Driving Innovation, Implementation, and Sustainability in a Learning Health System

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VHA Office of Research and Development
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Outline

- Implementation science in Learning Health Systems
- Aligning research and health system strategies
- Implementation study designs → accelerated uptake of evidence-based practices (EBPs)
Setting the Stage

- **Quality Improvement** → analysis of healthcare performance, and the systematic efforts to improve it

- *Implementation research* → scientific study of methods or strategies to promote evidence-based practice (EBPs) uptake in health care → improve outcomes

- *Implementation strategy* → An integrated set, bundle, or package of implementation interventions to enhance adoption of a clinical intervention

- *Learning Health System* → Using health system data to inform practice and generate new questions for further study
Using my old strategy will be productive right now…

… while trying this new strategy might be more productive at some point in the future...

Hmmm....

Meh.

Credit: Mark Bauer, MD Chris Miller, PhD,
It takes 17 years to turn 14 percent of original research to the benefit of patient care
Too often, we have assumed…
“If you build it…”
The Need for Top-down Support

• “C-suite” research needs of health systems
  – AHRQ Learning Health Care System Core Competencies
  – National Academy of Medicine: Future of HSR

“Health services research has been less influential in informing more nuanced management and implementation decisions that health systems face”
“Here is Edward Bear, coming downstairs now, bump, bump, bump, on the back of his head, behind Christopher Robin. It is, as far as he knows, the only way of coming downstairs, but sometimes he feels that there really is another way, if only he could stop bumping for a moment and think of it.”

--A.A. Milne
### The Disconnect: Research and Practice

#### How practitioners find out about research findings

1. Professional associations
2. Seminars/workshops
3. Email alerts
4. Journal articles *(Really?)*

#### How researchers communicate findings

1. Journal articles
2. Face-to-face meetings
3. Media interviews
4. Press releases
Implementation Research: Why Should We Care?

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:** \(50\% \times 50\% \times 50\% \times 50\% = 6\% \text{ benefit}\)

From Gila Neta, PhD, NCI
Overcoming the Persistent Research-to-Practice Gap

Existing providers don’t have the resources or training to implement evidence-based practices once the research dollars go away

- Research **not aligned** with clinical operations priorities
- Interventions **not designed** with frontline providers in mind
- **Variation** in organizational capacity, commitment
- **Top down** strategies do not engage middle managers
- Effective **implementation strategies needed at** all levels for consumers, providers, managers **innovate and own** process
- Implementation is **iterative**, not always linear
The Traditional Translational Research Pipeline (linear, sequential, but slow!)

- Preintervention
- Could a program work
- Does a program work
- Making a program work
- Effectiveness studies
- Efficacy studies
- Implementation
- Adoption/preparation
- Exploration
- Generalized knowledge
- Local knowledge
- Sustainment

* These dissemination and implementation stages include systematic monitoring, evaluation, and adaptation as required.

Implementation Research: Planning the Methods

What?
Evidence-based Interventions

How?
Implementation Strategies

Implementation Outcomes
Feasibility
Fidelity
Penetration
Acceptability
Uptake
Costs

Service Outcomes*
Efficiency
Safety
Effectiveness
Equity
Patient-centeredness
Timeliness

THE USUAL

THE IMPLEMENTATION PATHWAY

Health Outcomes
Satisfaction
Function
Health status/symptoms

Implementation Research Methods

* IOM Standards of Care

Implementation is Context Dependent, Multi-level Factors

STAKEHOLDERS AT ALL LEVELS!

From David Chambers, DPhil, NCI
Implementation Strategies

Achieving the Art of Implementation Practice

Implementation Strategies – highly specified, systematic processes derived from implementation frameworks or theories that are used and tested at the clinic or system level, to help providers implement EBPs

• Assumes guideline and toolkit dissemination with education are insufficient
• Reduce multi-level barriers to uptake, facilitate adaptation and adoption:
  – Provider and middle manager buy-in
  – Integrating the practice with administrative and system workflows
  – Tailoring for local contexts without compromising EBP core elements

• Like clinical interventions, implementation strategies are protocolized in research
Accelerate adoption of evidence-based practices into routine care

Three priority goals:
- Implement and sustain effective practices across various health settings
- Conduct rigorous evaluations with operations partners to optimize policies
- Promote implementation science across the translation pipeline

QUERI funds VA investigators to co-lead implementation and evaluation initiatives with clinical operations leaders
QUERI Funds Over 40 Centers Across U.S.

Seattle, WA
- Suicide Prevention
- Virtual Specialty Care
- Safety & Quality

Denver, CO
- Triple Aim

Iowa City, IA
- Hospital Prevention of Opioid Adverse Events

Madison, WI
- Infection Prevention

Indianapolis, IN
- Precision Monitoring
- Center for Evaluation & Implementation Resource

Ann Arbor, MI
- Personalized Care
- Long-Term Care

Buffalo, NY
- Dementia Management

Boston & Bedford, MA
- Access Policy
- eHealth
- Innovators Network (INPOWR)
- Patient Centered Care
- Bridging the Care Continuum
- Partnered Evidence-based Policy Resource Center

Palo Alto, CA
- Outpatient Medication Management
- Medication Safety

San Francisco, CA
- Measurement Science

Salt Lake City, UT
- Multifaceted Provider Support for OUD Treatment
- Antimicrobial Resistance

Los Angeles, CA
- Complementary & Integrative Health
- Health Equity
- Evidence-based OI for Women's Health
- EBQI for Medication-Assisted Treatment
- Care Coordination
- Women's Health

San Antonio, TX
- Point-of-care Ultrasound Training

Little Rock, AR
- Caring Contacts for Suicide Prevention
- Behavioral Health

Durham, NC
- VA CARES (Caregiver Support)
- SHAARK (Diffusion of Excellence)
- Function & Independence

West Haven, CT
- Stepped Care for Opioid Use Disorder
- Telemedicine for Medication-Assisted Treatment
- Chronic Pain

Key
- Partnered Evaluation Initiative
- VISN Partnered Implementation Initiative
- National Program Center
- Resource Center
### Interdisciplinary Team-Based
- Evidence-based Behavioral Health Interdisciplinary Program teams
- Integrated pain teams, Pharmacist led pain care program

### Personalized
- Caring Contacts for suicide prevention in non-mental health settings
- Automated Cognitive Behavioral Therapy for non-pharmacologic pain care

### Patient-Centered
- Stepped Care for Opioid Use Disorder
- Collaborative care model tailored to women Veterans with anxiety, depression, or PTSD

### Technology-Facilitated
- Telemedicine outreach for PTSD among rural Veterans
- Telemedicine for multimodal pain care and Medication Assisted Treatment
QUERI National Impacts

**QUERI Impacts**

**Implementation**
- 60+ effective practices being implemented across VA
- >96,000 Veterans Impacted
- >3,500 VA staff trained

**Evaluation**
- 25+ evaluations of national VA programs and policies

**Dissemination**
- 100+ tools/products developed
- 285+ journal publications
- 415+ conference presentations
QUERI Deploys Implementation Strategies to Promote Uptake of EBPs

- Evaluative and iterative strategies
- Provide interactive assistance
- Adapt and tailor to context
- Develop stakeholder interrelationships
- Train and educate stakeholders
- ID, prepare clinical champions
- Engage consumers
- Use financial strategies
- Change infrastructure, policies

Highly specified, theory-based methods used at the clinic or system level to help providers implement EBPs

Focus on improving provider technical and strategic skills

Like clinical interventions, implementation strategies are protocolized in research

Slide from Gila Neta, PhD, NCI
Examples of QUERI Implementation Strategies

LEAP: Learn, Engage, Act, Process

EBQI: Evidence-based Quality Improvement

IF: Implementation Facilitation

D4DI: Design for Dissemination & Implementation

A&F: Audit & Feedback

REP: Replicating Effective Programs
QUERI Systematic Review of Implementation Strategies to Use Beyond “Early Adopters”

Miake-Lye et al. VA ESP Report Scaling Beyond Early Adopters, 2019
Focus on Hard-to-Engage Sites

"Many sites are difficult. I don’t think that makes them bad sites"

"I give you a whole bunch of N-of-1s, but there’s a lot of experience there"

Best practice/new idea → Set up → Develop the scalable unit

Pilot project → Small clinical trials

"Regional roll-out" projects

"National roll-out" effort

Diffusion of Innovations curve
Phases of scale-up from IHI
QUERI pipeline
Common Challenges & Potential Benefits

- Low Bandwidth
- Local Innovations
- Competing Priorities
- Healthy Skepticism
- Taking the Long View
- Needs Alignment

Common
Potential

Aligning
Taking the Long View
Healthy Skepticism

Local Innovations
Competing Priorities
Low Bandwidth
Needs Alignment

Taking the Long View
Healthy Skepticism
Strategies for Hard-to-Engage Sites

Common Challenges

- Low Bandwidth
  - External facilitation
  - Web of support
- Local Innovations
  - Peer to peer communication
  - Kick the tires
- Competing Priorities
  - Tackling upstream issues
  - Visibility with multi-level leadership

Potential Benefits

- Active Resisters
  - Hard core/ soft periphery
- Taking the Long View
  - Engagement → Adoption
- Needs Alignment
  - Framing the pitch

Quotes:
- "they kind of stole from each other, which was great"
- "we’ll go fight the battles for you"
- "It’s not one size fits all. They have room to adapt"
Getting to Implementation Strategies: Hybrid Effectiveness/Implementation Designs

• Address limits of step-wise research, speed it up
• Promote external validity ("design-for-implementation")
• Blend effectiveness, implementation stages
• Used to identify, test, compare implementation strategies

Clinical Effectiveness

Hybrid Type 1: test clinical intervention, observe implementation

Hybrid Type 2: test clinical intervention & implementation strategy

Hybrid Type 3: test implementation strategies, observe clinical outcomes

Implementation

Transition to Existing Providers: Develop “First Follower”

Study-supported providers deliver intervention

Existing Providers deliver intervention
Hybrid Type 1 Example:
National Implementation of Collaborative Care Model (CCM) for Aetna Health Plan Enrollees with Mood Disorders from Small Group Practices

Collaborative Care Model

- Care Management
- Self-management support

Usual Care

- Wellness mailings

Graph: Depression Symptom Scores (PHQ-9): CCM vs. Usual Care

Observed barriers:
- PCP engagement
- Health plan turnover

Kilbourne AM et al, BMC Psychol, 2014
Hybrid Type 2 Example:
Implementing Doctor-Office Collaborative Care (DOCC) in Pediatric Practices

**DOCC**
- Care Management
- Family Support
- Provider Training & Consultation

**Usual Care**
- Standard primary care

*Manualized implementation strategy: REP DOCC toolkit, training, learning collaborative*

Kolko DJ et al, Pediatrics 2014

**Quality of Care: DOCC vs. Usual Care**

- % Tx Initiated
- % Tx Completed
Hybrid Type 3 Example: Enhanced REP National Adaptive Implementation Strategy (Re-Engage)

- Patients with serious mental illness lost to care were dying from unforeseen causes
- Brief outreach program (Re-Engage) shown to reduce mortality in SMI
- VHA released national directive implement Re-Engage across all sites
- Two-arm cluster randomized adaptive implementation trial comparing implementation strategies
  - REP initially used to implement program in 158 sites
  - Sites (N=89) not responding to REP only support randomized to receive Enhanced REP (added Facilitation) or continue standard REP
  - Enhanced REP Facilitation time= 7.3 hours per site for six months
Hybrid Type 3 Example: Enhanced Replicating Effective Programs (REP) Implementation Strategy

**Pre-implementation**
- Identification of quality gaps/barriers
- Identify stakeholders
- Identify and customize EBPs- local input
  - **Package** intervention
    - Manual core elements
    - Menu options (adapt)

**Implementation**
- Orientation
- Cross-functional team
- Training
- Technical assistance
- Evaluate
  - **Facilitation** *(Enhanced REP)*

**Sustainability**
- Further diffusion, spread
- Budget impact (return on stakeholder investment)
- Implementation “owner”
Hybrid Type 3 Example: REP vs. Enhanced REP

<table>
<thead>
<tr>
<th>Standard REP</th>
<th>Enhanced REP</th>
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<tbody>
<tr>
<td>• Package (toolkit, guide)</td>
<td>• Package (toolkit, guide)</td>
</tr>
<tr>
<td>• Training (calls, website)</td>
<td>• Training (calls, website)</td>
</tr>
<tr>
<td>• Brief technical assistance</td>
<td>• Brief technical assistance</td>
</tr>
<tr>
<td>• Uptake monitoring reports</td>
<td>• Uptake monitoring reports</td>
</tr>
<tr>
<td></td>
<td>• Match solutions to barriers</td>
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<tr>
<td></td>
<td>• Strategic thinking skills</td>
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<td></td>
<td>• Build coalitions</td>
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<td>• Business case to leaders</td>
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Hybrid Type 3 Example:
Immediate vs. Delayed Enhanced REP Implementation Strategy to Improve Uptake of Outreach Program for Veterans with SMI

Kilbourne et al. 2014, 2015
Hybrid Type 3 Sequential Multiple Assignment Trials (SMART) *Towards Precision Implementation*

- Multi-stage trials; same subjects throughout
- Each stage corresponds to a critical decision point
- Pre-specified measure of responsiveness
- Treatment options at randomization restricted depending on history of responsiveness
- Subjects randomized to set of treatment options

*The goal of a SMART is to inform development of adaptive intervention strategies*
Often insufficient evidence/theory to decide:

- Which implementation strategy(ies) should I start with?
- What should I do for sites that are non-responsive to first-line implementation strategy?
- What should I do for sites that are responsive to first-line implementation?

SMART designs can help to answer these questions.
Example: Adaptive Implementation of Effective Programs Trial (ADEPT) Study

The question:
What is the best way to implement a collaborative care model (Life Goals) in community-based practices to improve patient mental health outcomes?

Kilbourne AM et al. (2014). Implementation Science, 9(1), 132; R01 MH 099898
Background
Collaborative care models work

Practice guidelines: Best practice tx, metabolic syndrome for mental health conditions

Decision Support

Self-management

Access/Continuity

Life Goals sessions: CVD Risk, symptoms, healthy behaviors, provider engagement

Care management: Registry tracking (Symptoms, QOL, functioning), General Medical Provider Liaison

Kilbourne et al. Psych Serv 2008; 2013
ADEPT Setting: Community-based Practices in Michigan & Colorado
Implementation Strategy Options

REP (Replicating Effective Programs)
Provides intervention manualization, didactic training and technical assistance.

EF (External facilitation)
Help identifying & addressing barriers from an outside ‘expert.’

IF (Internal facilitation)
Inside expert who works with site leaders to address barriers & champion cause.

Less intensive  More intensive
Two Types of Facilitation

External facilitator (EF):
• Location: Off-site, research team member
• Topical focus: Benchmarking, coaching
• Role: Confidante, outside observer

Internal facilitator (IF):
• Location: On-site, direct report to leadership
• Topical focus: Leveraging, rapport-building, internal recognition, sustainability
• Role: Inside expert, champion

Run-In Phase
All sites offered REP to implement EBP; Patients start EBP by Month 3

**Non-Responders**
(<10 patients receiving LG OR <50% of patients receiving ≥3 LG sessions)

**Responders**

Month 6 Assessment
Add External Facilitation
REP+EF

Month 12 Assessment
Responders
Add IF
Cont REP+EF/IF

Follow Up
Month 18 Assessment
Continue REP (A)
Continue REP+EF (B)
Continue REP+EF/IF (C)
Continue REP (D)
Continue REP+EF/IF (E)
Continue REP (F)

Kilbourne et al, 2014; Funding: NIMH R01 MH99899
Results: Receipt of CCM (Life Goals)

Odds ratios for reporting receipt, months 6-18

Effect of EF+IF vs. EF only

Michigan vs. CO

Rural vs. Urban

High aggregate MH-QOL (At baseline)
Results: MH-QOL

$B_{EF} = 0.57$

$B_{EF+IF} = 0.02$

Difference in slopes: $t = -2.70, p < 0.01$

(Higher numbers better)
Results: PHQ-9

$B_{EF} = -0.14$

$B_{EF+IF} = -0.05$

_Difference in slopes: $t = 1.09$, $p = 0.28$_
In spite of its added expense and intensity, augmenting *EF* with *IF* did not lead to better downstream patient outcomes than offering *EF* alone.

**Why? We conjecture…**

- EF more easily scalable
- Potential EF dose response
- Heterogeneity in quality/activity of IFs
- Burden of EF+IF at initial assignment
Adaptive School-based Implementation of CBT (ASIC)

1 in 5 students affected by mood disorders, 20% receive any treatment
EBTs such as CBT are effective, school professionals not adequately trained
Organizational barriers to EBT uptake in schools

ASIC will compare the effectiveness of a statewide, school-level adaptive implementation intervention involving REP, provider-CBT Coaching, and school-based Facilitation versus REP alone on:

- Frequency of CBT delivered to students by SPs
- Student mental health outcomes

NIMH R01 MH114203 (PI: Kilbourne)
## Adaptive School-based Implementation of CBT (ASIC)

### Run-In Phase
- **REP Run-In**
  - **Oct-Dec, 2018**
  - Baseline assessment

### Phase 1: Coaching treatment
- **REP Didactic Training**
  - **Randomization 1**
  - 3 month assessment

### Phase 2: Facilitation treatment
- **ASSESSMENT SCHEDULE**

- **Jan 2019**
  - REP Didactic Training
  - Randomization 1
  - 3 month assessment

- **March 2019**
  - Assess Benefit from Facilitation
  - Randomization 2

- **April 2019**
  - 6 month assessment

- **October 2019**
  - Summer Break

- **Jan 2020**
  - 12 month assessment
  - Implementation strategies stop

- **April 2020**
  - 18 month assessment

### Potential to Benefit from Facilitation
- **R**
  - **REP only**
    - k=50 schools
    - N≥100 SPs
    - No Potential to Benefit from Facilitation (Anticipated 10%, k=5)

- **R**
  - **REP + Coaching**
    - k=50 schools
    - N≥100 SPs
    - Potential to Benefit from Facilitation (Anticipated 90%, k=45)

- **R**
  - **REP + Coaching**
    - k=50 schools
    - N≥100 SPs
    - No Potential to Benefit from Facilitation (Anticipated 50%, k=25)

- **R**
  - **REP + Coaching**
    - k=50 schools
    - N≥100 SPs
    - Potential to Benefit from Facilitation (Anticipated 50%, k=25)

### Assessments
- **A** (k=5; N=10)
- **B** (k=22; N=44)
- **C** (k=23; N=46)
- **D** (k=25; N=50)
- **E** (k=12; N=24)
- **F** (k=13; N=26)

### Disseminate Package:
- Website access with tools

### Identify Students:
- SPs identify students at-need for CBT

### Start ongoing technical assistance (TA)
- (web-based, monthly calls)
QUERI Updated Implementation Roadmap: Informing a High-Reliability, Learning Health Care System

Kilbourne et al, in press, Med Care 2019

**Leadership investment**

**Regional/local input process**

**Tell the story: ROI**

**Leadership ownership**

**Deploy implementation strategies**

**Engage the “GTD” folks**

**Embed national evaluation**

**Data to Knowledge**
- Pre-implementation
  - What problem are you trying to solve?
  - Who are the stakeholders?
  - What are the best practices?

**Knowledge to Performance**
- Implementation strategies (Technical skills, Adaptive/strategic support)
- Benchmark success

**Performance to Data**
- How do patients benefit?
- Provider/system impact
- Who owns the process?

**Sustainability**
- What do Veterans benefit?
- Provider/system impact
- Who owns the process?
QUERI Implementation Roadmap Components

- 3 Phases: pre-implementation, implementation, and sustainability
- 3 levels within each phase describing activities to:
  1. Support the uptake/sustainment of the EBP
  2. Activate stakeholders or local delivery capability
  3. Optimize use of data and measurement to assess progress
- Phases are iterative cycles of experimentation and refinement - expect to pilot & pivot (and sometimes, lather, rinse, repeat)
- Deploy different implementation strategies depending on context
- Flexible application – planning and evaluation of national program deployments or supporting scale-up and evaluation of local promising practices
## QUERI Implementation Roadmap Components

<table>
<thead>
<tr>
<th>Pre-implementation</th>
<th>Implementation</th>
<th>Sustainability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is being implemented?</strong></td>
<td><strong>Engage stakeholders</strong></td>
<td><strong>Sustain an intervention</strong></td>
</tr>
</tbody>
</table>
| Identify a problem and solution | • Identify high-priority need and goals  
• Agree on EBPs and settings  
• Clarify EBP core elements, adaptation options (consumer, provider input) | |  
• Develop business plan to continue EBP  
• Monitor for changes in EBP, whether different EBP is needed  
• Weigh costs of maintaining EBP |
| **Who and what settings are involved?** | **Activate implementation teams** | **Transition ownership to stakeholders** |
| Engage stakeholders | • Convey top-down practice support “push” to local sites from leadership  
• Empower bottom-up “pull” to enhance stakeholder buy-in at local level  
• Create stakeholder feedback channels | |  
• Provide management support  
• Plan and budget for resources  
• Support continuous learning and innovation in local stakeholder teams |
| **How is it being measured?** | **Monitor implementation progress** | **Ongoing Evaluation and Reflection** |
| Develop measures and data | • Report progress to stakeholders  
• Make data accessible to stakeholders  
• Adjust plan based on feedback | |  
• Consumer outcomes  
• Delivery of EBP (fidelity vs. adaptation)  
• Provider and system costs |
| Monitor implementation progress | | |

Kilbourne et al, Med Care, in press, 2019)
• The **Innovators Network** helps employees implement, disseminate and sustain innovative programs to serve Veterans.

• Each site (33 total) led by an Innovation Specialist provides employee training and guidance in the innovation development.

• Within sites, there funding opportunities for “Spark-Seed-Spread” projects.

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• The **Diffusion of Excellence Initiative (DEI)** aims to identify and spread promising clinical and administrative practices from employees.

• Facility directors bid on the most promising practices (Gold Status Practices) via a “Shark Tank” for further spread at their sites.

• QUERI provides implementation and evaluation support to Shark Tank winners.
Diffusion of Excellence Process & Goals

- **Identify**
- **Standardize**
- **Sustain**
- **Replicate**
- **Champion**

- Empower the Front Line
- Minimize Negative Variation
- Foster a Commitment to Excellence

Acknowledgements: Ryan Vega
2018: >500 promising practices, 100 semi-finalists selected (QUERI)

19 Shark Tank finalists pitched to facility leaders: ROI Performance

10 Shark Tank winners matched to QUERI implementation trainers
QUERI Implementation Strategy Learning Hubs

- Train providers in specific implementation strategies

- Most interventions never get implemented because the original research pays for the providers, and facilities may not sustain when funding goes away

- Strategies range from training, toolkit development, to engaging opinion leaders, mentoring champions

- QUERI Learning Hub Sites use evidence-based implementation strategies coordinated by Center for Evaluation & Implementation Resources
QUERI-Diffusion of Excellence Partnership:
IMPaCT Community Peer Support Implementation

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.

IMPaCT effectiveness demonstrated in 3 RCTs

Diffusion of Excellence BaseCamp:
IMPaCT obtains ongoing implementation support from QUERI D4DI Learning Hub and DEI Diffusion Specialists

IMPaCT applied to VHA Diffusion of Excellence, chosen to participate in their Shark Tank, selected as Gold Status practice.

HOSPITAL ADMISSIONS lowered by 30%
Implementation Strategies: Lessons Learned

- Need bottom-up as well as top-down support—specify from the start
- Show return-on-investment for leadership (WIIFM)
- Hard-to-engage sites are highly variable, require tailored strategies
- Providers “lead from the middle”, let them own the implementation
- De-mystify implementation science, train in implementation practice

“Let the other person feel that the idea was his or hers”- Dale Carnegie
THANK YOU!

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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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