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Examining Implementation of a Patient Activation and Self-management Intervention Within the Context of an Effectiveness Trial

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Abstract

This qualitative study examines factors important for delivering a patient activation/self-management intervention in 13 mental health clinics within the context of an effectiveness trial to inform understanding of real-world implementation. Eighteen key personnel were interviewed about the following factors relative to the intervention and its delivery: alignment with organization values/patient needs; buy-in/support from leaders and providers; roles played by leaders and key personnel; and availability of organizational resources. Where supportive, these factors facilitated the delivery of the intervention; elsewhere, they presented as impediments.

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Disclosures The first author's role was confined to the hybrid implementation study. The first author had no input into the design of the parent research study, no involvement in hiring the Site Investigators or Care Managers, and no involvement in the day-to-day activities of executing the parent research study. The second author of the paper was a Site Investigator for the parent research study and helped code interviews for the hybrid implementation study (minus any interviews from her clinic). A third coder was brought into code interviews from the second author's clinic. The third coder was previously a project coordinator of the parent research study. The first author ensured that any identifying information was removed from all interviews.

Findings from this study could help anticipate challenges to implementation that could be examined in a full-scale implementation study.

Keywords

Implementation research; Hybrid effectiveness-implementation research; Community mental health settings

Introduction

A critical issue in improving the quality of health care in the United States is closing the gap between the development of new, scientifically-proven interventions and the incorporation of these interventions into clinical practice (IOM 2001; Proctor et al. 2009). Implementation research aims to understand how to close the gap of translating research into practice and focuses on studying the factors, processes, and strategies that are associated with successful integration of evidence-based interventions into health care organizations (Rabin et al. 2008). Implementation research is traditionally conducted once effectiveness for the intervention is established. In contrast to effectiveness research, which emphasizes external validity and generalizability, implementation research focuses on “the adoption or uptake of clinical interventions by providers and/or systems of care” (Curran et al. 2012, p. 218). Some researchers contend that implementation-related questions could be addressed within effectiveness trials in order to expedite the translation of research to practice (Curran et al. 2012). Findings from such “hybrid effectiveness-implementation” studies could result in “more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers” (Curran et al. 2012, p. 217).

One of three hybrid effectiveness-implementation study designs proposed by Curran et al. (2012) entails gathering information on the delivery of the intervention during the effectiveness trial in order to inform future implementation studies of that intervention (Curran et al. 2012). Examples of questions that could be addressed by stakeholders (e.g., providers, administrators, patients) in this type of study include: “What are potential barriers and facilitators to ‘real-world’ implementation of the intervention?” and “What problems were associated with delivering the intervention during the clinical effectiveness trial and how might they translate or not to real-world implementation?” (Curran et al. 2012, p. 223).

This study utilizes an opportunity to examine factors associated with successfully delivering a promising patient activation and self-management intervention targeted towards racial-ethnic minority patients as the intervention itself is examined for effectiveness in order to inform what could happen in the implementation of the intervention in a “real-world” context. This information, in turn, could be used to help develop an implementation strategy that could be tested in a full-scale implementation study once evidence for the intervention is established.

Implementation Factors

Theories that guide implementation research have proposed a number of factors that play a key role in the successful implementation of interventions, including organizational-level, provider-level, and patient-level factors (Aarons et al. 2011; Damschroder et al. 2009; Greenhalgh et al. 2004). Based on a review and synthesis of the implementation literature, particularly within the mental health field, four broad categories of factors were selected to explore how they influence the delivery of the patient activation and self-management intervention in the clinics participating in an effectiveness trial. These four broad categories of factors consistently appear in models of implementation, where they are theorized to strongly influence the successful implementation of an intervention, particularly when found in combination (Aarons et al. 2011). These factors include: (1) alignment of the intervention with organizational goals and patient needs (Aarons et al. 2009, 2011; Drake et al. 2003; Klein and Sorra 1996; Rosenheck 2001; Torrey et al. 2001); (2) buy-in and support from leadership, providers, and administrative staff (Aarons et al. 2011; Corrigan et al. 2001; Fixsen et al. 2005; Ganju 2003; Greenhalgh et al. 2004; Rosenheck 2001; Torrey et al. 2001); (3) the role of leadership and key personnel in delivering the intervention (Aarons et al. 2011; Fixsen et al. 2005; Greenhalgh et al. 2004; Mancini et al. 2009; Torrey et al. 2001; Whitley et al. 2009); and (4) availability of organizational resources and infrastructure support for carrying out intervention activities (Aarons et al. 2011; Drake et al. 2003; Fixsen et al. 2005; Ganju 2003; Goldman et al. 2001; Mancini et al. 2009; Rosenheck 2001; Simpson 2002).

How an intervention aligns with the goals and needs of all organizational stakeholders (e.g., leaders, providers, and consumers) will likely impact the ease with which it is implemented (Aarons et al. 2011). Poor leadership, insufficient collegial support, and bureaucratic constraints have been shown to hamper the implementation of interventions (Aarons et al. 2011; Corrigan et al. 2001). Buy-in from all levels of an organization helps ensure implementation and wide-spread impact of the intervention (Rosenheck 2001). The time leadership and key personnel have to devote to the new intervention and any turnover in leadership or key personnel also influences the implementation of the intervention (Rosenheck 2001). Of course, the competence of those delivering the intervention is crucial for implementation (Greenhalgh et al. 2004). Finally, a stable and sufficient infrastructure support is not only essential for successful implementation, but also ensures the sustainability of the intervention (Goldman et al. 2001). An unstable infrastructure could impose or distract personnel and impede personnel's abilities to deliver the intervention effectively (Rosenheck 2001).

Methods

The hybrid effectiveness-implementation study (also referred to as the “hybrid study”) takes place within the context of effectiveness trial of a patient activation and self-management intervention called DECIDE. ¹We conducted a process evaluation to examine the delivery of

¹The parent effectiveness trial is referred to as a blended efficacy-effectiveness study in other manuscripts reporting findings from the parent study (Alegría et al., Under Review; Carson et al., Under Review) due to the research team's attempts to control several aspects of the effectiveness trial.

the DECIDE intervention in thirteen mental health clinics participating in the effectiveness trial of the intervention. A process evaluation is an approach designed to identify factors associated with successful implementation of an intervention, but whose findings are not used to influence the original delivery or implementation of the intervention (Curran et al. 2012).

The DECIDE Intervention

The DECIDE intervention seeks to teach racial–ethnic minority patients in outpatient mental health treatment a set of skills that promote a more active role in their mental health care encounter. Patient activation is defined as patients’ acquiring knowledge, skills, and beliefs which could enable them to take thoughtful action on their own behalf and actively engage in questioning and decision-making about their health and treatment (Barry and Edgman-Levitan 2012; Oshima and Emanuel 2013). Self-management describes patients becoming better managers of their own health condition by gaining knowledge and self-efficacy to become better aware of factors which could hinder or improve their health outcomes (Lorig et al. 1999).

The intervention consists of three 45-min psycho-health educational sessions where patients are taught how to formulate and ask questions about their mental health concerns and treatment, with the overall objectives of improving patients’ participation in key decisions regarding treatment and self-management of their illness and care. The DECIDE trainings were provided to patients by a Care Manager over the course of ~3–4 months. Site Investigators were responsible for supervising the effectiveness trial at each clinic and for overseeing the day-to-day activities of the delivery of the intervention to patients at the clinic.

The intervention is targeted to racial–ethnic minority patients and seeks to improve care for minority patients and reduce disparities in care. This targeting strategy assumes that if minority patients hold traditional role expectations of being passive recipients in their clinical encounter (Levinson et al. 2005; Xu et al. 2004), improving their level of activation and self-management of care could help “augment satisfaction with care, improve health care processes, ensure receipt of appropriate treatments, and enhance health outcomes” (Alegria et al. 2008, p. 248). The efficacy and effectiveness of the intervention have been fully described elsewhere (Alegria et al. 2008, under review).

Setting—The hybrid effectiveness-implementation study took place in all 13 mental health clinics that participated in the effectiveness trial of the DECIDE intervention. The clinics were located in Massachusetts (five clinics), Minnesota (three clinics), New Jersey (one clinic), New York (one clinic), North Carolina (two clinics), and Puerto Rico (one clinic). Eight of the clinics were community clinics affiliated with larger academic health centers while the remaining five clinics were community mental health clinics. The patient populations served by these clinics were predominantly female (69.1 %), Latino (66.2 %), non-US born (58.7 %), and non-employed (68.2 %). Depressive and anxiety disorders were the most common diagnoses recorded.

Study Sample—Seven Care Managers and 11 Site Investigators were selected to participate in the hybrid study due to their direct involvement and experience in delivering

the DECIDE intervention in the clinics that participated in the effectiveness trial. The first author of this paper, who was not a member of the effectiveness trial team, recruited all actively-involved Site Investigators and Care Managers on the DECIDE study team to participate in the hybrid study. The first author introduced the study to the Site Investigators and Care Managers during an effectiveness trial team meeting and followed-up with emails to recruit them to be interviewed for the qualitative study. All participating Site Investigators and Care Managers agreed to participate in the hybrid implementation study.

The seven Care Managers were bachelors or masters degree level staff members of the effectiveness study team and were responsible for delivering the intervention trainings to patients. The Care Managers had little prior clinical training, but a majority of them had prior experience as case-workers. Two Care Managers each delivered the intervention at two different sets of two clinics, respectively. Two other Care Managers delivered the intervention at two different sets of three clinics, respectively. The remaining three Care Managers delivered the intervention at one clinic each, respectively.

The 11 Site Investigators were clinician-researchers who were either affiliated with an academic institution or the mental health clinic and were responsible for ensuring that the DECIDE intervention was delivered to patients according to protocol. One clinic did not have a Site Investigator (the effectiveness study team was responsible for Site Investigator duties at that clinic). Six clinics each had one Site Investigator, respectively. One clinic had two Site Investigators. Two other clinics shared two Site Investigators. Finally, three clinics were all represented by the same Site Investigator.

Organizational Variables and the Semi-structured Interview Guide—A semi-structured interview guide addressed several factors that are widely viewed as essential in influencing the successful implementation of an intervention: (1) the alignment of the intervention to organizational goals and patient needs; (2) buy-in and support from leadership, providers, and administrative staff; (3) the role of leadership and key personnel in the delivery of the DECIDE intervention; and (4) availability of organizational resources to carry out day-to-day activities of the intervention. Care Managers and Site Investigators were specifically asked whether and how these factors influenced their delivery of the DECIDE intervention within the context of the effectiveness trial. While we asked about these factors in sequence, respondents often noted linkages among the factors throughout the course of the interview. Respondents were also asked open-ended questions to elicit additional factors that played a role in facilitating or impeding the delivery of the intervention. Other factors found in the literature to significantly influence implementation (Aarons et al. 2011; Greenhalgh et al. 2004), such as organizational climate and culture, were not explicitly addressed in the interviews because not all of those interviewed for the hybrid study were employees of the clinic, and therefore, were not all likely to be aware of the culture or climate of the clinic in which they were responsible for delivering the intervention. (See Appendix for Semi-Structured Interview Guide.)

Interview Procedures

The semi-structured interview guide was piloted in one of the clinics in the spring of 2011 (with one Site Investigator and one Care Manager) and revised based on feedback from the two subjects, other Site Investigators, researchers from the effectiveness study team, and authors of this paper. The interviews were then administered in the remaining 12 clinics in the fall of 2011, toward the end of the effectiveness study period. A total of 18 interviews were conducted (11 Site Investigators and seven Care Managers) from all clinics participating in the effectiveness study. The first author conducted each one-on-one interview with the Site Investigators and Care Managers over the telephone (with the exception of one interview conducted face-to-face).

Interviews lasted for ~45 min and were audio recorded. Each interviewee provided verbal and written informed consent to participate in the hybrid study. Recordings of the interviews were transcribed by research assistants. The Cambridge Health Alliance Institutional Review Board reviewed and approved the hybrid effectiveness-implementation study.

At the start of each interview and throughout the interview, the first author asked interviewees to consider how the factors affected the delivery of the DECIDE intervention, ignoring activities that would be found only in the context of a study. For example, some respondents brought up the topic of recruiting patients. In this case, the first author reminded the respondent that such activities were not the focus of this study.

At the beginning of the interview, the interviewer instructed respondents who represented multiple clinics in the study (e.g., 1 Site Investigator for multiple clinics) to give distinct answers for each of the clinics they represented. The interviewer reminded respondents who fell into this category of this throughout the interview as well. For those clinics that had more than one person representing the same type of stakeholder group (e.g., 2 Site Investigators for 1 clinic), the authors ensured that all of the responses for that stakeholder group were analyzed and looked for any incidences where a respondent of a stakeholder group at a clinic said one response while another respondent of the same stakeholder group at the same clinic said a contradictory response. These types of incidences never occurred.

Analysis

Coding of the qualitative data used two approaches simultaneously: (1) coding using the four aforementioned factors (i.e., a priori codes); and (2) open coding used to identify any new themes from the interview data. The first author ensured that any identifying information about the Site Investigators and Care Managers were removed from all interviews prior to coding. The coding process employed the constant comparative method, wherein coded text was compared and contrasted leading to revision in the codes as the coding of interviews progressed (Miles and Huberman 1994; Patton 2002).

The first author coded all interviews. Since the second author was also a Site Investigator, the second author coded all interviews except for interviews from her own clinic. An additional third coder was brought into code interviews from the second author's clinics and an additional set of three interviews. Coding reliability was established by having the first and second authors meet each time a set of three interviews were coded using a consensus

approach. In these meetings, the coders discussed the consistency of coding a priori codes, any open codes, and emerging themes. The first author and the third coder met to discuss the coding for the interviews from the second author's clinic. Additionally, the first and second authors met with the third coder to discuss the three additional interviews coded by the third coder. There were no major discrepancies in coding among the coders and the few minor discrepancies were resolved in discussions among the coders (Bradley et al. 2007).

The first and second authors organized the codes into themes by using inductive qualitative methodology to identify the most salient themes (Ryan and Bernard 2003). This method included iterative comparison of the themes derived from the a priori codes to any themes derived through open coding. Atlas.ti was used to store and organize the codes (Scientific Software Development 2010).

Results

Alignment of Intervention to Organization Values and Patient Needs

The decision by each clinic to deliver the DECIDE intervention as part of the effectiveness trial was, in part, shaped by how closely the intervention aligned with the clinic's values and its patient needs. Respondents frequently described their clinic's commitment to empowering and supporting its patients in making decisions about their own health care. They discussed the DECIDE intervention's emphasis on helping patients learn to talk with their providers in a way that not only communicated the patients' concerns and needs, but also did not conflict with their cultural beliefs. The clinics were similarly focused on meeting the cultural needs of their patients and providing culturally informed/sensitive treatment. One respondent said:

...the clinics are non-profit and their goals are to advocate for the Latino patients in the community, provide a voice for them, and provide adequate care and so I think the intervention aligns with that mission.

Another respondent added:

It is at least aligned with the values of where things are going both nationally and within the clinic where participants are, where patients are seen as active participants in their care...active participatory decision.

A major challenge identified by some respondents was the high no-show rate and poor retention of their patient population. They believed that the DECIDE intervention offered a potential solution, with its aims of increasing patient activation and improving self-management of mental health care. Thus, the DECIDE intervention upheld values of participating clinics while addressing one of the main issues clinics faced in achieving their purpose/mission. For example, one respondent said:

The goals are really important for our organization...that it could provide us with ideas on how to reduce the no show rate, and in the end encourage people to be more active in treatment.

One barrier to delivering the intervention that emerged from interviews was the potential for some patients to have difficulty attending three training sessions (as part of the DECIDE

intervention) in addition to attending provider appointments, due to their social/life circumstances. For example, many patients had a significantly long commute to the clinic or did not have reliable transportation, which in turn, led to difficulty in physically going to the clinic to attend the intervention training session. Some patients with children were unable to attend sessions due to a lack of affordable childcare. Some parents whose children accompanied them to intervention training sessions were forced to end the session early because they had to address their children's needs. The demands of the participants' job also diminished their time to attend training sessions. These fundamental issues raised by interview respondents reflected the real world problem of balancing patient activation needs with the patients' limited resources. One respondent explained:

Our participants, their schedules, their limited resources, with regards to transportation and child care. They couldn't just get away from work; you know a lot of these participants who were patients of the clinic...they had a couple of jobs...they may not have an understanding employer, they may not actually get much of a lunch break and often times they would try and squeeze an appointment so that made things challenging in regards to...how do we find a time to meet with the participants so that they don't have to come to the clinic twice, but also don't end up jeopardizing their jobs by staying longer than they would have stayed if they just had the appointment.

Leadership, Provider, and Administrative Buy-In and Support

Obtaining buy-in at each clinic was an essential step in delivering the DECIDE intervention at the clinic. Buy-in was facilitated when the intervention could more easily blend into the clinic rubric. An element that increased buy-in at the leadership and provider levels was the promise of the effectiveness of the intervention. One respondent said:

The issue of treatment engagement is one that people struggle with on a regular basis, so the promise of the intervention to help out with treatment engagement I think is something that caught everyone's attention.

Respondents noted the importance of buy-in at the level of leadership, providers, and even at the level of the administrative staff for the implementation of the intervention, for example:

It's really key to have somebody at the front desk whose sort of...they don't personally have to buy-into it, but it's helpful if they do or...they endorse why you're there or they think it's important enough...so you can...you know, getting the keys to the office, finding rooms.

The lack of administrative support at some clinics created significant challenges to delivering the intervention. One respondent discussed:

There was no point person, really, at the clinic so I think that was the most difficult aspect. There were people who we could contact, but there was no one who was there who I could sort of go to and was actively helping facilitate the process.

Although buy-in was obtained among most clinic leaders and providers, several respondents observed buy-into be difficult to obtain among providers with a psychodynamic orientation. Providers with this approach to treatment experienced the DECIDE intervention as

disruptive to building a therapeutic alliance with their patients, which they believed to be a critical aspect of the psychodynamic process. One respondent explained:

The therapeutic relationship is the most important aspect of their relationship...or of their therapy. So if the therapeutic relationship is valued more than...anything else, it felt like having a Care Manager work with one of their patients was like almost an intrusion.

In addition to push-back from providers with a psychodynamic orientation, a few respondents felt that some providers were threatened by the questions their patients generated during the intervention training sessions and brought to the provider sessions, noting some patients' perceptions that their providers were uncomfortable and reluctant to answer questions. One respondent provided the following example:

With some therapists, they felt threatened with the clients asking so many questions. So it really depended on the therapist...what the clients would tell me is that they wouldn't answer their questions directly or would ask the clients why are you asking so many questions...another participant told me that one of the therapists said, 'oh my God I feel like I'm being interviewed by you.'

Additionally, some respondents felt that providers did not fully understand the intent of the intervention. Another respondent discussed:

I don't think the clinicians really knew what the intervention was. I mean they knew the idea was about patient activation or patient-communication— that was the extent they knew...

Role of Leadership and Key Personnel in Delivering the DECIDE Intervention

Leadership at the clinics played an instrumental role in facilitating the day-to-day operations of delivering the intervention to patients. A few of the clinics experienced turnover in leadership during the course of delivering the intervention. Among those clinics that experienced leadership turnover, only two of the clinics experienced a disruption in the delivery of the intervention as a direct result of turnover in leadership. One respondent stated:

...it's a nonprofit so they have a board, and the board changed to a new director after the old, really well loved director retired. And there was, oh, they just did not like the new director at all. Yeah it was very different philosophy than all the clinicians at X Clinic. And there was this mass exodus, half of the clinical staff left...including three of my absolute main referral sources. So they just got up and left the clinic as kind of a statement. And so at that point, it [the intervention] just pretty much fell apart.

One of the clinics that experienced turnover in leadership also experienced a change in organizational goals and buy-in for the DECIDE intervention. The executive leadership of the clinic at the start of the study bought-in. However, with a change in leadership came a change in "philosophy", and subsequently, a disruption in the delivery of the DECIDE intervention. A respondent from this clinic describes how these issues affected the recruitment of patients and the delivery of the intervention:

But ultimately, between that lack of buy-in and between some huge—huge—huge, transitions that happened within the clinic and the administration, changes in executive directors and a change in philosophy along with that change in executive directors, a lot of providers left the clinic, and it was just so chaotic that it was hard to recruit [patients] there.

A few clinics experienced turnover in the Care Manager position. Among those few clinics, there were only two reported cases of lack of continuity of information between the outgoing Care Manager and the incoming Care Manager. One respondent discussed:

Because there was no continuity of information...when one Care Manager was there, they would know names when the people would come through, but when they [the Care Manager] left and a new person came, they didn't know. So there was no history there and people couldn't say, "oh yeah, no, we already...we already talked to that person."

The lack of availability of some Care Managers to conduct patient trainings also arose as an issue in some clinics. These few Care Managers had other work responsibilities outside of their Care Manager position (e.g., working on other studies), and thus, found it difficult to be available at all times to conduct patient trainings. This usually led to missed opportunities to meet with patients to conduct trainings, and in a few cases, missed appointments with patients to conduct trainings.

On a positive note, Site Investigators praised the work of the Care Managers in delivering the DECIDE intervention to patients. The Care Managers were described as great communicators and terrific problem solvers. They were respectful of the patients and mindful of their role of strictly delivering the DECIDE training to the patients and not stepping into the provider's role of treating patients. Care Managers worked hard to build relationships with providers and staff members in their respective clinics and these relationships helped facilitate the delivery of the intervention. Strategies Care Managers employed to strengthen their bond with providers and clinic staff included being visible within the clinic and interacting with providers and clinic staff as frequently as possible.

Organizational Resources to Support Delivery of the DECIDE Intervention

The lack of organizational resources at some clinics critically impacted the delivery of the DECIDE intervention in those few clinics. The lack of office space at some clinics to conduct the patient trainings was one of the most cited barriers to delivering the intervention. One respondent stated:

...you know a couple of times there were space issues where I had an appointment and I had to cancel it because there was no office available.

Another respondent stated:

...sometimes a patient calls you "oh I'm here, um I can do this now" and if it's someone that you've been having a hard time getting a hold of...you have to jump at that opportunity. That happened at least one time where I went to the clinic and there wasn't any space. And you know we really couldn't do anything about it.

In the incidences where finding office space was an issue, most Care Managers were able to overcome this constraint by working with their Site Investigators and the clinic staff to strategize ways to address the problem.

Discussion

This hybrid effectiveness-implementation study leveraged an opportunity to examine implementation-related questions within the context of an effectiveness trial. By examining factors associated with delivering the DECIDE intervention in mental health clinics while the intervention itself is examined for effectiveness, the study is able to offer timely insight into what may happen when the intervention is implemented and delivered in a real-world setting. This information can be used to develop an implementation strategy for the DECIDE intervention, which in turn, can be tested in a full-scale implementation study.

Two stakeholder groups, the Site Investigators and Care Managers presented complementary, rather than divergent, perspectives about factors affecting the delivery of the DECIDE intervention. The importance of the factors examined in this study in enabling (or impeding in some cases) the delivery of the intervention within the context of the effectiveness study corresponds to what the extant literature has found to be facilitators and barriers to implementing evidence-based practices (EBP) in a real-world context. The findings from this study also enable us to understand how the factors examined relate to one another, and how in combination they could facilitate or impede implementation.

The key informant interviews reveal the importance of aligning the intervention with clinic goals and patient needs. Aaron et al. (2011) contend that intervention fit should be considered at all levels of the health care organization (e.g., managerial, provider, and patient levels). This study found that a challenge in delivering the DECIDE intervention was that some patients had resource constraints that impeded their ability to attend training sessions provided by the intervention. The concern that EBPs require additional time of patients is not new (Aarons et al. 2009). A future implementation study could examine whether delivering the intervention via the telephone compared to delivering the intervention face-to-face is more desirable, more time sensitive to patients, and equally or more effective for patients.

Not surprisingly, we found high levels of concordance between the goals of the DECIDE intervention and stated values and missions of the clinics who chose to participate in this effectiveness study. In a real world setting, similar concordance may or may not occur. However, one could also find that key members of a clinic staff may not fully support the implementation of the intervention regardless of the high concordance between the goals of the intervention and the values and mission of the clinic. Two clinics in this study experienced this conflict, where although there was a high level of concordance between the values and mission of the clinic and the goals of the DECIDE intervention, weak buy-in and support for the intervention among some providers was observed.

Having providers and other staff members understand the rationale and theory behind a new intervention can help convince them to adopt the intervention and help facilitate the

implementation and delivery of the intervention (Corrigan et al. 2001; Fixsen et al. 2005; Torrey et al. 2001). Our findings suggest that a provider component in the implementation strategy of the DECIDE intervention (i.e., a provider training component) may allow providers the opportunity to better understand the intent of the DECIDE intervention. This provider training can be tested in the implementation trial to assess whether its inclusion improves the effectiveness of the DECIDE intervention by fostering an environment in which providers are more receptive to the questions of activated patients.

Leadership and staff turnover and organizational resource constraints are common barriers to implementing EBPs and sustaining it overtime (Corrigan et al. 2001; Fixsen et al. 2005; Ganju 2003; Goldman et al. 2001; Mancini et al. 2009; Rosenheck 2001; Torrey et al. 2001; Wiltsey Stirman et al. 2012) and were indeed barriers to delivering the DECIDE intervention in the effectiveness trial. In this study, we saw that a change in leadership brought with it a change in philosophy for one clinic, which precipitated an exodus of providers and disrupted the delivery of the DECIDE intervention at the clinic. The turnover of Care Managers and the limited organizational resources at the clinics also hindered the delivery of the intervention at some clinics. An implementation plan for the DECIDE intervention could assess whether the health care organization has adequate resources in place to implement and sustain the intervention and whether it has protocols and procedures in place to ensure that activities of the intervention are not disrupted in times of leadership and key personnel turnover.

Care Managers were praised for their excellent communication skills and problem-solving skills. These skills were valuable when the Care Managers had to work with clinic staff to troubleshoot issues that arose with finding office space to conduct patient trainings. On the other hand, the time availability of Care Managers to deliver the DECIDE trainings to patients proved to be an issue in a couple of the clinics. More research is needed to ascertain whether it is better for the Care Manager for the DECIDE intervention to be someone from the clinic staff who has experience performing Care Manager duties for other treatments offered in the clinic or to be someone newly hired for the position. Regardless, the Care Manager needs to be quite flexible regarding time available, given the limited availability of the patients targeted for this intervention—patients who may have difficulty getting time off from work, difficulty getting transportation to the clinic, or difficulty finding childcare for their children—all examples of problems experienced by the racial-ethnic minority patients in this study.

Overall, this study has identified several potential barriers and facilitators to implementing the DECIDE intervention in a real-world context, and has also suggested strategies for addressing the barriers and helping to ensure the successful implementation of the intervention in health care organizations in the future. In addition to the strategies for implementing the DECIDE intervention discussed above, a future implementation study for the DECIDE intervention could also examine the importance of the factors examined in this study by comparing them to factors not examined in this study (e.g., organizational culture and climate) and also further examine the importance of the relationship between these factors in implementing the intervention. Implementation researchers have found that there is a paucity of information in the literature about which factors are more or less important in

successfully implementing an intervention and whether the prioritization of these factors change over time as an intervention is implemented (Aarons et al. 2011; Øvretveit 2011). In addition to examining the prioritization of implementation factors, further understanding of how these factors interact with one another could be highly valued in the implementation research field.

Limitations

This hybrid effectiveness-implementation study is not without limitations. The study was unable to gain the perspectives of providers, patients, and other important stakeholder groups (e.g., administrative leadership and front-line workers) on what factors are important to implement the DECIDE intervention. Another key limitation was the difficulty, at times, for interviewees to focus on discussing factors important for delivering the intervention rather than focus on factors important for conducting the effectiveness trial. The interviewer sought to minimize this issue through instruction at the beginning of each interview and reminders during the interview to focus on issues relevant to the delivery of the DECIDE intervention. Despite these efforts, there were still a few times when the primary author and the coders who analyzed the data had to determine whether the data were focused on the delivery of the intervention. Finally, another limitation is the high level of concordance between the DECIDE intervention and the values and missions of the clinics that participated in the study. Implementation of the DECIDE intervention could be more challenging where such alignment is not present.

In spite of these limitations, this study is one of a few studies that address implementation related questions within the context of an effectiveness trial. As Curran et al. (2012) suggested in their recommendations for hybrid effectiveness-implementation studies, such a study should be conducted in conditions where strong face validity and indirect empirical evidence exist for the intervention as it relates to its applicability to a new setting, patient population, or delivery method. Further, any risk associated with the intervention needs to be minimal (Curran et al. 2012). Empirical evidence from the pilot study of the DECIDE intervention demonstrated strong face validity of the intervention with minimal risk to patients (Alegría et al. 2008). The team of this hybrid effectiveness-implementation study was also cognizant not to influence the effectiveness trial itself or influence whether clinics would opt to sustain the intervention once the effectiveness trial was over.

Conclusion

Findings from this study demonstrate the value of addressing implementation-related questions within the context of an effectiveness trial. The study was able to identify factors that could be considered when designing a strategy for implementing the DECIDE intervention in other health care organizations. Findings from this study can help to more rapidly develop and test implementation strategies for the DECIDE intervention and other similar interventions, and in turn, improve the likelihood of bringing such quality improving interventions to mental health care organizations seeking to provide innovative, high quality care to their patient population.

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Appendix

Interview Guide for Evaluating the Implementation of DECIDE

1. Description of DECIDE & Alignment with Clinic Values and Needs

- How would you describe the DECIDE intervention?
- Does DECIDE align with the values of your organization? How so? In what ways is DECIDE not aligned with the organization's values?
- Does DECIDE address the patient population needs of your organization or not? How so?

2. Buy-In

- How did the clinic leaders, providers, and staff members feel about the idea of implementing the DECIDE study in the beginning?
(PROBE: Value in implementing DECIDE; Enthusiasm for DECIDE; Time to implement DECIDE)
- Do you think buy-in occurred for the implementation of the DECIDE study (among the related personnel in the organization)?

If Yes - Why do you think buy-in occurred? Was it for most, some, or a few of the personnel?

If No - Why do you think buy-in did not occur?

- How do clinic leaders feel about the DECIDE study now?
- How do providers feel about the DECIDE study now?
- How do staff members feel about the DECIDE study now?

For Site Investigators Only

- What specific strategies did you use to get buy-in to implement the DECIDE study? Did they work?

3. Implementation—Overall

- How involved were you (are you) in implementing DECIDE?
- How do you think the implementation of the DECIDE study went in your clinic?
- On a scale of 1–5, with 1 worse than you expected and 5 better than you expected, how would you rate the overall implementation of the DECIDE study in your clinic?
- Why did you rate it this way?
- (If <5) What could have been done differently to bring your rating up to a 5?

4. Organizational Leadership

Now I am going to ask you some questions about the leadership at this clinic and their role in DECIDE project (not leadership from within the Research Team).

- Who played a leading role in implementing DECIDE at this clinic?
What is the person's role in the organization? (For each person identified)
Why do you consider that person to be a leader in implementing DECIDE? /What did that person do? (For each person identified)
- How much of a leading role did you play in the implementation of DECIDE?
- What was expected from leadership in implementing DECIDE?
- What did the leader(s) do well in implementing DECIDE?
- What could the leader(s) have done better in implementing DECIDE?

5. Workforce

Now I am going to ask you some questions about the workforce. Workforce can include, but is not limited to, the site investigator, the care manager, the director of the clinic, clinicians, and the administrative staff. I may sometimes refer to the workforce as staff members.

- Were there any workforce issues your organization had to deal with in implementing DECIDE? (**PROBE**: Staff turnover; under-resourced; burnout; resistance)

How did these issues affect implementation?

Were these issues resolved?

If yes, what strategies helped your organization overcome these challenges?

If no, what could have been done to overcome these challenges?

- What did staff members do well in implementing DECIDE? (Please identify staff member)
- What did staff members not do well in implementing DECIDE? (Please identify staff member)

6. Remaining Implementation Questions

- Was there a change in the implementation of DECIDE over time? If yes, how so?
- What helped facilitate the implementation of the DECIDE effectiveness study?
- What were some barriers/challenges to implementing the DECIDE effectiveness study?

Were these challenges resolved?

- If yes, what strategies helped your organization overcome these challenges?
- If no, what could have been done to overcome these challenges?

(Probes for Site Investigator who were fully involved in the study or Care Managers)

PROBE: Infrastructure (e.g., clinical record keeping; information systems); Policies and Practices (e.g., financing; approaching patients; handling new patients; referral practices); Bureaucratic/Administrative Challenges (e.g., Clinical Director)

- Has your clinic implemented other interventions similar to the DECIDE intervention? If so, how would you describe your experience with implementing DECIDE in comparison to implementing other interventions at your clinic?
- If the DECIDE intervention is found to be effective, hypothetically, what criteria would be used by the clinic in deciding whether to adopt and sustain the intervention?
- If you could predict the likelihood of DECIDE being adopted and sustained in your site after the study is over, what probability would you give it? Why?

Unlikely Somewhat Likely Likely

- If a health care organization decided to implement the DECIDE intervention (outside the context of a research study), what advice would you give them in implementing the intervention?
- Is there anything else you would like to add that would be helpful for us to know?

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