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Using the Quality Improvement (QI) Tool Failure Modes and Effects Analysis (FMEA) to Examine Implementation Barriers to Common Workflows in Integrated Pediatric Care

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Objective: To use quality improvement tools to optimize pediatric behavioral health (BH) integration, a promising approach to increasing access to behavioral health care services for children. ***Method:*** As part of the practice transformation efforts of a pediatric BH integration initiative implemented in three community health centers, we used Failure Modes and Effects Analysis (FMEA), a quality improvement tool, to examine barriers in implementing 2 core BH integration workflows: universal screening to identify developmental and behavioral concerns and implementation of real-time "warm" hand-offs. ***Results:*** Failure modes fell broadly into 2 categories across both workflows: (a) parental/caregiver characteristics and receptivity to the new workflow and (b) consistent implementation of the workflow by health center staff. Failures related to parental/caregiver characteristics included low literacy, language incongruence, and feeling burdened, intimidated, or offended by the screening process. Failures related to implementation of the workflow involved difficulties in administration of the correct age-appropriate screening form and incomplete hand-offs between primary care providers and behavioral health clinicians. Improvement strategies were identified to address both workflow failures, including making changes to electronic medical record functionality, modifying behavioral health clinician scheduling template, and retraining staff. ***Conclusions:*** Pediatric primary care practices planning for, or in the early stages of, BH integration may consider using the FMEA tool to support successful implementation.

Implications for Impact Statement

The present study demonstrates that Failure Modes and Effects Analysis (FMEA) is a useful quality improvement (QI) tool to identify barriers of implementing pediatric BH integration and systematically planning improvement efforts. Behavioral health clinicians, including pediatric psychologists, primary care providers, and other members of the primary care team can leverage these findings to inform behavioral health (BH) integration model implementation in the pediatric primary care setting.

Keywords: mental health, behavioral health integration, pediatrics, Failure Modes and Effects Analysis, quality improvement

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Approximately one in five children and adolescents has a mental health disorder (Merikangas et al., 2010). Yet, despite existence of effective evidence-based behavioral health (BH) treatments, about four in five children who need mental health services do not receive them (Dillon-Naftolin et al., 2017). Moreover, for those that do receive care, the average delay between onset of illness and intervention is 11 years (Wang, Berglund, Olfson, & Kessler, 2004). Common barriers to access include shortage of appropriate providers, insurance restrictions, long delays for services, and stigma (Alegria, Vallas, & Pumariega, 2010). These barriers are greater for historically marginalized and low-income children, with studies showing higher rates of unmet need for these groups relative to other children (Herbst, Margolis, Millar, Muther, & Talmi, 2016; Marrast, Himmelstein, & Woolhandler, 2016). Children of color, in particular, are disproportionately affected by structural inequities, such as poverty, unemployment, poor education, neighborhood violence, and racism (Caballero, Johnson, Buchanan, & DeCamp, 2017). The consequences of untreated mental health and behavioral problems in childhood are significant. They have profound long-lasting health, social, and economic consequences well into adulthood, which include chronic physical and emotional health issues, increased unemployment, and personal relationship difficulties (Burka, Van Cleve, Shafer, & Barkin, 2014).

Pediatric BH integration is a promising approach to address unmet BH needs and access to services for children and families (Molnar et al., 2018). Primary care settings play an important role in addressing the mental health needs of children and adolescents because of the frequency of medical visits in childhood, the long-term and trusting relationship between the primary care provider (PCP) and families, and the scarcity of specialty psychiatric care (Tyler, Hulkower, & Kaminski, 2017). Established primary care guidelines recommend assessing for and addressing behavioral, emotional, and social risk factors as part of routine primary care visits (Hagan, Shaw, & Duncan, 2017; Zuckerbrot et al., 2018). Integrated primary medical-behavioral health care models have the potential to promote healthy development, enable early identification of BH issues, and ensure access to timely treatment (Asarnow & Miranda, 2014). While many studies on the effectiveness of BH integration have focused on adults, existing evidence supports that the benefits of BH integration extend to children, with children who received integrated care interventions experiencing better BH outcomes relative to their peers who received usual care (Asarnow, Rozenman, Wiblin, & Zeltzer, 2015). Given the promise of BH integration to improve both access to BH services and child outcomes, strategies to support implementation goals take on new importance. One such strategy is conducting a Failure Modes and Effects Analysis (FMEA; Ashley, Armitage, Neary, & Hollingsworth, 2010). FMEA is a quality improvement (QI) tool that can be used to assess progress, feed experiential findings back to the practice, and plan iterative improvement activities to achieve implementation goals.

We used FMEA in TEAM UP (Transforming and Expanding Access to Mental Health Care in Urban Pediatrics), a pediatric BH integration initiative across three community health centers (CHCs), to examine barriers in implementing two core BH integration workflows. These workflows were universal screening to identify developmental and behavioral concerns and implementation of real-time "warm" hand-offs, which occur when a PCP identifies a BH issue and hands-off care to a BH clinician during the same primary care visit. Prior studies have established the feasibility and clinical benefits of screening for child BH concerns (Briggs et al., 2012; Schonwald, Huntington, Chan, Risko, & Bridgemohan, 2009). Similarly, studies have examined potential facilitators of warm hand-offs (Hiefner & Woods, 2019) and their impact on clinical care. However, less is known about implementation of these two essential workflows in pediatric settings and, to our knowledge, no paper has examined the utility of FMEA to improve BH integration implementation in pediatric primary care settings. In this study, we outline the use of FMEA to identify potential failures in these two foundational workflows, assess the relative impact of identified failures, and prioritize opportunities for improvement. We highlight FMEA as a data-driven QI approach to implementing pediatric BH integration and its potential to support pediatric primary care transformation initiatives.

Method

Sample and Setting

TEAM UP is a collaboration between researchers and clinicians at an academic medical center and three CHCs in the greater Boston area. It aims to improve life outcomes for low-income children by strengthening the ability of CHCs to recognize emerging child BH issues and intervene early with appropriate treatment. TEAM UP is a fully integrated model of care, seeking to ensure BH access at all touchpoints within the primary care setting. BH clinicians and community health workers serve directly as part of the pediatric primary care team, aligning with the highest level of SAMHSA's integration model (Heath, Romero, & Reynolds, 2013). The three CHCs involved in TEAM UP together serve about 23,000 patients per year, 28% of whom are under 18. Eighty-eight percent of the patient population identifies as a racial/ethnic minority and 30% are best served in another language, highlighting the racial/ethnic and linguistic diversity of the children and families served. Additionally, 91% of the patient population is at 200% or below the federal poverty level and 59% are insured by Medicaid (HRSA Bureau of Primary Health Care Health Center Data, 2018).

TEAM UP Intervention

TEAM UP began in December 2015 with a 6-month planning phase, followed by a 3-year implementation phase. The three CHCs entered TEAM UP with varying degrees of organizational readiness, prior experience with BH integration, and clinical staffing models. During the planning phase, CHCs utilized funding to augment staffing to include 2–3 BH clinicians and 2–3 community health workers, as well as project administrative staff (clinical champion, project manager, and data analyst). While all three CHCs used masters prepared social workers and licensed mental health clinicians, the TEAM UP model is inclusive of all BH clinicians, including psychologists.

TEAM UP partners worked together to codevelop and implement a clinical model to provide comprehensive BH care in the integrated pediatric setting. The model includes two domains: Strengthening Foundations and Transforming Care. The Strengthening Foundations domain describes organization-wide transformation to support delivery of integrated care. The Transforming Care domain is based on the National Academy of Medicine's Prevention Framework and outlines a stepped-care approach to promoting healthy development, enhancing universal screening for developmental, behavioral, and social needs, ensuring access to BH care, and connecting to specialty and community-based services (Mrazek & Haggerty, 1994). During the implementation phase, CHCs also participated in a Learning Community. The Learning Community provided clinical training in pediatric BH topics with role-focused support for BH clinicians and community health workers on core therapeutic skills, and implementation support through a data-driven QI framework. Figure 1 summarizes the TEAM UP model.

FMEA Methodology

FMEA is a QI tool developed in the automotive and aerospace engineering industries to identify, prioritize, and mitigate failures and errors of different system designs (Rhee & Ishii, 2003; Shorstein et al., 2017). FMEA has been adapted for use in health care settings to proactively assess and improve complex health care processes (Asgari Dastjerdi, Khorasani, Yarmohammadian, & Ahmadzade, 2017; Schurman, Gayes, Slosky, Hunter, & Pino, 2015). The Joint Commission on Accreditation of Health Care Organizations recommends FMEA as a risk management model for U.S. healthcare organizations. The Institute for Healthcare Improvement also includes FMEA in its QI Essentials Toolkit (Ashley & Armitage, 2010), components of which are familiar to CHCs and routinely utilized in QI efforts. The main objective of FMEA is to identify potential failure modes (i.e., ways in which something might fail), assess the causes and effects of the different failure modes, and develop and use strategies to eliminate or reduce the likelihood of the failure. It is helpful in uncovering what failures have the greatest potential for detrimental effects on a system and devising performance improvements before system design or during implementation. Additionally, the Institute for Healthcare Improvement's Toolkit supports conducting FMEA in the fast-paced and time-

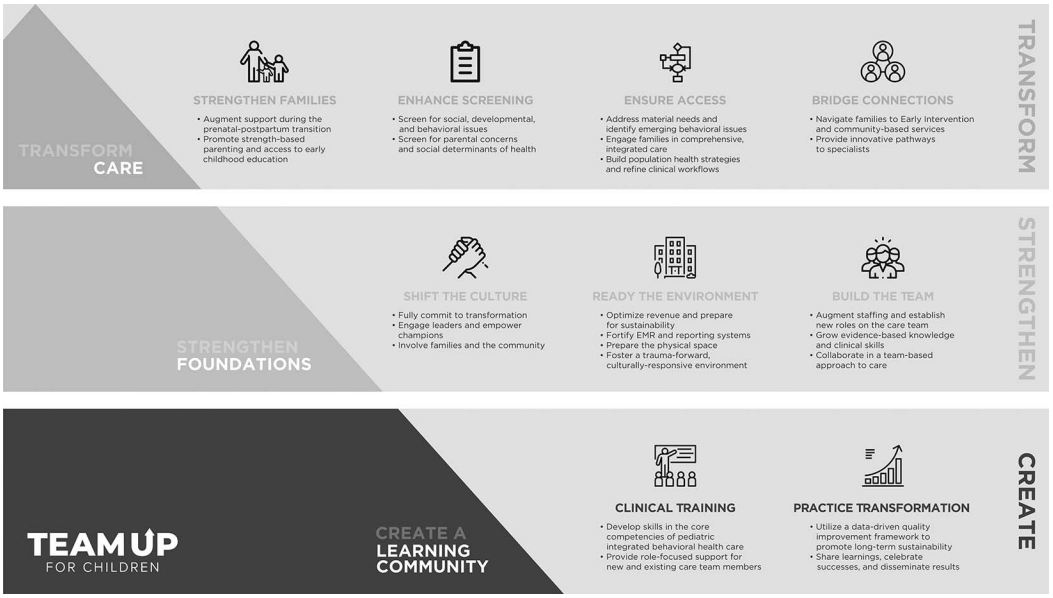

Figure 1. TEAM UP Transformation Model, reproduced by permission of TEAM UP.

constrained environment of pediatric primary care.

Data Collection

We completed the FMEA process at the three CHCs in accordance with the Institute for Healthcare Improvement's QI Essentials Toolkit. Each health center convened a multidisciplinary group meeting to participate in the FMEA process. At the start of each meeting, each person read and signed an informed consent form. On average, meetings lasted 60–90 minutes. The first meeting was convened at the start of the implementation phase and included a total of 26 participants across the three CHCs (CHC1: 9; CHC2: 7; CHC3: 10) representing PCPs, BH clinicians, community health workers, and other department staff. During the first meeting, each CHC collectively created a process map. The process map outlined every step in the delivery of BH care to a child, from initial screening through delivery of BH services. Final drafts of the process maps were put together by the research team and reviewed by CHCs for accuracy. At the midway point of the implementation phase, a second multidisciplinary group was convened to conduct the FMEA. Before the second meeting, CHCs reviewed and updated their original process map. The second meeting included a total of 20 participants across the three CHCs (CHC1: 8; CHC2: 4; CHC3: 8) representing PCPs, BH clinicians, community health workers, and other department staff. During the second meeting, participants were asked to examine their process map, identify all the ways in which the workflow might fail, and collectively create a list of failure modes (what could go wrong). Participants wrote each possible failure mode on a worksheet, and completed the worksheet independently, adding failure causes (why would the failure happen), and assigning a number value between 1 and 10 for three failure mode attributes: likelihood of occurrence, likelihood of detection, and severity should failure occur. The same FMEA process was completed for both universal screening and warm hand-off workflows. This protocol was approved by the Boston University Medical Center Institutional Review Board.

Data Analysis

For each failure mode identified, we calculated a Risk Priority Number (RPN)–the product of all three failure mode attributes (thus, ranging from 1 and 1,000). We then averaged

and ranked the RPNs for each failure mode in descending order. CHCs were asked to identify opportunities to address at least three failure modes. CHCs were encouraged to identify those failure modes with highest RPNs and suggest interventions to either decrease the likelihood that a failure mode would occur or increase the likelihood of detection. Each CHC documented their improvement plans on an FMEA worksheet which was used to follow up on their progress.

Results

In total, CHCs identified between 11 and 19 failure modes within the two workflows. Failure modes fell broadly into two categories: (a) parental/caregiver characteristics and receptivity to the new workflow and (b) consistent implementation of the workflow by CHC staff. All CHCs identified failures related to parental/caregiver characteristics and receptivity to the new workflow, such as issues of literacy, language incongruence, and feeling burdened, intimidated, or offended by the screening process. All CHCs also identified failures related to implementation of the workflow, such as staff not using the correct screening form and incomplete hand-offs between PCPs and BH clinicians. Some failure modes were common across the three CHCs, even if the RPNs differed. For example, low parental literacy was identified as a common failure mode within the universal screening workflow, but the RPN ranged from 123.90 to 276.32. Similarly, for the warm hand-off workflow, BH clinician unavailability was endorsed as a failure mode, with RPNs ranging from 50.4 to 164.77.

Universal Screening Workflow

CHCs identified a total of 6–11 failure modes in the universal screening workflow (CHC1: 11; CHC2: 8; CHC3: 6), with RPNs ranging from 34.33 −282.36. The failure mode with the lowest RPN was "[screening] scores not entered [in the electronic medical record (EMR)]" at CHC2 and the failure mode with the highest RPN noted was "parents feel the burden of answering all the questions" at CHC1. Of note, those with the highest RPNs across the three CHCs were all parental/caregiver characteristics. The failure modes with the highest and lowest RPN are displayed in Table 1.

Warm Hand-Off Workflow

CHCs identified a total of 4–8 failure modes for the warm hand-off workflow (CHC1: 8; CHC2: 4 CHC3: 5). These RPNs ranged from 28.5–299.22, with the lowest being "RN sends patient home by mistake [before warm hand-off completed]" at CHC2 and the highest being "urgent care [visits] weakest point for warm hand-off" at CHC1. Failure modes with the highest and lowest RPNs are displayed in Table 1.

Improvement Effort Plans Based on FMEA

CHCs identified planned improvement strategies that addressed failures in both workflows, including changes to the functionality of the EMR, modifying BH clinician scheduling templates, and retraining staff. Selected improvement strategies from CHCs' completed worksheets can be found in Table 2.

Each CHC shared its FMEA results and planned improvement strategies at a Steering Committee meeting, a forum for collective stewardship of TEAM UP charged with developing and refining the core components of the initiative. The common finding of the impact of parent/caregiver characteristics and receptivity to both workflows informed subsequent plans to engage patients and families in each CHC's BH integration efforts. CHC1 hosted a community event for families with young children to solicit direct feedback from parents/caregivers on how the CHC could best support the healthy development of their children; CHC2 launched topical workshops for parents/caregivers in its Head Start program, soliciting input from families on topics of interest; and CHC3 conducted a brief interactive survey with patients and families in the waiting room to better comprehend parental understanding of child development and developmental screening tools, and better inform patients and families about the screening process.

Discussion

This study utilized process mapping and FMEA to identify barriers to implementing universal screening and warm hand-offs, two key

Table 1
RPN for Highest and Lowest Failure Modes of Two Common BH Integration Workflows

BH integration workflow	Highest failure mode		Lowest failure mode	
	Failure mode	RPN	Failure mode	RPN
		Universal screening		
CHC1	Parents feel the burden of answering all of the questions	282.36	Change in visit priority/purpose	117.66
CHC2	Parental literacy	174.0	Results not entered (in the electronic medical record [EMR])	34.33
CHC3	Parents can get defensive, intimidated, or offended	159.84	Wrong age for The Survey of Well-being of Young Children screener is given	68.25
		Warm hand-off		
CHC1	Urgent care (visit) weakest point for warm hand-off	299.22	BH clinician in session and issue is not crisis	43.94
CHC2	Family (parent or child) declines services	57.75	RN sends patient home by mistake (before warm hand-off completed)	28.5
CHC3	(Request for warm hand-off) indicated in EMR . . . but no action was taken	240.0	Patient declines BH services	49.14

Note. CH = community health centers; BH = behavioral health; RPN = risk profile number.

workflows in pediatric BH integration. Failure modes fell across two broad themes: parental/caregiver characteristics and receptivity to the new workflow, and consistent implementation of the workflow by CHC staff. The outcome of the FMEA process resulted in changes to workflows and procedures such as functionality of the EMR and BH clinicians scheduling templates.

FMEA has been applied to examine complex health care processes, including addressing safety in blood transfusions (Mora, Ayala, Bielza, Ataúlfo González, & Villegas, 2019), communication between hospital staff (Bagnasco et al., 2013), administering intravenous drugs (Wetterneck et al., 2006), and reducing errors in chemotherapy (Kim et al., 2006). To our knowledge, this study is the first to apply FMEA to improve pediatric BH integration. Our findings support the strengths of FMEA cited in previous literature and further suggest that this process can be used successfully to support QI activities in primary care settings. The proactive risk assessment tool allows practices to identify pitfalls in complex, high-risk processes (Asgari Dastjerdi et al., 2017; Ashley et al., 2010), and provides a structured process for prioritizing improvement strategies, with RPNs serving as a useful guide (Lago et al., 2012).

Conducting our FMEA process across multiple practices contributes uniquely to the field of pediatric BH integration. To date, many studies documenting use of FMEA are conducted in one setting (Asgari Dastjerdi et al., 2017). Utilizing FMEA across multiple practices with distinctive contexts and diverse patient populations highlighted the commonalities of implementation challenges in pediatric BH integration. These common challenges may serve as a useful guide for future practices adopting integrated care, underscoring key implementation barriers to expect and, thus, plan for in advance. The focus of this QI approach on system design rather than singular incidents enables learning and implementation change within pediatric BH integration that is likely to impact a large number of patients (Jain, 2017).

Findings from the FMEA and extant literature both highlight the importance of addressing

Table 2
Excerpts From CHC1 and CHC3 FMEA and Improvement Strategies

BH integration workflow	Failure modes	Failure causes	RPN	Improvement strategies
		Universal screening		
CHC1	Parents feel the burden of answering all of the questions	• Coming in with multiple children • Competing needs • Physically holding too much (infant, bags, etc.) to fill out the forms	282.36	• Identify and remove previsit screening form questions that are most often skipped • Use electronic patient portal as another screening mechanism
	Literacy (regardless of health literacy)	• Healthcare staff not available to read screener to the patients • Insufficient time to go through screener with patient • Incompetent education system • Limited access to literacy program	276.32	• Learn best practices from other health centers to identify what can be adopted at this CHC
	Screener is in wrong language	• Screener is not available in preferred language • No interpreter • Preferred language is mislabeled in the patient's chart • Parent's language and patient's language may be different	225.94	• Make additional translations of screener available to staff
		Warm hand-off		
CHC3	Indicated in BH plan but no action was taken	• "Clicking fatigue" • Misunderstanding of fields • Not enough BH staff to review in timely manner	240.0	• Refresher training on action plans in EMR
	Electronic referral is made but missed	• Referral is sent in inconsistent ways/actions (telephone encounter, note) • Sent to wrong "bin" (in the EMR)	175.0	• Clarify and retrain on standard electronic referral process in EMR

Note. CH = community health centers; BH = behavioral health; RPN = risk profile number; FMEA = Failure Modes and Effects Analysis; EMR= electronic medical record.

parental/caregiver needs to improve clinical care. The high linguistic and racial/ethnic diversity of families seeking care in these settings requires a culturally responsive and effective approach to provide appropriate family centered services and address unique barriers (Britton, 2004). For example, conducting BH screening as a part of a broader strategy of family engagement, and framing screening as routine, are potential approaches to decrease stigma and support family clinician communication (Wissow, van Ginneken, Chandna, & Rahman, 2016). Streamlining screening questions and utilizing technological tools (e.g., an electronic patient portal) can also increase efficiency and reduce in-visit time spent on screening (Fothergill et al., 2013). Research finds the use of computer administration of screening can reduce literacy obstacles (e.g., through audio presentation), and is a preferred mode for a young population (Diamond et al., 2010).

Both the BH integration literature and our findings highlight the challenges of implementing a new workflow (Davis et al., 2013). In an evaluation of SAMHSA's Primary and Behavioral Health Care Integration grant, sites reported clinical workflow challenges such as data management, including issues related to EMRs, data collection, and reporting, and challenges merging primary and BH protocols at follow-up

(Scharf et al., 2013). Other studies have found that primary care settings often struggle to use BH clinicians in the ways intended by the integration model. Staff may be reluctant to interrupt the BH clinicians during a visit, or operational challenges in the clinic may prohibit PCPs and other primary care staff from efficiently utilizing the BH clinician (Reiter, Dobmeyer, & Hunter, 2018). Consistent with these prior studies, our findings yielded improvement strategies addressing EMR functionality and ensuring availability of the BH clinician for warm hand-offs.

While our findings outlined common pitfalls and sources of potential workflow failures, variations in risk categorizations highlight the importance of accounting for health center-specific characteristics. Caution should be taken before generalizing these findings to other primary care settings. Future practices must consider the specific context of each identified failure mode in prioritizing its own improvement strategies. It is important to note that while RPNs might be sufficient to suggest potential improvement pathways, other context-specific considerations will likely influence the way practices choose to focus their improvement strategies. Larger health system or institutional priorities, strategic aims, as well as availability of funding, can influence the decisions around how a pediatric practice chooses to focus its QI efforts.

Our results should be interpreted in light of several limitations. FMEA is generally seen as a time-consuming effort and difficult to integrate into the process of busy clinical practices (Jain, 2017). To address this potential challenge, TEAM UP leveraged CHCs' pediatric multidisciplinary team meetings to conduct the FMEA. Using this meeting limited the time and, therefore, the total number of workflows that could be assessed using FMEA. However, it did provide a venue that did not interfere with each CHC's daily operational constraints. We also made modest modifications to the FMEA categories in an effort to streamline the process and adhere to the limited time available. We did not utilize the failure effects component of the FMEA tool, which asks participants to note what might be the consequence of each failure; its inclusion may have impacted how individuals decided to score each failure mode. The possible subjectivity of RPN scores has also been highlighted as a limitation of FMEA (Arenas Villafranca, Gómez Sánchez, Nieto Guindo, & Faus Felipe, 2014). Different compositions of clinical teams introduce variability that might bias RPN scores. We do not believe this variation to be a strong driver in our study, given the consistency of the potential failures found across the three CHCs. Nevertheless, RPN values were seen as a guidance tool that again should be considered alongside other clinic and institutional priorities when planning improvement strategies and will ultimately differ within each practice context. We are unable to determine if FMEA improved the two clinical workflows. Future work could look to utilize this tool to track improvement over time. Despite these limitations, our findings underscore the feasibility of FMEA within the fast-paced pediatric primary care integrated setting.

This study describes a powerful tool for healthcare professionals, including pediatric psychologists, to put evidence into practice and ensure consistent implementation of high-quality healthcare (Schurman et al., 2015). While TEAM UP utilizes master's level BH clinicians, we believe our findings offer lessons learned that can support implementation in any integrated care settings, and with any BH clinician staffing model. For example, clinical models aimed at improving access to BH care often include psychologists who are integrated into primary care settings, as well as consulting psychologists and/or psychiatrists that work outside of primary care. Given that this lack of physical proximity may be a challenge to effective team functioning, the multidisciplinary focus of the FMEA process may be a feasible tool to develop and use mitigation strategies for this potential challenge (Ashley et al., 2010). Using a formalized QI framework that intentionally includes the input of various team members within the pediatric primary care team may also facilitate care team collaboration by increasing staff understanding of processes under review, and enhancing multidisciplinary teamwork and communication (Fong et al., 2019). Additionally, our findings might offer particularly unique insight for those clinical psychologists that may be supervisors within a clinical environment and have an interest in using a QI tool to improve a clinical workflow or implementation process.

Conclusion

FMEA is a tool that can be used to analyze and monitor clinical workflow improvements. This QI tool is particularly useful during implementation of new workflows, as it provides a systematic process for practices to identify and prioritize diverse, contextual barriers to implementing BH workflows and plan improvement efforts to mitigate or eliminate these barriers. Primary care practices planning for, or in the early stages of, implementing BH integration models may consider this tool as they develop strategies for successful implementation.

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