

Think Tank Summary: Advancing the Conceptual, Empirical, and Methodological State of Outcomes for Implementation Science

Enola Proctor, PhD
Gregory Aarons, PhD
Ramesh Raghavan, PhD

Key issue and challenge.

A critical yet unresolved issue in implementation science is how to evaluate successful implementation. This session addressed the concept of “implementation outcomes” (IO’s) distinct from service system and clinical outcomes. Advancing implementation science requires further conceptual, measurement development, and empirical work to determine metrics for assessing the success of implementation processes. Such work responds directly to the NIH PA 010-40, which invites studies that will accurately assess the outcomes of dissemination and implementation efforts.

The authors began the session with a brief presentation which included a proposed working “taxonomy” of eight conceptually distinct IO’s --acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability--along with their nominal definitions. Then we broke the session into three smaller groups, each discussing a different implementation outcome: fidelity, implementation costs, and sustainability. The approximately 150 think tank participants were from medical school settings, the VA, social services, and mental health. The range of public health issues of interest for the group included HIV, cardiovascular health, child-neglect, mental health, smoking cessation, drug abuse treatment.

Barriers and strategies to overcome the barriers.

In general, a number of barriers prevent accurate and valid assessment of implementation outcomes. The construct itself, implementation outcomes, is often confused with, or assessed incorrectly, through a sole reliance on clinical outcomes. Several other barriers include: a literature that employs overlapping concepts, inconsistent terminology, and is scattered across widely varying health and behavioral health fields. Moreover, studies that are assessing implementation outcomes directly tend to rely on “home grown,” unsystematic approaches. Very little psychometric work has been conducted on implementation outcomes. We now report the challenges, barriers and strategies to overcome them for each of the three major implementation outcomes addressed in this session: sustainability, fidelity, and implementation costs.

Fidelity. The first challenge with regard to “fidelity” is one of definition. The group discussed varying approaches to “How do we define fidelity,” and generated three constructs that could be parts of fidelity or could be other aspects of clinical intervention related to, but not a part of fidelity. The following constructs were discussed as defined by the group.

Adherence. Adherence is the degree to which a provider is delivering an intervention consistent with the core elements of that intervention. Core elements are those aspects of an intervention believed to be responsible for treatment effects. However, as with the constructs described below, the sense of greater complexity increased as the discussion went on. Still it was unclear just what components of an intervention should be included to represent adherence.

Competence - Was discussed as a characteristic of provider behavior that is distinct from fidelity or adherence but that could be related to the quality with which adherent treatment was delivered. It was more difficult to define just what makes up competence but was related to the provider’s interpersonal qualities and behaviors that facilitate effective services. It was not clear that competence did or did not include such constructs as working alliance or other non-specific factors.

Treatment Differentiation: This refers to fidelity or adherence that measures treatment elements unique to particular intervention of interest and not some other intervention. For example, cognitive-behavioral therapy for depression vs. interpersonal process psychotherapy would have different behaviors that would be assessed for adherence.

Next, the group discussed the degree to which providers can monitor their own fidelity. There was some disagreement about the ability of clinicians to report on their own fidelity. Some participants felt that clinicians could report accurately and others felt that clinicians could not accurately report on their own behaviors - even when questions were asked proximal to actual therapy sessions. For example, as providers can we know that we are delivering an intervention with fidelity in our interactions with a client/patient? If you aren't measuring it, can you know that it is indeed occurring? While there was some debate, the group was split on whether clinicians may be able to report on their own fidelity. The issue remained controversial among the group members with some expressing the view that it was possible and others remaining quite skeptical.

The group discussed developing the constructs of implementation fidelity separate from intervention fidelity. Implementation science is quickly developing models of implementation that can be tested. As with clinical interventions implementation interventions can be assessed and different implementation elements that are part of an implementation approach should be clearly operationalized and measured. The field needs to develop metrics of structure, process, and interrelationships to determine if implementation strategies are being conducted as designed. In addition, such metrics would facilitate determination of what adaptations or modifications are made for the unique challenges of implementation in various context. This approach can lead to a better understanding of how such modifications implementation models might impact implementation effectiveness.

Although fidelity is typically associated with clinical interventions, not all interventions or implementations are at the clinical level. This raised the issue of how we assess the fidelity of Evidence-based Policy implementation. Is it through the assessment of policy impact or would this be more akin to clinical outcomes? It seemed apparent that assessment of implementation fidelity for system or policy interventions might need a very different type of metric. This also begs the question of how fidelity data at this more macro level might be utilized to help guide implementation efforts.

This general discussion led to some additional questions. How do we calibrate fidelity measurement? How fine grained does fidelity measurement need to be? Can fidelity assess more macro general principles as in Multisystemic Therapy or is more micro assessment required to assess specific clinician behaviors.

The group discussed the optimal time to assess fidelity. That is, when in the process of implementation does it make the most sense to do fidelity measurement? The group discussed whether fidelity is something that should be assessed only during an implementation trial or if it should continue. The discussion leaned toward having some method to assess fidelity and use fidelity as a quality control mechanism that is ongoing. However, more feedback will be needed early in training, and then diminishing the amount of feedback as skill and expertise is developed.

The group also addressed the challenge of the manner in which fidelity feedback should be provided. Feedback should be reasonably quick in relation to a specific behavior. The analogy of a feedback bell or signal was offered, the idea being that early correction and positive reinforcement would result in provider behavior more consistent with the intervention model.

On a dimension of punitive to supportive, the group agreed that fidelity feedback should be provided more on the supportive dimension and not be used as a punitive measure (e.g., for human resources performance appraisal). The five A's of motivational interventions were brought up in the session. The recommendation was to use the "Ask, Advise, Assess, Assist, Arrange" process in relation to fidelity feedback.

A number of different methods of collecting fidelity data were raised, including direct observation, checklists, video or audio recording, and chart review. The relative merits associated with these different methods had to do with the complexity, cost, accuracy, and utility of their use.

Implementation costs. For the implementation outcome “implementation costs,” the group quickly agreed to focus on the costs of implementation as they accrued to agencies (provider organizations), and not to take a societal perspective on costs. Several issues were identified during the discussion.

First, many provider organizations may not be aware of implementation as a separate area of programmatic activity, instead equating it with training. Many organizations do not provide support for training or implementation, instead requiring that clinicians come to the organization fully trained in particular interventions. For such organizations, implementation costs may not be perceived to be of particular relevance.

Second, provider organizations are often not aware of implementation costs, often equating them with costs of an intervention. Even when they are aware of these costs, they may not have the resources, access to methodology, or in-house research capacity to estimate these costs. Indeed it is very hard to separate the costs of an intervention from the costs of an implementation. Provider organizations are largely shielded from the true costs of implementation because these are usually paid for by someone else.

The group identified several strategies to overcome barriers, recognizing first that reimbursement rates are inadequate to support increased costs of implementation. Current reimbursement rates are barely sufficient to meet costs of “usual care,” let alone ESTs. The current financial milieu doesn’t permit reimbursement rates to rise to adequately cover the costs of delivering ESTs.

The state of the science seems underdeveloped, and provides little guidance to provider organizations about how to ascertain the “true” costs of care (detailed below).

Sustainability. The group first agreed that the implementation outcome, “sustainability,” is relevant and important to a wide range of stakeholders: treatment developers who hope that their intervention will have continued use and lasting impact; agency directors who hope that their training investments won’t disappear with discontinued use of an intervention; funders of new programs and of research, who invest in developing, testing, and implementing a treatment; and communities who often feel “used” by research which brings external funding for treatment during a limited time but then stops, rendering the treatment or program unsustainable.

The group also raised the provocative question of whether sustainability is desirable, or if instead treatments should come and go, or come and then be adapted. A barrier to understanding, studying, and achieving sustainability is the notion that services should not be “static,” but rather change over time in response to new evidence.

Our current understanding of fidelity is limited because implementation science lacks guiding conceptual models, indicating which constructs are associated with sustainability.

As with the outcome fidelity, sustainability could refer to a specific empirically supported treatment, an evidence-based program, or a policy. The “purveyor” or agent advocating sustainability of each seems to differ, ranging from treatment developers, health advocates, consumer groups, and public health agencies.

Studying sustainability is particularly challenging, since most implementation research focuses on early stages, such as initial adoption or uptake. R01 studies typically end before sustainability even becomes a concern.

Questions for future research.

The panel, and think tank participants identified a number of questions, issues, and topics for future research: For the concept of implementation outcomes itself, it is important that scholarly work advance consistency of terminology; advance measurement; map inter-relationships among implementation outcomes; test the salience of various implementation outcomes to different stakeholders; test the salience of specific implementation outcomes over time during the implementation process; and employ implementation outcomes for testing implementation strategies.

For the outcome, implementation costs, researchers need to (1) provide organizations with a simple methodology to estimate the costs of interventions, and their implementation; (2) develop studies on the cost-effectiveness of interventions and implementation strategies; and (3) provide organizations with advocacy tools that can help them take their own data and advocate with policymakers on increasing reimbursement rates.

For the outcome sustainability, it is important to conduct research—such as group model building or concept mapping, to develop and refine conceptual models and theoretical frameworks of factors associated with sustainability. Research also requires clarity about the appropriate time frame to assess whether or not something has been sustained. Novel research designs will be needed, to extend observation and increase “n” beyond a single study.

Conclusion.

Conceptualizing IOs will help increase consistency of terminology in implementation science, enhance understanding of implementation processes, enable studies of the comparative effectiveness of implementation strategies, and enhance efficiency in implementation research.