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Mis-implementation of evidence-based behavioural health practices in primary care: lessons from randomised trials in Federally Qualified Health Centers

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Abstract

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Contributor Statement: A.R.D. led the conceptualization of this article, and drafted the introduction, discussion, and conceptual model. G.H., K.C.O., and L.S.M. each led drafting of a case summary, and contributed to overall conceptualization and writing of all sections of the paper; G.H. also led the comparison of case summaries. J.K.M., K.B., L.T., and A.C. contributed to the development of case summaries. M.S., M.K., and K.E.W. contributed to overall conceptualization and writing of all sections of the paper.

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Background: Implementing evidence-based practices (EBPs) within service systems is critical to population-level health improvements – but also challenging, especially for complex behavioral health interventions in low-resource settings. “Mis-implementation” refers to poor outcomes from an EBP implementation effort; mis-implementation outcomes are an important, but largely untapped, source of information about how to improve knowledge exchange.

Aims and objectives: We present mis-implementation cases from three pragmatic trials of behavioral health EBPs in U.S. Federally Qualified Health Centers (FQHCs).

Methods: We adapted the Consolidated Framework for Implementation Research and its Outcomes Addendum into a framework for mis-implementation and used it to structure the case summaries with information about the EBP and trial, mis-implementation outcomes, and associated determinants (barriers and facilitators). We compared the three cases to identify shared and unique mis-implementation factors.

Findings: Across cases, there was limited adoption and fidelity to the interventions, which led to eventual discontinuation. Barriers contributing to mis-implementation included intervention complexity, low buy-in from overburdened providers, lack of alignment between providers and leadership, and COVID-19-related stressors. Mis-implementation occurred earlier in cases that experienced both patient- and provider-level barriers, and that were conducted during the COVID-19 pandemic.

Discussion and conclusion: Multi-level determinants contributed to EBP mis-implementation in FQHCs, limiting the ability of these health systems to benefit from knowledge exchange. To minimize mis-implementation, knowledge exchange strategies should be designed around common, core barriers but also flexible enough to address a variety of site-specific contextual factors and should be tailored to relevant audiences such as providers, patients, and/or leadership.

Keywords

Mis-implementation; primary care; behavioral health; Federally Qualified Health Center

Background

Rates of behavioral health problems remain high in the United States (U.S.), with approximately 22.8% of adults meeting criteria for mental disorders and 16.5% for substance use disorders annually (Costello and Angold 2016, Substance Abuse and Mental Health Services Administration 2022). There is a growing body of behavioral health treatments (such as psychotherapy and medication) and service delivery approaches (such as collaborative care and telehealth) with demonstrated effectiveness, collectively referred to as evidence-based practices (EBPs; Fagan et al 2019, Kilbourne et al 2018). Before they can improve population health, however, knowledge about EBPs must be integrated into systems where people with behavioral health problems receive services. For adults, primary care is the most common setting to seek help with behavioral health problems (Robinson and Reiter 2016), as it tends to be more accessible and affordable (and less stigmatized) than specialty mental health or substance use treatment settings. Yet, most individuals never receive behavioral health EBPs as part of primary care treatment (Mechanic 2014). A

deeper understanding of why behavioral health EBPs are not routinely provided in U.S. primary care settings is needed to inform targeted reforms and strategies that can increase accessibility of high-quality care for these common problems.

Implementation science is an area of knowledge exchange research, originating in health care, that can help us understand the multi-level factors that influence the adoption and sustained delivery of EBPs in specific health care contexts (Kilbourne et al 2020). In the U.S., the Federally Qualified Health Center (FQHC) system was created to provide affordable access to primary care for underserved patients and communities, regardless of their ability to pay (Hébert et al 2018). FQHCs serve over 30 million patients annually, of whom 19% are uninsured and 61% are publicly insured; 41% are rural; and 64% are racial and/or ethnic minorities (National Association of Community Health Centers, 2023). Provision of behavioral health services is an important component of the FQHC mission (Mauch and Bartlett 2013), especially considering that low-income patients typically find primary care more accessible than – and preferable to – behavioral health specialty care. Implementation research with FQHCs has consistently revealed both enabling factors and barriers to implementing behavioral health EBPs across multiple domains of the healthcare system (see e.g., Kramer et al 2017, Mauch and Bartlett 2013), although these studies tend to focus mainly on cases of successful implementation.

The widely-used Consolidated Framework for Implementation Research (CFIR; Damschroder et al 2009, 2022b) provides a helpful method for organizing barriers and facilitators – collectively known as determinants – within five major domains: Intervention factors (e.g., brief EBPs fit into FQHC contexts well; those requiring complex or specialized resources may not), individual factors (e.g., providers with circumscribed roles may welcome EBPs that enhance their role; those who are overburdened and exhausted may resist), organization-level factors (e.g., FQHCs that emphasize competence and responsiveness to patient needs are more likely to adopt EBPs; those with rigid cultures are less likely), extra-organizational factors (e.g., federal mandates for EBPs increase adoption; limited funding options disincentivize use of EBPs), and process factors (e.g., alignment or mis-alignment of quality improvement activities and EBP implementation goals (Kramer et al 2017)). These domains or determinants can help contextualize barriers and strengths involved in successfully or unsuccessfully implementing behavioral health EBPs.

This paper focuses specifically on *mis-implementation*, which we broadly define as poor implementation outcomes that result in an EBP's discontinuation during or following organized efforts to implement it. The CFIR Outcomes Addendum (Damschroder et al 2022a) extends CFIR to conceptualize various implementation outcomes, which are the outcomes of efforts to adopt and use the EBP in practice; they are distinct from clinical effectiveness, which is necessary but not sufficient to benefit patients in the absence of successful implementation. Outcome domains in the Addendum include adoption, implementation, and sustainment – both actual and anticipated – as well as antecedent outcomes like perceptions of acceptability, appropriateness, and feasibility. Figure 1 uses CFIR to summarize relations between determinants (barriers and facilitators) and outcomes in mis-implementation.

Unfortunately, mis-implementation of behavioral health EBPs is common, and in turn access to EBPs remains limited (Stewart et al 2016). Mis-implementation may occur due to failure to implement an EBP that would have been beneficial (despite concerted efforts to prioritize it) and/or discontinuation of an EBP subsequently determined to be a poor fit, given that selection of EBPs that fit the practice context is a key task of implementation (Moullin et al 2019). The unifying feature of mis-implementation is not achieving or sustaining implementation. EBPs may also be discontinued due to lack of clinical effectiveness despite adequate implementation; such cases speak to the generalizability of the intervention to the particular patient population or implementation context and are beyond the scope of this paper's discussion (although we acknowledge that distinguishing between implementation vs. intervention failure is often difficult; see Mann et al. (2019), May et al. (2007). In low-resource settings like FQHCs, the consequence of mis-implementation is that vulnerable populations may continue receiving less effective care.

Ironically, even though implementation science represents an effort to bridge the research-to-practice gap, there are gaps *within* the field that limit its practical value (Vroom and Massey 2022) including a paucity of research on mis-implementation. Most implementation research either describes general predictors of implementation success across numerous sites or more in-depth descriptions of successful implementation efforts (for examples of the latter in FQHCs, see Fortney et al 2018, Mitchell et al 2020). This "file drawer problem," in which negative or null findings are less likely to be disseminated, is widely acknowledged in health research (Pautasso 2010). This problem threatens to limit the validity of implementation science for informing real-world implementation efforts – i.e., researchers may draw erroneous conclusions by overlooking cases in which desired outcomes were not achieved. Common challenges to mis-implementation research include the potential reputational impact to researchers and community members of sharing details of challenges and failures; limited remaining resources in projects that have already made extensive efforts for implementation to succeed; and bias in the peer review process for scientific publication toward positive findings.

Of the available literature on mis-implementation, some studies have focused on de-adoption of mental health EBPs (Massatti et al 2008), mis-implementation of a trauma intervention in a school setting (Nadeem and Ringle 2016), and case examples of child welfare interventions in community partnerships settings (Gopalan et al 2020). These studies described multi-level determinants that contributed to mis-implementation such as EBP-setting fit, workforce instability, leadership challenges, and lack of adequate funding, with in-depth descriptions of how the determinants manifested in each unique context (e.g., schools discontinuing a trauma EBP after new leadership shifted district priorities to re-focus on academics over social and emotional learning; Nadeem and Ringle 2016). However, none of these studies have focused on FQHC settings, and more broadly they did not present generalizable approaches to defining and measuring mis-implementation.

Recognizing the value of more in-depth research on mis-implementation and the need to ground implementation research within specific practice contexts, this paper presents a series of case examples from pragmatic clinical trials that experienced mis-implementation of behavioral health EBPs in FQHCs. Although there are important limits to the

generalizability of randomized trials to implementation practice, they are appropriate case examples (see e.g., Kennedy et al., 2014) because (i) mis-implementation is still common in this context, despite the extensive financial and personnel resources provided by a trial; and (ii) trials often provide rich data sources that can be used to understand mis-implementation more fully (e.g., documentation that permits distinguishing it from intervention failure). The case series represents a variety of FQHC community contexts, implementation strategies, and EBP characteristics, allowing us to compare and contrast cases while identifying generalizable knowledge for the field. Our research questions were: (1) What were the shared and unique mis-implementation outcomes observed across the case examples? and (2) What were the shared and unique ways that mis-implementation barriers were observed to relate to those outcomes?

Methods

Overview of Approach

The initial versions of case summaries were drafted by co-authors based on project records, capturing comparable information about each case using our framework (Figure 1) of mis-implementation outcomes and determinants adapted from CFIR (Damschroder et al 2022a, 2022b). Data sources used included quantitative surveys; qualitative interviews and focus groups; patient registries used to track delivery of the intervention; and team meeting notes that documented key events and decisions. Each data source was analyzed using routine methods; quantitative survey and registry data were analyzed using descriptive statistics, and qualitative interview/focus group transcripts and meeting notes were summarized using rapid content analysis. The authors prioritized data analyses that had already undergone peer review whenever feasible. More detail regarding the data sources for each case are described below.

Co-authors synthesized all information into a narrative description of the intervention and study, then identified and described key mis-implementation outcomes experienced. For each mis-implementation outcome they also identified and described implementation barriers that contributed to the outcome. In all cases, multiple study team members involved in initial data collection and analysis gave input on the summaries, to ensure accuracy and completeness. After the written case summaries were complete, the first two authors led all co-authors through an exercise of comparing the three cases to identify similarities and differences across cases. Specifically, we summarized mis-implementation outcomes and barriers for all three cases in a table and then identified common and unique mis-implementation outcomes experienced (Research Question 1) and barriers contributing to those outcomes (Research Question 2).

Case Background and Data Sources

The first case is **CLARO** (Collaboration Leading to Addiction Treatment and Recovery from Other Stresses), a trial that adapted, implemented, and tested collaborative care for opioid use disorder (OUD) co-occurring with major depressive disorder (MDD) and/or posttraumatic stress disorder (PTSD) in several health systems in the southwestern U.S. Collaborative care is a service delivery intervention in which a Care Coordinator works

with patients and their primary care teams to support treatment access and engagement for evidence-based clinical interventions. It has shown effectiveness in improving outcomes for patients with single diagnoses, but CLARO uniquely treats MDD, PTSD, and OUD within a unified model. The intervention was iteratively adapted for the patient population (co-occurring disorders) and local setting (low-resource clinics and state) using the Map of Adaptation Process to incorporate input from primary care partners, patient interviews, and beta-testing (MAP; McKleroy et al., 2006). Example adaptations include use of community health workers as care coordinators, modified training for behavioral health treatments to address co-occurring disorders, and having care coordinators screen patients for social needs (Osilla et al., 2022).

The CLARO intervention is evaluated in a pragmatic, randomized effectiveness-implementation trial that simultaneously examines the effectiveness of the intervention while also assessing contextual influences on its implementation. Our analysis focused on the full discontinuation of CLARO in a FQHC located in a rural community. Implementation supports used include facilitation of pre-implementation and active implementation planning with FQHC clinic champions (key stakeholders who served as points of contact and advocates for CLARO implementation); training and consultation for Care Coordinators and providers; monitoring fidelity and outcomes; and quality improvement (e.g., Plan-Do-Study-Act cycles). These supports were pre-planned, but modified over time in response to clinic needs (e.g., facilitation and quality improvement were intensified prior to discontinuation). Data for the analysis came from a pre-implementation organizational survey based on CFIR completed by clinic employees (67% response rate); a patient registry used by CLARO Care Coordinators to track delivery of the intervention; and notes from meetings with clinic champions and/or leadership.

The second case study comes from a pragmatic randomized trial called **eINSPIRE** (INtegrating Support Persons into Recovery) that tests the Community Reinforcement Approach and Family Training (CRAFT) intervention delivered via group telehealth therapy compared to usual care. CRAFT is an evidence-based approach for the family members or close friends (referred to as Support Persons) of individuals with a substance use disorder. In eINSPIRE, CRAFT was adapted to a group telehealth intervention for use by the support persons of patients with an opioid use disorder in an outpatient buprenorphine treatment setting (Osilla et al., 2022). CRAFT teaches support persons ways to engage and retain their loved ones into substance use treatment through positive communication, positive reinforcement, functional analysis, and other operant behavioral strategies (Meyers and Wolfe 2004, Smith and Meyers 2007). Clinic staff, patients, and support persons contributed to the development of eINSPIRE through interviews and focus groups, in which they provided feedback on the intervention that informed iterative adaptations.

For the eINSPIRE trial, patients were recruited at community health systems in Southern and Northern California that provide buprenorphine treatment and mental health services. This case summary focuses on one health system that experienced mis-implementation of eINSPIRE, a FQHC primary care clinic system that primarily serves individuals with Medicaid insurance and offers buprenorphine in seven primary care clinics. Patient recruitment began at this health system February 2020 (with initial kickoff activities

in-person before engagement switched to virtual due to the COVID-19 pandemic) and discontinued in December 2021. Implementation efforts were led by the research team, guided by clinic and patient advisory groups; eINSPIRE facilitators received training and weekly supervision from a clinical psychologist who reviewed session recordings to monitor fidelity. Insights into mis-implementation were identified through patient, support person, and staff focus groups that informed intervention adaptation; staff exit interviews; and research/clinical team meeting notes (including weekly enrollment reports).

The third case is a pragmatic randomized controlled trial (the Violence and Stress Assessment or **ViStA** study) that adapted collaborative care management for posttraumatic stress disorder (PTSD Care Management or PCM) and compared its effectiveness to minimally enhanced usual care. The evidence for the effectiveness of collaborative care for PTSD is more limited than for depression (Engel et al 2016, Fortney et al 2015, Roy-Byrne et al 2010, Schnurr et al 2013) and comes from high-resource health systems. As described in Meredith et al. (2016), the team adapted PCM to be appropriate for under-resourced FQHC settings that provide care primarily for un- and under-insured minority patient populations (e.g., using Bachelor-level Care Managers (CMs) as the PCM interventionists, materials in English and Spanish). Specifically, input from clinical staff at FQHC study sites was incorporated into intervention adaptations using group elicitation process methods, based on modified Delphi techniques (Dalkey, 1969), to prioritize barriers and strategies for addressing them.

The ViStA trial enrolled 404 patients from six FQHCs in the northeastern U.S. from June 2010 to October 2012. Based on the adaptation process, implementation of PCM was tailored to enhance feasibility (e.g., training busy staff in hour-long modules to minimize disruption; matching CM communications to primary care clinician preferences and structures) at each FQHC; an Advisory Group also provided guidance on intervention implementation and delivery throughout the trial. Data for the present analysis were drawn from initial site visit notes and CM monthly reports, the patient registry used by CMs, and exit interviews with FQHC staff across all six sites.

Findings

Case 1

The CLARO collaborative care intervention experienced low success in the rural FQHC system on the following implementation outcomes: adoption, acceptability, fidelity, and reach. Regarding low adoption by FQHC personnel, the study team assisted in the hiring and training of a care coordinator, who was available to serve patients from three clinics in the FQHC system yet received very few patient referrals from providers or staff. Across 10 months of active implementation, 44 eligible patients were identified of which 35 enrolled (~3.5 patients per month). Given that the FQHC system served over 12,000 patients, this also reflects low reach of the intervention on a population level. The study team made numerous efforts to address the low number of identified patients, but the options were eventually limited to self-administered tablet-based screening (due to concerns raised by FQHC leadership around confidentiality when asking patients about opioid use) which was never reliably completed. Low adoption and reach were the mis-implementation outcomes

that contributed the most to discontinuation of CLARO and were influenced by multiple barriers, which are described next before discussing other outcomes.

Prior to implementation, organizational survey responses indicated that 44% of FQHC staff perceived the CLARO intervention as complex, which presented a barrier to integrating it into existing FQHC workflows. This barrier was compounded by high staff turnover (inner setting) and minimal buy-in to CLARO implementation from staff/providers (individual domain). In addition, in the outer setting, the COVID-19 pandemic placed an additional burden on this rural healthcare system and the team learned that large research institutions from outside the community were viewed with skepticism. Furthermore, the implementation team faced challenges to their functioning, such as when a clinic champion left their job at the FQHC unexpectedly, or when the first care coordinator resigned after the FQHC required employees to work in-person following availability of COVID-19 vaccines. These situations required the team to quickly respond to cover existing patient caseloads and pursue hiring and training of another care coordinator.

There were also challenges with the management strategy at this FQHC following a top-down approach, which meant the success of the intervention relied on senior leadership prioritizing implementation. The study team had limited opportunities to work directly with staff and providers, which reflected broader communication challenges between these groups and leadership. The organizational survey and team discussions revealed that staff were reluctant to implement new programs in addition to their existing workloads (e.g., only 31% endorsed having balanced workloads on the survey). Furthermore, the complex hierarchy within the FQHC made it difficult to plan and execute changes needed for implementation. This apparent disconnect between leadership and staff/providers resulted in a discrepancy between leadership's expressed commitment to implementation and the actual follow-through on operational changes.

Another key mis-implementation outcome was the intervention's low acceptability to patients. According to care coordinators, many patients were hesitant to receive behavioral health treatment (which is encouraged in the collaborative care model) due to past negative experiences. The study team initially sought to adapt the intervention to better meet patient needs and address their concerns, but low provider adoption meant there were fewer opportunities to engage with patients and make improvements. Further, in this FQHC's rural setting, many patients did not have regular access to internet or phone services, which made it difficult to contact participants for recruitment and engagement with the intervention (which was primarily phone-based). Lastly, half of survey respondents indicated high stigma for opioid use disorder care in the community which further limited patient identification and engagement. At one point, the study team was made aware of significant confidentiality concerns that discouraged patients from seeking care. There was a perception in the local community that everyone knew each other's business, which was further complicated by the fact that patients' family and friends often worked at the FQHC.

Finally, despite having well-trained and dedicated care coordinators, there was low fidelity to the intervention. When care coordinators were able to engage patients, they reviewed all cases with the CLARO psychiatric consultant (who was an external expert in addiction

medicine and psychiatry) as another standard component of the collaborative care model. However, the consultant's recommendations were routinely not followed by the primary care providers. System leadership expressed to the study team that providers did not trust recommendations from a consultant who lived outside of the community and that neither the care coordinator nor psychiatric consultant were integrated into the care team. They also noted that it was hard to build a relationship with the care coordinator due to large amounts of staff turnover, and perhaps also due to the climate within the organization.

Case 2

For eINSPIRE (INtegrating Support Persons into Recovery), the primary mis-implementation outcomes identified were adoption, reach, and feasibility – which led to the research team and clinic administrators mutually deciding to discontinue the intervention. We first discuss low adoption or utilization by support persons and staff. Support person recruitment was challenging at this health system resulting in few support persons recruited for the study. Across 22 months of clinic staff screening patients, this health system screened 86 patients – notably lower than two other health systems who began enrollment at the same time. Furthermore, 31% of patient-support person dyads were screened ineligible at this health system (vs. 6–22% at the other health systems), 33% of eligible dyads refused participation (vs. 13–23%), and 30% of patients reported not having a support person (vs. 8–12%).

Data from meeting notes indicate that intervention facilitators also had challenges adopting the eINSPIRE intervention. These staff reported working with an unmanageably large caseload of patients and increased stressors related to the pandemic (e.g., counselors reported receiving multiple calls a day related to opioid overdose and other crises; an intervention facilitator homeschooling their children) making it difficult to screen patients for recruitment and implement the intervention with support persons. Even with support from a clinic champion who managed study workflows and communications across all seven clinics, intervention facilitators in this health system were unable to adopt these workflows because of heavy workloads, stress, and limited buy-in.

The second mis-implementation outcome experienced was limited reach where few support persons participating in the study attended the intervention. At the conclusion of the study at this health system, only 7 of 26 support persons randomized to the intervention attended groups. On multiple occasions, only one support person attended the group with two eINSPIRE facilitators. Staff indicated that broadening study inclusion criteria from only family members to include close friends (who may be less impacted by the patient's opioid use) may have resulted in low attendance. Data from meeting notes indicate that intervention facilitators had a lot of difficulty reaching support persons to conduct an orientation to eINSPIRE groups via telephone (e.g., these were introductory calls done prior to the first scheduled group). Facilitators reported that their existing clinic procedures were to attempt contact only twice, which was incongruent with our intervention protocol to call the support persons multiple times at different times over the course of the week. There was a disconnect between eINSPIRE and existing clinical and intervention protocols that may have affected support person intervention attendance.

Adoption and reach contributed to mis-implementation, and both issues seemed to arise from personnel perceptions that the intervention was not feasible due to aforementioned issues with caseloads and workflows. Yet, data from focus groups and interviews with staff, patients, and their support persons revealed that group telehealth therapy was seen as highly acceptable and filled a great need for support persons. One support person stated "I think it's a good thing for us to be able to understand more of what the people that are using go through" and one patient stated "I think it's good to educate people that aren't too familiar with buprenorphine." Over 90% of support persons agreed or strongly agreed to group telehealth being acceptable, 100% reported eINSPIRE was possible and doable, and 92% reported that it was workable in the clinic and easy to use. One support person stated group telehealth would be convenient with competing demands, "You don't have to find transportation there or childcare if it requires it," and another commented on its reach: "Well, I think that because it is over Zoom, it makes it easier for you to be able to reach out to people all over, versus just being in one specific area." Support persons reported high acceptability for participating in groups via Zoom and staff reported an existing infrastructure to do so. Despite the acceptability of the intervention, this case study provides insights to how low feasibility still contributed to mis-implementation.

Case 3

Mis-implementation of PTSD Care Management (PCM) in ViStA occurred in several ways across the six FQHCs. Although both health center staff and patients found the intervention acceptable and the additional time spent devoted to the PCM was not cost prohibitive, ViStA was not implemented as planned. The key mis-implementation outcomes were adoption, fidelity, feasibility, and sustainability.

First, the intervention was not fully adopted because it was too intensive and burdensome to patients and providers. Data from the patient registry indicated that many patients randomized to the intervention did not engage with the CM at all (27% with no adoption), and follow-up adherence to acceptability standards was low for those who did engage (average number of contacts with the CM was 4.2 of the 14 intended sessions. There were also some components of the intervention that CMs did not use, which further limited intervention fidelity. For example, the intent was for CMs to share structured feedback about patients with primary care providers on a regular basis either through regular huddles or through chart notes.

The monthly CM reports showed that most of the sites did not implement a process for regular communication in large part due to time limitations and also because time was not protected for health center providers to review study cases. As one CM reported, "My main concern now is devoting enough time to all of my care management patients. I have been able to get many of my patients in for back-to-backs but am having a difficult time reaching out to all of them for the follow-up calls." Only one of the six sites facilitated such communication; at that site, the CM was invited to review cases in-person during the weekly primary care provider meeting. At other sites, the feedback was more haphazard. For example, some sites received the feedback informally through "hallway" conversation and others were contacted by email to discuss patients that needed special attention or to share

recommendations about medication adjustment made by the behavioral health consultant. Providers at the other sites preferred that CMs send periodic emails and chart notes which yielded limited feedback to CMs. At the site that was able to have productive feedback sessions with PCPs, the CM explained:

> "We scheduled a feedback meeting and I was able to meet with 3 of the 4 primary care clinicians during this feedback luncheon session. The clinicians were very receptive … We went through each case and discussed the patient's PTSD symptoms and whether their current course of treatment was effective. … I was also able to discuss one of my patient's adverse reactions to her medication and offered my recommendation to the [clinician]. He listened to my recommendation and agreed to review the patient's chart to see what modifications can be made to her medications."

Additionally, contextual factors in the FQHCs made it difficult for health center staff to prioritize adoption of PCM in the first place. Prior to implementing the intervention, the team learned through site visits that none of the sites routinely assessed for PTSD and were only beginning to adopt routine screening for depression. Although staff accepted the presence of the CM and appreciated the additional support for managing patients with PTSD, they did not fully engage with the process as intended. The study research team hired the CMs and managed the intervention independently from other clinical processes. So, the PCM was not fully integrated into the health center workflow in most sites. At one FQHC, state restriction on interoperability between medicine and behavioral health records was an outer setting barrier that made care integration difficult. In terms of the individual domain, some FQHC providers were less apt to share ideas about improving care for PTSD broadly – they were stretched too thin to go much beyond their usual care practices.

Second, although patients and providers found the intervention acceptable, the feasibility of the intervention appeared low for FQHCs given that 14 intended contacts over a 1-year period took too much time for CMs and led to burnout on both the CMs' and patients' part (as discussed in weekly meetings with the Behavioral Health Consultant). Many patients felt that continuing to talk about their trauma over up to 14 sessions was causing them to relive their trauma experience and thus did not want to continue to engage in the CM calls. And much of the focus during CM calls was on managing their social determinants of health issues which were a key barrier to continuing with all of the intended sessions. Another feature of the planned intervention for ViStA that was infeasible was CMs facilitating access to non-medical resources in the community (e.g., battered women's shelters, financial support, nutrition aid) through locally tailored resource guides. Registry data indicated that while CMs did routinely provide information to patients, they did not use the registry to track whether patients accessed those services and if they were helpful. Patient interviews also revealed that some of those resources were not always available if they tried to obtain services.

Further, some sites did not have onsite behavioral health care and therefore had limited opportunity for coordination of care between the CMs and behavioral health interventionists on the team. Some providers felt that although assessing for PTSD was important, the site did not have the infrastructure to continue to screen for PTSD as necessary follow-up

behavioral health care was not available for positive cases. Another implementation feature that was not feasible to implement adequately was that the CMs could not always attend the weekly meetings with the Behavioral Health Consultant due to the burden of managing a large caseload of patients. While there were four CMs, only 1–2 CMs typically participated in these meetings. In addition to irregular participation, these meetings more often focused on addressing stress and burnout experienced by the CMs leaving limited time to actually review and discuss patient cases

Finally, although the PCM intervention was deemed acceptable by both patients from follow-up interviews and health center staff via exit interviews, it was not continued at any of the FQHCs once the trial was complete. Sustainability would have required additional staff time and resources (to implement use of a brief PSTD screener), and capacity for referring patients to evidence-based treatments that were not available in those FQHCs. As an example, the CM positions were provided from the research team resources e.g., CMs were hired and trained by the ViStA research team and therefore could not be easily integrated into the clinical process without additional resources. These difficulties with patient engagement combined with structural and staffing barriers suggest that collaborative care models for PTSD may be insufficient for treating PTSD without additional resources and support. The intervention, as intended, may have been too intensive for these low-resourced settings with mostly poor and minority patient populations.

Compare and Contrast Analysis of Case Summaries

Table 1 presents the matrix summarizing mis-implementation outcomes and barriers from each case summary. Across cases, limited adoption, reach, and/or fidelity to the interventions led to eventual discontinuation. Multilevel barriers contributing to these outcomes spanned all CFIR domains and included high intervention complexity, low buy-in from providers, staff burnout and turnover, lack of alignment between providers and leadership around implementation, and (in two cases) COVID-19-related strains on the FQHCs. The greatest number of barriers were in the inner setting and individual domains, although mis-match of the intervention and the setting was important, as well as external factors constraining the FQHCs.

For cases 1 (CLARO) and 2 (eINSPIRE), mis-implementation refers to full discontinuation of implementation activities within the sites. Both cases had low adoption of the intervention by staff at the sites, and low reach of the intervention to the target population. In contrast, case 3 (ViStA PCM) was not discontinued; although adoption was still a challenge, mis-implementation was primarily seen with acceptability and feasibility. The fact that the PCM trial was completed before the COVID-19 pandemic may partly explain why the intervention enrolled more patients (no reach issue) and was able to continue for longer. But ultimately, PCM was still not sustained at any participating FQHCs because the acceptability and feasibility issues were not resolved, and adoption remained low throughout the trial.

In contrast to CLARO, both ViStA PCM and eINSPIRE had high acceptability of the intervention by patients and health center staff. Outer setting factors related to the health system’s rural community were a major driver of low acceptability for CLARO among patients, whereas leadership and implementation issues contributed to low buy-in among

providers and staff. Despite their high acceptability, eINSPIRE and ViStA PCM both experienced low feasibility for the intervention within their site's contexts. For ViStA, this was due to the misalignment of the PCM intervention with the needs of patients – too many sessions and not enough focus on social determinants of health needs.

Discussion and Conclusions

The research summarized in this paper illustrates how studying mis-implementation is an important, but largely untapped, source of information about how to improve knowledge exchange practices for under resourced behavioral health service settings. We advanced the study of mis-implementation by adapting CFIR to conceptualize its determinants and outcomes, and applying the framework to three case examples from clinical trials conducted in FQHCs. In each case, multi-level barriers contributed to mis-implementation outcomes for a behavioral health EBP in FQHCs, limiting the ability of these systems to benefit from knowledge exchange. Our findings also demonstrate the complex interrelations among implementation and mis-implementation outcomes; for example, poor adoption and feasibility may not necessarily indicate low acceptability of the intervention (in fact, the opposite was true in some cases).

Learning from mis-implementation can help refine implementation strategies, which are formalized activities that guide knowledge exchange around EBPs to inform successful implementation. To overcome the barriers that cause mis-implementation, effective strategies need to be tailored to relevant audiences such as providers (e.g., offering resources and support, simplifying the EBP), patients (e.g., ensuring patient-centered interventions, increasing engagement), and/or leadership (e.g., maximizing alignment and problem-solving with providers). Each strategy should be designed to address common, core barriers – such as limited provider availability, competing health and social needs for patients, and need for alignment with available funding – but also flexible enough to address a variety of site-specific contextual factors. Such an approach contrasts with dominant "bottom-up" approaches to tailoring implementation strategies that have been conceptualized and tested in implementation research to date (Powell et al 2017). Such tailoring strategies have focused on selection of discrete strategies based on lists of barriers and facilitators, but have yet to perform better than standardized strategies in preventing mis-implementation (Baker et al 2010, Wensing et al 2009). Rather, flexibility within theoretical and practical coherence of an implementation strategy are likely ideal for maximum effectiveness (Damschroder 2020), not unlike how the collaborative care model underlying CLARO and PCM emphasizes core principles rather than rigidly defined practices (AIMS Center 2014). The increased challenges of implementation due to the strain of the COVID-19 pandemic on healthcare systems further underscores the need for flexibility.

Numerous other questions remain about the best ways to conceptualize, study, and address mis-implementation. For example, a key issue is how to define the boundaries of an EBP, given that the concept of mis-implementation presumes the practice would have been beneficial if it had been implemented (i.e., research findings would have been replicated). However, there have been many large-scale initiatives to widely implement practices without an established evidence base, or to implement practices uniformly

without regarding to the fit with specific settings or populations. These situations could represent mis-implementation within pre-implementation processes, which are not included in CFIR but are emphasized in other models like the phase-based Exploration, Preparation, Implementation and Sustainment (EPIS) framework (Aarons et al 2011, Moullin et al 2019). Furthermore, some communities may indeed benefit from practices not considered evidence-based by established standards, but instead locally developed and tailored to patient and community needs. Indeed, the trials included in our case examples focused on adaptations of established EBPs, representing "scaling out" of the evidence base to new populations and/or settings (Aarons et al 2017). Adaptation of well-established principles is the norm for implementation rather than the exception (Lau et al 2017, Park et al 2018). We need to continue to expand understanding of mis-implementation to accommodate the wide variety of knowledge sources used to inform implementation – avoiding rigid definitions of EBPs that are disconnected from community needs – across the various phases during which that knowledge is translated. Future trials may benefit from implementation of a community-engagement stakeholder workgroup from trial outset for providing patient and community perspectives and guidance as the intervention is developed, refined, and delivered.

It is important to recognize the limitations of this formative work. First, terminology in implementation research is complex (McKibbon et al 2010) and we made tradeoffs between specificity and clarity in our terminology decisions. For instance, we introduced a new term "mis-implementation" rather than using an existing term like "de-adoption" (Massatti et al 2008, Nadeem and Ringle 2016), which we found did not facilitate clear facilitation of the range of problems encountered in implementation outcomes. More refinement of our conceptualization is likely needed, particularly to clarify the boundaries between related concepts such as de-implementation of harmful or ineffective practices (McKay et al., 2018), or re-implementation of an EBP to address poor implementation outcomes (Moyal-Smith et al., 2023). Second, our adapted framework has not yet been used to study mis-implementation determinants and outcomes for other types of EBPs (e.g., medical, public health) and/or other settings (e.g., mental health, schools, child welfare) beyond behavioral health EBPs in FQHCs, which would help assess generalizability and further refine the conceptualization. Comparison of our findings to other mis-implementation studies (Gopalan et al 2020; Massatti et al 2008; Nadeem and Ringle 2016) suggests good potential for generalizability, since those analyses identified comparable determinants (e.g., EBP-setting fit, leadership) and outcomes – but this is no substitute for in-depth application of our framework. Third, our focus on federally funded trials limited the situations observed and types of EBPs implemented, and may have resulted in less comprehensive data on outer setting factors (beyond impressions of those in the inner setting) – e.g., our ability to link mis-implementation outcomes to COVID-19 pandemic dynamics is limited, despite its likely importance and high salience. Finally, collection of more common data elements across trials (e.g., measures of implementation determinants and outcomes) would have increased our ability to directly compare and contrast findings between studies at the construct, rather than domain, level.

In sum, we anticipate that our mis-implementation framework and case summaries can support more systematic study of mis-implementation in the future, building on other important initial studies (e.g., (Gopalan et al 2020, Massatti et al 2008, Nadeem

and Ringle 2016). Until much-needed system-level improvements in healthcare are possible, mis-implementation will remain a risk for any EBP and in particular for complex behavioral health interventions in low-resource settings like FQHCs. Continued bi-directional knowledge exchange with implementor health systems about their challenges and experiences will be vital to improving EBP availability to the benefit of patients, providers, and systems.

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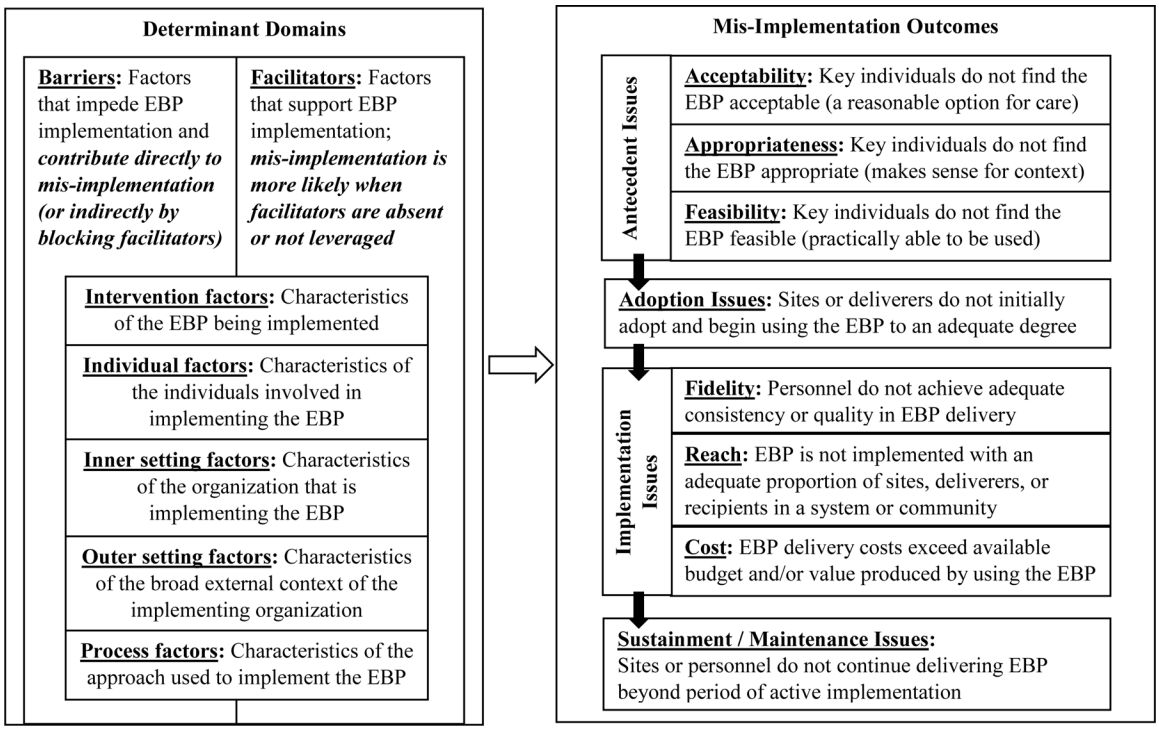

Figure 1:

Conceptual Model of Mis-Implementation Outcomes and Determinants Derived from the Consolidated Framework for Implementation Research

Note. EBP = evidence-based practice. Figure derived from the Consolidated Framework for Implementation Research (Damschroder et al., 2022a, 2022b).

Table 1:

Case-Specific Mis-Implementation Outcomes and Barriers, per the Consolidated Framework for Implementation Research

Mis-Implementation Case (intervention)	Mis-Implementation Outcomes	Barriers (by CFIR Domain)				
		Intervention	**Individuals**	**Inner Setting**	**Outer Setting**	**Process**
CLARO (Collaborative Care for OUD with co-occurring MDD and/or PTSD)	• **Adoption** of intervention by personnel low • **Reach** of intervention limited to only 35 patients • **Acceptability** to patients for engaging with behavioral health or care coordination was low • **Fidelity** low for providers using psychiatric consultation	• Providers perceive intervention to be complex	• Champion left clinic unexpectedly during implementation • Staff hesitant to implement new programs • Low buy in from providers/ staff for CLARO project	• Communication challenges between clinic leadership and providers/staff • High staff turnover, which contributed to stress and made relationship-building more difficult • Complex leadership hierarchy made it difficult to plan and execute changes	• Patient identification and engagement limited by community stigma and concerns about confidentiality • COVID-19 complicated implementation process (example, delayed CLARO launch) • Skepticism and distrust toward academic and government organization outside the community • Many patients did not have regular access to internet or phone service	• Mismatch between leadership's expressed commitment to implementation and the actual follow through on operational changes • Top-down approach overly relied on leadership for success (table continues)
eINSPIRE (Community Reinforcement Approach and Family Training for support persons of people with OUD)	• **Adoption** limited because staff could not enroll support persons or prioritize the intervention • **Reach** low as reflected by minimal attendance of groups by support persons • **Feasibility** issues made it difficult for personnel to focus on adoption or reach, despite high acceptability	• Intervention required more time than available to engage SPs	• Definition of support person to include friends affected engagement, as friends may have had lower motivation to attend classes compared to family • Low buy-in from frontline staff even though high buy-in from champion/ administrator	• Low capacity to engage target patient population from the community • Segmented team structure (intervention facilitators disconnected from champion and leadership)	• COVID 19 changed in-person to virtual groups, which may have affected SP engagement • High stress by SPs and intervention facilitators related to the COVID-19 pandemic	• Ineffective top-down approach to implementation led to frontline staff having difficulty with workflows the research team and clinic champion developed
ViStA PCM (PTSD Care Management)	• **Adoption** low as reflected by limited delivery of intervention, lack of integration into FQHC workflows • **Acceptability** issues reflected in low number of sessions; some components not delivered • **Feasibility** limited as care managers became burned out and	• Number of expected Care Manager contacts (14) too high to be feasible; only 4.2 encounters on average • Intervention content was not designed to fully address	• Limited openness to innovation among providers • Care Managers became burned out due to large caseload and number of intervention sessions • Patients reported that frequent discussion of	• Lack of behavioral health providers on site • Difficulty for Care Managers to communicate with providers • Staff work overload • Resources and staff not available to sustain intervention	• State restriction on interoperability between medicine and behavioral health records (one FQHC) made care integration difficult	• Health centers did not routinely screen for PTSD so intervention was not fully integrated into the center workflows • Most clinics did not facilitate huddles between Care Manager and providers • Care Managers did not

Mis-Implementation Case (intervention)	Mis-Implementation Outcomes	Barriers (by CFIR Domain)				
		Intervention	Individuals	Inner Setting	Outer Setting	Process
	lacked support for intervention • **Sustainment** not achieved at any FQHC sites	patient social needs	trauma histories was distressing			track community resources and maintaining a list of resources was challenging

Note. CFIR = Consolidated Framework for Implementation Research (Damschroder et al., 2022a, 2022b). CLARO = Collaboration Leading to Addiction Treatment and Recovery from Other Stresses. eINSPIRE = INtegrating Support Persons into Recovery (e-health version). ViStA PCM = Violence and Stress Assessment PTSD Care Management. PTSD = Post-traumatic stress disorder. FQHC = Federally Qualified Health Center.