Assessing Implementation Fidelity and Achieved Relative Strength in RCTs: Concepts and Methods

David S. Cordray
Vanderbilt University

Presentation

The Nebraska Center for Research on Children, Youth, Families and School
University of Nebraska
Lincoln Nebraska

April 19, 2010

Overview

- Research Context and Definitions
- A 4-step approach to assessment and analysis of implementation fidelity (IF) and achieved relative strength (ARS):
  - ***Model(s)-based***
  - ***Quality Measures of Core Causal Components***
  - ***Creating Indices***
  - ***Integrating implementation assessments with models of effects***

Distinguishing Implementation Assessment from the Assessment of Implementation Fidelity

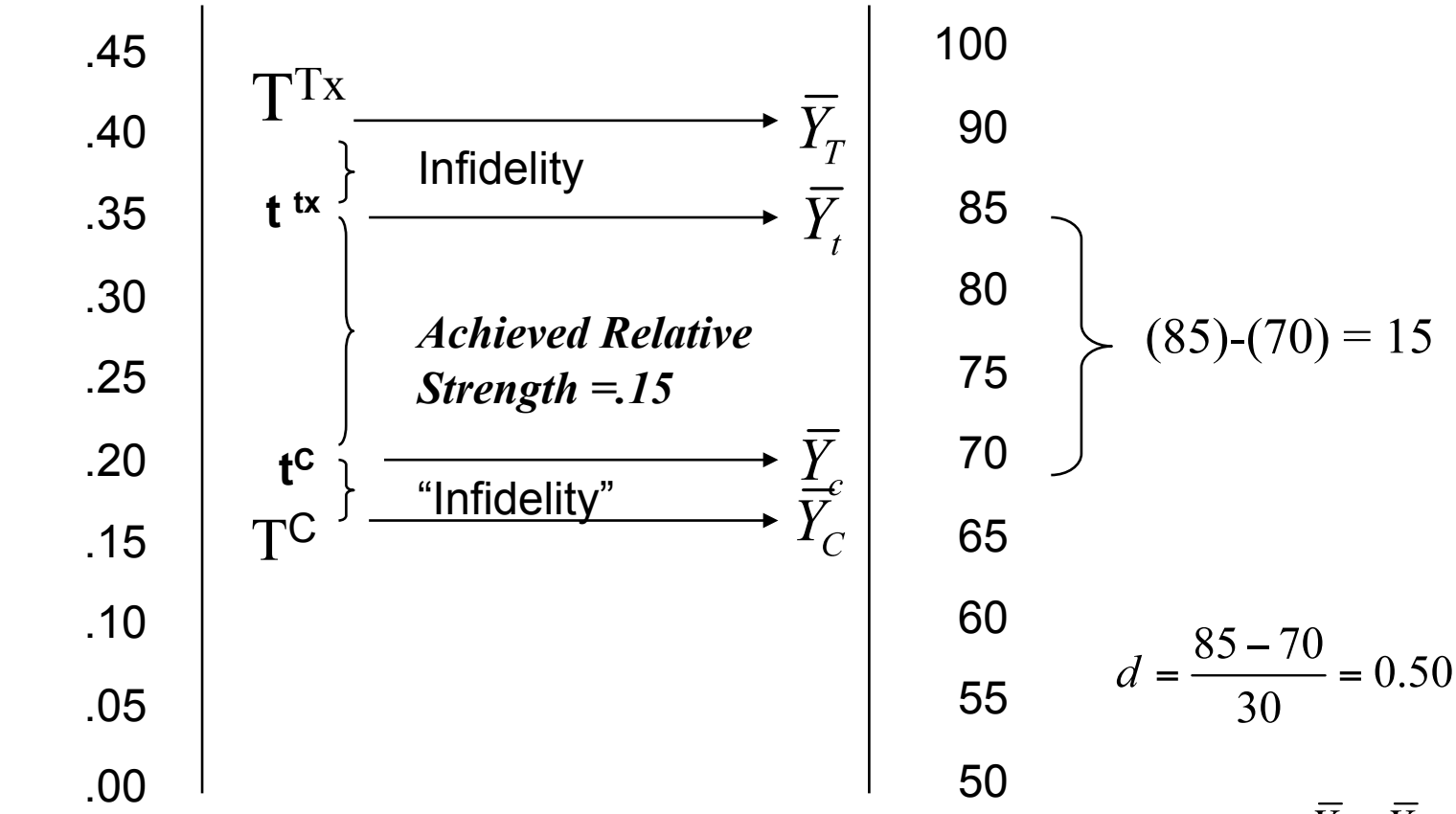
- Two ends on a continuum of intervention implementation/fidelity:
- A ***purely* descriptive** model:
  - Answering the question "What transpired as the intervention was put in place (implemented).
- Based on ***a priori* intervention model**, with explicit expectations about implementation of program components:
  - Fidelity is the extent to which the realized intervention ($\mathbf{t^{Tx}}$) is faithful to the ***pre-stated*** intervention model ($\mathbf{T^{Tx}}$ **)**
  - Infidelity = $\mathbf{T^{Tx} - t^{Tx}}$
- Most implementation fidelity assessments involve descriptive and model-based approaches.

Dimensions Intervention Fidelity

- **Aside from agreement at the extremes, little consensus on what is meant by the term "intervention fidelity".**
- **Most frequent definitions:**
  - **True Fidelity = Adherence or compliance:**
    - Program components are delivered/used/received, as prescribed
    - With a stated criteria for success or full adherence
    - The specification of these criteria is relatively rare
  - **Intervention Exposure:**
    - Amount of program content, processes, activities delivered/received by all participants (aka, receipt, responsiveness)
    - This notion is most prevalent
  - **Intervention Differentiation:**
    - The unique features of the intervention are distinguishable from other programs, including the control condition
    - A unique application within RCTs

Linking Intervention Fidelity Assessment to Contemporary Models of Causality

- **Rubin's Causal Model:**
  - True causal effect of X is $(Y_i^{Tx} - Y_i^{C})$
  - RCT methodology is the best approximation to this true effect
  - In RCTs, the difference between conditions, on average, is the causal effect
- **Fidelity assessment within RCTs entails examining *the difference between causal components* in the intervention and control conditions.**
- **Differencing causal conditions can be characterized as *achieved relative strength* of the contrast.**
  - **Achieved Relative Strength (ARS) = $t^{Tx} - t^{C}$**
  - **ARS is a default index of fidelity**



$$d = \frac{85 - 70}{30} = 0.50$$

$$d_{\text{with fidelity}} = \frac{\bar{Y}_T - \bar{Y}_C}{sd_{pooled}}$$

$$d = \frac{\bar{Y}_t - \bar{Y}_c}{sd_{pooled}}$$

$$d_{\text{with fidelity}} = \frac{90 - 65}{30} = 0.83$$

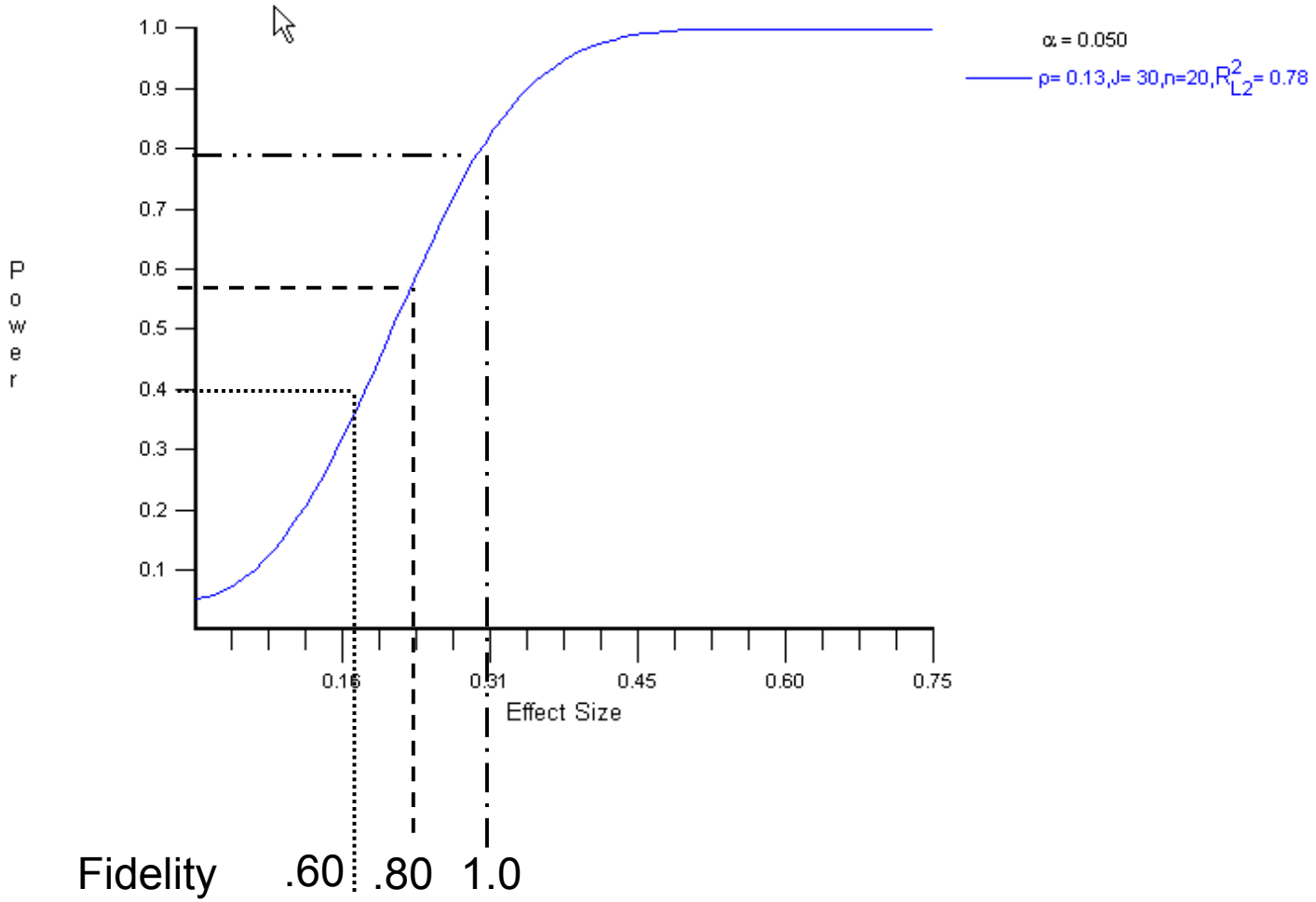
$$d = 0.50$$

Expected Relative Strength = (0.40-0.15) = 0.25

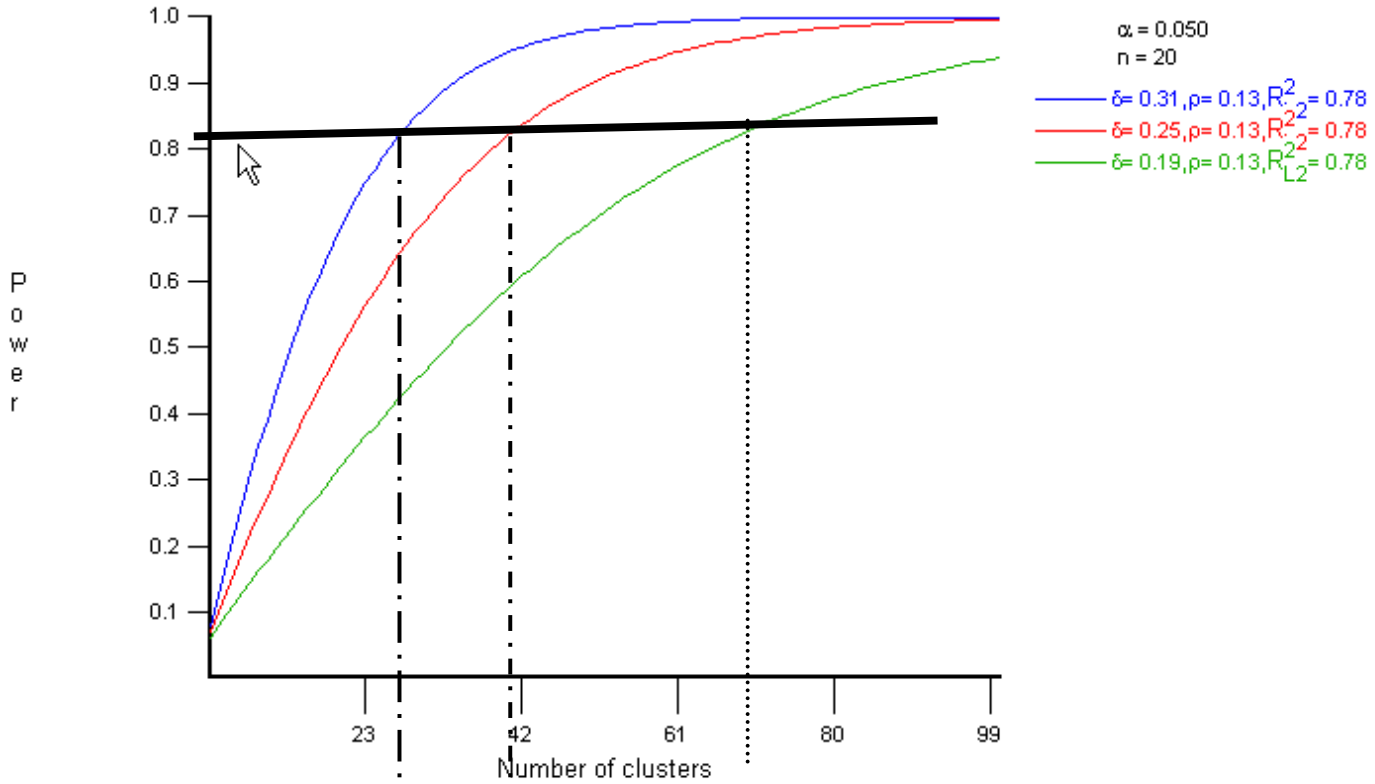
Why is this Important?

- **Statistical Conclusion validity**
  - **Unreliability of Treatment Implementation:** Variations across participants in the delivery receipt of the causal variable (e.g., treatment). Increases error and reduces the size of the effect; decreases chances of detecting covariation.
- Resulting in a reduction in statistical power or the need for a larger study….

The Effects Structural Infidelity on Power



Influence of Infidelity on Study-size

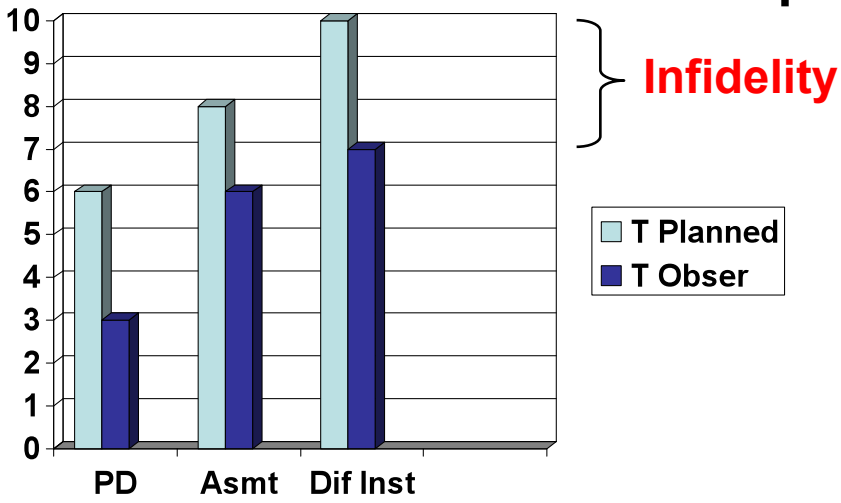


Fidelity 1.0 .80 .60

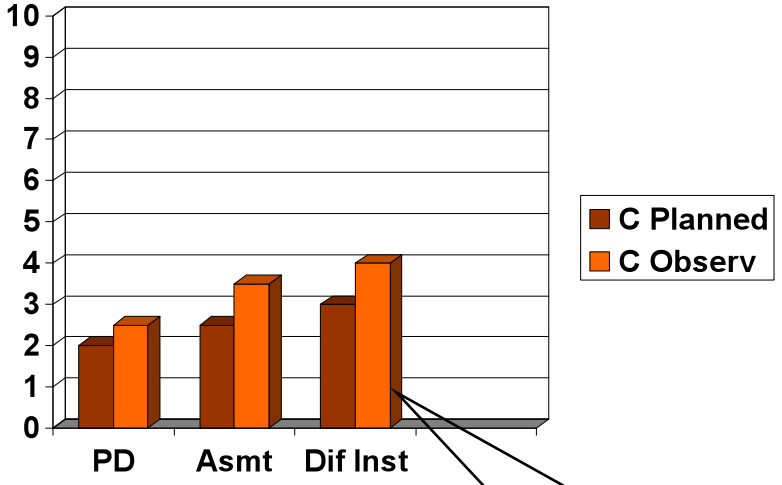
If That Isn't Enough….

- **Construct Validity:**
  - **Which is the cause? (T^{Tx} - T^{C}) or (t^{Tx} – t^{C})**
    - **Poor implementation:** essential elements of the treatment are incompletely implemented.
    - **Contamination:** The essential elements of the treatment group are found in the control condition (to varying degrees).
    - **Pre-existing similarities between T and C on intervention components.**
- **External validity – generalization is about (t^{Tx} - t^{C})**
  - **This difference needs to be known for proper generalization and future specification of the intervention components**

So what is the cause? …The achieved relative difference in conditions across components



Infidelity

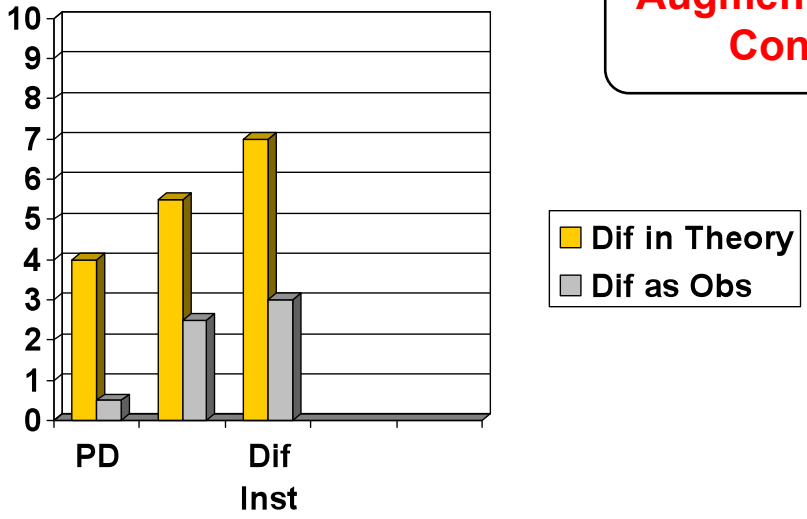


Augmentation of Control

PD= Professional Development

Asmt=Formative Assessment

Diff Inst= Differentiated Instruction



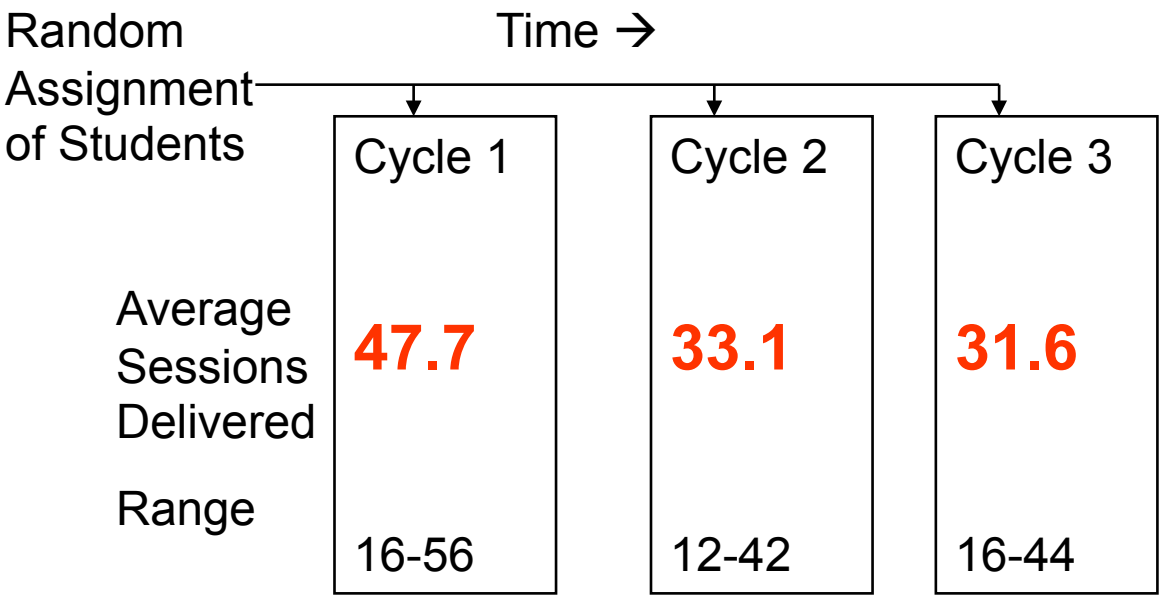
Some Sources and Types of Infidelity

- **If delivery or receipt could be dichotomized (yes or no):**
  - **Simple fidelity involves compliers;**
  - **Simple infidelity involves "No shows" and cross-overs.**
- **Structural flaws in implementing the intervention:**
  - **Missing or incomplete resources, processes**
  - **External constraints (e.g. snow days)**
- **Incomplete delivery of core intervention components**
  - **Implementer failures or incomplete delivery**

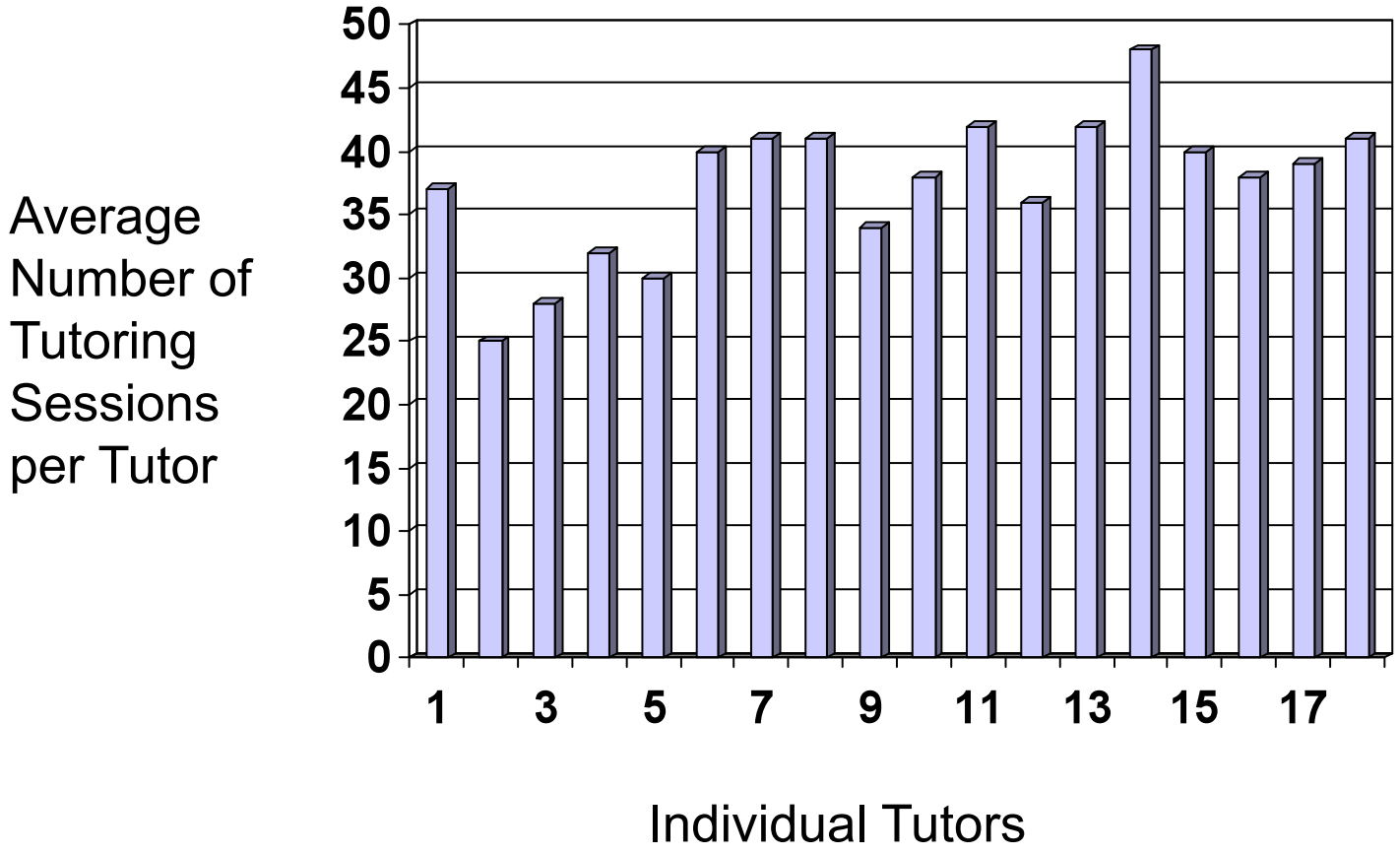
A Tutoring Program: Variation in Exposure

4-5 tutoring sessions per week, 25 minutes each, 11weeks

Expectations: 44-55 sessions



Variation in Exposure: Tutor Effects



The other fidelity question: *How faithful to the tutoring model is each tutor*?

In Practice….

- **Identify core components in the intervention group**
  - **e.g., via a Model of Change**
- **Establish bench marks (if possible) for T^{TX} and T^{C}**
- **Measure core components to derive t^{Tx} and t^{C}**
  - **e.g., via a "Logic model" based on Model of Change**
- **Measurement (deriving indicators)**
- **Converted to Achieved Relative Strength and implementation fidelity scales**
- **Incorporated into the analysis of effects**

What do we measure?

What are the options?

(1) Essential or ***core*** components (activities, processes);

(2) Necessary, but not unique, activities, processes and structures (supporting the essential components of T); and

(3) Ordinary features of the setting (shared with the control group)

- Focus on 1 and 2.

Specifying Intervention Models

- Simple version of the question: ***What was intended?***
- Interventions are generally multi-component, sequences of actions
- Mature-enough interventions are specifiable as:
  - Conceptual model of change
  - Intervention-specific model
  - Context-specific model

An Illustrative Simple Model of Change

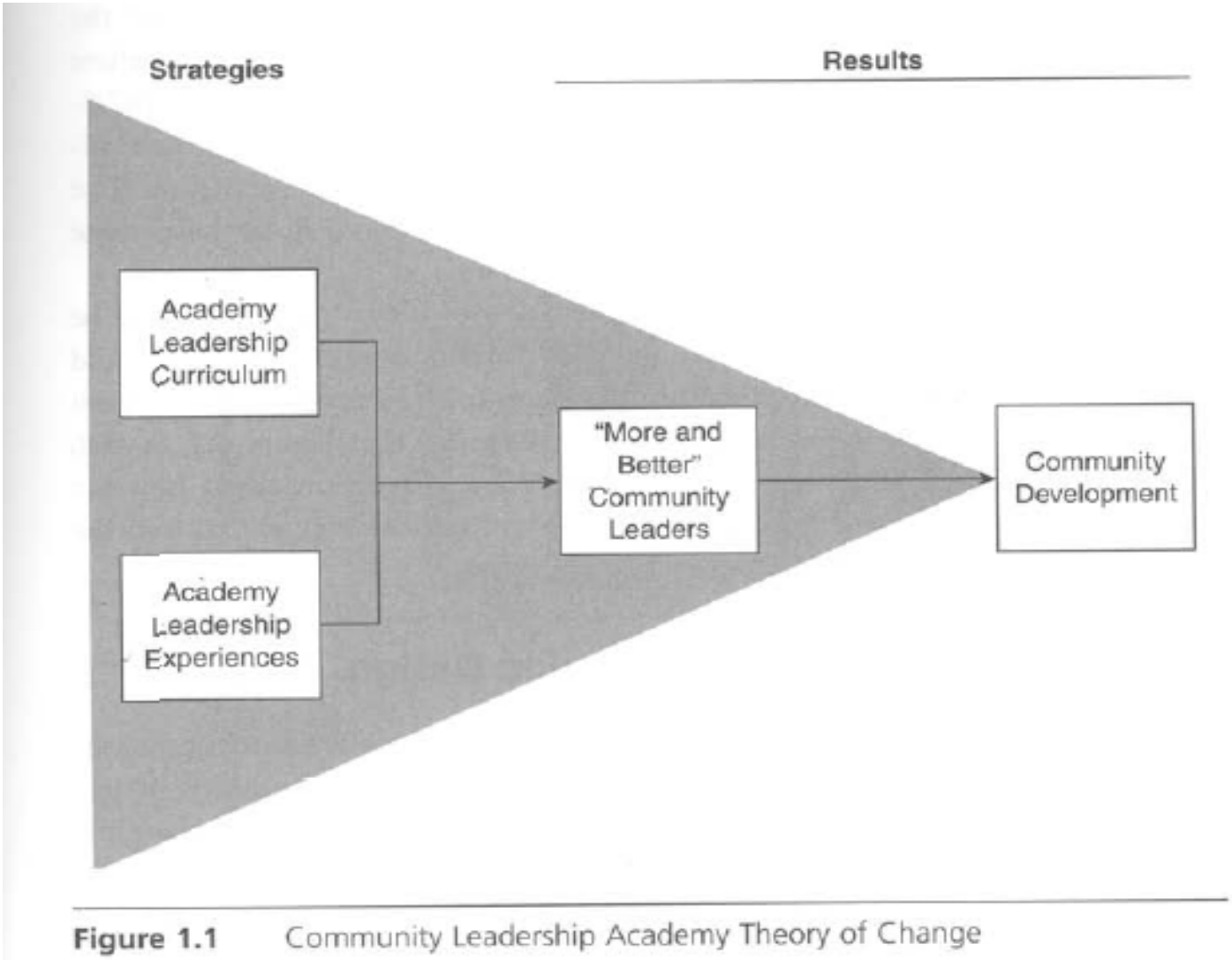


Figure 1.1 Community Leadership Academy Theory of Change

From: Knowlton & Phillips, 2009, The Logic Model Guidebook: Better Strategies for Great Results, p.7

The Logic Model and Conceptual Model

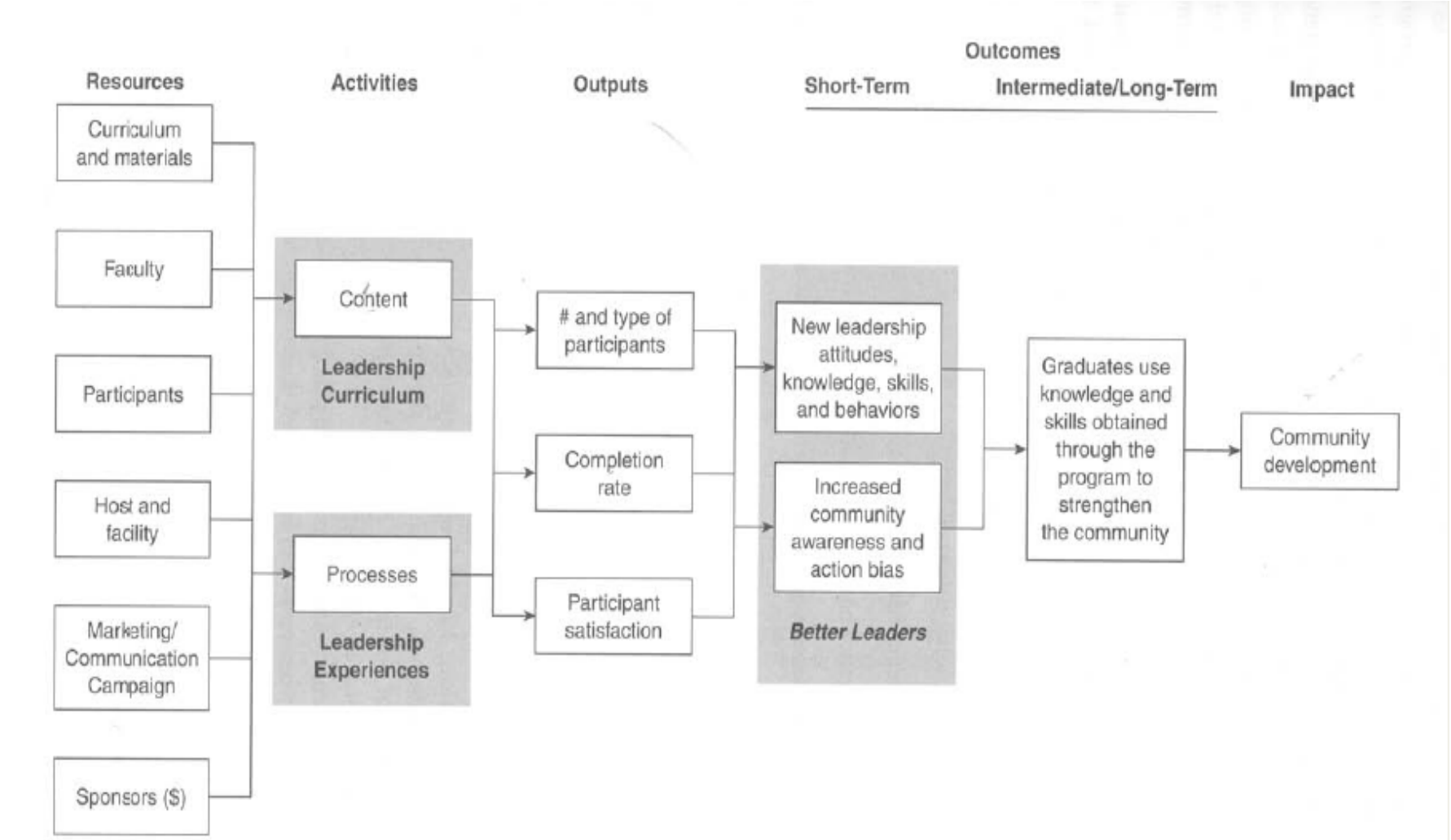


Figure 1.2 Community Leadership Academy (CLA) Program Logic Model

From: Knowlton & Phillips, 2009, The Logic Model Guidebook: Better Strategies for Great Results, p.9

The Generic Logic Model

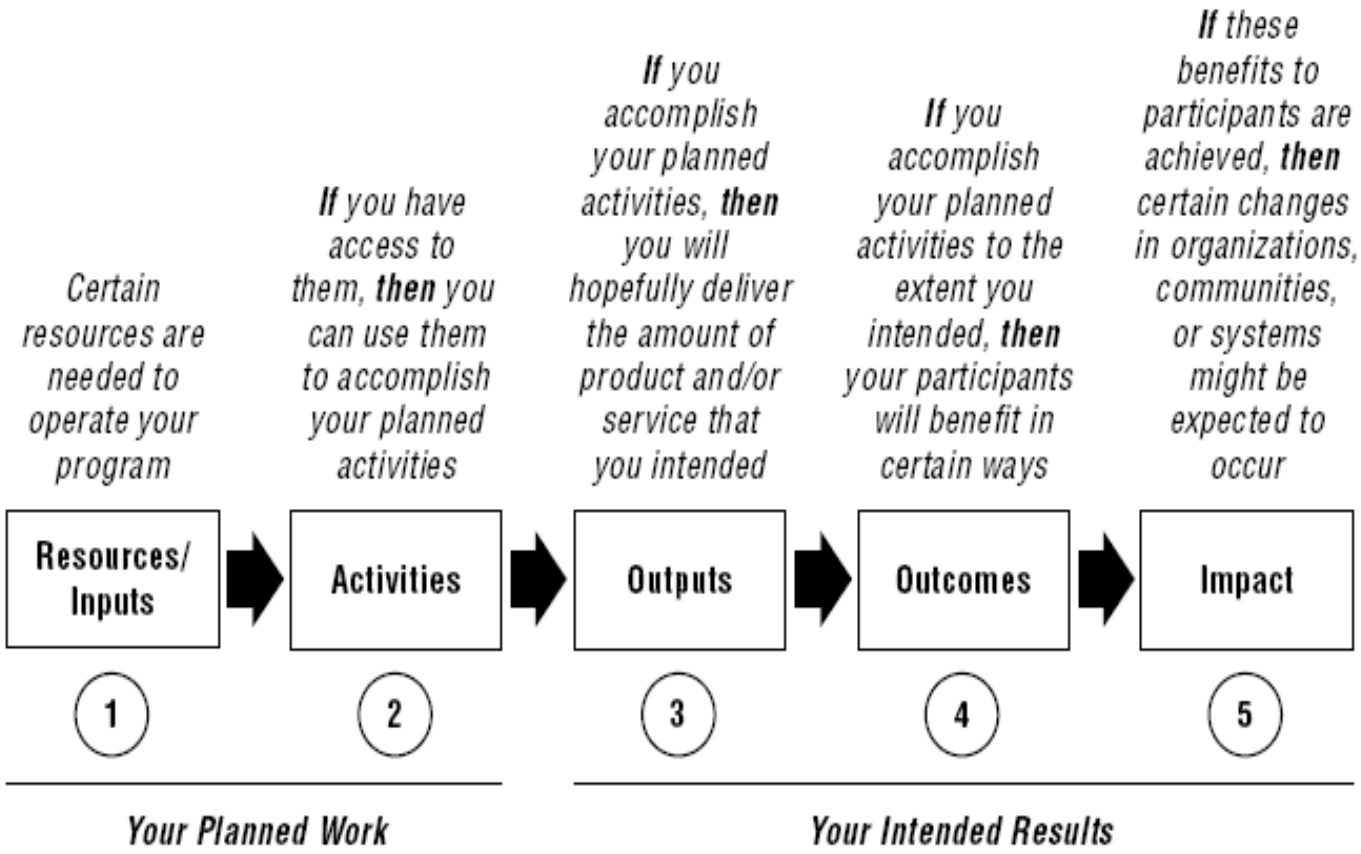


Figure 2. How to Read a Logic Model.

From: W.T. Kellogg Foundation, 2004

The Other Half of the Picture

Fidelity assessment within RCTs should examine *the difference between causal components* in the intervention and control conditions.

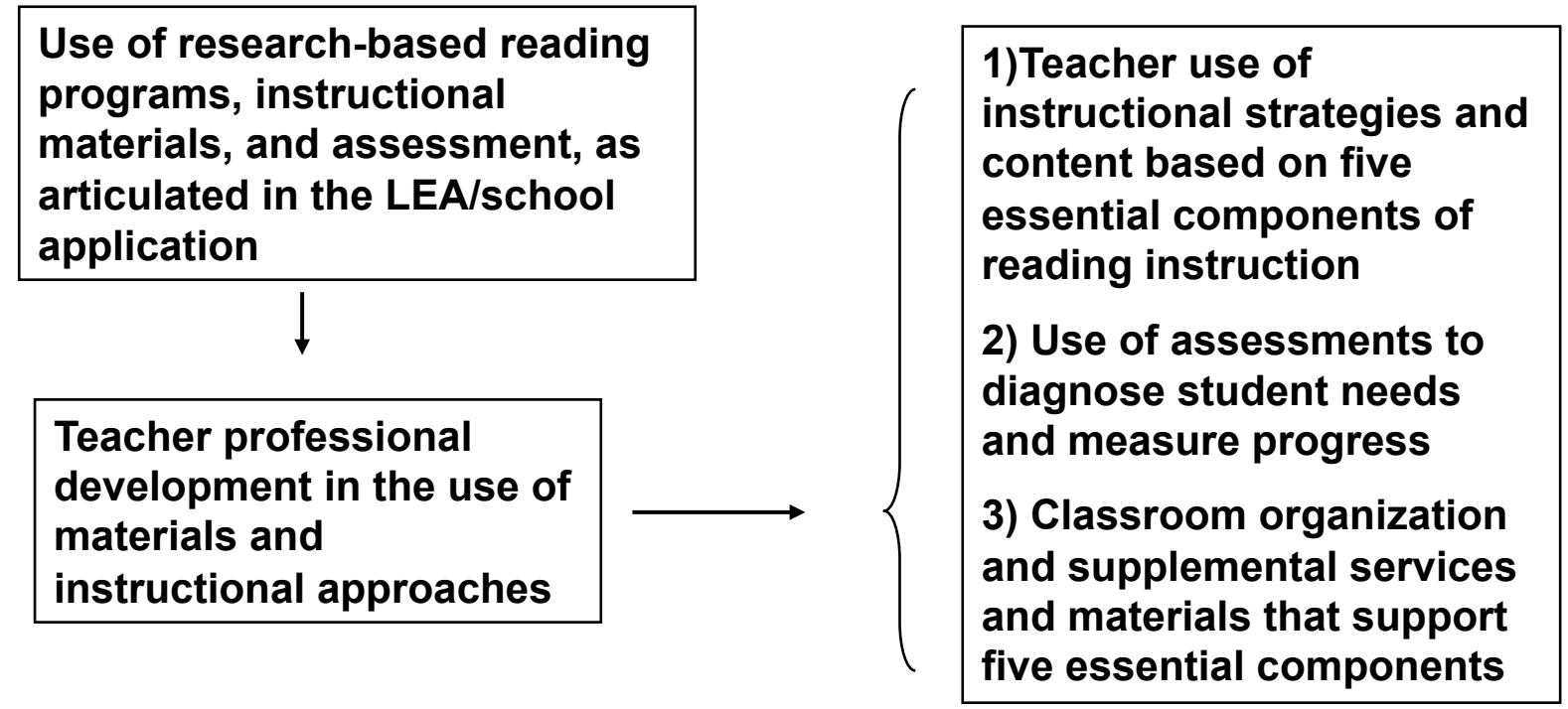
- **Differencing causal conditions can be characterized as *achieved relative strength* of the contrast.**
  - **Achieved Relative Strength (ARS) = $t^{Tx} - t^{C}$**
  - **ARS is a default index of fidelity**

Quality Measures of Core Components

- Measures of resources, activities, outputs
- Range from simple counts to sophisticated scaling of constructs
- Generally involves multiple methods
- Multiple indicators for each major component/activity
- Reliable scales (3-4 items per sub-scale)

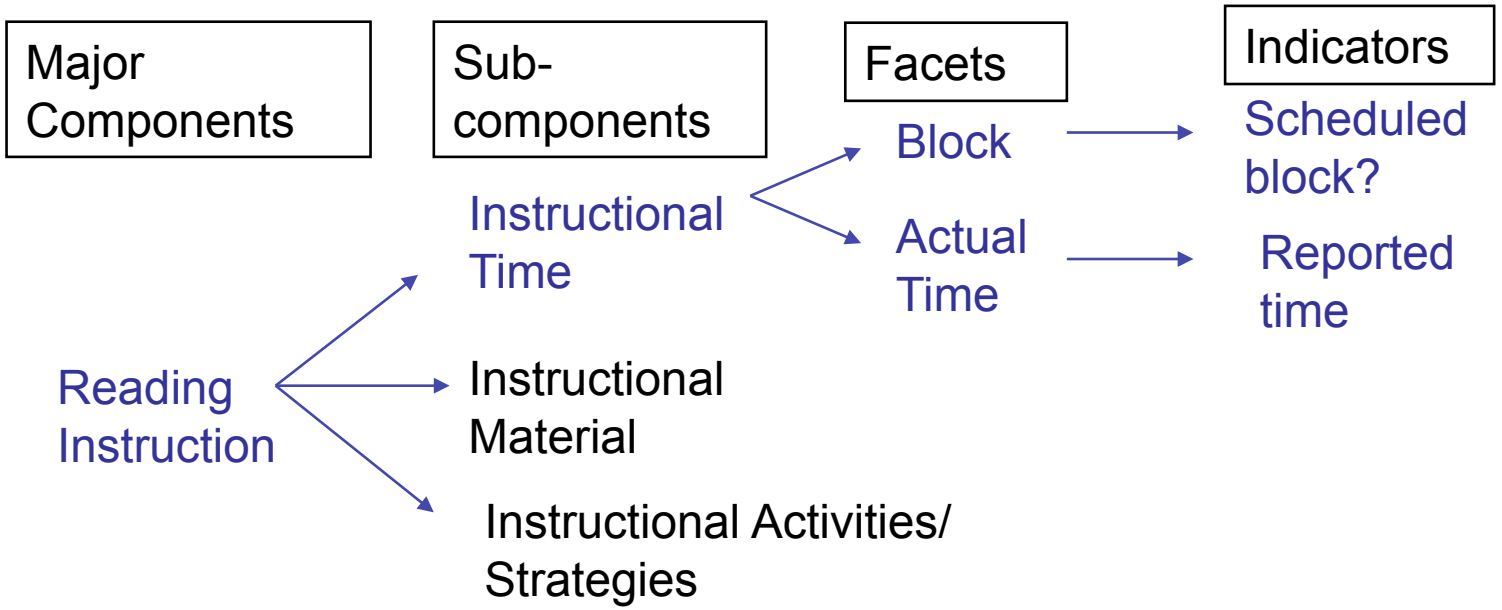
Core Reading Components for Local Reading First Programs

Design and Implementation of Research-Based Reading Programs



After Gamse et al. 2008

From Major Components to Indicators…



Reading First Implementation: Specifying Components and Operationalization

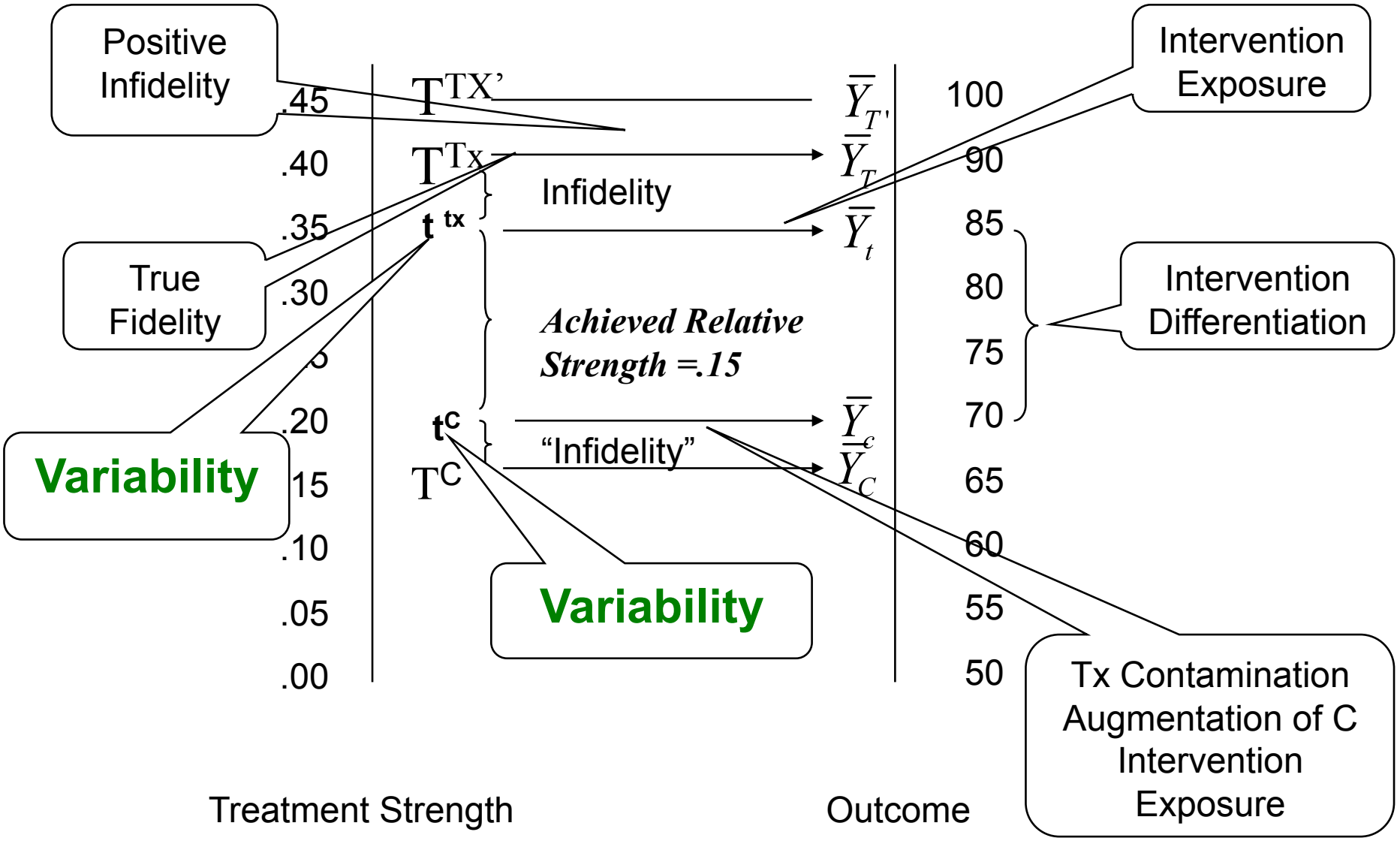
Components	Sub-components	Facets	Indicators (I/F)
Reading Instruction	Instructional Time	2	2 (1)
	Instructional Materials	4	12 (3)
	Instructional Activities /Strategies	8	28 (3.5)
Support for Struggling Readers (SR)	Intervention Services	3	12 (4)
	Supports for Struggling Readers	2	16 (8)
	Supports for ELL/SPED	2	5 (2.5)
Assessment	Selection/Interpretation	5	12 (2.4)
	Types of Assessment	3	9 (3)
	Use by Teachers	1	7 (7)
Professional development	Improved Reading Instruction	11	67 (6.1)
4	**10**	**41**	**170 (4)**

Adapted from Moss et al. 2008

Reading First Implementation: Some Results

Components	**Sub-components**	**Performance Levels**		**ARSI (U3)**
		RF	Non-RF	
Reading Instruction	Instructional Time (minutes)	101	78	0.33 (63%)
	Support	79%	58%	0.50 (69%)
Struggling Readers	More Tx, Time, Supplemental Service	83%	74%	0.20 (58%)
Professional Development	Hours of PD	41.5	17.6	0.42 (66%)
	Five reading dimensions	86%	62%	0.55 (71%)
Assessment	Grouping, progress, needs	84%	71%	0.32 (63%)
				0.39 (65%)

Adapted from Moss et al. 2008



Analyzing Variation in Implementation

Indexing Cause-Effect Linkage

- Analysis Type 1:
  - Congruity of Cause-Effect in ITT analyses
    - Effect = Average difference on outcomes →ES
    - Cause = Average difference in causal components → ARS (Achieved Relative Strength)
    - Descriptive reporting of each, separately
- Analysis Type 2:
  - Variation in implementation fidelity linked to variation in outcomes
    - Effect = outcomes
    - Cause= covariates (from ARSI)

Common Cause-Effect Scenarios

The Cause	The Effect	
	Low	High
Low	Low/Low = Cause-Effect Congruity	**Low/High = ????**
High	**High/Low = Dampening Process ????**	High/High = Cause-Effect Congruity

Cause-Effect Congruity: High/High Example

- Fantuzzo, King & Heller (1992) studied the effects of reciprocal peer tutoring on mathematics and school adjustment.
  - 2 X 2 factorial design crossing levels of *structured peer tutoring* and *group reward*
  - *45 min. 2-3 per week; 60-90 sessions*
- Fidelity assessments:
  - Observations (via checklist) of students and staff, rated the adherence of group members to scripted features of each condition;
    - 50% random checks of sessions
  - Mid-year, knowledge tests to index the level of understanding of students about the intervention components in each of the four conditions.

Fantuzzo et al. Continued

- Fidelity results:
  - Adherence (via observations):
    - 90-100% across conditions,
    - 95% overall
  - Student understanding (via 15 item test):
    - 82% SD=11% (range 47-100%); ANOVA=ns
    - Reward+structure condition: 84% Control: 86%
- Effects on mathematics computation:

  ES= (7.7-5.0)/1.71 = 1.58
- Congruity=High/High; no additional analyses needed

Exposure and Achieved Relative Strength

- Fantuzzo et al. example is:
  - Relatively rare;
  - Incorporates intervention differentiation, yielding fidelity indices for all conditions.
- More commonly, intervention exposure is assessed:
  - Yielding scales of the degree to which individuals experience the intervention components in both conditions
  - The achieved relative strength index is used for establishing the differences between conditions on causal components

Indexing Fidelity as Achieved Relative Strength

Intervention Strength = Treatment – Control

Achieved Relative Strength (ARS) Index

$$ARS\ Index = \frac{\mathbf{t}^{\mathrm{Tx}} - \mathbf{t}^{\mathrm{C}}}{S_T}$$

- Standardized difference in fidelity index across Tx and C
- Based on Hedges' *g* (Hedges, 2007)
- Corrected for clustering in the classroom

Average ARS Index

$$g = ARS = \left(\frac{\bar{X}_1 - \bar{X}_2}{S_T}\right) \times \left(1 - \frac{3}{4(n_{Tx} + n_C) - 9}\right) \times \sqrt{1 - \frac{2(n-1)p}{N-2}}$$

Group Difference

Sample Size Adjustment

Clustering Adjustment

Where,

$\bar{X}_1$ = mean for group 1 ($\mathbf{t}^{Tx}$)

$\bar{X}_2$ = mean for group 2 ($\mathbf{t}^{C}$)

S_T = pooled within groups standard deviation

n_{Tx} = treatment sample size

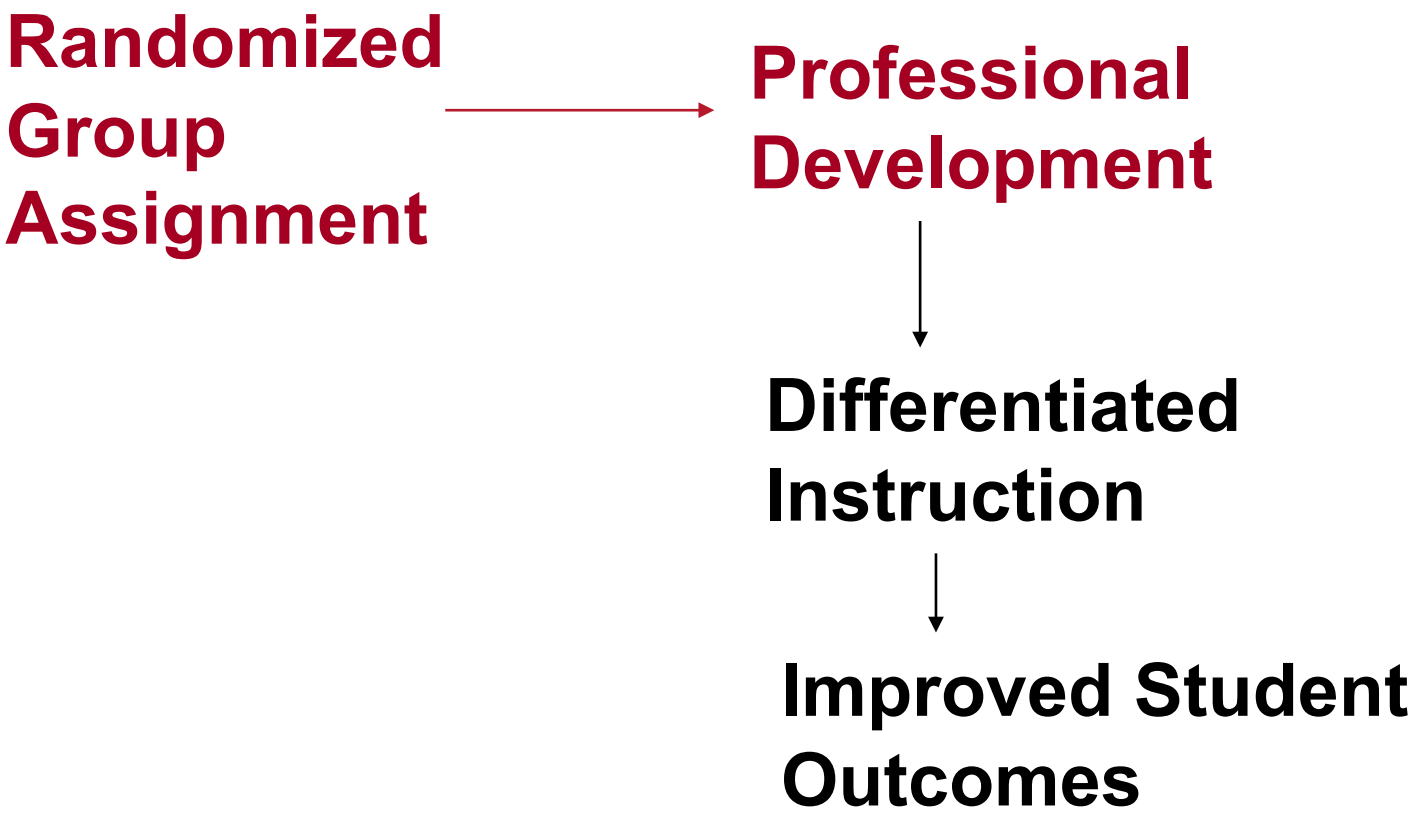
n_C = control sample size

n = average cluster size

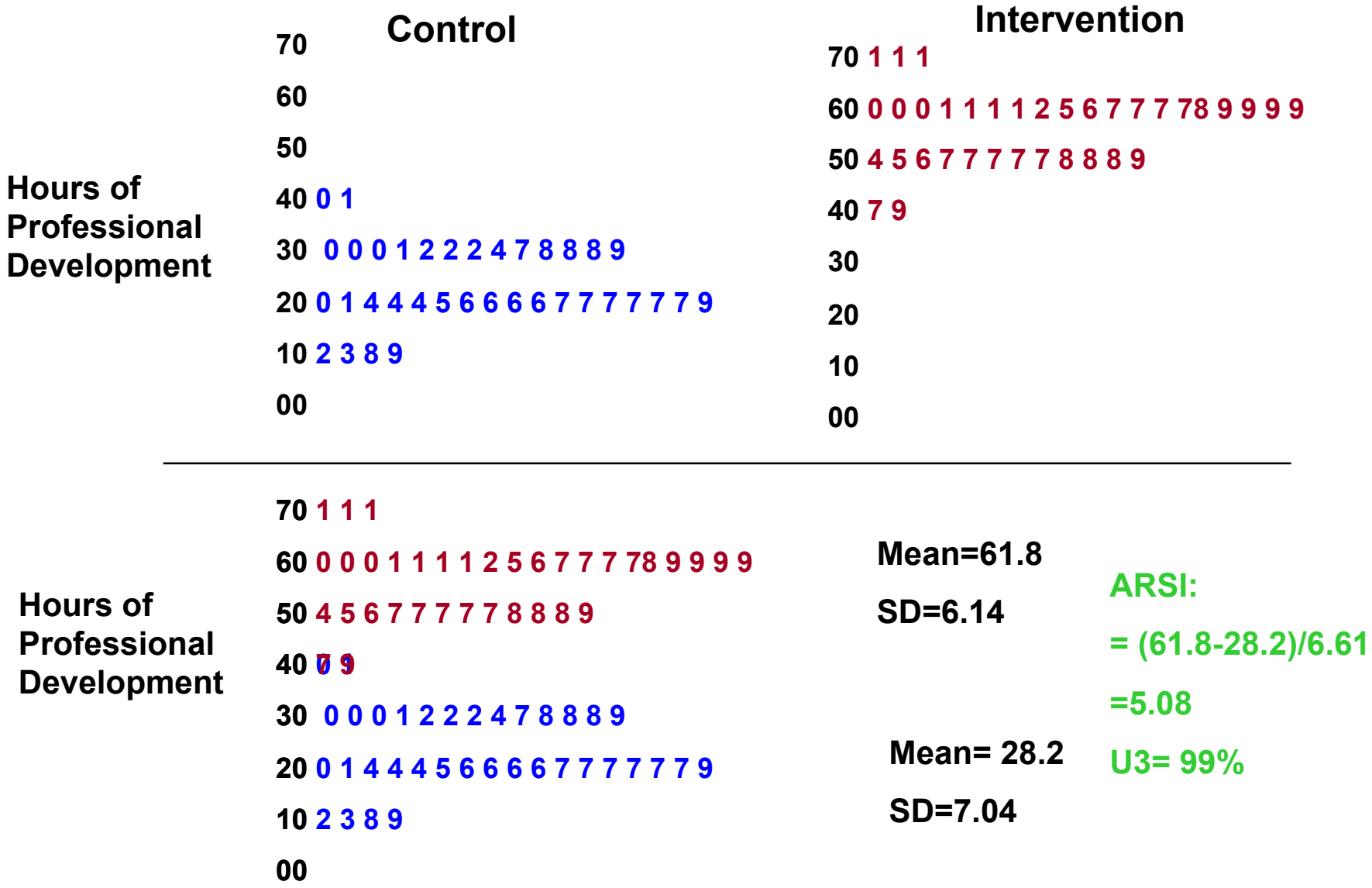
p = Intra-class correlation (ICC)

N = total sample size

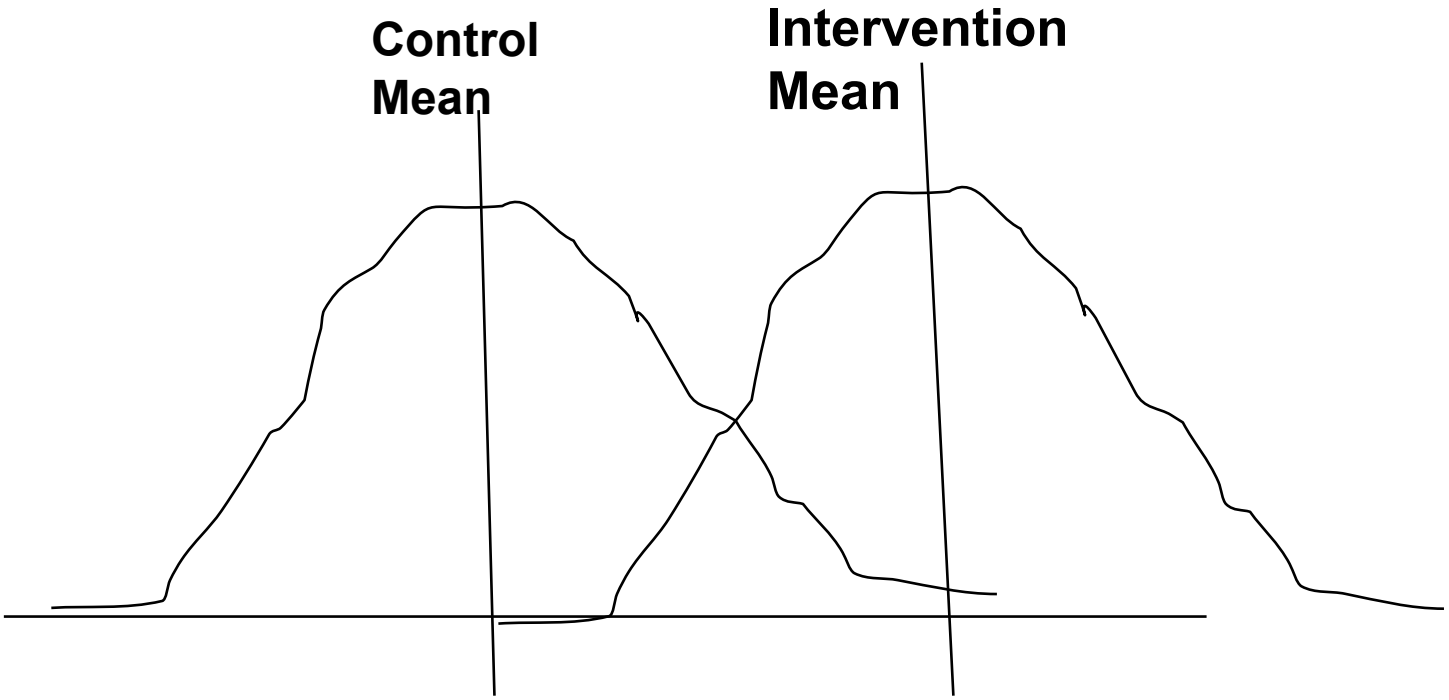
A Partial Example of the Meaning of ARSI



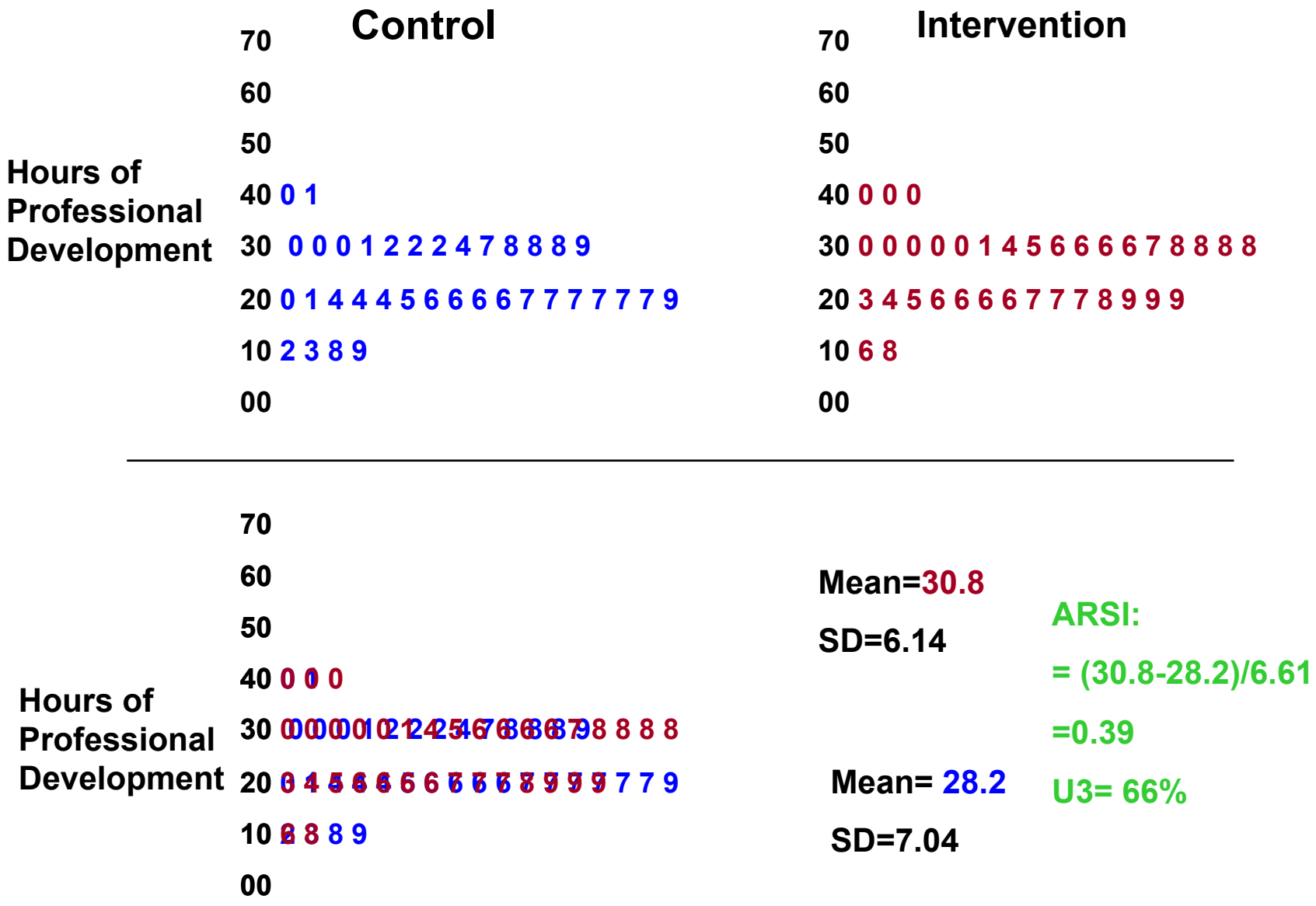
Very Large Group Difference, Limited Overlap Between Conditions



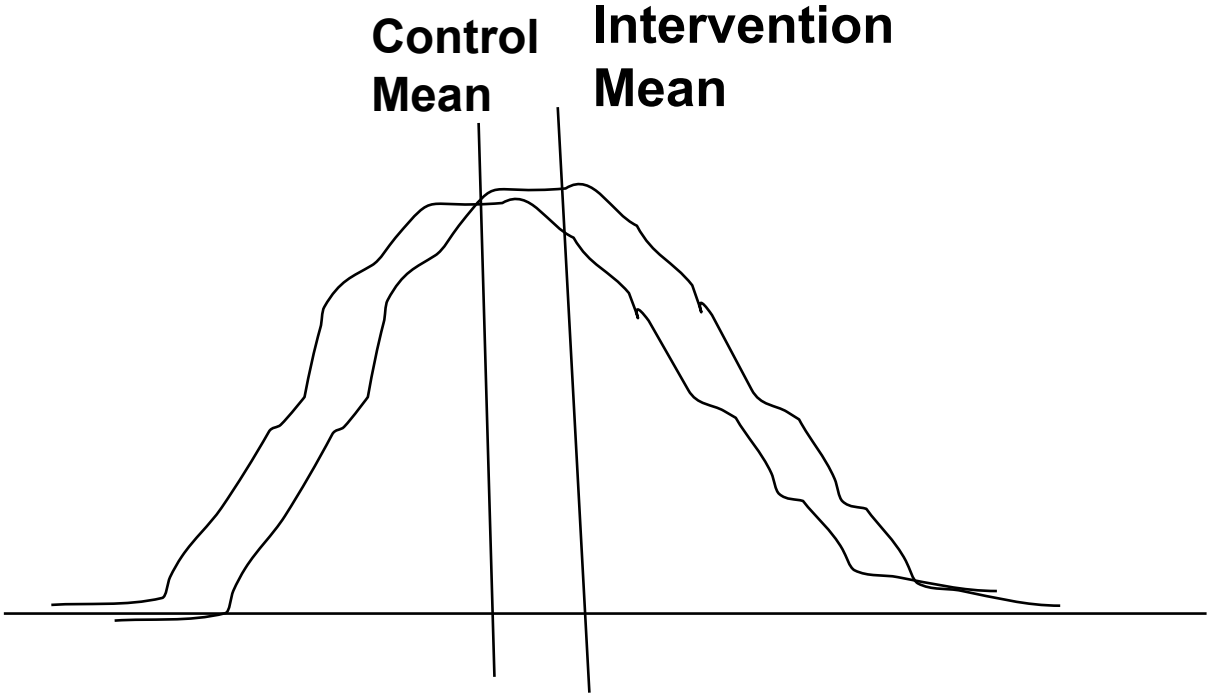
Cohen's U3 Index: Very Large Group Separation



Small Group Differences, Substantial Overlap



Cohen's U3: Little Group Separation



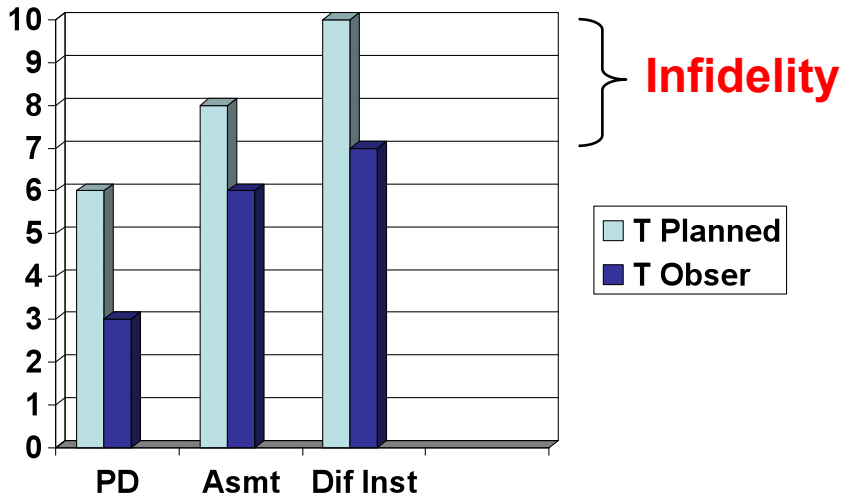
ARSI=0.39

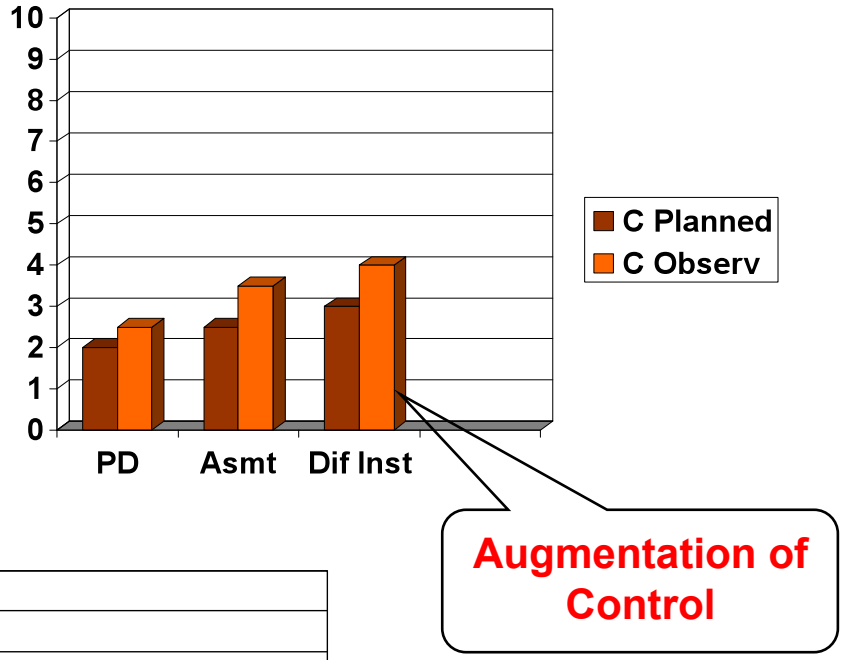
High/High and Low/Low Congruity

Hulleman & Cordray (2009) examined the results of a motivation intervention in the lab and in classrooms, not surprisingly…..

Measure	**Lab**	**Classroom**
Perceived Utility Value	**g = 0.45** **p = 0.03**	**g = 0.05** **p = 0.67**
Achieved Relative Strength:		
Binary	**0.65**	**0.15**

Calculating ARSI When There Are Multiple Components

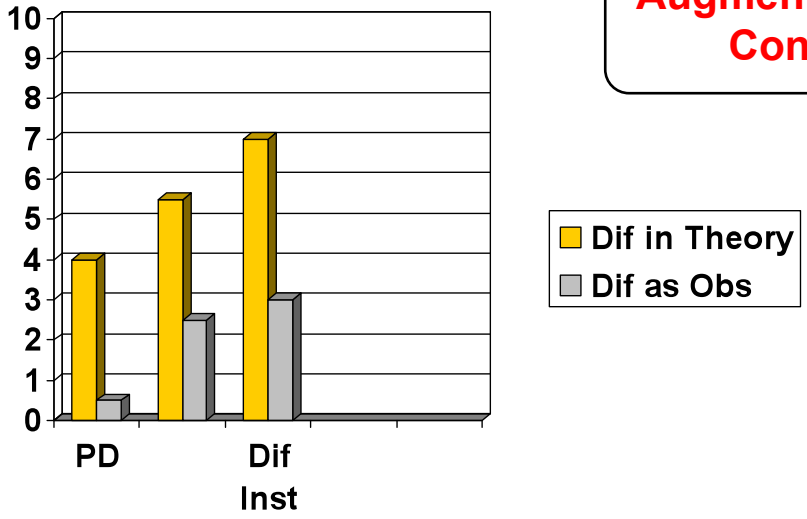




PD= Professional Development

Asmt=Formative Assessment

Diff Inst= Differentiated Instruction



Weighted Achieved Relative Strength

$$ARSI_{PD} = \frac{\bar{X}^{t^E} - \bar{X}^{t^C}}{Sd} = \frac{3 - 2.5}{2} = 0.25$$

$$ARSI_{Assess} = \frac{6 - 3.5}{3} = 0.83$$

$$ARSI_{DI} = \frac{7 - 4}{3.5} = 0.86$$

$$ARSI_{Weighted} = \sum w_j ARSI_j = .25(.25) + .33(.83) + .42(.86) = 0.69$$

Caveat

$$U3 = 76\%$$

Converting ARS into a Composite Fidelity Index

$$\text{Composite Fidelity} = \frac{\text{ARSI}}{\text{RSI wgt}} = \frac{0.69}{1.94} = .36$$

Where:

$$RSI = \sum w_j (RSI_j)$$

$$RSI_{PD} = \frac{\bar{X}^{T^E} - \bar{X}^{T^C}}{Sd} = \frac{6-2}{2} = 2.0$$

$$RSI_{Assess} = \frac{8-2.5}{3} = 1.83$$

$$RSI_{DI} = \frac{10-3}{3.5} = 2.0$$

$$RSI_{Weighted} = .25(2) + .33(1.83) + .42(2) = 1.94 \qquad U3 = 97\%$$

Main points….

- Analysis of intervention fidelity and achieve relative strength is a natural counterpart to estimating ESs in ITT studies.
- They provide an interpretive framework for explaining outcome effects.
- When ES and ARSI are discordant, serve as the basis for additional analysis.
- Next section focuses on analysis of variation

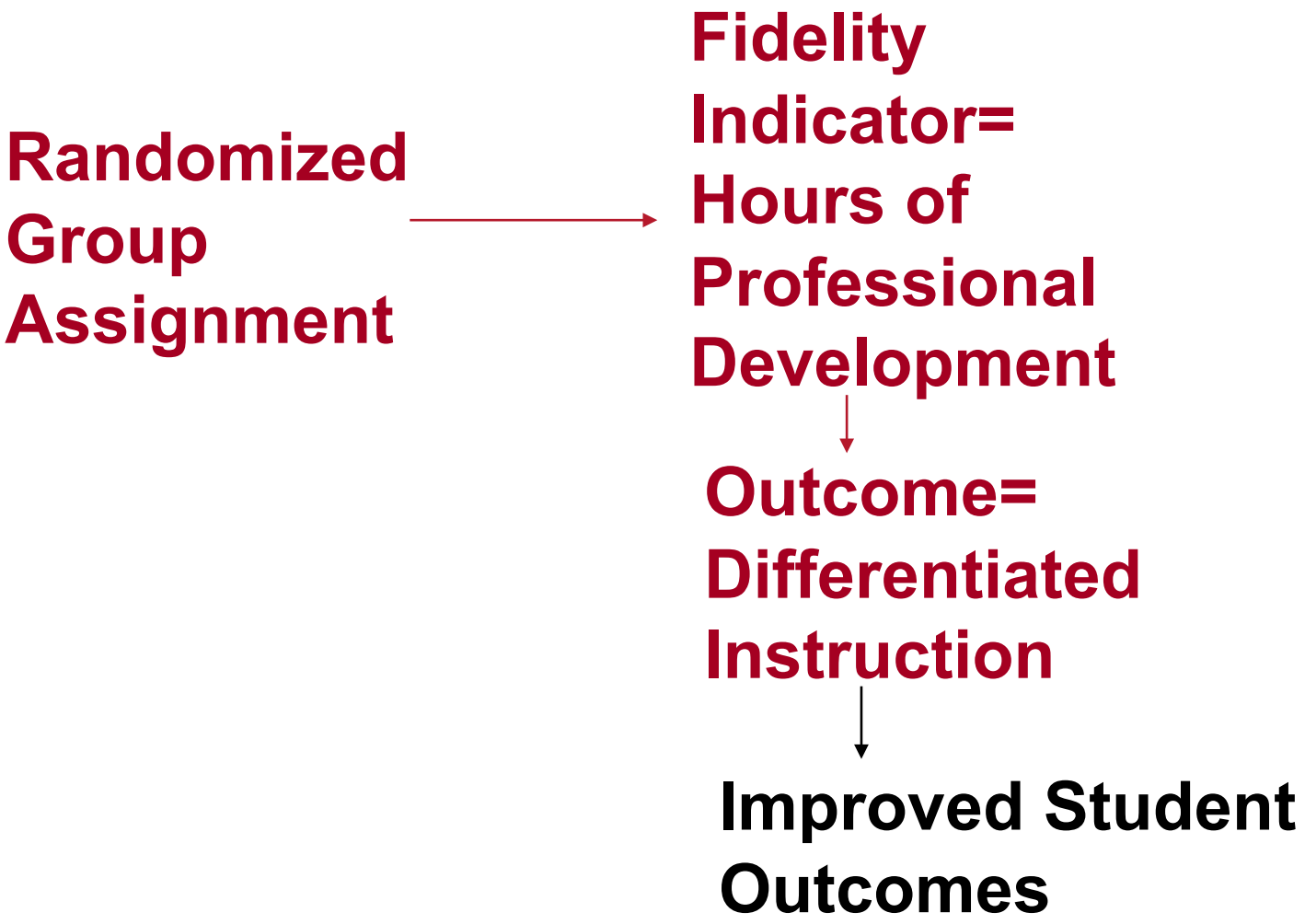
Analysis II

Linking Variation in Treatment Receipt/Delivery to Outcomes

Analyzing Variation in Treatment Receipt/Delivery Within Groups: Fidelity Indicators

- Rather than relying on the 0,1 coding of groups, fidelity indicators replace the group variable.
- New question being answered: What is the effect of treatment on those receiving treatment or TOT.
- Value of fidelity indices will depend on their strength of the relationship with the outcome;
- The greater the group difference, on average, the less informative fidelity indicators will be; and
- High predictability requires reliable indices

Using Group, Fidelity Indicators, or Both: A Simple Example



The "Value Added" of Implementation Fidelity/ARS Data

Group Separation	**U3**	**Predicting Level of Differentiated Instruction**	
		R^2_{Group}	**$R^2_{Hours\ Pro\ Development}$**
Small	**0.39**	**0.01**	**0.293*** **(0.28)**
Large	**2.36**	**0.215***	**0.437*** **(0.22)**
Very Large	**5.08**	**0.401***	**0.549*** **(0.15)**

EXAMPLE : Intent-to-treat (ITT) and Treatment- on-Treated (TOT): An Example

- Justice, Mashburn, Pence, & Wiggins (2008) examined:
  - Language-Focused Curriculum (LFC) in 14 classes;
  - Classes randomly assigned to LFC and control;
  - Core component of LFC is the use of language stimulation techniques (e.g., open questions, recasts, models); and
  - Outcome → Growth in expressive language examined (fall to spring)

Justice et al. Continued

- Implementation fidelity assessed:
  - 3 times using 2 hour observation (45 item check list) 50 min. video sample; and 40 weekly lesson plans.
- Fidelity score =
  - weighted sum of frequency of the use of 7 language stimulation techniques (range 0-21);
- Fidelity = score/21; averaged over observations
- Results:
  - LST teachers average fidelity = 0.57 (range 0.17-0.79)
  - Control teachers average fidelity = 0.32 (range 0.17-0.56)
  - ANOVA F=11.83, p = .005; d = ARSI = 1.71

Justice et al. Continued

Level 1

$$Y_{ij} = \beta_{oo} + \beta_{01}(\text{Fall Score}) + \beta_{02}(\text{Gender}) + \beta_{03}(\text{SES}) + \beta_{04}(\text{Attendance}) + r_{ij}$$

Level 2 → ITT

$$\beta_{00} = \gamma_{00} + \gamma_{01}(LFC) + u_{0j}$$

0,1 Group

Level 2 → TOT

$$\beta_{00} = \gamma_{00} + \gamma_{01}(LST) + u_{0j}$$

Fidelity Score

Justice et al. Results

Model	Reading Outcome	
	B	SE
Level 1		
Intercept	.139	
Fall Language scores	0.29**	0.06
Gender	-0.13	1.10
SES	0.10**	0.03
Attendance	0.19	0.24
Level 2 (ITT)		
Treatment (1)/Control (0)	0.64	1.43
Level 2 (TOT)		
Average observation	-0.03	0.04

What can we conclude about the ITT and TOT analyses?

- Few teachers exhibited high levels of LST use (core component of LFC)
- Fidelity overall = 0.45
- They argue, the large group difference (ARSI=1.71 for fidelity = 0.57 vs. 0.32) may not have been sufficient because the dosage (0.57) was so far below what is needed to affect language development.
- Other possibilities include:
  - Reliability of the scaling?
  - Use of average when trend in observations showed improvement?
  - Coverage of central constructs?
  - Functional form of fidelity-outcome linkage?

Hierarchy of Approaches

ITT and LATE

- ITT (Intent-to-treat) estimates (e.g., ES) plus:
  - an index of true fidelity:
    - ES=.50 Fidelity = 96%
  - an index of Achieved Relative Strength (ARS)
    - The Assign→ Hours of Professional Development example
- LATE (Local Average Treatment Effect):
  - If treatment receipt/delivery can be meaningfully dichotomized and there is experimentally induced receipt or non-receipt of treatment:
  - adjust ITT estimate by T and C treatment receipt rates.
    - Simple model can be extended to an Instrumental Variable Analysis (see Bloom's 2005 book).
- ITT retains causal status; LATE can approximate causal statements.

Treatment-on-Treated

- TOT (Treatment-on-Treated).
  - Two-level linear production function, modeling the effects of implementation factors in Tx and modeling factors affecting C in separate Level 2 equations.
  - Regression-based model, exchanging implementation fidelity scales for treatment exposure variable.
  - Simple: ITT estimate adjusted for compliance rate in Tx, no randomization
- Subject to mis-specification
- Useful in identifying potential differentiated effects and basis for new studies.

Descriptive Analyses

- Descriptive analyses:
  - Dose-response relationship
  - Partition intervention sites into “high” and “low” implementation fidelity:
    - ATOD prevention studies, the

      ES^{HIGH} =0.13 to 0.18

      ES^{LOW} =0.00 to 0.03

Key Points and Issues

- Fidelity assessment serves two roles:
  - Average causal difference between conditions; and
  - Using fidelity measures to assess the effects of variation in implementation on outcomes.
- Degree of fidelity and Achieved Relative Strength provide fuller picture of the results
- Modeling fidelity depends on the assignment model
- Most applications, fidelity is just another Level 2 or 3 variable.
- Uncertainty and the need for alternative specifications:
  - Measure of fidelity
  - Index of achieved relative strength
  - Fidelity-outcome model specification (linear, non-linear)
- Adaptation-fidelity tension

Additional Examples

EXAMPLE 2: An Elaborated Model: The Welfare to Work Experiments

- Howard Bloom and his colleagues (2005) assessed the effects of employment training on earnings in a classic set of welfare to work experiments.
- They modeled the effects of site-level implementation and program variations, controlling for client characteristics and unique aspects of site-level control conditions.
- This approach is commonly referred to as a production function: unfortunately these types of examples are very rare (but a great model for the future).

Bloom et al. Model Specification

Level 2 models

Factors affecting control group conditional mean earnings

Conditional program impact on earnings, in each office

Random Differences in the Control

Treatment

$$Y_{ji} = \alpha_j + \beta_j P_{ji} + \sum \delta_k CC_{kji} + \sum \gamma_k CC_{kji} P_{ji} + \kappa_j RA_{ji} + \varepsilon$$

Total Earnings

Assignment

Control

Client Characteristics

Some Bloom et al. Results

Cluster	Program Characteristic	B ($)	Adj B ($)
Implementation	Emphasis on quick job entry	720***	720***
	Emphasis on personal attention	428***	428***
	Closeness of monitoring	-197	- 197
	Staff caseload size	- 4***	- 268***
	Staff disagreement	124	124
	Staff-supervisory disagreement	-159*	- 159*
Activities	Basic education	- 16**	- 208**
	Job-search assistance	1	12
	Vocational training	7	71
Econ Environ	Unemployment rate	- 94***	- 291***

EXAMPLE 3: Analyzing the Reasons for Implementation Failure

- Hulleman & Cordray (2009) examined the sources of implementation failure.
- Focused on the classroom results where there were no motivation effects.
- Student behaviors were nested within teachers:
  - Teacher dosage
  - Frequency of student exposure
- Student and teacher behaviors were used to predict treatment fidelity (i.e., quality of responsiveness/ exposure).

Sources of Infidelity: Multi-level Analyses

Part I: Baseline Analyses

- Identified the amount of residual variability in fidelity due to students and teachers.
  - Due to missing data, we estimated a 2-level model (153 students, 6 teachers)

Student: $Y_{ij} = b_{0j} + b_{1j}(\text{TREATMENT})_{ij} + r_{ij}$,

Teacher: $b_{0j} = \gamma_{00} + u_{0j}$,

$b_{1j} = \gamma_{10} + u_{10j}$

Sources of Infidelity: Multi-level Analyses

Part II: Explanatory Analyses

- Predicted residual variability in fidelity (quality of responsiveness) with frequency of responsiveness and teacher dosage

Student: $Y_{ij} = b_{0j} + b_1(\text{TREATMENT})_{ij} + \mathbf{b_2(RESPONSE\ FREQUENCY)_{ij}} + r_{ij}$

Teacher: $b_{0j} = \gamma_{00} + u_{0j}$

$b_{1j} = \gamma_{10} + \mathbf{b_{10}(TEACHER\ DOSAGE)_j} + u_{10j}$

$b_{2j} = \gamma_{20} + \mathbf{b_{20}(TEACHER\ DOSAGE)_j} + u_{20j}$

Sources of Infidelity: Multi-level Analyses

	Baseline Model		Explanatory Model	
Variance Component	Residual Variance	% of Total	Variance	% Reduction
Level 1 (Student)	0.15437*	52	0.15346*	< 1
Level 2 (Teacher)	0.13971*	48	**0.04924**	**65***
Total	0.29408		0.20270	

* $p < .001$.

Case Summary

- The motivational intervention was more effective in the lab (g = 0.45) than field (g = 0.05).
- Using 3 indices of fidelity and, in turn, achieved relative treatment strength, revealed that:
  - Classroom fidelity **<** Lab fidelity
  - Achieved relative strength was about 1 SD less in the classroom than the laboratory
- Differences in achieved relative strength = differences motivational outcome, especially in the lab.
- Sources of fidelity: teacher (not student) factors

And, finally….