

Implementation Science Models & Methods to Advance Partnered Research

September 30, 2020

Donna Zulman, MD, MS

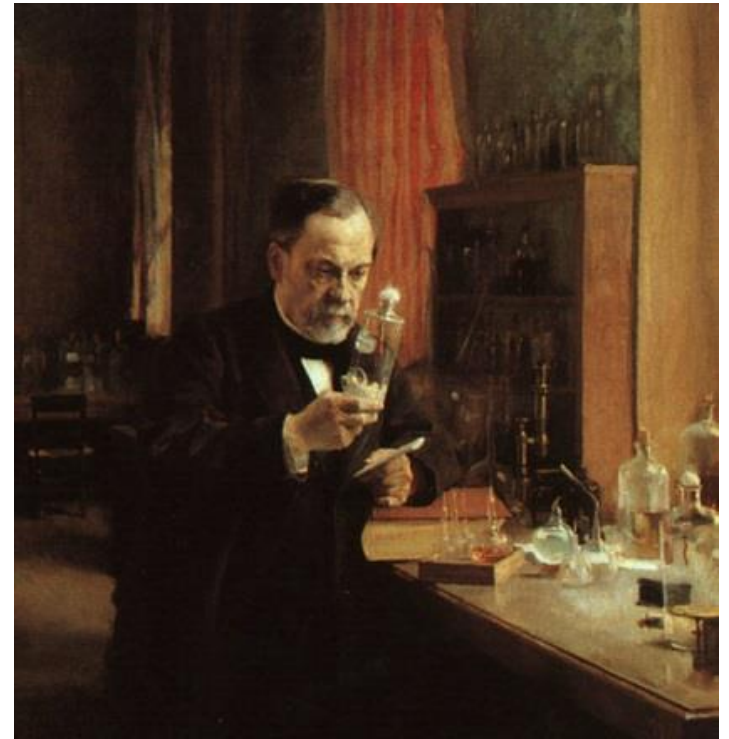
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Why do we engage in scientific inquiry?

“To that person who devotes his life to science, nothing can give more happiness than increasing the number of discoveries...

But his cup of joy is full when the results of his studies immediately find practical applications.”

- *Louis Pasteur*



Albert Edelfelt (1854-1905)
Louis Pasteur
1885

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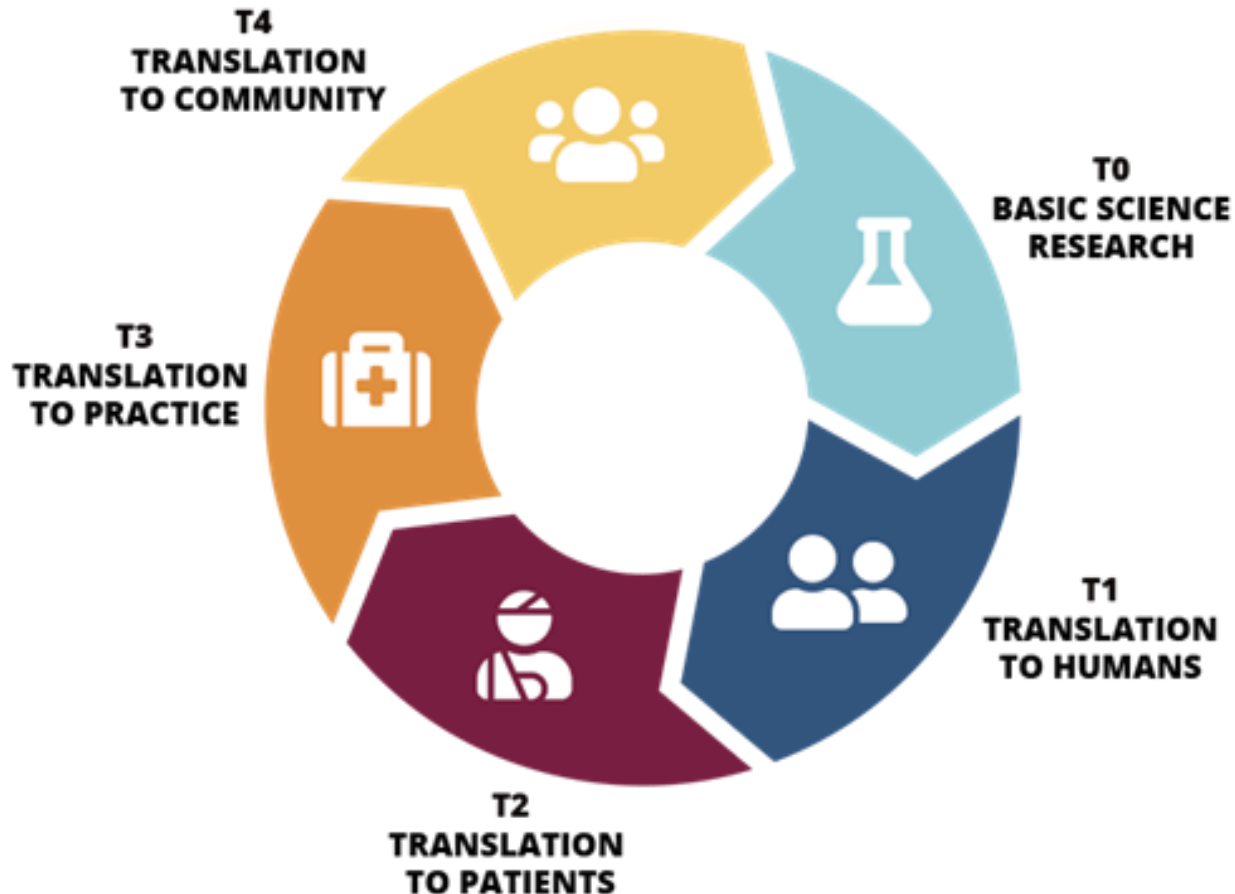
- *Louis Pasteur*

...also the goal of
partnered research!

Overview

- What is Implementation Science?
- Intro to implementation science methods
 - Defining the intervention
 - Identifying implementation strategies
 - Choosing a framework for your study
 - Selecting implementation outcomes
- Integrating implementation science into partnered research

Translational Research for Dissemination & Implementation



Science can help us understand not only what to implement but how to implement and disseminate effective interventions.

What is Implementation Science?

The scientific study of methods to promote the integration of research findings and evidence-based interventions into health care practice and policy

(NIH definition)

The ultimate goal of dissemination & implementation science is to ensure that advances in health science become standards for care in all populations and all healthcare settings.

(Russ Glasgow, *AJPH*, 2012)

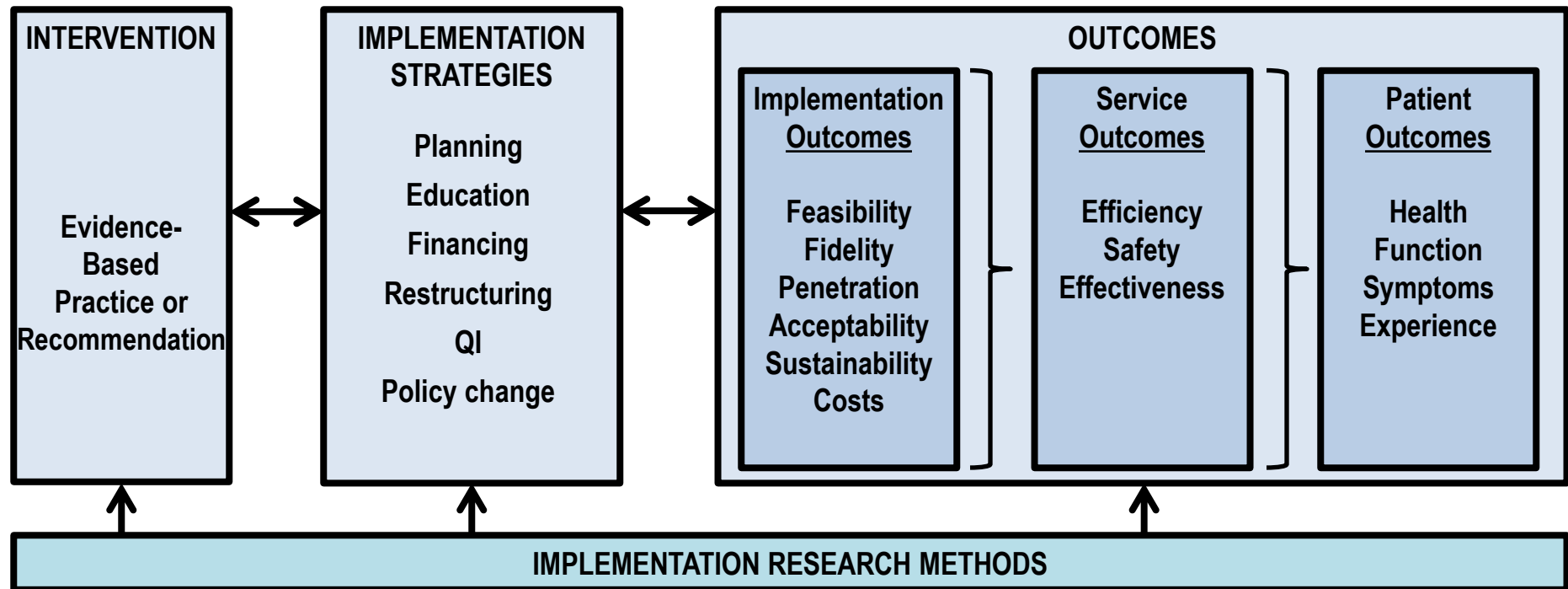
Implementation Science Questions

- Effectiveness (*Does it work... in the real world?*)
- Process of delivery (*How does it work?*)
- Acceptability (*Will people be willing to use it?*)
- Cost (*How much does it cost to implement?*)
- Appropriateness (*Is this the right intervention?*)
- Reach (*How many people are exposed and benefit?*)
- Intensity (*What is the expected strength of the intervention?*)
- Satisfaction (*Are stakeholders satisfied and to what degree?*)
- Sustainability (*Can it be continued over time?*)

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Framework for Implementation Research



Framework for Implementation Research

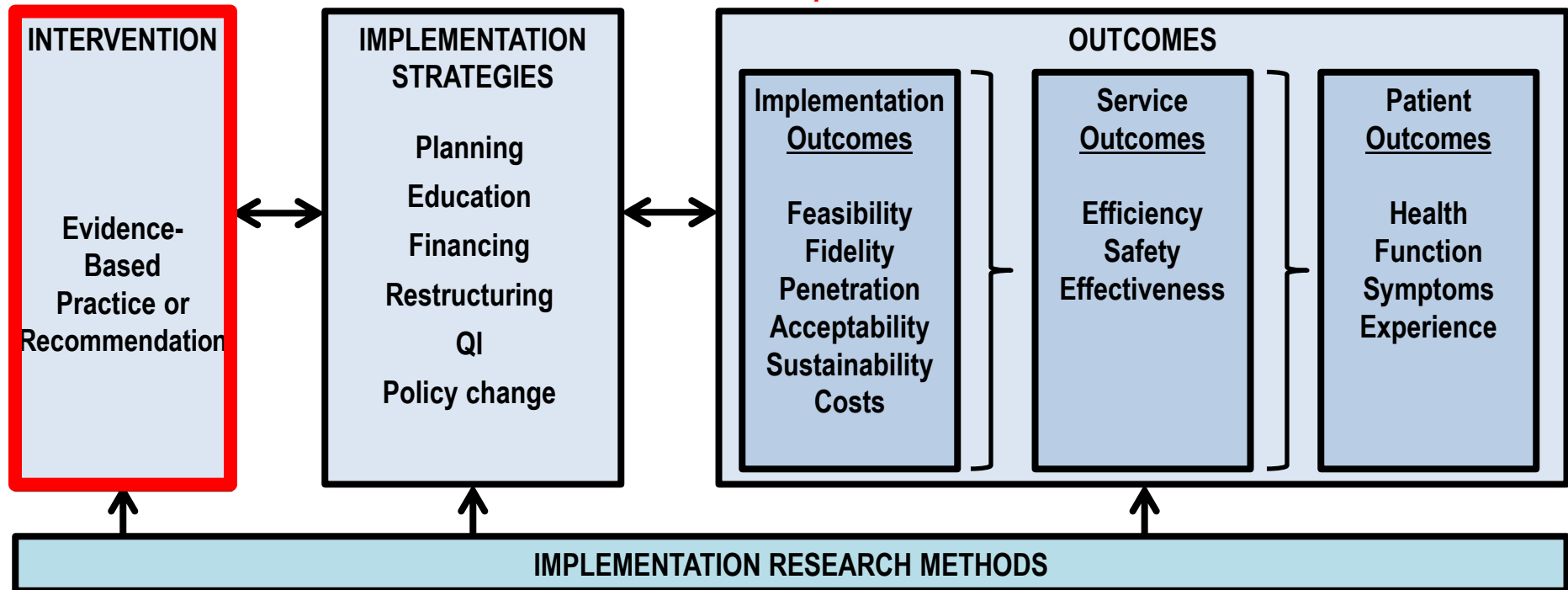
Colon cancer screening

Reducing chronic opioid use after surgery

Interdisciplinary team for high-risk patients

Optimizing glucose control

Goals of care conversations for patients with advanced illness



Note: clinical partner input about the intervention at early stages is high-yield and critical to their ongoing support

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Our aspirations...



“You know what I’d like to do, Caslow? I’d like to create a far-reaching, innovative program that will open a lot of channels, offer great opportunities, link up with all kinds of things, and enable something or other to happen. Any ideas?”

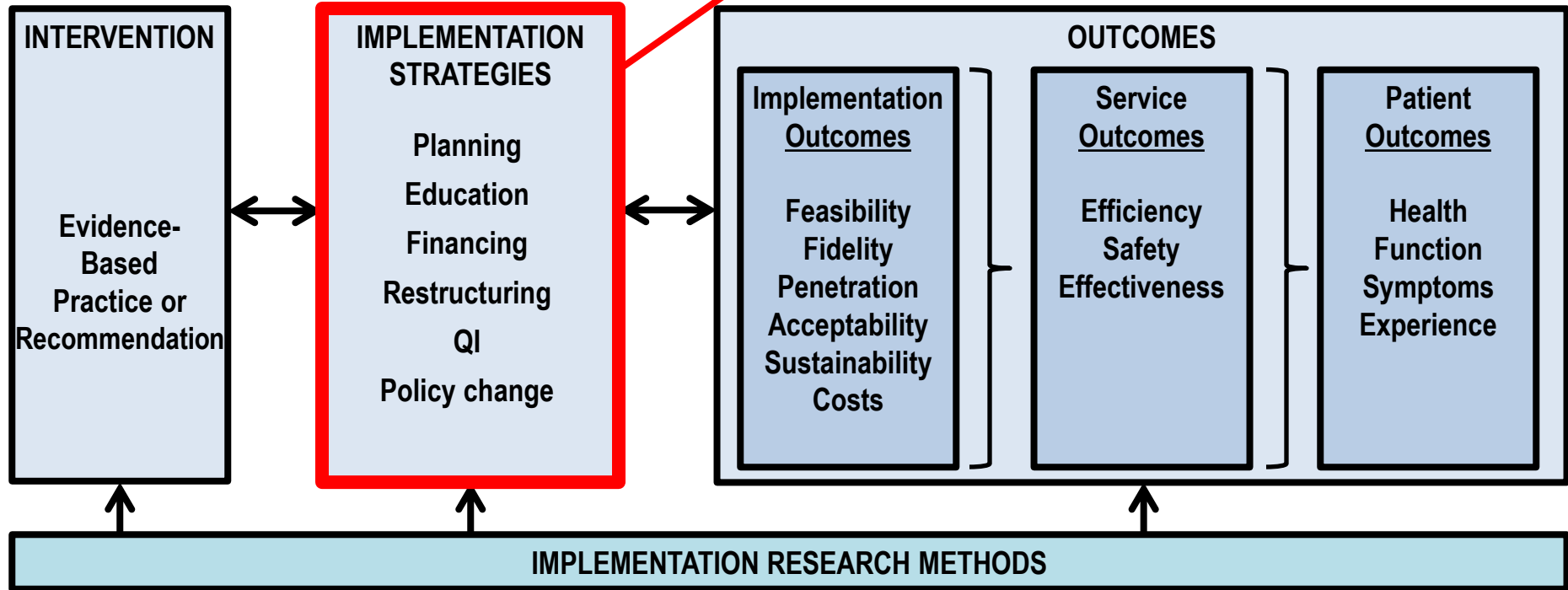
However...



Framework for Implementation Research

Colon cancer screening

*Educate clinicians and patients
Restructure care (RN-based population management)
QI (monitor/audit to increase screening rates)*



Note: implementation strategies must be viable to *(and may come from)* clinical partners

What are Implementation Strategies?

- The intervention/practice/innovation is **THE THING**
- Effectiveness research looks at whether **THE THING** works
- Implementation research looks at how best to help people/places **DO THE THING**
- *Implementation strategies* are the stuff we do to try to help people/places **DO THE THING**
- *Implementation outcomes* are **HOW WELL** they **DO THE THING**

Note: Partners care about all of these, but an “effective” intervention is useless to them without effective implementation

Implementation strategies help avoid the following...



“It seemed like a good idea at the time”
(Eccles)

Inc. THE GOOD COMPANY

Era of "Train and Pray" for Workers Must End

**“ISLAGIATT”
Approach**

Implementation Strategies

- The “how” of implementation/sustainment efforts
- Specified activities designed to put an intervention into practice (Fixsen, 2005)
 - The activities, actions, the causal agents for either the installation, the scale up, scale out or sustainment of an evidence-based practice, program or guideline
- May occur at one or more levels (e.g., provider, clinic, system)
- Range in scope:
 - Discrete single component (e.g., decision-support tool)
 - Package of components (e.g., toolkit)

ERIC: Expert Recommendations for Implementing Change

- Revised will full compilation of implementation strategies: Expert Recommendations for Implementing Change (ERIC) project (Powell, et al., ERIC Project, *Imp Sci*, 2015)
- 73 implementation strategies organized by cluster:
 - Adapt and tailor an intervention to local context
 - Change infrastructure (e.g., clinic layout/resources)
 - Develop stakeholder interrelationships
 - Provide interactive assistance
 - Support clinicians
 - Train and educate stakeholders
 - Use evaluative and iterative strategies- assess barriers, readiness
 - Engage consumers- build a coalition
 - Utilize financial strategies- incentives, change fees

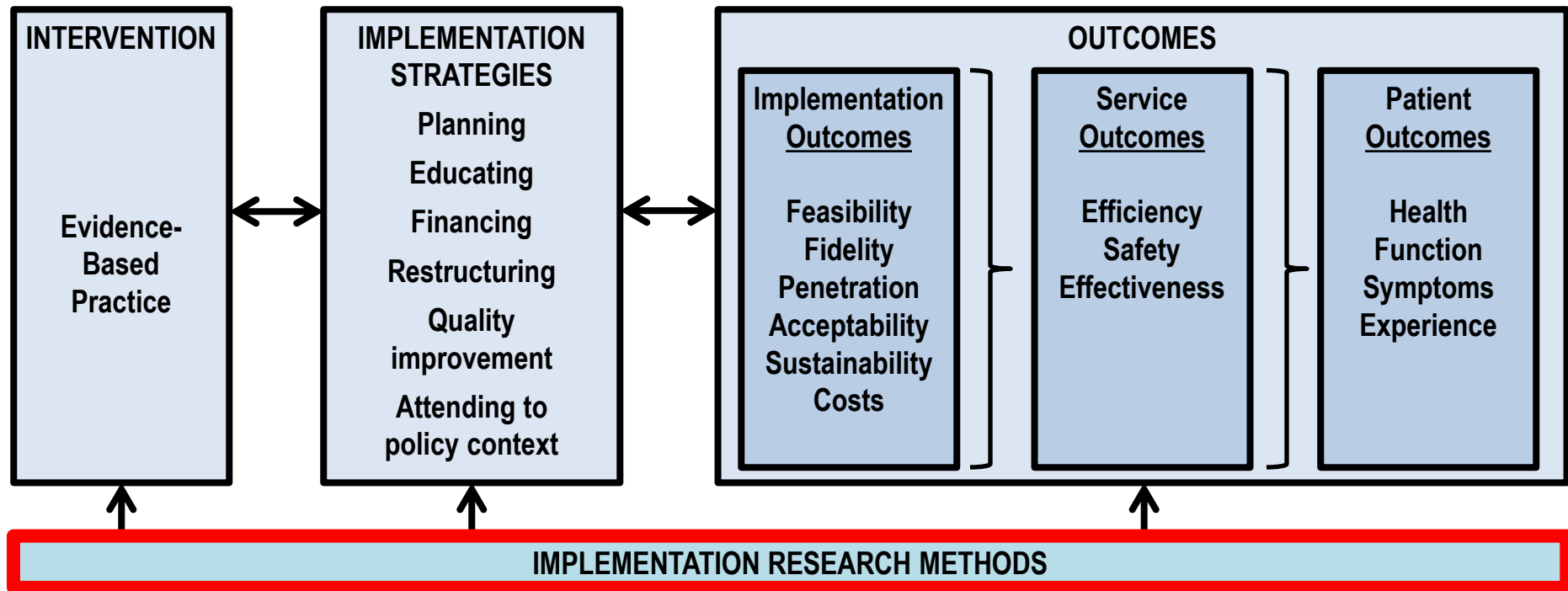
Example: Adaptive Implementation of Effective Programs Trial (ADEPT) comparing standard vs. enhanced implementation strategy

- **Evidence-Based Practice:** Life Goals for patients with mood disorders
- **Implementation strategies:**
 - External Facilitator (EF)- technical expertise about intervention
 - Internal Facilitator (IF)- on-site expert who reports directly to site leadership; internal implementation support
- **Objective:** compare EF vs. EF + IF to increase EBP implementation in community clinics
- **Outcomes:** mental health outcomes + implementation outcomes
- **Findings:** the simpler EF-only strategy performed as well, if not better, than the higher intensity, greater scope EF/IF approach

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Framework for Implementation Research



Implementation Research Methods

- Study designs vary:
 - e.g., RCTs, observational studies, formative vs. evaluative
- Mixed methods are common:
 - Quantify effectiveness, variation, implementation success
 - Qualitatively evaluate why/how something works, contextual influences, how the implementation process can be improved
- Implementation science framework is critical

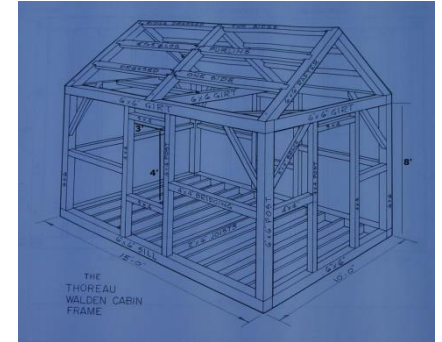
What is a Framework Anyway?



A conceptual framework identifies a set of variables and relationships that should be examined to explain [implementation]

Implementation Science Frameworks

- Provide a systematic structure for the development, management, and evaluation of implementation efforts
- > 60 frameworks exist
- Common frameworks used in implementation studies:
 - Determinant frameworks: PARIHS, CFIR
 - Describe factors (e.g. barriers, facilitators) that influence implementation outcomes
 - Evaluation frameworks: RE-AIM
 - Specify aspects of implementation that could be evaluated to determine implementation success



What information does your partner need to make decisions?

RE-AIM Framework



Reach: patient participation rate; representativeness of participants

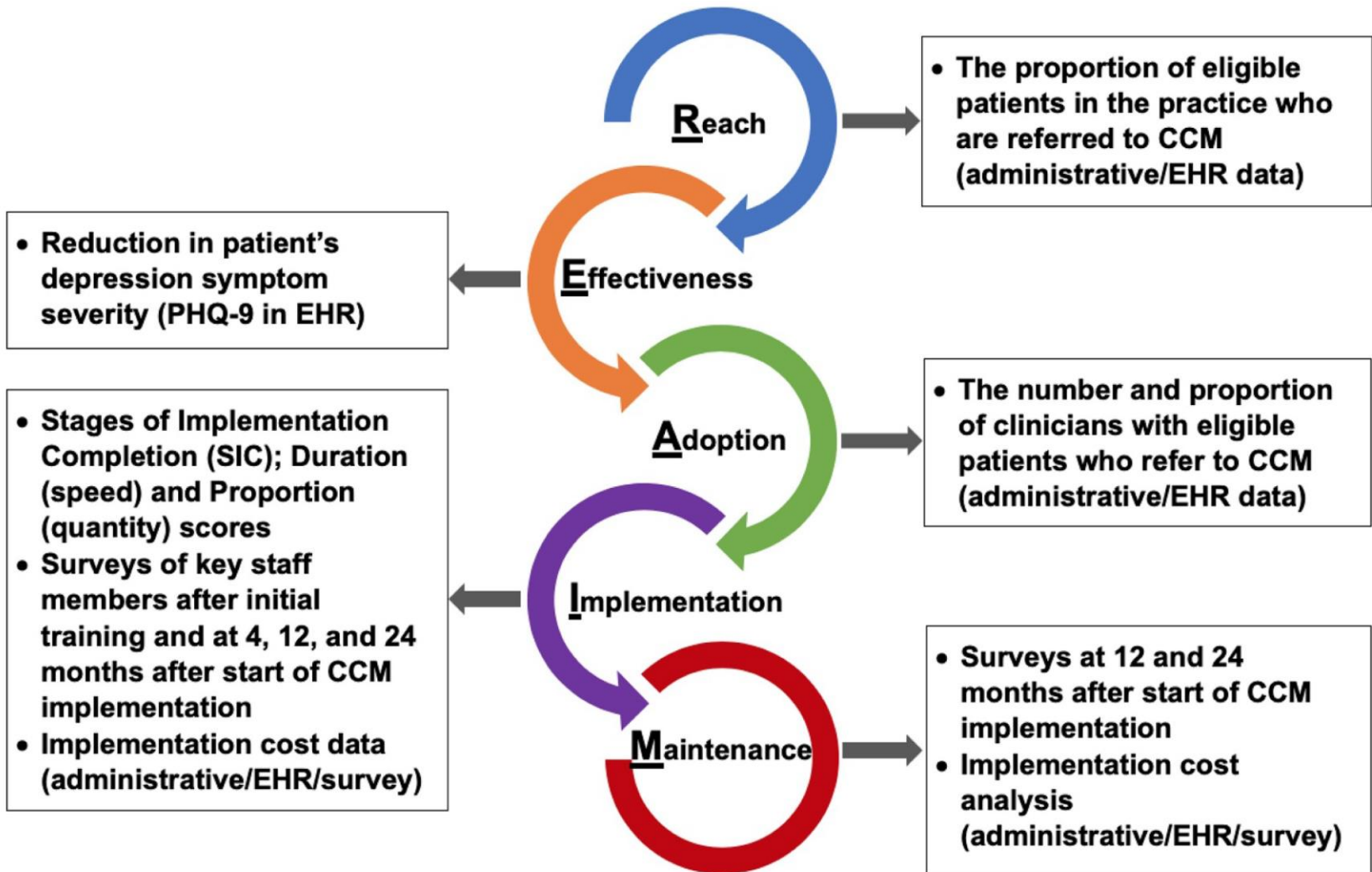
Effectiveness: measure of clinical and other outcomes of interest

Adoption: participation rate among settings; characteristics of participating sites

Implementation: consistency of intervention delivery across various staff and intervention components; cost of intervention, adaptations made by sites

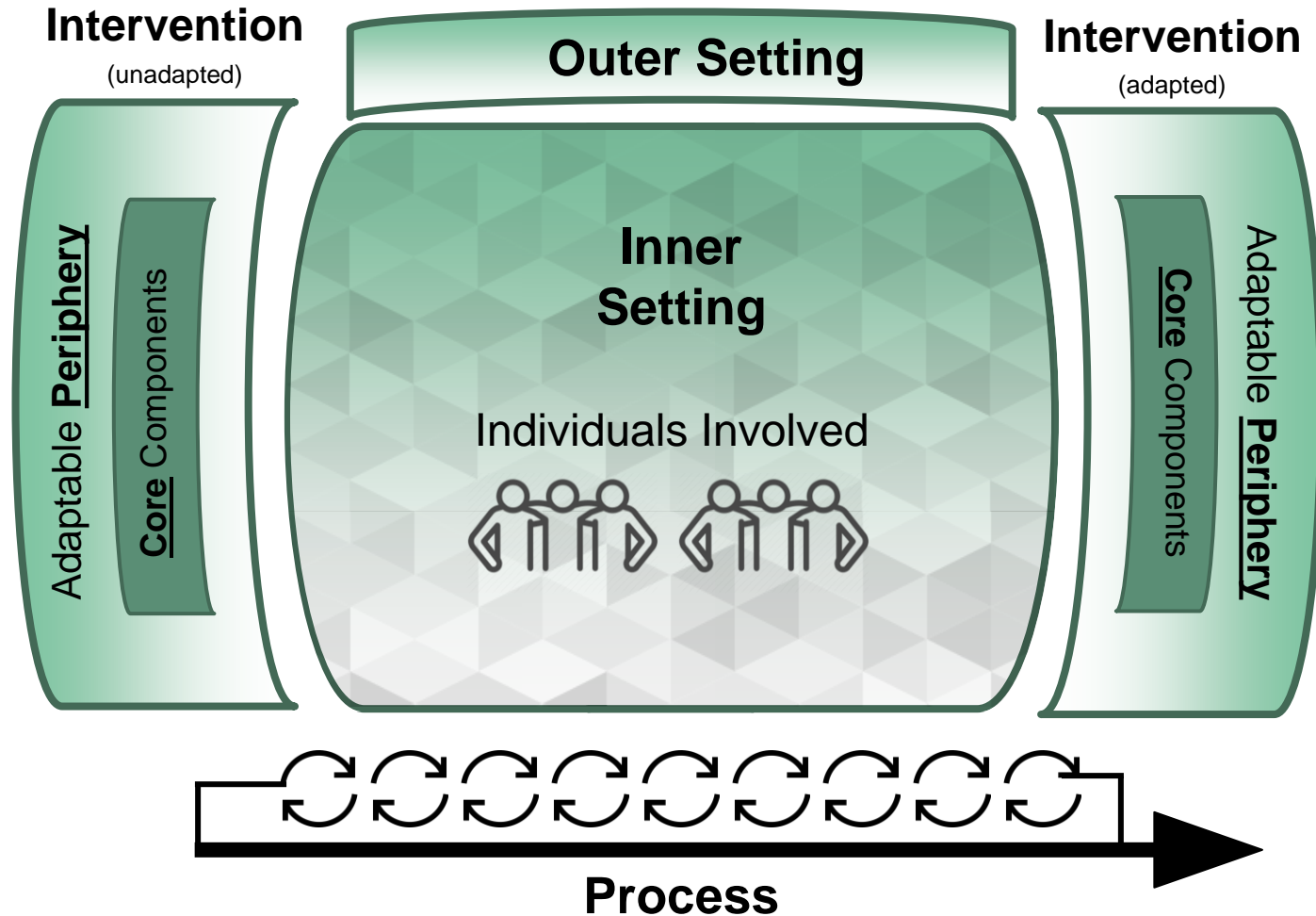
Maintenance: measure of program effectiveness >6 months after final intervention contact

RE-AIM evaluation of Collaborative Care Model



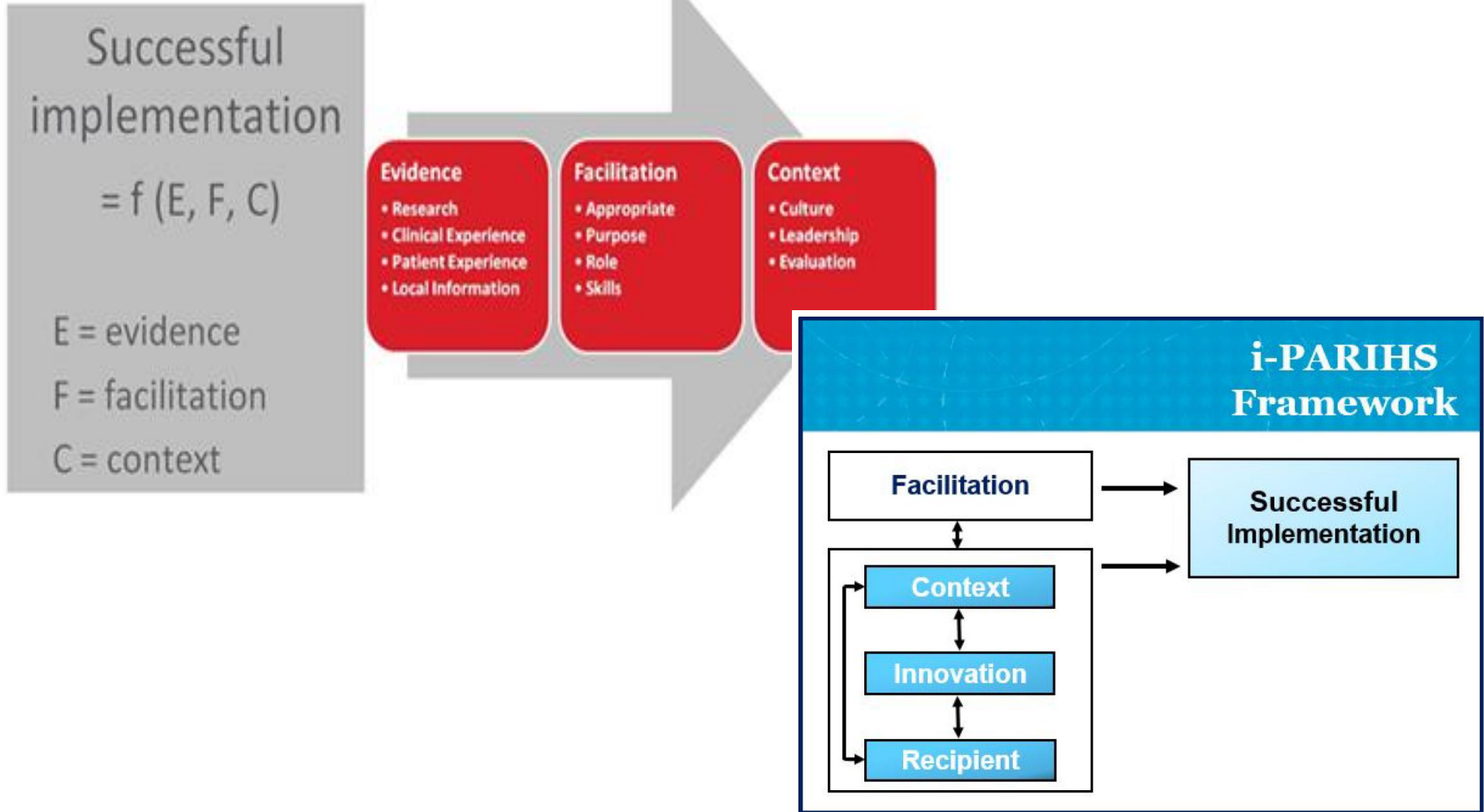
CFIR

Consolidated Framework for Implementation Research



PARIHS

Promoting Action on Research Implementation in
Health Services (PARIHS)



Kitson 1998; Harvey & Kitson, *Imp Sci*, 2016

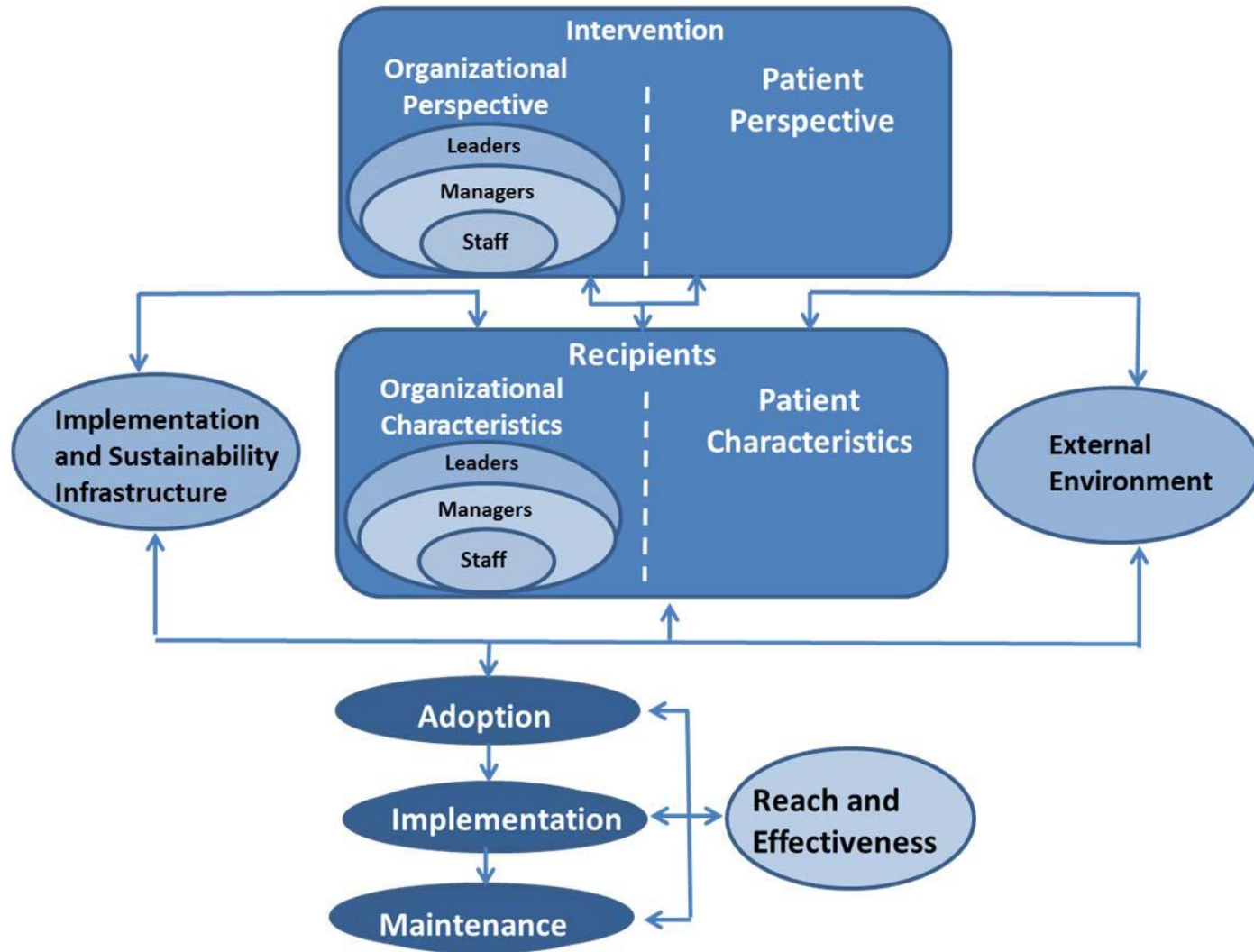
VA QUERI Implementation Facilitation Training Manual (i-PARIHS)

PRISM

Practical Robust Implementation and Sustainability Model

Domains:

- 1) the intervention or program of focus
- 2) intervention or program recipients (e.g., healthcare org, clinical team, patients)
- 3) implementation and sustainability infrastructure
- 4) the broader external environment

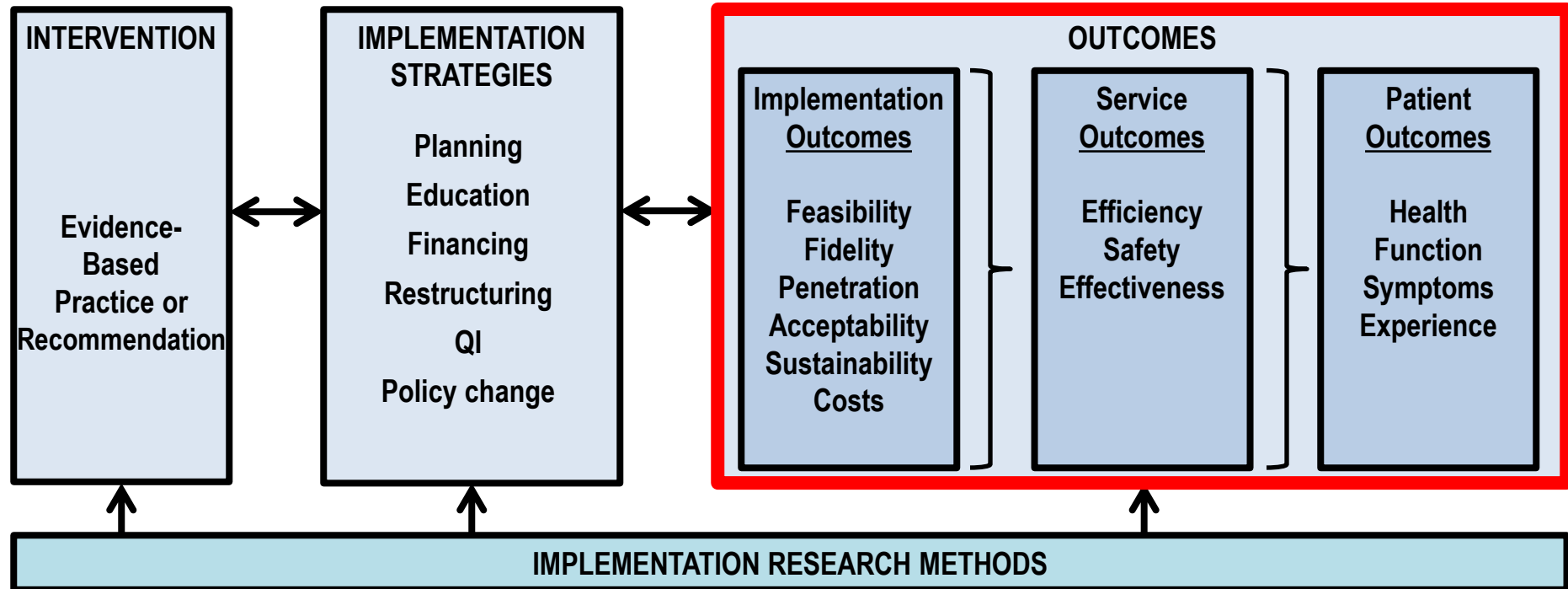


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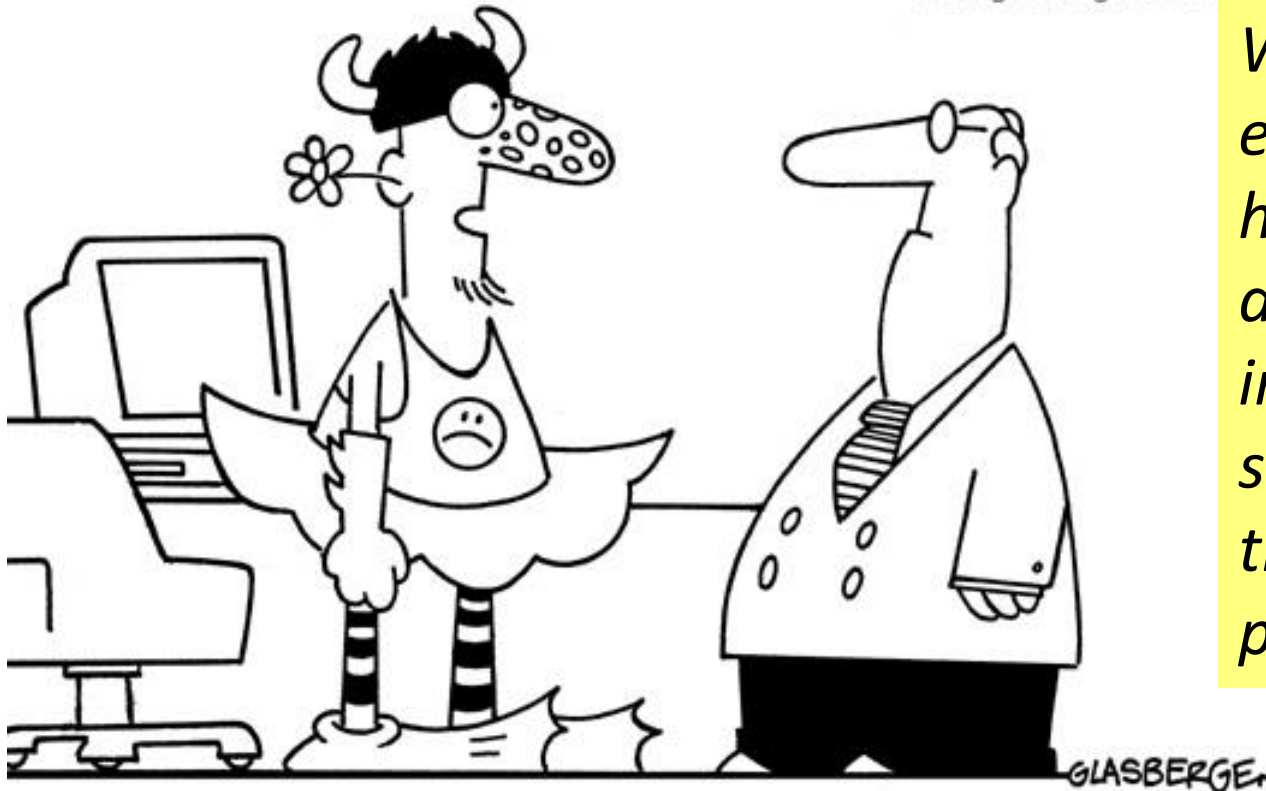
In order to optimize patient and population health outcomes (especially at scale), the implementation process must be effective



Note: focusing on outcomes that your partner cares about will increase their support for your project

How should we measure implementation success?

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www.glasbergen.com



*When
evaluating a
health care
delivery
intervention,
success is in
the eye of the
partner...*

“I am dressed for success! Of course, my idea of success may not be exactly the same as yours.”

How should we measure implementation success?

Often a function of...

- Provider acceptance
- High rates of intervention delivery to those who need it
- Implementation cost
- Sustainability after a trial period
- (Also effectiveness– if intervention ineffective, implementation is unlikely to be considered a success)

What partners care about!!

Study design should conceptually and empirically address how implementation process measures and outcomes influence overall success of the implementation effort

What types of measures are
important to evaluate
implementation and
dissemination
process and success?

Implementation Outcomes

- Reach
- Acceptability
- Appropriateness
- Adoption
- Feasibility
- Fidelity
- Implementation Cost
- Penetration
- Sustainability

Implementation Outcomes

- **Reach**
- Acceptability
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Absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative.

Focuses on the representativeness of individuals (i.e., patients), as opposed to penetration which usually focuses on organizational-level participation.

Who are your partner's priority patient populations?

RE-AIM (Reach)

Study Topic Area:		Study Setting:	
Dimensions/Items		Included? (Yes, No, Yes-Inappropriate Use, N/A)	
Reach			
Exclusion Criteria (% excluded or characteristics)			
Percent individuals who participate, based on valid denominator (not of volunteers who indicate interest)			
Characteristics of participants compared to non-participants or to target population			
Use of qualitative methods to understand reach and/or recruitment			

Adoption, reach, and implementation of a cancer education intervention in African American churches

Sherie Lou Zara Santos^{1*}, Erin K. Tagai¹, Mary Ann Scheirer², Janice Bowie³, Muhiuddin Haider⁴, Jimmie Slade⁵, Min Qi Wang¹ and Cheryl L. Holt¹

THING (intervention)

- Randomized 15 churches to Project HEAL (cancer educational intervention led by peer community health advisors)

Impl
Strategies

CHAs were trained using traditional (classroom, didactic) or technology (web-based training) approach

- CHAs conducted 3 group workshops on cancer early detection (breast, prostate, colorectal)

Impl
Outcome

Reach = $\frac{\# \text{ workshop participants enrolled in Project HEAL}}{\text{estimated number of eligible participants in church}}$

- 33% overall (43% for traditional, 22% for technology)

Implementation Outcomes

- Reach
- **Acceptability**
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Perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.

*Which clinicians/staff
will be critical to
successful
implementation?*

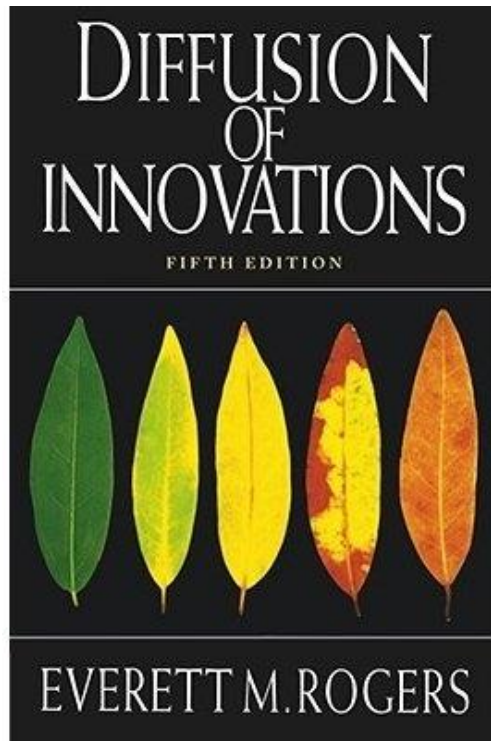
Implementation Outcomes

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Perceived fit, relevance, or ***compatibility*** of the innovation or evidence based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem

What are the priorities, needs, culture of your partner and key stakeholders?

Acceptability & Appropriateness Important Predictors of Adoption



- Potential adopters evaluate an innovation's...
 - Observed effects
 - Relative advantage (perceived efficiencies gained by the innovation relative to current tools/procedures)
 - *Acceptability*
 - Compatibility with existing system
 - *Appropriateness*
 - Complexity or difficulty to learn
 - Trialability or testability

Implementation Outcomes

- Reach
- Acceptability
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- **Adoption**
- Feasibility
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Intention or action to employ an innovation or evidence-based practice

Critical measure if evaluating implementation of an intervention across multiple sites

Organizational Factors Affecting the Adoption of Diabetes Care Management Processes in Physician Organizations

RUI LI, MM¹
JODI SIMON, MA¹
THOMAS BODENHEIMER, MD, MPH²
ROBIN R. GILLIES, PHD¹

LAWRENCE CASALINO, MD, PHD³
JULIE SCHMITTDIEL, PHD¹
STEPHEN M. SHORTELL, PHD, MPH¹

were delivered. Only 24% of adults with diabetes underwent three or more HbA_{1c} tests over a 2-year period (1).

Data from the 1999–2000 National

- Adoption Index: organization's use of DM patient registries, clinical practice guidelines, case management, and physician feedback
- National Survey of Physician Organizations and the Management of Chronic Illness (2000-2001)
- Certain organizational factors influence adoption rates: external incentives to improve quality, computerized clinical information systems, ownership by hospitals or HMOs

Implementation Outcomes

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The extent to which a new treatment or innovation can be successfully used or carried out within a given agency or setting

Partners might want evidence of feasibility at pilot site before rolling something out widely

Feasibility and acceptability of a computerised system with automated reminders for prescribing behaviour in primary care

J.D. Martens^{a,*,1}, T. van der Weijden^{a,b,1}, R.A.G. Winkens^{a,b,1}, A.D.M. Kester^{c,1}, P.J.H. ...^{d,1}

Impl Strategy

THING (Intervention)

- Automated alerts offer recs about appropriate prescribing: antibiotics and cholesterol/asthma/COPD meds
- Primary care providers

Implementation Feasibility Measures

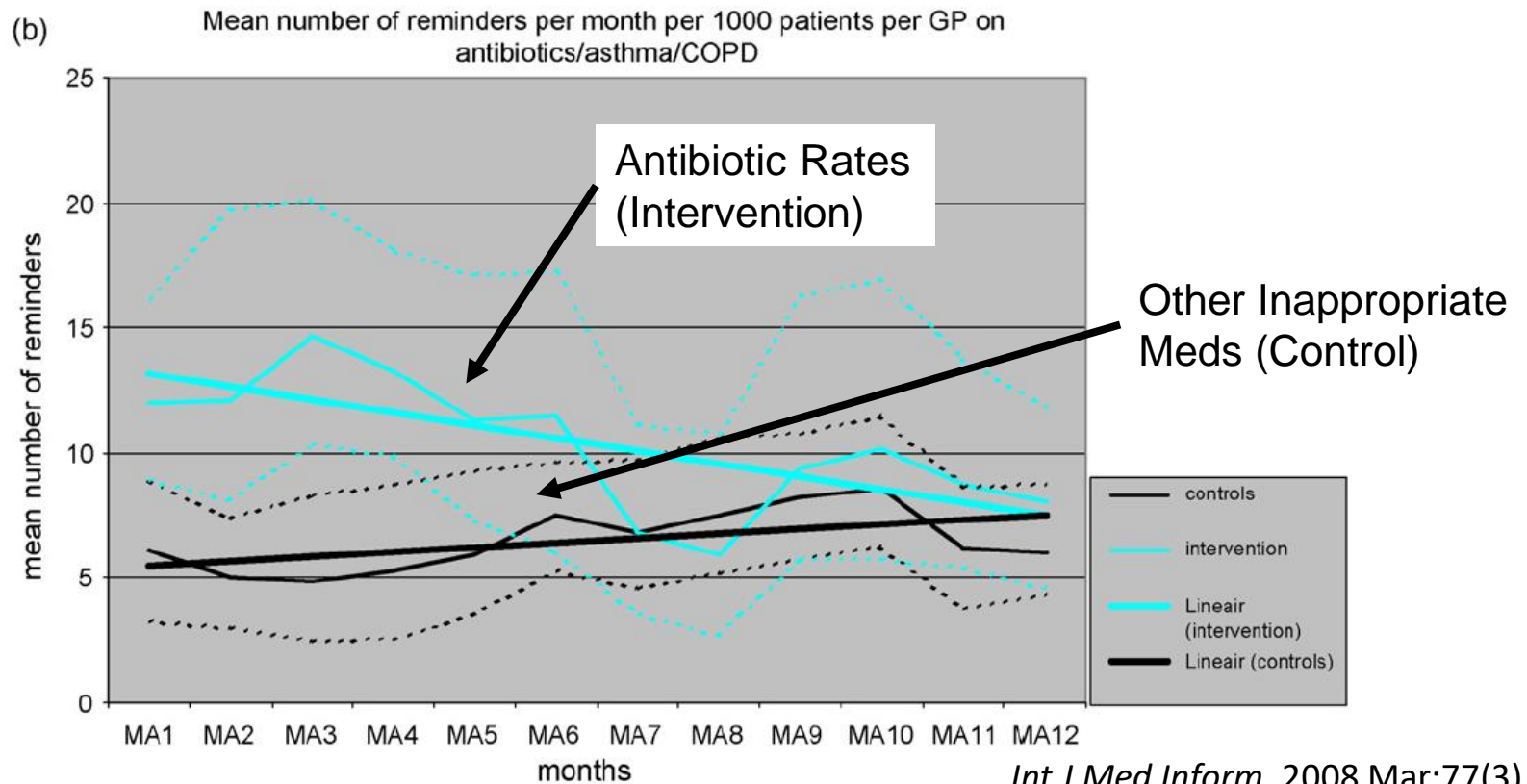
- How many providers had the program installed
- How many dropped out (e.g., due to technical problems or dislike for program)
- Number of reminders per provider per month
- Did it affect prescription rates?

Did the impl strategy help them DO the THING

Impl Outcomes

Feasibility and acceptability of a computerised system with automated reminders for prescribing behaviour in primary care

J.D. Martens^{a,*,1}, T. van der Weijden^{a,b,1}, R.A.G. Winkens^{a,b,1}, A.D.M. Kester^{c,1}, P.J.H. Geerts^a, S.M.A.A. Evers^{d,1}, J.L. Severens^{d,e,1}



Implementation Outcomes

- Reach
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- **Fidelity**
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The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by program developers

Fidelity Checklist

Shared Medical Appointments for Diabetes

SMA PROCESS & CONTENT ASSESSMENT: FOLLOW-UP SESSIONS

⊕ Date of Session: ____/____/____ Session #: ____ Facilitator: _____ Rater: _____ □

Scoring	
0	Did not demonstrate = this component was not demonstrated at all
1	Inconsistently Demonstrated = this component happened to some extent, but not for all group members, all of the time
2	Demonstrated consistently through entire session = this component was demonstrated consistently & appropriately throughout entire session
9	NA

Action Planning		Score
a	Facilitator prompted review of action planning	
b	Facilitator elicited discussion of successes/challenges since last session & initiated problem-solving approach when necessary to address barriers	
c	Facilitator prompted participants to identify <i>specific</i> small action steps for the next week (a "menu of ideas" for steps, current week topic)	
d	Facilitator & participants came to agreement on personal action step	
e	Facilitator assessed participants' self-confidence/readiness to follow-through on plan	
f	Facilitator helped participants identify barriers to success & problem-solve possible solutions to these contingencies	
g	(P2P cohorts only) Facilitator encouraged peer pairs to help each other review and modify their weekly action plans	

During the shared medical appointments, did facilitator:

- Prompt review of action planning?
- Elicit discussion of successes/challenges; problem-solving?

Implementation Outcomes

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- **Implementation Cost**
- Penetration
- Sustainability

*Particularly critical if
your partner is also
the payer*

The cost of implementation
from the payer's perspective

Stages of Implementation Completion (SIC)

- SIC: tool for tracking amount of time taken to complete imp activities, and proportion of activities completed
- 8 stages that reside within three phases of implementation

Pre-Implementation	1. Engagement
	2. Feasibility Assessment
	3. Readiness Planning
Implementation	4. Staff Hired and Trained
	5. Fidelity Monitoring Process in Place
	6. Services Begin
Sustainability	7. Ongoing Services
	8. Competency

- SIC can serve as a template for mapping implementation costs

Implementation Outcomes

- Reach
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The degree to which an intervention is integrated within target sites

Implementation Outcomes

- Reach
- Acceptability
- Appropriateness
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- Feasibility
- Fidelity
- Implementation Cost
- Penetration
- **Sustainability**

The extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing operations



Program Sustainability Assessment Tool

Partnerships: Cultivating connections between your program and its stakeholders

	To little or no extent			To a very great extent			Not able to answer	
1. Diverse community organizations are invested in the success of the program.	1	2	3	4	5	6	7	NA
2. The program communicates with community leaders.	1	2	3	4	5	6	7	NA
3. Community leaders are involved with the program.	1	2	3	4	5	6	7	NA
4. Community members are passionately committed to the program.	1	2	3	4	5	6	7	NA
5. The community is engaged in the development of program goals.	1	2	3	4	5	6	7	NA

Organizational Capacity: Having the internal support and resources needed to effectively manage your program and its activities

	To little or no extent			To a very great extent			Not able to answer	
1. The program is well integrated into the operations of the organization.	1	2	3	4	5	6	7	NA
2. Organizational systems are in place to support the various program needs.	1	2	3	4	5	6	7	NA
3. Leadership effectively articulates the vision of the program to external partners.	1	2	3	4	5	6	7	NA
4. Leadership efficiently manages staff and other resources.	1	2	3	4	5	6	7	NA
5. The program has adequate staff to complete the program's goals.	1	2	3	4	5	6	7	NA

Organizational Capacity

- Leadership effectively articulates vision of program to partners
- There's adequate staff to complete program goals

Examples of Implementation Outcomes

- Reach
- Acceptability
- Appropriateness
- Adoption
- Feasibility
- Fidelity
- Implementation Cost
- Penetration
- Sustainability

https://www.gem-measures.org/

Search engine for measures that map to specific implementation constructs (e.g. Adoption measures focusing on substance use interventions)



Home | Constructs | **Measures** | Datasets | Workspaces | About | My GEM | Glossary

Measures

Click on table headers to sort list alphabetically. To tailor the results below, use the "Quick Filter" button.

Add Measure

Search Measures:

Keyword:

Construct:

Content Area:

Showing 1 of 3

First Prev A B C D E F G **H** I J K L M N O P Q R S T U V W X Y Z Other [Next](#) Last [View](#) Translation Download

Measure ▲	Brief Description	Content Area	Construct	Avg Rating		
Henggeler et al - adoption, fidelity and appropriateness	The primary measures of interest were whether the therapists reported use of CM (adoption) with a su...	1. Substance Abuse	Adoption	Rate This!		

Selecting Implementation Outcomes

Outcome	Level of Analysis	Theoretical Basis	D&I Phase	Measurement Methods
Reach	Individual	RE-AIM	Exploration	Surveys, Admin data
Acceptability	Individual	Rogers (rel adv) Greenhalgh	Exploration, Imp, Sustainment	Survey, Interviews, Admin data
Appropriateness	Individual, Org, Policy	Rogers (compatibility)	Exploration Preparation	Surveys, Interviews, FGs
Feasibility	Individual, Org, Policy	Rogers (compat, trialability, obs)	Exploration Preparation	Surveys, Admin data
Adoption	Individual, Org, Policy	RE-AIM, Rogers (trialability, obs)	Preparation	Surveys, Obs, Interviews, Focus Groups, Admin data
Fidelity	Individual	RE-AIM (imp)	Implementation Sustainment	Obs, Checklists, Content analysis, Self-report
Cost	Individual, Org, Policy	RE-AIM	Exploration, Imp, Sustainment	Admin data
Penetration	Org, Policy	RE-AIM (necessary for reach)	Imp, Sustainment	Surveys, Interviews
Sustainability	Org, Policy	RE-AIM, Rogers (confirmation)	Sustainment, Exploration	Surveys, Interviews, Case Studies, Record review

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Spectrum of Partnered Research

Clinical Effectiveness Research

vs?

Implementation Research

Will an intervention work in this setting, for these patients?

What is the effect on clinical outcomes, patient experience, utilization?

Which method works better in facilitating implementation of an intervention?

Which core components are critical?

Hybrid Studies

**Clinical
Effectiveness
Research**

**Implementation
Research**

**Hybrid
Type I**

Determine
effectiveness

Better understand
context for
implementation

**Hybrid
Type II**

Determine
effectiveness

Determine feasibility
and/or impact of an
implementation strategy

**Hybrid
Type III**

Determine impact of an
implementation strategy

Assess clinical outcomes
associated with
implementation

Some final thoughts about implementation science & partnered research

- Implementation science principles, frameworks, & measures are often highly aligned with needs and priorities operations partners
- The language of implementation science resonates with partners- they want to what works and how to implement it to maximize uptake, spread, and effectiveness.
- In designing implementation science studies:
 - Identify a framework that fits your study question
 - Clearly define the intervention, implementation strategies, and outcomes of interest
- Considering implementation and dissemination issues early and often will maximize downstream impact of your work

Thank You!



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