

# LET'S GET REAL: PLANNING RIGOROUS PRAGMATIC HEALTH SERVICES RESEARCH FOR EQUITABLE, REAL-WORLD CARE

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VA QUERI, University of Michigan  
August 11, 2020

## Colorado Pragmatic Research in Health

2020 NATIONAL CONFERENCE

*Planning for Real World Impact*



LEARNING HEALTH SCIENCES



ACCORDS

ADULT AND CHILD CONSORTIUM FOR HEALTH OUTCOMES  
RESEARCH AND DELIVERY SCIENCE

UNIVERSITY OF COLORADO | CHILDREN'S HOSPITAL COLORADO

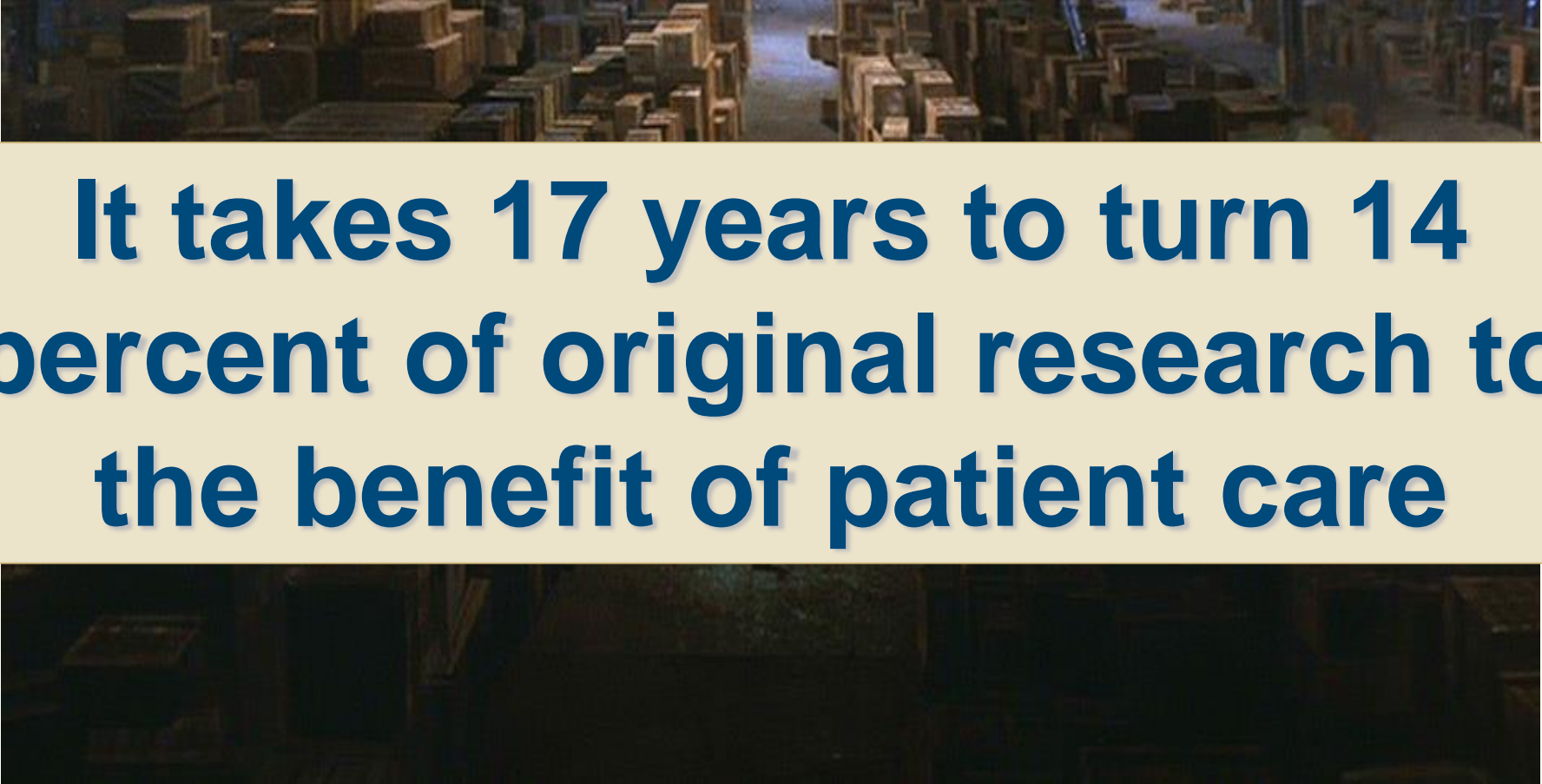
# Outline

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- Pragmatic research involves studying questions that are important to stakeholders (patients, practitioners, health systems, communities) in routine care settings among a broad representation of participants using relevant, often routinely-collected outcomes data
- Key frameworks, designs, and use cases: e.g., Replicating Effective Programs
- Community and multi-stakeholder partnerships: e.g., Re-Engage implementation study
- Planning for implementation and sustainment: QUERI Roadmap

# Why Pragmatic Research?

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**It takes 17 years to turn 14 percent of original research to the benefit of patient care**

# Partner or Perish: Health Care Research is Changing

- Beyond the academy
- Consumer-driven
- Information technology
- Social determinants
- Black Swans



# CPIC



Community Partners in Care (Wells, Jones)

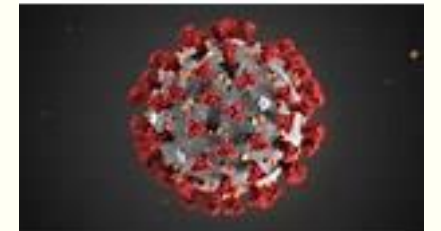
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## THE PATIENT WILL SEE YOU NOW

Why Visibility, Patient Experience, and Digital Marketing Are Key to Helping Medical Practices Thrive

**CRAWFORD IFLAND**

PUBLISHED BY + MESSENGER



# Pragmatic Research Core Concepts

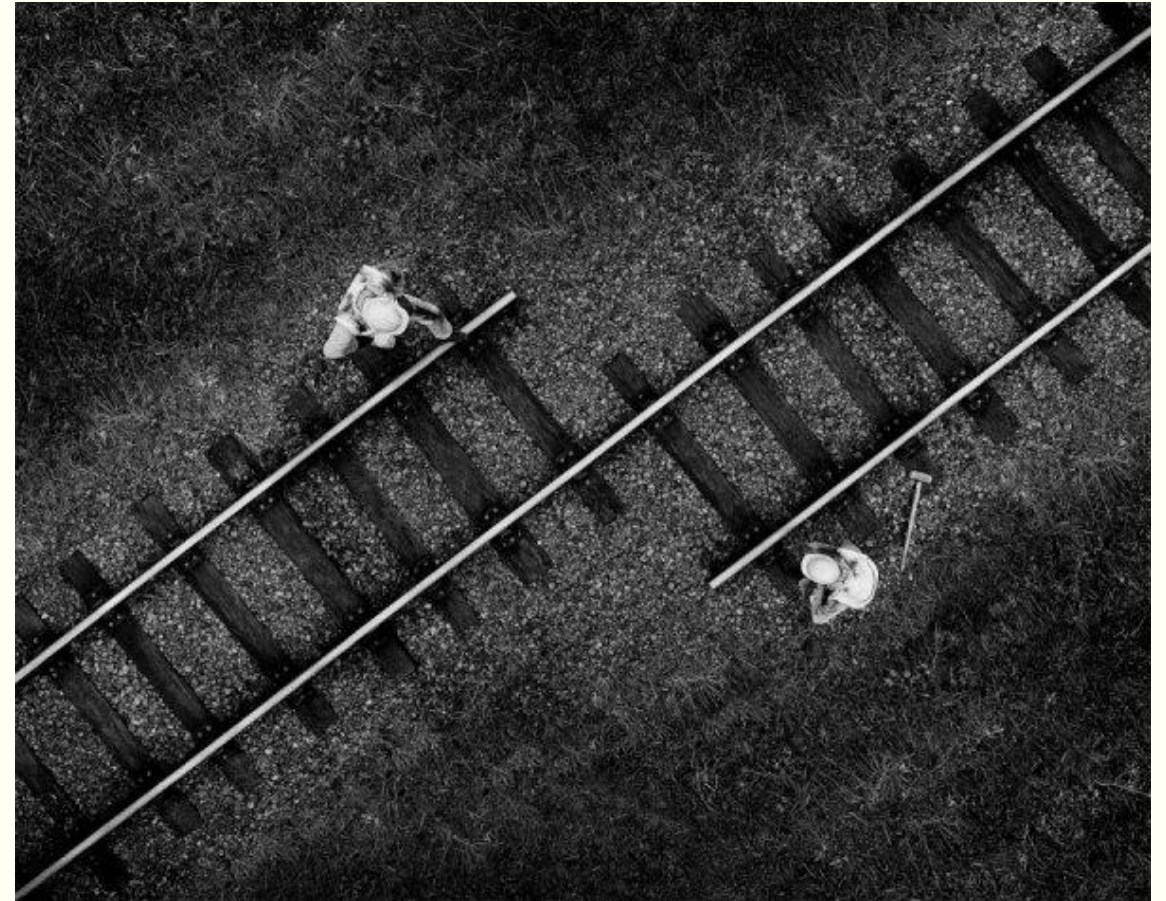
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- Problem-focused
- Ongoing, multi-stakeholder involvement
- Rapid and rigorous
- Implementation plan to support ownership and sustainment

# What are the Barriers to Pragmatic Research?

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- Timing: Research takes too long
- Framing: Problem-focused research, what the stakeholders value
- Incentives: Academic promotion vs. ongoing relationship-building
- Capacity: real-world research involves a wide range of skills



# The Disconnect: Research and Practice

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How practitioners find out about research findings	How researchers communicate findings
1. Professional associations	1. Journal articles
2. Seminars/workshops ?	2. Face-to-face meetings
3. Email alerts	3. Media interviews
4. Journal articles ( <i>Really?</i> )	4. Press releases

# Pragmatic Research: Diversity, Equity, & Inclusion

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## Shots

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TREATMENTS

# What's Behind The Research Funding Gap For Black Scientists?

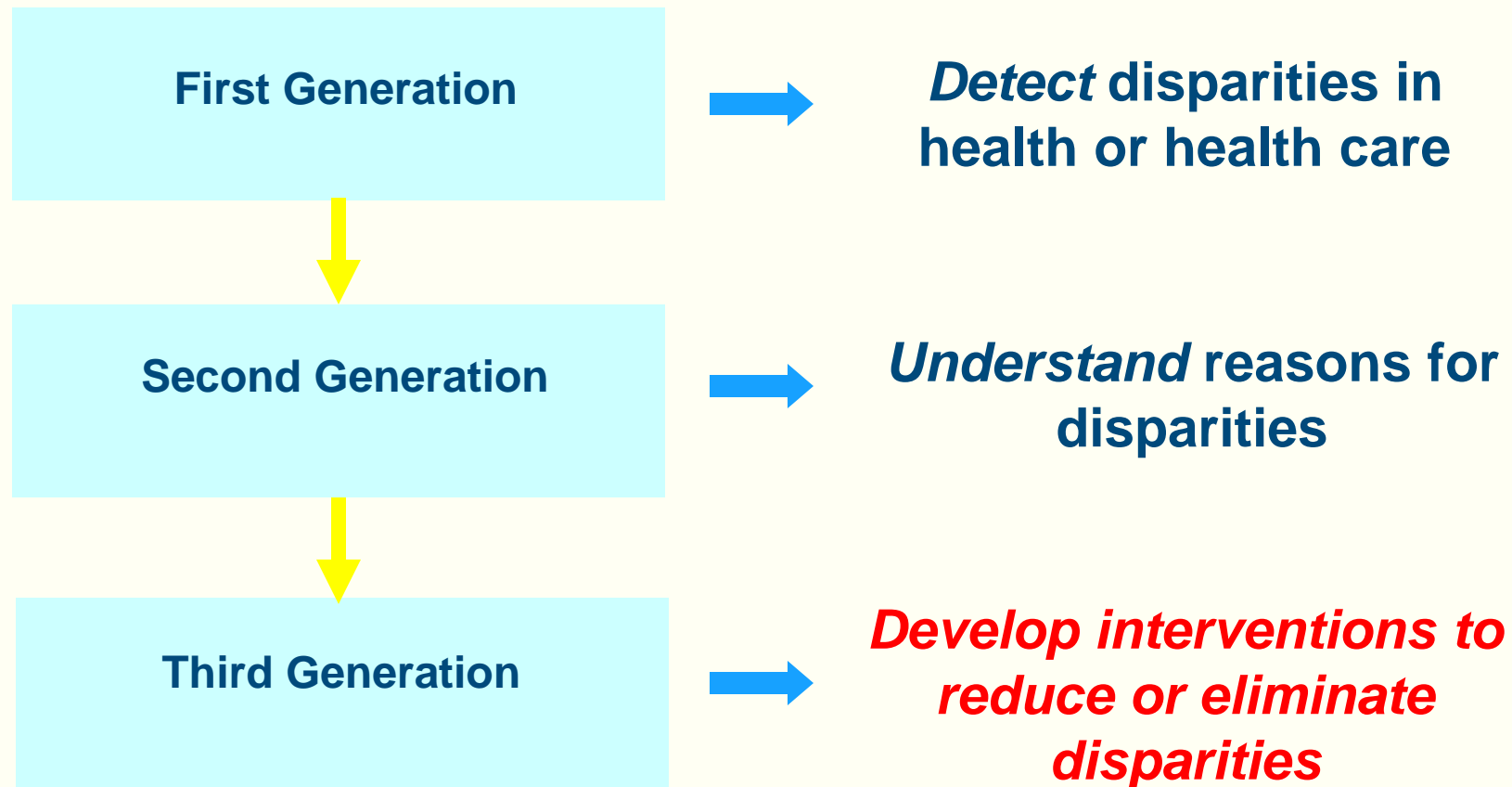
October 18, 2019 • 12:17 PM ET



# Pragmatic Research and Health Disparities

Center for Health Equity Research and Promotion (CHERP) Health Disparities Framework

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*Kilbourne et al., AJPH 2006; 96:2113-2121*



# Pragmatic Research and Multi-level Stakeholders



From David Chambers, DPhil, NCI



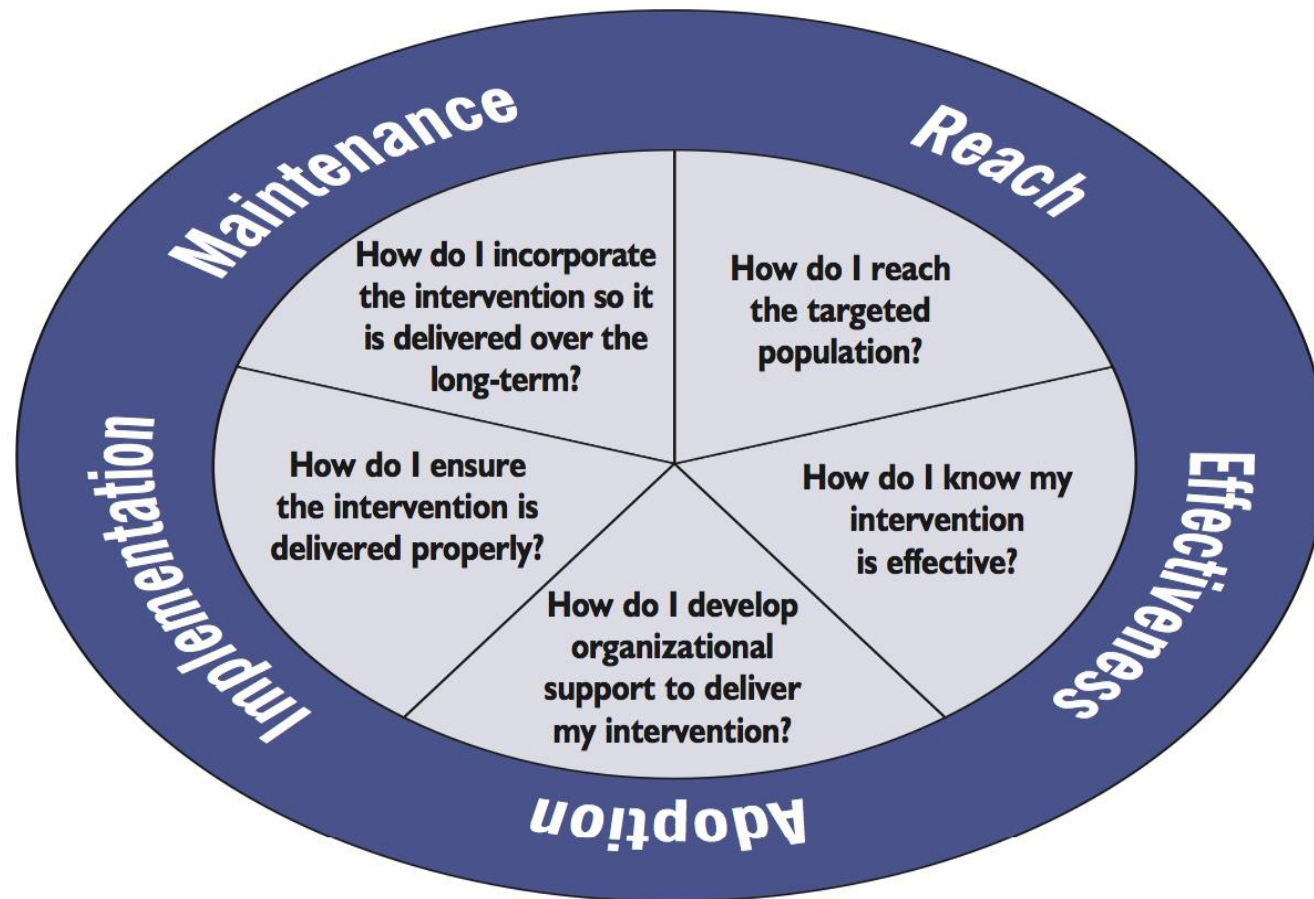
# Some Examples of Pragmatic Research Frameworks, Designs, and Use Cases

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- RE-AIM
- PRECIS-2
- Replicating Effective Programs
- QUERI Implementation Roadmap

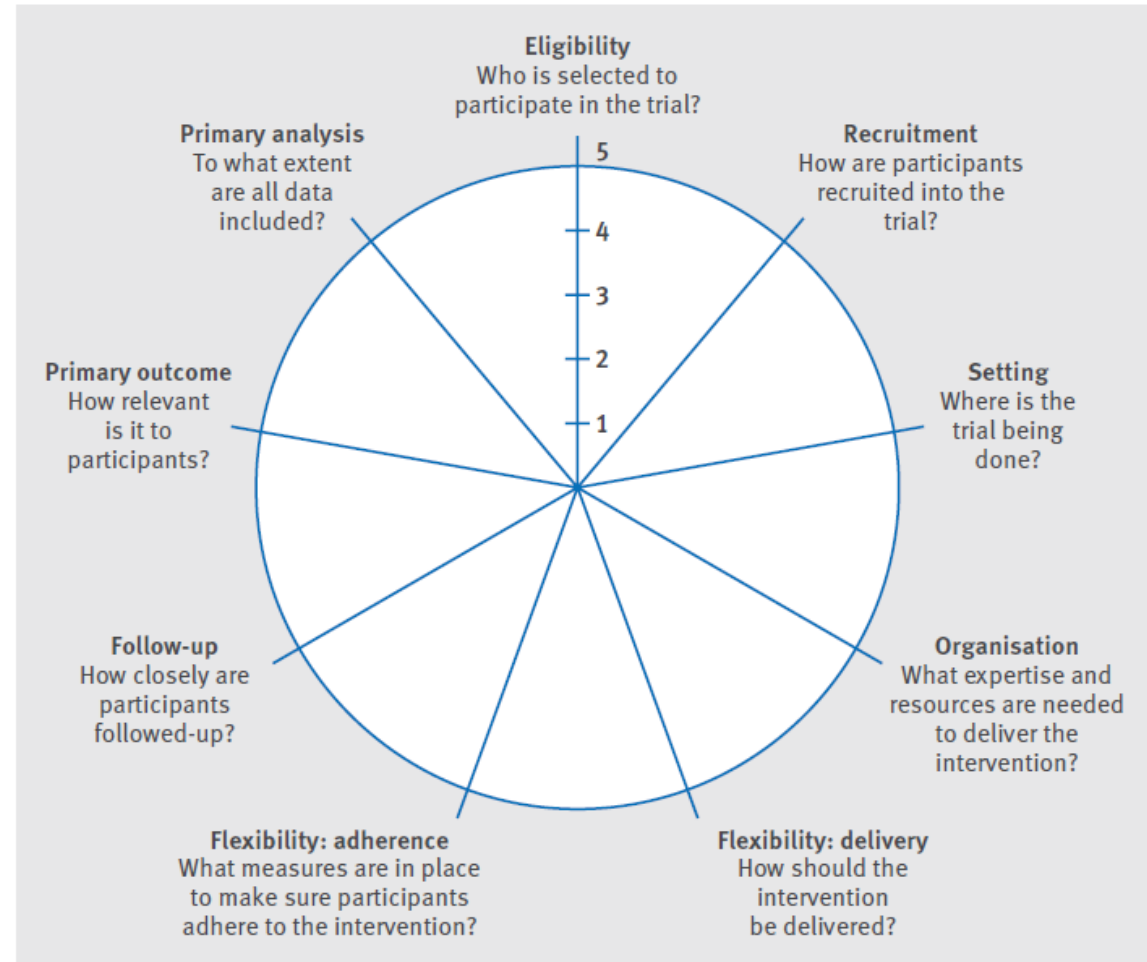
# RE-AIM

FIGURE 1. Elements of the RE-AIM Framework



# PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2)

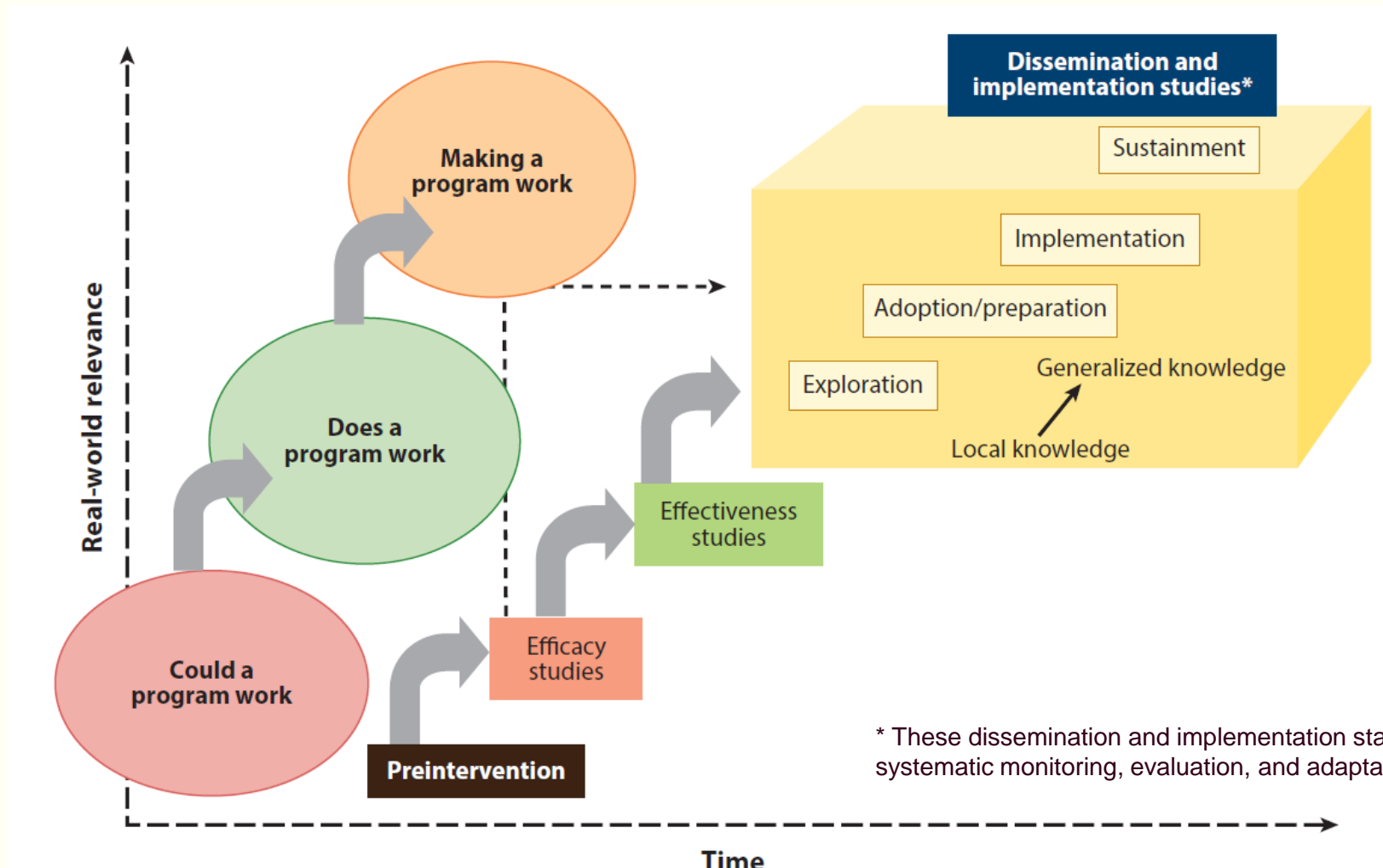
- Eligibility
- Recruitment
- Setting
- Organization
- Flexibility: delivery
- Flexibility: adherence
- Follow-up
- Primary outcome
- Primary analysis



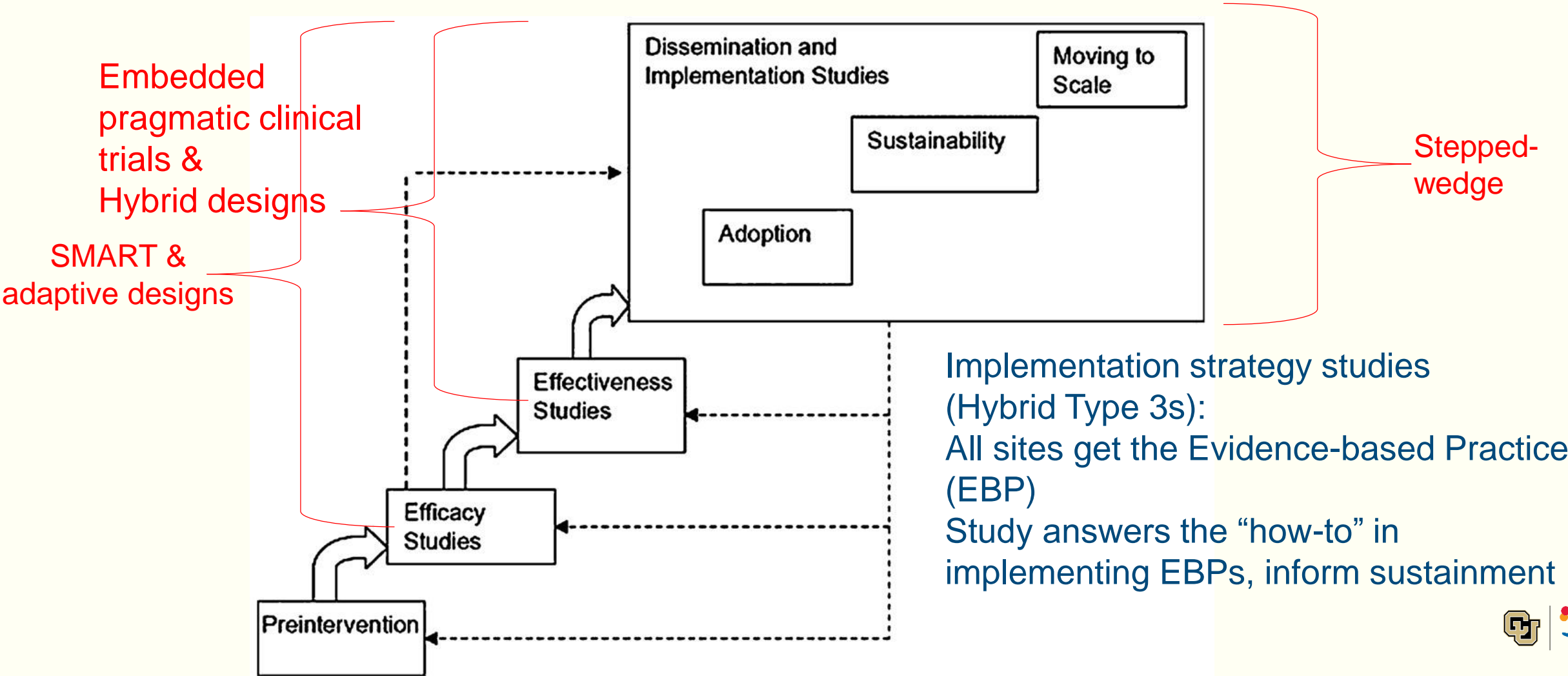
The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

Louden et al, BMJ, 2015

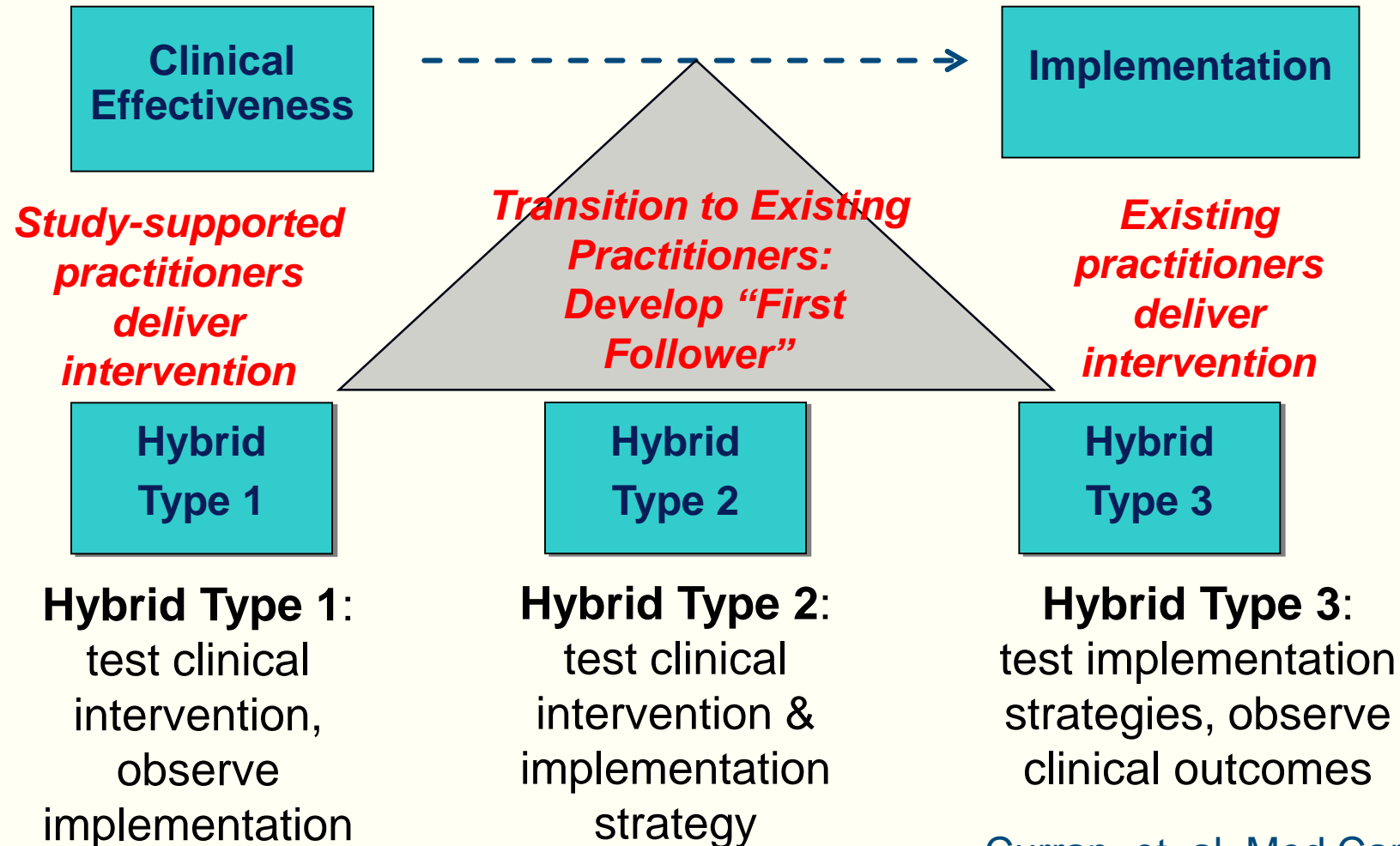
# Pragmatic Research: Beyond the Traditional Translational Research Pipeline



# Pragmatic Research Study Designs



# Hybrid Effectiveness/Implementation Designs





# Examples: VA Health Services Research and Development Pragmatic Research Trials

- In 2015, OMB provided VA HSR&D additional funding to launch randomized evaluations of programs and policies to inform a Learning Health System
- Aligned with new Laws requiring Government agencies to use evidence to support budgets (Foundations for Evidence-based Policymaking Act), as well as use real-world evidence in medical research (21<sup>st</sup> Century CURES Act)
- **Suicide risk** identification (REACH-Vet)
- Veteran-directed **home and community services**
- Risk tool + intervention for **high-risk opioid use**
- **Tele-dermatology** consults for remote Veterans
- New screen for **interpersonal violence**
- Reducing unnecessary **PPI** use

**VA STORM Patient Detail Report 2.0 BETA** Stratification Tool for Opioid Risk Mitigation

This report has been revamped to improve efficiency and accuracy. If you experience any issues please contact us.

Data displayed has a 1-2 day lag from CRS entry. This report is to be used along with the electronic medical record and direct discussion with the patient to help facilitate decision-making.

Home About Definitions User Guide Contact Us Quick View Report SSN Look-Up Save/Share Current View

Total Patients: 5

Patient Information	What factors contribute to my patient's risk?		How to better manage my patient's risk		How can I follow-up with this patient?		
	Relevant Diagnoses	Relevant Medications	Risk Mitigation Strategies	Non-pharmacological Pain Tx	Care Providers	Recent Appts	Upcoming Appts
<p>ZZTESTPATIENT,BATMAN MACK</p> <p>Last Four: 2179 Age: 28 Gender: M</p> <p><b>Risk: Suicide or Overdose (1 yr)*</b> Very High - Active Opioid Rx 31%</p> <p>PRF - High Risk for Suicide: No RISORD: Score: 7 Risk Class: 1</p> <p>Active Station(s) • (623) Muskogee, OK Chart Review Note</p>	<p>Substance Use Disorder</p> <ul style="list-style-type: none"> <li>Alcohol</li> <li>Amphetamine</li> <li>Nicotine</li> </ul> <p>Mental Health</p> <ul style="list-style-type: none"> <li>Depression</li> <li>PTSD</li> <li>Suicide Attempt or Ideation</li> </ul> <p>Medical</p> <ul style="list-style-type: none"> <li>Cancer - solid tumor without metastasis</li> <li>Osteoporosis</li> </ul> <p>Adverse Event</p> <ul style="list-style-type: none"> <li>Related to sedatives</li> </ul>	<p>Opioid</p> <ul style="list-style-type: none"> <li>ACETAMINOPHEN/HYDROCODONE                             <ul style="list-style-type: none"> <li>• Dr Zivago</li> </ul> </li> <li>Pain Medications (Sedating)                             <ul style="list-style-type: none"> <li>MIRTAZAPINE                                     <ul style="list-style-type: none"> <li>• Dr Zivago</li> </ul> </li> <li>TOPIRAMATE                                     <ul style="list-style-type: none"> <li>• Dr Zivago</li> </ul> </li> </ul> </li> </ul>	<p>MEDD &lt;= 90** <input checked="" type="checkbox"/></p> <p>Naloxone Kit <input checked="" type="checkbox"/> 8/4/2017</p> <p>Opioid Informed Consent <input checked="" type="checkbox"/> 3/15/2018</p> <p>Timely Follow-up (90 Days) <input checked="" type="checkbox"/> 3/15/2018</p> <p>Timely UDS (90 Days) <input checked="" type="checkbox"/> 1/9/2018</p> <p>Psychosocial Assessment <input checked="" type="checkbox"/> 8/3/2017</p> <p>Psychosocial Tx <input checked="" type="checkbox"/> 2/27/2018</p> <p>Bowel Regimen <input type="checkbox"/></p> <p>POMP <input checked="" type="checkbox"/> 7/11/2017</p> <p>Data-based Opioid Risk Review <input type="checkbox"/></p> <p>Safety Plan <input checked="" type="checkbox"/> 8/3/2017</p> <p>Active SUD Tx <input checked="" type="checkbox"/> 4/24/2018</p>	<p>Active Therapies <input checked="" type="checkbox"/> 8/3/15</p> <p>CIH Therapies <input type="checkbox"/></p> <p>Chiropractic Care <input type="checkbox"/></p> <p>Occupational Therapy <input checked="" type="checkbox"/> 3/15/15</p> <p>Pain Clinic <input type="checkbox"/></p> <p>Physical Therapy <input checked="" type="checkbox"/> 3/15/17</p> <p>Specialty Therapy <input type="checkbox"/></p> <p>Other Therapy <input type="checkbox"/></p>	<p>Care Providers</p>	<p>Specialty Pain</p> <p>None</p> <p>MH Appointment</p> <ul style="list-style-type: none"> <li>• 2/27/2016</li> <li>• 3/15/2016</li> </ul> <p>Substance Use Disorder Ind</p> <p>OtherRecent</p> <ul style="list-style-type: none"> <li>• 4/19/2015</li> <li>• 3/15/2016</li> </ul> <p>Physical Therapy</p> <p>Primary Care Appointment</p> <p>None</p>	<p>Specialty Pain</p> <p>None</p> <p>MH Appointment</p> <ul style="list-style-type: none"> <li>• 4/24/2015</li> <li>• 2/27/2015</li> </ul> <p>Substance Use Disorder Ind</p> <p>OtherRecent</p> <ul style="list-style-type: none"> <li>• 4/19/2015</li> <li>• 3/15/2016</li> </ul> <p>Magnetic Resonance Imaging/Mri</p> <p>Primary Care Appointment</p> <p>None</p>

# Veteran Directed Home and Community Based Services: Stepped Wedge Design

**PEPReC**

Partnered Evidence-based Policy  
Resource Center

➔ Every eligible site will participate in the HCBS program during the evaluation

VAMCs	3/2017	6/2017	9/2017	12/2017	3/2018	6/2018	9/2018	12/2018	3/2019	6/2019	9/2019	12/2019
1-7												
8-14												
15-21												
22-28												
29-35												
36-42												
43-49												
50-56												
57-63												
64-70												
71-77												

*Start times and exact number of sites in each step subject to change*

# Lessons Learned

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## Lessons learned:

- Hard to randomly assign roll-out; people who have bought in want to start
- Need to be sure of stakeholder (clinical operations) commitment
- Don't plan around new technologies that can get delayed
- Rollout can get overtaken by events

## Considerations going forward

- Is the extra rigor from randomization worth it? What are alternative designs?
- What questions are stakeholders ACTUALLY interested in?
  - Does It Work? vs. WHERE Does it Work? vs. How to make it stick?

# Making it Stick: Pragmatic Research on Implementation Strategies

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- Highly specified methods derived from frameworks or theories that are used and tested at the clinic, system, or community level to support existing practitioners in adopting EBPs
- Like clinical interventions, ***implementation strategies are protocolized*** in research
- NIH and VA fund comparative effectiveness studies of different implementation strategies (Hybrid Type 3 designs)
  - Appeal to community settings: ALL sites get the EBP and the study is about the best way to support practitioner uptake, sustainment of EBPs
  - Inform stakeholders on how to maintain EBPs once research dollars go away

# Implementation Strategies: Reducing the Quality Gap

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An intervention or treatment (EBP) is only as good as how and whether...

1. *It is adopted?*
2. *Practitioners are trained to use it?*
3. *Trained practitioners choose to use it?*
4. *Eligible populations/patients benefit from it?*

If we assume 50% threshold for each step... even with perfect access, adherence, dosage, and maintenance....

**Clinical Impact:**  $50\% \times 50\% \times 50\% \times 50\% = 6\%$  benefit



# Examples of Implementation Strategies

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Patient Safety  
checklists

Community  
engagement

Rapid-cycle  
testing,  
adaptation

**Focus: improving practitioner strategic skills, e.g.,**

- Adapting, owning the EBP
- Building local champions
- Business case to leadership

Develop  
stakeholder  
interrelationships

Audit &  
Feedback

Prepare clinical  
champions

**Address system barriers, e.g.,**

- Low bandwidth
- Social determinants
- Competing priorities

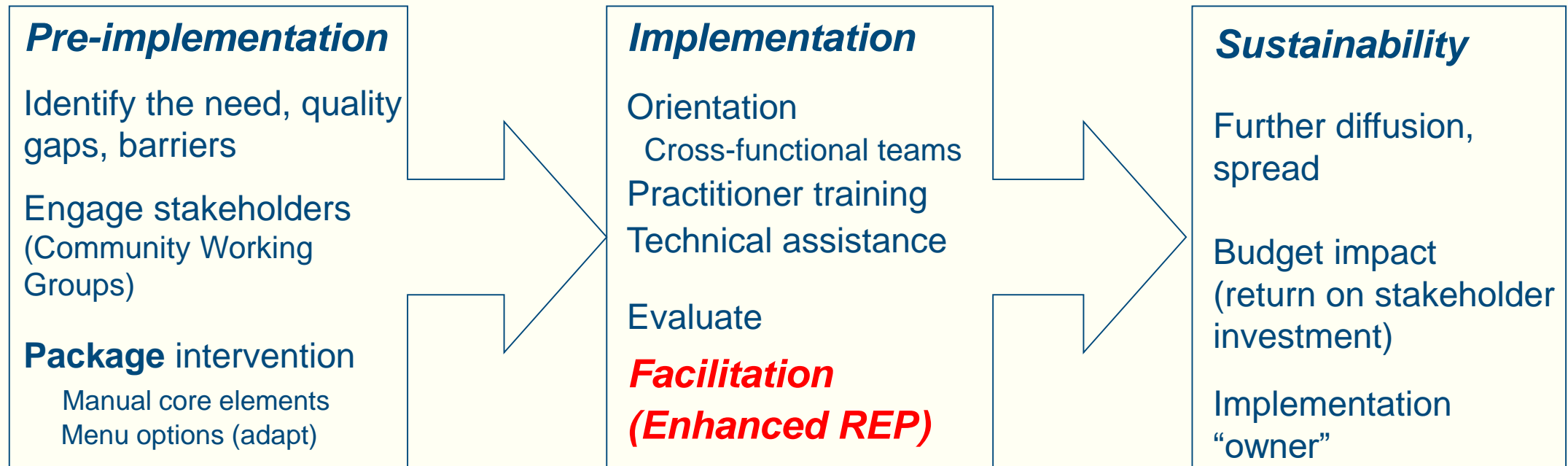
Interactive  
problem-solving

Financial,  
performance  
incentives

Change  
infrastructure,  
policies

# Pragmatic Research and Implementation: Replicating Effective Programs

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REP is a bundle of implementation strategies based on Social Learning Theory and Rogers' Diffusion of Innovation models, originally developed by the U.S. Centers for Disease Control and Prevention to enhance uptake of behavioral (e.g., HIV prevention) interventions.

# REP Example: Re-Engage National Program for At-risk Veterans Lost to Care

RESEARCH AND PRACTICE

## Reduced Mortality Among Department of Veterans Affairs Patients With Schizophrenia or Bipolar Disorder Lost to Follow-up and Engaged in Active Outreach to Return for Care

Chester L. Davis, ScD, MPH, Amy M. Kilbourne, PhD, Frederic C. Blow, PhD, John R. Pierce, MD, Bernard M. Winkel, EdD, Edward Huycke, MD, Robert Langberg, MA, David Lyle, Yancy Phillips, MD, and Stephanie Visnic, BA

Serious mental illness (SMI), including patients with schizophrenia and bipolar disorder, is associated with substantial functional impairment, morbidity, and premature mortality.<sup>12</sup> In a given year, Veterans Affairs (VA) treats more than 230 000 patients for SMI.<sup>3</sup> VA patients with SMI die on average 13 to 18 years younger than the US general population,<sup>1</sup> and this mortality gap exceeds 20 years in non-VA populations.<sup>2</sup> A key driver of premature mortality among VA and non-VA patients with mental disorders is medical comorbidity, and cardiovascular disease is the number 1 cause of death.<sup>4</sup> Persons with SMI have standard mortality ratios that are about 2.5 times greater than those of the general population.<sup>2</sup>

*Objectives.* We determined whether contacting Department of Veterans Affairs (VA) patients with schizophrenia or bipolar disorders (serious mental illness [SMI]) who had dropped out of care for prolonged periods resulted in reengagement with VA services and decreased mortality.

*Methods.* We developed a list of patients with SMI who were last treated in fiscal years 2005 to 2006, and were lost to follow-up care for at least 1 year. VA medical centers used our list to contact patients and schedule appointments. Additional VA administrative data on patient utilization and mortality were analyzed through May 2009.

*Results.* About 72% (2375 of 3306) of the patients who VA staff attempted to contact returned for VA care. The mortality rate of returning patients was significantly lower than that for patients not returning (0.5% vs 3.9%; adjusted odds ratio = 5.8;  $P < .001$ ), after demographic and clinical factors were controlled.

*Conclusions.* The mortality rate for returning patients with SMI was almost 6 times less than for those who did not return for medical care. Proactive outreach might result in patients returning to care and should be implemented to





# Re-engaging Veterans with SMI into Care (Re-Engage)

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2011: VA launches national policy to implement Re-Engage to identify, coordinate care for at-risk Veterans with serious mental illness

2011: VA Office of Mental Health endorses national study to inform optimal approach to enhance provider uptake of Re-Engage



Jeff Burk, PhD, Dave Carroll, PhD, national leads

VHA national network of Mental Health Recovery Coordinators

5-site pilot launch led by practitioners

2012-13 VA Office of Research funded Re-Engage implementation study

2013 - ReEngage national VHA performance measure

# Re-Engage Program

## VHA Mental Health Services

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1. Local mental health providers received list of Veterans with serious mental illness lost to care with last known patient contact information
2. Attempted to contact Veteran to assess status
3. For successful contacts – assessed clinical needs and schedule VA appointment if Veteran desires to return to care
4. Document efforts in a web-based registry, EHR

# Enhanced REP National Adaptive Implementation Strategy (Re-Engage)

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- Among sites not initially responding to a standard implementation strategy (REP), compare effect of adding Facilitation (Enhanced REP)
- Two-arm cluster randomized trial of a natural experiment of national program rollout (VHA Directive 2012-002)
  - REP initially used to implement program in 158 sites, >18,000 Veterans
  - 89 non-responding sites randomized to receive added Facilitation or continue standard REP
- Outcomes included uptake (EHR), return to care (VA admin data)

# Re-Engage Implementation Strategies

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## Standard REP

- Package (toolkit based on input)
- Training (calls, website)
- Brief technical assistance
- Uptake monitoring reports

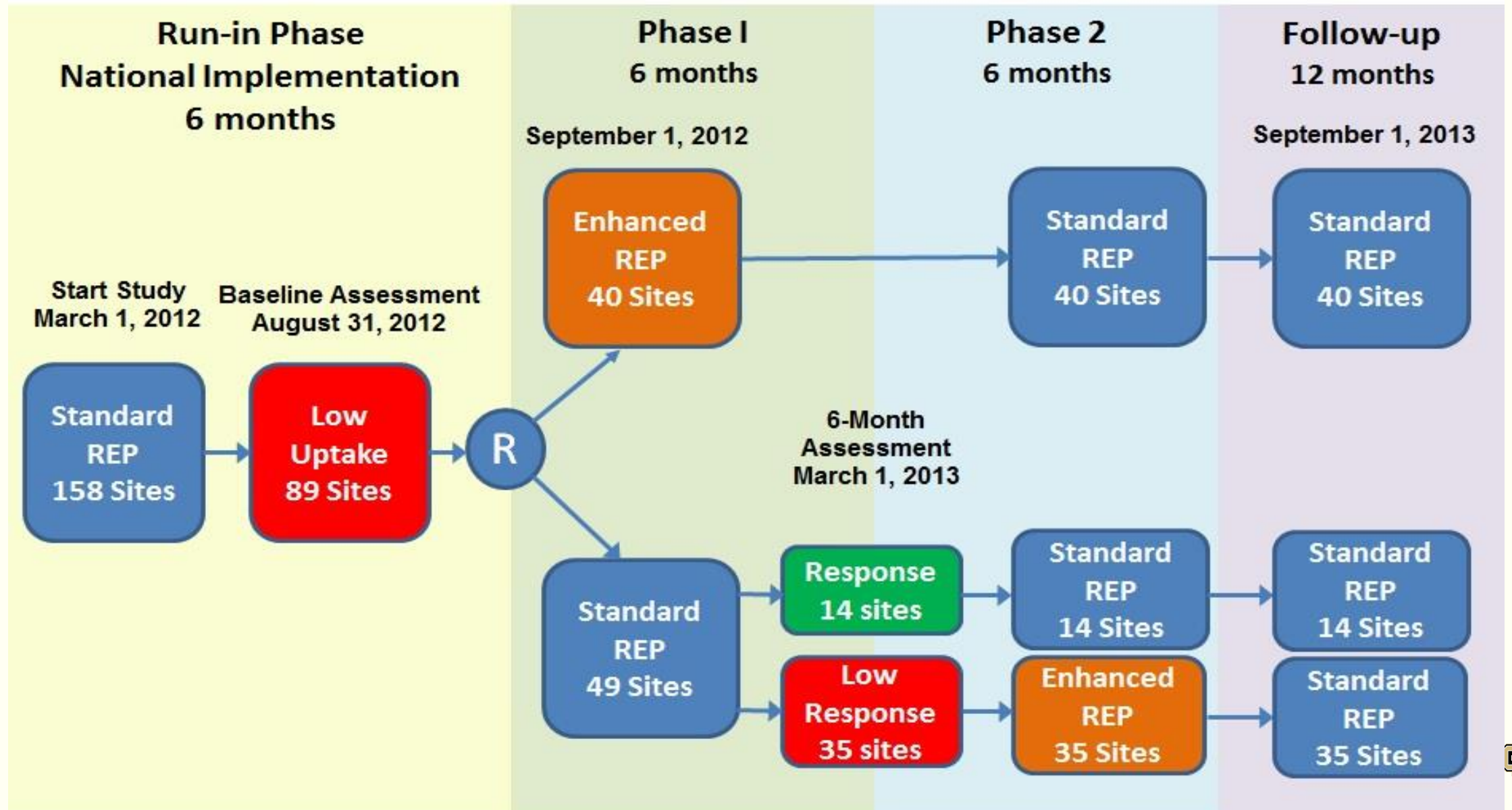
## Enhanced REP

- Package (toolkit based on input)
- Training (calls, website)
- Brief technical assistance
- Uptake monitoring reports
  - ❖ Needs Assessment
  - ❖ Garner local support
  - ❖ Identify problems/barriers
  - ❖ Problem-solve/action plan
  - ❖ Feedback/link to resources

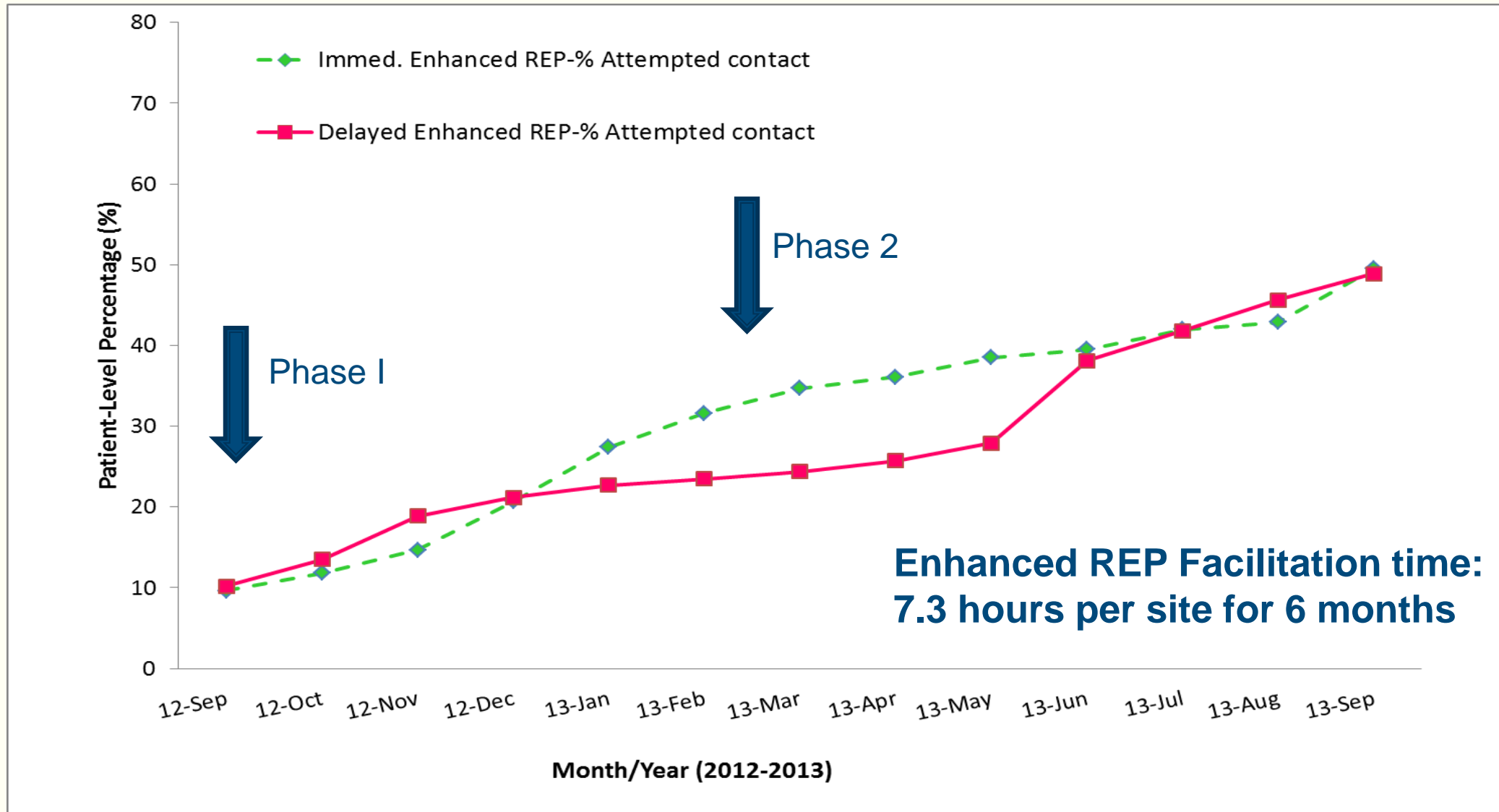
\* External facilitation by 3 doctoral-level mentees



# REP vs. Enhanced REP to Implement Re-Engage



# Enhanced REP Long-Term Outcomes

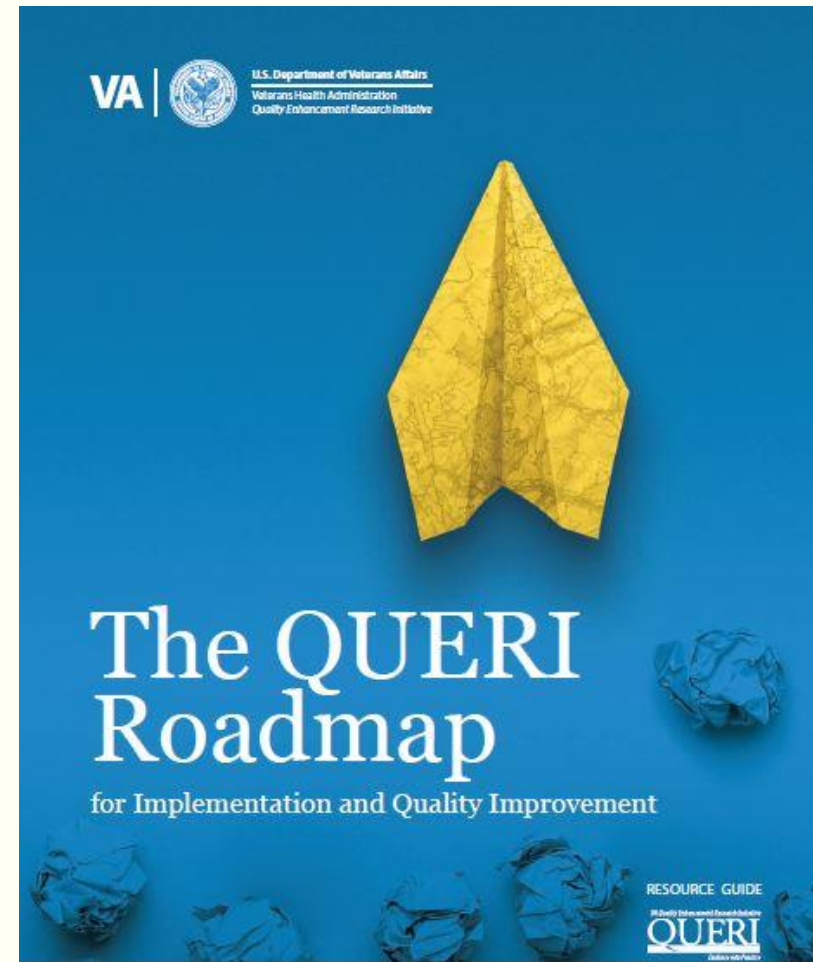
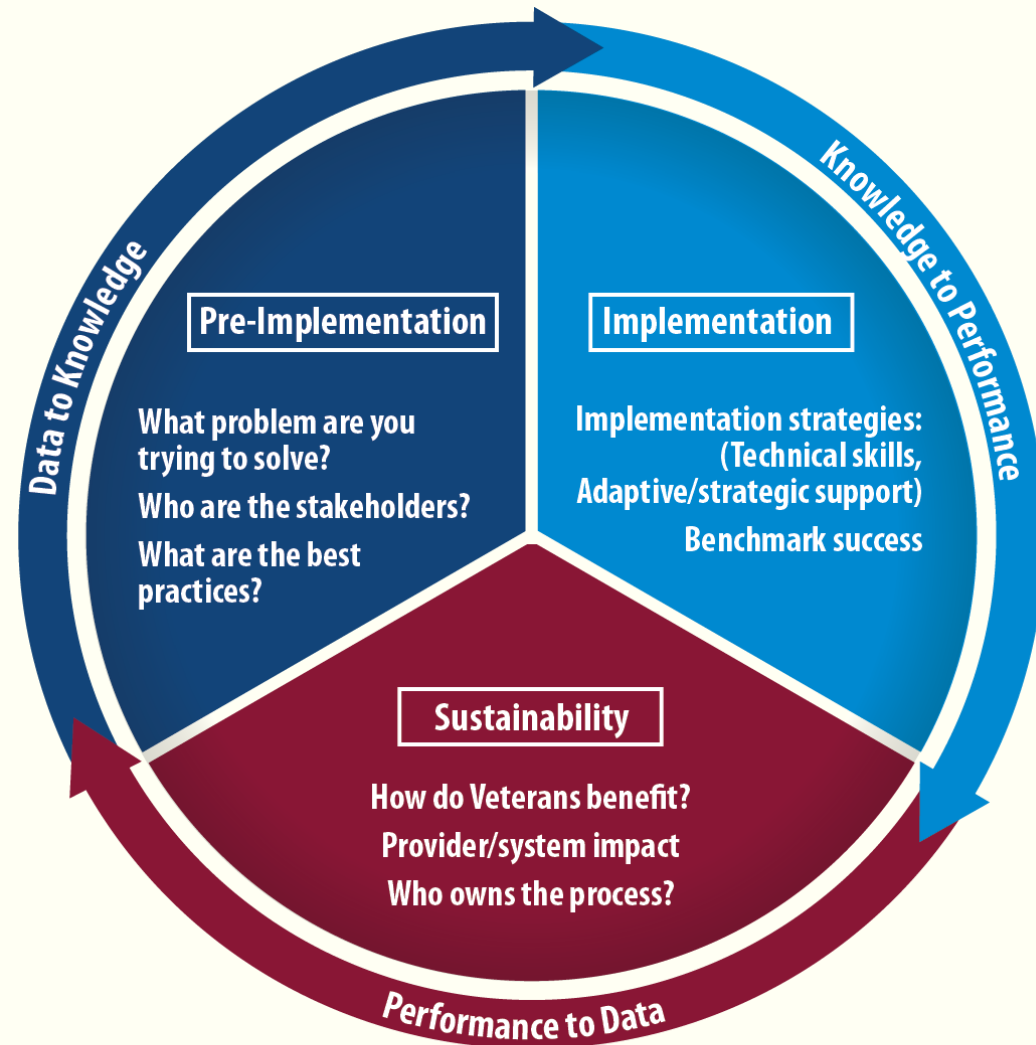


# Re-Engage and Pragmatic Research Core Concepts

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- Problem-focused: VHA found researchers to implement Re-Engage
- Ongoing engagement
  - National leaders (weekly calls, national directive)
  - Local providers (educational sessions, pilot sites, adaptations)
- Outcomes: low-burden, existing data
- Sustainment: VHA national program office “owner”

# Quality Enhancement Research Initiative (QUERI) Roadmap

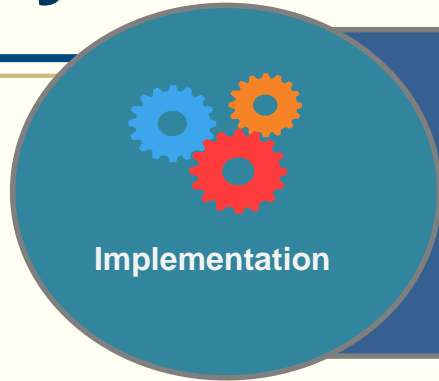


Kilbourne, et al, Med Care, 2019





# Quality Enhancement Research Initiative (QUERI)



More rapidly implement effective practices into routine care using quality improvement strategies

National Network of QUERI Programs

**60+ complex effective practices** implemented across VA by >3,500 providers, >250,000 Veterans



Support rigorous, stakeholder-driven evaluations of national programs and policies

Partnered Evidence-based Policy Resource Center (PEPReC)

**25+ rigorous evaluations** of national policies, e.g., suicide prevention, opioid misuse, health equity



Support implementation and quality improvement science across the translation spectrum

Center for Evaluation and Implementation Resources (CEIR)

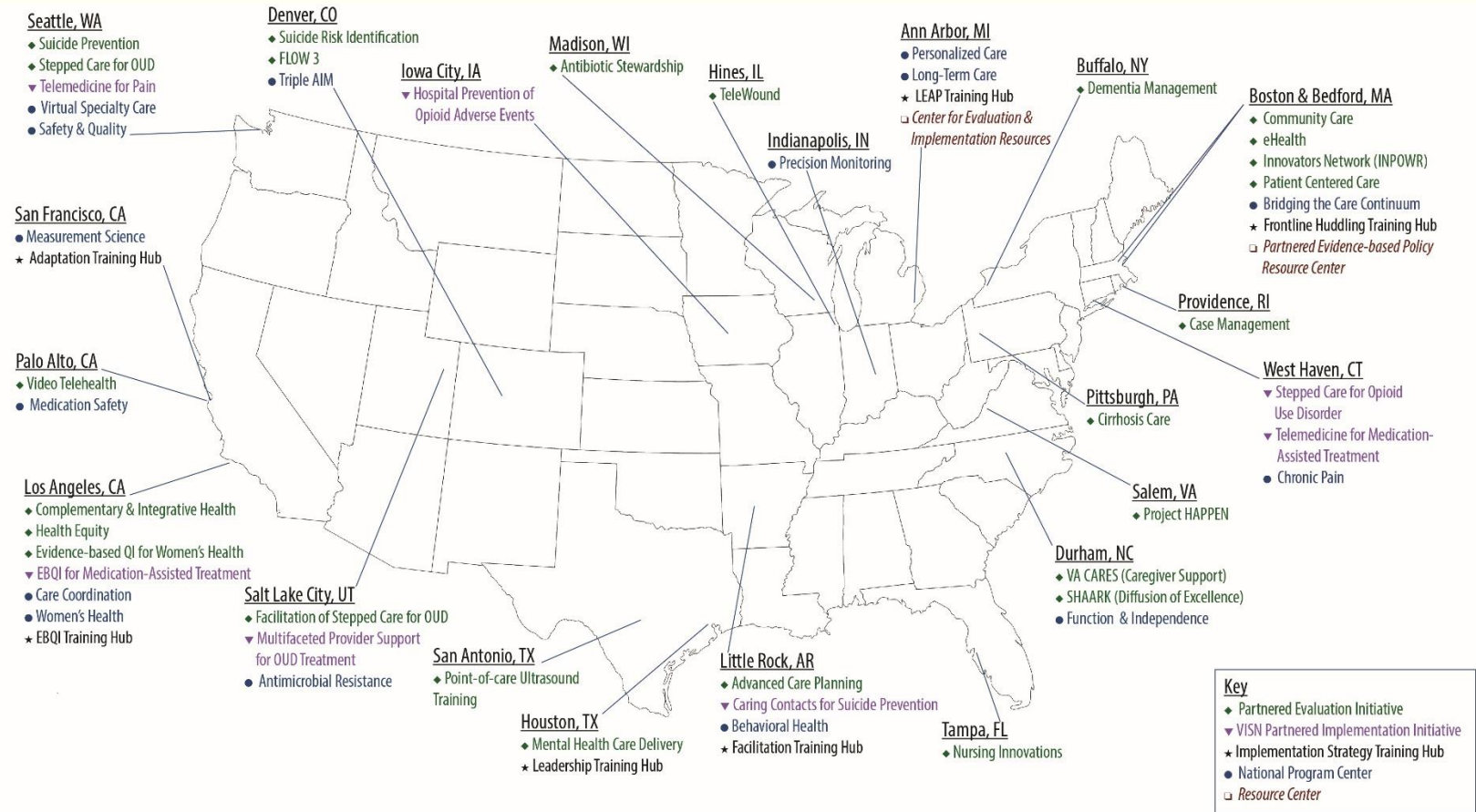
**Implementation Roadmap**  
**Evaluation Toolkit**

# 40+ QUERI Centers Across VA

**Mission:** Improve Veteran health by accelerating evidence into practice

**Vision:** Become a trusted purveyor of implementation science to enable more frontline providers deploying effective practices using quality enhancement methods

**Values:** Excellence, Commitment, Partnerships, Rigor, Resilience, Flexibility



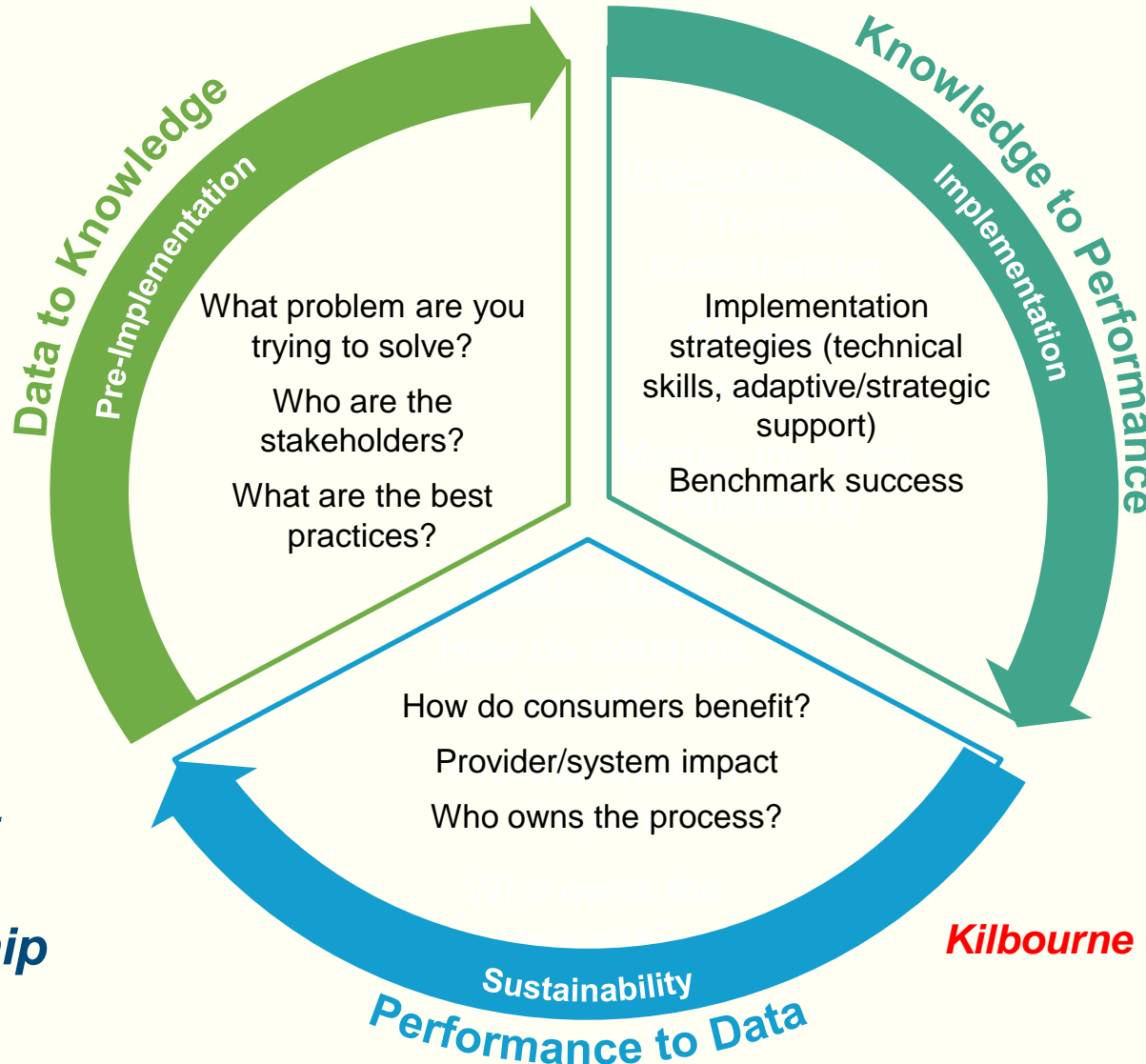
# QUERI Implementation Roadmap

**“Nothing about us without us”**

**Where the best ideas come from**

**Tell the story: return-on-investment**

**Stakeholder ownership**



**Engage the individuals who “get things done”**

**Embed meaningful evaluation measures**

**Kilbourne et al, Med Care 2019**




# Roadmap Guiding Principles

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- Implementation as a **dynamic, multi-phase process**
- Requires a combination of skill sets
  - Technical – content expertise, capacity-building, fidelity
  - Adaptive – user-centered design, addressing variation in diffusion across settings over time
  - Relational – motivational and psychological skills to effect organizational change
- Learning health system principles (teaming, psychological safety, etc.)
  - **Transactional Leadership** to create top down “*push*” for an EBP (vision, accountability)
  - **Transformational Leadership** creates bottom-up “*pull*” to own EBP (meaningful, engaging)
- Address **multi-level** barriers and solutions
  - Use theory to design behavior interventions to address individual and organizational determinants (barriers) to implementation
  - Use of tailored but well-specified implementation strategies
- **Rigorous evaluation** methods, designs, analyses

# QUERI Implementation Roadmap Checklist

	Pre-implementation	Implementation	Sustainability 
<b>What is being implemented?</b>	<b>Identify a problem and solution</b> <ul style="list-style-type: none"> <li>Identify high-priority need and goals</li> <li>Agree on evidence-based practices (EBP) and settings</li> <li>Clarify EBP core elements, adaptation options (consumer, provider input)</li> </ul>	<b>Implement an intervention</b> <ul style="list-style-type: none"> <li>Select implementation strategies</li> <li>Tailor strategies to local settings</li> <li>Disseminate implementation plan and support tools</li> </ul>	<b>Sustain an intervention</b> <ul style="list-style-type: none"> <li>Develop business plan to continue EBP</li> <li>Monitor for changes in EBP, whether different EBP is needed</li> <li>Weigh costs of maintaining EBP</li> </ul>
<b>Who and what settings are involved?</b>	<b>Engage stakeholders</b> <ul style="list-style-type: none"> <li>Cultivate leadership/stakeholder support</li> <li>Assess capacity, including barriers and solutions to EBP delivery</li> <li>Package EBP with delivery adaptations</li> </ul>	<b>Activate implementation teams</b> <ul style="list-style-type: none"> <li>Convey top-down practice support “push” to local sites from leadership</li> <li>Empower bottom-up “pull” to enhance stakeholder buy-in at local level</li> <li>Create stakeholder feedback channels</li> </ul>	<b>Transition ownership to stakeholders</b> <ul style="list-style-type: none"> <li>Provide management support</li> <li>Plan and budget for resources</li> <li>Support continuous learning and innovation in local stakeholder teams</li> </ul>
<b>How is it being measured?</b>	<b>Develop measures and data</b> <ul style="list-style-type: none"> <li>Design evaluation to match goals</li> <li>Identify measures of success and data sources</li> <li>Establish baseline performance</li> </ul>	<b>Monitor implementation progress</b> <ul style="list-style-type: none"> <li>Report progress to stakeholders</li> <li>Make data accessible to stakeholders</li> <li>Adjust plan based on feedback</li> </ul>	<b>Ongoing Evaluation and Reflection</b> <ul style="list-style-type: none"> <li>Consumer outcomes</li> <li>Delivery of EBP (fidelity vs. adaptation)</li> <li>Provider and system costs</li> </ul>

# QUERI Implementation Strategy Learning Hubs

- Train providers in specific implementation strategies to ensure sustainment of EBPs
- Learning Hub Sites coordinated by Center for Evaluation & Implementation Resources
- Strategies are evidence-based; Hubs structure training around QUERI Roadmap

For more information contact:

Veronica Williams (Veronica.Williams9@va.gov)



# QUERI Implementation Learning Hubs Training Diffusion of Excellence Winners (Gold Status Fellows)

- VA employees submitted their promising practice via a web portal
  - Provide estimated cost for implementation, steps of implementation
  - Outcomes measurement aligned with VISN performance metrics
- 2018: ~500 reviewed, 100 semifinalists reviewed by QUERI, 19 finalists, 11 Gold Status Practices, QUERI/CEIR implementation support



# VA IMPaCT Community Health Worker Program



The NEW ENGLAND  
JOURNAL of MEDICINE



Diffusion of  
**EXCELLENCE**  
Diffusing Best Practices Across VHA



VA Quality Enhancement Research Initiative  
**QUERI**  
Evidence into Practice

IMPACT effectiveness  
demonstrated in 3 RCTs



CHRONIC DISEASE  
CONTROL



QUALITY



MENTAL HEALTH



HOSPITAL  
ADMISSIONS  
lowered by 30%

IMPACT applied to Diffusion of  
Excellence portal, chosen to  
participate in their Shark Tank,  
selected as Gold Status practice



Dr. Judith Long, MD  
HSR&D

Crescenz VA Medical Center

IMPACT trains community health  
workers to join a health care  
team and provide social support  
to high risk patients

Diffusion of Excellence BaseCamp:  
IMPACT obtains ongoing implementation  
support from QUERI D4DI Learning Hub and  
DEI Diffusion Specialist to implement at >1 site

**CEIR**  
VA QUERI Center for Evaluation  
and Implementation Resources



Lynette Kelley &  
Marina McCreight, VA Colorado





# THANK YOU!

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Melissa Braganza and Faith Booker, QUERI

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Daniel Almirall, Shawna Smith, Celeste Liebrecht, University of Michigan

Kristen Abraham, Jeff Burk, Dave Carroll, VA

David Atkins, Naomi Tomoyasu, Liza Catucci, HSR&D

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*The views expressed are those of the authors and do not necessarily represent the views of the VA*

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