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Using Implementation Science to Guide the Integration of Evidence-Based Family Interventions into Primary Care

Justin D. Smith and

Center for Prevention Implementation Methodology, Department of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine

Jodi Polaha

Division of Primary Care Research, Department of Family Medicine, East Tennessee State University

Abstract

In this article, we demonstrate how an implementation science (IS) framework is coupled with the measurement of implementation outcomes to effectively integrate evidence-based family interventions in primary care. The primary care environment presents a number of challenges for successfully integrating such interventions. However, IS methods can improve the prospect of successfully implementing a new intervention while simultaneously and rigorously evaluating the impact on salient outcomes. We use our experiences across two pilot trials where the Family Check-Up, an evidence-based family intervention, was integrated into primary care. In these pilot trials, the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework and the Proctor et al. taxonomy of implementation outcomes were used to guide the implementation and evaluate its success. Grounding our presentation in our pilot work offers an illustration of applying the EPIS framework and outcomes measurement to real-world problems and contexts. When embarking on new efforts to integrate behavioral interventions into healthcare settings, the application of IS frameworks and measurement strategies can create generalizable knowledge that substantively contributes to a sparse literature. Today, those “in the trenches” who are translating evidence-based interventions to their setting can contribute to the corpus of research in integrated care by using IS methods to plan a new program and evaluate its feasibility, adoption, and reach.

Keywords

evaluation; Family Check-Up; implementation science; integrated care; primary care

Implementation science (IS) is the study of methods to promote the translation of scientific evidence into practice (NIH, 2013). Using IS methods can increase the likelihood of sustained delivery of evidence-based behavioral interventions. In addition, IS strategies can

Address correspondence to Justin D. Smith, Center for Prevention Implementation Methodology, Department of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine, 750 N Lake Shore Drive, Chicago, IL 60657. jd.smith@northwestern.edu.

The authors contributed equally to the development of this manuscript.

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improve the efficiency and reduce the resources (time, cost) required in a new implementation. IS methods overlap with those of program evaluation or quality improvement already used within primary care, but with a more explicit aim of using rigorous methods that lead to generalizable knowledge (Chambers, Wang, & Insel, 2010). Utilizing IS methods helps to address the demand that primary care demonstrates achievement of the Triple Aim (Berwick, Nolan, & Whittington, 2008); thus, primary care personnel are increasingly motivated to measure the cost, quality, and client experience of their services. Additionally, clinicians in real-world settings are ideally situated to test the “fit” of evidence-based interventions. By deploying IS methods, they can collect data with the integrity needed to contribute to the integrated care literature and contribute to generalizable knowledge.

This article introduces the reader to IS methods and describes how they can be used to evaluate the implementation of integrated care services. We use our experiences to illustrate two key aspects of IS when integrating an evidence-based family intervention (EBFI) in primary care. Specifically: (1) we describe the use of an *implementation framework*; and (2) we describe the assessment of *implementation outcomes*. Measuring appropriate outcomes and mapping these onto an established framework allows for comparability with other studies and replication. These are vital to generating generalizable knowledge from local contexts (Brown et al., 2017). We focus on EBFI because our experiences provide examples that ground IS concepts in the real world. However, note that what we describe here can and has been applied to other types of interventions and in other settings. To underscore the importance of an implementation project, a first step is to articulate what gap(s) in care it will address. We now provide a brief rationale for using EBFI in primary care to illustrate the use of IS methods.

The gap: Implementing evidence-based family interventions in primary care would increase access for children in need

EBFI are effective at preventing and treating youth problems (Van Ryzin et al., 2016). Most of these programs were designed for specialty settings (e.g., schools, juvenile justice) that have limited reach to families in need (Kolko & Perrin, 2014). Delivering EBFI in primary care could improve reach. In the United States, 92.9% of children have visited a primary care provider in the past year (Bloom, Jones, & Freeman, 2013), and about 15% of children seen in primary care have psychopathology (Williams, Klinepeter, Palmes, Pulley, & Foy, 2004). Parents trust their child’s pediatrician above all other sources for questions about psychosocial concerns (Polaha, Dalton, & Allen, 2011); however, when pediatricians refer them to mental health services, their attendance rate is low (Garland et al., 2005). Although primary care may increase access, most EBFI have not yet been integrated in a realistic way. Leslie et al. (2016) and Rubio-Valera et al. (2014) indicate the primary care setting presents unique barriers to implementation, including physical space, referral pathways, and personnel to deliver the intervention. The translation of EBFI therefore requires consideration of the interplay between system characteristics (e.g., organizational culture, physical structure, economics) and the core components of the intervention (Hoagwood & Kolko, 2009).

Illustrative examples: Pilot projects to implement the Family Check-Up in primary care

The Family Check-Up (FCU) is an EBFI for the prevention of problem behaviors and the improvement of child adaptation. It has been rigorously tested in diverse service systems, including public schools (Stormshak, Connell, & Dishion, 2009), home visitation (Dishion et al., 2008), and community mental health (Smith, Stormshak, & Kavanagh, 2015). Because of its brevity and flexible delivery format, the FCU is well suited for, but has not yet been tested, in primary care.¹

In this paper, two pilot studies of the FCU in primary care are used to illustrate the process of translating an EBFI to a novel setting using an IS framework and outcome measurement. The first author (Smith), in collaboration with Thomas Dishion (the FCU developer) and colleagues at Arizona State University (ASU), conducted a pilot feasibility study in two clinics (Montaño, Smith, Chiapa, Miloh, & Dishion, 2014): An outpatient pediatrics clinic serving adolescents ages 13 to 18 and a specialty clinic treating youth ages 6 to 18 diagnosed with non-alcoholic fatty liver disease. Both clinics were situated within a large urban children's hospital serving predominantly low-income (55% Medicaid) and ethnic minority (~65% non-white) patients. The second author (Polaha) and colleagues at East Tennessee State University (ETSU), in consultation with Thomas Dishion, conducted a pilot feasibility trial in a medium-sized, outpatient pediatrics clinic serving children ages 0 to 12 (Polaha, Smith, Smith, & Schetzina, 2015). This clinic, located in Southern Appalachia serves predominantly low-income (70.1% Medicaid) families. Both projects aimed to adapt the FCU for implementation in primary care, which required: (1) devising and installing a screening procedure to identify appropriate families; (2) shortening the time and number of contacts required to complete the FCU; and (3) developing a feasible plan to maximize access to FCU while limiting clinic disruption.

Applying an Implementation Science Framework

To direct project planning and guide the assessment of its effectiveness, the implementation team should prospectively employ an implementation framework. From the existing frameworks in implementation research (Tabak, Khoong, Chambers, & Brownson, 2012), we chose the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework (Aarons, Hurlburt, & Horwitz, 2011) because it efficiently yet comprehensively expresses the critical aspects of implementation through four distinct phases.

Within each phase, EPIS considers the influences of outer (service environment, interorganizational environment, consumer support) and inner context factors (intraorganizational and adopter characteristics) on the process. For example, during Exploration, agency leaders evaluate applicable policies and funding options (outer context). In the inner context, the organization's capacity to implement depends upon culture and

¹Two randomized trials are funded to test the implementation of FCU in primary care (grant DP006255, awarded to Cady Berkel and Justin Smith and grant DA036628, awarded to Ty Ridenour, Maureen Reynolds, and Daniel Shaw). The results were not published at the time of this writing.

leadership, as well as the characteristics of the individuals delivering the program (e.g., values, goals). In practice, ongoing assessment allows for the EPIS phases to operate as a continuous feedback loop for corrective action (Gallo et al., 2016). For example, during the implementation phase, there may be a need to address low reach, poor fidelity, or emerging barriers (e.g., staff turnover, policy changes), requiring a return to earlier phases. Thus, EPIS can simultaneously guide the implementation process and inform the ongoing evaluation of critical milestones.

We now illustrate how the first three phases of the EPIS framework informed our FCU pilots and can be applied to EBFI implementation in primary care. Additionally, we describe what the Sustainment phase would look like had our pilot projects entered this phase. Table 1 provides more detailed information on the activities of each phase of EPIS and the process and outcomes assessed in each pilot project. The complete results of these projects are not presented in this article but can be found in Montañó et al. (2014) and Polaha et al. (2015).

Exploration

During Exploration, key activities are determining the key stakeholders to engage, identifying mutual self-interests, and building relationships (Kellam, 2012). At ASU, the research team connected with a healthcare agency to form a partnership, whereas the leader of the ETSU project had an ongoing alliance with her clinic. In both cases, we engaged in dialogues with pediatricians, behavioral health supervisors, and other decision makers (clinic director, division chief) regarding challenges in meeting the behavioral health needs of their families that might be addressed if the FCU were made available (mutual self-interest). Inner context facilitators included a perceived need to incorporate behavioral health and a culture that valued EBFIs and innovation. For example, we provided an in-depth presentation of the FCU and obtained informal perspectives of clinical staff and leadership regarding the FCU's "fit" with the aims of primary care. The influential outer context factor was the Affordable Care Act and its emphasis on integrated care and the medical home (see Mechanic, 2012).

Preparation

Once the decision was made to adopt the FCU, three major decisions were made: funding the effort (outer context), determining who would deliver the program (inner context), and designating leaders in the system (a pediatrician and a social worker in Arizona, and a psychologist and a pediatrician in Tennessee) to work with the research team (inner context). Having internal leaders increases the probability of progressing to the Implementation phase (see Forgatch, Patterson, & DeGarmo, 2005). Both pilots were partially supported by grants from universities, which supported the FCU facilitators, the team members who would evaluate the implementation, and participant reimbursement for completing research activities. The FCU implementation plan was developed with an understanding of the organizational structure of the clinic in conjunction with our assessment of potential barriers and the identification of strategies to address them. Implementation strategies are interventions on the service system aimed at increasing adoption of new practices into routine care (see Waltz et al., 2015). For example, we needed a screening procedure to identify eligible families, as well as a process of staff accountability for collecting screeners, communicating results, and connecting the family to the FCU staff. Also, we proposed the

adaptation of the FCU to reduce the time and number of contacts to better align with the context. Once a plan was established, trainings were conducted for each role of the project.

Implementation

We found that the ideological fit of the FCU was a chief facilitator. A barrier that we encountered, expected in this setting, was limited space. Working with clinic leadership, we were able to secure space that would not disrupt services. Because our implementation strategy accounted for the inner context by incorporating stakeholder views, and articulated a process that placed as little burden as possible on their work, clinic staff were receptive to the screening procedure and recognized the value in offering an embedded family support program (the FCU). In the outer context, we engaged the intervention developer, who provided consultation, measured fidelity to the FCU, and helped troubleshoot challenges as they arose. During this phase, we began collecting implementation outcome data, which informed modifications to our process.

Sustainment

Sustainment typically refers to the factors that contribute to integrating the new practice into usual care (continued implementation). Our pilot projects did not enter the Sustainment phase. However, some of the factors that could have affected sustainment of FCU in our pilot projects were training personnel, establishing ongoing leadership support, identifying sources for reimbursement, and continuing the screening procedure. For example, in both pilots, graduate students delivered this FCU; however, training existing staff would have been a more sustainable solution. These staff could then train others (e.g., new hires) to deliver the intervention (i.e., train-the-trainer). An implementation outcome to measure the effectiveness of this strategy would be fidelity to the FCU protocol. Studies have demonstrated that the train-the-trainer model can effectively maintain fidelity to parenting programs over long periods in real-world service settings (e.g., Forgatch & DeGarmo, 2011).

Assessing Implementation Processes and Outcomes

One advantage of the EPIS model is that it focuses on factors that can be *measured*. Local contexts that apply a theory-guided *implementation framework and outcome assessment strategy* enables can produce generalizable knowledge. This is particularly true when combined with a sufficiently rigorous research design (Brown et al., 2017). Just as effect sizes from clinical trials can be compared when similar outcomes are targeted, so too can implementation outcomes be compared across projects with similar characteristics, as shown in our two examples.

We evaluated the success of our pilot trials using the Proctor et al. (2011) taxonomy of *implementation outcomes*, which are defined as the effects of deliberate and purposive actions to embed new interventions into real-world systems of care. Implementation strategy is the term given to the array of available actions (Waltz et al., 2015). The outcomes in the taxonomy are acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration, and sustainability. Figure 1 is a conceptual illustration that synthesizes the way the implementation framework, strategies, and outcomes are related. Their relation is integral

for selecting the outcomes that are applicable to the aims of the implementation at different stages (Proctor et al., 2011). In Figure 1, EPIS guides the identification of barriers and the corresponding implementation strategies to address them. The next step is to select how measure the effect of the strategies on salient implementation outcomes. This varies within and across the four phases as depicted by the funnel arising out of EPIS. The Proctor et al. taxonomy also includes service and clinical outcomes to show the downstream effects of improving implementation outcomes. Implementation research can also include evaluation of service and clinical outcomes alongside the focus on the effects of the implementation (Curran, Bauer, Mittman, Pyne, & Stetler, 2012). Table 1 contains a description of what was measured and how during the first three phases of EPIS in the two pilot projects. For example, rigorously assessing acceptability was a higher priority for ASU compared to ETSU. This was because the ETSU pilot was conducted in a clinic that was already familiar with and accepting of providing behavioral interventions to families whereas the clinics at ASU were not.

Selecting implementation outcomes occurred during the Preparation phase in collaboration with key stakeholders. In doing so, we aimed to reduce reporting burden on the system and families by using electronic health record data and keeping surveys brief. We now discuss how these data were collected in our pilot projects. The outcomes are presented in the order in which they aligned with EPIS in these projects.

Appropriateness

During the Exploration phase of the ASU pilot, we surveyed 20 primary care pediatricians to obtain their perspective on the greatest challenges in working with youth (Berkel et al., 2016). The top three reported were parenting issues, child behavior problems, and obesity. These results suggested that physicians would view FCU implementation as appropriate, considering the first two challenges are the primary targets of the FCU. Weight management would require augmentation, but beneficial effects of the FCU on excess weight gain in early childhood had already been established (Smith, Montaña, Dishion, Shaw, & Wilson, 2015).

Adoption

Sometimes referred to as “uptake,” adoption is the intention of the organization to use a new practice. In our pilots, we were most interested in adoption of (1) the screening process to identify at-risk families and (2) the FCU (by way of referral). At ETSU, adoption of these two elements was determined by calculating the ratio of (1) the number of children administered the screening tool divided by the total number of children who attended a well-visit and (2) the number of children referred to the FCU divided by the total number of children whose score on the screening tool exceeded the clinical cutoff. Results showed (1) 75% adoption of the screening tool and (2) 87% adoption of referral to the FCU over the first year of implementation. A month-by-month analysis of the screening tool adoption showed a drop-off after three months at which time providers became aware of some third party payers charging their patient high rates for the test and another drop off between July and September when new residents were being oriented (Figure 2).

Acceptability and feasibility

After 6 months of implementation, we measured general acceptability using the 15-item Evidence-Based Practice Attitudes Scale, which has good internal consistency ($\alpha > .75$) and validity (Aarons, 2004), and conducted a brief interview (Smith, Montaña, Mauricio, Berkel, & Dishion, 2016). Scores on the Evidence-Based Practice Attitudes Scale (mean = 2.93; out of 4) indicated acceptability (Montaña et al., 2014). Content analysis of the interview responses suggested that staff found the FCU to be acceptable, appropriate, and moderately feasibility for ongoing implementation. Concerns about feasibility were primarily due to clinic space limitations, stable sources of reimbursement, and program completion rates.

Fidelity

Training clinicians in community settings to deliver an EBFI as intended (i.e., fidelity to the protocol) is a significant challenge (McHugh & Barlow, 2010). The time involved in assessing fidelity is a major obstacle for many settings given that observation by an expert rater is preferred. FCU scientists developed the COACH, an observational rating system for fidelity to the protocol, which has been linked to positive program effects (Chiapa et al., 2015; Smith, Dishion, Shaw, & Wilson, 2013). The COACH assesses five dimensions of therapist skill prescribed to the FCU: Conceptual accuracy; Observant and responsive to client needs; Actively structures sessions; Careful and appropriate teaching; Hope and motivation are generated (for a detailed review, see Smith et al. (2013). For the ASU pilot, the COACH was used to train clinicians to competency during Preparation and then periodic fidelity checks were performed during Implementation. This approach is less burdensome than continual monitoring (e.g., rating all FCU sessions) but can still be effective at maintaining fidelity (e.g., Kershner et al., 2014).

Penetration

Penetration is the integration of the program within the service setting. We were most interested in the extent to which the FCU penetrated the population of children at-risk for significant problem behaviors. The definition of penetration provided by Stiles et al. (2002) was used: the ratio of the number of families engaging in the program compared with the total number of eligible families that are offered, or could be offered, participation. Penetration is often calculated at intervals to more closely approximate the number of families that require the FCU at any given point. As can be seen in Table 1, the pilot projects computed penetration rates in similar ways but with some variation. The penetration rate is a flexible index that can elucidate where the implementation is falling short, as was described in the ETSU study concerning adoption of the screener. Another example: Over a one-year period, ETSU's results showed a penetration rate of 100% for introducing qualifying families to the FCU and achieving contact with the clinician. However, although 69% completed the assessment, only 31% completed the feedback session. The most notable barrier to penetration was patient transportation to attend the final feedback session.

Limitations

The pilot studies described in this paper had the luxury of grant support. Primary care practices without this funding will need to consider the upfront cost to get the program up

and running, the ongoing costs of delivering it to families, and sustainable financing mechanisms (e.g., managed care reimbursement). The Affordable Care Act could expand reimbursement for EBFIs in primary care but this is not yet the case (Rawal & McCabe, 2016).

Conclusions

Using IS methods can increase the rigor of real-world practice change initiatives. In our case, the application of the EPIS framework provided a guide that allowed us to anticipate, measure, and preempt some barriers to implementation. At ETSU, the Preparation phase initiated an important dialogue among stakeholders regarding the impact of the FCU on space and existing behavioral health service delivery. We narrowed the scope of our pilot to address these concerns. The dialogue about how to implement the FCU was transparent and providers felt ownership going forward, which is reflected in our data showing adoption.

EPIS also gave us a structure onto which we are able to map our process in a replicable manner. Many projects aimed at integrating care lack this kind of framework and are therefore less generalizable and more difficult to publish. A “story” about how a program was implemented in one setting has only coarse meaning for implementation in another; however, organizing the story around a tested framework and assessing salient implementation outcomes allows for comparison. We measured essential indicators for understanding the success of embedding the FCU into primary care by engaging Proctor et al.’s taxonomy of implementation outcomes in synchrony with EPIS. For example, in the ASU trial, the team found that when the pediatrician simply referred families to the FCU, the likelihood of the family contacting the FCU therapist was low. So, the implementation plan was changed to incorporate a warm handoff between the pediatrician and FCU clinician to increase program enrollment. At ETSU, the outcomes indicated adoption of the screener and referral to FCU but lower penetration rates within the FCU. This led us to include social workers in home visits and to schedule longer well-visits for high risk families. We hypothesized that these strategies would address the barrier of attending a second clinic visit needed to complete the FCU. As translation of the FCU continues in primary care, the EPIS framework can be used to design implementation strategies in other “real-world” settings, such as clinics in health departments, family medicine or general internal medicine clinics. These settings will present unique challenges for implementation, such as a lower volume of pediatric patients.

The implementation science methods we describe are useful for those “in the trenches” who wish to pursue program development or who wish to scale up internal projects so that they contribute to the corpus of research in integrated care. Some key implementation data can be collected without undue burden making it within reach for providers with a desire to conduct research in their practice. Using IS methods increases the prospect of successful integration of evidence-based care by building investment, addressing barriers, and measuring the impact.

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How We Did It: Using Implementation Science Models to Research the Start of a New Program

Author Recommendations

If you are not a key stakeholder in the targeted implementation setting, engage a stakeholder consistent with an established community-research partnership model.

Choose an implementation framework to guide the process.

Assess implementation barriers and facilitators

Identify implementation strategies to address barriers.

Measure implementation outcomes such as adoption, penetration, cost, fidelity, and feasibility and discuss those outcomes using language consistent with the implementation science literature (see Proctor et al., 2011)

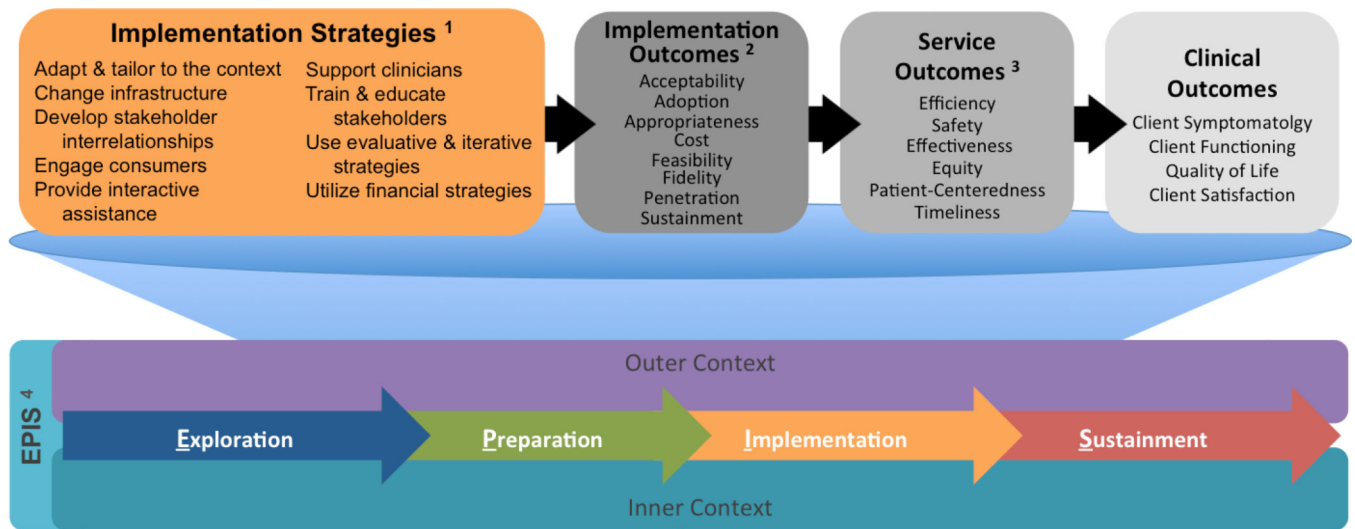


Figure 1. Conceptual model of the relations between an implementation framework, implementation strategies, and implementation outcomes.
 Note. ¹Waltz, et al. 2015. ²Proctor et al., 2011. ³Institute of Medicine Standards of Care, 2006. ⁴Aarons, Hurlburt, & Horwitz, 2011.

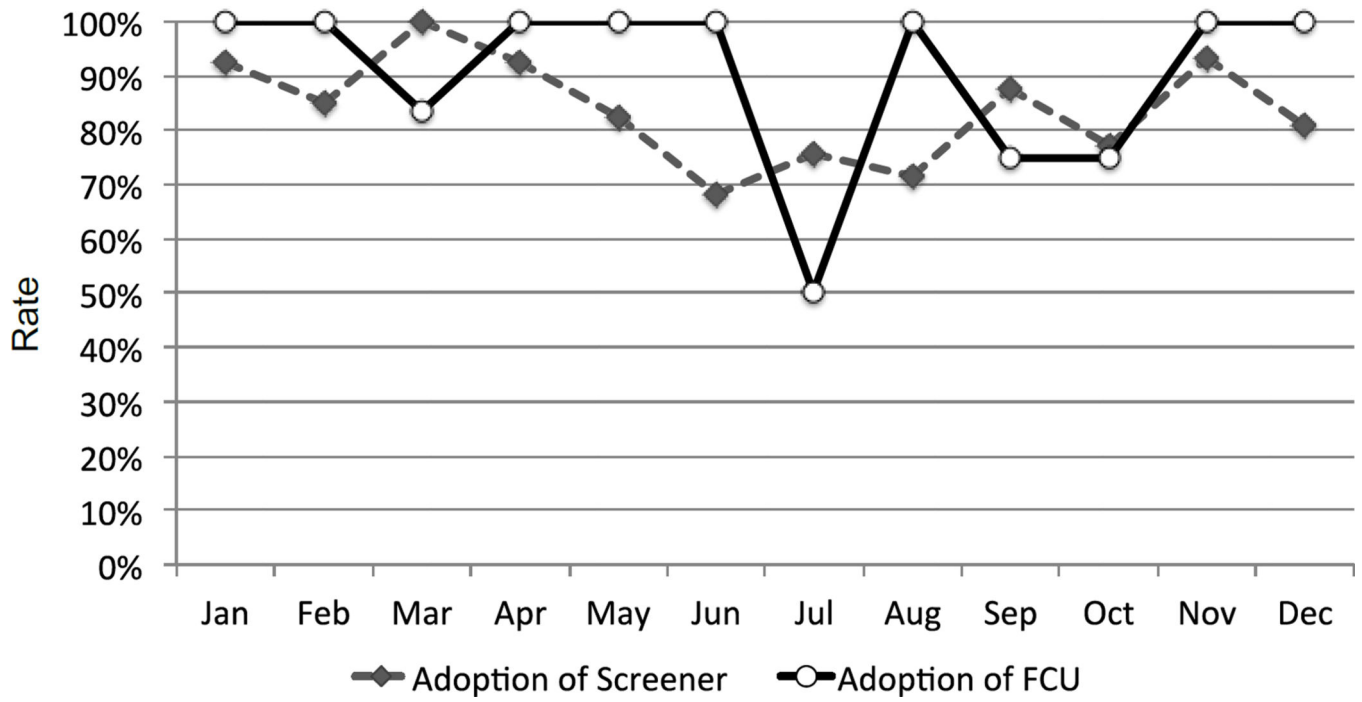


Figure 2. Monthly rate of adoption of screener and the Family Check-Up in the ETSU pilot project

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Table 1

Comparison of the pilot projects

	Pilot Study at Arizona State University	Pilot Study at East Tennessee State University
Setting	Two outpatient clinics in a large urban children's hospital (adolescent general pediatrics, non-alcoholic fatty liver disease)	One outpatient clinic in a medium-sized, general pediatrics primary care clinic serving low-income children ages 0 to 12
Exploration	FCU developer and collaborators conducted presentations to clinic providers and key decision makers (division chief, clinic director); surveyed pediatricians concerning challenges; discussed acceptability of and perceived need for FCU in clinics; met regularly to build trust	PI (Polaha) was already integrated into the clinic, providing other behavioral health services; worked with internal champions (a pediatrician, office manager, behavioral health staff) to assess for and develop interest in the project
Preparation	Meetings to discuss funding options, staffing and training needs, and developing a screening process for identifying at-risk families; applied for seed grant funding; identified senior leader to work with the ASU team; developed an implementation plan and plan to adapt FCU; conducted staff trainings	Implementation team identified to include diverse internal champions, develop screening and identification process, vet and adapt the FCU (in collaboration with developer), identify potential barriers (space and behavioral health staff time) and conduct clinic-wide staff training
Implementation	Screened and referred families to FCU; delivered FCU; worked with clinic leadership to address space barrier; consultation provided by the FCU developer's team; collected implementation data and modified delivery based on the results	Screened all well-child visits of 4–5 year-olds, referred to in-house FCU; delivered FCU; added additional acute referrals outside age range when referrals were low; collected implementation data and modified delivery based on results
Implementation Outcomes		
• Acceptability	Survey of pediatrician's challenges in working with children and families to determine alignment with goals of the FCU; informal inquiry following presentation of the FCU to staff and leadership; after 6 months of implementing the FCU, administered Evidence-Based Practice Attitudes Scale and conducted a brief interview that was qualitatively coded (content analysis)	Acceptability was assessed informally as part of the ongoing implementation team meetings
• Adoption	Tracked the use of the screening instrument and the proportion of children referred to the FCU (also see Penetration)	Tracked use of the screening instrument and proportion of children referred to the FCU
• Appropriateness	Same as for Acceptability	Same as for Acceptability
• Costs	No cost analyses were conducted	No cost analyses were conducted
• Feasibility	Same as for Acceptability	Same as for Acceptability
• Fidelity	COACH observational coding of FCU sessions during training and periodically during Implementation	No tracking of fidelity
• Penetration	Tracked the number of families meeting criteria for referral on the screening instrument and those that were referred to the FCU/ received at least one session/completed FCU feedback session to calculate proportions at different levels of penetration in the effort	Tracked the number of 4–5 year-olds attending a well-visit whose screening showed clinical significance; referrals to the FCU; receipt of at least one session; completed FCU feedback session; calculated monthly proportions over the first year of the pilot
• Sustainability	N/A	N/A

Note. An assessment of sustainability is not typical in pilot studies or in projects examining the early phases of an implementation effort as demonstrating adoption is seen as necessary precursor. However, assessing “perceived sustainability” can be presented alongside other data concerning feasibility.

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