

CONSORTIUM • PBRN

VA WOMEN'S HEALTH RESEARCH NETWORK

Supporting Practice and Research Collaboration

Spotlight on Women Cyberseminar Series

Funded by the VA HSR&D (Project# SDR 10-012)

Improving Care for Women Veterans: *Moving from Observational to Interventional and Implementation Research*



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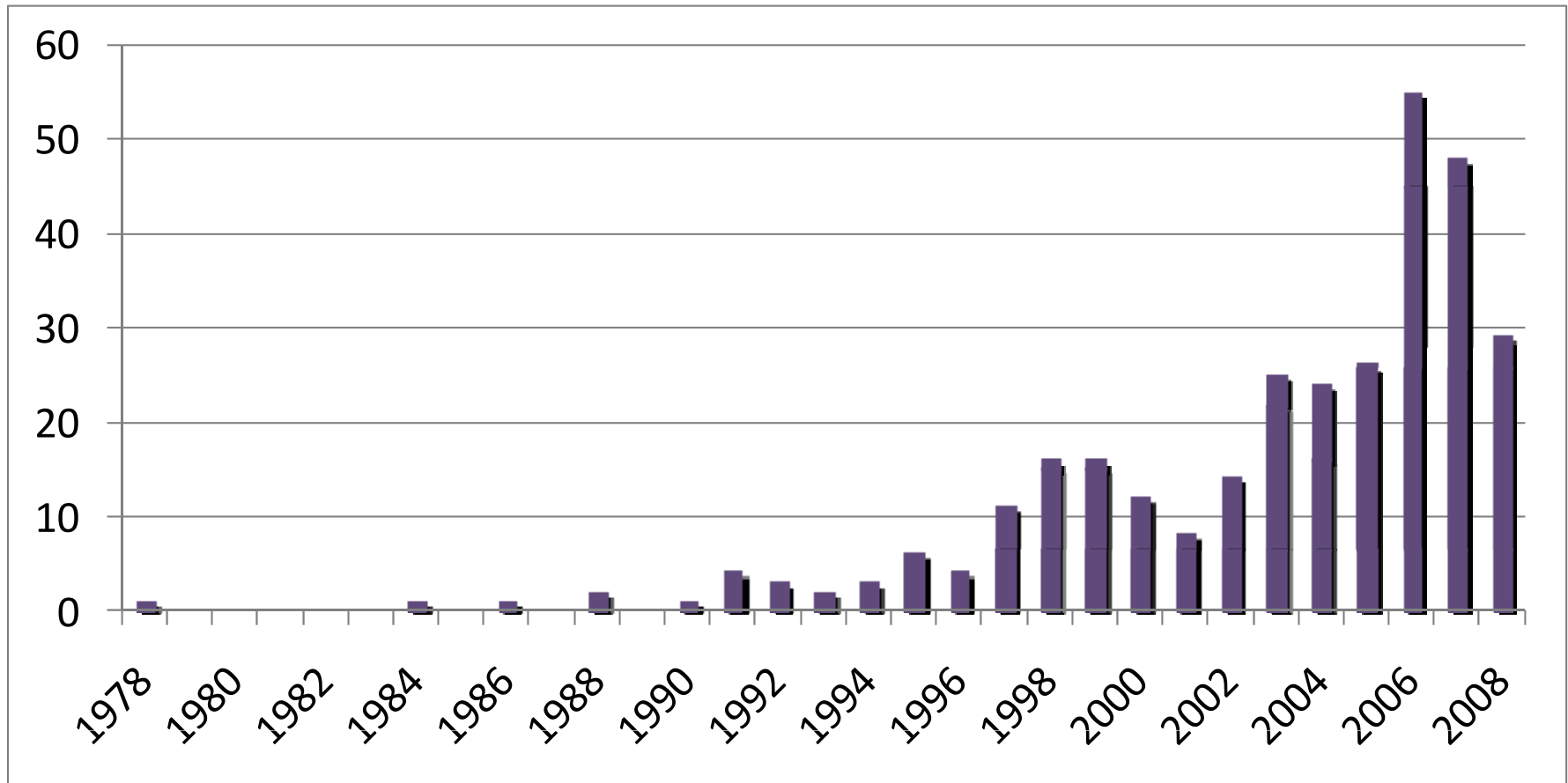
Elizabeth Yano PhD

*VA HSR&D CyberSeminar
November 2, 2010*

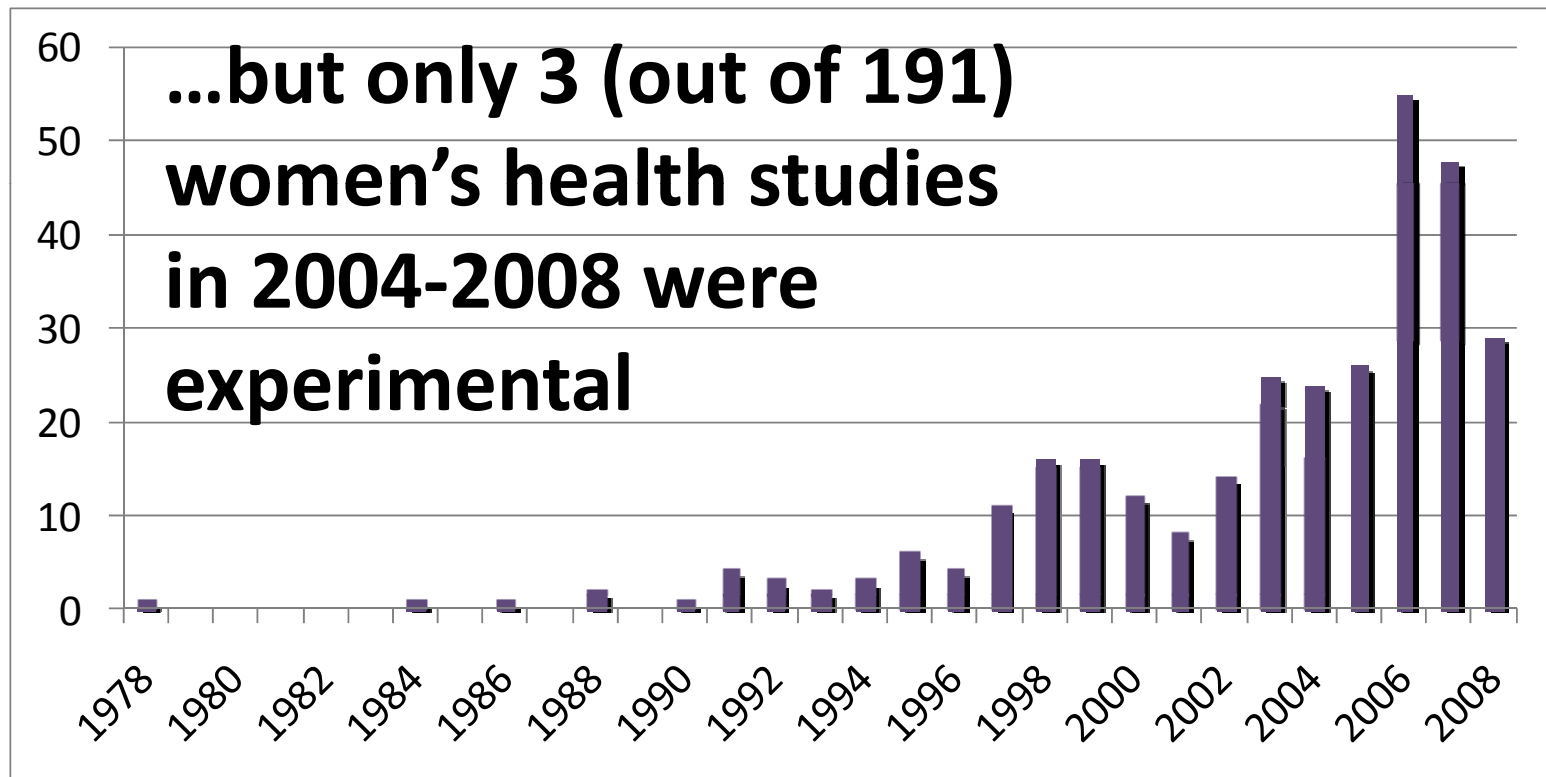
Why This Workshop?

- Rapid growth of observational studies in women's health
 - These studies have documented concerns about women veterans' health and their health care.
 - Intervention/Implementation studies (I/I) are sparse

Literature on Women Veterans Accelerating....



Literature on Women Veterans Accelerating....



Objectives of Workshop

- Opportunity to consider how *YOU* might move your own work from observational to I/I research
- Provide tools to help you get started
- Caveats
 - Workshop is a basic introduction
 - Additional resources available through
Women's Health Research Consortium
Practice-Based Research Network

Audience Poll – QUESTION 1

- Do you have prior experience with Intervention/Implementation research?

A: Yes

B: No

Audience Poll - QUESTION 2

- Do you have prior experience with Women's Health research?

A. Yes

B. No

Audience Poll - QUESTION 3

- Do you plan to conduct Women's Health Intervention/Implementation research in the future?

A. Yes

B. Maybe

C. No

Workshop Overview

- **Charge to the Field** (Linda Lipson MA)
- **Intervention Research** (Lori Bastian MD, MPH)
- **Implementation Research** (Becky Yano, PhD)
- **Multi-Site Research** (Ciaran Phibbs, PhD)
- **Women's Health Practice-Based Research Network** (Susan Frayne MD, MPH)

Charge to the Field

Linda R. Lipson MA

Director, VA HSR&D

VA Central Office



Intervention Research: *Getting Started*

Lori Bastian MD, MPH

Center for Health Services Research,
Durham VA;

Duke University Medical Center



Outline

- Use a case-based presentation to describe the steps needed to move from observational results to intervention research.
 - Hypotheses based on observational data
 - Systematic review of prior interventions
 - Develop a preliminary intervention and get input from your target audience
 - Pilot the Intervention and make adjustments
 - Test the intervention in a randomized controlled trial

Observational Studies

- Several observational studies have informed the field about women veterans.
- For example, my research focuses on the high rates of smoking among women veterans and the need to develop gender-specific smoking cessation interventions in the VA.

Observational Data

- As part of a recently completed HSR&D funded trial, we identified 471 chronically ill veteran smokers.
- Compared to men, women (N=40) were:
 - Reported higher depressive symptoms on CES-D
 - Experienced higher temptations to smoke in both social and stressful situations

Identify Research Question

- Based on known observational data, women veterans may benefit from an intervention that addresses self-efficacy to abstain from smoking in certain key situations.
- **Preliminary Question:**
Would women veterans benefit from an intervention that focuses on psychological support to resist temptations to smoke?

How to get started

- Intervention research is an intelligence gathering process that identifies possible strategy options to address the issue in question.
- It is important to know how others have addressed similar issues, the strategy mix used, the sequence of strategies, key lessons from others' efforts, and how this can be used to choose strategies for your situation.

Systematic Review

- Focuses on taking an evidence-based approach to developing new interventions by using prior research to inform strategy selection.
- Researching previous and current interventions serves to help identify what works, when and in what circumstances.
- It is useful to start by searching for systematic reviews on your particular topic of interest. I find it useful to start with the Cochrane Collection at www.cochrane.org

Cochrane Reviews

- Reviews are organized by topics.
- Tobacco Addiction (62)
 - Cessation (50)
 - Psychological support for behavioral change (9)
 - Self help (1)
 - Individual counseling (1)
 - Motivational interviewing (1)

Developing Intervention

- Based on results from Cochrane Review, **Motivational Interviewing** is effective.
 - MI is more effective if delivered by PCPs
 - One session is as effective as several sessions
 - 20 minute MI session is more effective than a shorter session

Input from your target audience

- Develop written and other intervention materials and get input from women smokers.
 - Focus groups
 - One-on-one structured interviews

Pilot Study

- If possible, apply for pilot funding
- Goals of pilot study:
 - Test logistics of study
 - Feasibility of recruitment
- Small numbers needed (n=10-20) and likely can be done at one site

Applying for VA Funding

- Contact the PBRN Clinical Trials Division for help with:
 - Determining sample size estimates and approximate number of sites needed to meet your recruitment goals (Special populations of women veterans may need more sites).
 - Identifying site coordinators in preparation for writing an HSR&D IIR or a Cooperative Studies proposal.

Advancing Implementation Research: *Moving Evidence into Practice*



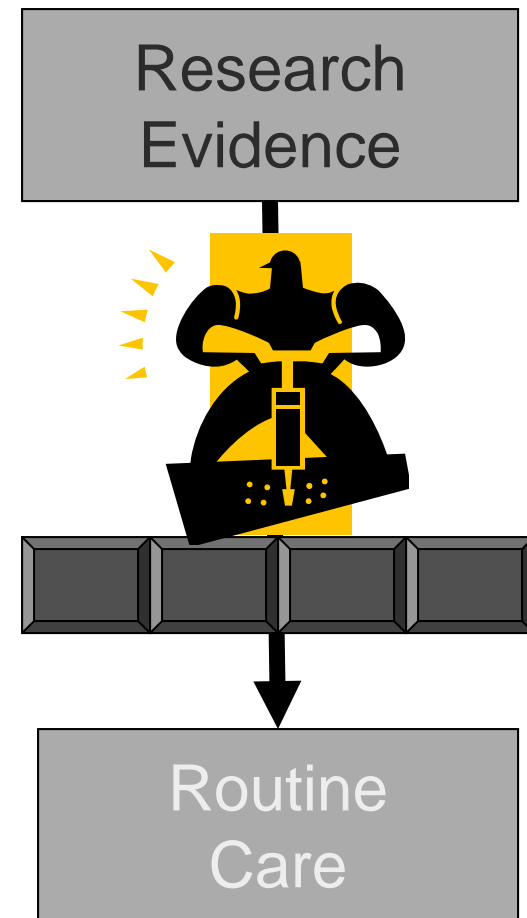
Elizabeth Yano, PhD

VA HSR&D Center of Excellence for the
Study of Healthcare Provider Behavior;
UCLA School of Public Health

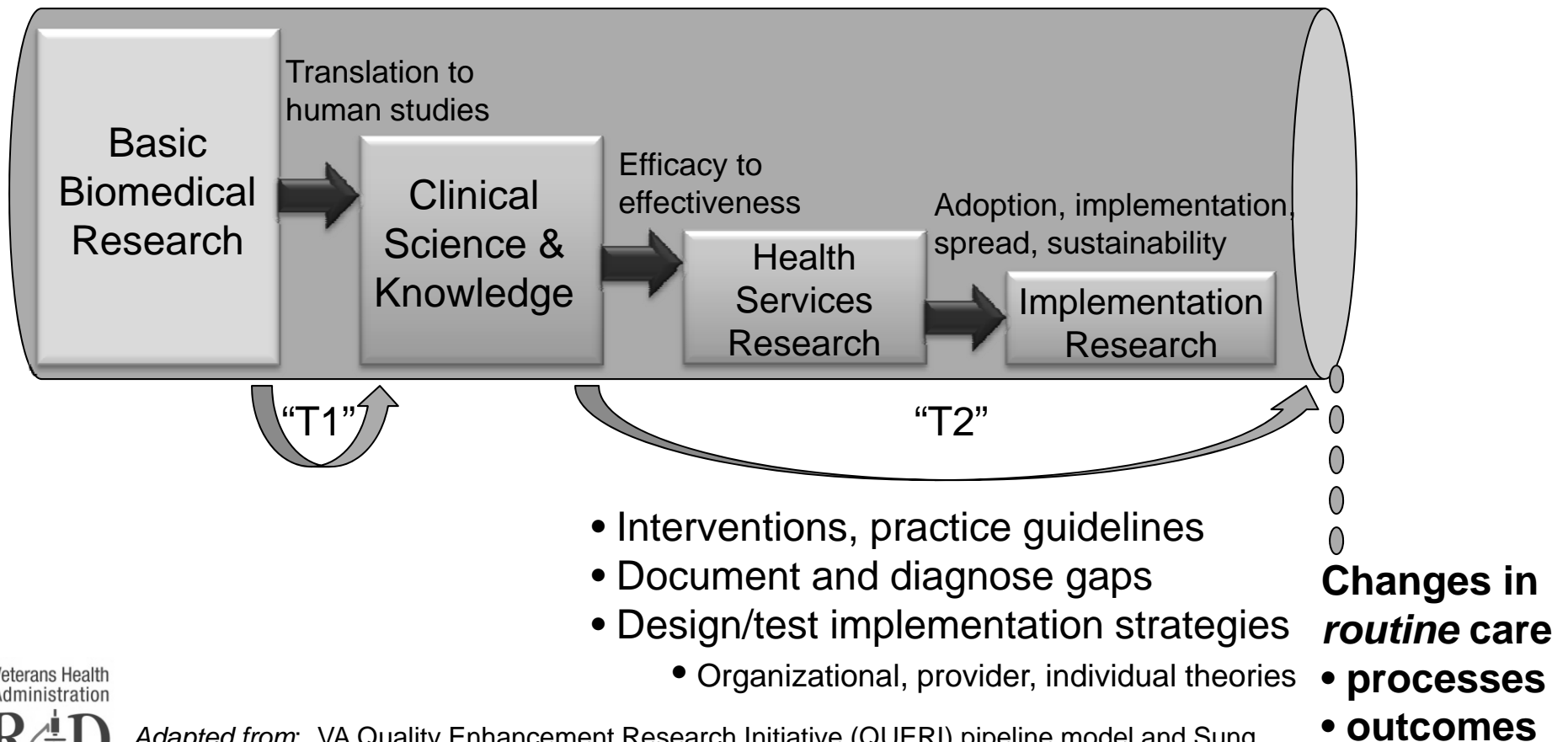


What is implementation research?

- Majority of research evidence about effective care does **not** make it into routine practice
 - Estimates span 15-30 yrs
- Implementation research focuses on methods to promote uptake of evidence
 - No longer studying the original intervention (*we know it works*)
 - Now studying an implementation strategy as the “intervention”



Research-to-Practice “Pipeline”



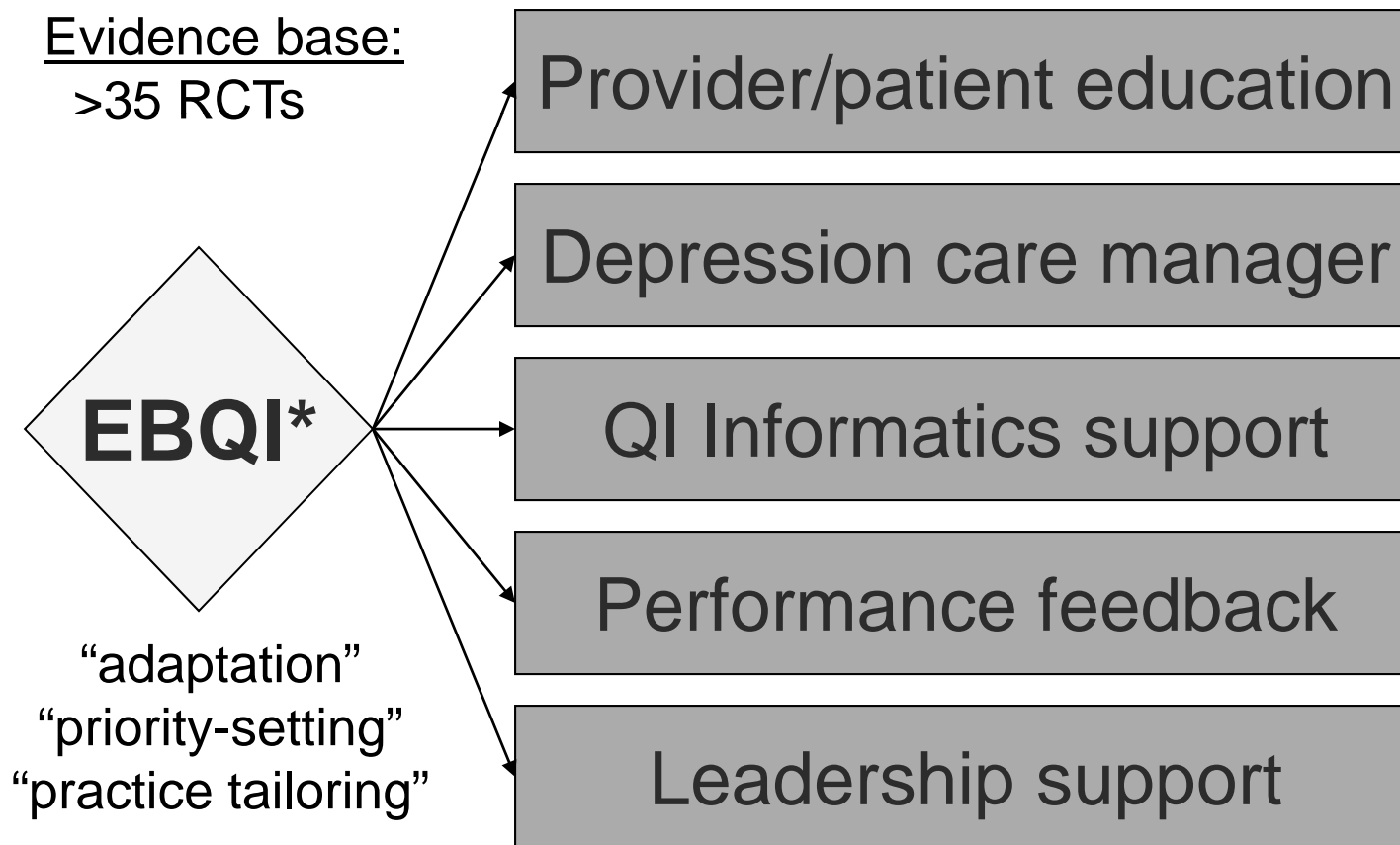
So why is implementation of evidence into practice so hard?

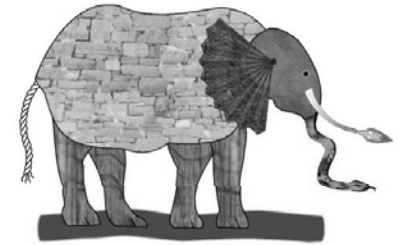
- Under what conditions was “evidence” derived?
 - Patients selected to reduce complexity
 - Tested in favorable environments
 - Factored out patient, provider and contextual variables (organizational and area)
 - Researchers work to ensure protocol adherence
- How different are “routine care” settings from those in which evidence was derived?

Evolving Research-Clinical Partnerships

- From researcher control to control of others
 - Need for tools to support their control and “ownership” in ways that support fidelity
 - Need for processes/procedures for ongoing adaptation (but in view of evidence of what works)
 - Need for tools/materials to orient new team members, new leaders
- Need for ongoing consultation as evidence changes, new challenges emerge

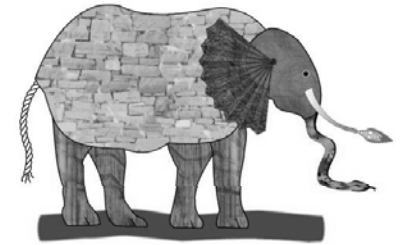
Example: TIDES Depression Collaborative Care





Context Matters

- Design for it
 - 2:1 intervention-to-control sites x 3 networks (6 intervention + 3 control sites total) → unit of analysis typically the *practice*
 - VA network leaders chose sites, we randomized within network (blocked on network characteristics)
- Importance of input from sites
 - Attitudes/beliefs/experiences (e.g., perceived need for intervention, competing demands, staff open to innovation, PC-MH relationship)
 - Resources (e.g., perceived time to use program and participate in implementation, organizational structure, staffing, prior QI experience, tools, access to informatics support)
- Variation in people/places → variable implementation



Need Multiple Data Sources

Data Sources	Types of Measures
Semi-structured interviews (leaders, managers, teams, providers)	Level of participation, implementation, experiences
Organizational surveys (VA network, facility, practice, partners)	Clinic structure, process changes, facilitators, barriers
Administrative data (including electronic medical record data)	Diagnoses, visits, prescriptions, costs
Patient surveys	Process and outcome changes (e.g., PHQ9), comorbidities, use
Provider surveys	Knowledge, attitudes, behaviors
Practice checklists	Implementation of new care components (including fidelity)

Generating the Evidence: *Depression*

- Identify target problem
 - Epidemiologic studies on prevalence, impact of depression and location in primary care
- Define best practices (guidelines)
 - Systematic reviews (and meta-analysis) showing CBT and antidepressants equally effective
 - Expert panel methods to develop guidelines

Generating the Evidence: *Depression*

- Assess care variations
 - Quality measures based on medical record and survey
 - Worse care for minorities, managed care identified in large studies
- Develop intervention models and evaluate effectiveness
 - Provider behavior and QI theory for design
 - Randomized trials of collaborative care

Generating the Evidence: *Depression Collaborative Care*

- Identify successful model characteristics and develop implementation models
 - Qualitative research on models, organizations, predictors of success and barriers
 - Quasi-experiments based on diffusion, provider behavior change, and QI theory
 - Literature synthesis and meta-analysis

Implementing the Evidence: *Depression Collaborative Care*

- Identify successful implementation models, implement as routine policies/procedures
 - Quality improvement theories used to engage organizations and their leaders
 - Quality improvement type measurement
 - Qualitative research on organizations/models
 - Policy analysis and theory to understand/foster policy uptake, incentive changes for spread
- Evaluate system performance measures

Multi-Site Research

Ciaran Phibbs PhD

Health Economics Resource Center,
VA Palo Alto

Stanford University



Multi-Site Research: Benefits

- Meeting recruitment targets
- Preventing burn-out in available pool of subjects/clinicians
- Enhancing generalizability
- Building professional connections

Multi-Site Research: Barriers

- Identifying sites and site leads
- Addressing local logistics
 - IRB/R&D
 - Engaging clinicians
 - Hires
- Understanding the local patient population and clinical environment
- Coordinating efforts across sites

Lessons from Cooperative Studies Program



- Recruitment is hard
 - Even with extensive experience, most CSP studies have recruitment problems
 - Need to allow for this in planning
 - Have contingency plans for *when*, not if, recruitment lags
- Network/Program can really help
 - Provides expertise that is hard for any individual investigator to assemble
 - Help with planning study so that you plan appropriately and realistically

VA Women's Health Practice-Based Research Network

Susan Frayne MD, MPH

Center for Health Care Evaluation,
VA Palo Alto;
Stanford University



Funding: VA HSR&D SDR 10-012

Women's Health PBRN: Overview of Design

- Network of partnered VA facilities
- Provides infrastructure
- Targets
 - researcher-initiated, funded research projects
 - clinician-initiated quality improvement projects

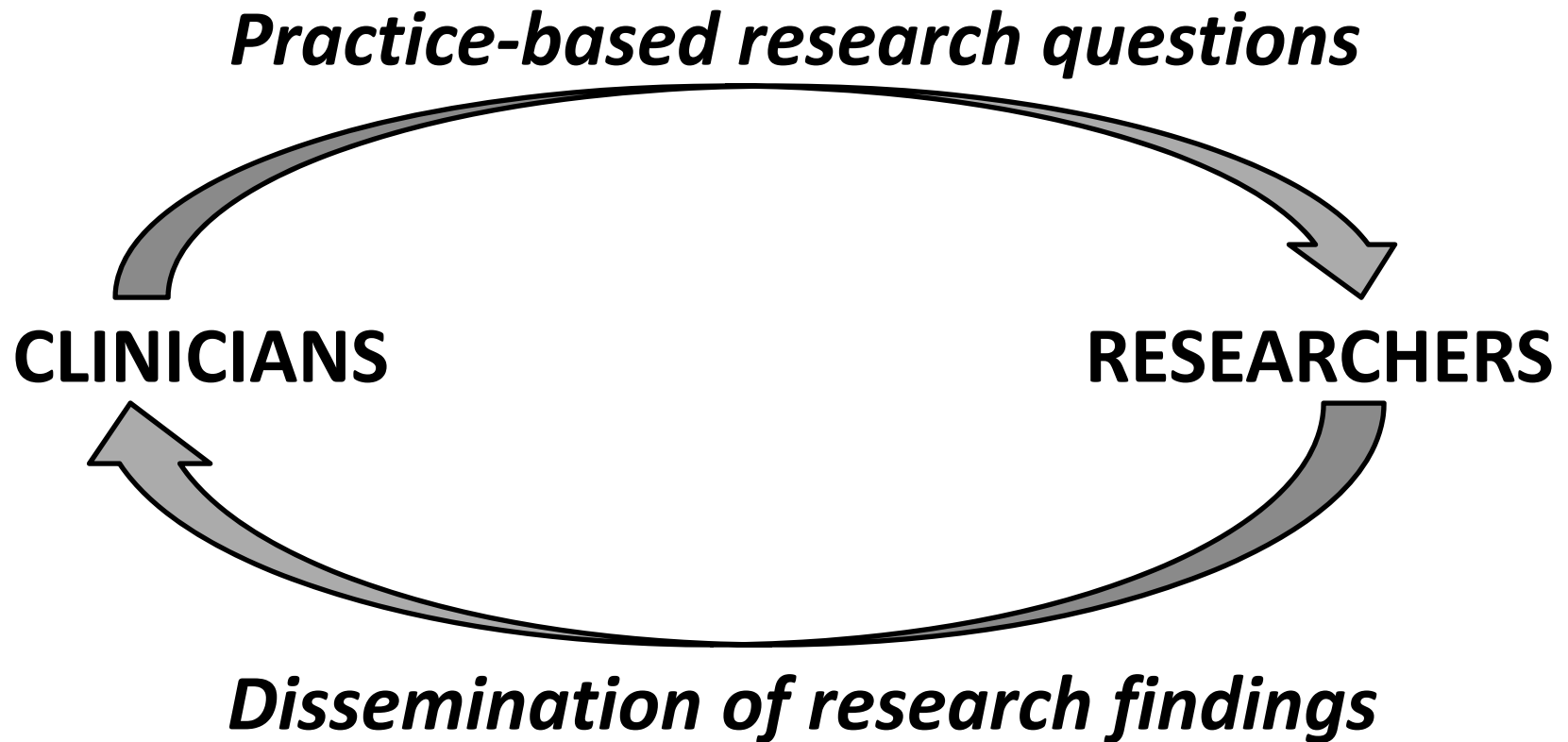
Building the Network: *Initial Sites*



Rationale for a VA Women's Health PBRN


- Facilitate conduct of *multi-site* women's health research
 - Address complexities of multi-site research
 - Overcome problem of small N at any one facility
- Promote the study of questions *informed by clinical practice*
- Foster *dissemination*
- Encourage sense of *community* among women's health researchers and clinicians

Women's Health PBRN: Bi-Directional Collaboration



Infrastructure Components



- 
- **Facilitate conduct of studies in local clinics**
 - Build relationships w/ local facility leaders/clinicians
 - Identify clinic-specific barriers/solutions to promote recruitment and minimize disruptions in clinic flow
 - **Facilitate local research administration**
 - Determine site-specific research requirements (R&D, IRB etc.) and contacts
 - Maintain generic position descriptions at sites to expedite hiring

Infrastructure Components

- **Solicit research using PBRN**
 - Outreach to investigators
 - Women's health researchers
 - Other researchers wanting to increase enrollment of women
 - Provide information about known priority areas
 - Detect emerging practice-based priority areas

Infrastructure Components



- **Support the grant application process**

- Discuss evolving study aims
 - Alignment with priority areas
 - Emphasis on intervention/implementation research
 - Other studies welcome, e.g., qualitative methods, observational studies
- Gauge interest of site clinicians re participation
- Connect researchers with resources (CSP, HERC, other collaborators)
- Provide information relevant to grant proposal preparation
- Provide specialized methods expertise
- Review protocols to provide feedback

Infrastructure Components



- **Promote success of funded PBRN studies**

- Upon notification of funding, assist PI with local issues (e.g., IRB, logistic issues related to clinic settings)
 - Note: PI will negotiate with participating site leads regarding services to be provided locally, budgetary needs of the sites, and whether the site lead will be an investigator
- Monitor progress of ongoing studies (with ultimate responsibility resting with the project's PI)
- Ongoing contact with sites
 - local problem-solving and team-building
 - training in relevant research methods (to enhance standardization of measurement and quality of data collection across sites)

Infrastructure Components

- **Promote dissemination**

- Women's Health Research Consortium
- PBRN Site clinicians
- Women's Health Strategic Health Care Group/
Women Veteran Program Managers
- Steering Committee

Patricia Hayes PhD; David Atkins MD; Joseph Francis MD, Grant Huang PhD; Susan McCutcheon EdD, RN; Paula Schnurr PhD; Gerry McGlynn MEd; Margaret Mikelonis ANP; Michael Parchman MD; Alina Salganicoff PhD; Amy Street PhD; Donna Washington MD

Accepting the Charge to Increase Intervention/Implementation Women's Health Research

- **What can YOU do?**
- **How can the Consortium/PBRN help?**

Extra Slides

What is a PBRN?



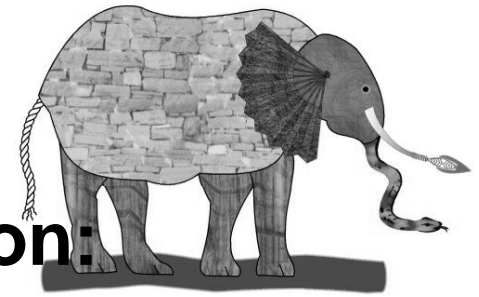
Definition (AHRQ):

“...a group of ambulatory practices Typically, PBRNs draw on the experience and insight of practicing clinicians to identify and frame research questions whose answers can improve ... practice By linking these questions with rigorous research methods, the PBRN can produce research findings that are immediately relevant to the clinician and, in theory, more easily assimilated into everyday practice.”

Clinician-centric

Uses Clinical Practices as Laboratories

Research-to-Practice Implementation: Trajectory Toward National Rollout



**Depression
Collaborative
Care Model**

20+ year evidence base (efficacy/effectiveness)
Single and multi-component interventions
Multiple settings

TIDES

WAVES

COVES

ReTIDES

**National
Rollout**

Process
Evaluation

Outcomes
Evaluation

Cost Assessment
Stakeholder Analysis
Formative Evaluation

Impact evaluation
Cost-effectiveness
National "bridge" interviews
Process tools

Ongoing
Performance
Monitoring

