

# Hybrid Effectiveness-Implementation Study Designs for Enhanced Research Impact

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Provider Behavior



# Acknowledgements

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# Outline

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- Review efficacy trials, effectiveness trials, and implementation research
- Describe hybrid designs
- Provide examples of each type of design
  - Type I: The Rewarding Early Abstinence and Treatment Participation Study
  - Type II: Enhancing Quality in Psychosis (EQUIP) study
  - Type III: Blended Facilitation to Enhance PCMH Program Implementation
- Raise questions to consider in hybrid designs

# Clinical Efficacy Trials

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- 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

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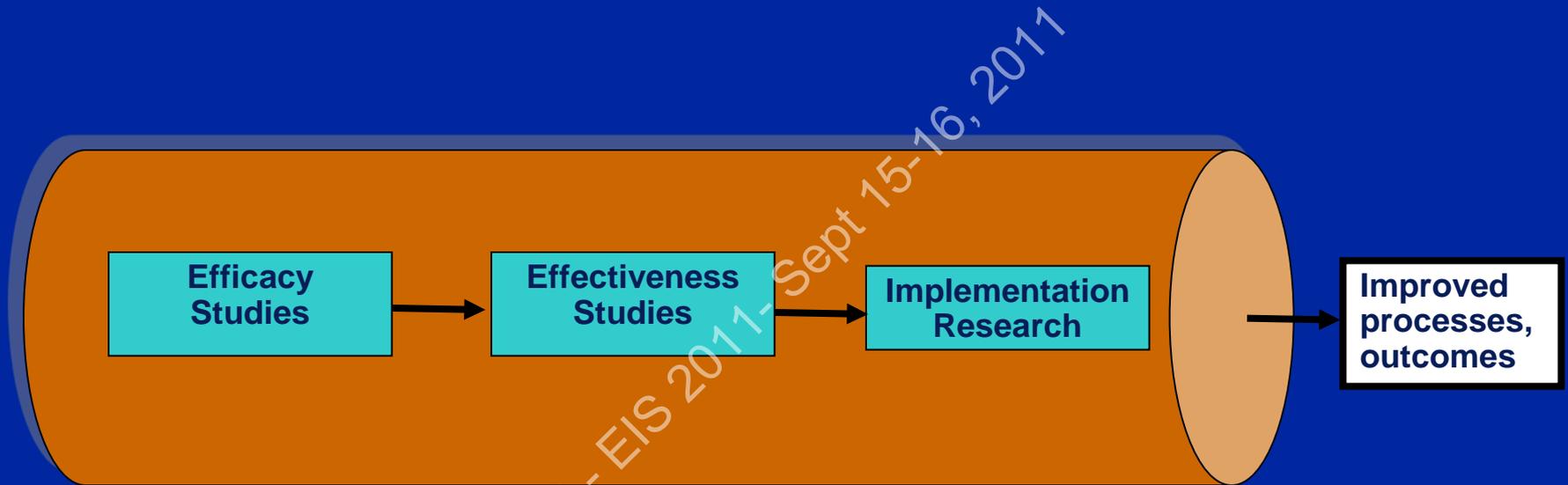
- Follow efficacy research trials
- Outcomes: typically clinical  
(e.g., symptoms, side effects, hospitalizations)
  - Process measures considered secondary
- Levels of analysis: patient, clinical unit
- Favor external validity: “real” clinics; larger and more diverse samples

# Implementation Research

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- Focus: enhancing 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

# Clinical Research-Implementation Pipeline



# Shortcomings of a “Two-Track” or “Sequential” Model

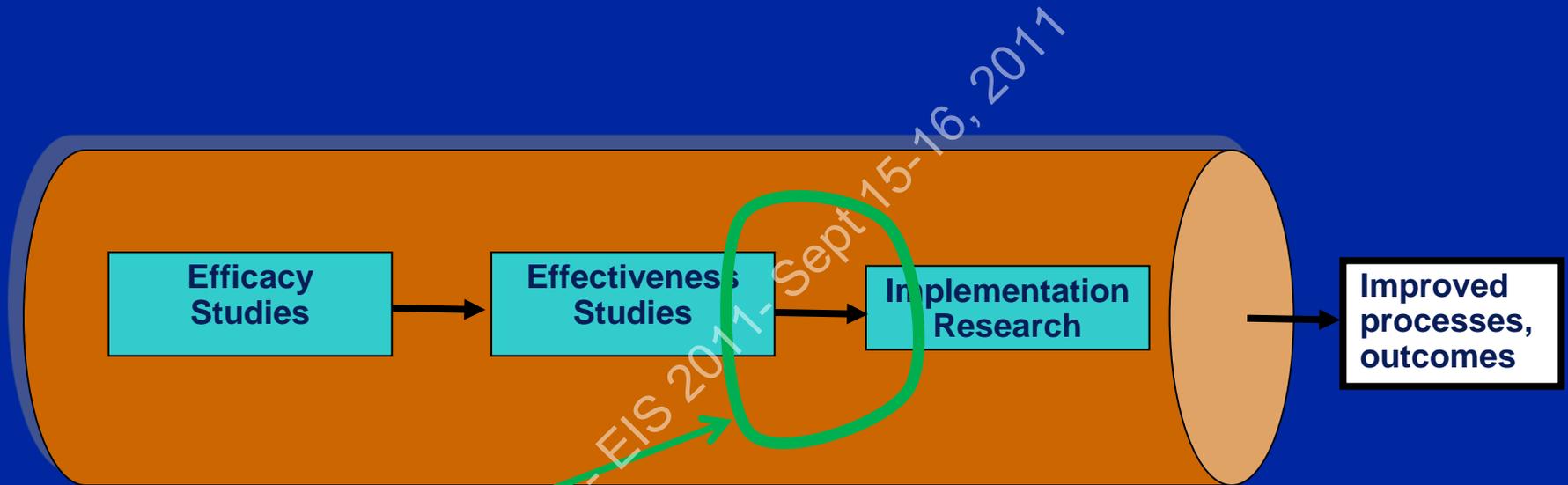
- Traditional clinical effectiveness research tends to declare victory early
  - The clinical intervention is considered finished when effects are shown in one or more “real world” settings
- Traditional implementation research tends to buy into the fantasy
  - The fantasy: intervention is ready for wide dissemination
- Endless RCTs of innumerable tweaks for countless specific application...each followed by an implementation study
- The cost: Long loops; long time to public health impact

# Hybrid Designs

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- Hybrid definition: Something of mixed origin or composition
  - In this case: Clinical Effectiveness Trial + Implementation Trial
- Rationale:
  - To optimize uptake of evidence-based care
  - To speed throughput from clinical evidence to public health impact

# “Newer” Clinical Research-Implementation Pipeline



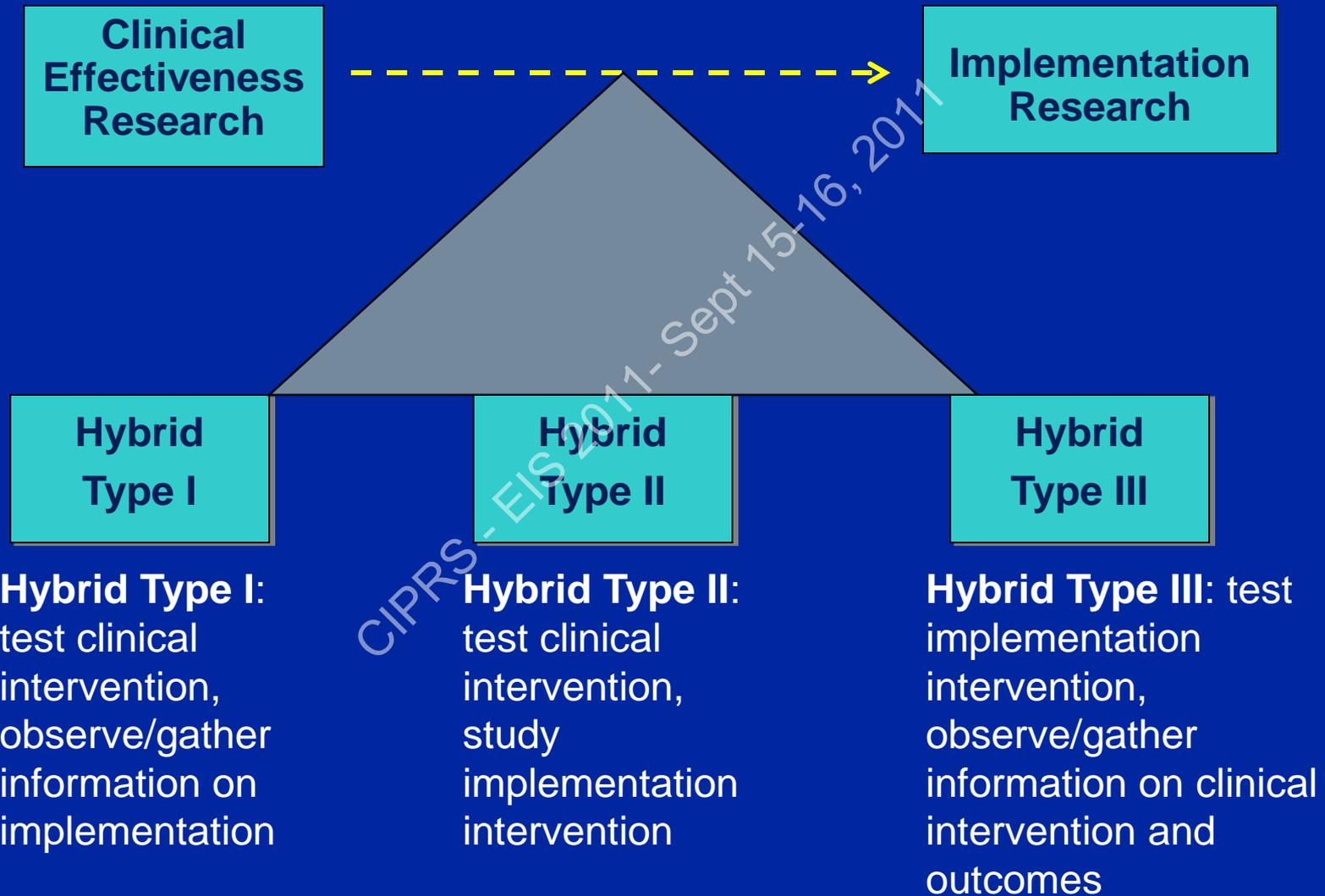
**Spatially speaking, our Hybrids “go” in here...**

# Some Definitions

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- **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



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# Alternative Look at Hybrid Types

| Focus                 |     | Implementation         |                        |
|-----------------------|-----|------------------------|------------------------|
|                       |     | Yes                    | No                     |
| Clinical Intervention | Yes | <b>Hybrid Type II</b>  | <b>Hybrid Type I</b>   |
|                       | No  | <b>Hybrid Type III</b> | Observational Research |

# And one more alternative...

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

# Some Important Questions to be Addressed

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

# A Critical Hybrid Component: Evaluating the Trial Process

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- **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

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- **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 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 the clinical intervention

# Hybrid Type II Designs

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- Indications:
  - Robust clinical intervention data available
  - Barriers and facilitators data available
- Data: Two “sets” of data: clinical (patient- or clinic-level) and implementation (patient-, provider-, clinic-, site-level)
- Evaluation:
  - Identify contextual influences on clinical intervention and implementation throughout
  - Data used to maximize uptake of the intervention throughout the study (tailoring)

# Hybrid Type II Example

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Enhancing Quality of care In Psychosis  
(EQUIP2)

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# The Quality Problem

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- Schizophrenia is the most common serious mental illness
- Evidence-based practices exist; in routine practice, patients do not receive these services
- Outcomes generally poor in usual care

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

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

# Design

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- Implement and evaluate chronic care model (intervention) using Evidence-Based Quality Improvement (EBQI) tools and strategies (implementation)
  - Clustered, clinic-level controlled trial
- Enrollment
  - 4 VISNs, 8 clinics
  - 201 staff (clinicians + administrators)
  - 801 patients

# Specific Aims

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## EFFECTIVENESS

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

## IMPLEMENTATION

- 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

# Evidence-Based Quality Improvement (EBQI): Implementation Tools & Strategies

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# Data for Formative Evaluation

*Pre-Implementation*

*Implementation*

*Post-Implementation*

## Developmental

- field notes
- documents (minutes, etc.)
- ORC & Burnout Inventory
- key stakeholder interviews

## Implementation-Focused

- Site Director field notes
- Quality Coordinator logs
- documents (education)
- key stakeholder interviews

## Progress-Focused

- QI data (QI teams, Quality Reports from kiosks)

## Interpretive

- field notes
- key stakeholder interviews
- ORC & Burnout Inventory

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# Hybrid Type III Designs

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- **Definition:**
  - Test implementation strategy, observe/gather information on clinical intervention and outcomes
- **Description:**
  - Implementation trial with added 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

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## 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

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- 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 intervention implementation
  - Post-implementation

# More Considerations

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- 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?

# Some Ecological Challenges in Hybrid Research

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- Lack of shared concepts, constructs, vocabulary within the field
- Lack of familiarity, appreciation, impetus for *implementation science* issues outside of the field
  - Grant reviewer expertise across the spectrum
  - Editorial interest/expertise among top journals
  - Academic promotion path complex
- Lack of familiarity, appreciation, impetus of *clinical intervention trials complexities* within the implementation field

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