

**Improving Care Quality through
Hybrid
Implementation/Effectiveness
Studies:
Best Practices
in Design, Methods, and Measures**

Amy N. Cohen, PhD

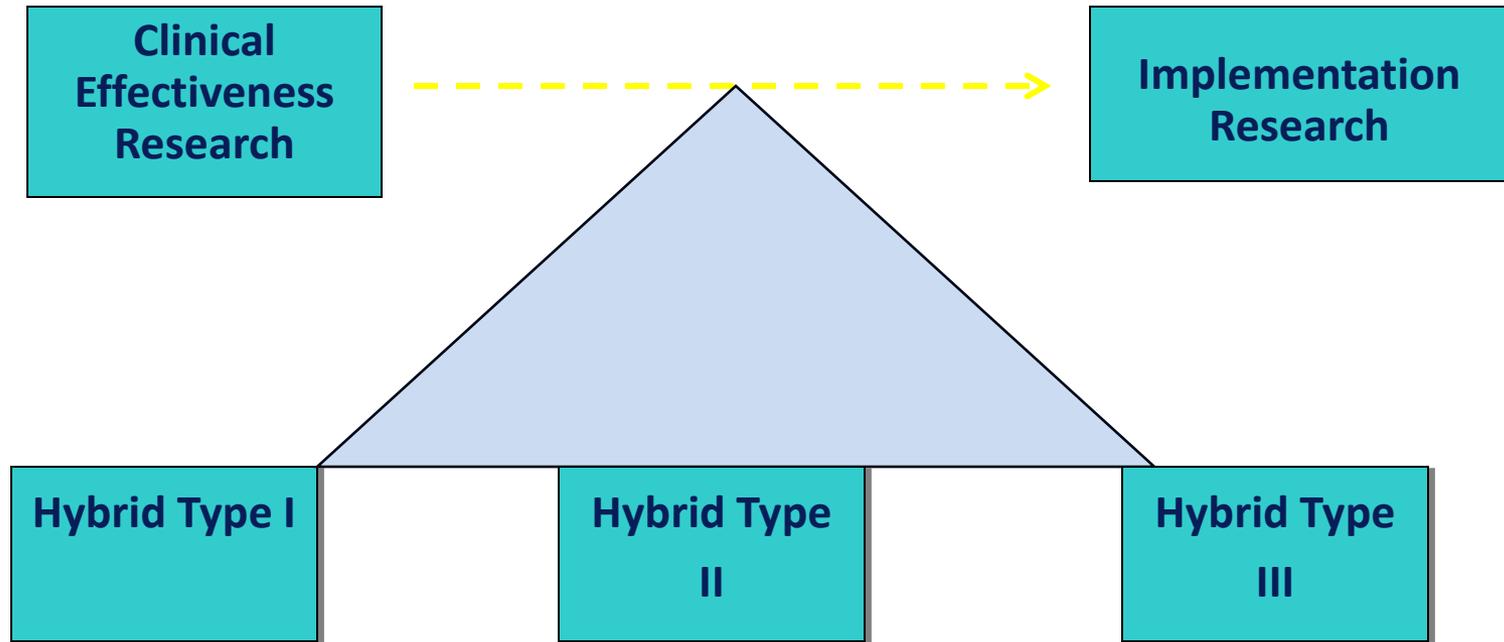
Mona Ritchie, LCSW, PhD(c)

Alison B. Hamilton, PhD, MPH

CIPRS National Cyberseminar

3/5/15

Types of Hybrids



Presentations

Presenter	Amy Cohen	Mona Ritchie	Alison Hamilton
Study Name	EQUIP-2	Blended Facilitation	Eban II
Design	Hybrid Type II	Hybrid Type III	Hybrid Type II
Conceptual Model(s)	Simpson Transfer Model, PRECEDE	PARiHS, RE-AIM	Program Change Model
Setting	Specialty Mental Health	Primary Care with Mental Health Integration (PC-MHI)	Community-Based Service Organizations
Study Target	Individuals with schizophrenia	Primary Care Clinics	HIV-serodiscordant couples
Measurement	Mixed methods with patients, clinicians, and key stakeholders	Mixed methods with patients, clinicians, and managers	Mixed methods with couples and key stakeholders
Organization	VA	VA	Community
Funding	VA HSR&D QUERI	VA HSR&D QUERI	NIMH
Funding Dates	July 2005-May 2011	Feb 2009-July 2013	June 2012-Mar 2017

Poll Question

- Which of these topics would you most like to learn about?
- Hybrid study designs
- Implementation strategies
- Conceptual models
- Evaluation methods

Improving Care Quality in Specialty Mental Health using a Hybrid Type II Design

Amy N. Cohen, PhD



VA
HEALTH
CARE

Defining
EXCELLENCE
in the 21st Century

The Quality Problem in Specialty Mental Health

- Schizophrenia is the most common serious mental illness
 - 1% of the population
 - 10% of all permanently disabled people
 - die 11-17 years prematurely
- Evidence-based practices exist
 - not available or severely underutilized
 - outcomes much worse than expected

EQUIP:
Enhancing Quality of care In
Psychosis

Primary support from VA HSR&D QUERI



Hybrid Type II Design of EQUIP

- Intervention effectiveness: chronic care model
 - Evidence-based practices
 - Patient level data to assess intervention effectiveness
- Implementation of evidence-based quality improvement (EBQI) tools and strategies
 - Patient-, provider-, and organizational-level data to assess implementation process and outcomes
 - Evaluation data was used to optimize implementation

Why a Hybrid Type II and not Type I or Type III

- We knew evidence-based practices existed; We knew barriers and facilitators to those services (from our own Type I study)
- No multisite studies had substantially improved the quality of care for schizophrenia within the context of usual care (effectiveness)
- Needed to study an implementation approach to increase uptake of evidence-based practices

EQUIP Design

- Clinic-level controlled trial
 - 801 patients with schizophrenia, 201 clinicians
- Research-Regional leadership partnership
 - 1 intervention, 1 control in each of 4 VA regions (8 medical centers)
 - Strategic Planning to choose evidence-based practices (weight, employment)
- Quantitative Assessments
 -
- Qualitative Assessments
 - Patients: 15 months only
 - Clinicians and Leadership: 0, 7, 15 months

EQUIP Specific Aims

Intervention (Chronic Care Model)

- Evaluate effect of intervention on
 - provider competency, treatment appropriateness, patient outcomes, service utilization

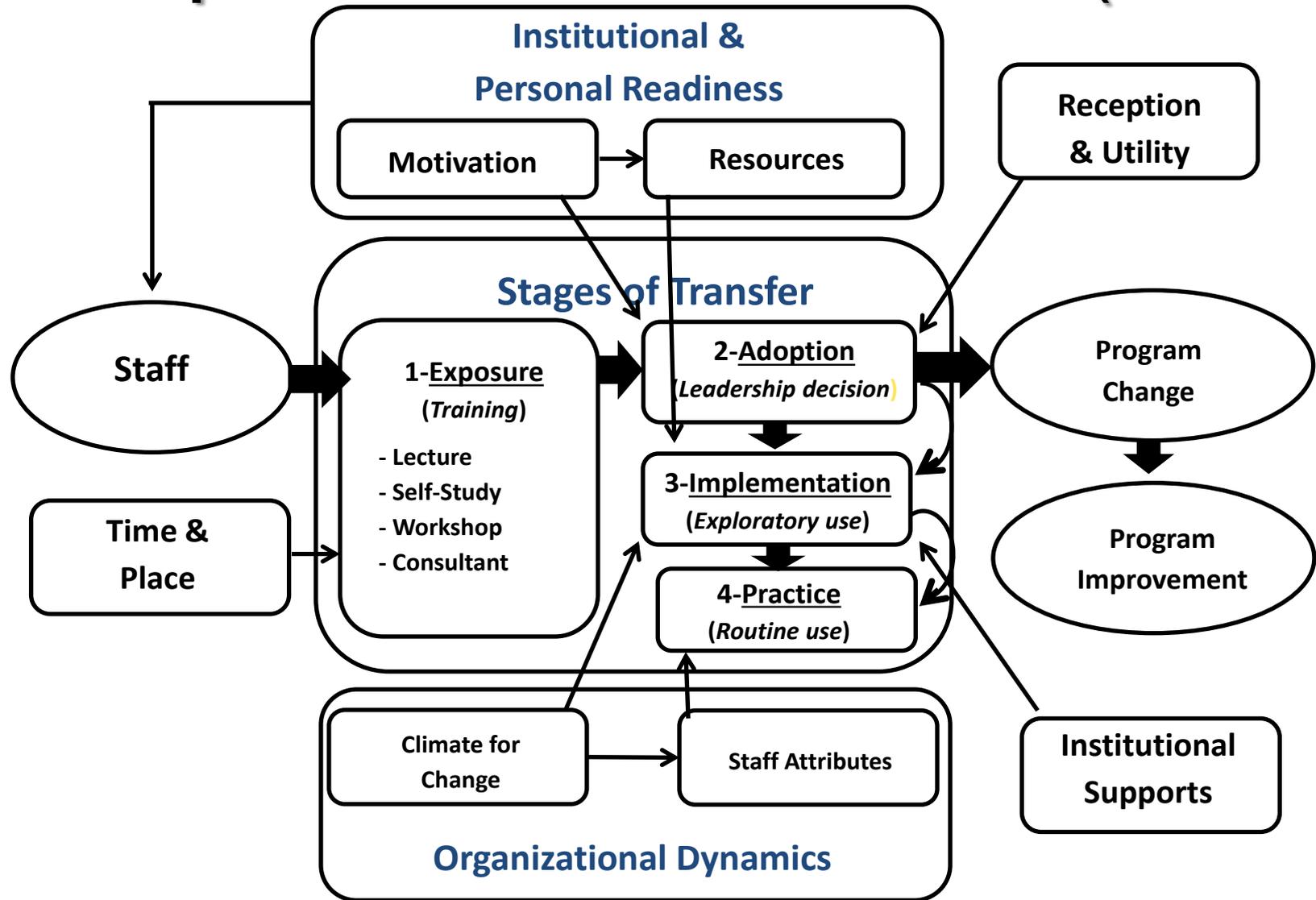
Implementation (Evidence-Based Quality Improvement)

- Using mixed methods, evaluate processes of and variations in care model implementation and effectiveness to strengthen implementation and to:
 - assess acceptability of the care model, and barriers and facilitators to its implementation
 - understand how the project's strategies and tools affect care model implementation
 - analyze the impact of individual care model components on treatment appropriateness

EQUIP Conceptual Framework

- Important to have a theory of organizational change driving the design of implementation research
- We used the Simpson Transfer Model (STM)
 - Stages of organizational change
- We supplemented STM with PRECEDE (predisposing, reinforcing, and enabling factors in diagnosis and evaluation model)
 - Needed specific behavior change concepts
 - Needed model that emphasized active participation of target audience

Simpson Transfer Model (STM)

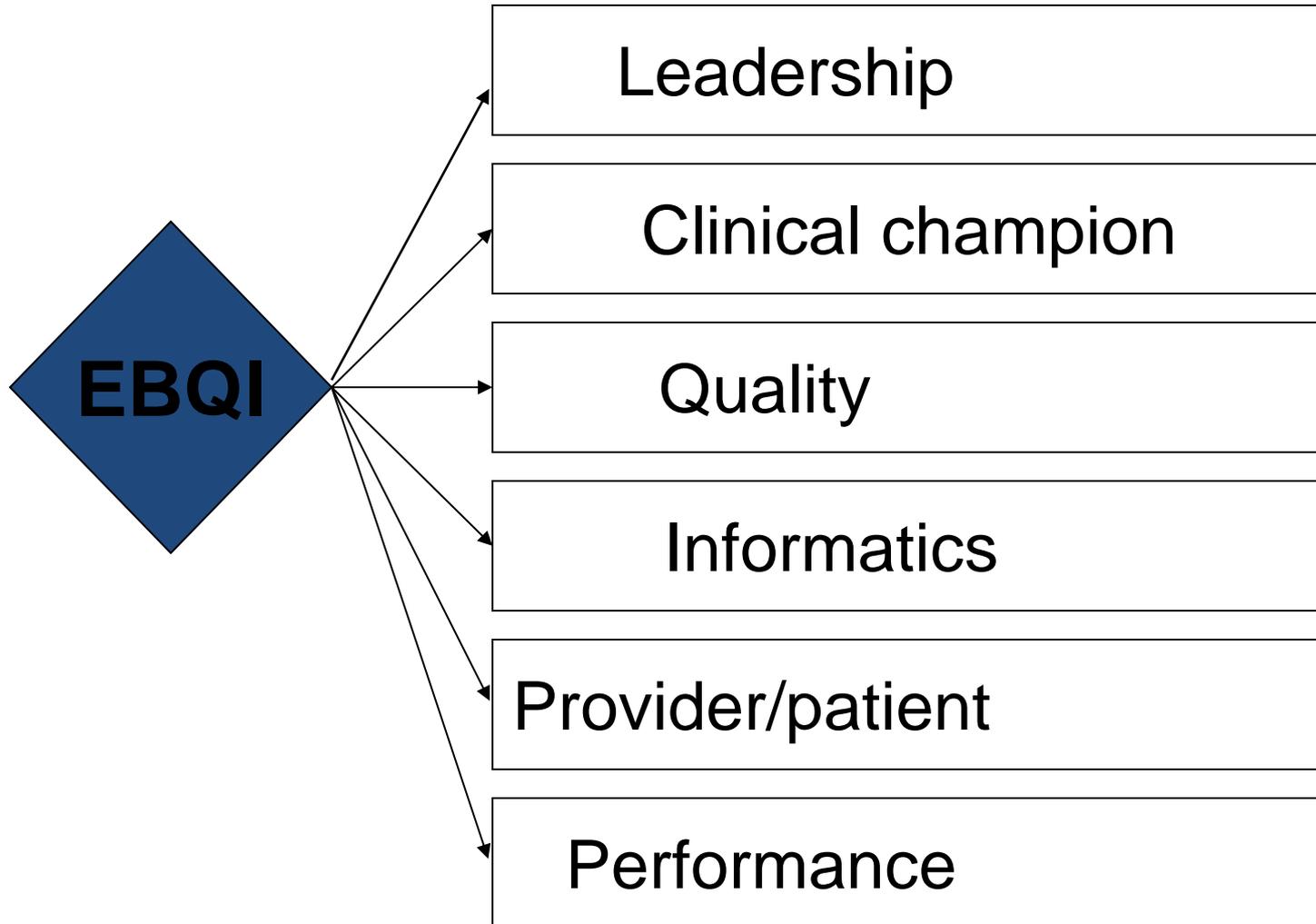


Implementation Strategy: Evidence-Based Quality Improvement

- Structured form of Continuous Quality Improvement that,
 - 1) incorporates a research/clinical partnership
 - 2) uses top-down and bottom-up features to engage organizational leaders and quality improvement teams in adapting and implementing improvements
 - 3) focuses on prior research evidence regarding clinical guidelines, validated care models, and clinician behavior change methods

GOAL: translate research on care delivery models into routine practice

Implementation Strategies & Tools



Lining up the Framework (STM) with Formative Evaluation Measures



Developmental

- Field notes
- Documents (minutes, etc.)
- Organizational Readiness for Change & Maslach Burnout Inventory
- Key stakeholder interviews

Implementation-Focused

- Field notes
- Quality Coordinator logs
- Documents
- Key stakeholder interviews

Progress-Focused

QI tools

Interpretive

- Field notes
- Key stakeholder interviews
- Organizational Readiness for Change & Maslach Burnout Inventory

Lessons Learned

- In retrospect—necessary components for success:
 - Multidisciplinary research team, strong project director
 - Early relationship-building with relevant leaders (regional, local)
- Conceptual framework to guide conceptualization of project
- Identification of local priorities; care target “menu”
- Assessment of readiness for implementation; tailoring based on that assessment
- Flexible implementation strategy with clear components
- Regular, scheduled communication with sites
- Field notes; minutes on calls; emails

EQUIP Team

VISN 3

Eran Chemerinski, MD (PI: Bronx)
Charlene Thomesen, MD (PI: Northport)
Mara Kushner Davis, CSW
Ann Feder, LCSW
Bruce Levine, MD
Claire Henderson, MD, MPH
Deborah Kayman, PhD
Helen Rasmussen, PhD
Amy Look

VISN 16

Anna Teague, MD (PI: Houston)
Dean Robinson, MD (PI: Shreveport)
Kathy Henderson, MD
Vance Hamilton, MD
Deborah Mullins, PhD
Avila Steele, PhD
Christy Gamez-Galka, PhD
Ethel Williams, RN

VISN 22

Christopher Reist, MD (PI: Long Beach)
Peter Hauser, MD
Larry Albers, MD
Kirk McNagny, MD
David Franklin, PsyD, MPH
Stacey Maruska, LCSW
Kathy Allan, RN

VISN 17

Max Shubert, MD (PI: Central Texas)
Kathryn Kotrla, MD
Wendell Jones, MD, MBA
Paul Hicks, MD
Staley Justice, MSW
Sherry Fairchild, PhD
Kathryn McNair, RN

Los Angeles MIRECC (Coordinating Site)

Alexander S. Young, MD, MSHS (PI)
Fiona Whelan, MS
Youlim Choi

Amy N. Cohen, PhD (co-PI)
Alison Hamilton, PhD, MPH
Paul Jung

EQUIP Bibliography

- Chinman M, Young AS, Schell T, Hassell J, Mintz J. Computer-assisted self-assessment in persons with severe mental illness. *J Clin Psychiatry*. 2004 Oct;65(10):1343-51.
- Young AS, Mintz J, Cohen AN, Chinman MJ. A network-based system to improve care for schizophrenia: the Medical Informatics Network Tool (MINT). *J Am Med Inform Assoc*. 2004 Sep-Oct;11(5):358-67.
- Young AS, Cohen AN, Mintz J. A vignette in the chapter on information systems. In: *The Institute of Medicine, Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series*. 2006. Washington DC: National Academies Press. Pages 241-242.
- Chinman M, Hassell J, Magnabosco J, Nowlin-Finch N, Marusak S, Young AS. The feasibility of computerized patient self-assessment at mental health clinics. *Adm Policy Ment Health*. 2007 Jul;34(4):401-9.
- Brown AH, Cohen AN, Chinman MJ, Kessler C, Young AS. EQUIP: Implementing chronic care principles and applying formative evaluation methods to improve care for schizophrenia: QUERI Series. *Implement Sci*. 2008 Feb 15;3:9.
- Cohen AN, Glynn SM, Hamilton AB, Young AS. Implementation of a family intervention for individuals with schizophrenia. *J Gen Intern Med*. 2010 Jan;25 Suppl 1:32-7.
- Hamilton AB, Cohen AN, Young AS. Organizational readiness in specialty mental health care. *J Gen Intern Med*. 2010 Jan;25 Suppl 1:27-31.
- Cohen AN, Chinman MJ, Hamilton AB, Whelan F, Young AS. Using patient-facing kiosks to support quality improvement at mental health clinics. *Med Care*. 2013 Mar;51(3 Suppl 1):S13-20.
- Hamilton AB, Cohen AN, Glover DL, Whelan F, Chemerinski E, McNagny KP, Mullins D, Reist C, Schubert M, Young AS. Implementation of evidence-based employment services in specialty mental health. *Health Serv Res*. 2013 Dec;48(6 Pt 2):2224-44.
- Niv N, Cohen AN, Hamilton A, Reist C, Young AS. Effectiveness of a psychosocial weight management program for individuals with schizophrenia. *J Behav Health Serv Res*. 2014: 1-10.
- Armstrong NP, Cohen AN, Helleman G, Reist C, & Young AS. Validating a brief version of the mental health recovery measure for individuals with schizophrenia. *Psychiatric Services*,65(9), 2014: 1154-1159.

Blended Facilitation to Enhance Primary Care Mental Health Program Implementation

Mona Ritchie, M.S.W., Ph.D. Candidate



VA
HEALTH
CARE

Defining
EXCELLENCE
in the 21st Century

Background

- Integrated primary care mental health EBPs improve care
- VA Primary Care-Mental Health Integration (PC-MHI) Initiative began in 2007
 - Requires that facilities implement co-located collaborative care and care management in primary care settings
 - Includes national support for implementation
- But VA facilities were slow to implement these models

Blended Facilitation Study

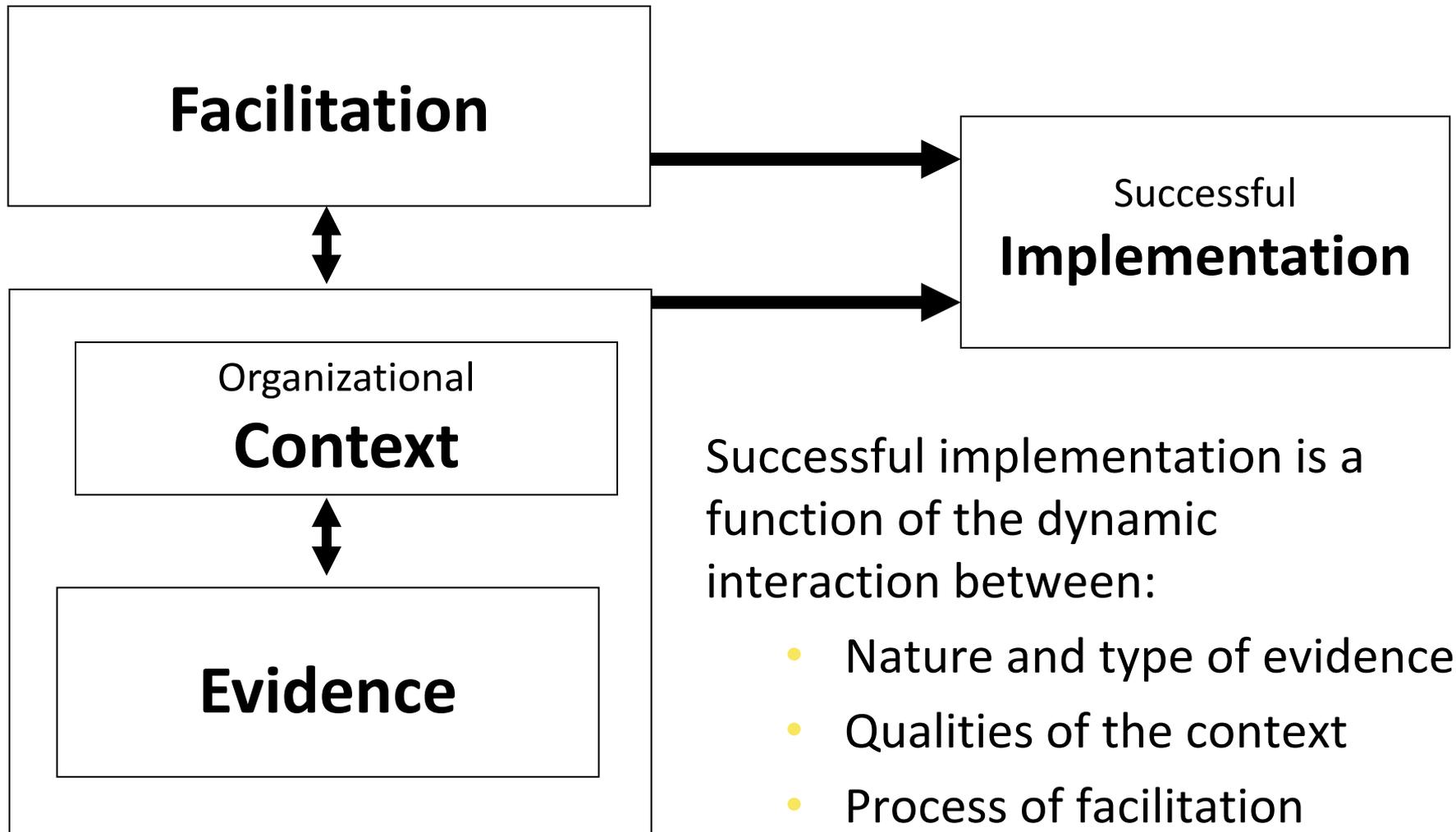
- VA HSR&D QUERI-funded study
(SDP 08-316; PI: JoAnn Kirchner, MD)



Facilitators implemented the external/internal implementation facilitation (IF) strategy as a clinical initiative to enhance implementation of PC-MHI at study clinics.

- Purpose of the study:
 - Conduct an independent evaluation
 - of the IF strategy

PARIHS Conceptual Framework



External/Internal IF Strategy

- **National Expert External Facilitator**

- Expert in IF techniques, implementation science and PC-MHI
- Links to program developers/content experts/implementation resources
- Trains/mentors Internal Facilitator

- **Internal Regional Facilitator**

- Resides within regional network clinical structure
- Familiar with organizational structures, climates, cultures and clinical settings within the network
- Works directly with site level personnel
- Ensures that programs incorporate new initiatives to maximize sustainability and fidelity to the programs
- Allows the institutional knowledge gained from the implementation process to remain within clinical network

External/Internal IF Strategy

- Facilitation Activities
 - Local change agent participation
 - Conduct detailing and education
 - Stakeholder engagement
 - Program design and adaptation
 - Formative evaluation
 - Monitoring and feedback-monthly meetings
 - Establish communities of practice
 - Fidelity assessment

Hybrid III Study Design

- Controlled trial of an implementation strategy (external and internal facilitation) to support adoption of mandated Primary Care-Mental Health Integration models
- 8 matched pairs of sites with comparison sites receiving “standard” dissemination plan supported by national clinical program office
- Multiple uptake and fidelity measures across providers and sites
- Patient health outcomes not available, assessed proportion of patients receiving PC-MHI services

Why a Hybrid Type III and not Type I or Type II

- Not Type I

Focus was not on testing the clinical intervention (PC-MHI), nor patient outcomes

- Not Type II

Needed more emphasis on implementation strategy, effectiveness of intervention was not a concern

Study Design

- Quasi-experimental
- 16 PC Clinics implementing PC-MHI:
 - 8 IF & 8 matched comparison sites in 4 VA networks
 - 4 of 8 IF sites selected for intensive case study
- Consensus matching
 - Networks matched on organizational structure and support for PC-MHI
 - Network MH Directors identified clinics unable to implement PC-MHI without help
 - Clinics matched on size, location, perceived need, perception of evidence, general clinic innovativeness, academic affiliation

Study Aims

1. Test the effectiveness of the IF strategy versus standard national support on extent of clinic-level outcomes, provider behavior change, and changes in Veterans' service utilization
2. Assess a) *organizational context*, perceptions and attitudes regarding *evidence* for primary care mental health programs, and b) the *facilitation* process within the context of those findings
3. Collect time data on *facilitation* activities for use in a future proposal to determine the cost of using the IF strategy

Study Methods

Facilitation
of PCMH program implementation

Successful
Implementation

Organizational
Context



Beliefs about
Evidence
for PCMH programs

Aim 2a

Assess Context & Evidence

Measure baseline organizational
context factors & assess
perceptions of evidence
[all sites] QUAL

Study Methods

Facilitation
of PCMH program implementation

Successful
Implementation

Organizational
Context

Beliefs about
Evidence
for PCMH programs

Aim 1, 2b, 3

Assess Facilitation Process

Collect activity/time data on
facilitation activities (QUAL/QUAN)

Assess process, perceptions of
process [case study sites only]
(QUAL)

Study Methods

Facilitation
of PCMH program implementation

Successful
Implementation

Organizational
Context

Beliefs about
Evidence
for PCMH programs

Effectiveness of IF Strategy
Using RE-AIM dimensions:
Reach (QUAN)
Effectiveness (QUAN)
Adoption (QUAN)
Implementation (QUAL/QUAN)
Maintenance (QUAN/QUAL)
[all sites]
AND
Aim 2b comparisons

Lessons Learned

Implementation Facilitation Strategy

- Expect the unexpected
- Assess the political landscape early in the process
 - New policy implementation initiatives can compete for resources

Evaluation

- Understand/monitor broader policy context; added support for policy can impact the study
- Stakeholders at facilities trying to avoid implementation or accountability may also avoid engaging in research activities
- Having one person involved across all components of a mixed methods study can maximize opportunities for interaction between study components and integration of the data

Facilitation & Research Teams

Implementation Facilitators

National Expert External Facilitator

JoAnn E. Kirchner, MD (VA, UAMS)

Internal Regional Facilitators

Katherine M. Dollar, PhD,

Patricia Gundlach, MSSW

Evaluation Team

Co-PI:

Geoff Curran, PhD (VA, UAMS)

Co-investigators:

Mona Ritchie, MSW , PhD(c) (VA, UAMS, UAF)

Louise Parker, PhD (VA, UMass Boston)

John Fortney, PhD (VA, UW/Seattle)

Chuan-Fen Liu, PhD (VA, UW/Seattle)

Project staff:

James Townsend, DHSc, MBA, MIS

Jeffery Pitcock, MS

References

- Glasgow, R.E., McKay, H.G., Piette, P.D., Reynolds, K.D. The RE-AIM framework for evaluating interviews: What can it tell us about approaches to chronic illness management? *Patient Educ Couns* 2001; 4:119-27.
- Harvey, G., Loftus-Hills, A., Rycroft-Malone, J., Titchen, A. McCormack, B. Seers, L. Getting evidence into practice: The role and function of facilitation. *J Adv Nurs* 2002;37:577-88.
- Helfrich, C.D., Damschroder, L.J., Hagedorn, H.J., Daggett, G.S., Sahay, A., Ritchie, M., Damush, T., Guihan, M., Ullrich, P.M., Stetler, C.B. A critical synthesis of literature on the Promoting Action on Research Implementation in Health Services (PARIHS) framework. *Implement Sci* 2010;5:82.
- Kirchner, J.E., Edlund, C.N., Henderson, K., Daily, L., Parker, L.E., Fortney, J.C. Using a multi-level approach to implement a primary care mental health (PCMH) program. *Fam Syst Health* 2010;28(2):161-74.
- Rycroft-Malone, J., (2004). The PARIHS Framework: A framework for guiding implementation of evidence-based practice. *J Nurs Care Qual* 2004;19:297-304.
- Stetler, C.B., Legro, M.W., Rycroft-Malone, J. Bowman, C. Curran, G., Guihan, M., Hagedorn, H., Pineros, S. Wallace, C.M. Role of external facilitation in implementation of research findings: A qualitative evaluation of facilitation experiences in the Veterans Health Administration. *Implement Sci* 2006: 1,23.

Bibliography

- Publications

Kirchner JE, Ritchie MJ, Pitcock JA, Parker LE, Curran GM, Fortney JC. Outcomes of a Partnered Facilitation Strategy to Implement Primary Care – Mental Health. *J Gen Intern Med* 2014;29(4):904-12.

Kirchner JE, Kearney LK, Ritchie MJ, Dollar KM, Swensen AB, Schohn M. Lessons learned through a national partnership between clinical leaders and researchers. *Psychiatr Serv* 2014;65(5):577-9.

Ritchie, M.J., Dollar, K.M., Kearney, L.K., Kirchner, J.E. Responding to needs of clinical operations partners: Transferring implementation facilitation knowledge and skills. *Psychiatr Serv* 2014;65(2):141-3.

- Training Manual:

Kirchner JE, Ritchie MJ, Dollar KM, Gundlach P, Smith JL. Implementation Facilitation Training Manual: Using External and Internal Facilitation to Improve Care in the Veterans Health Administration. Access at:
<http://www.queri.research.va.gov/tools/implementation/Facilitation-Manual.pdf>

Implementation and Effectiveness of an
Evidence-Based Intervention in
Community-Based Organizations:
Design, Conceptual, and Measurement Considerations

Alison B. Hamilton, PhD, MPH

Background: HIV among African Americans

- African Americans have been affected by HIV more than any other racial/ethnic population
 - 47% of persons diagnosed with HIV in the US in 2012 and 43% of all persons living with diagnosed HIV in 2011 were African American (Siddiqi et al., 2015)

interventions have focused heterosexual African Americans and their disproportionate HIV risk

- Evidence-based interventions vary in implementation and sustainability
- **Eban** (Yoruba for “fence”) fills the gap in interventions for at-risk African American couples
 - Multi-site RCT (El-Bassel et al., 2010)

Eban II: Hybrid Type II Design

Using a hybrid type II design, this study investigates:

- (1) factors associated with successful implementation in 10 CBOs in two regions in California
 - (2) effectiveness of the intervention as delivered to 180 couples in the CBOs
- “Successful implementation” = number of couples served + three completed cycles of the intervention + delivery of the intervention with high fidelity + high level of satisfaction with the intervention
 - Also studying sustainability and cost effectiveness of the intervention

Why a Hybrid Type II and not Type I or Type III

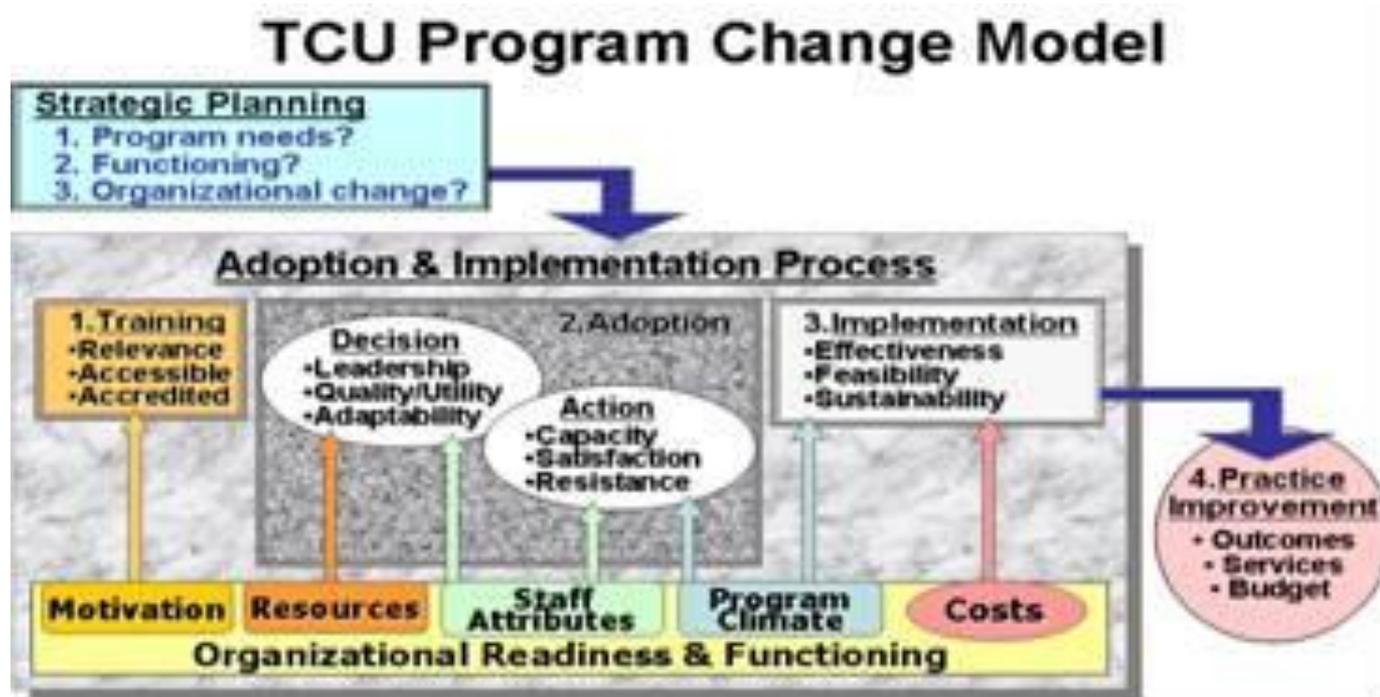
- Established efficacy of intervention, but no effectiveness data in “real world” circumstances, i.e., routine care in community settings
 - Importance of client-level outcomes under less controlled conditions
- Needed to evaluate implementation strategies and tools used to support uptake of the intervention across varied organizational contexts

Eban II: Hybrid Type II Design (cont.)

- Implementation
 - Mixed methods evaluation throughout each phase of the Program Change Model (Simpson & Flynn, 2007)
- Effectiveness
 - Waitlist design: randomly assign couples in a 2:1 design to intervention or waitlist
 - Delivery of intervention at two randomly selected CBOs per year (randomized "roll-out" implementation/dynamic wait-listed design; Brown et al., 2009)
- Sustainability
 - Nine-month assessment after completion of three 8-week intervention cycles
 - Successful sustainability=two eight-week cycles of the intervention + fidelity to intervention core elements

Conceptual Model for Implementation

- Protocol-based implementation approach
- Conceptual guidance from the Program Change Model (PCM; Simpson & Flynn, 2007)
 - Model of phased organizational change from exposure to adoption, implementation, and sustainability



Implementation Strategies & Tools by PCM phase

Training phase tools

Eban training manuals
Eban videos
Eban SharePoint

Adoption phase tools & strategies

HIV fact sheets for providers and patients
Project kick-off meetings
Site coordinators
Recognition for staff participation

Implementation phase strategies

State of CA Implementation Network
monthly inter-agency calls, newsletters
Frequent site visits
Continual feedback on implementation
Technical assistance
Pre-sustainability workshops

Practice improvement strategy

Project wrap-up retreat

Implementation Aim: Organizational Assessment Measures

- Web-based, individualized link to SurveyMonkey
- Completed by staff (target n=100) who provide direct client care
- One time only, at baseline; approx 30 min to complete
- Measures
 - Survey of Organizational Functioning (Simpson & Flynn 2007)
 - Evidence-Based Practice Attitudes Scale (Aarons 2004)
 - Maslach Burnout Inventory (Maslach & Jackson, 1981)
 - Familiarity with treatment of couples

Semi-structured interviews

- Pre- & post-implementation, and post-sustainability
- Key stakeholders (n~50) at participating CBOs

Lessons We're Learning in Eban II

- Community-level barriers
 - Competitive economic times
 - Changing HIV-related resources & policies
- Agency-level barriers
 - Staffing, turnover, funding, time limitations
 - Recruitment limitations
- Couples-level barriers
 - Limited socioeconomic resources, housing instability
 - Resistance to HIV testing
 - Substance abuse, family issues
- Scientific challenges
 - Maintaining study design and intervention fidelity/integrity (Cunningham & Card, 2014)
 - Managing “extreme adaptation” and variation

Eban II Research Team

PI: Gail E. Wyatt, Ph.D., UCLA

Co-Investigators:

Alison B. Hamilton, Ph.D., M.P.H., UCLA
& VA

David Holtgrave, Ph.D., Johns Hopkins

Honghu Liu, Ph.D., UCLA

Brian Mittman, Ph.D., VA & Kaiser

Nicholas Moss, M.D., M.P.H., Alameda
County Public Health Department

Project Coordinators:

Alicia Eccles, M.P.H. (Southern CA)

Craig Hutchinson, M.P.H. (Northern CA)

• Facilitators:

• Teri Davis, Ph.D. (Supervisor)

• Danielle Campbell, M.P.H.

• LeVell Brevard

Administrative Support:

Louise Datu

Community Partners:

AIDS Healthcare Foundation

AIDS Project Los Angeles

Spectrum/O.A.S.I.S.

CAL PEP

WORLD

HEPPAC

Allen Temple Baptist Church

T.H.E. Clinic

Consultants:

C. Hendricks Brown, Ph.D.,

Northwestern University

Nan Laird, Ph.D., Harvard University

References Cited

- Mental health provider attitudes toward adoption of evidence-based practice: the Evidence-Based Practice Attitude Scale (EBPAS). *Ment Health Serv Res*. 2004 Jun;6(2):61-74.
- Brown CH, Ten Have TR, Jo B, Dagne G, Wyman PA, Muthén B, Gibbons RD. Adaptive designs for randomized trials in public health. *Annu Rev Public Health*. 2009;30:1-25.
- Cunningham SD, Card JJ. Realities of replication: implementation of evidence-based interventions for HIV prevention in real-world settings. *Implement Sci*. 2014 Jan 6;9:5.
- El-Bassel N, Jemmott JB, Landis JR, Pequegnat W, Wingood GM, Wyatt GE, Bellamy SL; NIMH Multisite HIV/STD Prevention Trial for African American Couples Group. National Institute of Mental Health Multisite Eban HIV/STD Prevention Intervention for African American HIV Serodiscordant Couples: a cluster randomized trial. *Arch Intern Med*. 2010 Sep 27;170(17):1594-601.
- Maslach C, Jackson SE. The measurement of experienced burnout. *J Org Behav*. 1981;2(2):99-113.
- Siddiqi AE, Hu X, Hall HI. Mortality Among Blacks or African Americans with HIV Infection - United States, 2008-2012. *MMWR Morb Mortal Wkly Rep*. 2015 Feb 6;64(4):81-6.
- Simpson DD, Flynn PM. Moving innovations into treatment: A stage-based approach to program change. *J Subst Abuse Treat*. 2007 Sep;33(2):111-20.

Bibliography

Hamilton, A.B., Mittman, B., Williams, J., Liu, H., Eccles, A., Hutchinson, C., Wyatt, G. (2014). Implementation of an evidence-based HIV risk reduction intervention in community-based organizations: Protocol. *Implementation Science, 9, 79.*

Acknowledgements:

Funded by NIMH (R01 MH093230)

Special thanks to Dr. Chris Gordon

For More Information



Amy N. Cohen
amy.cohen@va.gov

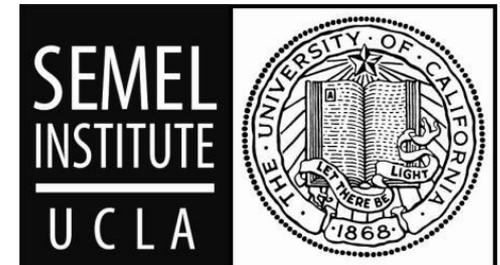
Mona Ritchie
mona.ritchie@va.gov

Alison Hamilton
alison.hamilton@va.gov



CSHIIP

Center for the Study of Healthcare
Innovation, Implementation & Policy



Poll Question

- Which implementation science topic should be addressed in a future Cyberseminar?
- Hybrid study designs
- Implementation strategies
- Conceptual models
- Evaluation methods