Combining Clinical Effectiveness Trials and Implementation Research: A hybrid trial design

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Outline

- Quick review of efficacy trials, effectiveness trials, and implementation research

- Describe hybrid designs

- Type II hybrid design example
  - VA EQUIP2 study
Clinical Efficacy Trials

- Address whether a treatment improves outcomes under controlled conditions

- **Outcomes: clinical**
  - (e.g., symptoms, side effects, hospitalizations)
    - Process measures not considered

- **Level of analyses: patient, clinical unit**

- Favors **internal validity**: are changes attributed to the intervention and nothing else
Clinical Effectiveness Trials

- Follow efficacy research trials

- **Outcomes**: typically clinical
  - (e.g., symptoms, side effects, hospitalizations)
  - Process measures considered secondary

- **Level of analyses**: patient, clinical unit

- Favors **external validity**: “real” clinics; larger and more diverse samples

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

- **Focus**: enhancing uptake of established clinical interventions

- **Outcomes**: process measures
  - (e.g., rates of adoption, utilization of service, context)
    - Clinical outcomes data considered not needed since intervention is established

- **Level of analyses**: provider, clinical unit, or facility

From Curran, G., Bauer, M., Stetler, C., Mittman, B.
Clinical Research-Implementation Pipeline

- Efficacy Studies
- Effectiveness Studies
- Implementation Research

Improved processes, outcomes
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

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

- 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

From Curran, G., Bauer, M., Stetler, C., Mittman, B.
“Newer” Clinical Research-Implementation Pipeline

From Curran, G., Bauer, M., Stetler, C., Mittman, B.
Types of Hybrids

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

**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
## Alternative Look at Hybrid Types

<table>
<thead>
<tr>
<th>Focus</th>
<th>Implementation</th>
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<tbody>
<tr>
<td>Clinical Intervention</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>Hybrid Type II</td>
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<tr>
<td>Hybrid Type I</td>
<td></td>
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<tr>
<td>No</td>
<td>Hybrid Type III</td>
</tr>
<tr>
<td>Observational Research</td>
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From Curran, G., Bauer, M., Stetler, C., Mittman, B.
And one more alternative...

<table>
<thead>
<tr>
<th>Study Characteristic</th>
<th>Hybrid Type 1</th>
<th>Hybrid Type II</th>
<th>Hybrid Type III</th>
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<tbody>
<tr>
<td>Research Questions (examples)</td>
<td><strong>Primary Question:</strong> Will a clinical treatment work in this setting/these patients? <strong>Secondary Question:</strong> What are the potential barriers/facilitators to a treatment’s implementation?</td>
<td><strong>Primary Questions:</strong> Will a clinical treatment work in this setting/these patients? Does the implementation method show promise?</td>
<td><strong>Primary Question:</strong> Which method works better in facilitating implementation of a clinical treatment? Which core components are critical? <strong>Secondary Question:</strong> Is the treatment effective in this setting/these patients?</td>
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</tbody>
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From Curran, G., Bauer, M., Stetler, C., Mittman, B.
Enhancing QUality of care In Psychosis (EQUIP2):

A hybrid type II trial

VA HSR&D QUERI (MNT 03-213)
# EQUIP Team

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- Jennifer Pope, BS
- Patricia Parkerton, PhD
- Youlim Choi

- Amy N. Cohen, PhD (co-PI)
- Alison Hamilton, PhD, MPH
- Stone Shih
- Paul Jung
The Quality Problem

- 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
Hybrid Type II: more details

- **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)
Why a Hybrid Type II and not Type I or Type III

- We knew EBPs existed; We 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

- 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

INTERVENTION
- 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

- Leadership support
- Clinical champion
- Quality manager
- QI Informatics support
- Provider/patient education
- Performance feedback
Stages of Formative Evaluation

Pre-Implementation

Developmental
“Diagnostic” of the existing context (baseline assessment)
- organizational readiness for change
- expectations of project
- existing services and structure of care

Implementation-Focused
“Actuality” of implementation
- barriers to change
- adjustments to interventions

Progress-Focused
“Monitoring impacts & indicators of progress toward goals”
- dose & intensity of intervention

Implementation

Post-Implementation

Interpretive
“Uses results of all other FE stages”
- key stakeholder experiences
- could “re-diagnose” the context

From Stetler et al., JGIM, 2006
Data for Formative Evaluation

Pre-Implementation

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

Implementation

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

Progress-Focused
• QI data (QI teams, Quality Reports from kiosks)

Post-Implementation

Interpretive
• field notes
• key stakeholder interviews
• ORC & Burnout Inventory
How do you work with the data?

- 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
- Papers throughout
- Where to publish?
Tuesday, June 14th
8-9:30am (room 617)

**Effectiveness of Interventions in Behavioral Health Care:**
Alexander Young: Implementation of Evidence-Based Weight Practices in Specialty Mental Health (EQUIP2)
• Acknowledgements
  • VA HSR&D and QUERI (MNT 03-213)
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  • VA HSRD Center of Excellence, Study of Healthcare Provider Behavior
  • NIMH UCLA-RAND Center for Research on Quality in Managed Care

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References