IMPLEMENTATION SCIENCE:
OVERVIEW AND OPPORTUNITY FOR SAMHSA

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EXECUTIVE SUMMARY

This is an invited report on implementation science for SAMHSA leadership. The purpose is to provide an overview of the emerging science of implementation, and to suggest implications for SAMHSA's leadership, administrative and funding role in the delivery of behavioral health services in the US. The report is a rapid response, and one interpretation of a broad, complex and dynamic field. Because it is authored by one individual, inherent bias exists. The report organizes and interprets implementation science by a selection of the most robust, trailblazing frameworks that lend to ease of application and real-world relevance. In addition, these frameworks are widely adopted, prominent, and the subject of active research programs—so continued use and refinement is ongoing. There are three types of frameworks presented and described: 1) A *Determinant* framework that delineates contextual barriers and facilitators to the implementation process (the Consolidated Framework for Implementation Research [CFIR]); 2) a *Process* framework that outlines the stages and associated activities from start-up through maintenance (Exploration, Preparation, Implementation and Sustainment [EPIS]); and 3) an *Evaluative* framework to systematically track implementation outcomes (Reach, Effectiveness, Adoption, Implementation and Maintenance [RE-AIM]). The rationale for why and how to utilize these frameworks is simply described. Implementation strategies are the "interventions" of the implementation process and should not be "one size fits all" but tailored to determinant and process variables (CFIR and EPIS components); ultimately focused on achieving the outcomes defined by RE-AIM. The intersection of strategies with determinant, process and evaluation frameworks is critical. Otherwise we can expect the *status quo* in the persistent gap in behavioral health care access and quality. Designs to evaluate the success or failure of implementation, as well as the systems, organizations, providers and purveyors of implementation, are also presented.

By applying implementation science, the opportunities for SAMHSA, as outlined, do not seem to have increased budget implications. But rather involve an intentional shift in how new and existing funding mechanisms are evaluated at the proposal stage, in how to monitor at the performance stage, and how to ensure sustainment. Specific policies and practices are suggested and involve concrete recommendations about the types of data to collect, ways to foster accountability in performance, mechanisms to perform monitoring and feedback functions, and leverage leadership to forge partnerships at multiple levels.

Proposed herein is an approach that implementation science would bring to bear to guide SAMHSA in scaling up and sustaining evidence-based practices and programs for the public behavioral health benefit.

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1. OVERVIEW

Health care in general, and behavioral health care in particular, endures a persistent challenge in translating research-based evidence to routine practice. Estimates range from 17 years to scale 14% of discoveries. Although models from business and managerial science exist, these are based on the potential for profitability--taking an innovation to market. In the world of behavioral health, whether it be prevention or treatment, substance use or mental health services, the goals are less about profit and more about public health benefit. In fact, in most cases, the objects or contents of translation are neither novel medications nor ingenious devices; But instead multi-component psychosocial interventions or services. These services tend not to be so unique, easily packaged, or branded. Furthermore, thus far, the majority of these interventions or services are not necessarily directed at the wallets of the consumers of the services (clients, patients, families). They are primarily designed for the systems, organizations and clinical providers who will deliver them. In a sense, these prevention and treatment services providers are the *de facto* end users.

Implementation science is an emerging discipline that has, as its primary purpose, the understanding of the process of translating research discovery into routine practice settings. In essence, this means bringing the most effective prevention and treatment services to scale so that more people can receive them. Ultimately, the goal is to improve the outcomes and lives of those individuals, families and communities who may be at increased risk for behavioral health problems. Implementation research has a "patient-centered" core value. It embraces issues involving access to the best care possible, acceptability and preference, safety, and equity versus disparity.

As a scientific discipline, implementation research is at an early stage of development. Initially, implementation activities were not guided by theory, but were common sense exercises in trial and error. The findings from any one project could not be extended more broadly. Over the past 20 years, a plethora of theories, models and frameworks have since evolved to try to explain the complex processes of implementation. When attempts to gather data that might be generalizable outside of a particular implementation project occurred, qualitative or formative methods were often used. These qualitative approaches were necessary to confirm, refute or refine the early stage implementation theories, models and frameworks.

At these present time, implementation research is turning the corner toward more quantitative methods. As Deming noted, "without data, all you have is opinion." Measurement and reliable metrics are the crucible of science. Although the processes of implementation are numerous, complex and multi-leveled, the burden of those aiming to study implementation is to develop sound instruments and valid tools with which to measure every aspect of the process. Otherwise, findings may neither be replicable, generalizable nor comparative.

Until just recently, implementation science occupied a small space in biomedical research funding, scientific journal articles, and national conferences. This is slowly changing. Information about implementation science is expanding if not exploding in scale and scope. There is a dedicated journal, two national conferences yearly, federal support for over 60 Clinical Translational Science Centers across the US, Patient-Centered Outcomes Research Initiative (PCORI) funding, and health systems' investment in population health. These are all demonstrative implementation science as a growing enterprise.

This report is submitted in response to a specific request to the author from SAMHSA leadership. There are two primary objectives. The first is a concise, pragmatic and actionable summary of the implementation science in behavioral health. The second is to make recommendations on how SAMHSA might leverage implementation science in their major role as funder of behavioral health and support services across the US.

This is a 90-day rapid response to a SAMHSA request and must be acknowledged for its limitations.

First, it is neither a systematic nor narrative review of the historical or scientific literature on implementation research in health or behavioral health. Second, it was not developed by expert consensus from a representative and select group of implementation researchers, policymakers, systems leaders, prevention/treatment providers and consumers and families. As such, it represents a potentially biased and blind-spotted review from one individual. It is submitted by one person with experience as a clinician, behavioral health organization leader, health systems consultant, and SAMHSA and NIH funded health services and implementation researcher. It is both an overview of the field and with suggestions for how SAMHSA might approach funding services, fund purveyors of training, technical assistance and implementation support, evaluate performance from an implementation and sustainment perspective, link funding to performance, and use implementation research to shape the quality of behavioral health care for persons in the public US health care sector. In addition, beyond block grant funding, SAMHSA often extends resources to expand capacity or to implement new initiatives. These mechanisms are typically-time limited. How these initiatives could and should be sustained is critical to SAMHSA's return on investment. SAMHSA's leadership role in implementing AND sustaining evidence-based programs is potentially enormous.

Reference citations have been truncated, however, major citations of seminal or key published resources are inserted. SAMHSA leadership might also consider the major scholarly research text by:

Brownson et al (2012) *Dissemination and Implementation Research in Health*

http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199751877.001.0001/acprof-9780199751877

And a practical text by:

McGovern at al (2013) *Implementing Evidence-Based Practices in Behavioral Health*

http://www.hazelden.org/OA_HTML/ibeCCtpItmDspRte.jsp?item=385151&sitex=10020:22372:US&HZPRD=LEPQCexKBgDuN5tTOv3iTv7NoB&HZPRD_pses=ZG51F1FDDC80E94D1E18528E72D1F18DD17AD70A8BA4BE463DF1849463149677DA62F0CA2F4081D5DAFDE688B1DEFF9205

Two national organizations, sponsoring annual conferences, provide excellent opportunities to learn about late-breaking research, themes of how the field is progressing, and to network with established and emerging implementation researchers:

https://societyforimplementationresearchcollaboration.org/

https://obssr.od.nih.gov/event/9th-annual-conference-on-the-science-of-dissemination-and-implementation-mapping-the-complexity-and-dynamism-of-the-field/

2. DEFINITIONS

Implementation science: The scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices or programs into routine practice, in order to improve the quality of health services and care. Implementation science aims to contribute generalizable knowledge along the continuum of diffusion-dissemination-implementation-sustainment.

Diffusion: The passive, untargeted and unplanned spread of new practices or innovation.

Dissemination: The active spread of information about new practices to an intentional target audience using planned strategies.

Implementation: The process of putting to use or installing a new practice within a system, organization, program/clinic, team or individual provider.

Sustainment: The process of maintaining the use and quality (fidelity) of a practice beyond a period of active implementation, typically beyond two years or after start-up funding is spent.

Quality improvement: The use of specific methods and measures to implement or sustain a practice or work process with the goal of *local* improvement within an organization, program/clinic, team or individual provider. Common methods include: LEAN, Six Sigma and Plan-Do-Study-Act rapid change cycles. Quality Improvement (QI) activities are required by certain accreditation (e.g. Joint Commission) and certification (e.g. National Committee for Quality Assurance) entities.

Learning health systems: The use of uniform standardized health record or insurance claims data by health systems to inform care process and procedures, typically by identifying patterns or variation in outcomes or cost, and replicating practices of positive outliers and eliminating practices of negative outliers (e.g. US Veterans Health Affairs QUERI).

3. CONCEPTUAL MODELS AND FRAMEWORKS

A burgeoning of theories, models and frameworks in implementation science has led to a "Tower of Babel" situation with multiplicity in language and interpretation. This is common to an early developmental stage of a new discipline. Terminology, explanatory concepts and extrapolations from related disciplines (psychology, engineering, organizational and managerial science) run rampant. Over time, language becomes more consensus-based. Schemes about how processes should take place, and what might influence them, are increasingly developed. In the absence of theory, models or frameworks, phenomena are uninterpretable, patterns unrecognized, and experiences not generalizable to new situations. Alternatively, what about common sense? Isn't implementation simply about money and resources? If the object or practice to be implemented is paid for, and the resources are in place to deliver it, then what could go wrong? Common sense is of course an "informal theory" that might be testable. Money (incentives) and resources (workforce and environment) are components of implementation and sustainment among other "independent variables" in all implementation theories, models and frameworks. Theories, models and frameworks render experience more interpretable within a meaningful context, and contribute toward a body of knowledge. Theory can also create blind spots, so it is important to be open to surprise and disproof.

A recent paper by Nilsen (2015) outlines a useful taxonomy of implementation theories, models and frameworks. Nilsen reminds us of the distinction among theories, models and frameworks, but in his taxonomy, frameworks emerge as the most pragmatic level of applicability. Because this report is necessarily focused on the practical role SAMHSA may enact, the framework taxonomy is utilized.

The Nilsen taxonomy is presented in Table 1. The three major types of frameworks are listed, defined, and with exemplars for each type.

TABLE 1: NILSEN TAXONOMY OF IMPLEMENTATION FRAMEWORKS

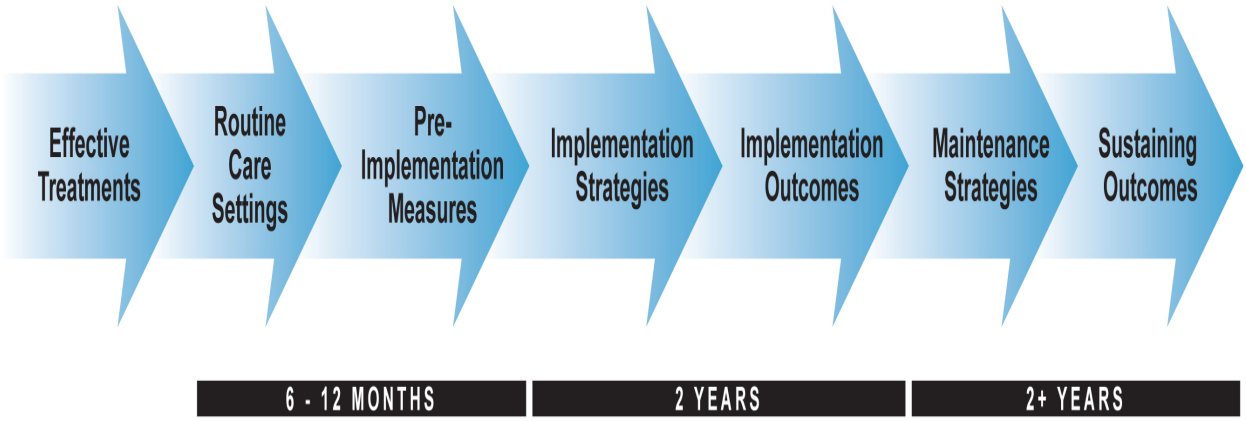
FRAMEWORK TYPE	DESCRIPTION	EXEMPLAR
Determinant	Identifies dimensions and types of barriers and facilitators to the implementation process; Contextual or structural factors; Moderators (fixed) and mediators (levers); Independent variables that influence dependent variables (outcome)	Consolidated Framework for Implementation Research (CFIR)(Damschroder et al, 2009)
Process	Identifies the stages or phases of the implementation process and suggests key or critical tasks by stage	Exploration, Preparation, Implementation Sustainment (EPIS)(Aarons et al, 2011)
Evaluation	Identifies aspects or goals of implementation that could determine success or failure	Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM)(Glasgow et al, 1999)

The exemplars chosen to represent the three framework types are based upon: their respective track record of use and breadth of adoption; the potential for quantitative measurement; and ongoing refinement by the developers or others in the field; and, a bias toward face validity, transferability, and ease of application. Other frameworks are available and can be reviewed in Damschroder et al (2009), Nilsen (2015) and Tabak et al (2012).

Visualizing implementation

In Figure 1, we simplified the process of implementation and sustainment (McGovern et al, 2013). The figure is reductionistic and ignores the complexity and dynamic recursive nature of the implementation process. Nevertheless, it serves as a basic organizing scheme and visual heuristic to the overview of implementation science in this report.

FIGURE 1: IMPLEMENTATION FLOW DIAGRAM



"Effective Treatments" could be either a FDA-approved medication (e.g. buprenorphine), an evidence-based psychosocial therapy or prevention practice (e.g. smoking cessation counseling), an overarching principle with multiple components (e.g. trauma-informed care), or any other practice, service, guideline or activity. Aspects about the object of implementation are critical. One important aspect may be the quality or preponderance of the evidence in its favor versus what is currently in place.

"Routine Care Settings" can be systems, networks, organizations, programs, teams or providers. The culture, readiness, capacity and fit of the setting for the practice is crucial. Fixed and pliable aspects of the setting are complex. The setting could be as large as the United States, the State of California, a health system (Kaiser), an organization or a group of providers (psychiatrists working in a county in Virginia).

"Pre-Implementation Measures" include the aspects Nilsen described as a *Determinant* type framework. This includes contextual factors that could undermine or accelerate an implementation. Aspects of the "effective treatment" being implemented, as well as characteristics of the "routine care setting" including the people who work there, would be components of this section.

Within a *Process* type of framework, as in Aarons et al (2011) EPIS, these three elements ("Effective Treatments", "Routine Care Settings" and "Pre-implementation Measures") comprise the *Exploration* and *Preparation* stages, and the stage-wise associated activities.

"Implementation Strategies" are the interventions of the implementation process. These strategies are hypothesized to be the cause of the desired implementation outcomes. Much like interventions, an empirical objective is to determine which strategies are most effective for what evidence-based practice to be implemented, under what circumstances, in what context, and resulting in what kind of outcomes.

Also, of course, we want to know how strategies compare with one another so we can choose the best one. The forthcoming section on Implementation Strategies will address these topics. As a preview, and to adjust expectations toward the realistic, there are no clear answers to these questions thus far.

"Implementation Outcomes" are the intended effects of the implementation strategy, and presumably involve: 1) a significant increase in the number of people who receive the "effective treatment"; 2) a more significant improvement in their lives and functioning (versus with what services they may have previously been receiving); 3) a significant increase in the number of organizations, programs, providers who deliver the "effective treatment"; 4) indications that the "effective treatment" is being delivered by design and with high fidelity; and 5) that plans are in place to sustain these gains beyond the life of the active implementation phase.

Note that the "Implementation Strategies" and "Implementation Outcomes" components fit into the EPIS *Implementation* stage.

Within the EPIS Process type framework, both the "Maintenance Strategies" and "Sustaining Outcomes" components fall into the Sustainment stage. Parallel to our scientific understanding of the long term effects and outcomes of our prevention and treatment interventions, the current evidence for maintenance and sustainment remains limited. As with treatment outcomes, these outcomes are probably the most important for us to understand and ensure—otherwise practices drift back to pre-implementation levels. A substantial loss in voltage in the best possible outcomes is a negative consequence.

The sequence of events in this visual depiction of the implementation process serves as an outline for the next four sections of this report:

- The intervention, service or practice to be implemented (section 4)
- Contextual barriers and facilitators to implementation—Determinants (section 5)
- Stages of implementation and associated activities—Process (section 6)
- Implementation Outcomes—Evaluative (section 7)

4. **THE INTERVENTION, SERVICE OR PRACTICE TO BE IMPLEMENTED**

In medical specialties such as surgery, it may be that specific techniques in procedures are causal of significantly better outcomes as measured by mortality, infection and restoration of functioning. In the practice of general medicine, including primary care, particularly in the management of chronic diseases, there are better things to do than others but outcomes and functionality are more complex—and not always causally connected to the right medication, guideline or procedure. In behavioral health, including prevention and treatment, determining the evidence for superior effectiveness, in either the long or short term, is also not so simple. Rogers' (1962) noted, "the more complex the intervention, the more difficult the implementation." For the most part, interventions in behavioral health are complex, multi-component, and often delivered by more than one person. Furthermore, unlike a medication, pill or compound, there can be wide variation in how the complex, multi-component, team-based intervention is rendered.

Thus, the selection of the intervention, service or practice to be implemented is an important consideration.

In some instances, the selection is a FDA-approved medication. The medication has been determined to be safe and effective in clinical trials, but may not yet be prescribed to scale for the patients who could benefit. Examples are smoking cessation medications for persons with serious mental illness who smoke or addiction medications for persons with opioid use disorder. It is possible to identify what medications are proven, and also which are underutilized in terms of unmet need.

There are a variety of methods to evaluate the hierarchy of evidence for a non-medication intervention, but there is no pure FDA-equivalent for psychosocial treatments (McGovern & Carroll, 2003).

SAMHSA has developed the National Registry of Evidence-Based Programs and Practices (NREPP) as a mechanism to guide the selection of a practice or program to implement.

https://www.samhsa.gov/nrepp

Professional organizations have also delineated qualifications for determining a psychosocial prevention or treatment practice or program to be "evidence-based." An example of one is the American Psychological Association Division of Clinical Psychology's list of empirically-supported psychological interventions.

http://www.div12.org/psychological-treatments/

Some programs, such as Integrated Dual Disorder Treatment (IDDT) is for persons with severe mental illness and substance use disorders are delivered in the community and by teams. IDDT is envisioned to be a long term care option. Thus unlike a medication or even a time-limited psychosocial treatment, as a multi-disciplinary, multi-component, long term treatment it is far more complex to deliver and therefore to implement and sustain.

It is also possible that some implementations are desired but not specific interventions, services or programs per se. Instead these may be overarching approaches or meta-strategies. Examples include: recovery-oriented, culturally competent, gender sensitive, trauma-informed, and consumer and patient-centered. To the degree these approaches are not operationalized, they may be challenging to implement and even more challenging to know if implementation has occurred. Nonetheless, the

implementation of these approaches or meta-strategies may result in far more benefit than an FDA-approved medication or NREPP listed psychosocial therapy.

It is also possible that some interventions, programs, services or practices are not necessarily evidence-based as decreed by meta-analyses or systematic review standards. But they may be better than what is presently available, popular because of ease of delivery, attractive because of the model or its developer, or seem to meet the needs of patients and families when there is nothing else available. Two interventions, SBIRT for alcohol and drug use disorders, and Seeking Safety for co-occurring PTSD and substance use disorders, are examples.

Within health care systems, some programs are practices are mandated by policy and procedures. These type of programs may require wider use, or scaling up from a small proportion of sites to the majority of sites. The "proof" for these programs may not be iron-clad, but the mandate is significant. Replicating Effective Programs (REP) in the US Veterans Health Affairs system is an example (Kilbourne et al, 2007).

Conversely, there may also be a time for "de-implementation." De-implementation may be useful when practices are in place or even common, but which have been proven to be harmful, contradicted, or simply ineffective (Prasad & Ioannidis, 2014). Lessons from wound care in the US Civil War resulted in the implementation of more cleansing of the wound with soap and water and the de-implementation of first line cauterization and/or amputation.

In the Exploration stage of the implementation process, it is crucial to identify, understand, and explain the who, why, how and what of the object of implementation.

5. DETERMINANTS: CONTEXTUAL BARRIERS AND FACILITATORS TO IMPLEMENTATION

Tabak et al (2012) conducted a comprehensive review of determinant and other frameworks and concluded the Consolidated Framework for Implementation Research (CFIR)—developed by Laura Damschroder and colleagues in 2009—was among the most thorough and empirically-ready. A recent review of research with the CFIR by Kirk et al (2016) finds the framework to be widely adopted and growing. In a new field seeking to established core batteries of process and outcome measures, it would seem the CFIR has the inside track to be *the* Determinant type framework.

The CFIR delineates a list of critical determinants that could make or break an implementation project. It has as its contextual focus the organization and the persons working within it. Because much of the work of behavioral health, particularly in the public sector, involves systems and networks of organizations, the CFIR is an excellent fit as the Determinant framework. Also, because of workforce turnover in public health care organizations, implementations directed solely at individuals (e.g. mental health clinicians, addiction counselors) are likely to be ineffective and short-lived at best. An alternative for a determinant framework that might work better with a workforce of more stable individual providers (individual physicians or private practice therapists) is the Promoting Action on Research Implementation in Health Services (PARIHS) (Kitson et al, 1998; Rycroft-Malone, 2010).

The CFIR elements include aspects regarding the *Perception of the Intervention, service or program* that is the object of implementation. This includes the quality and enormity of the evidence in favor of the program. Is it *that* good? Also, the perception about whether it fits, is doable, too complicated, and/or can be adapted or adjusted based upon the needs of patients and the organization.

The CFIR also addresses elements from outside the organization-- *Perceptions about the System and Community*. These factors include the community of potential patients and families. But it also includes the oversight and funding entities, other organizations, and the meso-system (e.g. health plan, state agency, health system central office) that may or may not offer support for an implementation.

The pragmatic appeal of the CFIR is in its appreciation and examination of factors at the level of the *Perceptions about the Organization*. These include variables such as leadership involvement and commitment, workflow, readiness, implementation climate, culture and communication. In addition, structural aspects such as the size, maturity and resources accessible to the organization are potential determinants.

The fourth dimension or level involves the *Perceptions of individual providers or clinicians*, or deliverers of the program, interventions or services. What is their perception about the object of implementation? Do they feel they can do it well, what are their incentives, how does it fit into their professional role identity?

Thus, there are four main dimensions to the CFIR that constitute the multi-level waterfront of determinants. These dimensions are:

A) Perceptions of the Intervention;
B) Perceptions of the System and Community;
C) Perceptions of the Program (i.e. organization); and
D) Perceptions of the Clinicians (or others) Who Will Use the Intervention

Damshroder et al defined these dimensions as “characteristics of the intervention”, “outer setting”, “inner setting” and characteristics of the individuals.” In the complete CFIR there is also a fifth dimension focused on the planning and process of the implementation strategy. Although this dimension is important, we consider these elements in the section on Implementation Strategies later in this report. Since the original version of the CFIR was developed in 2009, more scientific insight into tailoring strategies to context and stage have evolved. This progress is reflected in the section devoted to implementation strategies.

The CFIR is undergoing constant refinement and improvement, as well as increasingly applied to address implementation problems and projects. The website is an excellent resource: http://www.cfirguide.org/

As a Determinant type of framework, the CFIR provides a checklist of potential enablers and destroyers of an implementation or sustainment activity. These are not only passive barriers and facilitators, but can also supply actively positive or negative influences. Thus, any implementation activity that does not address these determinants, either by ignorance, fiat or conviction that one-size-fits-all, is doomed.

Implementation strategies must be responsive, adaptive, matched and tailored to these contextual determinants.

These determinants may be static and fixed or dynamic and flexible. Examples of static determinant variables may be the size of the organization or current workforce (e.g. no medical professionals). Although these can change, they may not be so easily altered. Other determinants may be more belief-based. These are more dynamic and pliable and may involve perceptions for the strength of evidence for intervention to be implemented (“What do the meta-analyses say? How much better is it than what we are already doing?”), or its anticipated complexity (“We have never done urine drug screens in our clinic before and it raised many concerns’). Identifying such perspectives and having a plan to address them is paramount to success.

It is also common for perceptions to be widely variable in an organization. For example, some family medicine physicians may be more willing to address depression in their everyday work, including talking about it and prescribing anti-depressant medications. Whereas others may consider this outside the scope of practice or outside the time allocated for the 15-minute patient visit. Determinants may be positive or negative in valence, and may be mixed across staff members, both within and across disciplines.

As the Kirk et al (2016) systematic review of the CFIR reports, the majority of the framework’s applications in implementation projects examine barriers and facilitators by using formative or qualitative methods. Key informant interviews, focus groups or rapid ethnography are used to gather impressions about determinants of an implementation, either before or after it occurs. This methodology provides rich information to help plan an implementation project, design an implementation research experiment, or conduct an “implementation autopsy” as to why an implementation failure occurred.

Although formative study and qualitative data provide deep and rich insight, they often do not yield comparable or replicable findings. Thus, there is a strong argument for designing a quantitative measure of these determinant variables. One that could provide a metric across studies and over time. Given past experience developing organizational level measures of complex multi-level constructs, we have been

using a mixed-methods measure, the CFIR Index, to obtain determinant level data gathered via site visit, key informant interview and observation. Psychometric properties (reliability and validity) are acceptable and refinement is ongoing (Assefa & McGovern, 2017).

There are 30 items, rated as a composite of observations on a 5-point scale. Ratings are made on the degree the variable is a barrier (-2) or a facilitator (+2) or neutral (0). Mid-range or scores reflecting some variation, but directionality, are scored either a "-1" or "+1".

The complete CFIR Index, by the four dimensions and thirty individual items, is presented in Table 2. Scores can be derived by individual items or by dimension (average of score= sum of all scores/# of item in the dimension).

How is information on a determinant framework such as CFIR useful to programs, organizations, systems, intervention developers, purveyors and SAMHSA?

Systematically gathered formative or quantitative information, gathered at the beginning or planning stage of an implementation endeavor, can help determine whether or not to proceed, how implementation strategies will address barriers as well as capitalize on facilitators. Raising awareness, identifying and documenting these CFIR framework factors overcomes the often blind, naïve and unilateral approach to an implementation. In recognizing and reporting on these variables, a more complex and tailored strategy should result. Thus, it is important for these data, qualitative or quantitative, to be collected at the proposal stage or baseline stage of the endeavor.

Because some of the CFIR variables may be mediators of implementation, they could serve as the target for a component of the implementation strategy. For example, CFIR item D2, "Clinician Self-Efficacy", may improve with training, consultation and experience in delivering the intervention (e.g. naltrexone). It is also useful to evaluate changes in barriers and facilitators during the course of the project. Expected reductions in barriers based on the hypothesized target of the implementation strategy can help in determining continuing the course or making changes. Along with implementation outcomes (see Evaluative Framework section), measuring and reporting on changes in contextual factors is important to compare varying strategies being used. For example, in one state, a state grant-funded ECHO approach is the implementation strategy used to support new FQHC-based prescribers of buprenorphine, whereas in another state a learning collaborative for team-based care in FQHCs is the selected strategy. How do these strategies compare in affecting barriers and facilitators? And, of course, how do these strategies differ in their impact on implementation outcomes is the overarching question.

At the end of an active implementation stage of a project, systematically assessing the current state of contextual barriers and facilitators will suggest likely sustainment outcomes or serve as the basis for a sustainment plan.

To persons who design interventions, data from the CFIR, are in effect, market research. What does the field of public sector prevention and treatment need and how does my intervention fit? Because their role is to foster implementation, purveyors must be well-aware of the barriers and facilitators of the organizations with which they interact. Otherwise, they are simply involved in diffusion at best.

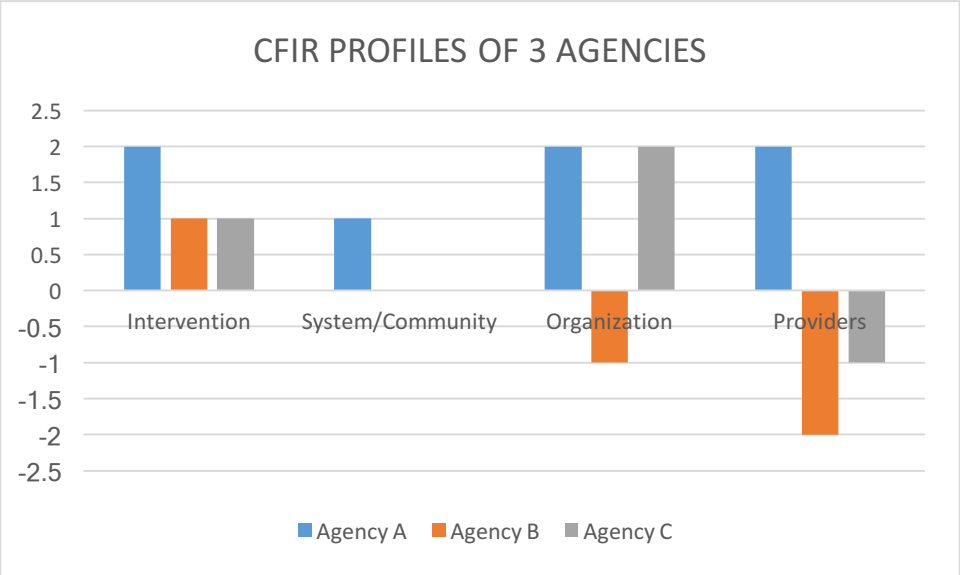
TABLE 2: CFIR INDEX

DOMAIN/CONSTRUCT	SHORT DESCRIPTION[1]
A. Perceptions of the Intervention	
A1. Intervention source	Perception of key stakeholders about whether the intervention is externally or internally developed.
A2. Evidence strength and quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes
A3. Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
A4. Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
A5. Testability	The ability to test the intervention on a small scale in the organization [8], and to be able to reverse course (undo implementation) if warranted.
A6. Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement
A7. Costs	Costs of the intervention and costs associated with implementing that intervention including investment, supply, and opportunity costs.
B. Perceptions of the System and Community	
B1. Patient needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately known and prioritized by the organization.
B2. Network connectivity	The degree to which an organization is networked with other external organizations.
B3. Peer pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge.
B4. External policy and incentives	A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
C. Perceptions of the Program	
C1. Structural characteristics	The social architecture, age, maturity, and size of an organization.
C2. Networks and communication	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C3. Culture	Norms, values, and basic assumptions of a given organization.
C4. Implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
C5. Tension for change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
C6. Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
C7. Relative priority	Individuals' shared perception of the importance of the implementation within the organization
C8. Organizational incentives	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect.
C9. Goals and feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff and alignment of that feedback with goals.
C10. Learning climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation
C11. Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.

C12. Leadership engagement	Commitment, involvement, and accountability of leaders and managers with the implementation
C13. Resource availability	The level of resources dedicated for implementation and on-going operations including money, training, education, physical space, and time.
C14. Access to knowledge and information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
D. Perceptions of the Clinicians Who Will Use the Intervention	
D1. Clinician knowledge and beliefs about the intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
D2. Clinician self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
D3. Clinician stage of motivation for the intervention	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D4. Clinician identification with the program	A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization.
D5. Other clinician attributes that might influence the implementation of the intervention	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

Depicted in Figure 2 is a hypothetical CFIR Index baseline assessment of 3 agencies participating in a plan to implement an evidence-based prevention practice. Variation exists. Agency 1, with all scores above "0", seems ready and likely to embrace the practice. Although the practice is perceived somewhat positively (score of +1), Agency B perceives the System/Community to be neutral and with strong barriers at their organizational and provider level. Agency C perceives the practice positively, and has great organizational facilitators supporting its adoption. Agency C's providers however are raising concerns noted in the -1 score. These are dimension averages; Details from the individual items yield more specificity as prime targets for actionable implementation (or sustainment) strategies.

FIGURE 2: ILLUSTRATION OF HOW CFIR INDEX DESCRIBES CONTEXTUAL VARIATION BY AGENCY



Either objective CFIR Index data or formation information gathered qualitatively are very useful in designing a customized implementation strategy and documenting system variation at baseline.

As the primary federal funding agency for these services, SAMHSA can serve a leadership, steering and quality monitoring role, by encouraging a greater level of rigor and specificity in implementation and sustainment activities, within both new and ongoing projects across the US. More detail on how to shape these activities is presented in the final section of this report.

6. PROCESS: STAGES OF IMPLEMENTATION AND ASSOCIATED ACTIVITIES

There are numerous process models of implementation. Perhaps the most landmark are those by Everett M. Rogers from the University of Iowa in 1962 (*Diffusion of Innovation*) and in 2005 by Dean L. Fixsen and colleagues from the University of South Florida (*Implementation Research*). Out of agricultural science, Rogers developed a stage theory of diffusion and adoption. The Fixsen et al monograph brought the best of experience at the time, primarily from the fields of prevention and education, and helped to develop our understanding of multi-level roles and determinants that remain relevant today. In fact, much of the existing science of implementation is built upon this early work.

At present, there are numerous process frameworks from which to choose. However, based on the developers' steadfast refinement and rigorous pursuit in developing measures of the core components by stage (Greg Aarons and colleagues at the University of California at San Diego), the EPIS has both current viability and a high ceiling for widespread adoption.

In addition to identifying and understanding (and measuring) contextual determinants in an implementation project, it is useful to know the stage at which various key stakeholders are engaged in the process. Because implementation involves translational activities across multiple levels, strong partnerships are key to success. Without a partnership, the implementation will fail.

The EPIS is an acronym for *Exploration*, *Preparation*, *Implementation* and *Sustainment*. Interestingly, Rogers had described stages of "awareness" and "interest" which correspond to Exploration, "trial testing" which corresponds to Preparation, and "adoption" which corresponds to implementation.

The *Exploration* stage involves awareness of either an issue needing attention, an opportunity for improvement, or dealing with a problem. There may be a system or funder *push* to initiate the exploration. There may also be an awareness that an opportunity exists to improve practice or get better outcomes. It's also possible that there is the potential for increased revenues or profits. Consumers may also drive this stage. The voice of the consumer of services and families, or of contract providers such as schools or networks may push for something different. Across organizations and networks there may be competition, social norming, or crowdsourcing of new practices or programs. These are all external (outer context) factors. Factors at this stage and internal to the organization include a *pull* for an innovation. This pull may either be particular to the new intervention or program, but could also be a trait of the organization. This is a cultural value of innovation. Leadership that calls attention to the problem or the need for a change, and prioritizes it, is of huge significance. Individual clinicians or practitioners may also be at a tentative stage of exploration. How does the potential intervention meet an unmet need, is an advantage over what is presently being done or how does it fit with values? Across all levels, at this stage, references from other other systems, organizations and providers who have done it and like it can be encouraging.

The *Preparation* stage involves making the decision and commitment to proceed. This involves being sure the evidence is strong enough to go through the trouble of implementation. Feasibility of implementation by conferring with, learning from, or hearing testimony from similar organizations may be necessary. External consultation, from a systems leader, regulatory official, or esteemed purveyor of implementation strategies and/or evidence-based content may be useful to tip the scales. Similar to the Exploration stage, the push from regulatory and funding entities, consumers and families, and other professional networks may contribute to advancing thru ambivalence, anxiety, and competing priorities.

Within the organization, leadership commitment to resources (buying required equipment or materials), freeing up staff time for training (didactic lectures, workshops), collecting data, and other administrative activities is essential. Thus, the concrete tasks of having the time and resources set aside and ready to execute the implementation are made available at this stage. Individual clinicians are evaluating how how the implementation will affect their work—is it additive or substitutive?—is their any credit or a lack thereof for their participation. They may be more or less aligned with the decision to commit to implementation. They may also be confident or anxious in their ability to learn and deliver the intervention with acceptable quality. During the Preparation stage an organization and providers might try to simulate the active implementation, either thru role-play, behavioral rehearsal, simulated patients, walk-thru, or drafting a step-by-step flowchart of the process.

Active Implementation is akin to a business start-up—everything you thought would happen or planned inevitably didn't, or at best, happened differently. The active implementation phase begins with the launch of the delivery of the new intervention, program or service. Planned aspects of delivery might include identifying appropriate recipients, offering the service, observing its acceptability by patients or clients, the real workflow, and the actual response of patients/clients to the intervention. In addition, experiences of ease or frustration, unanticipated problems or challenges, and surprises, serve to stimulate revision to the plan and protocol. Questions about whether the intervention or service is being delivered with fidelity also arise. Fidelity monitoring and feedback of outcomes, including patient/client satisfaction, are key tasks at this stage. If other providers, programs, organizations or systems are involved in active implementation, it is useful to share successes and challenges to normalize the experience. It is also useful to identify providers, programs or organizations within the system who may serve as role models for workflow or good execution or performance on other tasks. In a learning collaborative implementation support strategy, practices or programs present their approach. Other providers benefit by example. During the active implementation phase, it is also be important to use fidelity and outcome data to identify high performance, and facilitate the influence of these positive outliers to replicate or extend their strategies to others in the system. In addition to the learning collaborative strategy, the VHA QUERI and Replicating Effective Programs takes this approach (Kilbourne et al, 2017).

The *Sustainment* stage risks a return to *status quo*, particularly with the loss of the additional grant funding and resources that may have been available to support the active implementation. Unfortunately, because of failure to plan for sustainment, or a pervasive and frequent belief that the implementation was to be time-limited, evidence-based interventions, programs or services are often discontinued at this stage. Therefore, sustainment considerations are critical to confront and resolve at the preparation stage. In fact, if Active Implementation stage funds are provided as start-up, much like in venture capital, those who are funded would need to develop a realistic plan to continue the service. Otherwise, there is not even a minimal return on the investment. Sustainment stage tasks are the outcome of careful planning at the Preparation stage. In the Active Implementation stage, negotiations with funders and "institutionalization" of the intervention, program or service into the job descriptions of workers, pharmacy formularies, care model processes, and absorbed by the culture. Further, there is a risk of voltage loss in outcomes and drift in fidelity. Therefore, an important task at this stage is to use either external or internal monitoring of fidelity and outcomes. Feedback to providers, programs or agencies with simple dashboard-type data can contribute to effective sustainment.

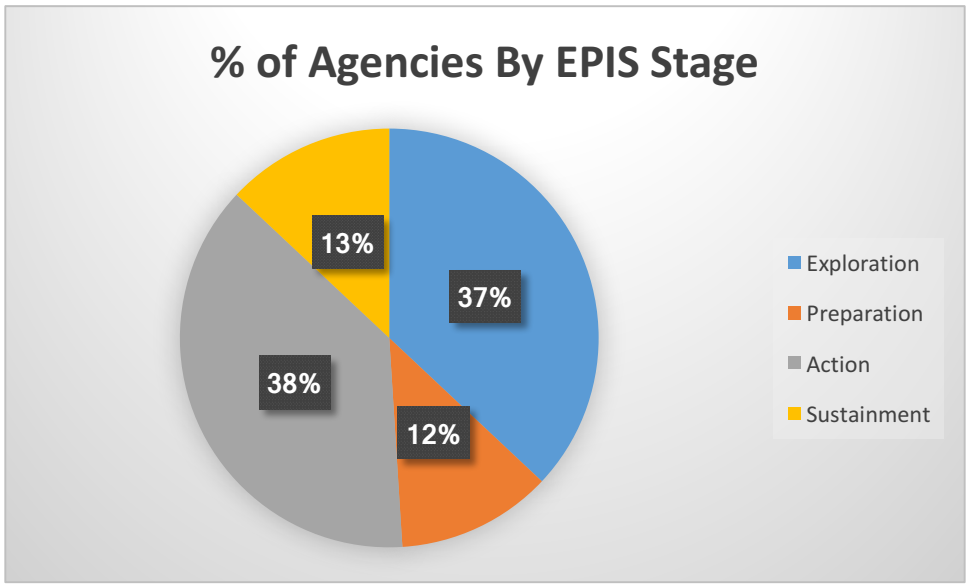
A brief summary of the EPIS stages, and key foci and tasks by stage is presented in Table 3.

TABLE 3: EPIS STAGE, FOCUS AND TASKS	
STAGE	**PRIMARY FOCUS AND TASKS**
Exploration	Awareness of need, opportunity to improve, fix a problem; Evaluate the options
Preparation	Decide, commit, prioritize; Leadership buy-in; Concrete preparations including budget, contracts, training, materials; Protocol development
Implementation	Patient, client, group, organization and system at ground zero start-up; Adapt and troubleshoot workforce and workflow; Get advice; Measure fidelity and outcomes
Sustainment	Transfer reinforcements to continue; Standardize/routinize process; Measure fidelity and outcomes

How is information on a process framework such as EPIS useful to programs, organizations, systems, intervention developers, purveyors and SAMHSA?

There are obvious parallels between the EPIS and Prochaska and DiClemente's Stages of Change model. Exploration is akin to Precontemplation and Contemplation, Preparation to Preparation, Action to Action, and Sustainment to Maintenance. Just like the Stage of Change, it is important to match implementation activities to the appropriate stage. Although there is no formal measure of EPIS stage, categorization of individual providers, teams, organizations or even states can be done based on implicit and explicit information as well as the activities that are being conducted. Figure 3 illustrates how this information may be useful for organization leaders, systems leaders, purveyors, and for SAMHSA to know at baseline and over the course of an implementation endeavor. If the endeavor is successful, the proportion (i.e. number of agencies in category of all agencies) passing from exploration and preparation *into* action, and from action *into* sustainment, would be an excellent benchmark achievement.

FIGURE 3: ILLUSTRATION OF BASELINE EPIS STAGE OF IMPLEMENTATION OF A HYPOTHETICAL PRACTICE BY A NETWORK OF AGENCIES ACROSS A STATE SYSTEM



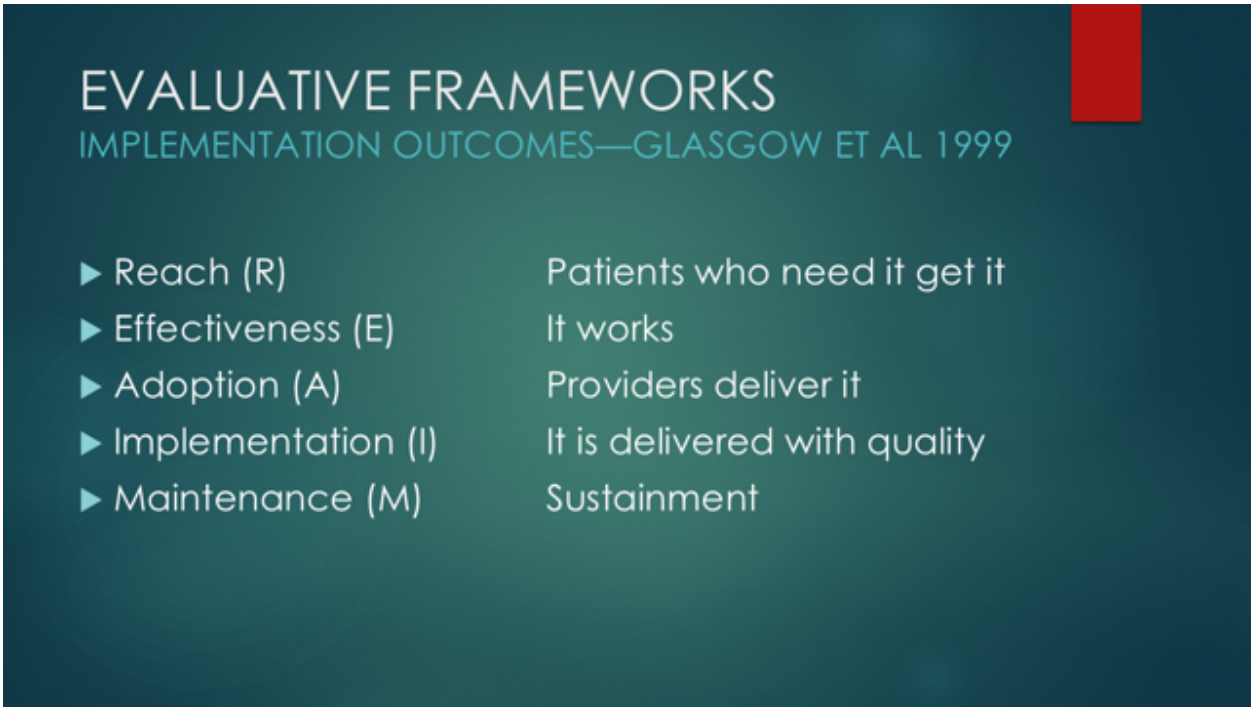
7. **EVALUATION: IMPLEMENTATION OUTCOMES**

Implementation outcomes are not typically measured by anyone other than implementation scientists. Interestingly, implementation outcomes are relatively simple to gather, and easy to interpret. Complex statistics are not required.

RE-AIM

Glasgow et al's (1999) RE-AIM evaluation framework is parsimonious and elegant. Nilson (2016) identified it as the most widely adopted set of variables used to evaluate implementation outcomes. Table 4 defines each letter character of the RE-AIM acronym, and explains their meaning.

TABLE 4: RE-AIM FRAMEWORK



Reach (R) is intended to measure the scale of the evidence-based practice, intervention, service or program. The question, "Has X been brought to scale?" is answered by Reach. Simply calculated, Reach is a proportion of the number of people who receive the intervention (numerator), divided by the number eligible or the number targeted (denominator). For example, for persons with opioid use disorder seeking treatment in a county in Oregon, Reach might be calculated by the number of persons prescribed a FDA-approved medication (numerator) divided by the number of persons with an opioid use disorder presenting for treatment. Although this is a simple count, it is important to define the meaningful denominator. In fact, there may be more than one denominator and therefore several meaningful measures of Reach. Continuing with this example, the denominator could, in addition, to the number of patients with opioid use disorder presenting for treatment, be further refined by the total number of those who are interested in medication for their substance use disorder. The denominator may also be a population health consideration, and be determined by an estimate of the number of persons with opioid use disorder, seeking treatment or not, in the county. The public health goal of

most implementation endeavors is to increase the proportion of people obtaining the evidence-based treatment of all those who need (and/or want) it. Thus, this is the fundamental metric of access.

Effectiveness (E) is the outcome measure that reflects a positive response to the intervention by those who receive it. This may be in comparison to those who do not receive it, or it may simply be a measure of change from baseline over time. Back to the example of persons in treatment for opioid use disorders. Effectiveness may be measured by the proportion of opioid negative urine drug screens, decease in illegal activity, or improved role performance at work and in primary relationships. Depending on the evidence-base of the intervention, program or service being implemented, as well as any adaptation from the original model that may occur, effectiveness at the patient level may not need to be measured. Patient level or effectiveness outcomes may not be required for iron-clad effective evidence-based interventions (e.g. antiretroviral therapy for HIV/AIDS). Patient level outcomes are also expensive and intensive to collect. However, many funders of an implementation activity, or local officials who have supported the implementation, perhaps with funding, may demand to see measures of patient improvement. They want to know if it makes a difference in their local community. Some simpler measures of effectiveness might include consumer (patient) satisfaction, reduction in emergency department visits, or decrease in psychiatric hospitalizations. In the Design section, there are types of implementation studies that vary based upon the degree of emphasis on effectiveness or implementation outcomes. In general, the more established the intervention's effectiveness, the less critical this dimension is to measure.

Adoption (A) is a frequently used term but often misunderstood. As an implementation research outcome indicator, Adoption refers to the uptake and use of the evidence-based practice, program or service by the target deliverers. Like Reach, Adoption is often a calculation of proportion of the number of individuals, programs or agencies delivering the practice divided by the total number of those who could or should. Challenges may be in the nuance meaning in the selection of certain denominators instead of others. This is similar to calculating Reach. In our example of the case of opioid use disorders, adoption of medication assisted treatment by physicians might be calculated by the number of physicians in Arizona who have obtained the X waiver to prescribe buprenorphine divided by the number of licensed physicians in Arizona. A statewide effort to increase medication assisted treatment may have an Adoption goal such as this. Alternatively, adoption might be measured by the number of physicians who have prescribed buprenorphine to at least 10 patients in the past 6 months, divided by the number of physicians with the X waiver. Depending on the implementation question, the options for measuring adoption rates may vary. It is also possible to collect more than one measure of adoption outcomes. Because most of our implementation strategies are directed at those involved in service delivery (health systems, health care organizations, clinicians, prevention specialists, schools, etc.), rather than individual consumers or families, adoption is a key measure of implementation outcome. Unlike effectiveness, Adoption is not an optional implementation outcome metric.

Implementation (I) is more specific to the quality, integrity or fidelity with which the evidence-based practice or program is being implemented. If the new program is not being implemented as designed, or as close as possible to it, the program may not be any more effective than "services-as-usual." There is likely a "break even" point where if the intervention is not delivered with acceptable fidelity, it is not worth implementing. Furthermore, in some instances it may be harmful. Therefore, some measure of quality assurance, fidelity or adherence/competence is important to determine whether the intervention is being delivered as it should be. Fidelity or adherence to guidelines may be challenging

data to collect. Large scale data draws (e.g. from state prescription drug monitoring programs; claims data) may be one way to track quality. Psychosocial and behavioral therapies have adherence/competence measures designed by the therapy developers. These can be used to audit sessions and evaluate fidelity. Machine learning techniques can rapidly audit electronic health records, texts, audiotapes or videotaped interactions. Fidelity measures exist for many evidence-based services such as Individual Placement and Support (IPS) or Assertive Community Treatment (ACT). In our example, quality of buprenorphine care can be monitored within the context of a learning collaborative or practice improvement collaborative. Within these types of multi-level multi-component implementation strategies, adherence to guidelines can ensure care quality and minimize diversion: urine drug monitoring; checking state prescription drug monitoring program; diagnosing opioid use disorder; appropriate dosing; and recovery supports. Although fidelity and care quality may be difficult to measure, they are critical to effective and worthwhile implementation and sustainment. Diffusion and dissemination activities, such as training and workshops, without fidelity monitoring, are ineffective.

Maintenance (M) connects with the EPIS stage of sustainment. Generally, this includes the continuation of implementation outcomes over an active implementation period, sometimes determined to be two years-post-launch. Simple, ongoing measures of Reach, Effectiveness, Adoption and fidelity that either remain stable or grow are the goals of maintenance (and sustainment) evaluation. Measures of maintenance may be particularly important with the most recent infusion of federal funds (CURES ACT) to expand access to medications for opioid use disorder. As a 2-year start-up investment, how many patients continue medication, how many new patients start medication, how many providers continue to prescribe and at what capacity, how many hub and spoke are networks are in place and functioning, are critical Maintenance outcomes to plan for and to measure over time. How these outcomes are maintained in the absence of bolus start up funds is of national concern.

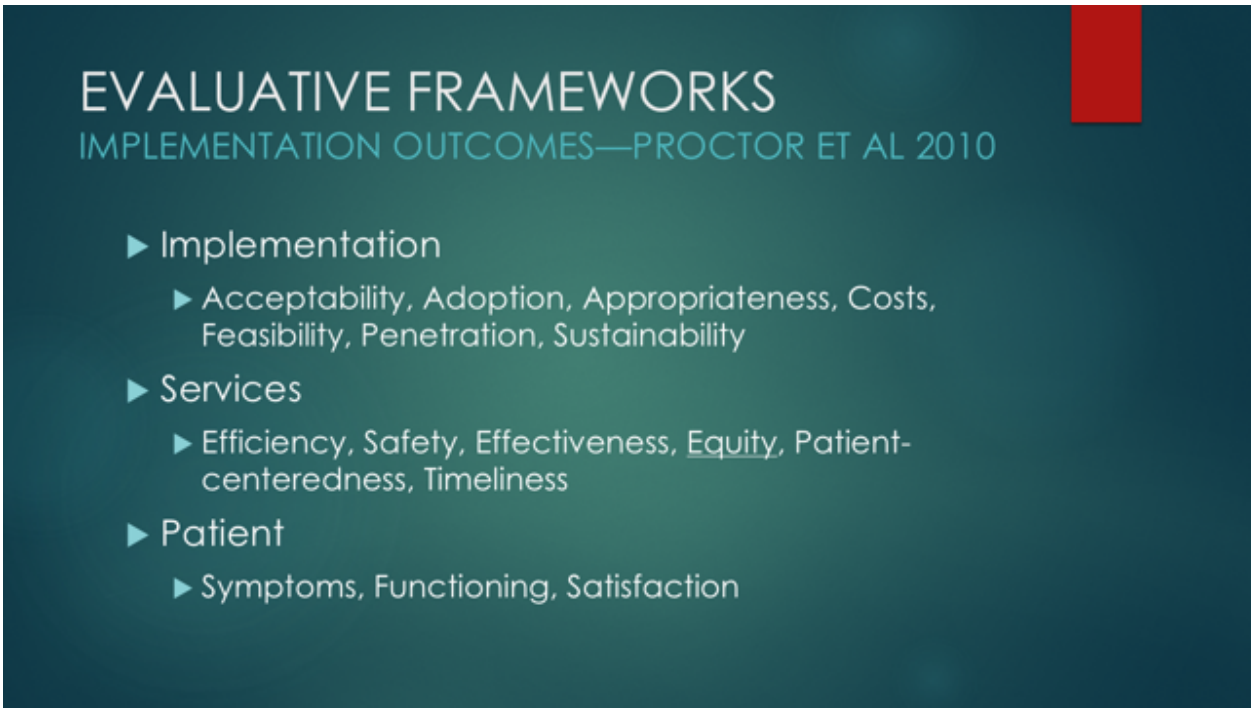
PROCTOR ET AL IMPLEMENTATION OUTCOME TAXONOMY

Nilsen also acknowledges the Proctor et al taxonomy as a multi-level evaluation framework. Proctor et al (2010) add more detail to the RE-AIM core implementation outcomes: acceptability, appropriateness, feasibility and cost. These factors may be more salient during the Exploration stages.

The Proctor et al taxonomy draws on the landmark Institute of Medicine Quality Chasm report (2001) and lists services level outcomes as a component or extension of implementation outcomes: efficiency, safety, effectiveness, equity, patient-centered and timely. These factors relate to how the intervention, service or progam is delivered. One very important variable is equity, or its inverse—disparity. Within the context of examining implementation outcomes, particularly in Reach, disparity in access to the evidence-based practice can be examined. For example, if because of age, race, culture, ethnicity or disability, it is determined that people do not have equitable access to the practice then we have a disparity. For example, there is a disparity where because of psychiatric disability, affected persons do not have equitable access to smoking cessation treatments. Or because women are of child-bearing years, they do not have equitable access to medications for opioid use disorder. During the course of an implementation endeavor, it is important to measure access and engagement of all persons who could potentially benefit from the practice. If disparity is revealed, strategies to address them should be undertaken, including the potential for adapting or modifying the intervention if necessary.

Table 5 depicts the full Proctor et al taxonomy.

TABLE 5: PROCTOR ET AL TAXONOMY OF IMPLEMENTATION OUTCOMES



As noted previously, in the pursuit of Effectiveness outcomes at the patient or individual consumer level, Proctor et al describe a more detailed category. Symptom reduction or improvement, functioning and satisfaction are examples of patient level outcomes that would support the commitment to, and validation of, the implementation and sustainment process.

Quality improvement activities measure implementation outcomes but focus on local change and impact. Also, the activities often focus on process improvements rather that scaling up new practices.

Learning health systems use many data-based approaches to improve care, reduce cost and enhance the patient experience. Using "big data" analytics, learning health systems explore standardized databases to identify variation in care process and outcomes. One strategy involves identifying high performers (outcomes, cost) and then deconstructing their practices. Once these practices are differentiated from average or negative outliers, the goal becomes to expand what successful practices do to all practices. Because the data gathered, the populations studies, and the organizational characteristics unique to the health care system, these activities may not be generalizable. In addition, many of these activities are propriety in a competitive health systems marketplace.

How is information on an evaluation framework such as RE-AIM useful to programs, organizations, systems, intervention developers, purveyors and to SAMHSA?

It would seem indisputable that measures of implementation outcome are of great relevance.

Persons who need services, deserve the best that are available.

Providers of services should be motivated to deliver the most effective option, and do it correctly. Beyond the circumscribed short-life of a start-up infusion of money and resources, people who get the best service and those who deliver it deserve for it to continue. The measures of outcome as defined by RE-AIM are useful to providers to feedback the quality of care they offer.

Organizations who have invested time and opportunity costs in change and improvement need dashboard data to confirm they are headed in the right direction, and in the case of maintenance, holding the course.

Systems of care, including multi-site organizations, networks, states, counties and tribes have an interest in standardizing care across sites. This does not mean industrialization or loss of individualized, patient-centeredness. But particularly with an investment in innovation and implementation, systems leaders want metrics to evaluate variation, progress and achievement of goals.

Intervention developers are interested in data as to how their intervention or program is being scaled up, and how it spreads to other populations, settings and locations.

Purveyors commit their time and effort to dissemination, often via training and workshop, but often question the impact of their work in changing everyday practice of their audience. Some purveyors extend their involvement beyond the classroom to coaching, consulting, technical assistance, facilitation and/or implementation support. These activities may be face-to-face, onsite, teleconference, videoconference, accompanied by manuals, toolkits and checklists, time-limited or open-ended. The impact of these efforts can be informed and evaluated by the outcomes of RE-AIM.

SAMHSA is in position to positively influence prospective and existing grantees engaged in implementation, scale up or spread of evidence-based approaches. SAMHSA can leverage grantees' level of sophistication in the implementation process. First, by asking them to understand and document contextual factors and the baseline stage of their implementation endeavor. Second, by determining the stage of implementation. Last, even more critically, obtaining metrics that track the impact of these implementation endeavors on Reach, Effectiveness, Adoption, Implementation and Maintenance, are imperative to obtain at baseline, during and post-implementation, and over time. The specifics of the measures of these constructs must be customized and tailored to the endeavor at hand. But these constructs must be measured to have any idea how and what has occurred for the investment.

8. IMPLEMENTATION STRATEGIES

Implementation strategies are the "interventions" of the implementation process. These are the "how" of an implementation or sustainment endeavor. These are the activities, the actions, the causal agents, of either the installation, the scale up, scale out or sustainment of an evidence-based practice or program. Prioritized by the Institute of Medicine and the National Institutes of Health, effective implementation strategies should accelerate the closing of the gap between access to and the quality of behavioral health care in the US.

Clearly, given their importance, top priority should be given to conceptualizing and designing the most effective--and cost-effective--implementation strategies. How to tailor or match strategies to any implementation problem or scenario must also be a priority. Finally, the evaluation of implementation strategies, including their comparative effectiveness and costs, is critically important.

Unfortunately, the current state of the evidence for the efficacy, effectiveness, or the comparative superiority of specific strategies is unavailable--much like the prior state of psychosocial therapies over 30 years ago. It was not until standardized definitions of psychosocial therapy components, including manualization, adherence and competence ratings to ensure fidelity, and a series of rigorous evaluations from efficacy thru effectiveness randomized clinical trials could we determine the "evidence-base" and relative performance of a psychosocial therapy. Much like the FDA-approval process for medications, psychosocial therapies achieve a higher evidentiary base if they are validated by independent researchers (not just the therapy developers), systematic or Cochrane reviews, and meta-analyses.

Numerous attempts to conduct systematic reviews, meta-analyses and even narrative reviews or compilations of implementation strategies have been substantially limited. Significant problems exist in the consistency of language of implementation strategies, the precision in their description and procedures, and the lack of theoretical, empirical or even pragmatic justification. Powell et al (2015) document significant problems in terminology, specifically, *homonymy* (same terms different meanings), *synonymy* (different terms, same meaning) and *instability* (unpredictable shifts in meaning over time).

Over the past four years, implementation scientists have made extensive contributions to increase clarity and the potential for rigor in the selection, tailoring, comparative effectiveness and essential ingredients to implementation strategies. Within the next few years, significant progress will be made in these pursuits. Large scale multi-state, multi-site, SAMHSA funded initiatives stand to serve as a useful platform for these advances.

As an outcome of the Expert Recommendations for Implementing Change (ERIC) project, Powell et al (2015) used a rigorous and tediously thorough methodology to compile a list of discrete implementation strategies. The project began with a detailed review of 41 previous published compilations, and then through a three round series of a modified-Delphi reviews of candidate strategies, a national panel of fifty-seven experts identified a final compilation of 73 implementation strategies. The list and associated definitions for each strategy are presented in the original Powell et al (2015) article.

This list of strategies is presented in Table 6.

TABLE 6: COMPILATION OF DISCRETE IMPLEMENTATION STRATEGIES (n=73)

Strategy	
Access new funding	Inform local opinion leaders
Alter incentive/allowance structures	Intervene with patients/consumers to enhance uptake and adherence
Alter patient/consumer fees	Involve executive boards
Assess for readiness and identify barriers and facilitators	Involve patients/consumers and family members
Audit and provide feedback	Make billing easier
Build a coalition	Make training dynamic
Capture and share local knowledge	Mandate change
Centralize technical assistance	Model and simulate change
Change accreditation or membership requirements	Obtain and use patients/consumers and family feedback
Change liability laws	Obtain formal commitments
Change physical structure and equipment	Organize clinician implementation team meetings
Change record systems	Place innovation on fee for service/formularies
Change service sites	Prepare patients/consumers to be active participants
Conduct cyclical small tests of change	Promote adaptability
Conduct educational meetings	Promote network weaving
Conduct educational outreach visits	Provide clinical supervision
Conduct local consensus discussions	Provide local technical assistance
Conduct local needs assessment	Provide ongoing consultation
Conduct ongoing training	Purposely reexamine the implementation
Create a learning collaborative	Recruit, designate and train for leadership
Create new clinical teams	Remind clinicians
Create or change credentialing and/or licensure standards	Revise professional roles
Develop a formal implementation blueprint	Shadow other experts
Develop academic partnerships	Stage implementation scale up
Develop an implementation glossary	Start a dissemination organization
Develop implementation tools for quality monitoring	Tailor strategies
Develop and organize quality monitoring systems	Use advisory boards and workgroups
Develop disincentives	Use an implementation advisor
Develop educational materials	Use capitated payments
Develop resource sharing agreements	Use data experts
Distribute educational materials	Use data warehousing techniques
Facilitate relay of clinical data to providers	Use mass media
Facilitation	Use other payment schemes
Fund and contract for the clinical innovation	Use train-the-trainer strategies
Identify and prepare champions	Visit other sites
Identify early adopters	Work with educational institutions
Increase demand	

From Powel et al, Implementation Science (2015) 10:21

The above list features discrete strategies that are usually combined together as a multi-level, multi-faceted implementation strategy. Nonetheless, surprisingly, in the face of evidence for implementation ineffectiveness, “Conduct educational meetings” and “Conduct ongoing training” are the two most common discrete implementation strategies deployed today. These discrete strategies may be useful in the context of other strategies (e.g. Audit and Provide Feedback), but not as stand alones. Some might argue that training—in response to a barrier that includes knowledge gap—may be necessary but insufficient as a potentially effective implementation strategy.

TAILORING IMPLEMENTATION STRATEGIES

Analogous to the clinical situation, if implementation strategies are the "interventions" of the implementation process, the context factors—barriers and facilitators—are the diagnoses, problem lists and strengths of the individual, organization or system. Further, the patient stage of readiness or motivation is quite similar to the stage-wise EPIS model. The goals of the clinical practice---good outcomes. In implementation and sustainment activities—the goals can be captured within the RE-AIM framework.

At times, clinical practice has been criticized for a *one-size-fits-all* approach despite well-worn aspirational phrases such as "individualized treatment planning" or "patient-centered" or even "precision medicine." Implementation activities often suffer the same tendency, especially if the implementation strategy purveyor has a longstanding tradition and is completely organized to deliver one discrete implementation strategy (i.e. didactic education, training and workshops).

Mittman (2012) was among the first to suggest the critical importance of tailoring implementation strategies to context. Although the evidence for tailoring strategies is forthcoming, there is some consensus about logical approaches. For instance, ignoring that clinicians work within an organization or program, and directing the entire implementation strategy at clinicians' skill level in the evidence-based practice will likely have no impact on the services that are offered and billed for by the organization. As a starting point, a discrete implementation strategy should be matched to an identified barrier, the level (clinicians, organizations, systems, consumers), and the type of intervention being implemented. Barriers can be systematically catalogued using the either the CFIR or PARHIS determinant frameworks. Still evolving is the science behind which strategies for which barriers, how to prioritize barriers to address, and which strategies are best suited for which level. Further, because multi-level, multi-component strategies bundle any number of discrete strategies, knowing what are the most cost-effective and efficient combinations would be useful. Akin to a treatment plan, a proposal for an implementation activity, either to install a new practice, scale and existing practice, or de-implement an established but ineffective practice, should require an implementation strategy plan.

To illustrate a tailored Implementation Strategy Plan, Table 7 outlines the basic components (column headings) and provides a linkage by barrier (CFIR Index items) to specific discrete strategies (rows). Having baseline measures of outcomes (using the RE-AIM framework) enables evaluation of the effectiveness of the strategies to attain implementation goals. EPIS stage, either at the individual or organizational level, may also be informative in selecting strategies from a menu.

In this example, the implementation challenge is to expand access to medications for opioid addiction in a hypothetical county system. In many instances, the response to this problem might include special funds to that offer training to behavioral health clinicians and physicians to increase awareness and perhaps the number of doctors who can prescribe buprenorphine. As a follow-up, there may be an effort to connect local leaders and champions with the Providers Clinical Support System for Medication Assisted Treatment (http://pcssmat.org/). But as can be gleaned from the illustration on Table 7, a systematic assessment of determinants provides a much more targeted starting point. Although other discrete strategies could conceivably have been selected from the ERIC menu, this plan suggested a multi-level (3 levels), and multi-component (11 discrete strategies) within a purposeful and measurement based implementation activity.

TABLE 7: IMPLEMENTATION STRATEGY PLAN

BASELINE RE-AIM ESTIMATES	CFIR INDEX BARRIERS (Scores of -2)	DISCRETE IMPLEMENTATION STRATEGIES	DETAIL ON DELIVERY OF STRATEGY	RE-AIM OUTCOMES
R: 5% of persons with OUD in Redwood County who are in treatment receive MAT E: 50% of those in treatment are retained for 6 months A: 5 physicians have waiver; 1 of 6 behavioral health organizations offer MAT I: No information on guideline adherence M: No information on maintenance. New implementation project i.e. Preparation Stage of EPIS	B. Systems/Community			R: Change in % persons with OUD on MAT E: Change in % in continuing care at 6 months A: Change in # of waivered physicians and in # of patients per physician; Change in # of behavioral health organizations offering MAT I: Change in performance on QI measures gathered in learning collaborative M: Now in Active Stage of EPIS; Planning for sustainment through insurance reimbursement activities
	B1. Patient needs & resources	-Involve patients/consumers and family members	-Convene community members, consumers of services and persons in recovery to document need, want and barriers	
	B2. Network connectivity	-Conduct local consensus discussions -Create a learning collaborative -Promote network weaving	-Meet with organization leaders in network to establish vision and processes -Learning collaborative for continuous problem solving and capacity building; Data collection on quality measures	
	B4. External policy & incentives	-Access new funding -Fund and contract for the clinical innovation	-Negotiate with state, county and private insurance plan to increase benefit coverage; -Incentivize programs to deliver MAT	
	C. Program			
	C6. Compatibility	-Visit other sites -Provide local technical assistance	-Address negative beliefs about MAT -Demonstrate how it is working and with good outcomes -Support changes in program	
	D. Clinicians			
	D2. Clinician self-efficacy	-Facilitation -Shadow other experts -Provide ongoing consultation	-Hands on case consultation to increase confidence and autonomy	

This Implementation Strategy Plan is one practical method to tailor the selection of implementation strategy to the specific barriers and levels of the implementation context. Powell et al (2015) recently described four process methods that could also be used to select strategies. These methods, drawn from implementation science, public health, engineering and marketing include: 1) Concept Mapping; 2) Group Model Building; 3) Conjoint Analysis; and 4) Intervention Mapping. All of these procedures feature a shared-decision making approach by engaging key stakeholders in how they prefer to address barriers to the implementation problem. The attributes of using any of these methods are:

- Involves, upfront, key stakeholders which serves to galvanize commitment to the endeavor;
- Provides a systematic, transparent and replicable method of strategy selection;
- Appreciates the complexity of the implementation effort (one size does not fit all);
- Risks using previously disproven or ineffective strategies because of key stakeholder opinion;

- Requires outside expert facilitation; and
- No evidence for their superiority over other methods of selection and tailoring of strategies.

Nonetheless, it is important to describe a logic model rationale for the specific strategies matched to context, stage, level, type of evidence-based practice or program. If this description cannot be provided, then the potential impact is dubious.

REPORTING IMPLEMENTATION STRATEGIES

As previously noted, the lack of precision and specificity in defining, delivering and reporting on implementation strategies has limited the evidence-base and undermined the generalizability of any one project to the field. In fact, there are some efforts to evaluate one strategy across disease types (e.g. learning collaboratives), multiple strategies with one disease states in one system (e.g. PTSD in the VA), but generally not across conditions, interventions, or systems.

Numerous implementation experts have written about the importance of transparency in reporting on implementation strategies (Albrecht et al, 2013; Davidoff et al, 2008; Proctor et al ,2013). The guidelines, at minimum, would include a definition and operationalization of:

a. The actor—who is doing the strategy?

b. The action—what is the strategy (strategies)?

c. The target—what is being addressed?

d. Temporality—how often and over what time frame?

e. Dose—how much action is being delivered?

f. Outcomes—what are the hypothesized effects?

g. Empirical, theoretical or pragmatic justification—why is this approach being taken?

Colquhoun et al (2014) added one more element to this list, “Mode of Delivery”---Face-to-face, web-based, telephone and teleconference, mass media or combinations.

In addition to these specifications, it is important to report on the involvement of target participants in the implementation strategy process. This would be captured in an Extended CONSORT diagram, including a count of the target audience (e.g. all physicians in Redwood County), the number eligible, interested and enrolled, the number continuing, and the number completing the implementation project. An example of an extended CONSORT in an implementation evaluation can be found in Nordstrom et al, 2015).

TRACKING THE USE OF IMPLEMENTATION STRATEGIES

Another way to track participation and degree of engagement in an implementation project is thru the Stages of Implementation Completion (SIC) scheme devised by Saldana (2014). The SIC identifies key milestones in an implementation project (e.g. signing the contract; attending the project launch meeting; CMO attending leadership summit) and tracks completion and *duration* to completion. Both of these variables provide useful information on dose and motivational aspects to participation. Otherwise,

it is impossible to tell the relative influence of the strategy itself on outcome. Without this information, all projects would be *intent-to-treat* type evaluations.

TRACKING THE DELIVERY OF IMPLEMENTATION STRATEGIES

With respect to the extended CONSORT and SIC—both have to do with the audience or participants in the project. At what level are they engaged and do they receive the implementation strategy. This is similar to tracking receipt of, adequate dose and compliance in a medication trial, or a trial of cognitive behavioral therapy. But what about the deliverers of the strategy? Have they delivered the strategy as designed? Have they delivered it well? Are all deliverers of the strategy equal?

As with any clinical intervention or implementation strategy, it is imperative to monitor the fidelity and skill with which the strategy is being delivered. Thus we examine variation in how purveyors or deliverers vary in adherence and competence. Then determine how these variations influence participation and outcome. For example, a state wants to offer a learning collaboratives to counties implementing an evidence-based prevention practice. The state leaders organizing the event have heard that learning collaboratives are popular, and in fact a few of the leaders of the counties' prevention services have suggested this approach. The state offers a series of 6 webinars focused on the evidence for and application of the prevention practice in routine school settings. CME didactic content is presented using shared PowerPoint slides, and there is ample time for questions. Because this series does not include three of the four core ingredients to an Institute for Health Care Improvement (IHI) learning collaborative (didactic component, case or practice presentation, common QI data collection and reporting, PDSA activities), this would not be a high fidelity learning collaborative strategy.

Fidelity and skill may also come into play in explaining variation in implementation outcomes. In large systems implementation projects there are often several coaches, facilitators, consultants or purveyors. These individuals may vary on any number of variables including content expertise, style, demographics, experience, other life circumstances; but they should not vary in how they deliver the implementation strategy or how they respond and adapt to issues that arise from their participants. But it is likely they do vary.

Using a fidelity measure to capture variation in the delivery of a strategy is important for two reasons: a) quality monitoring of the strategy's delivery; and 2) as a predictor of differences in participant engagement in the project as well as implementation outcomes.

IMPLEMENTATION STRATEGY COSTS

Raghavan (2012) described the importance of capturing the costs of engaging in an implementation strategy. The relative costs of participating or using one strategy over another, when there are no differences in outcomes may guide the selection of one strategy over another. Also, in the context of a shared decision making conversation, weighing relative costs and benefits is instrumental to an informed choice. This is neither cost-effectiveness nor cost outcome but rather a determination of the relative costs to use an implementation strategy. Specific costs include: direct labor costs, indirect labor costs and non-labor costs. An example of a high cost strategy that is effective is manual-guided therapy fidelity monitoring. This may include supervisor time to either directly observe or review video- or audio-tape recordings of therapy sessions. Challenges in maintaining this strategy in routine practice have reduced its sustainability in routine settings and systems (e.g manualized therapies in the SAMHSA

multi-site, multi-state Cannabis Youth Treatment project). Some health care systems, e.g. VA, have experimented with electronic health record templates, random auditing, and machine learning for greater efficiency in adherence and competence monitoring of evidence-based therapies for PTSD.

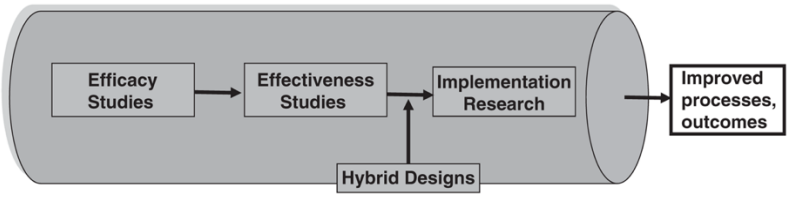
Cost analyses provide realistic data upon which to base informed decisions about the selection of implementation strategies.

9. EVALUATION DESIGNS

There are two seminal articles on dissemination and implementation research designs.

The first is by Curran and colleagues (2012) describing the features of 3 types of hybrid effectiveness-implementation research designs. The three designs vary based upon the ratio of emphasis from effectiveness to implementation.

FIGURE 4: THE TRANSLATIONAL PIPELINE (From Curran et al, Medical Care 2012)



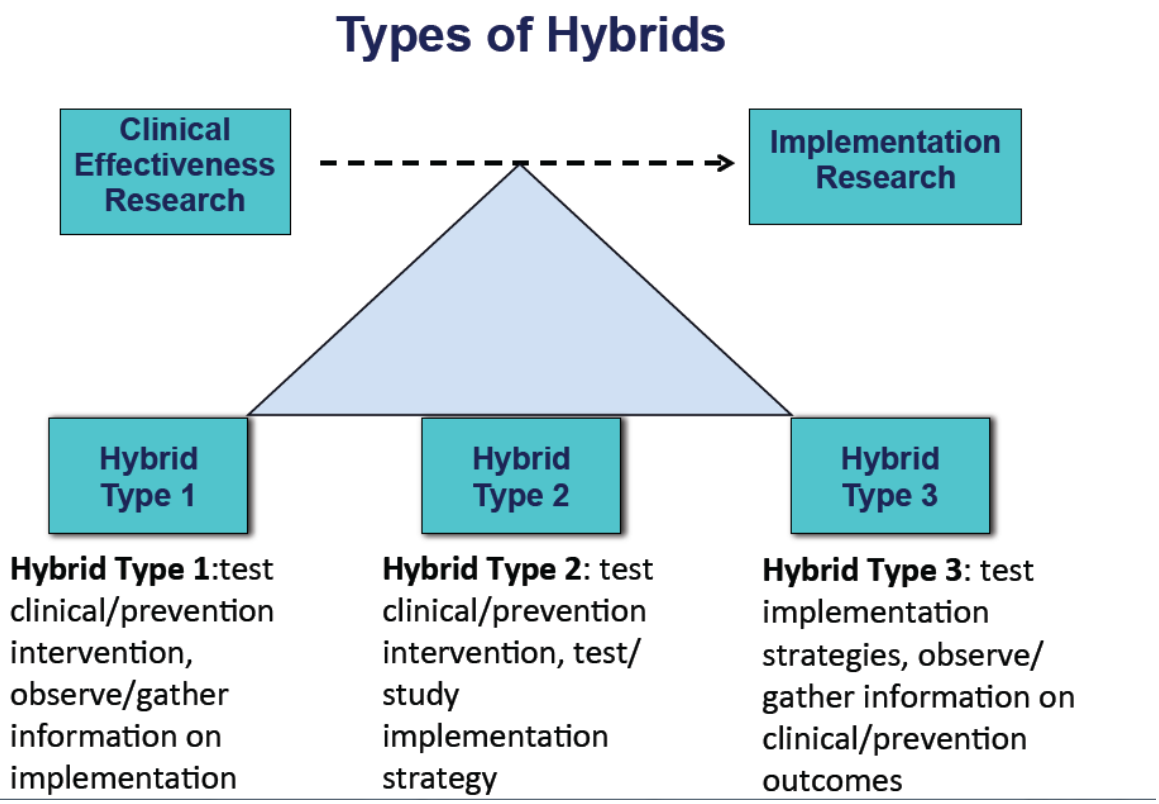
The Type 1 Hybrid Design emphasizes effectiveness (for example patient level improvement in symptoms, functioning and satisfaction with care) over aims and methods to evaluate implementation aspects. Many studies of mHealth platforms of care delivery are presently at the Type 1 Hybrid level of design.

Type 2 Hybrid Designs are balanced in emphasis on effectiveness and implementation outcomes. Studies in this category often involve an extension of a well-established evidence-based practice to a new setting or population or an expert consensus based program that is generally regarded as the right thing to do. An example may be school based prevention programs with multiple components for which implementation issues and local impact on children and systems both must be evaluated.

Type 3 Hybrid Designs are used when the evidence-base is well-established for the practice or program to be implemented. FDA-approved medications and screening often fall into this category. For example, screening for tobacco use in primary care may be evaluated for implementation but not for its impact on changes in tobacco use behavior or reduction in associated disease rates.

Persons reviewing evaluation proposals should consider the available evidence for an intervention and if significant, not necessarily overburdening the project design with the costs associated with effectiveness or individual level outcomes.

FIGURE 5: TYPES OF HYBRID DESIGNS (From Brown, 2017)



The second major contribution to evaluation design is found in an article by Brown et al (2017).

Outlined are three broad categories of designs that provide within-site, between-site, and within- and between-site comparisons of implementation strategies.

WITHIN-SITE DESIGNS

Post design of an implementation strategy to adopt an evidence-based practice or program in a new setting: In these projects, there is typically a strong degree of evidence for an intervention or process so the emphasis is on a new installation—and not a change from pre- to post. Also because of the strength of evidence, patient level outcomes are not usually being considered. An example may be the use of screening for cannabis use among adolescents in a pediatric practice. The target may be to increase number of patients screened, number of patients screened positive, and number of follow-ups by pediatricians during the office visit. Multi-level, multi-component strategies are likely needed to achieve these outcomes.

Pre-Post design of an implementation strategy of an evidence-based practice or program already in use: In this type of design, the evidence-based program is already in place, but the reach or adoption may be lower than desirable, or there could be wide variation in implementation. So, now that we have installed the process to address cannabis use with our pediatric patients, we realize that not all doctors

are attending to the screen results or mentioning it in their visits. A compilation of discrete implementation strategies, including audit and feedback, changes to the electronic health record system (reminders), and identify and prepare champions (positive outliers) can be deployed. The pre-post comparison is on reach and adoption outcome changes from time 1 to time 2. Incremental or stepped wedge aspects could also be studied, starting out with less intensive strategies (audit and feedback—academic detailing) then adding higher cost components if necessary.

BETWEEN-SITE DESIGNS

New implementation strategy versus usual-practice implementation designs: The goal of this type of project is to evaluate if a new strategy is better than whatever currently exists. A more rigorous design involves random assignment. To control for the unique features of a single site being compared with another single site, multiple sites can be involved. This is a cluster-group randomized controlled trial design. It is possible that two multi-level, multi-component implementation strategies are being compared (for example, academic detailing versus learning collaborative to increase the number of pediatricians addressing cannabis use). But in real world practice, because of limited consultation resources (and a belief in or preference for one strategy over others), a wait-list control, roll out, or stepped wedge design is more typical with multiple sites within a system.

Head-to-head randomized implementation trial design: As in the example above, this type of design pits two comparable implementation strategies against one another, and measures the impact on outcomes (RE-AIM). In these projects, there may be more inherent interest in patient or individual level outcomes. Thus, these may be hybrid designs that evaluate both implementation (# of screens, # of follow-ups, # of pediatricians) and effectiveness (change in youth awareness, motivation and cannabis use).

Factorial designs: These designs involve two or more implementation strategies but manipulate components. In the illustration of youth cannabis use, this type of design may involve changing the screening format (interview by medical assistant or self-administered via iPad in waiting room), the use of electronic prompts (on/off) and academic detailing or learning collaborative. Factorial, multiphase optimization implementation strategy (MOST) trials, or sequential multiple assignment randomized implementation (SMART) trials are examples of evaluations where multi-level and multi-component strategies are being de-constructed. Although complicated because of the amount and frequency of measurement, as well as the need for extensive tracking and project management, the results from these evaluations provide good information about essential ingredients and mechanisms of action.

WITHIN- AND BETWEEN-SITE DESIGNS

These designs can be used in large scale projects and are often called “roll-out” designs. In particular, they may involve a baseline period and staggering the start of two or more implementation strategies. The comparisons occur within sites--how much do they improve on implementation outcomes over time and by intervention, and also between sites--what is the difference in implementation outcomes between sites based on the implementation strategy being deployed.

Brown et al (2017) provide more detail on these designs and also consideration for data analyses and interpretation. It is important to know the major design features in terms of balancing effectiveness and implementation outcomes, and the approaches to both small and large scale evaluations.

SAMHSA: LEVERAGING ROLES AND OPPORTUNITIES

The second and final major goal of this report is to make recommendations on how SAMHSA could leverage implementation science in their major role as funder of behavioral health and support services across the US.

In the US, many federal government agencies support and promote the availability of behavioral health care. SAMHSA, including the Center for Substance Abuse Treatment, Center for Mental Health Services, Center for Substance Abuse Prevention and the Rehabilitation Services Administration. Another federal agency involved in the funding of behavioral health services is the Center for Medicare and Medicaid Services. Lastly, given the increased recognition that without behavioral health there is no health, the Health Resources and Services Administration is increasingly engaged in the intersection of mental and physical health prevention, treatment and services.

In this final section, suggestions are offered to assist the leadership of SAMHSA consider approaches to leverage their authority and administrative role to increase access to and quality of evidence-based programs and services. Historically, SAMHSA has provided excellent leadership and steering via funding, policy and dissemination of information. Exemplar upstream initiatives such as the National Implementing Evidence-Based Practice Project and the establishment of the National Registry of Evidence-Based Practices and Programs are representative of key actions that have had a national downstream impact.

Nonetheless, estimates of routine access to evidence-based practices continue to be low. In fact, a recent article by Bruns et al (2016) suggests that at the state level, the rates of availability of evidence-based practices may be declining. Thus, it is understandable that SAMHSA is exploring new ways to move the needle on RE-AIM within the systems for which they have jurisdiction. Implementation science may be useful as one way to do this.

As a single-author report, the suggestions provided must be interpreted as limited, inherently biased and not comprehensive. In many respects, these suggestions can be perceived as the start of the conversation. An advisory and/or workgroup composed of SAMHSA leaders, implementation scientists, prevention and treatment leaders, state agency officials, consumers and family members, health information technologists, CMS and health plan experts, systems engineers and health economists might be charged to develop key practical and actionable strategies.

The “infrastructure” upon which the suggestions herein are built include: 1) Data collection; 2) Accountability in Performance; 3) Monitoring and Feedback; and 4) Partnerships.

In 2013, to scale up evidence-based programs, using a checklist-type format, we outlined roles and responsibilities of federal agencies state government health authorities, purveyors (technical assistance, trainers, expert consultants, technology transfer centers, developers), organization executive leaders, organization clinical leaders, team leaders or supervisors, practitioners or clinicians, and clients and community stakeholders (McGovern et al, 2013). Along with the Brownson et al (2012) text and the historical reference by Fixsen et al (2005), this is a key reference to which the reader might want to refer more closely.

With respect to the federal agency role (i.e. SAMHSA), the checklist of actions has been revised and is now grouped into the four stages of the EPIS model: *Exploration, Preparation, Implementation and Sustainment*.

Exploration

- Use epidemiological data to define need of population
- Use services data to document ratio of met to unmet need
- Gather and maintain active repository of verified information about the services being offered by SAMHSA funded entities at the state and organizational level (i.e. prevention and treatment locator platform)
- Use services data to explore variation in services offered, services utilized and in cost and outcomes (state, systems and/or organization level)
- Develop strong bidirectional partnerships with state agency leaders on common mission
- Develop strong bidirectional partnerships with NIH officials to increase funds for research that directly addresses public health service implementation problems, then use this research to translate prevention and treatment services with a strong evidence-base
- Inform states and/or purveyors of the requirement to collect and report systematic data on barriers and facilitators to implementing the evidence-based practice or program (e.g. CFIR), variation by organization in provider in stage (e.g. EPIS), baseline measures of RE-AIM of the evidence-based practice or program, and detail a specific plan for how implementation strategies will be tailored to context, stage or other factors, and how the strategy will effect the RE-AIM outcomes

Preparation

- Compile and organize the evidence on a candidate evidence-based practice (literature reviews, meta-analyses, expert panels)—verify its strength, value and feasibility
- Disseminate evidence in usable form for states, purveyors, and treatment providers (manuals, toolkits, treatment improvement protocols)
- In preparation for initiative or policy launch, make public statements, produce documents, and provide conferences webinars and resources to ignite partnerships
- At new grant/contract proposal or application/contract renewal, require states, contractors and/or purveyors to document systematic data on barriers and facilitators to implementing the evidence-based practice or program (e.g. CFIR), variation by organization in provider in stage (e.g. EPIS), baseline measures of RE-AIM of the practice or program, and a plan for how implementation strategies will be tailored to effect the RE-AIM outcomes
- Organize tangible supports by arranging for the allocation resources or incentives for evidence-based practices or programs
- Prioritize the evidence-based practices or programs in directives, rules and policies
- Fund practices and programs that are proven to be effective, and eliminate funding for practices and programs that are ineffective

Implementation

- Coordinate and communicate with other government offices and publically recognize states and systems engaged in implementing the practice
- Simplify rules for accessing funding for implementing evidence-based practices
- Establish conferences, webcasts, and learning networks or systems as a means to provide mechanisms for mutual learning, problem solving and to energize partnerships
- Develop mechanisms for assessing state, purveyor and organization level implementation outcomes using the RE-AIM evaluative framework
- Generate aggregate reports on program and client outcomes using reliable and valid standardized data gathered from funded programs
- Develop web-based directories that list organizations that are successfully delivering the evidence-based practice
- Support and evaluate purveyors based on RE-AIM goals and outcomes, the systematic tailoring of implementation strategies and supports matched to barriers and facilitators, stage or other measurable factors.

Sustainment

- Continue to communicate with other government offices through public service announcements and awards to states and organizations sustaining the evidence-based practice or program
- Build in mechanisms to reinforce permanence and predictability in funding, such as through block grant mechanisms or federal health care coverage and reimbursement mechanisms
- Continue to provide mechanisms for relaying updates and new developments for mutual learning and problem solving through conferences, webcasts and learning networks or systems
- Continue gathering and reporting RE-AIM data at the state and organizational level
- Maintain and update web-based directories of organizations that have verifiable delivery of the evidence-based practice or program
- Support and evaluate purveyors (technical assistance, trainers, expert consultants, technology transfer centers, developers) on RE-AIM outcome sustainment, tailoring sustainment strategies based upon new or continuing barriers and facilitators, and assist purveyors in revising and updating practice and program information based on the latest evidence
- Re-evaluate treatment services data to document ratio of met to unmet needs, and examine for change, and for decreasing disparities by race, ethnicity, geography, age, gender, disability or other determinant
- Continue to use services data to explore variation in services offered, services utilized and in cost and outcomes

Learning health systems—VA, Kaiser, Geisinger, Ford, InterMountain, SAMHSA—depend on reliable and when possible--real time--data on services, costs and outcomes to make informed decisions. These decisions might entail identifying practice variation or high versus low performers; discontinuing an ineffective practice; scaling up a more effective practice; installing a new practice to address a problem (e.g. opioid overdose death); or recognizing inequity in who gets high quality care. All systems aspire to have real-time dashboards of these indicators, but in reality most only obtain estimates thru the rear view mirror.

The degree to which SAMHSA can obtain data on the US population needs for behavioral health prevention and treatment, document the gap in service delivery, would be a major step in defining the scope of the problem. It would also enable us to measure our progress. Thus, the value of Data Collection as a core component of the suggested "infrastructure."

Accountability in Performance entails verification of delivery of evidence-based practices or programs, most likely by independent, random audit. Organizations must document or prove an evidence-based practice or program is offered to list it in the SAMHSA treatment locator. Providers must document the evidence-based practice or program is delivered in order to get the highest reimbursement rate (P4P; or Delaware incentive model). Regulatory authorities (states, counties) already serve in this role, but typically do not have an evidence-based practice or quality focus.

A significant suggested change to the *status quo* would be in how states, contractors and purveyors are accountable to use tailored strategies to implement and/or sustain an evidence-based practice or program, to systematically document contextual determinants (barriers and facilitators), and to report on implementation outcomes. Many existing grants and contracts with states, contracts with consultant experts, and contracts with purveyors focus on the quantity of services (clients), events (number of trainings) and budget reporting (staff and hours allocated). Despite the evidence that trainings have no impact on practice, or on effective implementation, trainings continue to be the most widely offered activity by purveyors. The Addiction Technology Transfer Centers primarily offer training and to a lesser extent coaching or support. The PCSS-MAT offers training and mentorship. ECHO offers practice-based case learning and expert consultation. Technical assistance centers vary in the type of training (didactic, role playing, behavioral rehearsal), use of ongoing consultation, coaching, facilitation, implementation support, fidelity monitoring, and clinical supervision. Requiring purveyors or state grant applications to link multi-level, multi-component implementation strategies to the contextual barriers and facilitators of their target audience, and then measure RE-AIM indicators at baseline and over the course of their work is unprecedented. Yet, this would be what implementation science suggests will lead to a greater impact; without a doubt versus a series of trainings and workshops in a one-size-fits-all approach.

Requiring this type of information from applicants for target capacity expansion grants or other new initiative grant mechanisms would not be difficult. Furthermore, the ingenuity of those purveyors and the states they serve would likely result in significant advances in implementation science. Requiring this information over the course of a grant as a measure of performance, and to track critical implementation outcomes would be easier than tracking patient level outcomes using the GPRA. Requiring the prospective or existing grantee to plan for sustainment, to build in strategies to increase its probability, and to measure it, would go far to reducing voltage drop, quality drift, or the disappearance of the evidence-based practice altogether.

Many parallels have been drawn between the clinical and implementation enterprises. Several of these have been pointed out within this report. Just like in measuring a patient's response to a medication, or to cognitive behavioral therapy using the PHQ-9, Monitoring and Feedback could be an extremely valuable tool to encourage a more positive trajectory of evidence-based practice. The Individual Placement and Support model of supported employment for adult persons with serious mental illnesses uses fidelity ratings across a national learning collaborative to foster high performance of employment specialists across multiple states. What if states and counties kept track of RE-AIM outcomes, from baseline to over time? What if purveyors reported on RE-AIM outcomes, or on methods they tailored

implementation strategies to overcome significant barriers? What if SAMHSA (or a contracted entity) kept track of these data and provided feedback to key stakeholders? States vary in how data are gathered, evidence-based practices supported, performance measured, and feedback provided (Finnerty et al, 2009). Moving forward, if the recommended data are required by SAMHSA, we could learn so much from the states and the purveyors who are able to implement and sustain practices most effectively and efficiently.

The basic scientist can spend hours upon end in her lab and work toward discovery and innovation within a sphere of relative social isolation. She can publish many papers and win prizes. The clinical scientist can work with his team and study site to test a new therapy, and interact with clinicians and patients at the clinic, colleagues in his department, and a broader network of associates at national meetings. The results of a 12-week trial with 75 subjects can be the start-up for a better medication for pharma to market and proliferate. The implementation scientist works with a wide variety of stakeholders, from systems leaders to providers to intervention developers to consumers and families. In order to be successful, this variety of scientist cannot work in isolation, and cannot work for a fixed period of time. Partnerships with all stakeholders—relationships built on trust, respect and a belief in a common mission—are essential. In fact, the old adage has been adapted to "partner or perish."

It would seem obvious to most that we are failing to translate evidence-based treatments to the public health benefit. Disparities are rampant. Few get the care they need or deserve. This would seem to be a chronic and vexing problem we can all rally around. SAMHSA is in position to lead and forge a new strategy for an implementation and sustainment Partnership. This partnership must include sister federal agencies, state government health authorities, purveyors (technical assistance, trainers, expert consultants, technology transfer centers, developers), organization executive leaders, organization clinical leaders, team leaders or supervisors, practitioners or clinicians, and clients and community stakeholders. We must all agree that the status quo, or that anything goes, is not working.

Most reviews and reports of this type end with a recommendation that has significant budgetary impact—typically a requirement for increased funding. It is not obvious that the overview and opportunities for SAMHSA outlined here come at significant or greater cost. Changes in policy, in contracting, in stipulations in grant applications and awards, that incorporate implementation science related Data Collection, Accountability in Performance, Monitoring and Feedback, and Partnership may actually have negligible budget consequences.

We may all agree there is a persistent gap in access and quality of behavioral health prevention and treatment services. We may not all agree on the mechanisms to eliminate this canyon-size gap.

Proposed herein, is an approach that implementation science would bring to bear.

BIBLIOGRAPHY

Aarons, GA, Hurlburt, M, Horwitz, SM. (2011). Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Administration and Policy in Mental Health and Mental Health Services Research* 38(1): 4-23.

Albrecht, L, Archibald, M, Arseneau, D, Scott, SD. (2013). Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implementation Science* 8: 1-5.

Assefa, M, McGovern, MP. (2017). Operationalizing the Consolidated Framework for Implementation Research: The CFIR Index. *Implementation Science*. Under review.

Brown, CH, Curran, G, Palinkas, LA, Aarons, GA, Wells, KB, et al. (2017). An overview of research and evaluation designs for dissemination and implementation. *Annual Review of Public Health* 38:1-22.

Brown, CH. (2017). Dissemination and implementation research designs. Presentation at the annual Implementation Research Institute, Washington University at St. Louis, St. Louis MO: June 12.

Brownson, RC, Colditz, GA, Proctor EK (Eds). (2012). *Dissemination and implementation research in health: Translating science to practice*. New York: Oxford University Press.

Bruns, EJ, Kerns SEU, Pullmann, MD, Hensley SW, Lutterman, T, Hoagwood, KE. (2016). Research, dat, and evidence-based treatment use in state behavioral health systems, 2001-2012. *Psychiatric Services* 67:5.

Colquhoun, H, Leeman, J, Michie, S, Lokker, C, Bragge, P, Hempel, S, et al. (2014). Towards a common terminology: A simplified framework for interventions to promote and integrate evidence into health practices, systems and policies. *Implementation Science* 9: 1-6.

Curran, GM, Bauer, M, Mittman, B, Pyne, JM, Stetler, C. (2012). Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care* 50: 217-26.

Damschroder LJ, Aron, DC, Keith, RE, Kirsh, SR, Alexander, JA, Lowery, JC. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science* 4: 1-15.

Davidoff, F, Batalden P, Stevens, D, Ogrinc, G, Mooney, S. (2008). Publication guidelines for quality improvement in health care: Evolution of the SQUIRE project. *Quality and Safety in Health Care* 17 supplement: 3-9.

Finnerty, MT, Rapp, CA, Bond, GR, et al. (2009). The State Health Authority Yardstick (SHAY). *Community Mental Health Journal* 45: 228-236.

Fixsen, DL, Naoom, SF, Blasé, KA, Friedman, RM, Wallace, F. (2005). *Implementation research: A synthesis of the literature*. Tampa FL: University of South Florida.

Glasgow, RE, Bogt, TM, Boles, SM. (1999). Evaluating the pubic health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health* 89: 1322-27.

Institute of Medicine. (2001). *Crossing the quality chasm: A new health system for the 21st century*. Washington DC: National Academy Press.

Kilbourne, AM, Newmann, MS, Pincus, HA, Bauer, MS, Stall, R. (2007). Implementing evidence-based interventions in health care: Application of the replicating effective programs framework. *Implementation Science* 2: 42.

Kirk, MA, Kelley, C, Yankey, N, Birken, AS, Abadie, B, Damschroder, L. (2016). A systematic review of the use of the Consolidated Framework for Implementation Research. *Implementation Scien*ce 11: 72.

Kitson, AL, Rycroft-Malone, J, Harvey, G, McCormack, B, Seers, K, Titchen, A. (2008). Evaluating the successful implementation of evidence into practice using the PARiHS framework: Theoretical and practical challenges. *Implementation Science* 3: 1.

McGovern, MP, Carroll, KM. (2003). Evidence-based practices for substance use disorders. *Psychiatric Clinics of North America* 26: 991-1010.

McGovern, MP, Saunders, EC, Kim, E. (2013). Substance abuse treatment implementation research. *Journal of Substance Abuse Treatment* 44(1): 1-3.

McGovern, MP, McHugo, GJ, Drake, RE, Bond, GR, Merrens, MR. (2013). *Implementing evidence-based practices in behavioral health*. Center City MN: Hazelden Publishing.

Mittman, BS. (2012). Implementation science in health care. In RC Brownson, GA Colditz, EK Proctor (Eds). *Dissemination and implementation research in health: Translating science to practice* (pp. 400-418). New York: Oxford University Press.

National Institutes of Health. Dissemination and implementation research in health (R01). 2017. Available online: https://grants.nih.gov/grants/guide/pa-files/PAR-16-238.html Accessed September 4, 2017.

Nilsen, P. (2015). Making sense of implementation theories, models and frameworks. *Implementation Science* 10: 53.

Nordstrom, BR, Saunders, EC, McLeman, B, Meier A, Xie, H, et al (2016). Using a learning collaborative strategy with office-based practices to increase access and improve quality of care for patients with opioid use disorders. *Journal of Addiction Medicine* 10(2): 115-121.

Powell, BJ, Beidas, RS, Lewis, CC, Aarons, GA, McMillen, JC, Proctor, EK, Mandell, DS. (2015). Methods to improve the selection and tailoring of implementation strategies. *Journal of Behavioral Health Services & Research* 44(2): 177-194.

Powell, BJ, Waltz, TJ, Chinman, MJ, Damschroder, LJ, Smith, JL, Matthieu, MM, Proctor, EK, Kirchner, JE. (2015). A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science* 10:21.

Proctor, EK, Silmere, H, Raghavan R et al. (2012). Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* 38(2): 65-76.

Proctor, EK, Powell, BJ, McMillen, JC. (2013). Implementation strategies: Recommendations for specifying and reporting. *Implementation Science* 8: 1-11.

Raghavan, R. (2012). The role of economic evaluation in dissemination and implementation research. In RC Brownson, GA Colditz, EK Proctor (Eds). *Dissemination and implementation research in health: Translating science to practice* (pp. 94-113). New York: Oxford University Press.

Rogers, EM. (1962). *Diffusion of innovations*. New York: Free Press.

Rycroft-Malone, J. (2010). Promoting action on research implementation in health services (PARiHS). In J Rycroft-Malone, T Bucknall (Eds). *Models and frameworks for implementing evidence-based practice: Linking evidence to action.* (pp. 23-50). Oxford: Wiley-Blackwell.

Saldana, L. (2014). The stages of implementation completion for evidence-based practice: Protocol for mixed-methods study. *Implementation Science* 9: 43.

Tabak, RG, Khoong, EC, Chambers, DA, et al. (2012). Bridging research and practice. Models for dissemination and implementation research. *American Journal of Preventive Medicine* 43(3): 337-350.