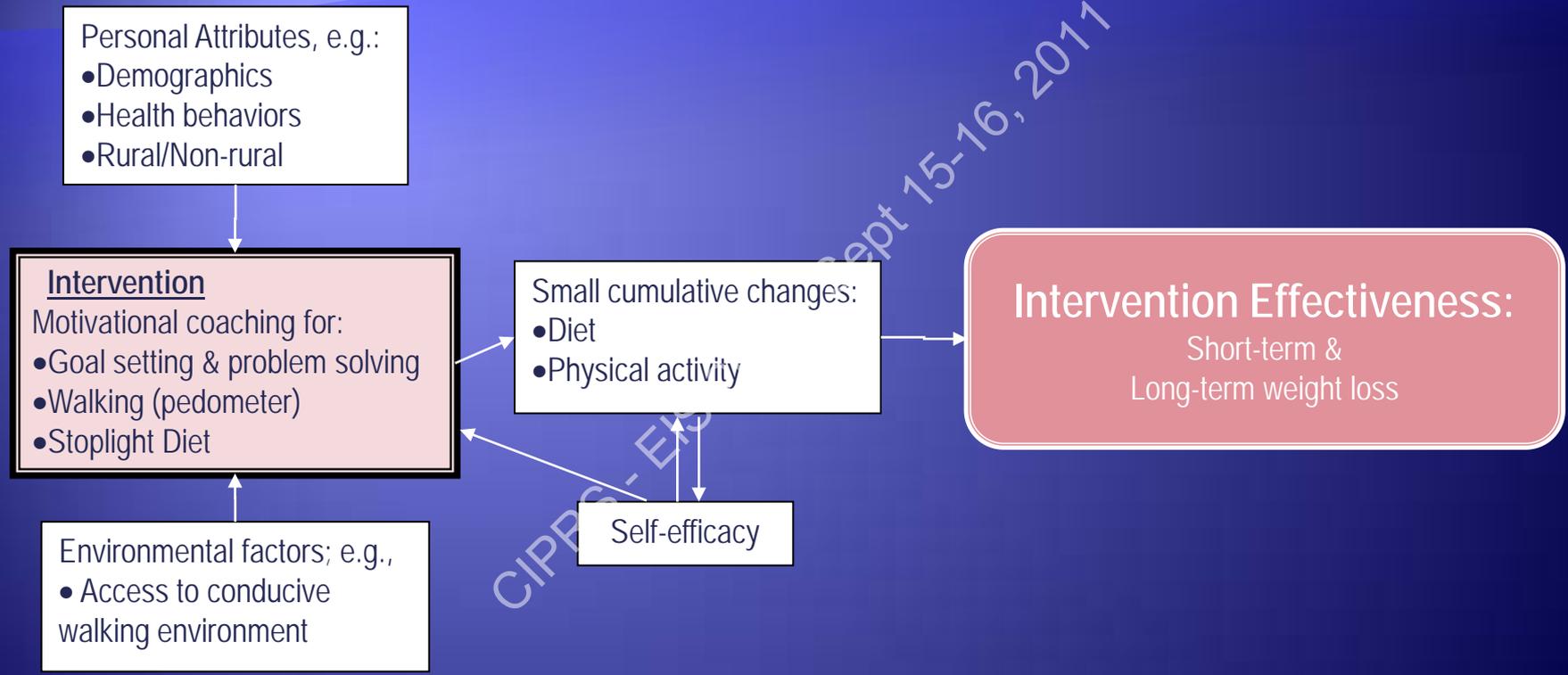
THERE'S NO BUDGET FOR TRAINING, SO WE'LL BE RELYING ON GUESSING MORE THAN USUAL.



Theory in Interventions

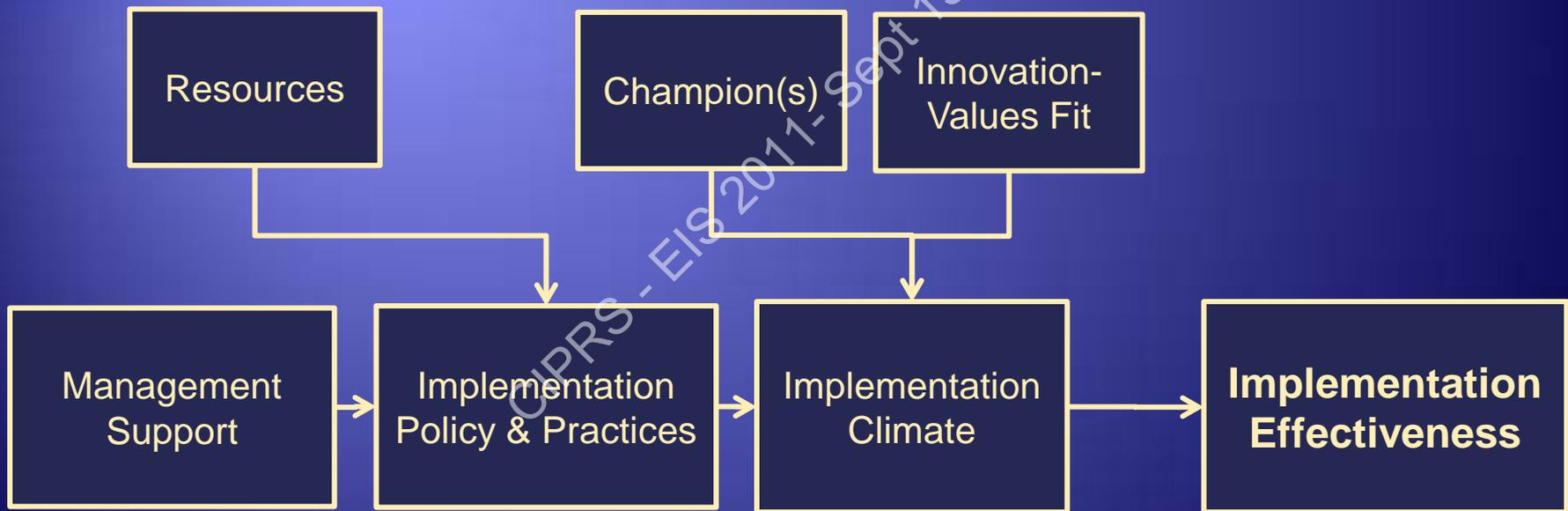
- ◆ Example
 - ◆ Weight Loss Intervention: ASPIRE-VA
 - ◆ Social Cognitive Theory
 - ◆ Self-Regulation Theory
 - ◆ Evidence
 - ◆ Pedometers to increase physical activity through walking
 - ◆ Stoplight Guide to improve diet
 - ◆ Small changes work
 - ◆ Motivational coaching

ASPIRE-VA Theoretical Framework



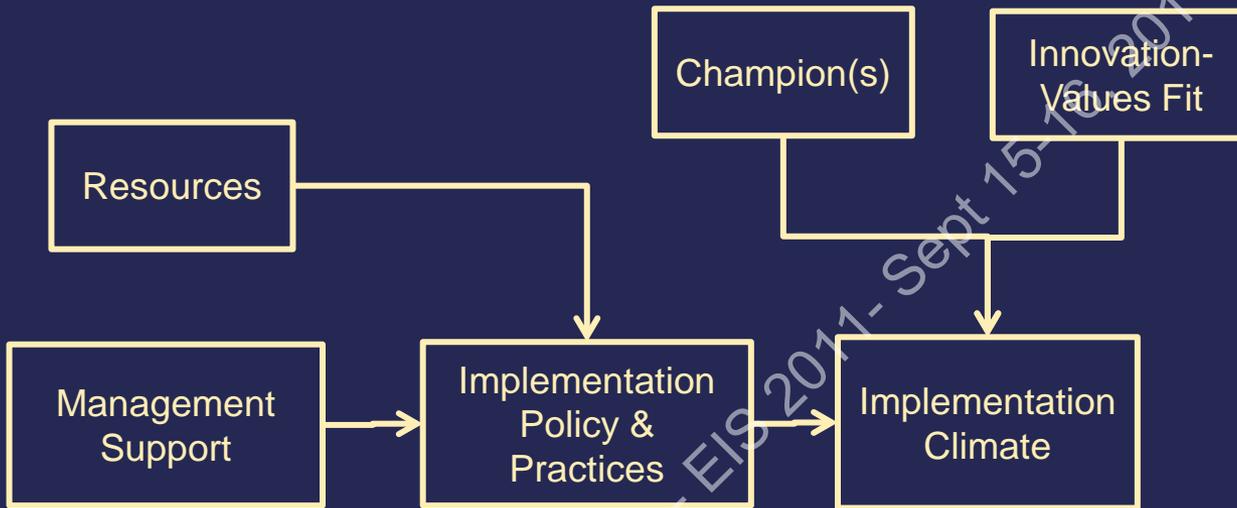
Theory in Implementation

- ◆ Implementation Framework for Complex Innovations

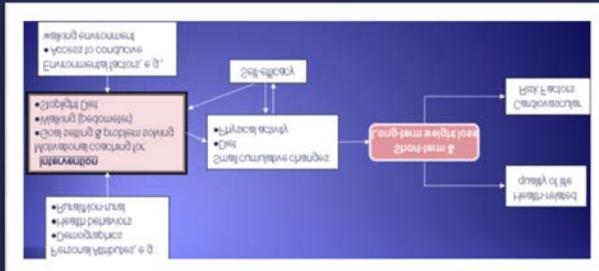


Role of Implementation

Implementation Effectiveness



Intervention Effectiveness



Program Outcomes

Type III Errors

- ◆ Incorrect conclusions about effectiveness of the intervention may result when
 - ◆ No treatment or too little treatment was actually provided
 - ◆ The wrong treatment was provided
 - ◆ Treatment is nonstandard, uncontrolled, or varies across settings/population
- ◆ ...all resulting from inadequate implementation

Implementation Defined

- ◆ Efforts designed to get evidence-based practices and related products into use
- ◆ Implementation typically follows dissemination and includes:
 - ◆ Identifying barriers, facilitators and strategies to reduce, overcome, leverage them
 - ◆ Adapting the targeted practice to the context
 - ◆ Developing a tailored implementation strategy

Implementation Research

- ◆ “ the scientific study of methods to promote the uptake of research findings for the purpose of improving quality of care ”

McDonald et al., 2004 Toward a Theoretic Basis for Quality Improvement Interventions in K.G. Shojania et al., Closing the Quality Gap.

- ◆ “. . .scientific investigations that support movement of evidence-based, effective health care approaches (e.g., as embodied in guidelines) from the clinical knowledge base into routine use.” Rubenstein & Pugh, 2006

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

Theory-driven implementation enables us to accomplish these objectives

State of the Literature - 1

- ◆ Systematic reviews of interventions consistently show
 - ◆ Some work some of the time
 - ◆ None work all of the time
 - ◆ More research needed to figure out what works where and why

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State of the Literature – 2

- ◆ Largely atheoretical
 - ◆ Related to implementation¹
 - ◆ *...and, by the way, too often, for interventions as well*
- ◆ Theory used only as heuristic²
 - ◆ Dropped after the introduction
 - ◆ Used to organize discussion of findings

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State of the Literature - 3

- ◆ Inadequate descriptions of intervention(s), context, and implementation¹⁻³
- ◆ Large majority of trials have no qualitative component
- ◆ Implementation studies suffer from small samples
 - ◆ Example from very recent paper:⁴
 - ◆ “Findings revealed limited information about attributes of successful and unsuccessful team initiatives, barriers and facilitators to team initiatives, unique or combined contribution of selected interventions, or how to effectively establish these teams.”

Theory as a Way Forward

- ◆ “Generalization through theory’ potentially offers a more efficient and appropriate method of generalization than study replication in many possible settings” (p 2)
 - *International panel convened by AHRQ to improve the design, evaluation, and reporting of research for patient safety practices*
- ◆ Build knowledge through strengthened confidence in the usefulness of a theory
- ◆ Identify factors that predict likelihood of success
- ◆ Guide adaptation of the intervention and tailoring of implementation
 - ◆ Through knowledge of determinants – or levers – of change

Case Example

- ◆ Mixed methods study of barriers and facilitators of MOVE! Program implementation in VA
 - ◆ MOVE! Weight Management Program disseminated in January 2006
 - ◆ Purposive sample of 5 sites
 - ◆ Maximize variation with respect to program volume
 - ◆ Indicator of implementation effectiveness
 - ◆ Semi-structured interviews with 24 stakeholders
 - ◆ 83% of those contacted and invited, participated in the study

Hybrid 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	Observational Studies
		Implementation Study	

Study Aim

- ◆ Identify differences in organizational factors between facilities with high MOVE! implementation effectiveness versus those with low implementation effectiveness
- ◆ Help explain the high variation in levels of patient participation observed across VHA facilities

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Study Design

- ◆ Embedded mixed methods study
 - ◆ Qualitative and quantitative data
 - ◆ Semi-structured interviews
 - ◆ 5 purposively selected sites
 - ◆ 24 participants

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Theoretical Frameworks - 1

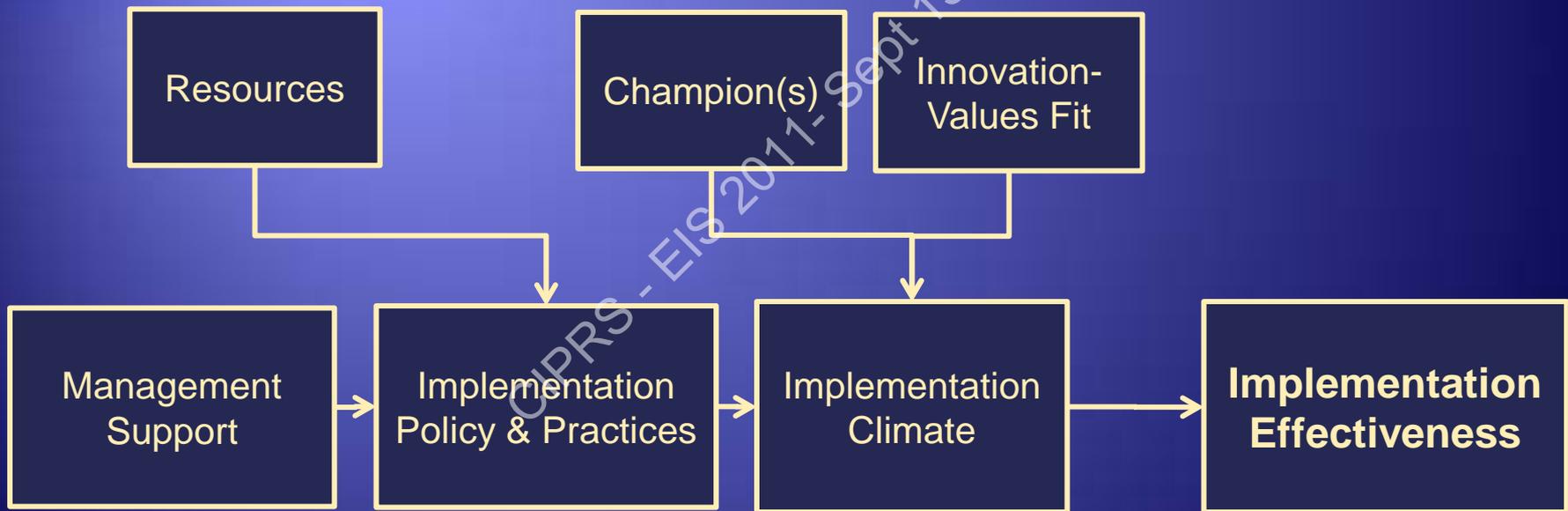
- ◆ Consolidated Framework for Implementation Research (CFIR) – *Qualitative Data Collection*
 - ◆ Comprehensive framework to promote consistent use of constructs, terminology, and definitions
 - ◆ Consolidates existing models and frameworks
 - ◆ Comprehensive in scope
 - ◆ Tailor its use to the study

CFIR: 5 Major Domains

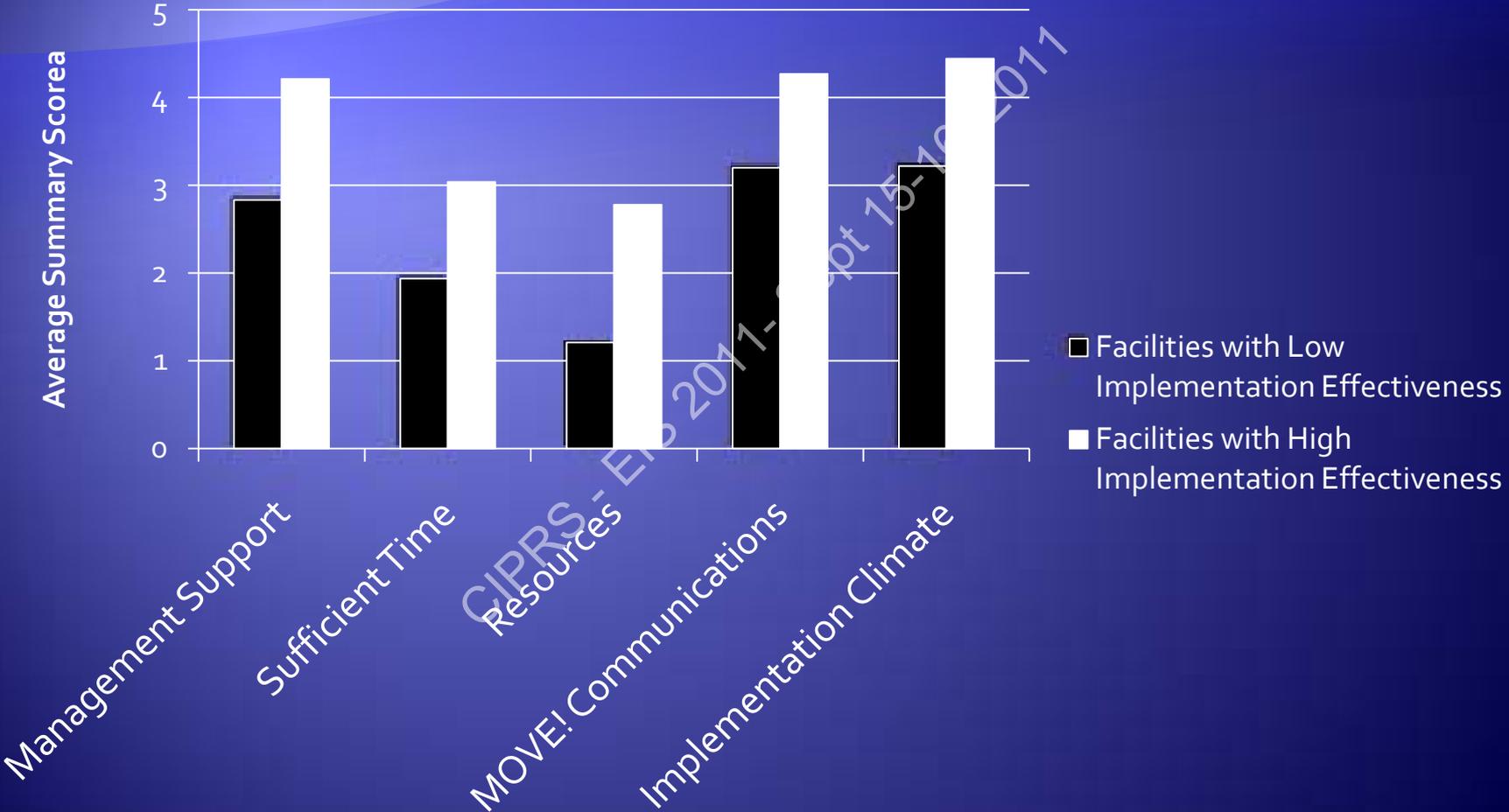
- ◆ **Intervention**
 - ◆ 8 Constructs (e.g., evidence strength & quality, complexity)
- ◆ **Outer Setting**
 - ◆ 4 Constructs (e.g., patient needs & resources)
- ◆ **Inner Setting**
 - ◆ 14 constructs (e.g., leadership engagement, available resources)
- ◆ **Individuals Involved**
 - ◆ 5 Constructs (e.g., knowledge, self-efficacy)
- ◆ **Process**
 - ◆ 8 Constructs (e.g., plan, engage, champions)

Theoretical Frameworks - 2

- ◆ Implementation Framework for Complex Innovations – *Quantitative Data Collection*



Quantitative Results

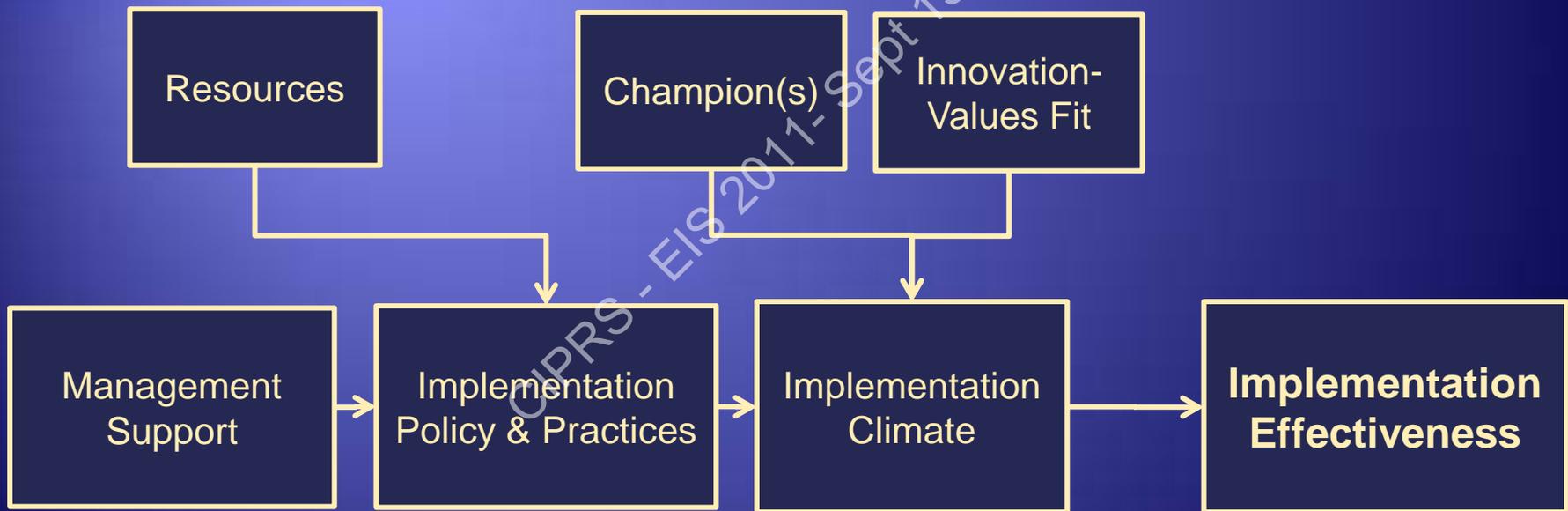


Qualitative Results

- ◆ Importance of Champions was mixed
 - ◆ Appointed but largely absent in one low and one high implementation site
- ◆ Innovations-values fit is important
 - ◆ I would say 99.99%...of the providers recognize that [obesity] is in some way hindering their success in managing diabetes or managing blood pressures or managing hyperlipidemia...So everyone is very receptive...to refer the patients to MOVE! [MOVE! Coordinator]
 - ◆ Lack of fit at 2 low implementation sites

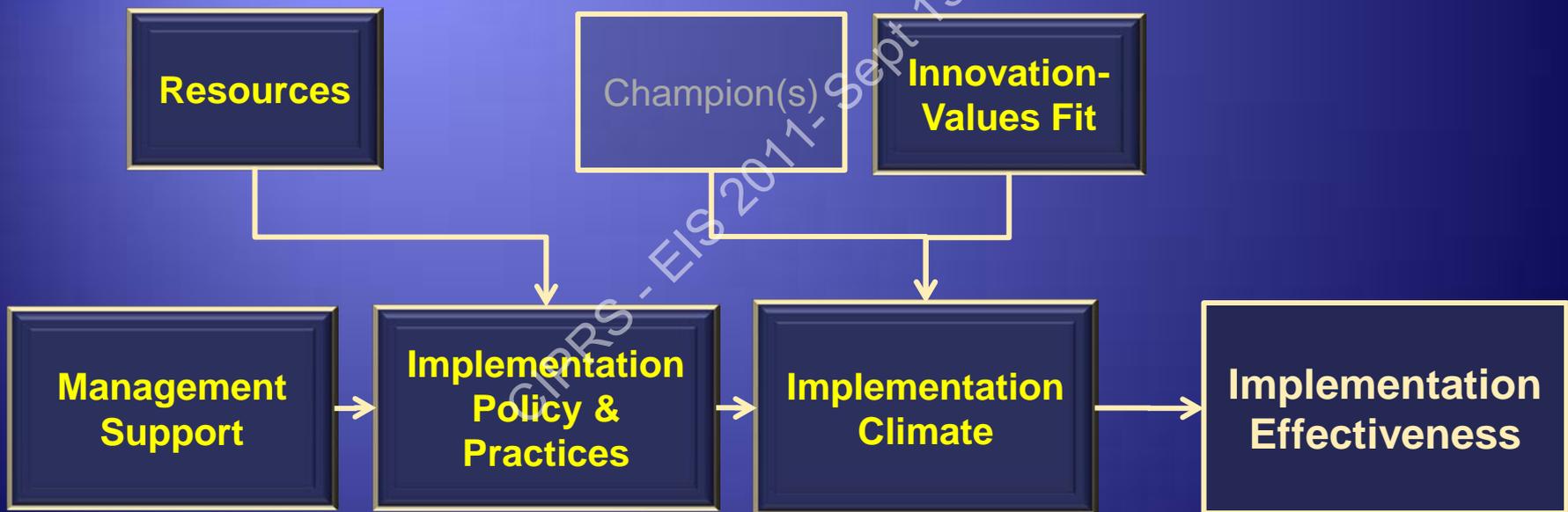
Theoretical Framework

- ◆ Implementation Framework for Complex Innovations



Were the theories useful?

- ◆ Implementation Framework for Complex Innovations



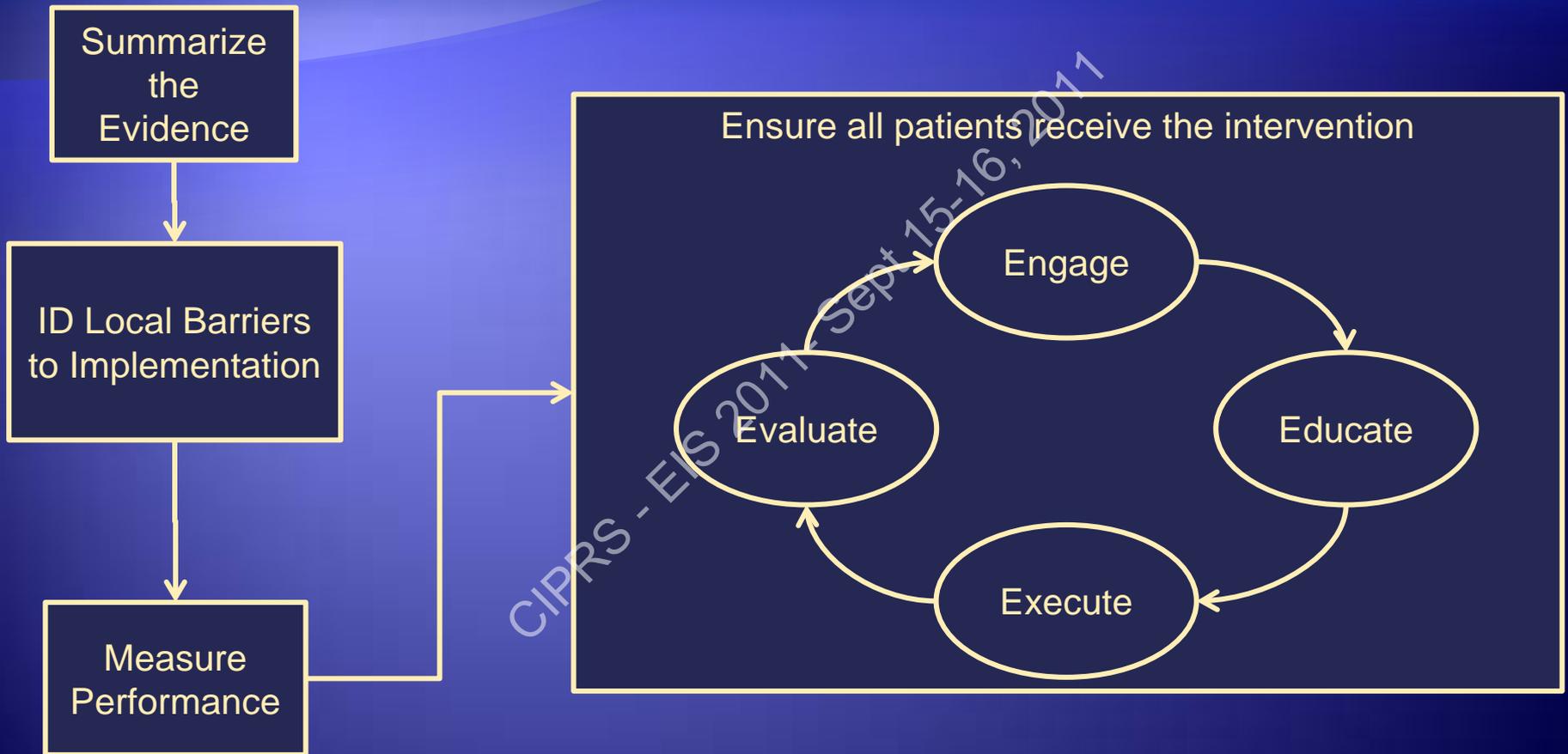
Were the Theories Useful?

- ◆ Additional insights & constructs were identified through CFIR. E.g.,
 - ◆ “Teamness” mattered: the degree to which MOVE! teams coalesced
 - ◆ Perception of intervention characteristics
 - ◆ Strength & Quality of evidence
 - ◆ Relative Advantage
 - ◆ Perception of patient needs & resources
- ◆ Not all CFIR constructs were salient

Types of Theories

- ◆ Multiple theories often needed
 - ◆ 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
 - ◆ Process theories – (aka prescriptive, planned action)
 - ◆ How implementation should be planned, organized and scheduled
 - ◆ Mixed theories
 - ◆ Elements of both

Pronovost's "4E's" Process Theory



Choosing Theory – 1

1. Consider nature of the theory
 - ♦ Process v. explanatory
 - ♦ Context (e.g., policy, organization)
 - ♦ Discipline (e.g., social science, psychology)

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Choosing Theory – Example

1. Consider nature of the theory
 - ◆ Process v. explanatory
 - ◆ Explanatory theories were used:
 - ◆ Framework for Complex Interventions
 - ◆ CFIR
 - ◆ Context
 - ◆ Organization

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Choosing Theory – 2

1. Consider nature of the theory
 - ◆ Process v. explanatory
 - ◆ Context (e.g., policy, organization)
 - ◆ Discipline (e.g., social science, psychology)
2. Consider level at which it will be applied
 - ◆ Individuals
 - ◆ Teams
 - ◆ Organization
 - ◆ System

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Choosing Theory - Example

2. Consider level at which it will be applied
 - ◆ Organization
 - ◆ Teams
 - ◆ Importance of coalescing teams (“teamness”)
 - ◆ Individuals
 - ◆ Physician Champion
 - ◆ Formally appointed implementation leader
 - ◆ System
 - ◆ Role of system-wide performance measurement

Choosing Theory – 3

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

Conducting Theory-based Implementation Studies

1

Assess targeted
EBP change and
context

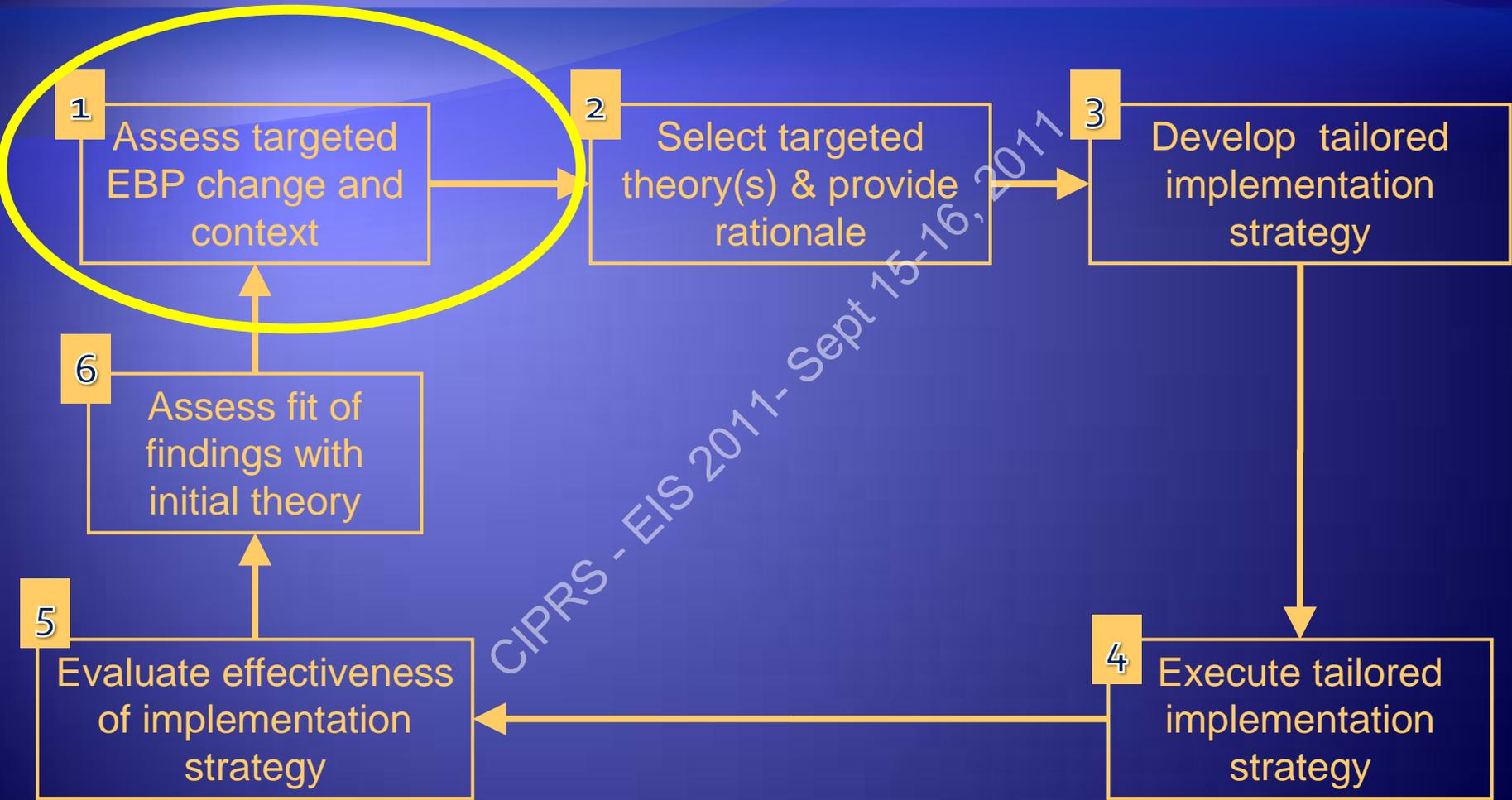
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Using Theory: A Few Notes

- ◆ There are no right or wrong theories
- ◆ There are better fitting theories that explain why a specific strategy or mechanism causes the intended change
- ◆ The implementation strategy(s) may be operationalized from the theoretical concepts.
- ◆ To apply the better fitting theory, you'll need to specify several key issues.

Note: Operational definition= a clear, concise detailed definition of a construct's measure and actionable components so that all have the same understanding of how to put it into practice and collect it or determine whether its correct or not.

Conducting Theory-based Implementation Studies



Case Example: Post Stroke Depression (PSD) Screening and Rx

- ◆ *Adapted and implemented VA annual depression clinical reminder for stroke patients receiving follow up care in primary or neurology outpatient care clinics*
- ◆ *Objective was to improved PSD screening among veterans with recent ischemic stroke and to support providers in taking action when PSD was detected*
- ◆ *2 VA Medical Centers (2 PC and 2 Neuro clinics)*

Case Example: PSD continued

- ◆ Quasi experimental
- ◆ Compared patients receiving post stroke outpatient care one year prior to intervention period (control group) to patients receiving post stroke outpatient care during the (intervention period).
- ◆ Formed teams (including front line clinicians, clinical application coordinators) at both sites to develop the local clinical reminders and implementation strategies

Hybrid Trial Designs

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		Implementation Study	

Assess targeted EBP change & context

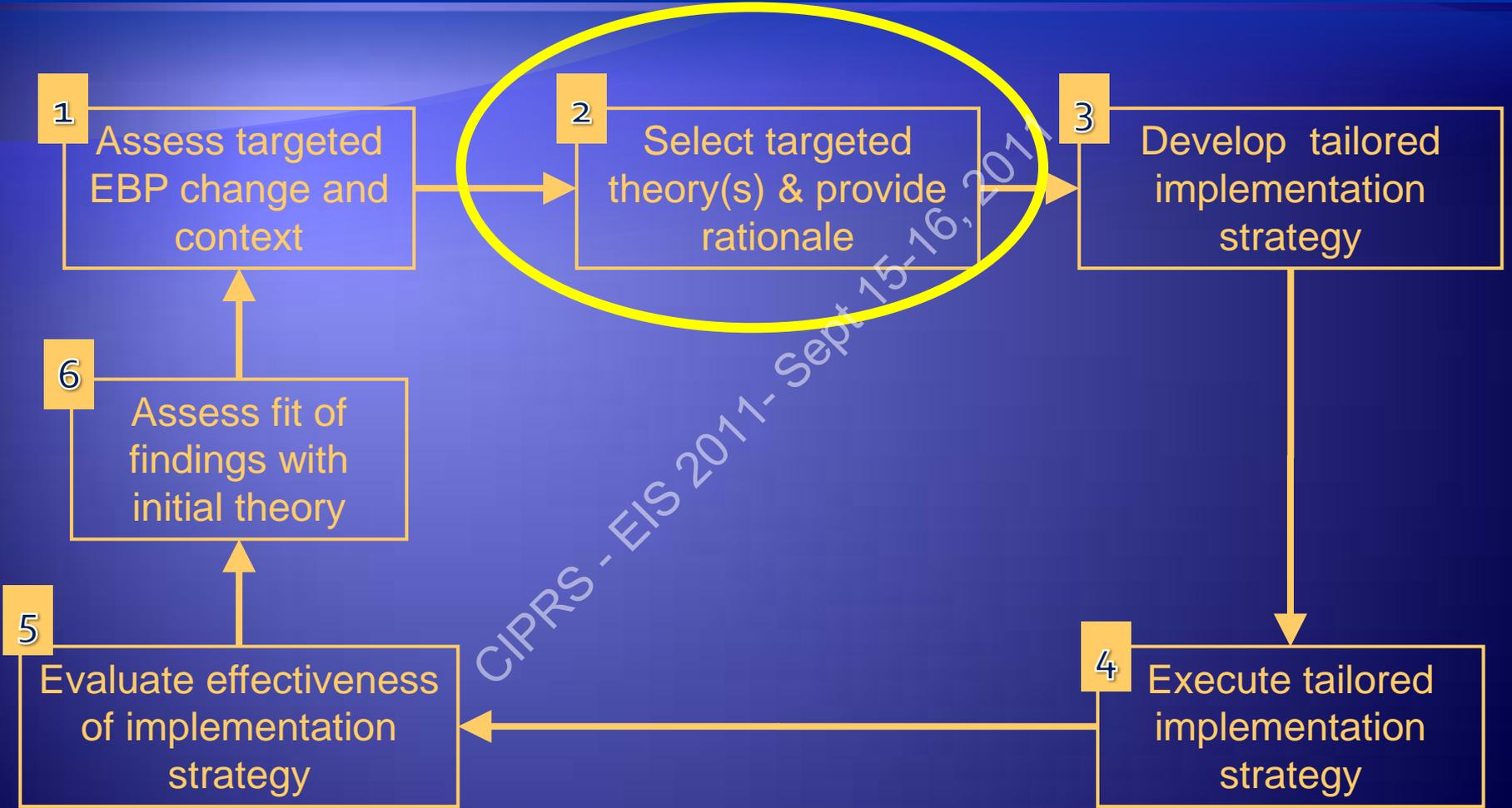
- ◆ What are the change objectives?
 - ◆ HEALTH DELIVERY SYSTEM INTERVENTION
 - ◆ Screening for depression within 6 months post stroke during primary care or neurology outpatient clinics
 - ◆ Treatment provided when PSD detected
- ◆ Who are the targets? [Identify level at which change occurs]
 - ◆ Individual Clinicians and Clinic Check-In
 - ◆ Primary Care Providers
 - ◆ Neurologists
 - ◆ Nurses
 - ◆ Regions (2)

Case Example: PSD Continued

- ◆ Identify Characteristics of the Change
 - ◆ Change is peripheral to perception of current practices
 - ◆ Change is simple
 - ◆ Motivation to change = Improve patient outcomes
 - ◆ [PSD at risk for worse functional outcomes, mortality]

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Conducting Theory-based Implementation Studies



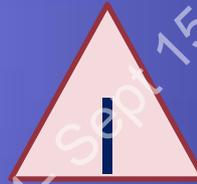
What is the mechanism/strategy for which you expect the change to occur?

- ◆ How do you expect to get from

CURRENT
PRACTICE



EBP

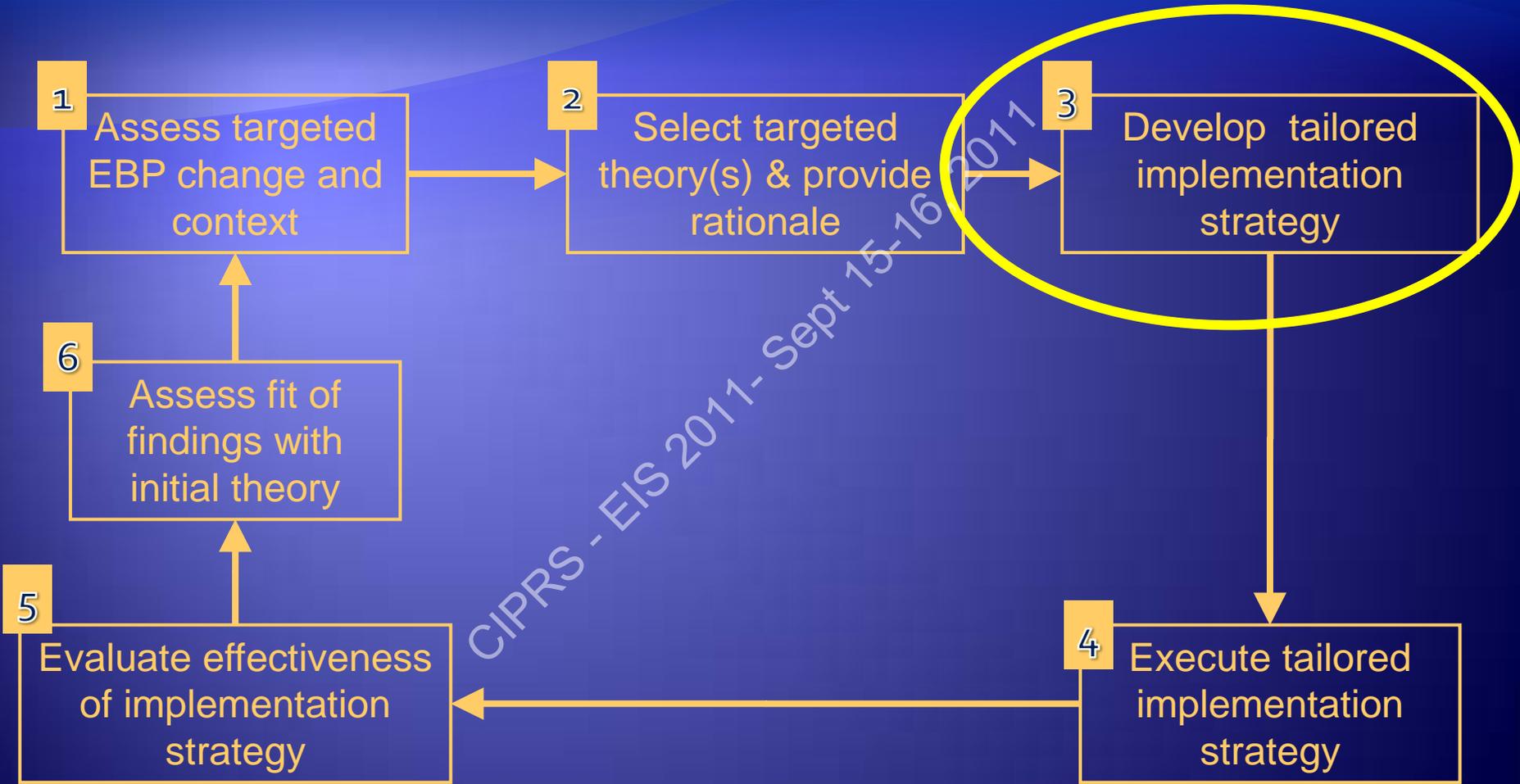


- ◆ Where are you now?
- ◆ Where do you want to be?
- ◆ Potential Barriers to change?
- ◆ Possible facilitators to Change?



=HOW to get to desired outcomes, EBP

Conducting Theory-based Implementation Studies



Identify Actionable Factors for Implementation Intervention

- ◆ Map out the tasks of the current state of the EBP
- ◆ Map out the tasks of the ideal state of the EBP
- ◆ What are the differences between current and ideal?
- ◆ What needs to happen to transition from current to ideal state? **Actionable Factors**
 - ◆ Does the strategy need to differ by setting/organization/group?

Map out the Current State of Tasks

◆ Neurology Outpatient Clinic Visit

- ◆ Patient checks into clinic w/nurse
- ◆ Patient sees Neurologist
- ◆ Neurologist may or may not screen for PSD, refer to MH or prescribe RX
- ◆ Pt accepts or refuses Rx/referral

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IDEAL STATE of TASKS

- ◆ PSD Screening & Treatment in NEUROLOGY OUTPATIENT CLINICS
 - ◆ PT CHECKS IN
 - ◆ PT SCREENED FOR STROKE DURING PAST 6 months
 - ◆ If yes, screened for depression.
 - ◆ Positive screen is flagged to neurologist
 - ◆ Neurologist confirms dx, treats or refers to MH
 - ◆ PT accepts or refuses RX

Differences Between Current and Ideal States

ACTIONABLE FACTORS	RATIONALE	SUPPORTING THEORY
Clinical Informatics Support –check in screener for stroke during past 6 months – nurse		
Neurology knowledge and acceptance of depression screening in post stroke care		

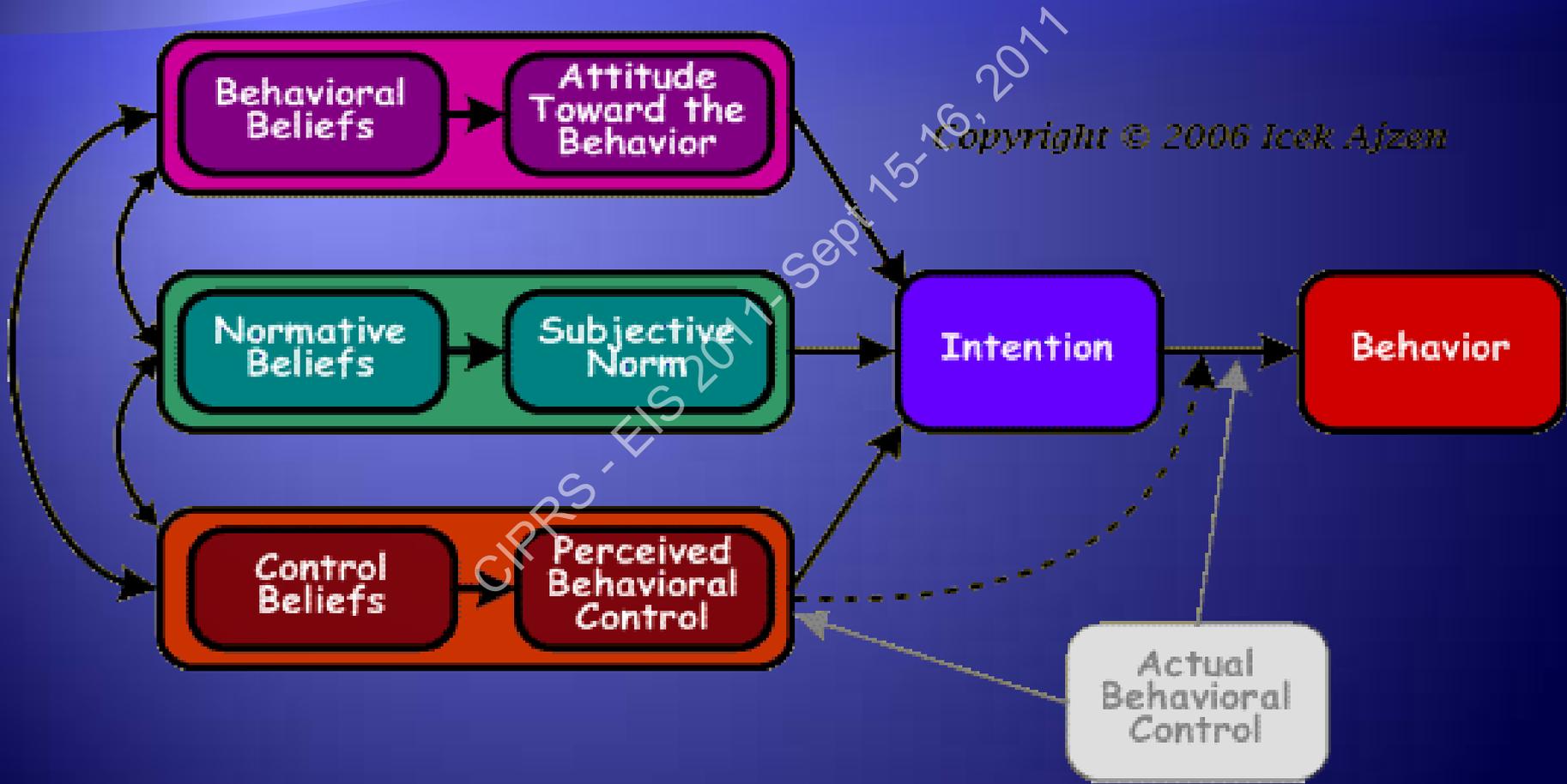
Rationale for the Theory(s)

- ◆ RATIONALE = Justification for selection and operational definition of the concept as applied to your specific implementation program.

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Individual Level Change

Theory of Planned Behavior



Select Theory and Provide Rationale

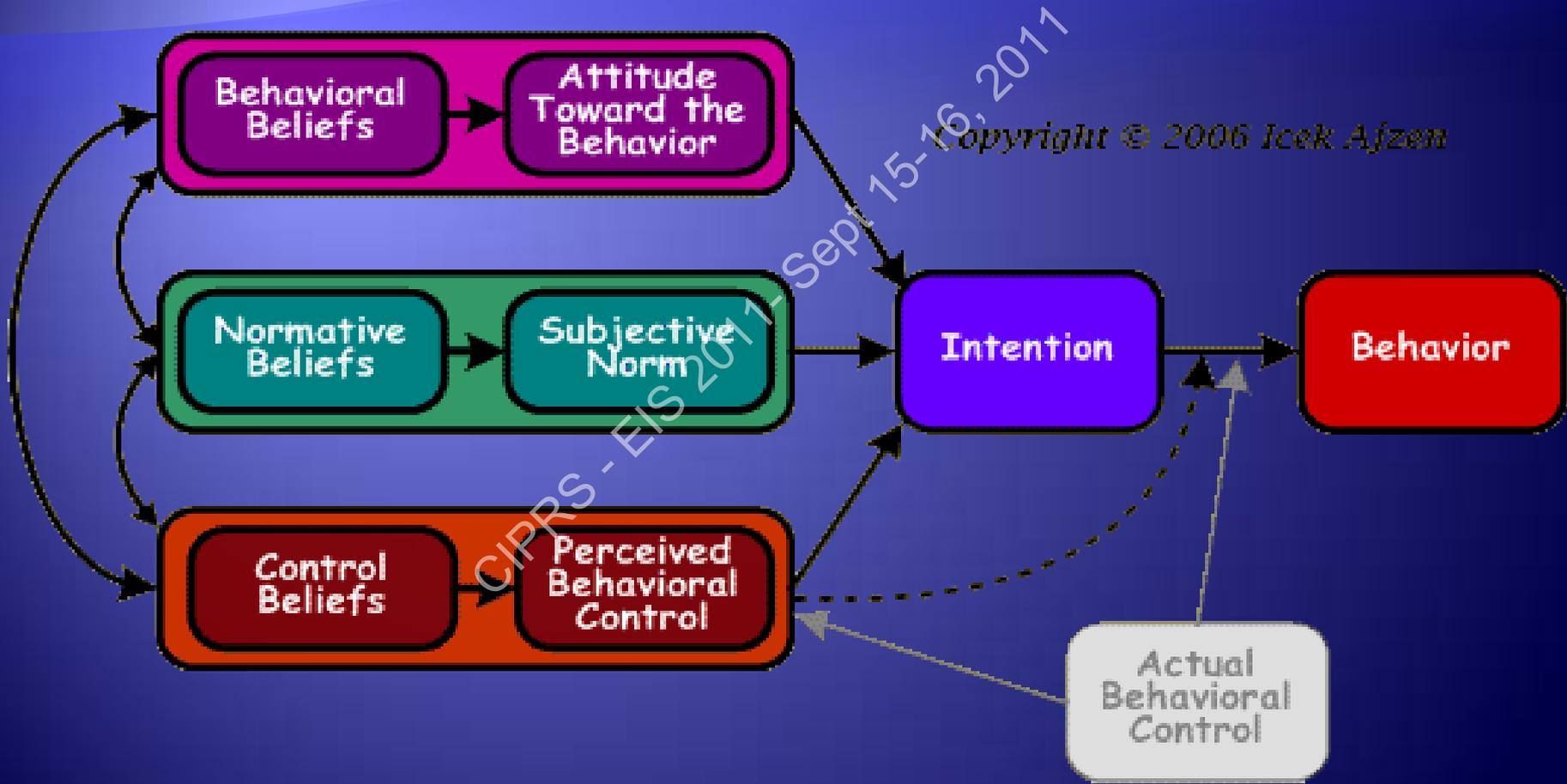
ACTIONABLE FACTORS	RATIONALE	SUPPORTING THEORY
Clinical Informatics Support –check in screener for stroke during past 6 months – PC/Neurology and clinical reminder	Establish as a perceived social norm with local clinical champion modeling and promoting practice	
Neurology knowledge and acceptance of depression screening in post stroke care	Include in competency evaluations ; use of local clinical champions to promote the need and value, establish as a perceived social norm; model the behavior to increase self-efficacy	

Select Theory and Provide Rationale

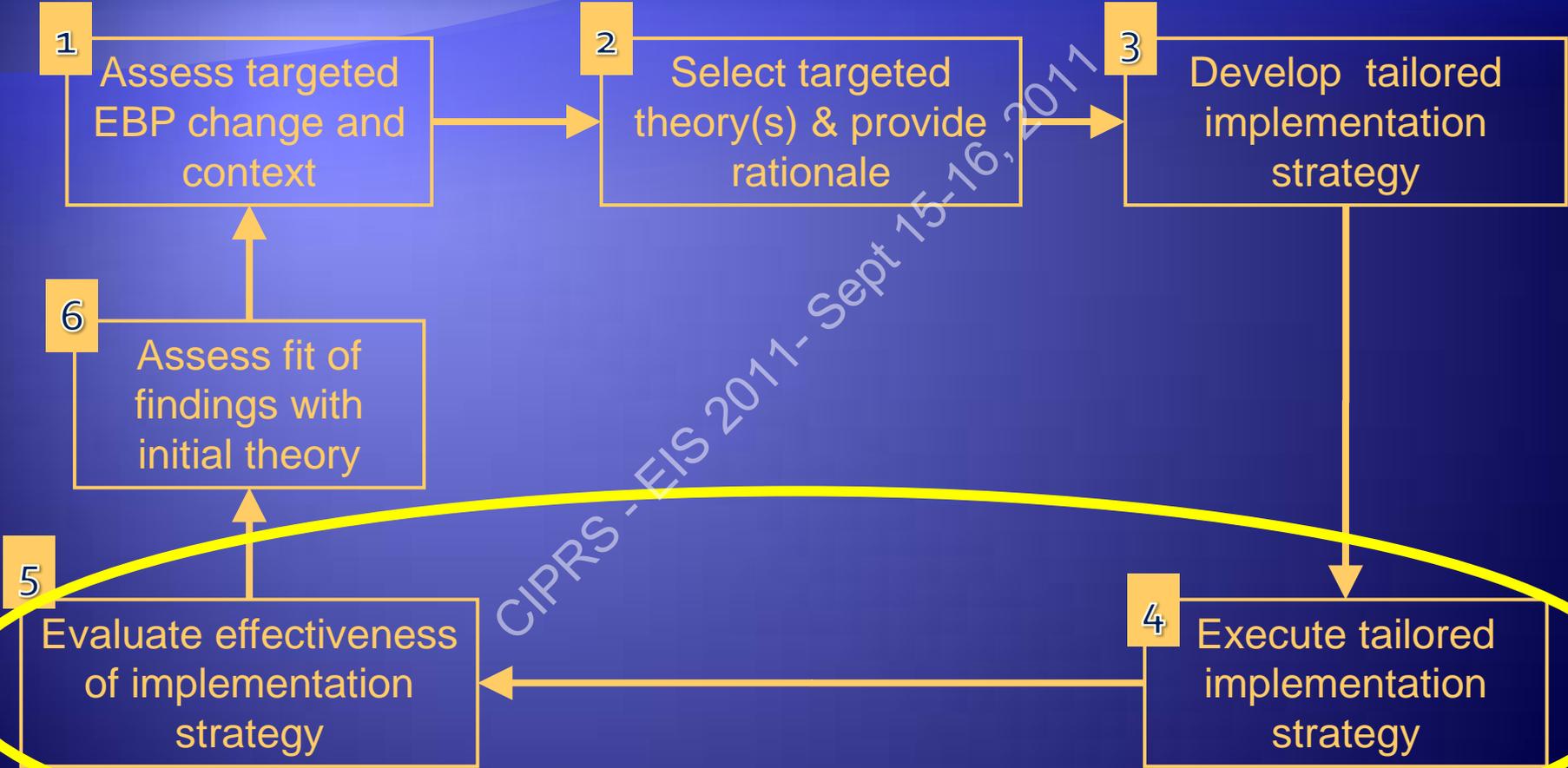
ACTIONABLE FACTORS	RATIONALE	SUPPORTING THEORY
Clinical Informatics Support – check in screener for stroke during past 6 months – Neurology and clinical reminder	Use of built in electronic prompt as a cue to action; Establish as a perceived social norm with local clinical champion modeling and promoting practice	Theory of Planned Behavior
Neurology knowledge and acceptance of depression screening in post stroke care	Include in competency evaluations ; use of local clinical champions to promote the need and value, establish as a perceived social norm; model the behavior; peer support/vicarious learning	Theory of Planned Behavior

Individual Level Change

Theory of Planned Behavior



Conducting Theory-based Implementation Studies



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Assess Context (CFIR constructs)

- ◆ Adaptability – the degree to which an intervention can be adapted, tailored, refined or reinvented to meet local needs;
- ◆ Peer Pressure – Competitive pressure to implement an intervention (Service chief endorses or discourages practices)
- ◆ Implementation Climate – the capacity for change and extent to which use will be rewarded

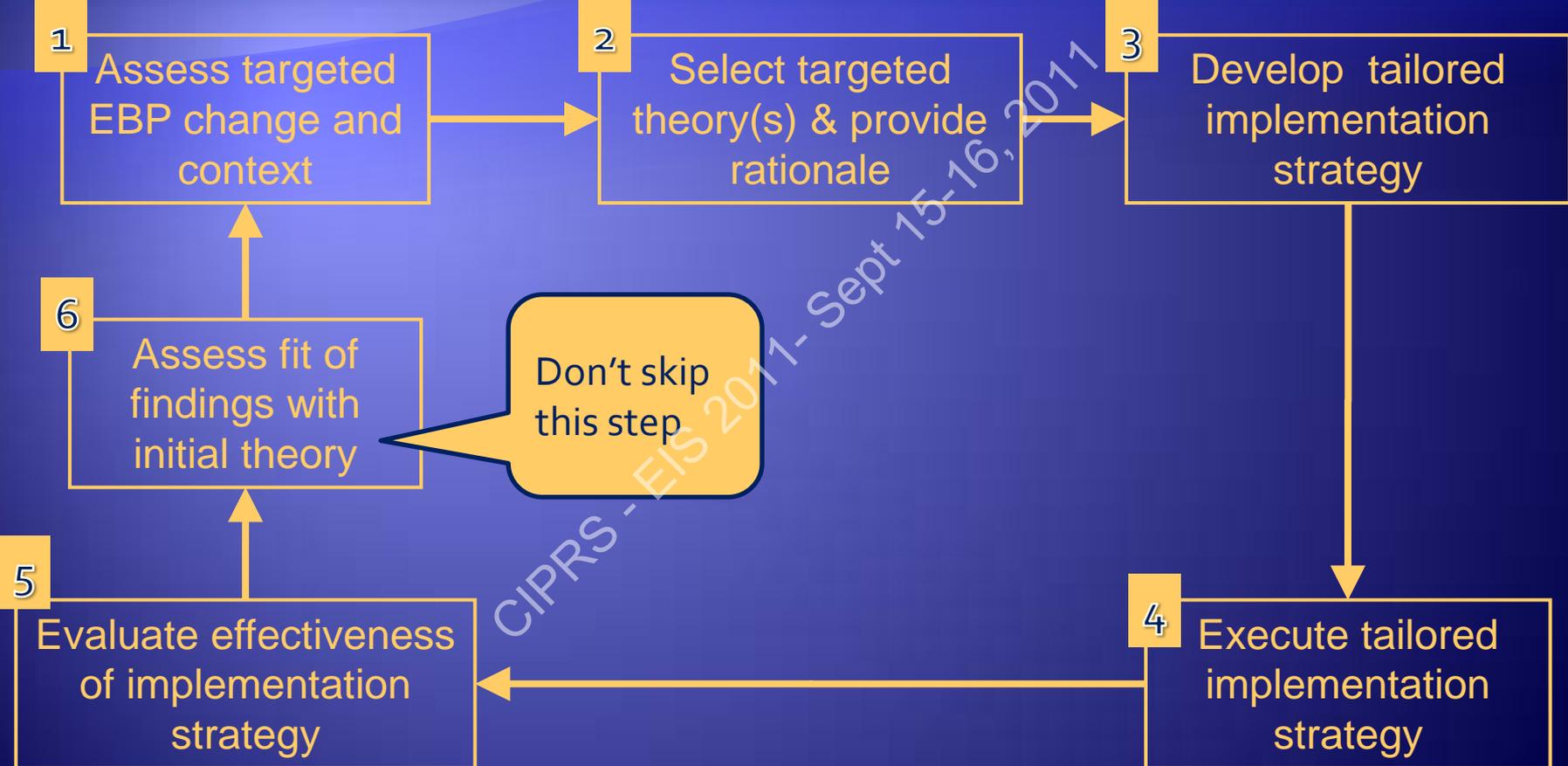
Execute & Evaluate

◆ Evaluation

◆ Processes

- ◆ PSD screening increased (85% intervention vs 50% control)
- ◆ Treatment action was received (83% intervention vs 73% control)
- ◆ Lack of clinical champions in specific clinics were related to less use of clinical reminder
 - ◆ 1 site = neurology outpatient service did not believe they should screen for depression; however their PC did well on depression screening in general and found it easy to adapt
 - ◆ 1 site=neurology service had strong champion who believed in PSD screening and Rx; however their PC did not believe stroke patients should be flagged in PC and lacked a champion.

Conducting Theory-based Implementation



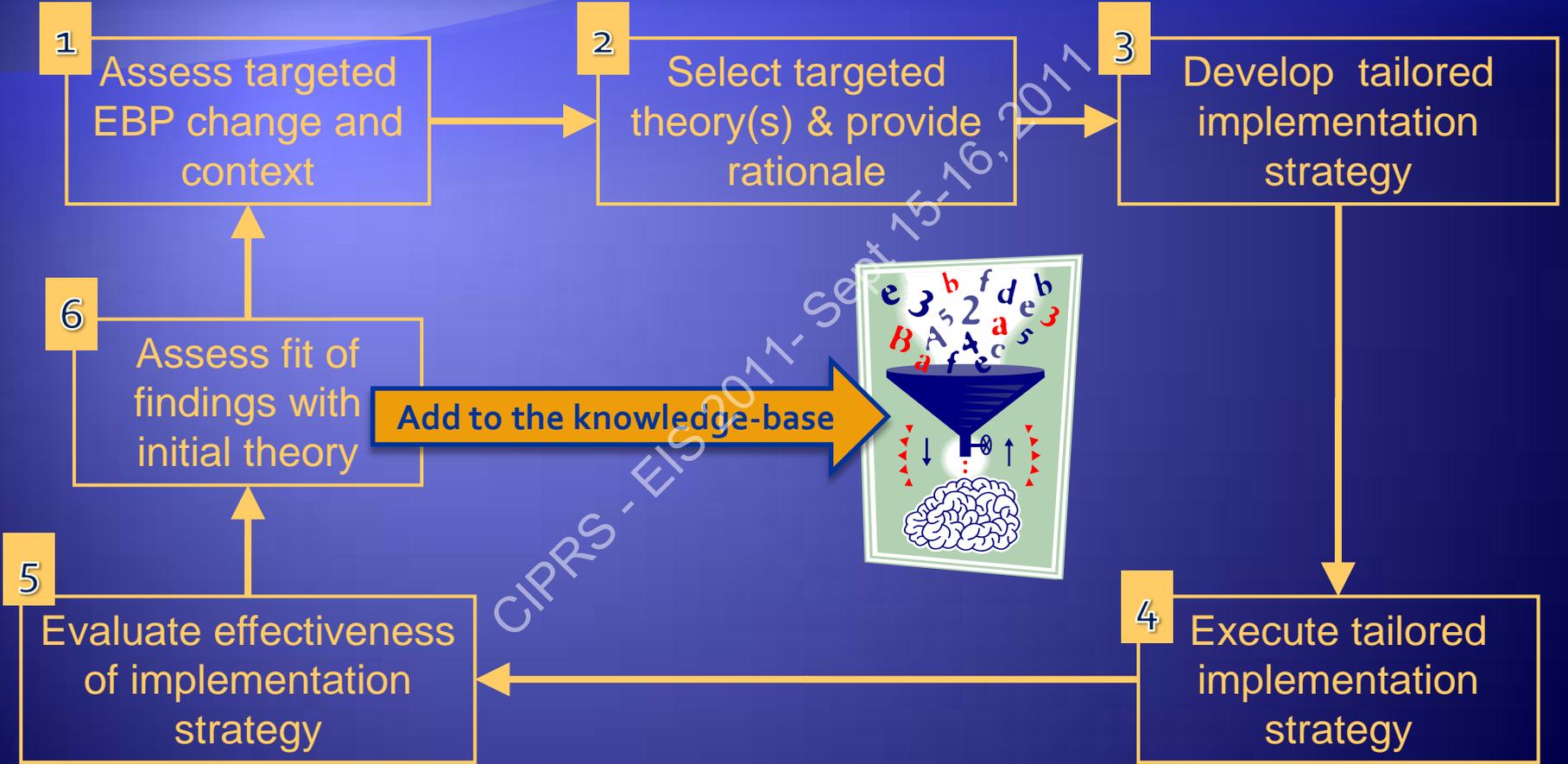
Assess Theory

- ◆ 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?

Was the Theory Useful?

- ◆ We used theory to guide the intervention
- ◆ Did not evaluate each component of the theory
- ◆ Do over
 - ◆ Survey the front line clinicians who had the opportunity to use the clinical reminders
 - ◆ Measure the constructs of the theory (perceived social norms, behavioral intention, etc)
 - ◆ Evaluate the theoretical impact on the implementation of the PSD clinical reminder

Conducting Theory-based Implementation



Key Points

- ◆ Use pre-implementation work to target your implementation critical factors
- ◆ Provide rationale for selection of theory
- ◆ Clearly define your strategies so that others may replicate to generalize beyond your specific efforts
- ◆ Balance theoretical components with pragmatic factors identified from the targeted users of EBP
- ◆ Evaluate usefulness of theory(s) used

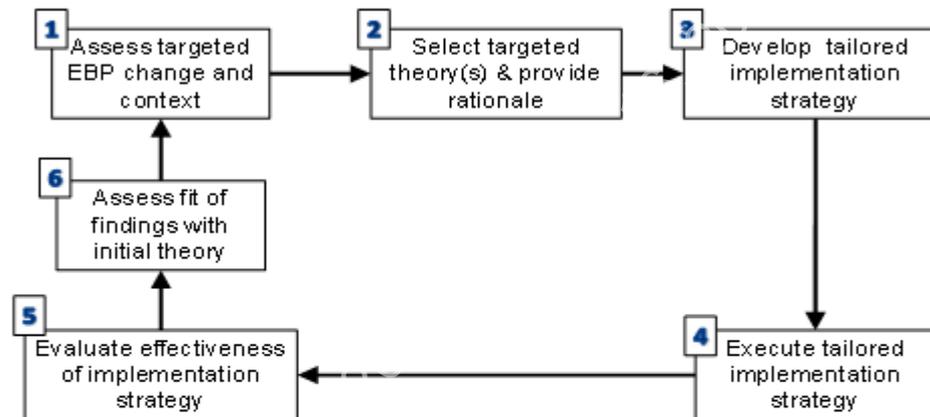
Help!

- ◆ Implementation Science is relatively new
 - ◆ What is the dependent variable?
 - ◆ How to measure?
 - ◆ What is success?
- ◆ Mutable v. immutable variables
- ◆ Resources
 - ◆ CIPRS
 - ◆ Your EIS mentors
- ◆ You are not alone!

Worksheet for Implementation Theory Workgroup Break-out

Day 1: Afternoon

Conducting Theory-based Implementation Studies



Adapted from: Sales A, Smith J, Curran G, Kochevar L: Models, strategies, and tools: Theory in implementing evidence-based findings into health care practice. *J Gen Intern Med* 2006, 21(Suppl 2):S43-49.

1. Assess Targeted EBP Change & Context

Assess the change

- Identify the targeted EBP change

Goal:

Key Features of EBPs to be implemented:

Check Which Feature(s) Apply_ (See Tip Sheet & Glossary)

- Clinical Treatment Intervention:

- Patient Health Promotion/Self-Management Intervention:

- Health delivery system intervention:

Characterize the change**? Identify the levels at which the change will occur:**

- Individual Clinicians
- Individual Managers
- Team
- Clinic or Unit
- Facility
- VISN/Region
- Other

? Identify characteristics of the change

- Is the change “core” or “peripheral” to individuals’ perception of current practices/processes? Explain.

- Is the change “complex” or “simple”?

- What is the motivation to change?

Assess the Context

- Using the CFIR list of constructs, identify the “most important” constructs likely to influence implementation and why and how they (are likely to) manifest.

Construct	Why & How

2. Select Targeted Theory(s) & Provide Rationale



Level of Theory	Specific Theory <i>(Refer to Classification of Theories & Example Theory Diagrams)</i>	Rationale <i>(What is your rationale for selecting this theory?)</i>
<input type="checkbox"/> System or network <i>Describe:</i>	Name: Type: <input type="checkbox"/> Explanatory/Descriptive <input type="checkbox"/> Action/Prescriptive	
<input type="checkbox"/> Organization <i>Describe:</i>	Name: Type: <input type="checkbox"/> Explanatory/Descriptive <input type="checkbox"/> Action/Prescriptive	
<input type="checkbox"/> Team: <i>Describe:</i>	Name: Type: <input type="checkbox"/> Explanatory/Descriptive <input type="checkbox"/> Action/Prescriptive	
<input type="checkbox"/> Individual Level <i>Describe:</i>	Name: Type: <input type="checkbox"/> Explanatory/Descriptive	

References

ASPIRE-VA Theoretical Framework Slide: Damschroder, L. J., Lutes, L. D., Goodrich, D. E., Gillon, L., & Lowery, J. C. (2010). A small-change approach delivered via telephone promotes weight loss in veterans: Results from the ASPIRE-VA pilot study. *Patient Education and Counseling*, 79, 262-266. doi: pec.2009.09.025

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Type III Errors Slide: Fixsen DL, Naoom SF, Blase KA, Friedman RM, Wallace F. *Implementation Research: A Synthesis of the Literature*. Tampa, FL: University of South Florida, Louis de la Parte Florida Mental Health Institute; December 27, 2007 2005.

Implementation Defined Slide: Stetler C, Mittman B, Francis J: Overview of the VA Quality Enhancement Research Initiative (QUERI) and QUERI theme articles: QUERI Series. 2008, 3:8

State of the Literature – 2 Slide:

1. Foy R, Ovretveit J, Shekelle PG, et al. The role of theory in research to develop and evaluate the implementation of patient safety practices. *Quality & safety in health care*. Feb 11 2011.
2. Helfrich, C. D., Damschroder, L. J., Hagedorn, H. J., Daggett, G. S., Sahay, A., Ritchie, M. et al. (2010). A critical synthesis of literature on the promoting action on research implementation in health services (PARIHS) framework. *Implement Sci*, 5(1), 82. doi: 10.1186/1748-5908-5-82

State of the Literature – 3 Slide:

1. Glenton, C., Lewin, S., & Scheel, I. B. (2011). Still too little qualitative research to shed light on results from reviews of effectiveness trials: A case study of a Cochrane review on the use of lay health workers. *Implement Sci*, 6(1), 53. doi: 10.1186/1748-5908-6-53
2. Weiner, B. J., Amick, H. R., Lund, J. L., Lee, S. Y., & Hoff, T. J. (2011). Use of qualitative methods in published health services and management research: a 10-year review. *Medical Care Research and Review*, 68(1), 3-33. doi: 10.1177/1077558710372810
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