Learning How Things Work in Complex Early Childhood Interventions: Research Frameworks and Methods to Support Causal Reasoning

Presenters: Kirsten Kainz, Allison Metz, Noreen Yazejian, University of North Carolina at Chapel Hill

Discussant: Meka Sales, The Duke Endowment

Overview

This symposium will present three papers about research methods relevant for causal reasoning during complex early childhood intervention development and implementation, followed by discussion from a unique stakeholder in complex evaluations, a funder. Complex interventions involve multiple components delivered by multiple agencies and/or departments within an agency. The first paper serves as a conceptual framework for causal reasoning in the early stages complex intervention development. The second paper describes a systematic method for operationalizing the core functions of underspecified components of a complex intervention. The third paper presents examples of data collection strategies for complex evaluations. All together the three papers demonstrate methods that are intended to support learning about complex interventions, learning which poses two distinct categories of tensions and tradeoffs for evidence use.

First, intervention development and implementation require not only that evidence be gathered through evaluation, but also that practitioners and other stakeholders related to the intervention have a chance to make sense of emerging evidence and guide program adaptation through decision making based on evidence. Therefore, evaluation methods must yield evidence that is timely and actionable to support decision making about program implementation. Second, complex interventions have multiple intervention components with varying levels of specification and operationalization. Consider the introduction of evidence-based home visiting to a county health system, where the home visiting program is well operationalized but communication among referral agencies such as obstetric and pediatric care systems and public and private early childhood education systems is not yet established. Full access to and participation in evidence-based home visiting – and subsequent countywide impact on early childhood well being – will not be realized in the absence of a coordinated referral system, but such a system will have to be developed during implementation of home visiting services. Therefore, evaluation must involve design and testing strategies that reveal effective components of complex interventions that are underspecified at the start of implementation.

The discussant will reflect on the challenge of gathering evidence of impact in complex interventions from the unique perspective of a funder. The discussant will also facilitate questions from and discussion with the audience.
A Framework for Thinking about Cause and Effect in Complex Interventions

Kirsten Kainz, University of North Carolina at Chapel Hill

Background/Context

Researchers carefully design intervention evaluations to identify effects of known causes (e.g., improved reading outcomes resulting from reading intervention). However, successful replication and transport of interventions, even those deemed efficacious through rigorous evaluation, rely on more than estimates of effects generated under rigorous design. Replication and transport require well developed theories of cause that account for the constellation of factors that underlie an observed effect – factors known and manipulated by the experimenter, factors known and not manipulated by the experimenter, and factors unknown to the experimenter. Such factors include moderators and mediators of intervention effects as well as post-randomization group differences that serve as other causes of the observed effect (Deaton & Cartwright, 2017; Shadish, 2010).

Causal theorizing can be improved through reasoning about and evidence of the necessary and sufficient factors required for a cause to produce an effect. Mackie’s description of insufficient but non-redundant parts of an unnecessary but sufficient condition (INUS: Mackie, 1974 as presented in Illari and Russo, 2014) can be helpful for thinking about the factors that contribute to, enhance, or constrain effects from education interventions. Mackie’s classic example is the case of an electrical short-circuit leading to a house fire. The short-circuit alone is not sufficient to cause a fire. Rather, fuel and oxygen are needed for the fire to result. Still, the short-circuit is a salient cause, even if insufficient to produce the effect in isolation.

Identifying a constellation of causal factors and their relative contribution to effects observed in education interventions delivered to individuals or in classrooms can be challenging. The challenge increases with additional intervention components. Interventions that occur at organizational or community levels and require coordinated action across multiple agencies and at multiple levels of an agency pose more and more unknown challenges for causal reasoning. In many cases organizational/community interventions combine well operationalized and perhaps even evidence-based components that, to be implemented, require additional components in the form of coordination and communication across multiple levels (teachers, principals, central office) and agencies (public schools, youth serving organizations, county government). In such cases coordination and communication functions serve as critical intervention components that might be unidentified or under-specified at the start of implementation. A framework of guiding questions for evaluation can support learning about critical intervention components, allowing for better reasoning about the necessary and sufficient components of organizational/community interventions that lead to desired impacts.

Purpose/Objective/Research Question
The purpose of this work is to articulate a classification of guiding questions that can structure the initial phases of implementation and evaluation of organizational/community interventions. The classification is derived from existing frameworks for complex evaluation, implementation methods, and developmental evaluation methods.

In 2000 and then again in 2008 the Medical Research Council – the UK counterpart to the National Institutes Health - issued a framework for evaluating complex medical interventions, where the definition of complex included interventions delivered to organizational and community targets (Campbell et al., 2000; Craig et al., 2008). The framework recommended multiple phases of inquiry with attention to: 1) intervention development and operationalization; 2) feasibility and piloting; 3) evaluation; and 4) dissemination and implementation. In the development phase inquiry should be guided by three aims.

1. Identifying the evidence base
2. Identifying or developing theory
3. Modeling processes and outcomes

Implementation and developmental evaluation methods (Kainz & Metz, 2017; Patton, 2010) echo the need for greater focus on operationalizing the actors and actions that make up complex interventions. The classification of questions presented in Table 1 serves as a guide for early stages of organizational/community intervention development, where exploratory and implementation-focused methods can serve to expand the initial evidence base, improve theory about how an organizational/community intervention works, and operationalize the core intervention components.

Table 1. A Classification of Questions to Guide the Development of Organizational and Community Interventions

<table>
<thead>
<tr>
<th>Class of Questions</th>
<th>Motivating Question</th>
<th>Sub-Questions</th>
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<tbody>
<tr>
<td>Actors</td>
<td>What are the intervention components and who delivers them to whom?</td>
<td>Which agencies and departments are participating?</td>
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<td></td>
<td></td>
<td>What roles are required?</td>
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<td></td>
<td></td>
<td>Who are the intervention targets?</td>
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<tr>
<td>Actions</td>
<td>What are the core functions embedded in the intervention components?</td>
<td>What activities will be performed?</td>
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<td></td>
<td></td>
<td>How will quality of activities be defined and by whom?</td>
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<tr>
<td>Infrastructure</td>
<td>What resources, including</td>
<td>What communication</td>
</tr>
<tr>
<td>Evidence</td>
<td>What can be learned from early implementation that warrants adaptations to our intervention theory?</td>
<td>Are roles and activities feasible from the perspective of actors?</td>
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<tr>
<td></td>
<td>Routines and technologies, support the core functions of intervention components?</td>
<td>Are roles and activities implemented with quality?</td>
</tr>
<tr>
<td></td>
<td>Routines are required?</td>
<td>Does infrastructure support quality implementation?</td>
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<td></td>
<td>What information sharing routines are required?</td>
<td>Are key stakeholder perspectives represented in the work?</td>
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<td></td>
<td>What decision making routines are required?</td>
<td>Are unintended consequences observed?</td>
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<td></td>
<td>Who needs to know about implementation status and quality?</td>
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References


Practice Profiles: A Method for Operationalizing the Core Components of Complex Initiatives, So That these Components Can be Evaluated and Improved through Agile Research Methods

Allison Metz, University of North Carolina at Chapel Hill

Background/Context
Multi-agency community interventions pose unique challenges for implementation and evaluation. Communities are often unable to use existing manualized programs to address complex and emerging challenges. In these cases, communities deliberately choose innovations using available knowledge that meet the unique needs of the target population, are based on theoretical assumptions, and are feasible to implement within a specific context. In doing so, communities regularly begin with conceptually defined strategies. This is particularly relevant for multi-level, multi-organization community interventions. For example, although some components of a multi-agency community intervention will be well operationalized at the start of intervention (e.g., evidence-based program), other related elements will be designed during the intervention (e.g., engagement approaches, data sharing processes) and careful study is required to identify roles, communication, and infrastructure supports essential for achieving intended impact.

A lack of specificity also inhibits evaluators from using causal models to explain whether complex initiatives have their intended benefit, what specific components of the initiative contributed to specific community and population outcomes and under what conditions, and what components of the initiative are scalable and sustainable. This paper will describe in greater detail the purpose of using practice profiles, the methods for developing practice profiles, and intended benefit of using practice profiles for evaluators, funders, and communities.

Purpose/Objective/Research Question
Evaluators play a critical role in testing the assumptions of multi-level, multi-component complex initiatives. In order to test the underlying assumptions that connect initiative components to intended outcomes, evaluators must 1) support community partners and funders in operationalizing core functions of the initiative so these functions can be evaluated and improved; 2) support the integration of research evidence and practice knowledge in the articulation of the initiative’s core functions; 3) support alignment among core functions and community partners involved in the initiative; and 4) identify whether there are gaps in partner expertise as it relates to the execution of core functions.

Research questions that guide the evaluation design include: 1) what are the core functions of the initiative? 2) who is responsible for core functions? 3) are core functions well operationalized, so that they are teachable, learnable, doable, and assessable? Practice profiles are a method for answering these questions.

Setting
The setting for the practice profile development and subsequent evaluation of initiative components is the community itself. Practice profiles require a systems approach to identify core components of the initiative and cultivate engagement among key partners to facilitate understanding of how these components produce change for communities.

Population/Participants/Subjects
Practice profile development strategically engages diverse stakeholders, including service recipients and community members who represent knowledge from multiple system elements. A stakeholder is anyone who affects or is affected by a change and therefore has a stake in the change. What is uniquely explicit within the approach is that engaging and learning with stakeholders is intended to foster both the operationalization and acceptability of the multi-level, multi-agency components, thereby increasing the likelihood that components are teachable, learnable, doable and assessable by the evaluation team. Stakeholder groups include practitioners, children, families and service recipients, community partners, organization leaders, and funders.

Intervention/Program/Practice
A practice profile includes the following components:

- The philosophy, values, and principles that underlie the innovation. These guide the practitioner’s decisions and ensure consistency, integrity, and sustainable effort across all practitioners.
- Clear description of the essential functions. These define the role of practitioners and inform activities within each phase of work. Essential functions provide a clear description of the features that must be present to say that the innovation is being used and to achieve outcomes.
- Operational definitions of the essential functions. These describe the core activities associated with each essential function and allow the innovation to be “teachable, learnable, doable, and assessable” across a range of contexts. Operational definitions promote functional consistency across practitioners at the service delivery level.
- Practical assessments of performance. This assesses whether the innovation is implemented as intended. Fidelity assessments are used to improve practitioner competency and implementation supports such as training and coaching.

Data Collection and Analysis
The development of practice profiles requires a specific methodology to ensure the inclusion of research evidence, the alignment of competencies with the practice model’s theory of change, and the recognition of “what works” in practice through the experience of staff, families, and key stakeholders. Implementation teams conduct the following interrelated steps in an iterative process to identify the principles, core components, and activities of staff: 1) document review; 2) semi-structured interviews; 3) systematic scoping review; 4) vetting and consensus process; 5) usability testing. These steps are described in greater detail below.

Findings/Results
Results of the Practice Profile include a better and shared understanding of the core functions of implementing actors and partners responsible for executing the core functions of the initiative. This process will also help identify and articulate responsibility for each of the functions among project partners. Information from the practice profile will ensure that the core initiative functions are teachable, learnable, doable, and assessable.

**Data Collection Strategies to Facilitate Learning about Cause and Effect in Complex Interventions**

*Noreen Yazejian, University of North Carolina at Chapel Hill*

**Background/Context**
Multi-organization interventions that aim to disrupt social forces and change systems to achieve population-level outcomes pose multiple challenges for researchers attempting to understand cause and effect relations. Such interventions may be quite costly, and funders and other stakeholders expect answers about efficacy. Random assignment studies are likely logistically impracticable in such situations, and would be theoretically challenged by the inability to specify all possible mediators and moderators of effects. Given this, there is a need for data collection strategies to facilitate learning about cause and effect relations in systems interventions. Traditional implementation evaluation methods with comparison samples may be used to examine whether such interventions achieved effects, but cannot answer questions about why effects were achieved (or not) or how the system intervention realized its outcomes. This methodological paper will draw on examples from evaluations of four system-level early childhood interventions that included multiple strategies and agencies working to change population-level outcomes for children and families. The paper will highlight data collection strategies that were used to facilitate systematic learning about cause and effect in these interventions.

**Purpose/Objective/Research Question**
The purpose of applying the data collection frameworks described in this paper is to understand cause and effect relations when a randomized study is both impracticable and likely of limited value because of the inability to specify all mediating and moderating variables. The data collection methods described can be applied to learn about how and why complex interventions achieve outcomes.

**Setting**
The examples used to describe the data collection methods proposed in this paper were all early childhood system interventions. Two were statewide, with one located in the northwest U.S. in a state with many frontier counties and another in
a southeastern state; one occurred in four rural counties in a southeastern state; and one was county-wide, located in the southeast in a large county that included both urban and rural areas.

Population/Participants/Subjects
Evaluating complex early childhood system initiatives involves collection of information from multiple stakeholders, including practitioners, service recipients, community partners, agency leaders, and funders. For the example methods described in this paper, the primary participants were practitioners, families, community partners, organization leaders, and funders.

Intervention/Program/Practice
The four examples of system interventions that will be used to highlight data collection strategies included multiple program components (e.g., home visiting, early literacy, child care). All four included components that have previously been shown through randomized trials to be effective. Three of the projects have been completed, and one is ongoing.

Research Design
The four system interventions were evaluated with implementation and developmental evaluation methods, with a deep focus on understanding the implementation of strategies for supporting the interventions. The evaluations did not examine the specific programs (e.g., Nurse-Family Partnership or Reach Out and Read) that were implemented as part of the initiatives, but rather the inter-relations, supports, and competencies across the system of services that were being provided. All four evaluations sought to provide actionable information to funders and providers to monitor and guide implementation and to provide information about how and why the interventions worked.

Data Collection and Analysis
Two overarching approaches to data collection were used in evaluating the systems interventions and will be described as the focus of this methods paper. First, the evaluations used network mapping techniques to understand the partners involved, their inter-relationships and connections (including communication, authority, and decision-making structures), and changes in partners and connections over time. In one project, quantitative surveys were used with stakeholders that were analyzed to create visualizations of agency linkages and strength of connections. These visualizations revealed differences related to community context that related to program implementation, and the information informed funders of program needs. In another project, qualitative data were gathered through key informant interviews with multiple stakeholders. These data were analyzed to create visualizations of linkages, and analyses revealed gaps in connections that would be necessary for successful implementation. In one case,
the data revealed power and governance imbalances that impeded initiative progress. The illumination of these gaps and imbalances helped explain why less than optimal outcomes were achieved toward an understanding of causal mechanisms in the system. For both methods (quantitative survey and qualitative interviews), conducting the mappings at multiple time points in the project allowed for tracking changes in connections over time.

Second, the evaluations used competency assessments to understand the nature of infrastructure supports available within the system to ensure that the defined core functions of the initiative were able to be carried out with fidelity. Quantitative data were gathered through team-based infrastructure assessments that were administered as consensus-scored surveys. Qualitative data were gathered through key informant interviews. Both sources of data were gathered periodically and analyzed to determine whether infrastructure was in place and in service to core functions. For one statewide system intervention, the results revealed differences in infrastructure related to community context, which was useful to partners and funders in increasing supports. These data were also analyzed to examine whether there were associations between system competencies and implementation outcomes toward an understanding of causal pathways.

**Findings/Results**
This methodological paper provides examples of data collection techniques that can be used in complex system initiatives to inform learning about cause and effect. The example methods related to network mapping and competency assessment both provided evidence at the system level about the functions, structures, and supportive capacities necessary to achieve outcomes in systems initiatives with multiple agencies.

**Conclusions**
Complex system initiatives pose many challenges for evaluators. Funders and other stakeholders of such initiatives need information to understand how and why they work. This paper provides example data collection techniques from four large-scale early childhood interventions that allow specification at the system level of structures and supports that may explain outcomes. No one method can answer all questions, particularly in complex system initiatives. Combinations of methods are needed. We argue that data collection methods such as those described in this paper are best suited to answering questions about how and why system initiatives achieve their outcomes.