Pre-Implementation and Hybrid Effectiveness-Implementation Study Designs

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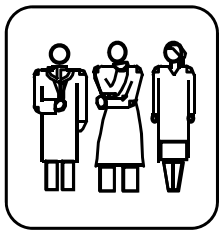
Enhancing Implementation Science in VA
May 17, 2012



VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

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Acknowledgements

Many thanks for content:

- Mark Bauer
- Amy Cohen
- Deborah Delevan
- Geoff Curran
- Hildi Hagedorn
- JoAnn Kirchner
- Brian Mittman
- Cheryl Stetler
- Alex Young

Today's Presentation

- Review characteristics of efficacy trials, effectiveness trials, and implementation research
- Describe pre-implementation (QUERI Step 3) designs and methods
  - Provide examples of Step 3 studies
- Describe hybrid designs
  - Provide examples of each type of hybrid design
  - Raise hybrid design considerations
- Questions

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Clinical Efficacy Trials

Address whether a treatment improves outcomes under controlled conditions

- Outcomes: clinical

  (e.g., symptoms, side effects, hospitalizations)

  - Process measures not considered

- Levels of analysis: patient, clinical unit

- Favor internal validity: are changes attributable to the intervention and nothing else?

Clinical Effectiveness Trials

Typically follow efficacy research trials

- Outcomes: typically clinical
  (e.g., symptoms, side effects, hospitalizations)
  - Process measures considered secondary
- Levels of analysis: patient, clinical unit
- Favor external validity: "real" clinics; larger and more diverse samples

From Curran, G., Bauer, M., Stetler, C., Mittman, B.

Implementation Research

Enhance uptake of established clinical interventions

- Outcomes: process measures

  (e.g., rates of adoption, utilization of service, context)
  - Clinical outcomes data may not be of primary interest since intervention is established

- Levels of analysis: provider, clinical unit, facility

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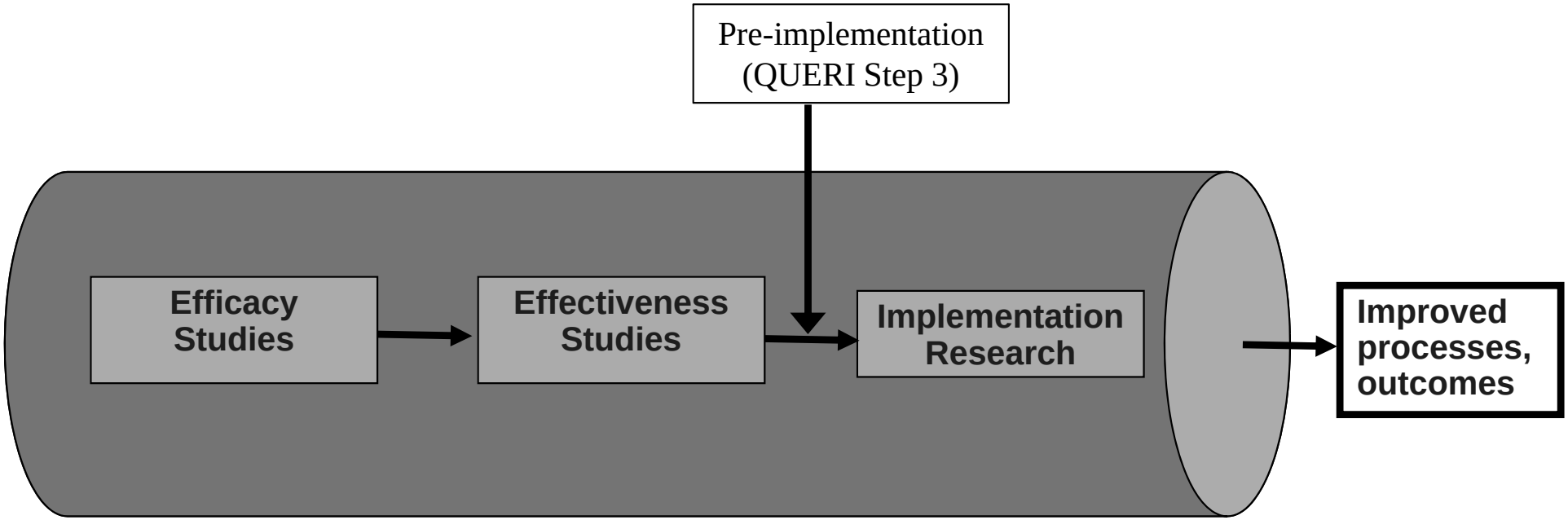
Clinical Research-Implementation Pipeline



QUERI Step 3

- Measure and diagnose quality/performance gaps
- Importance of systems-thinking
  (i.e., understanding social systems)
- "Diagnosis"
  - Results in the identification of actionable factors contributing to performance gaps and actionable reasons for failures in implementing innovations (QUERI website)

Stetler et al. 2008

QUERI Step 3

3A. Measure existing practice patterns and outcomes across VA and identify variations from evidence-based practices (“quality/ performance gaps”)

3B. Identify determinants of current practices

3C. Diagnose quality/performance gaps

3D. Identify barriers and facilitators to improvement

Pre-Implementation Studies

- Observational, cross-sectional, and longitudinal studies
- Methods to consider:
  - Measurement of practice variation via chart review, administrative database analysis
  - Modeling determinants of clinical practice
  - Semi-structured interviews, focus groups
  - Surveys
  - Policy/archival review
  - Expert panels, Delphi consensus

QUERI Step 3 Example: Diabetes Mellitus-QUERI

Purpose of Step 3 study: To understand the circumstances of preventable visual loss among patients with diabetes; focused on timing of laser eye surgery as a key issue in preventing visual loss (Krein et al., 2008)

- Physician reviewers examined and analyzed medical records using preset criteria regarding optimal timing of photocoagulation
- Identified patients whose visual loss was considered preventable by earlier treatment.
- Found that two-thirds of cases were associated with problems related to surveillance of those with identified disease, including inadequate follow-up, delays in treatment scheduling, or unexpectedly rapid disease progression.
- Results identified a lack of close follow-up of those with known disease as a potentially important gap in quality of care.

- **High priority issue (Step 1) + evidence to support a change in a performance measure (Step 2) + identified gap in quality of care (Step 3)→IMPLEMENTATION (Steps 4/5/6)**

QUERI Step 3 Example: HIV/Hepatitis QUERI

Purposes of Step 3 study: To identify possible gaps in HIV testing in VA and to understand the source of gaps in care and discern facilitators that would improve current practice (Goetz et al., 2008)

- Reviewed VA policies regarding HIV testing
- Surveyed providers' practices and attitudes regarding HIV testing at two VA facilities
- Conducted systematic review of 62 studies of HIV testing practices, attitudes, barriers, etc.
  - Note: some evidence for Step 3 can come from prior/published research
- Found organizational barriers to testing (policies)
- Found provider barriers to ordering HIV tests (survey)
- Found that higher acceptance rates were associated with confidentiality protections, and the provider's belief that testing would be beneficial (systematic review)
- **High priority condition (Step 1) + evidence-based guidelines for HIV testing (Step 2) + identified gap in quality of care (Step 3)→ IMPLEMENTATION (Step 4)**

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Hybrid Designs

Concept introduced in 2008; presented subsequently; published in 2012

From 2008:

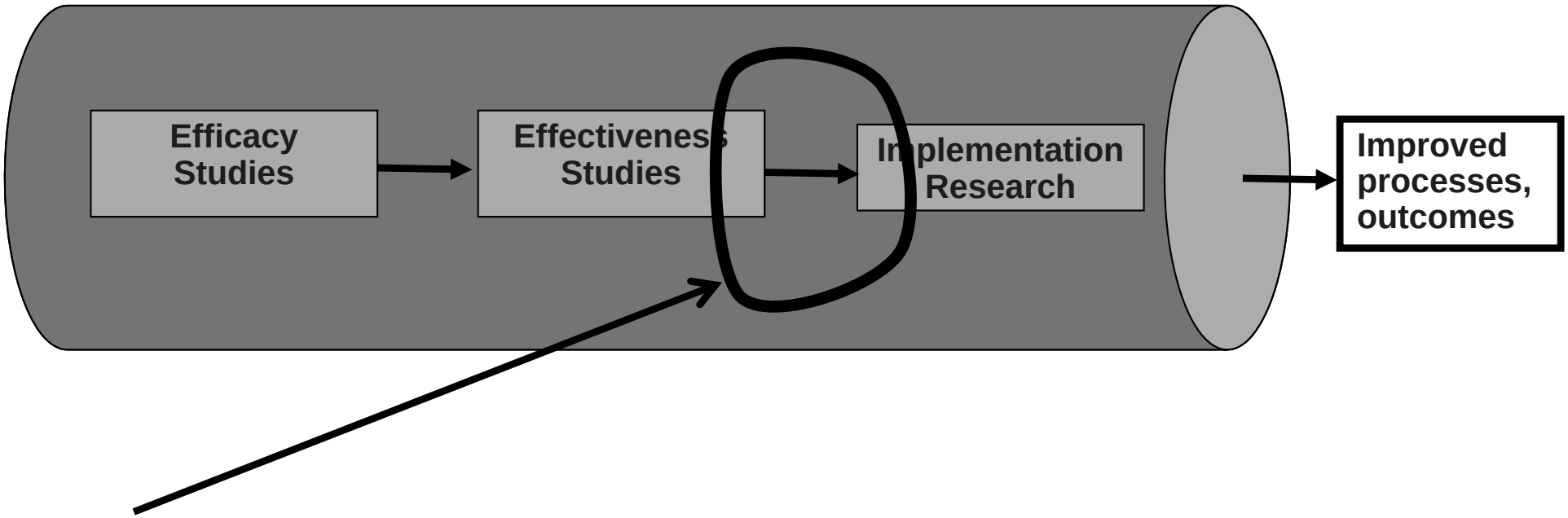
Hybrid study design should:

- Involve the most realistically rapid timeline given the complexity of the implementation program,
- Focus during the study on progress and identify both potential and actual influences on the progress and effectiveness of implementation efforts through the use of formative evaluation, and
- Plan action during the study, as needed based on formative data, to refine the change intervention, resolve mutable barriers, and enhance available facilitators, in order to optimize:

Hybrid Designs (2008 cont.)

- Preliminary use of the implementation strategy to achieve or at least assess its potential;
- The goal of clinically meaningful, not just statistically significant, evidence-based practice;
- Understanding of the black box of implementation, including cost-benefit;
- Identification of outstanding research questions; and
- Development of a replicable implementation program.

“Newer” Clinical Research-Implementation Pipeline



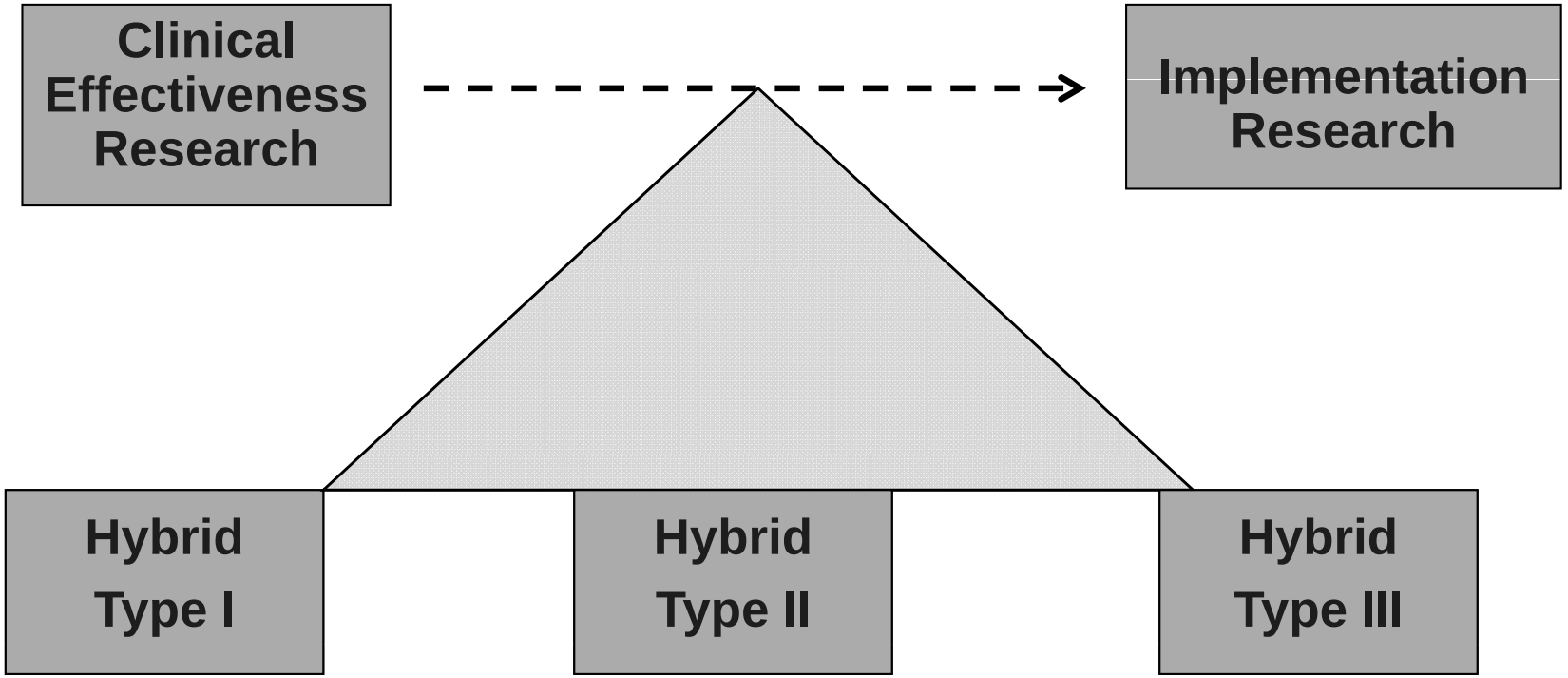
***Spatially* speaking, our Hybrids “go” in here…**

From Curran, G., Bauer, M., Stetler, C., Mittman, B.

Some Definitions

- Clinical Intervention: Clinical initiative, manipulation, change to be introduced into a healthcare venue
  - e.g., collaborative care for depression
  - May include health promotion or delivery system interventions
- Implementation Intervention: “A single method or technique to facilitate change” (QUERI Glossary)
  - e.g., automated clinical reminder, performance feedback
- Implementation Strategy: “An integrated set, bundle, or package of [implementation] interventions” (QUERI Glossary)

Types of Hybrids



Hybrid Type I: test clinical intervention, observe/gather information on implementation

Hybrid Type II: test clinical intervention, study implementation intervention

Hybrid Type III: test implementation intervention, observe/gather information on clinical intervention and outcomes

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Alternative Look at Hybrid Types

Focus		**Implementation**	
Clinical Intervention		Yes	No
	Yes	**Hybrid Type II**	**Hybrid Type I**
	No	**Hybrid Type III**	Observational Research

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And one more alternative…

Study Characteristic	**Hybrid Type 1**	**Hybrid Type II**	**Hybrid Type III**
Research Questions (examples)	Primary Question: Will a clinical treatment work in this setting/these patients? Secondary Question: What are the potential barriers/facilitators to a treatment's implementation?	Primary Questions: Will a clinical treatment work in this setting/these patients? Does the implementation method show promise?	Primary Question: Which method works better in facilitating implementation of a clinical treatment? Which core components are critical? Secondary Question: Is the treatment effective in this setting/these patients?

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Some Important Questions to be Addressed

- What clinical intervention or implementation barriers or problems emerge early on?
- In what ways are clinical intervention effects sensitive to implementation process factors?
- What changes to the implementation strategy, or the clinical intervention, could be made to improve uptake?

A Critical Hybrid Component: Evaluating the Trial Process

- Process Evaluation:
  - Identify influences on process of implementation or clinical intervention prior to, during, and/or after study
  - No data fed back during study
  - Typical of Type 1 designs
- Formative Evaluation:
  - Identify influences on process of implementation or clinical intervention prior to, during, and after study
  - Data used to optimize implementation or clinical intervention processes during study
  - Typical of Types 2 & 3 designs

Hybrid Type I Designs

- Definition:
  - Test clinical intervention, observe/gather information on implementation
- Description:
  - Clinical effectiveness trials with added *process evaluations* of implementation
- Indications:
  - Some effectiveness data available, clinical intervention likely to move toward implementation more rapidly if key implementation factors identified

Hybrid Type I Example

The Rewarding Early Abstinence and Treatment Participation Study (Hagedorn et al.)

- Clinical Intervention: Incentive intervention in SUD treatment
- Why Type I?
  - Few effectiveness trials and none with a large sample of VA patients.
  - Obtaining clinical funds for incentives was not feasible without further evidence specific to VA.
  - Main aim of this study was to demonstrate effectiveness with VA population
- Why not just an effectiveness trial?
  - Main goal of research agenda is to support broad implementation in VA
  - Inclusion of process evaluation would inform future implementation trials
- Process evaluation measures
  - Research Team Observation Log:
    - Record details of interactions with staff particularly those focusing on reactions of staff to the intervention, barriers to implementation, recommendations for improvements.
  - Data NOT used to optimize implementation

Hybrid Type II Designs

- Definition:
  - Test clinical intervention and study implementation strategy
- Description:
  - Effectiveness and implementation trial with formative evaluation throughout to:
    - Identify contextual influences on clinical intervention and implementation throughout
    - Collect and analyze data that will maximize uptake of the intervention throughout the study (tailoring)
- Indications:
  - Robust clinical intervention data available
  - Barriers and facilitators data available

Hybrid Type II Example

Enhancing QUality of care In Psychosis (EQUIP-2)
(Young, Cohen, Hamilton, et al.; VA HSR&D QUERI MNT 03-213)

- Clinical Intervention: Chronic care model
- Why Type II?
  - Evidence-based practices for patients with serious mental illness are known but
    - No multisite studies have substantially improved the quality of care for schizophrenia within the context of usual care (need effectiveness study)
  - Known barriers and facilitators to uptake (EQUIP-1)
  - Need to study our implementation approach to increase uptake of EBPs
    - Our approach: evidence-based quality improvement

Hybrid Type II Example (cont.)

Design

- Clustered, clinic-level controlled trial
- Enrollment
  - 4 VISNs, 8 clinics
  - 201 staff (clinicians + administrators)
  - 801 patients
- Formative evaluation measures
  - Organizational readiness and staff burnout survey pre/post
  - Semi-structured interviews pre-, mid-, and post-implementation
  - Fieldnotes, logs, minutes

  - Evaluation data WAS used to optimize implementation

Hybrid Type III Designs

- Definition:
  - Test implementation strategy, observe/gather information on clinical intervention and outcomes
- Description:
  - Implementation trial with formative evaluation throughout, plus evaluation of health outcomes
- Indications:
  - Robust clinical intervention data available but effects suspected to be “vulnerable” during implementation trial (i.e., most of the time)
  - High level need for clinical action despite limited evidence base

Hybrid Type III Example

Blended Facilitation to Enhance PCMH Program Implementation (Kirchner, Curran, et al.)

- Controlled trial of an implementation strategy (internal and external facilitation) to support adoption of three models of integrated primary care and mental health
  - 16 matched sites with comparison sites receiving "standard" dissemination plan supported by national clinical program office
  - Multiple uptake and fidelity measures across providers and sites
- Patient-level analysis of depression outcomes
  - Depression symptoms
  - Hospitalization

Hybrid Design Considerations

- Which hybrid type?
- Which implementation framework?
- Randomization or quasi-experimental or both?
- What is the sampling frame?
- What are the unit(s) of analysis?
- What are the domains of interest / measures to gather?
- Study tasks (& duration):
  - Pre-implementation
  - During implementation
  - Post-implementation

More Considerations

- Challenge: concurrent data collection and analyses
- Not parallel data (effectiveness and implementation); need to address both simultaneously; mutually informative
- Team expertise/size needed to accomplish this type of interpretation
- Manuscripts throughout
- Where to publish?

Questions?

For further information:

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