Methods for Evaluating Effectiveness of Implementation Strategies Using a Randomized Implementation Trial

C Hendricks Brown
Director, Prevention Science and Methodology Group
Director, Social Systems Informatics
University of Miami Miller School of Medicine
chbrown@med.miami.edu

Penn State Prevention Research Center and Methodology Center
Acknowledgements

Co-Authors

Patti Chamberlain, OSLC
John Landsverk, Rady Children’s Hospital
Lisa Saldano, Center for Research to Practice
Larry Palinkas, USC
Mitsu Ogihara, U Miami

Prevention Science and Methodology Group
Acknowledgements

• NIMH R01 MH076158 Chamberlain PI, Community Development Teams to Scale-Up MTFC in California
• NIMH P30MH074678-03 Landsverk, PI, Advanced Center to Improve Pediatric Mental Health Care
• NIDA R01 DA019984 Poduska, PI, A Follow-up of Classroom Services to Prevent Drug Use
• NIDA R21DA024370 Poduska, PI, Scaling-up Prevention Services for Early Drug Abuse Risk in School Systems
• NIMH/NIDA R01-MH040859, Brown PI, Methods for MH/DA Prevention and Early Intervention, Prevention Science and Methodology Group (PSMG)
Outline of Concepts and Methods

1. Methods Problems and New Directions for (Prevention) Implementation Science
   - Measurement to Monitor Implementation Stage
   - Models to Represent and Analyze Implementation
   - Testing to Evaluate Implementation Strategies

2. Roll-Out Implementation Trials: CAL-40 Experience
   - Testing: Randomized Implementation Trial
   - Measure: Stages of Implementation Completion (SIC)
   - Model: Directed Action (DATI)

3. Conclusions
Implementation Research

Involves the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings – Chambers 2008

Implementation Science

Producing general, replicable knowledge regarding the success (or failure) of implementation strategies
1. Methods Problems and New Directions for (Prevention) **EXPERIMENTAL** Implementation Science

- **Individual Interventions in Medicine**
  - 1940’s: Clinical Trial
  - . . .: Adaptive Intervention
  - 1970s: Place-Based
  - . . .: Longitudinal Trial

- **Group Level Interventions in Prevention**
  - 1970s: Place-Based
  - . . .: Longitudinal Trial

- **System Level Interventions for Implementation**
  - 2000s: Interactions within and across systems

Penn State Prevention Research Center and Methodology Center
If Randomized Trials Are to Play an Important Part in Implementation

- **Correspondences** with Existing Trials
  - Research Questions → Testable Hypotheses
    - Efficacy, Effectiveness, Implementation?
  - Trial Conduct and Protocols
  - Population → Sample Selection
  - Random Assignment
  - Evaluation

- **Extensions of Existing Trials**
- **Real Differences with Existing Trials**
Changing Research Questions
Effectiveness vs Implementation

System to Support Adoption

Intervention

System to Support Adoption

Intervention
Intervention Research Phases, Including Implementation

Domain of Implementation Science

- Sustainability
- Fidelity
- Adoption
- Effectiveness
- Efficacy

Domain of Implementation Science

O’Connell, Boat & Warner, 2009  NAS
Phases of Implementation Research and Related Hypotheses

• **Adoption** – increase quantity and speed of adopting interventions in communities
  Does Strategy A increase adoption of B?

• **Implementation Fidelity** – improve the quality of program delivery
  Does Strategy A increase fidelity, fit or successful adaptation over B?

• **Sustainability** – maintain quality and expand the quantity of program delivery
  Does Strategy A improve quality of delivery of “Intervention Agents” over time compared to B?
Implementation Method: Testing

• There is a role for randomized implementation trials, especially at this early stage of the science
Why Trials? There are very few Broad Street Pump Handles Left to Remove

John Snow’s Map of London

1849 proposed

1854 500 deaths to ~ 0

Removal of Pump Led to Immediate Reduction in Cholera Deaths
Dealing with “Sample Size”

• 40 Randomized Counties still need a large effect
• “Roll-Out Trials” – eventually all communities get the active intervention
• “Cumulative Trials” -- Implementation strategy evolves over time; combined analyses reflecting these changes

Brown et al., 2008 ARPH, Brown et al., 2006 Clinical Trials
Randomized Trials Are Well Represented in Implementation

**Prevention:**
- PROSPER, Communities that Care

**Child welfare/mental health implementation**
- 9 of 338 studies had a comparison group
  - 8 of 9 used a randomized trial

**Quality Improvement in Health Care**
- Cochrane Collaboration Effective Practice and Organization of Care Review Group (EPOC) Reviews –
  - 57% exclusively Randomized Trials

Landsverk, Brown, Chamberlain et al. (accepted for publication)
Landsverk, Brown, Rolls Reutz et al (2011)
2. Methods Illustrations from the CAL-40 Implementation Trial

Test Implementation of Multidimensional Treatment Foster Care in 40 Counties in California

Objective: Test the effectiveness of the Community Development Team (CDT), a theory driven model to promote the adoption, implementation, and sustainability for delivering the evidence-based Multidimensional Treatment Foster Care (MTFC) intervention in California counties that are not already using MTFC.

Method: Randomize counties into 6 equivalent clusters, 3 of which receive CDT, other 3 receive standard implementation.

Measures: Time it takes to adopt, recruit staff, train, and place youth in MTFC homes, receive certification
Outcome(s) of the CAL-40 Randomized Implementation Trial

How fast do counties in the two conditions adopt, implement with fidelity, and sustain the intervention? **Survival Analysis**

Primary Outcome: Time county takes to achieve certification of sustainability.

Secondary Outcome: Timing in Attaining Stages of Implementation Completion (SIC)
Changing Research Questions
Effectiveness vs Implementation

System to Support Adoption
Intervention

System to Support Adoption
Intervention
Two-Arm Trials
Effectiveness vs Implementation

Existing Implementation Supports for County, Agency, Group Home

MTFC Intervention

Control Condition

MTFC Intervention

CDT Implementation Supports for County

Standard Implementation Supports for County

Youth

Youth

Youth

Youth

Youth

Penn State Prevention Research Center and Methodology Center
Randomly Assign 40 Counties

Inclusion/Exclusion Criteria
All Counties Included Except
Early Adopters
Counties with too few Placements
One where Court Case Occurring (LA)

Counties balanced on Fixed Factors (SES, Size, EPSDT), then Randomized to TIME 3 Cohorts and CONDITION of Implementation Strategy (Community Development Team, CDT, and Independent)

Account for County level Clustering in CDT condition
Initial CAL-40 Design

COHORT 1

40 CA Counties

26 Wait Listed

CDT

Stnd

Wait Listed

COHORT 2

13 Wait Listed

COHORT 3
Intervention Assignment

• Randomly Assigned to Condition and Timing (Cohort)
• Roll-Out Trial, Dynamic Wait-Listed Design
  Brown et al., 2006 Clinical Trials

REMARK
NEARLY IMPOSSIBLE TO HAVE A TRUE CONTROL
Issues in the CA-MTFC Design

1. Acceptance of the Design was Complete
2. Some Counties Were Not Ready to take Part
   Moved Up Counties from Next Cohort, but remained in same implementation condition
Consort Diagram

Assessed for eligibility, n=58.

Excluded n=18.
- Already had implemented MTFC, n=9
- Fewer than 6 youth per year, n=8
- Los Angeles County, n=1

Formed 6 equivalent clusters by matching background, n=40.

Randomized the clusters to 3 cohorts and 2 conditions, n=40.

Cohort 1, n=12.
- CDT, n=6
  - Accepted, n=4
  - Declined, n=2
  - Filled by cohort 2 counties, n=0
  - Received, n=4
- IND, n=6
  - Accepted, n=4
  - Declined, n=2
  - Filled by cohort 2 counties, n=0
  - Received, n=4
- 2 counties moved up

Cohort 2, n=14.
- CDT, n=7
  - Accepted, n=7
  - Moved to cohort 1, n=2
  - Expected to be filled by cohort 3 counties, n=2
  - Expected to receive, n=7
  - Invited to ‘go early’, n=3 (no counties accepted invitation)
- IND, n=7
  - Accepted, n=7
  - Moved to cohort 1, n=0
  - Expected to receive, n=7
  - Invited to ‘go early’, n=3 (2 counties accepted invitation)
  - Expect to be filled by declined cohort 1 counties, n=2
  - Expect to receive, n=7

Cohort 3, n=14.
- CDT, n=7
  - Accepted, n=4
  - Declined, n=1
  - Pending, n=2
  - Expect to be filled by declined cohort 1 counties, n=2
- IND, n=7
  - Accepted, n=6
  - Declined, n=0
  - Pending, n=1
  - Expect to be filled by declined cohort 1 counties, n=2
  - Expect to receive, n=9

Penn State Prevention Research Center and Methodology Center
EBP Advice Network by Implementation Stage & Agency

Implementation Stage:
Blue = Implementing (1)
Red = Considering (2)
Green = Declined to participate (3)
Gray = Not Applicable (8)
White = missing data (0)

Agency:
Square = Child Welfare (1)
Up triangle = Mental Health (2)
Diamond = Probation (3)
Plus = Not Applicable (4)
Circle = missing data (0)

Combination of Network Survey and Interview: (Source: Palinkas 2011)
Exogenous Factors

Running Randomized Trials During a Recession

Solution: Expand trial by adding 13 counties in a second state (Ohio), using equivalent inclusion/exclusion criteria and random assignment
## Types of Protocol Deviations

<table>
<thead>
<tr>
<th>Deviations</th>
<th>Example</th>
<th>Response</th>
<th>Consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Need to Impose Protocol Rules</td>
<td>Counties talk to other counties assigned to different strategies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocols were Followed</td>
<td>When County Was not Ready to Start in their Assigned Cohort</td>
<td>Randomly and Blindly Selected County in SAME Condition in Next Cohort</td>
<td>So Far Little Imbalance, little indication of differential replacement bias</td>
</tr>
<tr>
<td></td>
<td>Interactions of Counties in Different Conditions</td>
<td>Allowed and measured</td>
<td>Potential reduction in statistical power</td>
</tr>
<tr>
<td>Protocols were Not Followed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Protocols Available</td>
<td>Stagnancy of County Governments’ Budgets</td>
<td>Extend trial to another state with same inclusion/exclusion criteria</td>
<td>Statistical Power</td>
</tr>
</tbody>
</table>

Penn State Prevention Research Center and Methodology Center
Measurement: SIC

Ability to Measure Implementation Milestones

**SIC** Stages of Implementation Completion

- **Whether** they are achieved
- **How long** it takes to achieve
- With what **quality** are they achieved
- In what **quantity** are they achieved
## Measurement: Stages of Implementation Completion (SIC)

<table>
<thead>
<tr>
<th>Stage by Agent (s)</th>
<th>Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8 Stages</strong></td>
<td></td>
</tr>
<tr>
<td>1. Engagement</td>
<td>System Leader</td>
</tr>
<tr>
<td>1. Considering feasibility</td>
<td>System Leader, Agency</td>
</tr>
<tr>
<td>1. Planning/readiness</td>
<td>System Leader, Agency</td>
</tr>
<tr>
<td>1. Staff hired and trained</td>
<td>Agency, Practitioners</td>
</tr>
<tr>
<td>1. Fidelity monitoring process in place</td>
<td>Practitioners, Child/Family</td>
</tr>
<tr>
<td>1. Services and consultation begin</td>
<td>Practitioners, Child/Family</td>
</tr>
<tr>
<td>1. Fidelity, competence, &amp; adherence</td>
<td>Practitioners, Child/Family</td>
</tr>
<tr>
<td>1. Sustainability (certification)</td>
<td>System, Agency, Practitioner</td>
</tr>
</tbody>
</table>

Chamberlain et al., 2010
Contemplation/Pre-Adoption (Wang, Saldana et al., Implementation Science, 2010)

Factors affecting time decision to consider

Figure 1 Survival curves for days-to-consent for rural and non-rural counties. The two curves depicted Kaplan-Meier estimator for days-to-consent outcome of rural (population ≤ 200,000) and non-rural counties (population > 200,000) from day 0 to day 733, where rural counties is shown in dotted and non-rural counties in solid lines.
## Sub-Stages

<table>
<thead>
<tr>
<th>Stage 3: Readiness Planning</th>
<th>Date of cost/funding plan review (start)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date of staff sequence, timeline, hire plan review</td>
</tr>
<tr>
<td></td>
<td>Date of Foster Parent recruitment review</td>
</tr>
<tr>
<td></td>
<td>Date of referral criteria review</td>
</tr>
<tr>
<td></td>
<td>Date of communication plan review</td>
</tr>
<tr>
<td></td>
<td>Date of second in-person meeting held</td>
</tr>
<tr>
<td></td>
<td>Date written implementation plan complete (completion)</td>
</tr>
</tbody>
</table>
Three Interrelated Characteristics in Monitoring Implementation
First Sign in a Window

Cheap
Fast
Accurate
Next Sign

Cheap
Fast
Accurate

Pick any Two
Cost, Speed, Accuracy are Interrelated
Thermodynamics Ideal Gas Law (Clausius Clapeyron)

P – Pressure
V – Volume
T – Temperature

\[ PV = r \, T \]

\[ T = \frac{PV}{r} \]
Three Interrelated Characteristics in Monitoring Implementation

**Speed** — time to milestone attainment

**Quality** — how well is a program implemented

**Quantity** — how much is implemented
Functional Relationship like $PV = rT$

- $T$ – Time
- $F$ -- Fidelity or Quality
- $Q$ -- Quantity

\[ T = \text{fctn}(F, Q) + \text{error} \]
Differential Goals of Implementation Strategies

Three Alternative Strategies for Implementation

- High Speed, High Quality, Low Quantity (CAL-40 MTFC Implementation)
- High Speed, Low Quality, High Quantity (DEBI Program w/o Fidelity Supports)
- Low Speed, High Quality, High Quantity (GBG with Intensive Coaching)

True Goal

CAL-40

Good Behavior Game Implementation

CDC-DEBI

Penn State Prevention Research Center and Methodology Center
Modeling: Directed Action

- Represent the Implementation Strategy through intentional steps
- Logic Model $\rightarrow$ Agent-Based Modeling
Directed Action

DATI Diagram

Director (D) → Action (A) → Target (T) → Intent (I)
Computational/Simulation Modeling

Ability to Describe What the Implementation Strategy is

**DATI** Director, Action, Target, Intention
Multilevel, Systemic Logic Model for Implementation

- CDT
- County Plan for Implementation
- MTFC Support Training Institute
- Standard
- Clinical Support Staff: Select and Train Foster Parents
- Foster Parent: Parenting Practices
- Youth: Less Runaways

Penn State Prevention Research Center and Methodology Center
2. Measurement of the Implementation Process


Who does what to whom for what intended purpose?

DATI: Director, Action, Target, Intention
MTFC Intervention

Director: Clinical Support Team (Intervention Agent)
Action: Deliver MTFC Support Protocol
Target: Foster Parent
Intention: Improve Parental Monitoring

Parent Actions
   Director Foster Parent
   Action: Improve Parental Monitoring
Target: Youth
Intention: Decrease Runaways
Agency Services

Director: Agency
Action: Provide MTFC Services
Target: Clinical Support Team

Intention: Deliver MTFC Support Protocol

MTFC Intervention

Director: Clinical Support Team
Action: Deliver MTFC Support Protocol
Target: Foster Parent

Intention: Improve Parental Monitoring
**MTFC Support Training**

Director: MTFC Training Organization

Action: Train Staff in Implementing MTFC Support

Target: **Clinical Support Team**

Intention: Deliver MTFC Support Protocol

---

**Agency Services**

Director: **Clinical Support Team**

Action: Deliver CDT Implementation

Target: Foster Parent

Intention: Improve Parental Monitoring
CDT Program

Director: California Institute of Mental Health Broker
Action: Community Development Team
Target: County Social Services

Intention: Arrange Training of Agency

County Implementation Plan
Director: County Social Services
Action: Arrange Training of Agency
Target: Agency

Intention: Train Staff to provide MTFC Support
Conclusions

• Randomized Implementation Trials (RITs) are likely to be used, especially in this first phase of research.

• Randomization to **time** of implementation, and also type of implementation strategy, since communities are not likely to tolerate non-active control.

• Major Outcomes of RITS are Time, Quality, Quantity; potentially generic measures like SIC could be used.

• There is substantially less control in RITs, so modifications in the design may need to happen.

• Modeling of implementation strategies will need objects like DATIs to represent and simulate implementation effects.
Related Papers

Aarons GA, Hurlburt M, Horwitz SM. Advancing a Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors. *Administration and Policy in Mental Health and Mental Health Services Research*. In press.


Chamberlain, P, Marsenich L, Sosna, T, et al. (accepted for publication). Three collaborative models for scaling up evidence-based programs.

References


Landsverk, Brown, Chamberlain, Palinkas, Horwitz (in preparation). Design and Analysis in Dissemination and Implementation Research


O’Connell, Boat & Warner, 2009 Preventing mental, emotional, and behavioral disorders among young people: progress and possibilities NAS


program: A baseline survey within a randomized controlled trial. Implementation Science.

Valente (2010), Social Networks and Health: Models, Methods and Applications

Wang, Saldana, Brown, Chamberlain (2010). Factors that influenced county system leaders to implement an evidence-based program: a baseline survey within a randomized controlled trial. Implementation Science.