Randomized Implementation Trial Designs That Respond to Community and Research Needs

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Introduction

Three (Four) Case Studies of Randomized Trials testing Implementation

There are many challenges

- Nature of the Partnerships
- Measures to Collect
- Design + Protocol
- Analysis

Prevention Science & Methodology Group

USF – C. Hendricks Brown, Principal Investigator
Getachew Dagne, Co-Principal Investigator,
Brinales, Wang, Greenbaum, Toyinbo, Guo, Singer, Yampolskaya, Kim
UCLA– Bengt Muthén, Co-Principal Investigator, Nylund, Clark
American Institutes for Research– Kellam, Poduska, Windham
Hopkins– Ialongo, Stuart
U Maryland, Petras
Center for Research to Practice– Reid, Chamberlain, Smith
Stanford -- Jo
George Washington– Howe, Molock
Arizona State U – MacKinnon, Tein
UC San Diego – Landsverk, Aarons, Hurlburt
UC Davis – Masyn
U Colorado -- Henry
U Miami – Szapocznik, Pantin, Prado, Henderson, Schwartz, Feaster, Lopez
U Rochester – Wyman, Cross,
Washington U -- Peña
U Washington – Brown
U Western Ontario – Klein
Harvard–Indurkhya
U South Carolina – Van Horn, Malone
U Texas, San Antonio -- Wang

PSMG
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Presentations

A. Implementation Design Strategies and Challenges for an Evidence-Based Program: Multidimensional Treatment Foster Care Implementation in California

Authors: C, Hendricks Brown, University of South Florida (presenter)
Patti Chamberlain Center for Research to Practice,
Wei Wang, University of South Florida
Hyungtae Kim, University of South Florida

B. Community Partnerships to Support Prevention Research from Effectiveness to Implementation

Jeanne Poduska, American Institutes for Research: Presenter
Hendricks Brown, University of South Florida
Wei Wang, University of South Florida
Sheppard Kellam, American Institutes for Research

C. **Cumulative Randomized Trial of a Youth Suicide Prevention Program**
Authors:
Peter A. Wyman, University of Rochester (presenter)
C. Hendricks Brown, University of South Florida
Mark LoMurray, Sources of Strength Program, Bismarck, North Dakota

Built-In Biases in Community Interventions Without a Trial

Choose one community where intervention is implemented

Afterwards find a community that is closely matched and see if same changes occur

1. Community Readiness Different
2. Time period may be different

Trials

Brown: **CAL-40 Trial**

Improve the county-wide adoption rate of MTFC -- randomize counties

Poduska: **Whole Day Trial: WD Trial**

Test effectiveness, sustainability, and scalability of an integrated WD intervention

-- randomize classrooms/teachers

Wyman: **Georgia Gatekeeper Trial**

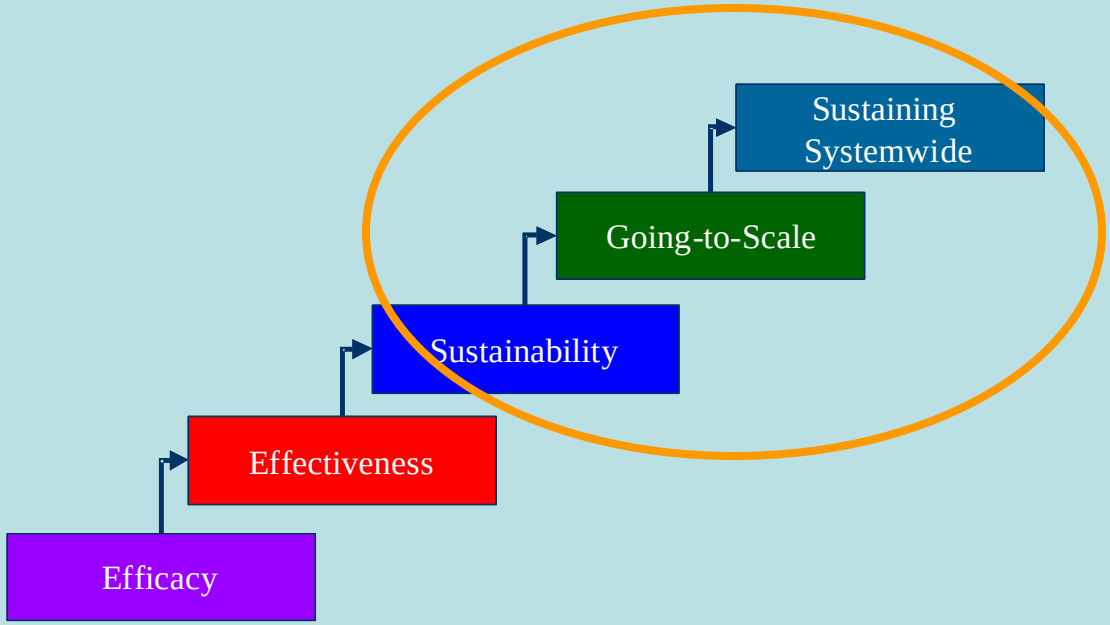
Test effectiveness of QPR as it is “rolled out” in a community.

Sources of Strength Trial

Test mediators, effectiveness, and sustainability of Sources of Strength for suicide prevention.

-- randomize schools

Implementation Questions



Common Implementation Research Questions

How to test whether intervention effects are sustained as supports are lifted?

How to increase the adoption of a program, by communities as well as individuals?

Does adaptation change outcomes?

What support structures lead to successful implementation, high fidelity, and sustainability?

Why are Trials Important in Implementation Science? 1.

- Hallmark of Science is Replicability
- Test (and revise) Generalizable Theories of Implementation in Specific Settings

  Alternative is to have case studies

Well Conducted Randomized Trials as Scientifically Rigorous in Drawing Causal Inferences

Grades of Evidence (Canadian, US Preventive Task Forces ’92)

1. **Multiple, repeated randomized clinical trials**
2. **Single randomized clinical trial**
3. Non-randomized experiment
4. Pre-post design w/o control
5. Expert opinion

But

Trials useful for implementation research if they are designed to answer these questions.

Ex: Do Antidepressants Cause Suicide in Youth?

Blinded, placebo controlled efficacy RCTs

Exclude anyone who is suicidal

Primary question is efficacy

No standardized procedure for collecting adverse event data.

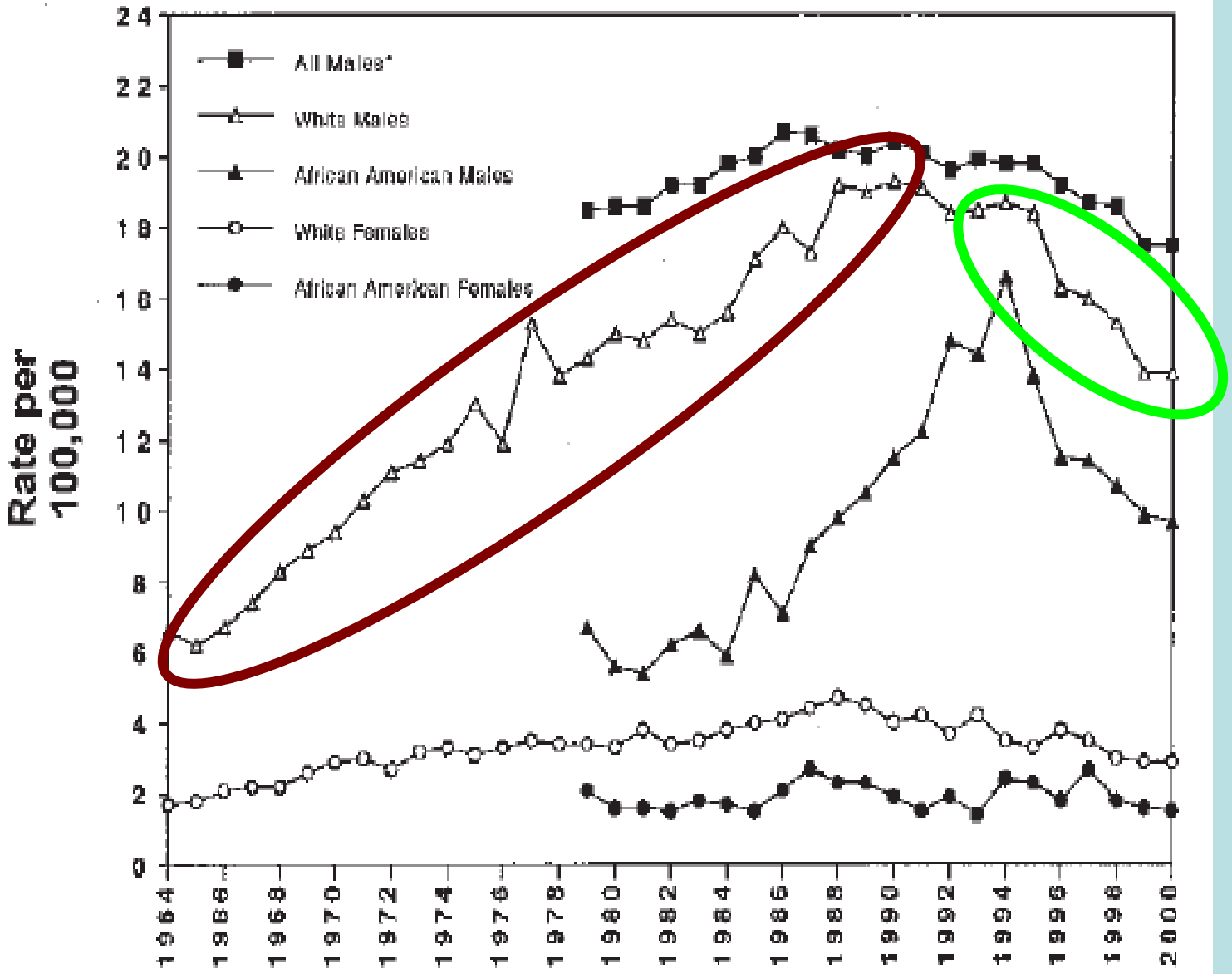
Gibbons, Brown, et al., (2007) A J Psychiatry

Why Trials? 2.

Distinguish Program Effects from Background Variation or Trends

GA Gatekeeper Trial

US Rates of Completed Suicide for Youth (CDC)



Why Trials? 3.

Trials Necessary to Detect Changes in the Magnitude of the Effects that Interventions are Likely to Have

Sources of Strength

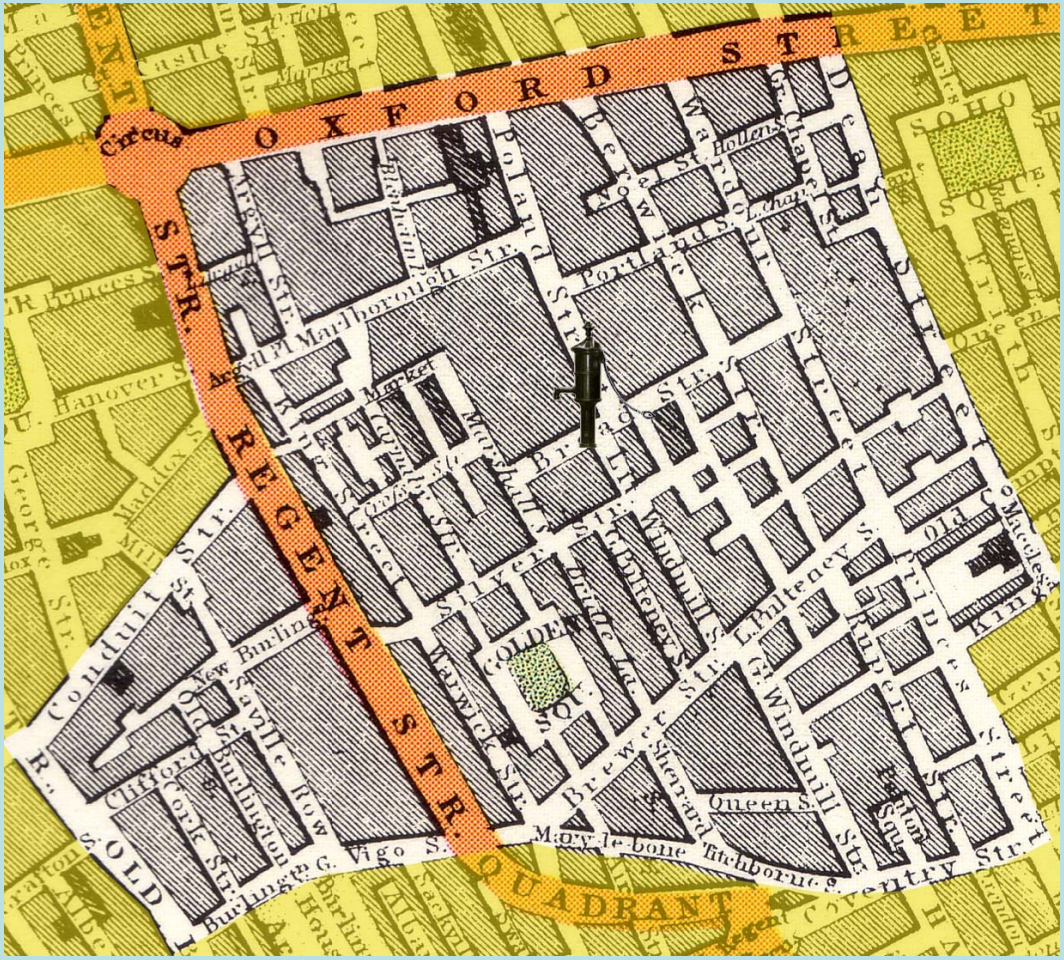
There are very few Broad Street Pump Handles Left to Remove

John Snow's Map of London

1849 proposed

1854 500 deaths to ~ 0

Removal of Pump Led to Immediate Reduction in Colera Deaths



Why Trials? 3.

Formal testing of Mediation and Moderation

WD Trial

MacKinnon, Lockwood, Brown, Wang (2007). Clinical Trials

Brown, Wang, Kellam, Poduska (2008). Drug and Alcohol Dependence

Why Trials? 4.

Our implementation model could well be wrong.

Without a comparison, can't distinguish between a fault in our model vs. external factors.

CAL-40 Trial

Baltimore Prevention Program – less effect in 2nd cohort

Kellam, Brown, Poduska, Wang, et al. (2008). Drug & Alcohol Dependence

What do these Implementation Trials Look Like and Why are They Special?

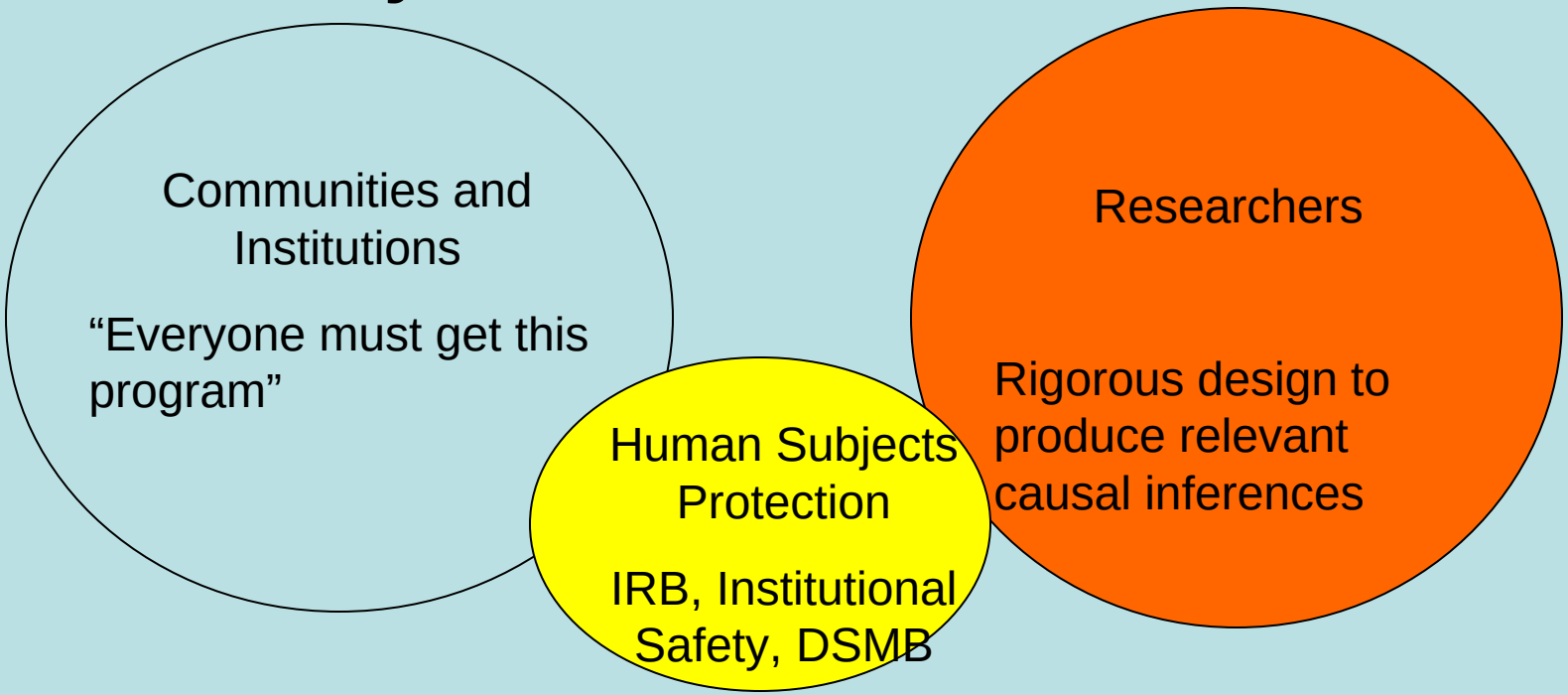
Multilevel

The type of knowledge that can be collected once communities/institutions have decided that they will adopt a program.

Culture and Climate for change

What things are Unique about Implementation Trials

1. The Role of Partnership between Community, Institution, and Researchers



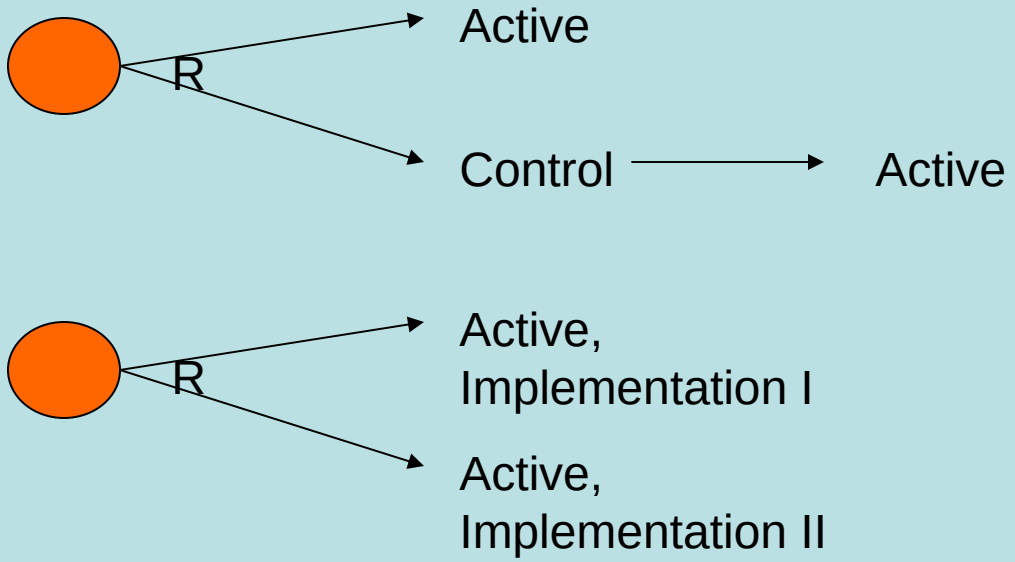
What is Unique about Implementation Trials

2. Intervention Arm Assignments

Efficacy/ Effectiveness Trials

Active Condition vs. Control

Implementation Trials



What is Unique about Implementation Trials

3. Open to Unanticipated Events that Cannot be Controlled but Must be Handled to Maintain the Design's Integrity

Types of Protocol Deviations

Deviations	Consequence to Causal Inferences
No Need to Impose Protocol Rules	None
Protocols were Followed	Typically None
Protocols were Not Followed	Possibly Severe
No Protocols Available	Possibly Severe

CAL-40 Trial

NIMH R01 Implementation Trial

Chamberlain, Brown, Reid, Saldana, Marenich, Sosna, Padgett, Bouman, Wang

Chamberlain et al., (2008). Adm Policy MH

Chamberlain et al., (2009). DeGennaro & Fogel

Multidimensional Treatment Foster Care MTFC

- Alternative to incarceration or placing youth in residential or group care
- 24 hour support for foster parents backed up by a clinical team
  - Behavioral parent training and support
  - Family therapy for bio parents
  - Skill training for youth
  - Supportive therapy for youth
  - School-based behavioral interventions
  - Psychiatric consultation and med mgt

MTFC Efficacy and Evidence-Based

Chamberlain & Reid, 1998;
Leve, Chamberlain & Reid, 2005

MTFC is

- one of 10 evidence-based National Model Programs rated by the Office of Juvenile Justice and Delinquency Prevention (OJJDP) (Elliott, 1998),
- One of nine National Exemplary Safe, Disciplined, and Drug-Free Schools Model Programs.

CAL-40 Trial

MTFC – “Evidence-based Program”
Offered to all California Counties -- MH, CW, JJ
10% Early Adoption

Can Implementation be Increased for Non-Early Adopters?
Community Development Teams (CDT)
versus assistant to counties independently (IND)

Randomize Counties to 2 Different Models of Technical Assistance: CTD or IND

Outcomes
- Proportion of counties that adopt MTFC and the rate of adoption.
- Stage of MTFC implementation that counties attain.
- Fidelity of implementation, including model adherence and practitioner competence.
- Sustainability of the program over time.

Implementation Trial, Not Effectiveness Trial

Randomly Assign Counties

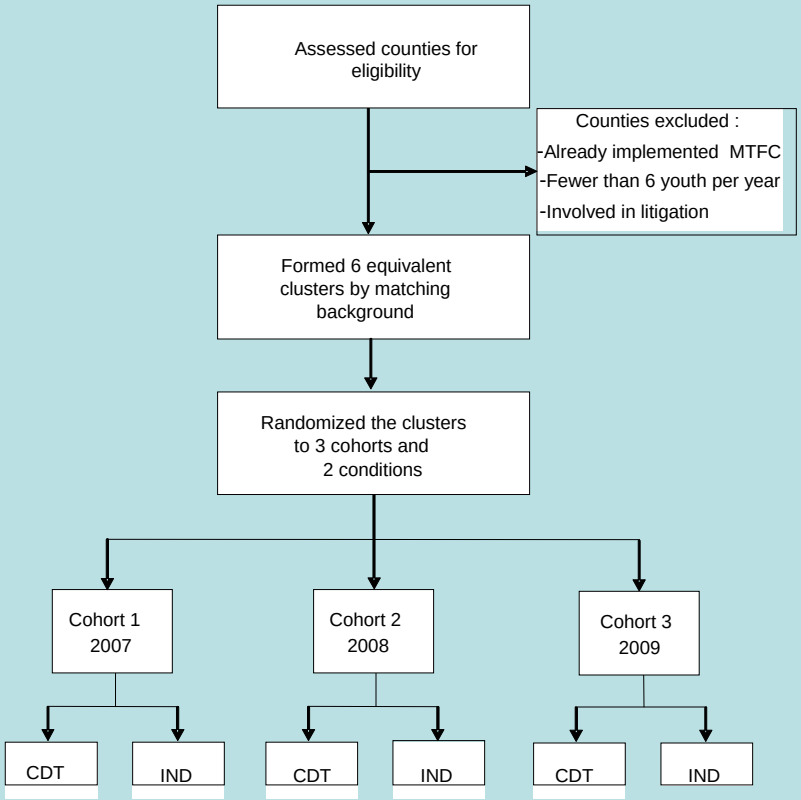
Inclusion/Exclusion Criteria

All California Counties Included Except

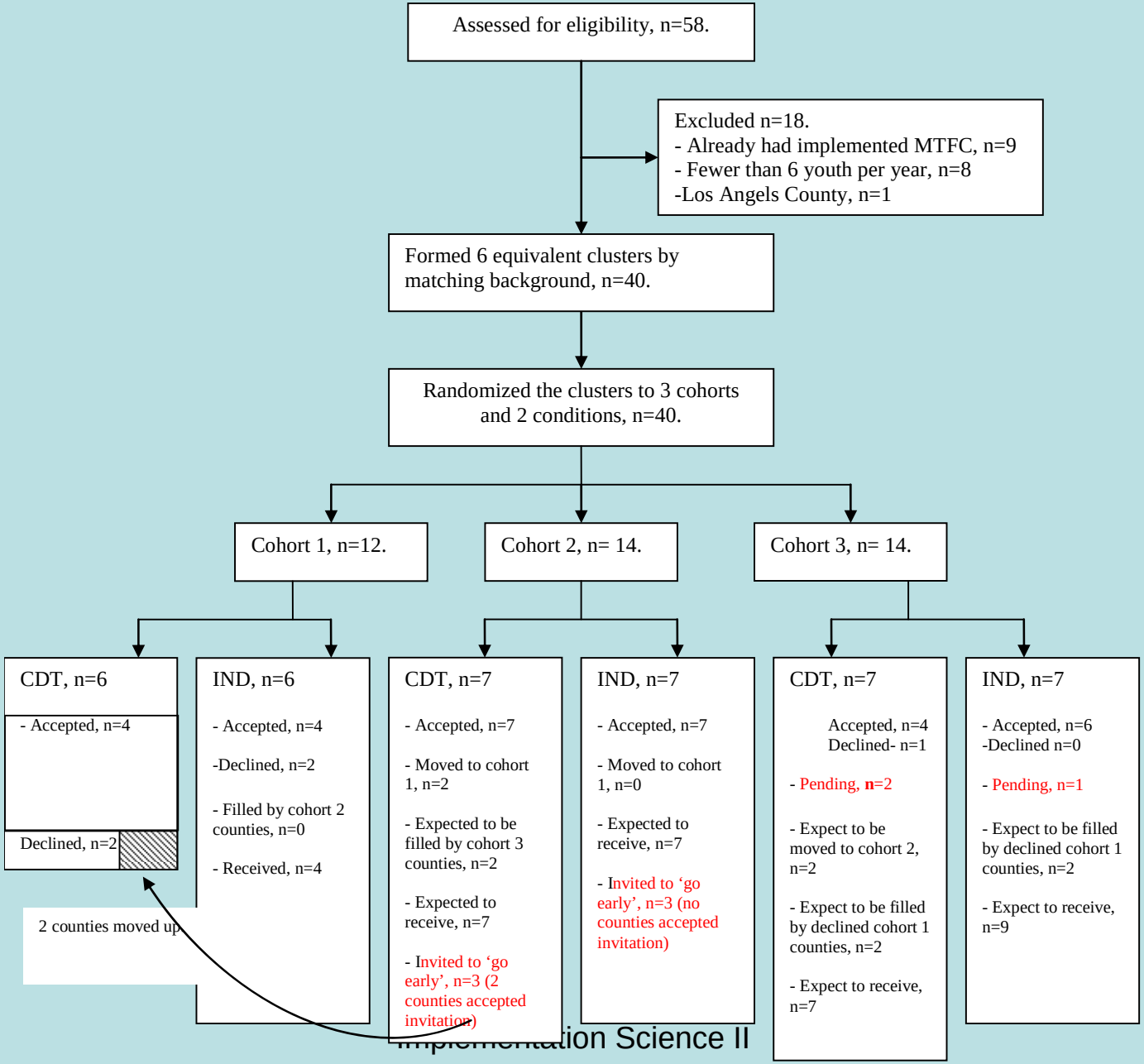
- Early Adopters
- Counties with too few Placements
- One where Court Case Occurring (LA)

Counties balanced 3 Cohorts and 2 Intervention Conditions (CDT and IND)

Randomization Design



Consort Diagram



Issues in the CA-MTFC Design

Acceptance of the Design was Complete

Some Counties Were Not Ready to take Part

Moved Up Counties from Next Cohort

Rural Counties required some adaptation

Management of Peer-to-Peer Communications

New Issue

Running Randomized Trials During a Recession

Primary Outcome is Time it Takes for a County to Place its First Family in MTFC Foster Care

Types of Protocol Deviations

Deviations	Example	Response	Consequence
No Need to Impose Protocol Rules	All Counties Were Willing to Participate		
Protocols were Followed	When County Was not Ready to Start in their Assigned Cohort	Randomly and Blindly Selected County in SAME Condition in Next Cohort	So Far Little Imbalance, little indication of differential replacement bias
	Interactions of Counties in Different Conditions	Allowed and measured	Potential reduction in statistical power
Protocols were Not Followed			
No Protocols Available	Stagnancy of County Governments' Budgets	Extend trial to another state with same inclusion/exclusion criteria	Statistical Power

Summary

Cal -40 testing two Implementation Strategies

Protocols Can Lay Out Strategies to Maintain Design that are Anticipated

Need to deal with Unanticipated Events in Implementation Trials