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Quantitative Approaches for Studying Context-Dependent, Time-Varying, Adaptable Complex Social Interventions

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Quantitative Approaches for Studying Context-Dependent, Time-Varying, Adaptable Complex Social Interventions

or

What to do when you wish to conduct a quantitative study to evaluate an implementation strategy that varies across time and place, for which outcomes are affected by site characteristics to a greater extent than by the intervention, and where intervention effects are largely indirect?

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What to do when you wish to conduct a quantitative study to evaluate an implementation strategy that varies across time and place, for which outcomes are affected by site characteristics to a greater extent than by the intervention, and where intervention effects are largely indirect?

In other words:

How do we evaluate the large set of implementation strategies that do not show consistent, large effects across diverse quality/implementation problems and settings?

Acknowledgements

- Susanne Salem-Schatz
- Paul Plsek
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Implementation research definition

Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services.

It includes the study of influences on healthcare professional and organizational behavior.

Eccles and Mittman, 2006

Implementation research goals

1. Develop reliable strategies for improving health-related processes and outcomes; facilitate widespread adoption of these strategies

2. Produce insights and generalizable knowledge regarding implementation *processes*, *barriers*, *facilitators*, *strategies*

3. Develop, test and refine implementation theories and hypotheses; methods and measures

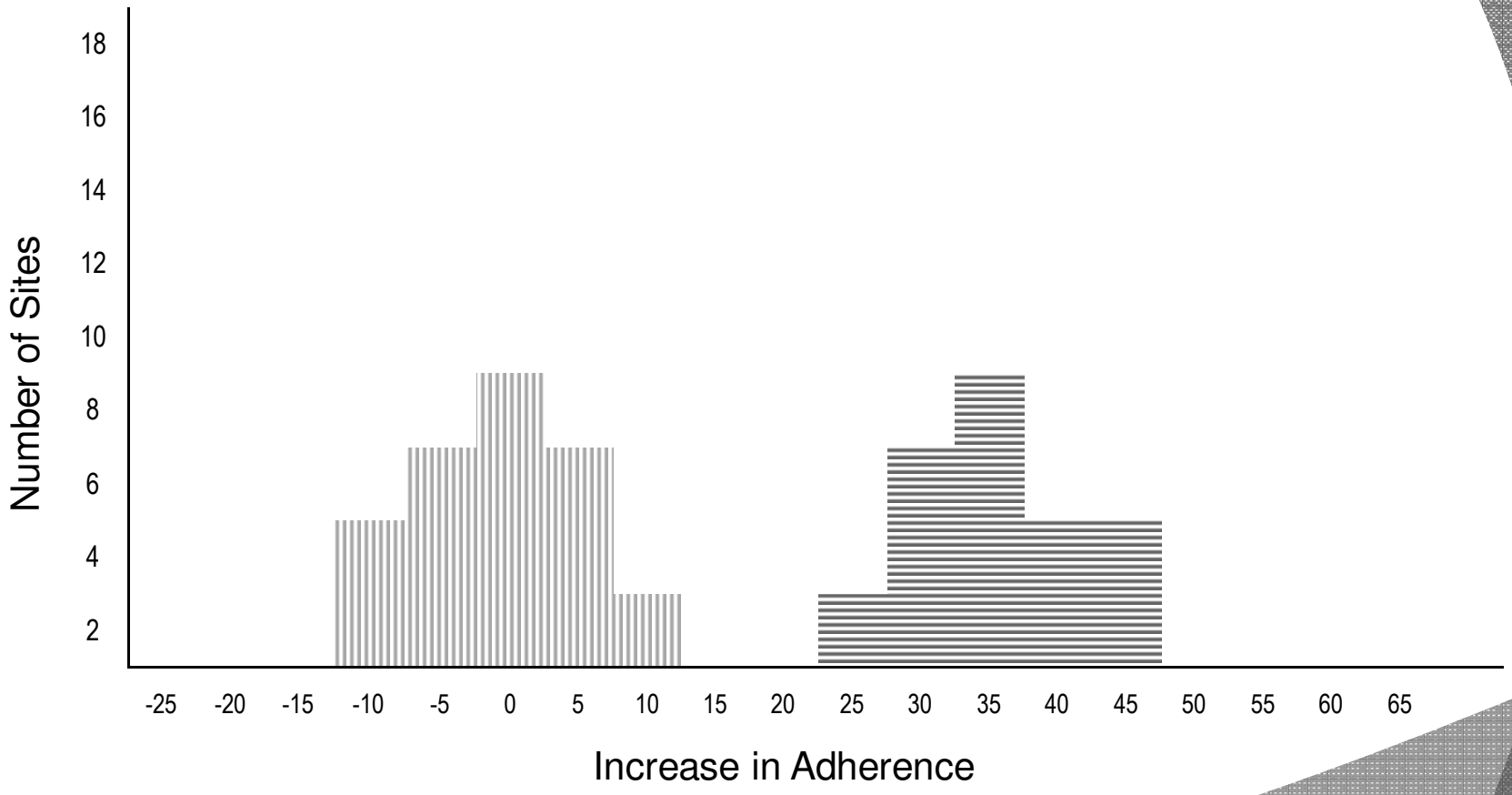
Implementation research goals

1. Develop reliable [effective] strategies for improving health-related processes and outcomes
   - Assumes "reliable strategies" can be developed

Unfortunately:

- Implementation <u>outcomes</u> are strongly influenced by contextual factors; implementation strategy *main effects* are often weak
- Implementation <u>strategies</u> and <u>processes</u> are strongly influenced by contextual factors, leading to significant variations across time and place
- Implementation strategy <u>impacts</u> are often indirect (mediated), and thus attenuated and variable

Impacts of implementation strategies:
Scenario A: Strong effects, moderate variance



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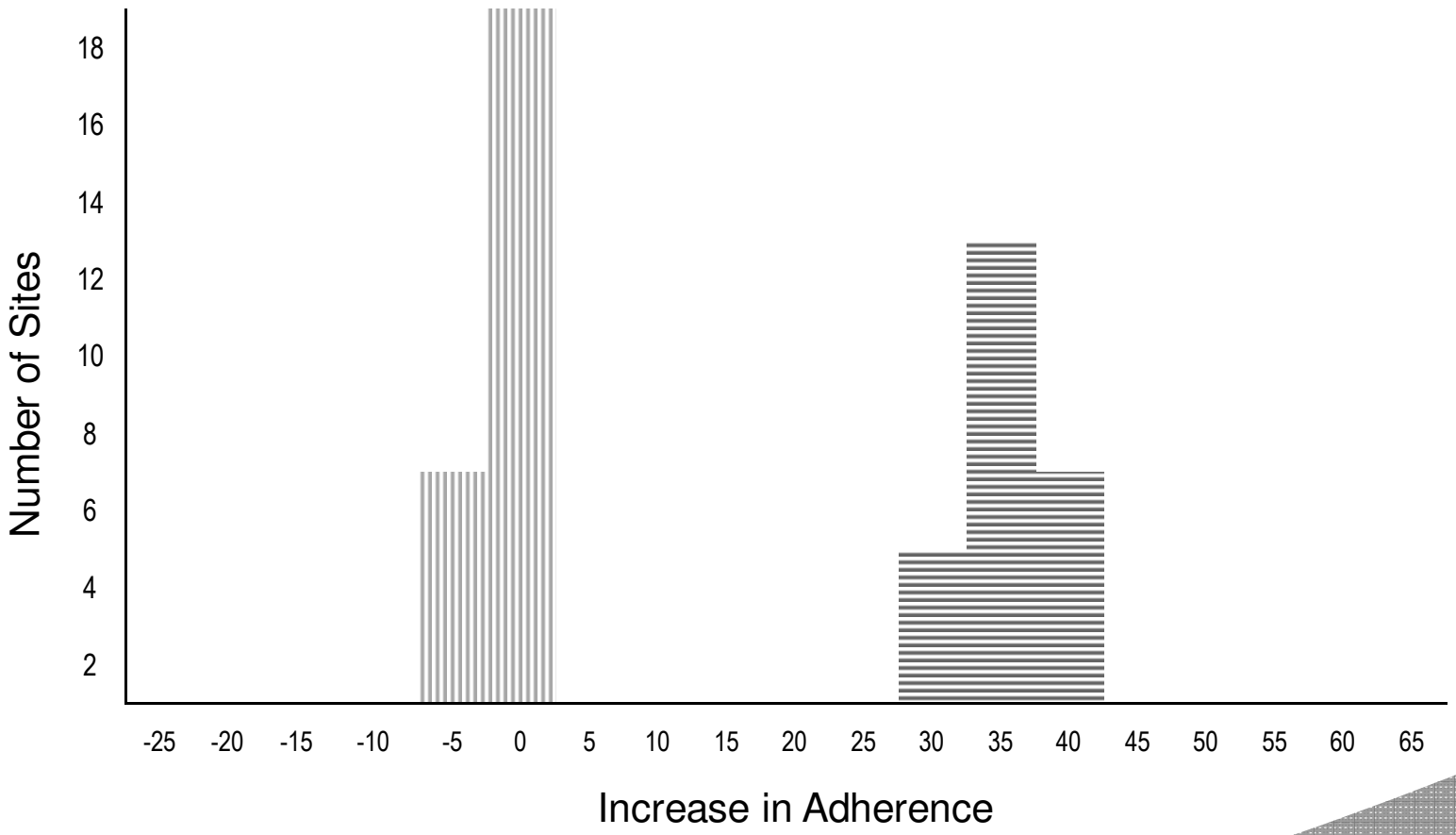
Impacts of implementation strategies:

Scenario B: Strong effects, very low variance



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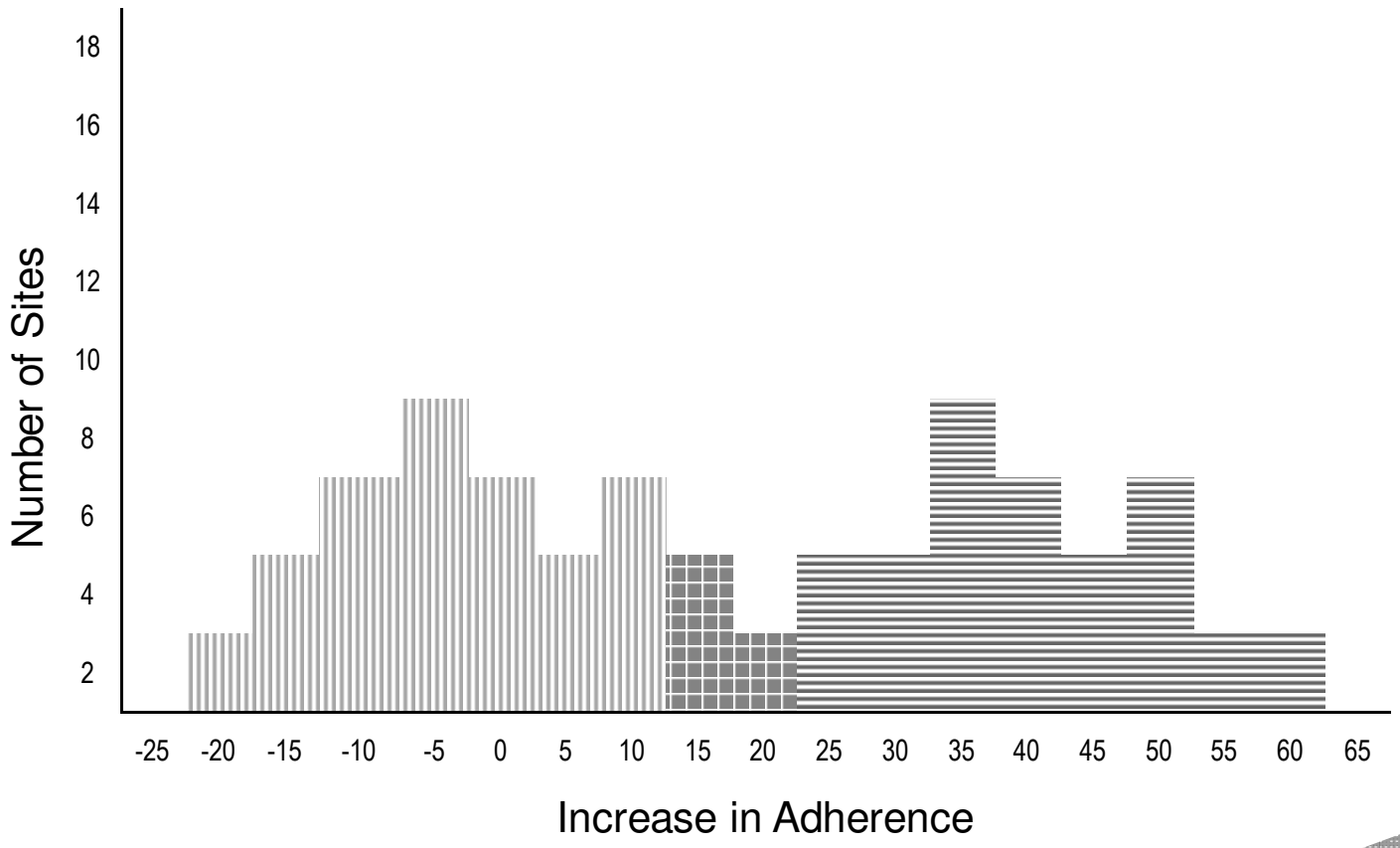
Impacts of implementation strategies:

Scenario C: Strong effects, high variance



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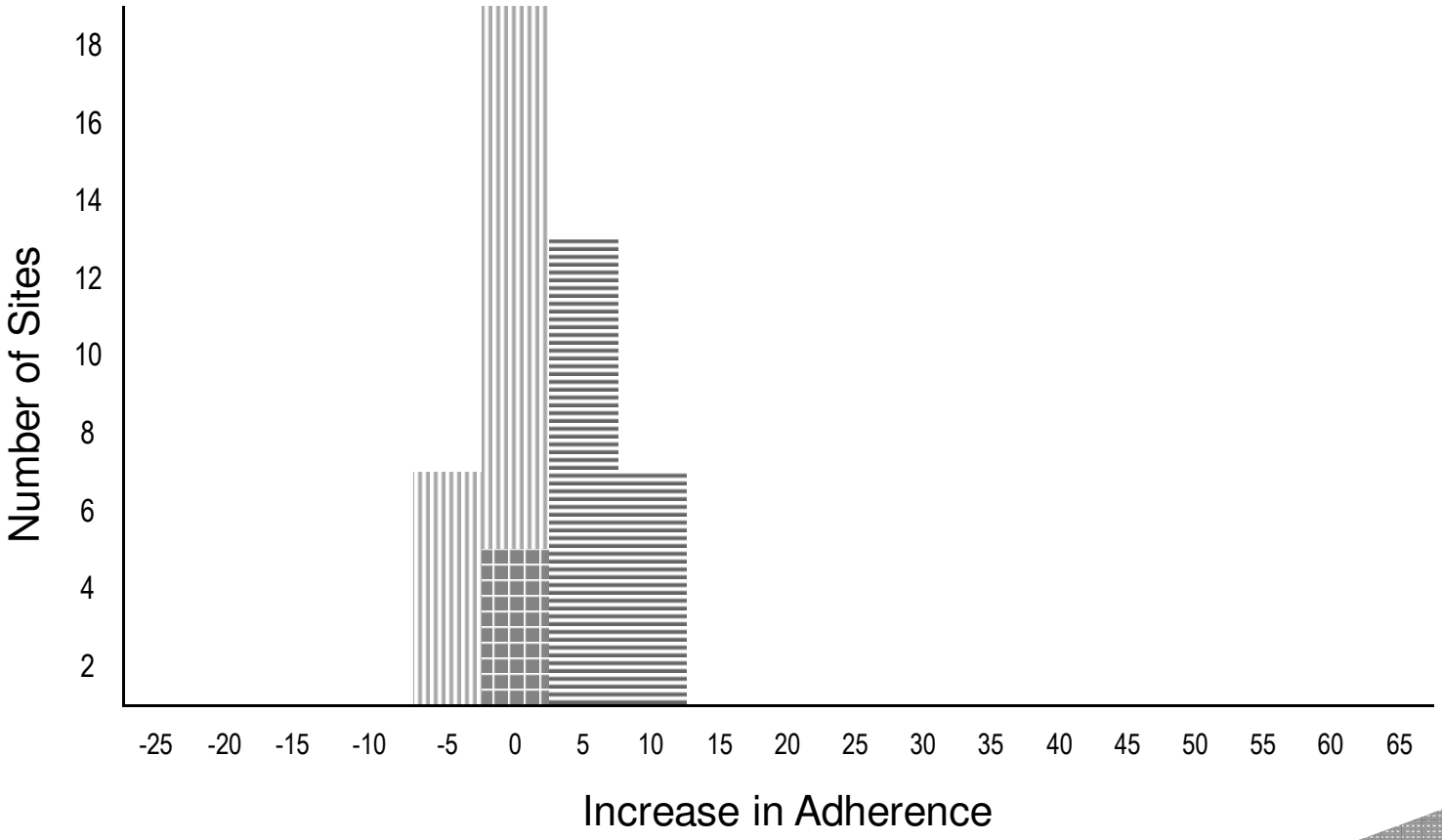
Impacts of implementation strategies:

Scenario D: Weak effects, very low variance



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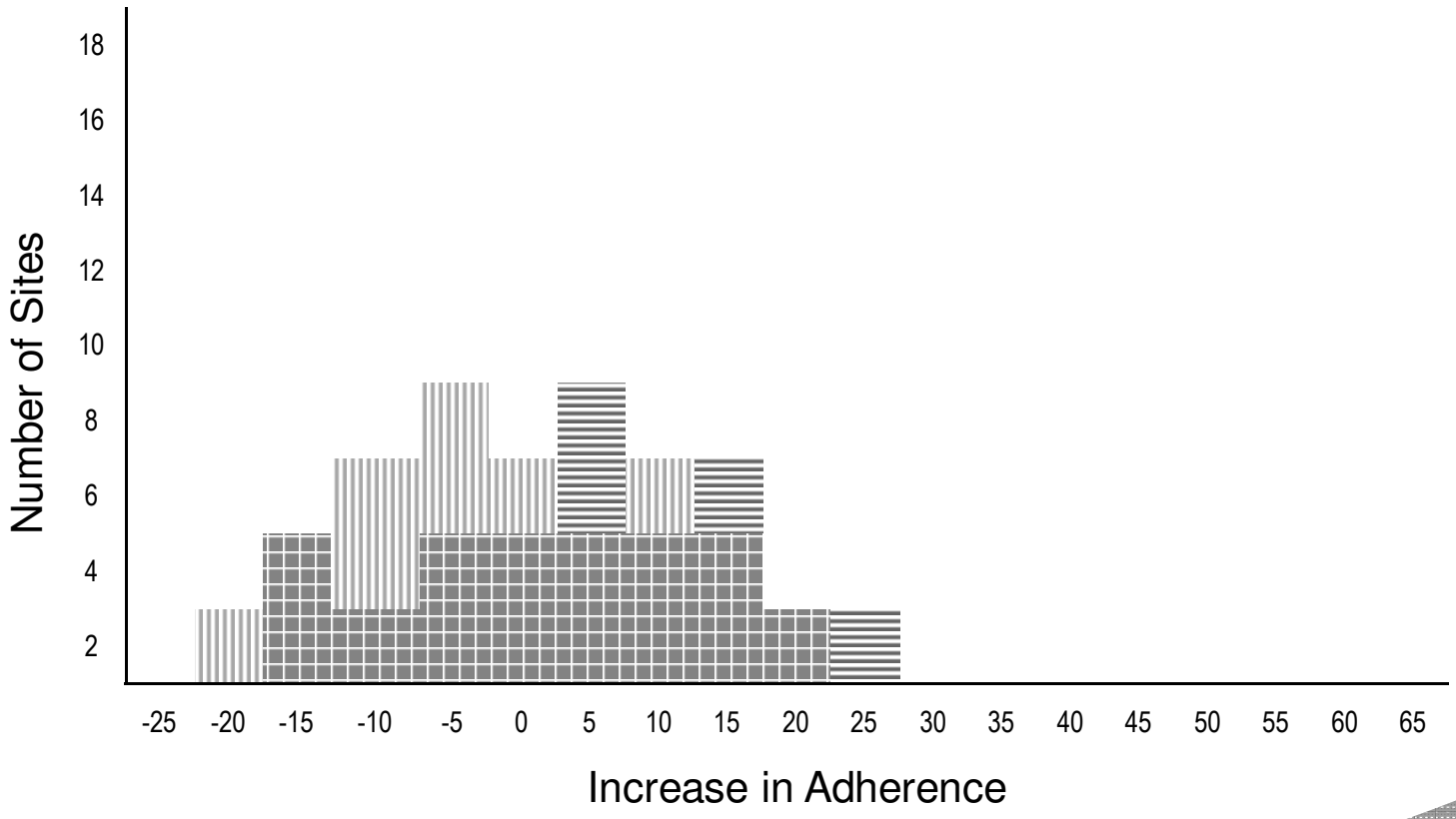
Impacts of implementation strategies:

Scenario E: Weak effects, high variance



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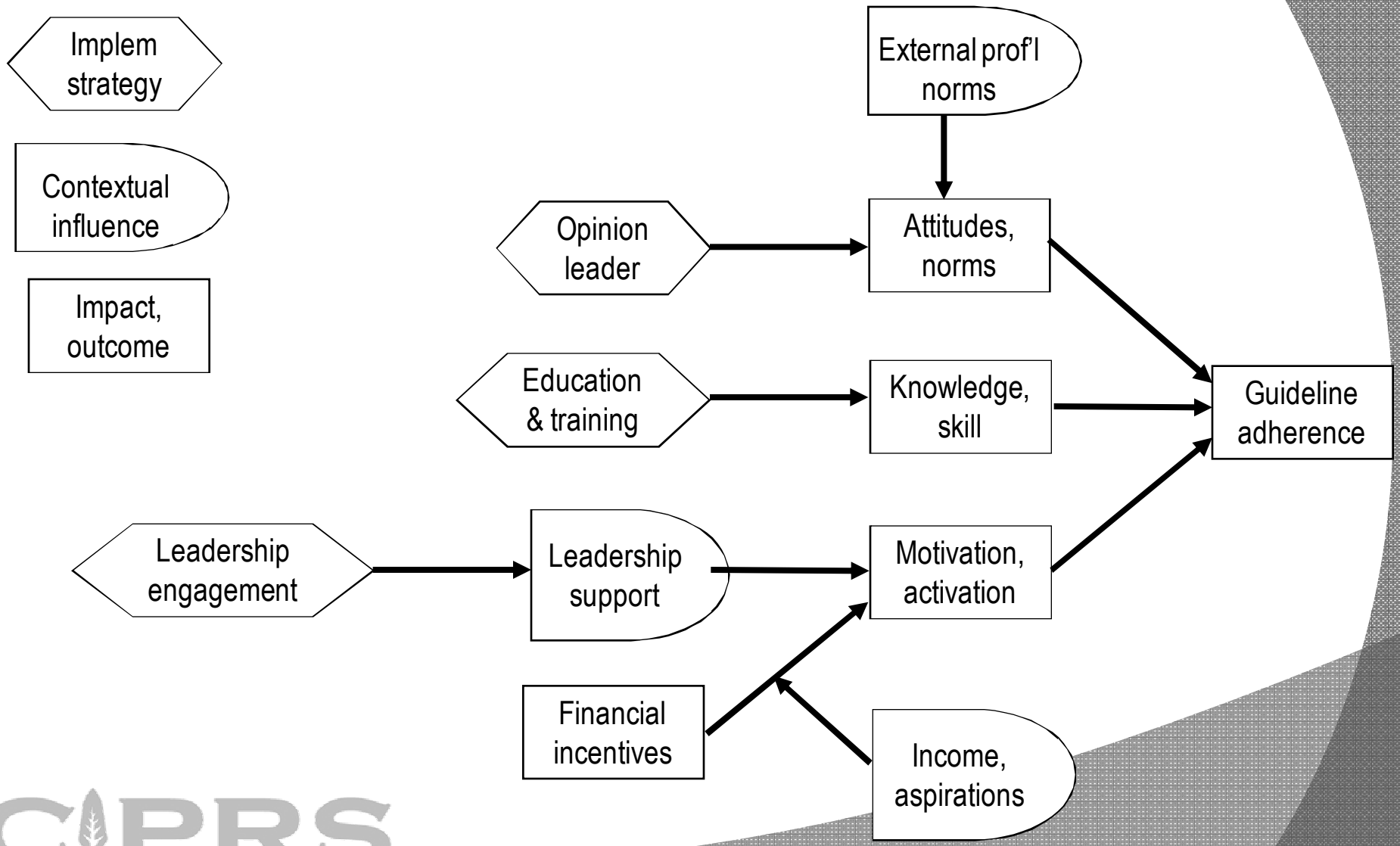
Key sources of heterogeneity, weak main effects, null findings

- Contextual factors affect implementation outcomes; main effects of the implementation strategy are often weak
  - Contextual influences (covariates)
- Contextual factors affect implementation (1) strategies and (2) processes (impacts) – leading to variation across time and place
  - Adaptive (and unstable) treatments (1)
  - Moderator effects (2)
- Implementation strategy impacts are often indirect (mediated), attenuated and variable
  - Mediator effects

Contextual, mediator, moderator effects



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Contextual influences on outcomes

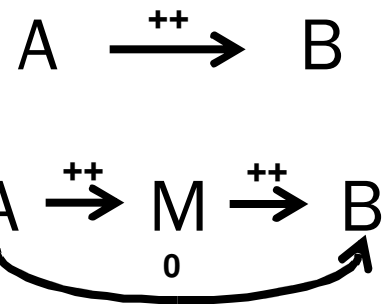
- Considerable guidance available (observational designs, interaction effects, propensity scores, etc.)
- See Duan et al., Chapter 12. Description of Ideal Evaluation Methods: Quantitative Approaches to Context Heterogeneity in Shekelle PG et al., *Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria*. AHRQ Publication No. 11-0006-EF, December 2010. Rockville, MD: . Agency for Healthcare Research and Quality, www.ahrq.gov/qual/contextsensitive/

Moderators

- A moderator is a variable that affects the relationship between an independent and dependent variable
- Examples: income level/aspirations moderate the effect of financial incentives on clinician practices; budget, leadership and culture moderate the impact of an QI initiative on quality
- Evidence regarding moderator variables provides insights into variations in program effectiveness: where, when, why and for whom programs are effective

Mediators and mediation

- A mediator is a variable that explains or carries the relationship between an independent and dependent variable



- Example: leadership activation mediates the impact of a leadership engagement intervention on quality
- Evidence regarding mediator relationships explains variations in program effectiveness, apparent weaknesses in effectiveness, and guides actions to increase effectiveness

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Moderators and mediators: selected references

- Frazier PA, Tix AP, Barron KE. Testing moderator and mediator effects in counseling psychology research. J Couns Psychology. 2004;51:115-134.
- MacKinnon DP, Fairchild AJ, Fritz MS. Mediation analysis. Annu Rev Psychol. 2007;58:593-614.

Related concepts and published discussions

Heterogeneity of treatment effects

- Duan Gabler NB, Duan N, Liao D, Elmore JG, Ganiats TG, Kravitz RL. Dealing with heterogeneity of treatment effects: is the literature up to the challenge? Trials. 2009 Jun 19;10:43.
- Kravitz RL, Duan N, Braslow J. Evidence-based medicine, heterogeneity of treatment effects, and the trouble with averages. Milbank Q. 2004;82(4):661-87.

Related concepts and published discussions

Personalized medicine, patient-centered outcomes research

- Lee JJ, Xuemin Gu, Suyu Liu. Bayesian adaptive randomization designs for targeted agent development. Clin Trials. 2010 Oct;7(5):584-96. Epub 2010 Jun 22.
- Khoury MJ, Rich EC, Randhawa G, Teutsch SM, Niederhuber J. Comparative effectiveness research and genomic medicine: an evolving partnership for 21st century medicine. Genet Med. 2009 Oct;11(10):707-11.
- Garber AM, Tunis SR. Does comparative-effectiveness research threaten personalized medicine? N Engl J Med. 2009 May 7;360(19):1925-7.

Related concepts and published discussions

Adaptive trials

- Müller HH, Schäfer H. Adaptive group sequential designs for clinical trials: combining the advantages of adaptive and of classical group sequential approaches. Biometrics. 2001 Sep;57(3):886-91.
- Lang T. Adaptive trial design: could we use this approach to improve clinical trials in the field of global health? Am J Trop Med Hyg. 2011 Dec;85(6):967-70.

Related concepts and published discussions

Theory-based evaluation realistic evaluation

- Greenhalgh T, Humphrey C, Hughes J, Macfarlane F, Butler C, Pawson R. How do you modernize a health service? A realist evaluation of whole-scale transformation in London. Milbank Q. 2009 Jun;87(2):391-416.
- Rycroft-Malone J, Fontenla M, Bick D, Seers K. A realistic evaluation: the case of protocol-based care. Implement Sci. 2010 May 26;5:38

Related concepts and published discussions

Theory-based evaluation realistic evaluation

Generating, testing and refining program theories is "not a logical-deductive exercise. Rather, it is an interpretive task and will be achieved only through much negotiation and contestation."

(Greenhalgh et al, 2009)

"Two practical lessons we have learnt through the project management plan include the need to ensure … adequate time for discussion and debate, and developing flexible, yet transparent approaches for tracing iterative processes."

(Jo Rycroft-Malone, 2010)

Related concepts and published discussions

Path analysis, structural equation modeling

- Aarons GA, Sommerfeld DH, Walrath-Greene CM. Evidence-based practice implementation: the impact of public versus private sector organization type on organizational support, provider attitudes, and adoption of evidence-based practice. Implement Sci. 2009 Dec 31;4:83.
- Scott SD, Plotnikoff RC, Karunamuni N, Bize R, Rodgers W. Factors influencing the adoption of an innovation: an examination of the uptake of the Canadian Heart Health Kit (HHK). Implement Sci. 2008 Oct 2;3:41.

Introduction to Structural Equation Models

Martin L. Lee, PhD

What are we going to do today?

- What is SEM?
- Research questions you can address using SEM
  - Models you can fit using SEM
- SEM assumptions
- Model Identification
  - How to set up a 'testable' model

What is SEM?

- An extension of the general linear model that enables researchers to fit more than one regression equation simultaneously

- Encompasses a larger number of statistical procedures including latent variable analysis, confirmatory factor analysis, causal modeling, LISREL analysis, growth curve modeling, etc.

Characteristics of SEM Analysis

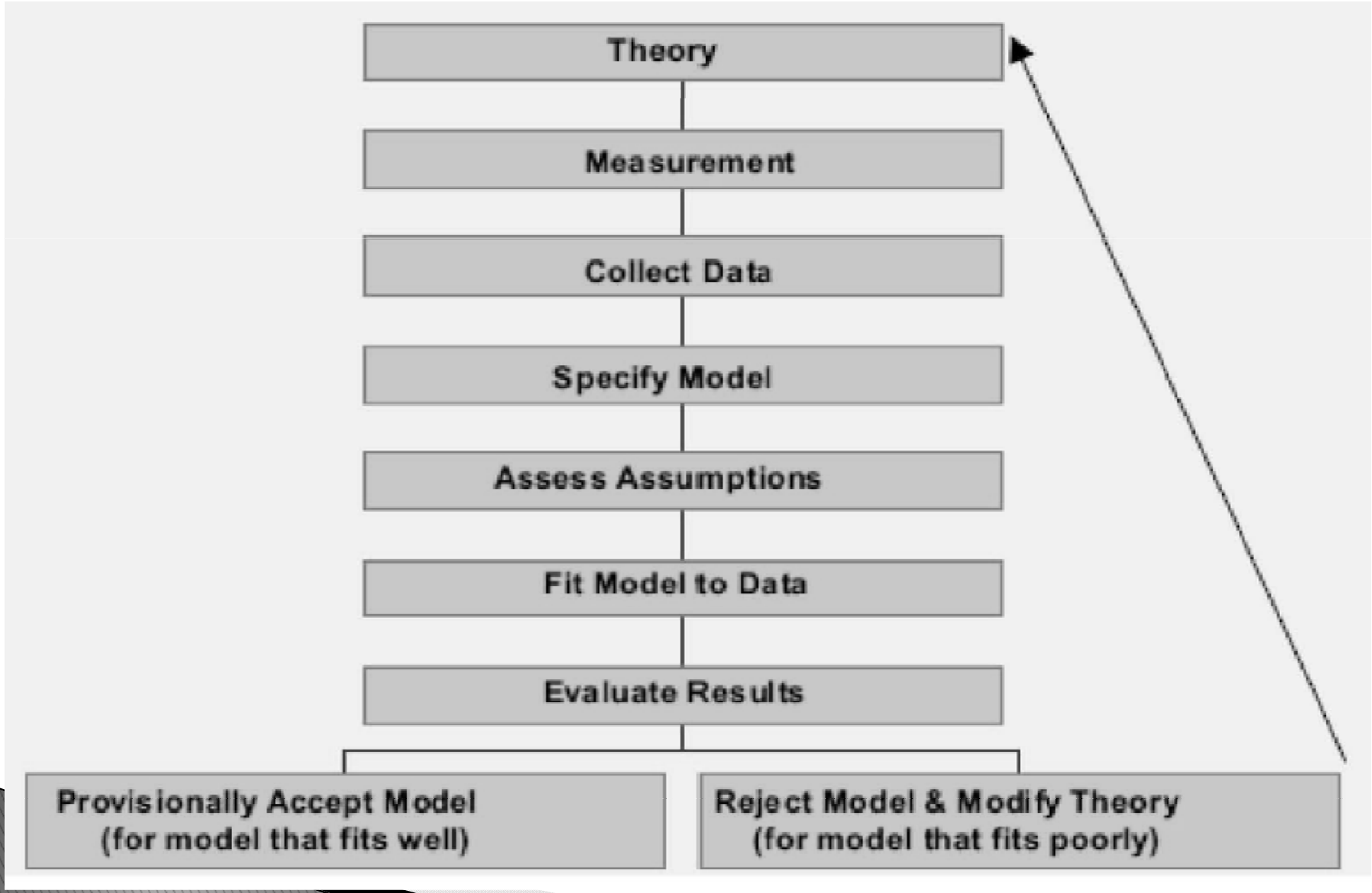
- Estimation of multiple and interrelated dependence relationships
- The ability to represent "unobserved“ concepts into these relationships

What is the purpose of SEM?

- The primary purpose of SEM rests in the adequacy of a predetermined theoretical model to explain relationships among observed variables and/or unobserved variables

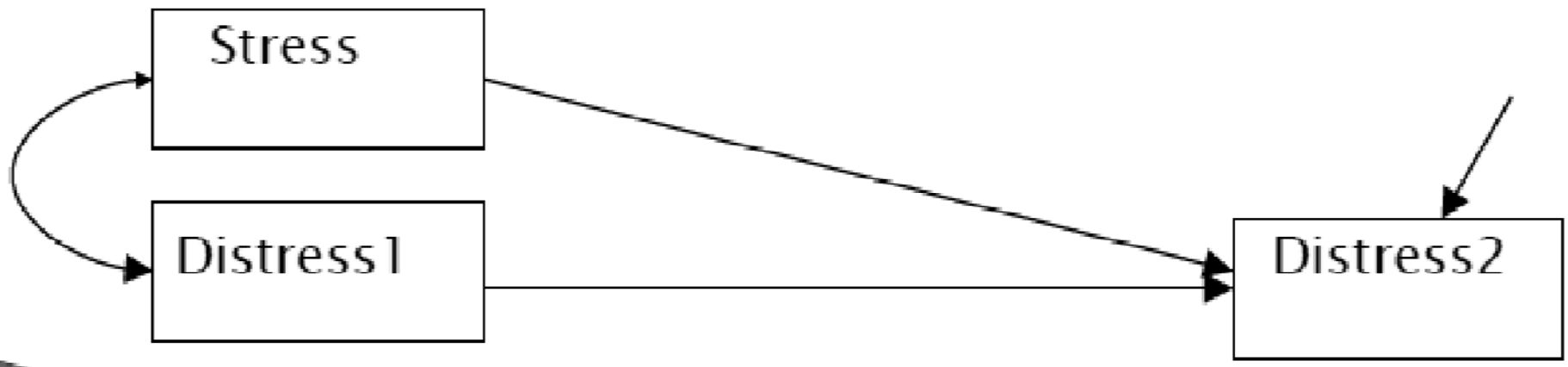
- By far, the strongest argument in support of SEM is the need for researchers to explicitly state their a priori causal theory

Steps in using SEM



Example of an SEM

- Extreme stress is known to lead to psychological breakdown (Battle fatigue, PTSD)
- Severe stress is believed to cause depression, anxiety disorder, psychosis



Stress causes distress and psychopathology

- To what extent is this common belief true?
- How much stress is needed to cause distress?
  - For a unit change in stress, how much do we expect distress to increase?
- How do we account for the many persons who experience stress who manage to function without psychopathology?
  - Is the purported causal process universal, or does it operate only in a subset of the population?

What is the difference between SEM and other procedures?

- Multiple Regression – several predictors can be used to predict the criterion, but only one DV can be modeled

- Multivariate Multiple Regression – several predictors and criterions can be used, but statistically only one relationship is estimated (between the linearly combined DVs and linearly combined IVs)

What is the difference between SEM and other procedures

- Factor Analysis – several factors can be extracted from a set of variables, but we cannot simultaneously examine complex relationships among the factors

- Multilevel Modeling – does not handle factors (latent variables) or larger models (e.g. , variables that are simultaneously predictors and outcomes) as easily as SEM

Important Advantages of SEM

- The incorporation of latent variables can significantly reduce measurement error
  - In other words, the more indicators you have for a factor the better
- Graphical modeling interface
- Availability of tests of 'Global Model Fit'
- Ability to include multiple outcome variables
- Ability to model error terms
- Ability to test coefficients across multiple groups

Intro to SEM Analysis

- The goal is to get the estimated population covariance matrix to be as close to the sample covariance matrix as possible –with as few “free” parameters as possible (i.e. , you want to explain as much of the sample covariance structure as possible with the simplest model)

- This involves minimizing the ’residual covariance matrix‘
  - Residual matrix:
    - Estimated population matrix – Input sample matrix

SEM Inputs

- Independent variables
  - Predictors, e. g. , quality of father's occupation
- Dependent variables
  - Outcomes, e.g., quality of an obtained job after university
- Mediating variables
  - Intermediate outcomes on the path to the ultimate outcome, e.g., level of degree obtained at university

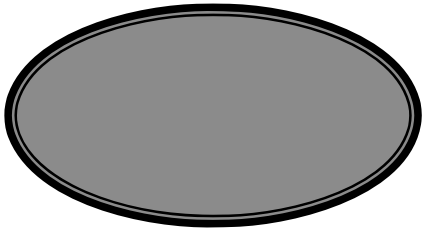
SEM Lingo

- Manifest or observed variables
  - Measured variables that are often indicators of a factor (latent variable)
- Latent variables
  - Unobserved variables or factors
    - Inferred from the shared variance among observed variables
- Path diagrams
  - Visual representations of relationships among variables

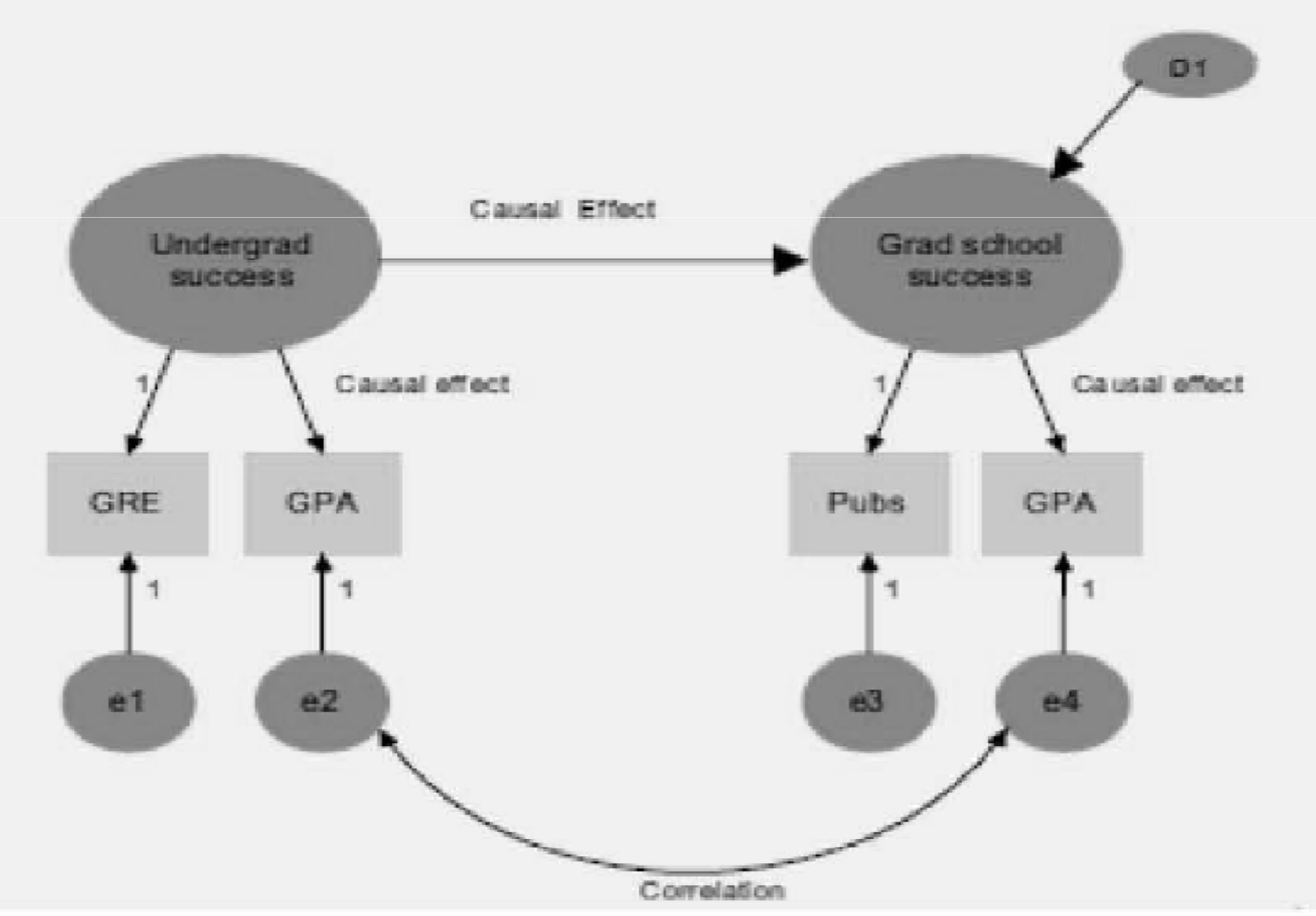
SEM Lingo

- Measurement Model
  - Involves relationships among observed variables or the specification of indicators for latent variables
- Structural Model
  - Involves relationships among latent variables
  - Often contains the "risky predictions" of the model
- Note: The fit of the structural model cannot be assessed until there is evidence that the measurement model is correct (more to come)

Understanding/Creating Path Diagrams

- Latent variables = circles or ovals 
- Observed variables = rectangles
- Correlation/Covariance = curved arrows
- Directional effect = straight arrows

Path Diagram of an Educational Model

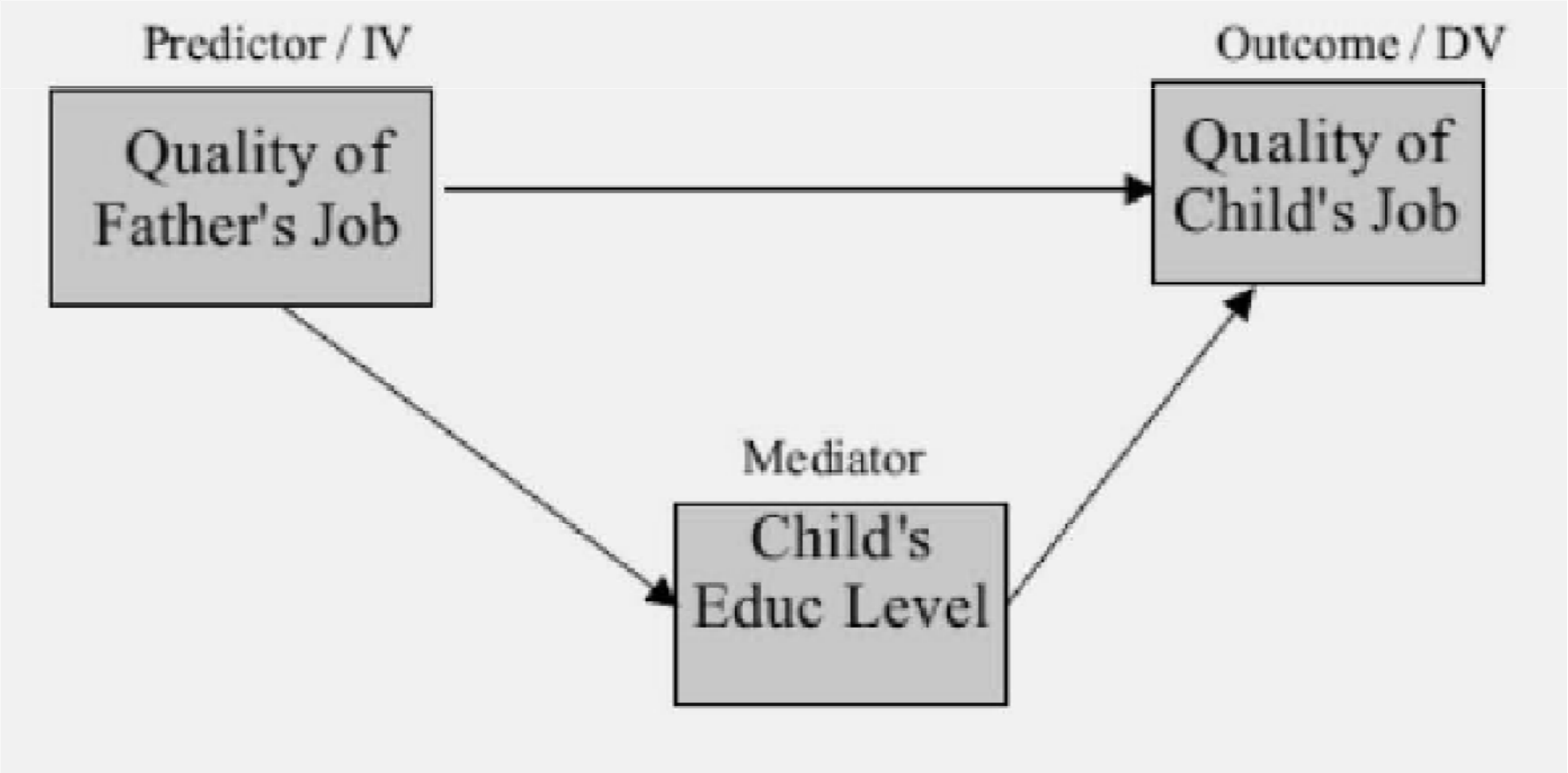


Models you can fit using SEM

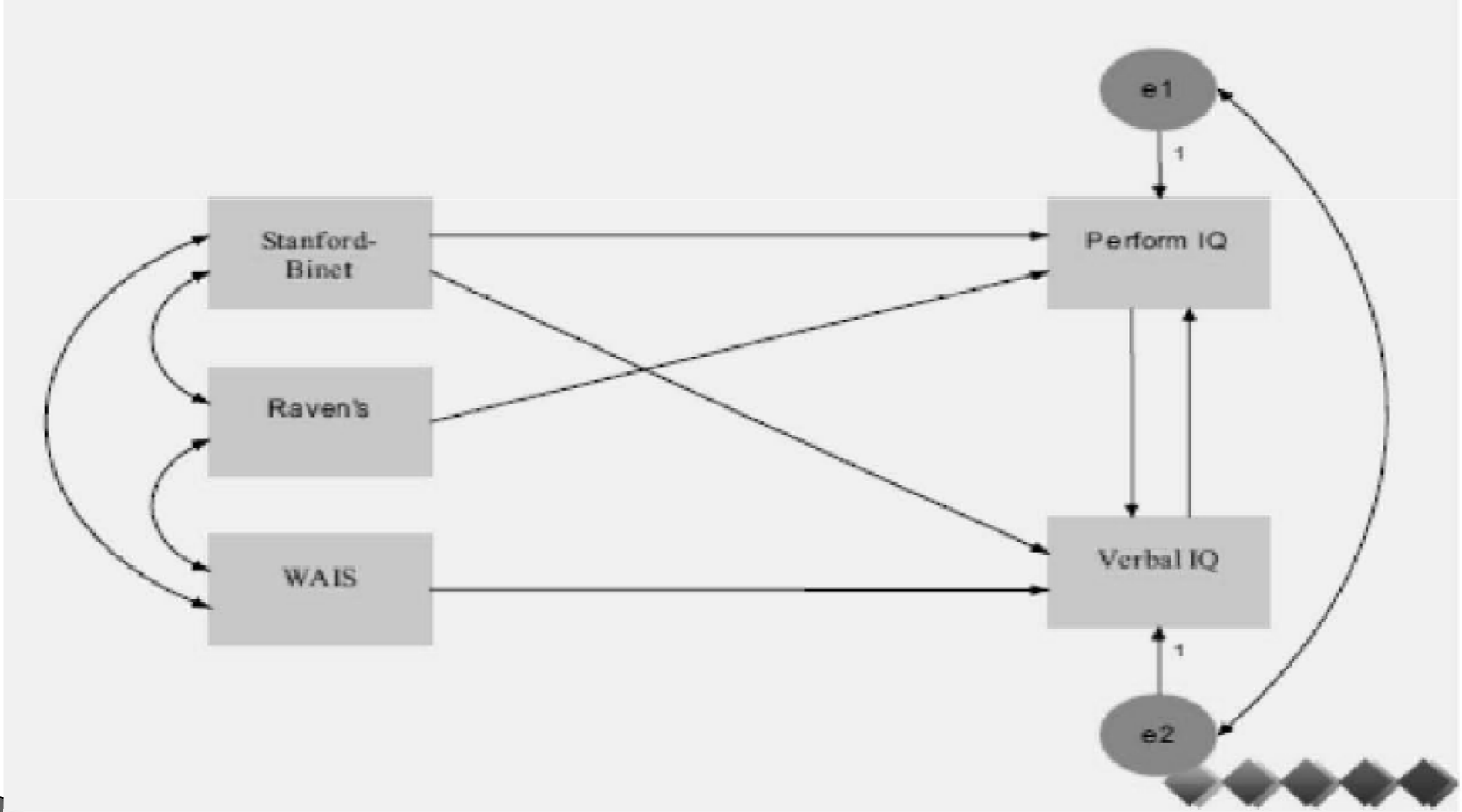
- Regression models with multiple dependent measures (path analysis)
- Mediation models
- Factor analysis models for scale development
- Longitudinal growth models
- Reciprocal causality models
- Many others

Path Analysis: Is there an indirect effect of quality of father's job on child's job quality?

- The specified model:



Reciprocal Causality Model



SEM Requirements/Assumptions

- A reasonable sample size
- Continuous and normally distributed dependent or mediating variables
- Complete data or appropriate handling of incomplete data
- Theoretical basis for model specification and causality interpretation
- Linear relationships among variables

Sample Size

- Five cases minimum per estimated parameter [Bentler & Chou (1987)]
- Monte Carlo studies recommend 100 cases minimum; 200 is better for modest models [Loehlin (1992)]
- Larger models require more cases
  - i.e., models with more latent variables or parameter estimates
- Example rule of thumb:
  - $N \geq 8*J$, where J is the number of observed variables in the model

Distribution

- Dependent and mediating variables are assumed to be continuously and normally distributed
  - Each observed variable should be univariate normal
  - All variables should be joint multivariate normal

Evaluating Models

- SEM models can never be accepted; they can only fail to be rejected
  - *Provisionally accept* models that fit well
  - Other alternative models may fit the data equally well, if not better, than the proposed model
  - Researchers must be vigilant for and test reasonable alternative models

- Models that fail to fit well can be rejected

Causality

- Use of SEM entails causal uncertainty, especially with cross-sectional data that are not collected under controlled, randomized designs
  - Recall that to infer cause and effect we require temporal ordering, existence of a covariance, and control for other potential causes
- A lot of criticism has been directed at SEM because of associated terms such as "causal modeling" and "causal pathways"
- It is important to remember that SEM still falls under the category of a "correlational analysis"

Parcelling

- What if you have 35 responses to a questionnaire on depression and you want to include all of them as predictors?
  - You can!
  - Or, you can "parcel" the items to reduce the number of predictors
    - There should be strong theory to support the parcels

Establishing Structural Model Relationships

- Relationships in the structural model often involve the important hypotheses of the study
  - For example, a researcher may be interested in confirming an existing theory or deriving a new theory

- These may involve relationships among latent variables, observed predictors of latent variables, latent predictors of observed variables, between-group differences on relationships/means, etc.

Competing Models Strategy

- In a competing models strategy you are interested in comparing the fit of two different models (i.e., determining if one model fits the data "significantly" better than another model)

- In order to be able to conduct a null hypothesis test that the fit is equivalent the models must be "nested" (i.e., one model is a subset of another)
  - If the models are not nested, the AIC statistic can be used to assess which model "fits" better

SEM Software

- AMOS
  - Best diagrammer; bootstrap; easiest to use
  - Lack of categorical and multilevel options
  - www.smallwaters.com

- Mplus
  - Best modeling capabilities, especially for medical data
  - No diagrammer; defaults can be confusing
  - www.statmodel.com

SEM Software

- LISREL
  - Fairly flexible, especially for large models
  - Not intuitive
  - www.ssicentral.com

- EQS
  - New version 6.0 will have numerous features
  - New version 6.0 release delayed indefinitely
  - www.mvsoft.com

SEM Software

- SAS
  - CALIS procedure may be used to fit SEMs
  - Many modern features are absent (e.g., multiple sample models)