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Evaluating the Implementation and Impacts of Integrated Depression and Diabetes Treatment in India: A Process Evaluation of the INDEPENDENT Study

By

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Doctor of Philosophy

Behavioral Sciences and Health Education

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Abstract

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By Leslie Carol Munoz Johnson, MPH, MLitt

The mental health treatment gap in low- and middle-income countries (LMICs) is a significant public health problem. The number of people living with chronic diseases is increasing in LMICs, with depression negatively impacting people's health and chronic disease management. Faced with a shortage of trained mental health professionals and a high burden of diabetes, India presents an ideal setting to test a non-specialist health worker-led, chronic disease-focused depression treatment model. There is growing evidence that integrated models of chronic disease care offer effective, low-resource alternatives to specialty mental health care, but currently there is a lack of evidence documenting how integrated depression treatment models are implemented and adapted for use in LMICs. The INDEPENDENT study was designed to test a collaborative, health worker-led care delivery model for depression and diabetes in ambulatory diabetes clinics in India. The aim of this mixed methods dissertation was to fill this gap in the literature and gain a comprehensive understanding of how health care providers implement an integrated depression and diabetes care model in India, and how patients respond to this model of care. Three studies were conducted as part of this dissertation. Study one identified what resources, mechanisms, and contextual factors are necessary to successfully integrate depression treatment in the diabetes care setting in India. Study two identified the factors that determine patients' motivation to engage in an integrated depression treatment model and self-manage their diabetes and depressive symptoms. Study three identified patient practices and strategies that enabled patients receiving the INDEPENDENT care model to reduce their depressive symptoms and self-manage their chronic conditions. Results of this dissertation suggest that the successful implementation of an integrated depression and diabetes care model is feasible in a low-resource setting, but that care coordinators require additional support and training if they are to take on the burden of patient mental health care. The accumulation of health education, motivation, and engagement triggered patient activation, with positively deviant patients identifying strategies to overcome barriers to self-management. Future work should test the presented program theories in new settings to evaluate how different contexts impact implementation processes and patient experiences.

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Cardio-metabolic diseases, such as diabetes, and mental health conditions, such as depression, require long-term, comprehensive medical management combined with lifestyle modifications (Prince et al., 2007). Despite congruencies between recommended evidence-based behavioral interventions for patients with diabetes and depression, respectively, comprehensive care is limited by prohibitive costs, weak health care systems, poor health systems coordination, and shortage of skilled personnel, especially in low- and middle-income countries (LMICs). The impact of comprehensive care approaches is also limited by patient engagement. Patients with diabetes and co-morbid depression are less likely to attend medical appointments or adhere to medical treatment plans because they often experience reductions in emotional and physical energy levels that reduce their ability to carry out self-management practices or attend appointments (see Figure 1.1 for an illustration of the bi-directional relationship between diabetes and depression) (Gonzalez et al., 2008; Bowser, Utz, Glick, & Harmon, 2010; Egede & Ellis, 2008). The difficulty in identifying patients with diabetes and co-morbid depression also creates challenges for efforts to target this population for healthcare quality improvement interventions.

In order to improve the delivery of physical health care among patients with co-morbid depression, health services interventions have focused on coordinating care for patients through referral systems and the delivery of psychotherapy in the primary care setting (Butler et al., 2011; Egede, 2006). Patients with mental health conditions, however, receive poorer health monitoring in primary care settings, compared to patients without mental health conditions (Ludwick & Oosthuizen, 2009; Frayne et al., 2005; Egede, 2007). While efforts are being made to improve the quality of care people with mental health conditions experience in the primary

care setting (Hardy & Gray, 2012; Hardy & Gray, 2014), alternative care models that combine physical and mental health care services in a specialized care setting are emerging. For example, a care model developed out of Australia uses specialized cardiometabolic health nurses to provide physical health care to community-based mental health consumers (Happell, Stanton, & Scott, 2014). The vast majority of these health systems innovations are developed in high-income countries though, which contributes to a widening gap in health service needs when one considers where the global burden of depression and diabetes occurs.

Current projections estimate that by 2030 developing countries will see a 69% increase in the number of people with diabetes, compared to a 20% increase in developed countries, with India having the largest absolute number of adults with diabetes in the world (Shaw, Sicree, & Zimmet, 2010). The bi-directional link between diabetes and depression is well documented and it is estimated that approximately 15.1% of the roughly 72.9 million people with diabetes in India are affected by depression (Mohan, Sandeep, Deepa, Shah, & Varghese, 2007; International Diabetes Federation, 2017), nearly double the prevalence rate documented in the United States among adults with diabetes (Chaoyang, Ford, Stringe, & Mokdad, 2008). Therefore, it is important that researchers test the effectiveness and understand the implementation of integrated care models for diabetes and depression in LMICs, and India specifically.

Integrated healthcare models are used to increase health system coordination for specific populations, though often these care models are developed for patients with chronic multi-morbidity (Dorling, Fountaine, McKenna, & Suresh, 2015). Integrated care models require a patient-centered approach with several interacting multi-level interventions, making these models both a promising way to treat patients with multiple chronic conditions and a difficult

intervention to evaluate due to its complexity (Tsiachristas, Stein, Evers, and Rutten-van Molken, 2016; Goodwin, 2016; Rutten-van Molken, 2017). In addition to having multiple interacting components, the evaluation of integrated care models is complicated by the inclusion of individualized care approaches, which make dose and fidelity difficult to assess, and by the care models' sensitivity to local context (e.g., having low-cost pharmacies to refer patients to, the availability of gyms within the community, climate).

Integrated care approaches for depression and diabetes offer one approach for providing depression treatment in LMICs. LMICs have limited resources for treating mental illnesses (Patel, Araya, & Bolton, 2004) and approximately 20% of LMICs do not even have access to commonly prescribed anti-depressants (WHO 2001). In India, the mental health treatment gap exceeds 90% (Patel et al., 2016) and, due to the shortage of trained mental health professionals, the recommended first-line interventions for psychological treatments are often unavailable (Patel et al., 2017).

Merging and adapting models of integrated care delivery from the US [TEAMcare (Katon et al., 2010b)] and India [CARRS Translational Trial (Manisha, 2012)], a study team of investigators from the US and India developed the INtegrating DEPrEssioN and Diabetes treatmENT (INDEPENDENT) treatment model. This model involved non-physician health workers as the coordinator of care delivery for depression and diabetes in ambulatory diabetes clinics in India. The INDEPENDENT care model focuses on reducing depressive symptoms and cardiovascular disease (CVD) risk factors ($\geq$50% reduction in HbA1c, $\geq$5 mmHg reduction in systolic blood pressure (SBP), or $\geq$10 mg/dl reduction in LDL-c) among out-patients with diabetes. To qualify for participation, patients must have had one or more poorly controlled CVD risk factors and moderate to severe depressive symptoms. This was defined as at least one of:

HbA1c ≥8.0%, SBP≥140 mmHg, or/and LDL-c≥130mg/dl and the presence of depressive symptoms defined by a Patient Health Questionnaire [PHQ-9] score≥10. This care model seeks to improve patient health outcomes and quality of life via four components: (1) health worker-led participant-activation; (2) care coordinator-led coordination; (3) web-enhanced decision-support software; and (4) multi-disciplinary team treat-to-goal reviews. Uniquely, the INDEPENDENT care model is an intervention that supports care delivery with decision-support software and patient case reviews with psychiatrists, endocrinologists, and a trained care coordinator.

The INDEPENDENT study is a randomized controlled implementation trial at four clinics in India and compares the care model described to usual care. Findings from this study will provide evidence of the effectiveness of a culturally-tailored, chronic disease-focused depression treatment model in India.

The following sections will outline current gaps in research related to evaluating the implementation of integrated care models, with the aim of informing the process evaluation of the INDEPENDENT care model. First, the intervention components constituting the INDEPENDENT care model will be described. Second, a review of theory-informed implementation research regarding integrated care models will be presented. Lastly, methodological approaches to evaluating the implementation process of integrated care models will be outlined.

The INDEPENDENT Care Model

The vast majority of clinical trials examining the impact of integrated care models have been conducted in the United States. A systematic review conducted by Dorling and colleagues (2015) found that only one third of the 112 clinical trials evaluating the impact of integrated care for people with diabetes between 2003-2013 were conducted outside of the United States. All of

the non-US studies, however, were conducted in high-income countries. Trials on collaborative, integrated care among patients with diabetes and depression have exclusively been conducted in the United States and the United Kingdom, thus offering limited generalizability for this body of research (Katon et al., 2010a; Katon et al., 2010b; Katon et al., 2004; McGregor, Lin, Katon, 2011; Coventry et al., 2012). The INDEPENDENT study is the only randomized, controlled trial of collaborative, integrated care strategies among people with co-morbid diabetes and depression conducted in India. For the primary outcomes, the study team will assess the intervention's effectiveness by measuring improvements in depression symptoms and risk factors for CVD.

Evidence of integrated care model effectiveness for chronic diseases. The four main components of the INDEPENDENT care model consist of (1) health worker-led participant-activation, which is centered on goal setting, (2) care coordinator-led individualization of care plans, which supports individualized care, (3) web-enhanced decision-support software, which allows the care delivery team to better track patient health outcomes and prompt care modifications, and (4) multi-disciplinary team treat-to-goal case review meetings. These intervention components operate together to enhance care for chronic, complex, progressive, and costly conditions: depression and diabetes.

Health worker-led participant-activation plays an important role in treating patients with chronic diseases because clinical diagnosis and patient awareness of her/his condition(s) are the first steps in initiating clinical- and self-care for depression and diabetes (Wagner, Austin, & Von Korff, 1996). In addition, behavioral activation and motivation are both critical for adherence to chronic care self-management plans (Naik, Kallen, Walden, & Street, 2008; Parchman, Zeber, & Palmer, 2010). Lack of motivation can act as a patient-level barrier to treatment, but with the proper support to build self-efficacy and develop appropriate chronic disease management goals,

individuals can work towards achieving their health goals (Prince et al., 2007; Lorig, 2006; Bodenheimer & Handley, 2009; Miller & Bauman, 2014). A study by Naik and colleagues (2011) found that diabetic patients participating in a clinician-led, patient-centered self-management intervention showed significant improvements in HbA1c levels at one-year follow-up, compared to diabetic patients receiving treatment as usual. The intervention group participants attended sessions to establish self-management action plans and tracked their progress with the assistance of their team of care providers (Naik et al., 2008). Building patients' self-efficacy through education, monitoring, and feedback is essential in enhancing goal commitment for a patient (Bandura, 1997), thus centralizing the role of healthcare providers and care coordinators in integrated, coordinated care models.

Care coordinator-led individualization of care plans is an intervention component that aligns with the Chronic Care Model's (Wagner, 1998) patient-centered treatment approach, which engages patients in medical decisions and tailors treatment to meet patients' individual needs and accommodate those needs as they change over time (American Diabetes Association, 2016). Through therapeutic approaches, such as motivational interviewing (Welch, Rose & Ernst, 2006), providing patient-education, employing self-efficacy enhancement strategies, and monitoring depressive symptoms and CVD indicators, the care coordinators trained as a part of the INDEPENDENT study were supposed to provide on-going, individualized patient care to study participants in the intervention arm (Mohan et al., 2015). Further enhancing the responsiveness of this care model, the care coordinators utilized decision-support software equipped with evidence-based algorithms that recommend treatment options based on updated lab results and patient health information (Mohan et al., 2015). The use of decision-support systems in clinical trials for chronic care management of diabetic patients has proven effective in

improving the quality of patient care and patients' behavioral and health outcomes (Goderis et al., 2010; Piatt et al., 2010; Piatt et al., 2006; Lee et al., 2011; Smith et al., 2008; Glasgow et al., 2005; Carter, Nunlee-Bland, & Callender, 2011; Ali et al., 2016), suggesting it may benefit complex, coordinated care models integrated into diabetes care platforms. In India, one cluster-randomized trial among adult hypertensive patients found that the use of clinical decision support systems was more effective and cost effective compared to a chart-based support system (Anchala et al., 2015). The decision support and electronic health record (DS-EHR) system used in the INDEPENDENT study also incorporates alerts, reminders, and feedback loops into its operations, components that improve healthcare provider efficiency (Baptista et al., 2016).

The last intervention component, multi-disciplinary team treat-to-goal reviews, strengthens the integrated care model by allowing patients to receive depression and diabetes monitoring and treatment in one healthcare setting. The Chronic Care Model advises coordinating care through a team-based approach when resources are available because it creates a healthcare delivery system that is less reactive and more proactive (American Diabetes Association, 2016). The case review meetings achieve this goal by bringing together care coordinators and specialist physicians with expertise in diabetes and depression treatment to provide population health management at the clinic level. Using the DS-EHR to identify poorly controlled cases of diabetes and depression, the specialists investigate where treatment gaps may have occurred and approaches for improving care. It is then the responsibility of the care coordinator to relay that information to the usual care diabetes physicians (UCDPs). This process both promotes accountability among the health care providers and patient self-management when coupled with education, goal-setting, and the active monitoring of depression and diabetes health indicators. The team-based approach, in conjunction with the use of a

decision-support system, allows for more timely and appropriate care, factors that have been identified as reasons why diabetic patients, in particular, have difficulties achieving and maintaining desired health outcomes (Davidson, 2009). With researchers advocating for team-based approaches to treating patients with diabetes and depression and recent evidence suggesting that this model is effective and cost-effective (Katon et al., 2010b; Katon et al., 2012; Tapp et al., 2012; Farooq, 2013), further research is needed to examine how effective this care model is across different settings (e.g., LMICs), and how implementation differs in those settings.

Models of integrated care that have been proven effective in one healthcare setting cannot be implemented in another without first carefully considering the factors that facilitated or inhibited the implementation of that model in the original setting(s). The following section will outline factors known to influence the successful implementation of integrated care models.

Facilitating the Successful Implementation of Integrated Care Models

With the movement towards integrated care models in health care settings, researchers have turned to implementation science to better understand what determinants contribute to the successful implementation of health systems interventions. Nilsen (2015) proposed a taxonomy of the existent implementation theories, models, and frameworks in order to guide researchers in their selection and application of approaches in implementation research. This taxonomy is composed of five categories: (1) process models; (2) determinant frameworks; (3) classic theories; (4) implementation theories; and (5) evaluation frameworks. Nilsen derived these categories from three identified aims of implementation theories, models, and frameworks, which include characterizing the process of research translation (i.e., models that seek to describe or guide the process of translating research into practice), explaining determinants of

implementation outcomes (i.e., frameworks and theories that seek to describe determinants of implementation and their influence on implementation outcomes), and evaluating the implementation process (i.e., frameworks that seek to specify aspects of the implementation process that should be evaluated and how to structure the evaluation). The distinction between these approaches lies in that theories specify mechanisms of change, while models and frameworks have descriptive roles to describe implementation practice and highlight factors that influence implementation outcomes, respectively. The major weakness identified with the approaches identified, however, is the lack of evidence of what determinants act as barriers and facilitators to implementation success and how those determinants operate in relationship to one another (Nilsen, 2015). Existing determinant frameworks, while useful in promoting a multilevel view of implementation, do not present causal mechanisms for how change occurs during the implementation process. This leaves implementation researchers dependent on individual and organizational change theories that do not fully capture the dynamic relationships among characteristics of the user, implementer, and innovation.

Though varying in scope and definitions, the most commonly utilized determinant frameworks generally consider implementation processes to be influenced by the following types of determinants: characteristics of the implementation object; characteristics of the adopters; characteristics of the end users; characteristics of the context; and characteristics of the strategy facilitating implementation (Nilsen, 2015). In order to identify and describe known determinants of implementation of integrated healthcare models, applications of an implementation theory widely used to understand the implementation of integrated care models will be reviewed, the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Helfrich et al., 2010). The PARIHS framework has been used as a theoretical guide for a diverse

array of international implementation studies, thus providing empirical support for the use of this framework (Helfrich et al., 2010; Rycroft-Malone, 2010; Kitson, Harvey, & McCormack, 1998).

Promoting Action on Research Implementation in Health Services (PARIHS).

PARIHS is a framework that helps adopters predict and/or explain implementation process and outcomes in health care settings. The PARIHS framework originally consisted of three determinants, 'evidence', 'context', and 'facilitation', which function together to facilitate successful implementation (Rycroft-Malone, 2004). The construct of 'evidence' as defined in the PARIHS framework addresses characteristics of the implementation object, and also includes characteristics of the adopters and end users as an aspect of this construct. Each of the three core constructs is composed of sub-elements (Figure 1.2). The factors informing each sub-element are then classified as either 'low' or 'high', where factors considered 'high' are more likely to contribute to a successful implementation of evidence into practice. For example, in the PARIHS framework the concept 'patient experience' is a sub-element of the construct 'evidence'. According to the PARIHS framework, if patients are not involved (a 'low' factor) then implementation will be less likely to succeed, whereas if patients are seen as a part of the decision-making process (a 'high' factor) then implementation success is likely (see Figure 1.3).

This framework was developed upon the premise that the most successful implementation occurs when factors associated with all three constructs are 'high' (Kitson et al., 1998). Kitson and colleagues (2008) operationalized this framework by creating measurements for the constructs 'evidence' and 'context', where the sub-elements map onto statements that are rated on a 5-point Likert scale (Kitson et al., 2008). Additional work has built upon these measures, using the available descriptions of sub-elements and their factors, to create a diagnostic tool that evaluates measures within each construct (Bansod, 2009). The data collection

tools composing the PARIHS toolbox draw from several well accepted evaluation tools for organizational change and leadership (Avolio & Bass, 2004; Tejeda, Scandura, & Pillai, 2001; Lehman, Greener, & Simpson, 2002; Flynn, Goldsmith, & Eastman, 1996; Howell, Shea, & Higgins, 2005). While robust in expounding which factors may act as barriers to implementation success, this framework is not comprehensive in regards to the sub-elements constituting each construct and it lacks evidence of the relationships within and between constructs (Helfrich et al., 2010).

The PARIHS framework was recently refined to improve its utility (Stetler, Damschroder, Helfrich, & Hagedom, 2011). Among other modifications, the framework now includes an additional construct, 'recipient,' which encourages users to explicitly consider the impact of individuals, who affect and are affected by implementation, on implementation processes and outcomes (Harvey & Kitson, 2016). The growing body of evidence highlighting the importance of context (Flottorp et al., 2013; Damschroder et al., 2009; Harvey, Humphreys, Rothwell, & Hegarty, 2015; Wiechula, Shanks, Shultz, Whitaker, & Kitson, 2015; Mays & Smith, 2013; Chaudoir, Dugan, & Barr, 2013; Tomoaia-Cotisel et al., 2013; Ashton, 2015) also led to the expansion of this construct in the PARIHS framework, which now defines 'context' as consisting of two layers, inner (e.g. local and organizational setting's resources, culture, leadership, and orientation to evaluation and learning) and outer (e.g. wider health system's policy, social, regulatory, and political infrastructure) (Harvey & Kitson, 2016). Because the updated framework was only recently released, applications of the PARIHS framework referenced in this literature review refer to the framework in its original form.

Application of PARIHS to the evaluation of integrated care models. Studies utilizing the PARIHS framework have identified context as the most prominent determinant influencing

the successful implementation of integrated care models, with mixed evidence on the importance of facilitation (Nilsen, 2015). Context is defined as "environment or setting in which people receive health care services" and consists of the following sub-elements: culture; leadership; and evaluation (McCormack & Kitson, 2002, p. 96; Rycroft-Malone, 2004). A concept analysis conducted in the process of refining and validating the PARIHS framework found that the key characteristics of an enabling 'context' included having clear boundaries, appropriate resources, receptivity to change, appropriate and transparent decision-making processes under accepted leadership, and having established feedback systems (McCormack et al., 2002).

Implementation researchers applying this framework highlight the importance of context as a determinant of successful implementation, and that the definition of context is broad enough to apply to different levels of healthcare innovations (i.e., not only the clinical setting where patients receive services, but the system and community levels where care coordination, population health management, outreach, and policy decisions occur for integrated care approaches). Examples of the PARIHS framework in application illustrate its utility. MacKenzie (2007) used the PARIHS framework to implement the Liverpool Care Pathway (LCP), an evidence-based integrated care model for the delivery of end-of-life care. Results from this pilot found that factors related to context, culture, and leadership in particular, and facilitation (i.e., the method of facilitation to bring about successful implementation (Rycroft-Malone, 2004)) had the greatest influence on successful implementation (MacKenzie, 2007). When investigating the implementation of two evidence-based guidelines for peri-operative fasting in an acute care setting, Rycroft-Malone and colleagues also identified context as being the most influential implementation determinant, and further elaborated that communication challenges, professional culture clashes, power structures, and unclear ownership of the

implementation process were barriers to change (Rycroft-Malone et al., 2013). Thus, it is evident that context strongly impacts the implementation process when the introduced change is incongruent with the existing healthcare system's structure, processes, and culture.

A case study of an initiative to expand access to an integrated physical and mental care model, Project SCAN-ECHO, among veterans with hepatitis C also found the PARIHS framework effective in identifying what factors are necessary for the successful implementation of an integrated care model (Rongey, Asch, & Knight, 2011). Once again, the most emphasized construct was 'context', under which the authors posited that knowledge of key incentives for collaboration and implementation could be identified and enhanced in order to promote adoption and sustainability of the care model in the health care setting. Since one of the main components of Project SCAN-ECHO is the collaboration between primary and specialty care physicians, a thorough exploration of the clinical context in which this intervention takes place could help identify characteristics of physicians who best facilitate a team-based approach (Rongey et al., 2011). The existent applications of this framework with integrated and coordinated care programs provide a starting point for identifying and describing determinants of successful implementation for integrated care models.

Gaps in implementation research on integrated care models. Additional research is needed to describe what barriers and facilitators exist to implementing integrated care models. Relying on questionnaires to identify barriers and facilitators to implementation, factors deemed relevant by the researchers (Nilsen, 2015), keeps researchers from identifying novel barriers and facilitators. Additionally, researchers should seek to examine how multiple factors work together to hinder or enhance implementation, as the synergist effect may differ from the impact of individual factors on implementation. Determinant frameworks can be expanded with

qualitative research on what hinders and enables implementers' actual experience, the extent to which those factors impact their practice, and the ways in which those factors operate together to influence implementation. A study by Sharp and colleagues (2004) used the PARIHS framework to conduct a theory-based content analysis of interviews with health professionals seeking to identify barriers and facilitators to implementation of a health intervention for heart disease patients. The findings indicated that intervention processes and context were barriers to implementation, but the research team limited data findings to those factors identified in the PARIHS framework and did not seek to code novel barriers and facilitators (Sharp, Pineros, Hsu, Starks, & Sales, 2004). Results reported from the qualitative analysis found that the difference in study outcomes varied according to how implementers understood the implementation process and the resources available to them.

The focus on health professionals' perspectives is central to implementation research because of their role throughout the implementation process in healthcare settings. Without the experiences and beliefs of service users, however, researchers cannot fully understand what factors facilitate or hinder implementation success. Though the PARIHS framework includes 'patient experience' as a sub-element of evidence, this mostly serves as a measure of whether patients were engaged in formative work and the extent to which implementers valued the information the patients provided in that phase. The framework's new construct of "recipient" better highlights the importance of the user experience by promoting a thorough exploration of the relationship between the innovation and both the patient and the implementers. This is accomplished through the consideration of factors such as recipients' values and beliefs, goals, power and authority, and time, resources, and support (Harvey & Kitson, 2016).

Context is a critical concept for understanding implementation, yet researchers in the field of implementation science have yet to define context or establish approaches for capturing and interpreting how context impacts change in health care systems (Nilsen, 2015). Future work needs to leverage this construct to its full potential in order to better describe this determinant of implementation. This will be particularly important when evaluating the effectiveness of health service interventions across different health systems or cultural contexts. Due to the fact that most integrated care interventions are carried out in high-income countries (Dorling et al., 2015; Unutzer et al., 2012; Reynolds & Sutherland, 2013), there are currently no studies that have verified the relevance of these implementation frameworks and constructs or identified and described determinants of implementation in LMICs. Given the increasing global burden of disease in LMICs (Vos et al., 2015), research in this area is needed to facilitate the implementation of integrated care models in LMICs. Furthering our understanding of the implementation context can improve our ability to understand what factors are most important when implementing models of care across different countries with differing levels of resources (Ashton, 2015).

A comprehensive process evaluation is critical to understanding the implementation process of integrated care models in LMICs. The following section provides an overview of what approaches exist to evaluate implementation processes appropriately and effectively.

Evaluating the Implementation Process

Knowledge of the effectiveness of healthcare innovations is necessary, however, it is not enough to measure study outcomes and cost-effectiveness to determine the success of the implementation process. The implementation process is driven by the individual perceptions of implementers and services users. As such, any efforts to document the process and quality of

implementation require capturing the characteristics, perceptions, and experiences of these actors.

Given the growing interest in the role of context in the implementation process, researchers are turning to evaluation frameworks that have the capacity to examine complex interventions and explore the outcomes of culturally-bound dynamic relationships (McCormack et al., 2002; Manley, 2000). These evaluation frameworks are distinguished from ones previously used to evaluate health interventions because they incorporate a focus on process measures and promote the use of mixed qualitative and quantitative methods. In 2008, the Medical Research Council (MRC) recognized the need for incorporating process evaluations into randomized trials, later establishing a process evaluation framework to help guide researchers seeking to evaluate complex interventions (Craig et al., 2008). The MRC process evaluation framework aims to identify causal mechanisms and contextual factors associated with outcome variations, all in relation to the fidelity and quality of the implementation process (Moore et al., 2015). Despite offering case examples of its application, little guidance is offered on how to apply this framework. However, the main constructs of the MRC process evaluation framework align with another evaluation framework developed decades earlier, the realist evaluation framework (Pawson & Tilley, 1997). The lifespan of realist evaluation has allowed the creation of numerous instructional texts detailing the ontological and epistemological assumptions underpinning this theory-based framework that provide guidance on application. Realist evaluation provides an approach to examining complex interventions, offering researchers the ability to examine context in relationship to changing intervention mechanisms and outcomes.

The realist evaluation framework. A type of theory-driven evaluation, the realist evaluation framework provides an alternative to traditional quantitative forms of evaluation that

only examine outcome data. Rather, this framework seeks to complement outcome data with explanations of why and how intervention outcomes were achieved. The philosophical underpinnings of this approach propose that individuals are agents of change independent of their environment (Pawson & Tilley, 1997). Causal mechanisms are described as generative, whereby mechanisms are triggered by interactions between actors and their environment. Creators, Pawson and Tilley, propose that in order to determine what works, for whom, in what circumstances, and why, researchers must identify and examine the intervention's underlying mechanisms, the contexts under which the mechanisms operate, and the patterns of outcomes produced by the intervention (Pawson & Tilley, 1997; Mark & Julnes, 1998; Hewitt, Sims, & Harris, 2012). In sum, the realist evaluation framework operates through three key concepts: (1) mechanisms, (2) contexts, and (3) outcome patterns (Pawson & Tilley, 2004). Mechanisms describe the processes of how implementers and users interpret and act on intervention components. These mechanisms are predetermined by the program theory and are tested as a part of the evaluation process. Context describes the conditions that support or hinder intervention mechanisms. Outcome patterns are the results achieved through the activation of different combinations of mechanism and context. Realist evaluation tests and refines context-mechanism-outcome configurations (CMOCs) to predict and explain under what conditions the intervention will work and for whom (Figure 1.4). The framework is considered methodologically flexible because it calls for one or more quantitative and qualitative methods as they are determined necessary to test the hypothesized CMOCs (Pawson & Tilley, 2004).

Applications of the realist evaluation framework. The realist evaluation framework has become increasingly utilized among researchers in a variety of fields, most recently with implementation researchers (Rycroft-Malone, 2010; Wiechula et al., 2015; Tolson, McIntosh,

Loftus, & Cormie, 2007; Bick, Rycroft-Malone, & Fontenla, 2009; Wand, White, & Patching, 2010; Moore, Moore, & Murphy, 2012; Mackenzie, Koshy, Leslie, Lean, & Hankey, 2009; Chouinard et al., 2013), including in the evaluation of integrated care models (Busetto, Luijkx, Huizing, & Vrijhoef, 2015; Horsley, 2015; Dalkin, 2014; Chiclowska, Rea, & Burholt, 2015). These studies found this approach successful in identifying conditions of successful implementation. Busetto and colleagues undertook a realist evaluation of the implementation of integrated care among patients with Type 2 diabetes (Busetto et al., 2015). Their findings provided in-depth feedback from health professionals about the barriers and facilitators for each chronic care model (Wagner, 1998) component and Implementation Model level (Grol & Wensing, 2004). Busetto and colleague's two site case study provides information about contextual elements of the implementation process that could hinder efforts to scale up an integrated care model for people with Type 2 diabetes. Examples are insufficient integration between patient databases, patients' insufficient medical and policy-making expertise, and funding mechanisms. The study also provides insight into the factors that make the care model (un)manageable for health professionals (e.g. decreased earnings for some health professionals, perceptions of competition between health professionals, and a shift in work load between health professionals). These are factors which speak to the sustainability of the intervention. Findings from this study, however, are limited due to their exclusion of patient feedback.

Despite the fact that the realist evaluation framework is grounded in the knowledge that intervention outcomes are influenced by all stakeholders, including service users, few studies seek feedback from users. A study by Dalkin included patients and their family members as stakeholders in the evaluation process and benefited from a more robust and meaningful description of the posited CMOCs' mechanisms (Dalkin, 2014). This mixed-methods study used

the realist evaluation framework to analyze data collected as a part of a study implementing an Integrated Care Pathway (ICP) and found that it was useful in providing information on conditions of successful implementation, despite its complexity (e.g. number of stakeholders involved and intervention mechanisms) (Dalkin, 2014). Several CMOC's related to the use and functioning of the ICP were individually examined and Dalkin discovered that leadership and support, advance preparations, communication between patient and provider, and multicomponent health messaging were key to successful implementation. These findings largely stemmed from interviews with patients and family members, further demonstrating the need for additional research including service user perspectives.

The flexibility of this model is not without challenges in application. A review of empirical applications of realist evaluation in health systems research found that the approach has been applied inconsistently (Marchal, Van Belle, van Olmen, Hoeree, & Kegels, 2012), due to varied interpretations of Pawson and Tilley's (1997) seminal work, *Realistic Evaluation*. In some studies, researchers reported that they found the approach difficult to apply, most commonly when it came to selecting appropriate methodologies and distinguishing between mechanisms and context. More recent applications of this framework have overcome the latter issue by differentiating at what levels certain factors act as mechanisms versus contexts, or by acknowledging that a multitude of mechanisms may be operating at any given time (Rycroft-Malone, 2010; Byng, Norman, Redfern, & Jones, 2008).

Methodological and knowledge gaps in the evaluation of integrated care models. The approaches to evaluation for healthcare services and systems that embrace mixed quantitative and qualitative approaches are still developing. At the same time, countries require more innovative ways to increase the effectiveness of their healthcare systems with fewer resources, a

point that will continue to drive the development and refinement of integrated models of care. These models of care are often complex, featuring multiple levels of stakeholders, intervention components, and electronic systems to manage patient health information. As a result, they require evaluation approaches that account for their dynamic and multicomponent natures. More research is needed around best practices for conducting process evaluations of integrated care models.

There is a noted lack of process evaluation data around the implementation of integrated care models (Busetto et al., 2015; Shinde et al., 2013; Knowles, Chew-Graham, Adeyemi, Coupe, & Coventry, 2015; Ling, Brereton, Conklin, Newbould, & Roland, 2012). Recognizing the paradigm shift towards collaborative and streamlined patient management, particularly for patients with chronic diseases, researchers are now advocating for the development of evaluation measures for integrated health care, both process and outcome, that will allow insight into how these models operate (Grant & Chika-Ezerioha, 2014). To date, though, the evaluation of integrated care models for chronic diseases has relied almost exclusively on outcome measures data. In studies of people with diabetes, most commonly this has been the mean difference in HbA1c (Dorling et al., 2015). The reliance on quantitative measures provides a measure of central tendency observed in a population and makes it difficult to answer the how's and why's that are central to process evaluation. Even as researchers seek to utilize multiple quantitative and/or qualitative methods, in parallel or sequence, the challenge of synthesizing and interpreting the different sources of data still exists.

Another major limitation of the implementation science around integrated care is the lack of service user representation. To date, stakeholder feedback has been limited to data collected from implementers. For example, in a recent study by Busetto and colleagues (2015), researchers

evaluated the implementation of an integrated care model for diabetes by interviewing various care providers who were involved with the implementation process. They did not include any patient input, despite proposing this in the study protocol (Busetto, Luijkx, & Vrijhoef, 2014). Not surprisingly, the findings from their evaluation were lacking in evidence of patient-level barriers and facilitators—a key dimension highlighted by the Implementation Model, a model that outlines six levels of health care whereby change can be helped or hindered in the implementation process (Grol & Wensing, 2004).

The construct 'patient needs and resources' is also one of the four constructs of the Consolidated Framework for Implementation Research (CFIR) that were identified as being key in distinguishing between low and high implementation (Damschroder & Lowery, 2013). Searches of Medline and Google Scholar produced only two qualitative evaluations of interventions using integrated care models focused on mental health service delivery that included interviews with patients (Knowles et al., 2015; Chatterjee et al., 2008). The first, the MANAS trial (Chatterjee et al., 2008), incorporated patient feedback on trial processes and utility, which complemented interview data from the trial implementers. This trial took place in India but focused on the integration of mental health care into primary care settings and, therefore, is different in function than integrated care models addressing multiple chronic diseases. The second study, based in the United Kingdom, focused on understanding the needs of people with depression and multi-morbidity; only including a few questions (not discussed in the findings) about how collaborative care was delivered and implemented (Knowles et al., 2015).

The current body of evidence for integrated care is lacking in data that support its success in LMICs. As the only trial of integrated care for depression and diabetes in a LMIC (Mohan et al., 2015), the findings from this process evaluation of the INDEPENDENT trial will broaden the

implementation research evidence-base to have a more global focus, highlighting a country where integrated diabetes and depression care models have a vast potential to impact population health. Because the realist evaluation framework's strength is in providing insights specific to a given context, its application to an integrated care model in a LMIC will expand previous research and can also provide additional insights into the barriers to and facilitators of successful implementation of such models in high-income countries (HICs).

Rationale for Research

Little is known about the factors that hinder or enhance the implementation and sustained use of chronic disease-focused depression treatment models in LMICs. To date, no work has set out to validate whether known barriers and facilitators to integrated care in HICs are consistent across LMICs. This study will complement the few existing process evaluations with unique insights from the implementation of an integrated care model for diabetes and depression in a LMIC. Identifying the mechanisms underlying an integrated diabetes and depression care model in India could inform efforts to further disseminate this type of integrated care model in low-resource settings and provide confirmation of program theories that has only thus far been tested in HICs. Additionally, the inclusion of service user perspectives is something that only recently has been spotlighted, with frameworks like PARIHS formally recognizing its importance with the addition of a 'recipients' construct in its refined framework (Harvey & Kitson, 2016).

The growing demand for approaches to evaluate complex interventions has prompted the recent development of the MRC and the modification of the realist evaluation framework to meet these needs (Craig et al., 2008; Moore et al., 2015; Bonell, Fletcher, Morton, Lorec, & Moore, 2012), yet few studies have fully employed a realist approach to identify, test, and refine program theory involved in an integrated care model; none have been in an LMIC. The aim of

this process evaluation of the INDEPENDENT trial was to identify how context shapes implementation success in relationship to intervention mechanisms and outcomes. A realist evaluation framework will be used in order to distill the model's causal mechanisms and identify what resources are required to implement and sustain this treatment approach. Conducting a process evaluation of an integrated care model focused on context and engaging all involved actors is critical. Understanding the factors that influence implementation through these determinants will be important in determining: (1) the feasibility and acceptability of integrated care models in LMICs; (2) the utility and contribution of integrated care models in allowing adults to manage their co-morbid conditions in different contexts; and (3) the integrated care model's fit within the broader context of care delivery, given the experiences of both patient and providers. A comparative case study approach was used. Two of the four INDEPENDENT study sites were selected, based on the contrast offered by their geographic location, institution type, and approach to implementing the intervention.

The knowledge generated by this dissertation has implications for the implementation of quality improvement interventions in chronic-care treatment models and for the sustainability and transferability of integrated diabetes and depression care models in India and low-resource settings. Findings provide insights into what some of the main underlying causal mechanisms and linked contextual factors are for this type of integrated treatment model and how to motivate patient attendance and engagement in self-management practices for chronic disease care, in addition to identifying effective patient strategies for chronic disease self-management by comparing patient experiences between groups of patients who were most and least successful in reducing their depressive symptoms.

This dissertation consists of one study, with an embedded case study of a sub-sample of intervention-arm patients interviewed in this evaluation. A realist evaluation framework was used as a theoretical guide because it takes into account individual, interpersonal, institutional, and infrastructural characteristics and contexts when examining changes in behaviors and system operations. Chapter 2 presents findings of the process evaluation from the perspective of the intervention implementers (i.e., care coordinators, endocrinologists, and psychiatrists). Four hypothesized CMOCs developed according the realist framework were tested and refined to develop a middle-range theory of the implementation of integrated care in a LMIC. Chapter 3 presents the experience of intervention-arm patients through the testing and refining of one CMOC that focuses on the factors that facilitate patient participation and activation in the self-management of diabetes and depressive symptoms. Chapter 4 presents a positive deviance approach to identifying patient strategies and practices that are key for improving depression treatment and control within the diabetes care platform in India. Lastly, Chapter 5 presents a discussion of the evaluation findings as a body of work in relationship to what is known about the implementation of integrated care models in HICs, providing research, clinical, and health systems implications of this work.

Figure 1.1 Factors that Contribute to the Bi-directional Relationship between Diabetes and Depression

Depression

- Reduced emotional & physical energy

- Feeling hopeless

- Physical inactivity

- High calorie intake

- Decreased medical adherence

- Missed appointments

- Excess cortisol production

Diabetes

- Diabetes complications

- Stress of diabetes care

- Pharmacologic treatment side-effects

- Biochemical changes caused by diabetes

- Effects of diabetic neuropathy
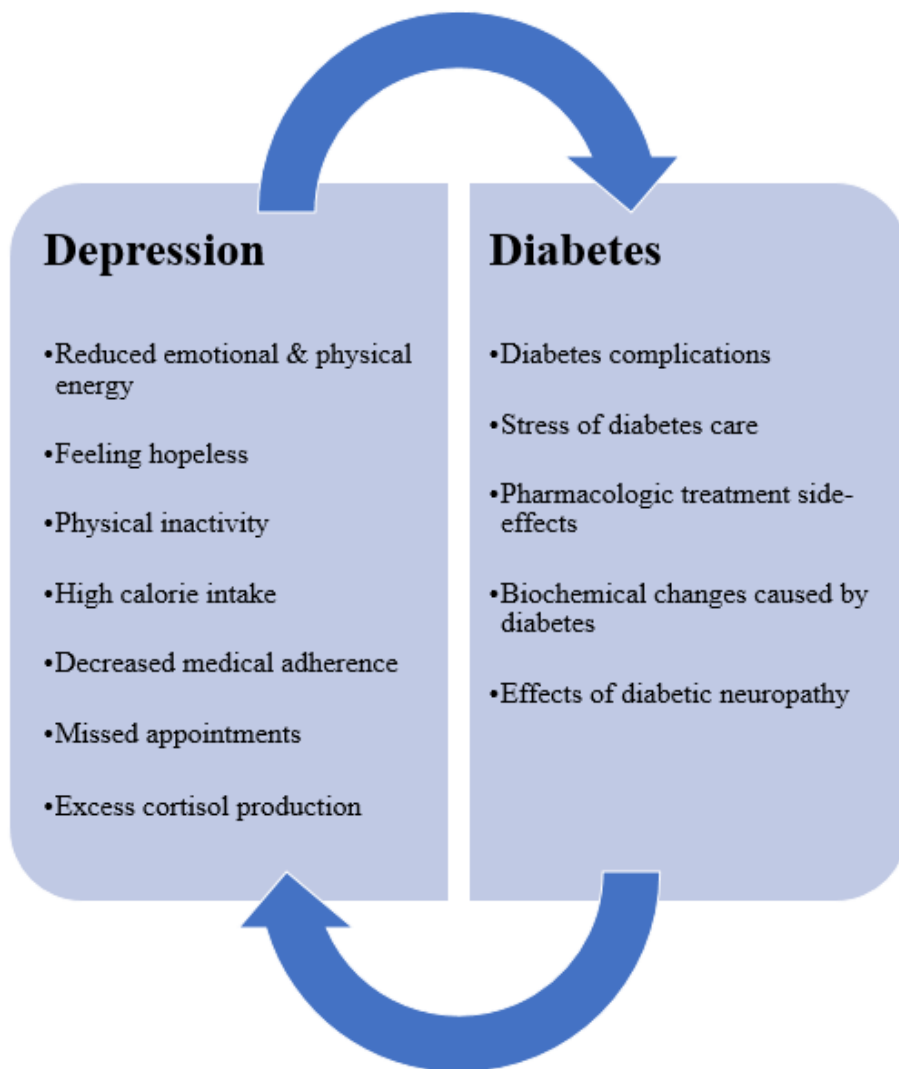
Figure 1.2 PARIHS Framework Constructs and Sub-elements
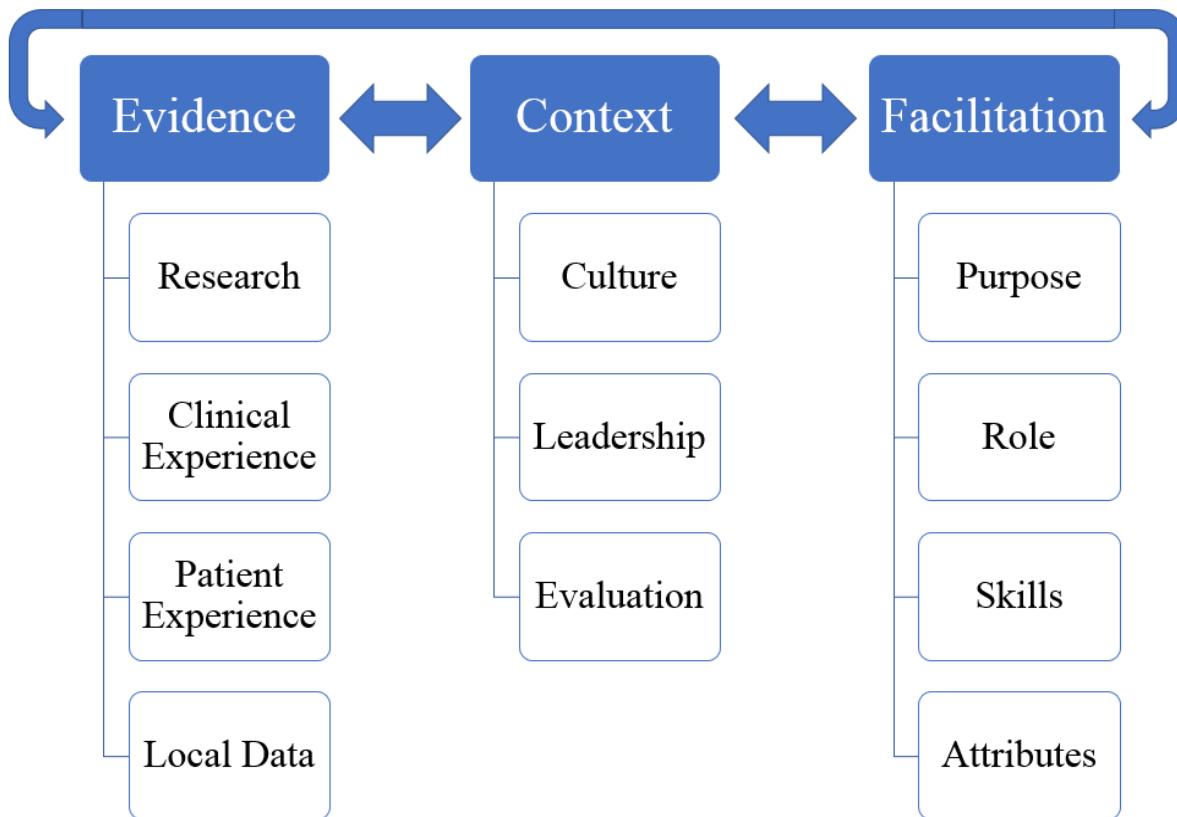
Figure 1.3 PARIHS Framework Matrix of Influence
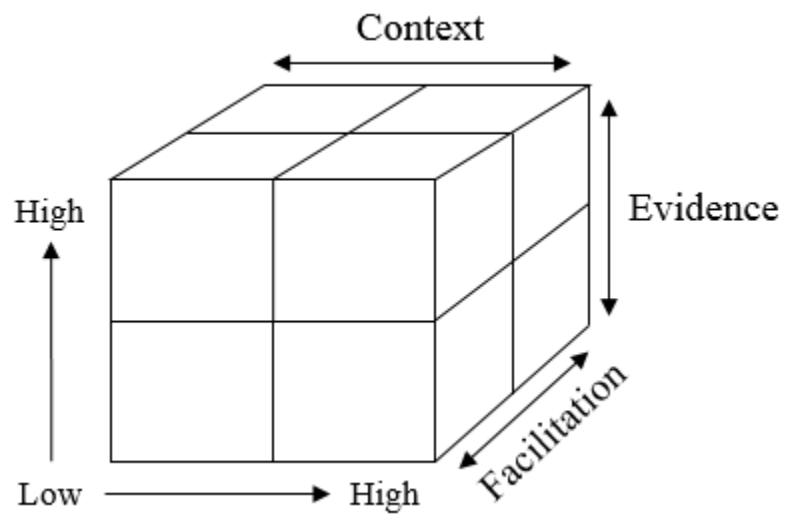
Figure 1.4 Realist Evaluation Context-Mechanism-Outcome Configuration
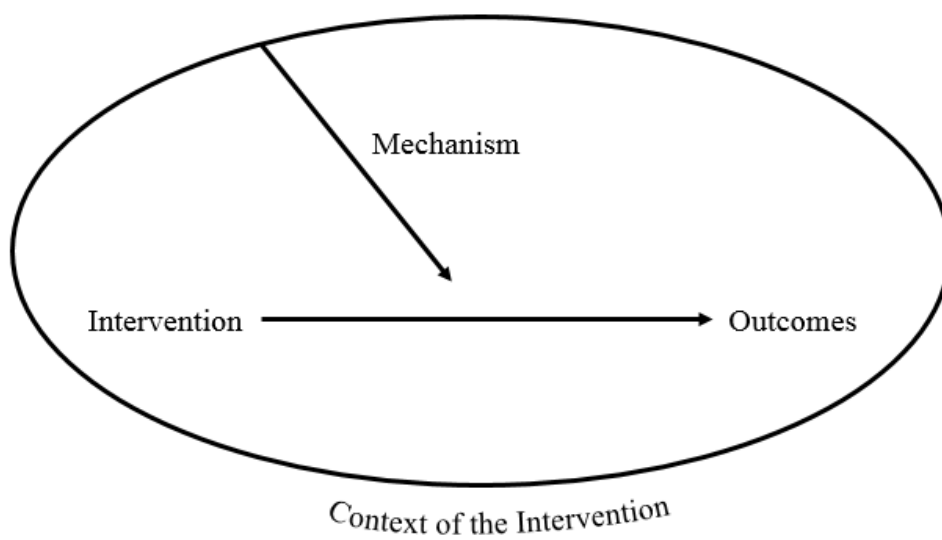
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Chapter 2: A Realist Process Evaluation of a Chronic Disease-focused Depression Treatment Model in

India

Abstract

The aim of this study is to evaluate the implementation of the INDEPENDENT care model, in order to determine what key resources, mechanisms, and contextual factors are necessary to integrate depression treatment in the diabetes care setting in India. A realist evaluation framework was employed to conduct a comparative case study. The initial program theory was formed through a process of document review and the conduct of four unstructured key informant interviews with program investigators and study software designers. The program theory was then tested against data from clinic observations, the decisions support and electronic health records system (DS-EHR), and 11 semi-structured interviews with health care providers to produce a refined program theory. Physicians were comfortable dictating diabetes treatment plans, but relied on care coordinators and the site psychiatrist to finalize depression treatment for patients. Care coordinators took on the primary responsibility for patient health education and counseling, but indirectly addressed mental health concerns by using colloquial terms for depression and redirecting patients to focus on their diabetes self-management, as a way to improve their mood. Care coordinators perceived their responsibilities to be manageable with adapted case review resources, on-going training, and additional on-site support. The psychiatrists had to adapt their approach to case reviews in order to feel comfortable providing treatment oversight for patients they had never consulted with in-person. The results of this study demonstrate that strengthening provider support systems and communication channels improves care coordination, the physicians' ability to determine patient treatment plans, and the specialists' ability to oversee aspects of both depression and diabetes care. Health care provider trainings prior to implementation should address providers' perceptions of depression-related stigma, and integrated depression care models should provide private counseling spaces and mental health support for care coordinators.

Introduction

Of those individuals living with a mental health condition in low- and middle-income countries (LMICs) few receive treatment due to a scarcity of trained mental health professionals and the inequitable distribution of resources for mental health care (Kakuma et al., 2011; Saxena, Thornicroft, Knapp, & Whiteford, 2007). In India, efforts to increase access to mental health care were proposed within the District Mental Health Program (DMHP) under the government's 1982 National Mental Health Program (NMPH) (Director General of Health Services, 1990). One of the specified approaches advocated for by the NMHP is to integrate basic mental health care into the broader system of health services in India. This approach was later echoed by the World Health Organization's Mental Health Gap Action Program (Director General of Health Services, 1990; World Health Organization, 2015).

Evidence that non-specialist health worker-led interventions are effective in providing mental health care in LMICs has led efforts in India to focus on using lay health workers (i.e., non-mental health specialists who have minimal training in mental healthcare but are supervised by specialists); largely within the primary care level of health services (Patel, 2009; van Ginneken et al., 2011; van Ginneken et al., 2017). Despite the longevity of these programs, assessments of how these initiatives were implemented have been limited, with case studies of implementing districts revealing a lack of evaluation plans to track and assess results of DMHP activities (Government of India, 2011; Kumar, 2005). In order to understand how to effectively deliver evidence-based mental health interventions across the diversity of healthcare settings in India, robust evaluations of how different forms of mental health interventions are implemented—both integrated and standalone, and at all levels of the health care system—are needed.

The INDEPENDENT Care Model

The INtegrating DEPrEssioN and Diabetes treatmENT (INDEPENDENT) care model was designed to improve access to mental health care and improve depression and cardiometabolic disease outcomes among patients with diabetes and co-morbid depressive symptoms (Kowalski et al., 2017). The INDEPENDENT care model was tested in four diverse outpatient diabetes clinics in India and included the following main components: care coordinator support, evidence-based electronic care prompts, and case review oversight (Figure 2.1).

The care coordinators (CCs) for this care model were non-specialized support staff members who provided depression and diabetes self-care support, monitored patient health outcomes with the use of a decision support and electronic health record (DS-EHR) system, and served as a link between the patients, the patients' usual care diabetes physicians (UCDPs) who provide routine care for patients, and the specialists (i.e., a psychiatrist and endocrinologist) involved in case reviews.

The DS-EHR system was a tool to support population health management within each clinic. The system was created to store data on patient labs and consultation results and then analyze those data to produce clinical care prompts and visual indicators of patients' health status, individually and at the clinic-level. The care prompts were based on an algorithm developed by the investigators and built on previous successes of a similar model in a study of diabetes quality improvement in India (Ali et al., 2016; Singh et al., 2018).

The case reviews were designed to be bi-monthly meetings of the CCs, the specialist psychiatrist, and the specialist endocrinologist to discuss and modify patients' care plans. The case review meetings focused on patients whose indicators suggested poor control of their

diabetes and depressive symptoms, and were intended to make care more proactive instead of waiting for the next visit several months away.

This multi-component INDEPENDENT care model was evaluated in a randomized, controlled trial, for which the methodology and a more comprehensive description of the model components are detailed in a previous paper (Kowalski et al., 2017). A total of 404 patients were randomized to either the intervention or the usual care arm. Patients in the usual care arm continued to see their UCDP for diabetes management. Usual care was, however, enhanced as UCDPs were notified of their patients' depressive symptoms at baseline so that they could be referred for mental health treatment outside of the clinic.

While the design, theoretical basis, and training for the underlying care model components were the same across clinics, each clinic made some adaptations to the processes of how they incorporated the intervention components into their clinic flow. For example, there was variation in the number of CCs employed, the frequency of case reviews, the level of involvement of the specialist endocrinologists and psychiatrists, and the degree of training and support made available to CCs and UCDPs.

The goal of this project, therefore, was to understand how the intervention worked in different settings using a realist evaluation approach (Pawson & Tilley, 1997). This approach was selected for this process evaluation as it takes into account the processes that enable outcomes to be achieved, with a sensitivity to context (Pawson & Tilley, 1997).

Theoretical Framework

Pawson and Tilley's *Realist Evaluation* offers an approach to examine individual, interpersonal, institutional, and infrastructural characteristics and contexts while investigating the processes and outcomes of a complex intervention. This theory-based evaluation framework

operates through three key concepts: (1) context, (2) mechanism, and (3) outcome pattern, that together form context-mechanism-outcome configurations (CMOCs) (Pawson & Tilley, 1997).

Context describes the conditions that support or hinder intervention mechanisms (McCormack, Kitson, & Harvey, 2002). Mechanisms describe the process of how implementers and users interpret and respond to intervention resources (Pawson & Tilley, 2004). These mechanisms are predetermined by the program theory and are tested as a part of the evaluation process. Outcome patterns are the results achieved through the activation of different combinations of mechanisms and context. Realist evaluation tests and refines permutations of CMOCs that predict and possibly explain under what conditions the intervention will work, why, and for whom (Pawson & Tilley, 1997). The resulting refined program theory illustrates a set of conditions that allow for successful intervention implementation. However, realist evaluation dictates that the same outcome patterns can be achieved through different combinations of mechanisms and contexts (Pawson & Tilley, 1997).

This paper seeks to answer the following research question and sub-questions:

What are the important context-mechanism-outcome configurations surrounding the implementation of the INDEPENDENT trial?

  a. *What are the resources and features of the clinical context that trigger mechanisms of change?*
  b. *What are the mechanisms which enable successful implementation outcomes?*

The actors, intervention components and resources, and anticipated intermediate and long-term outcomes of the INDEPENDENT trial formed the basis of this process evaluation. A logic model organizing these elements by intervention inputs, mechanisms, context, and outcome was developed (Figure 2.2) to elicit the initial program theory. The hypothesized causal mechanisms underlying the INDEPENDENT trial, as depicted in the logic model, are summarized in Table

2.1. Only those mechanisms linked to the intervention implementation by both CCs and health care providers are tested in this paper.

Findings from this evaluation will help interpret the trial results and depict how the four core principles of collaborative care operate within an integrated depression and diabetes care model in urban diabetes clinics in India. While not predictive, the refined CMOCs will outline mechanisms central to the care model's implementation.

Methods

This realist evaluation employed a comparative case study design using two urban diabetes care centers in India, one government clinic in the North and one private clinic in the South. Data collection occurred in alignment with the phases of realist evaluation: identify, test, and refine program theory (see Table 2.2) (Pawson & Tilley, 1997). The RAMESES II reporting standards for realist evaluations was followed to ensure the study design, methodology and results are clearly reported in accordance with the realist evaluation framework (Wong et al., 2016).

First, a document review and key informant interviews with two trial investigators and two software architects for the DS-EHR system were conducted to identify the initial program theory for the INDEPENDENT trial. Second, observations of the two clinic settings were carried out over six weeks at the start of the evaluation, in order to observe the implementation of trial protocols prior to conducting interviews. Insights garnered from initial and on-going clinic observations were used to refine the semi-structured interview guide for CCs and health care providers, and served to test the program theories and verify qualitative findings in the analysis phase. Then, one-on-one interviews were conducted with 11 CCs and healthcare providers (i.e., usual care diabetes physicians and specialist endocrinologists and psychiatrists) responsible for

implementing the INDEPENDENT care model. The CCs and healthcare providers were purposively sampled to achieve maximum variation in implementation experiences (see Table 2.3). Lastly, physician- and clinic-level data about patient visits and treatment decisions-making processes were extracted from the DS-EHR software and CC log books. The process of theory refinement is described in the data triangulation and theory refinement section below.

Observation Procedures

Unstructured observations of the clinic settings were noted in a field notebook by LJ, both at the onset and throughout the evaluation, in order to inform data collection and verify findings from the interview data. In the first six weeks, observations at the government clinic were noted daily, Monday through Friday, for periods of time approximately two hours in duration. Observations varied by the time of day so as to capture variation in clinic activities, settings, and actors. While the majority of intervention activities occurred in two accessible, adjoining rooms, physician consultations took place on another floor that required a security badge to enter. As a result, only two brief 15-minute observations of this setting were completed. Observations of the private clinic settings were conducted over a two-day visit in the first six weeks, allowing for 10 hours of clinic observations of both the physician waiting area and the study office where patients were counseled. Due to the paucity of time in the private clinic at the start of the evaluation, additional observations were conducted prior to starting and throughout the data collection process at this site to ensure patient interviews were conducted with a sensitivity to the clinical context. Attendance and observation of the case review meetings across both sites were completed at later dates, as the schedule permitted.

Interview Procedures

Key informant interviews were conducted with two program investigators and two study software (DS-EHR) designers as a part of the first phase of this realist process evaluation. A logic model was developed based on the study protocol and additional information derived from the document review process. The logic model was then used to facilitate a discussion with these key informants regarding the hypothesized study mechanisms, key contextual elements, and the functions and perceived utility of the DS-EHR software for intervention implementers. Information garnered from these interviews resulted in modifications to the study logic model and informed the development of the initial program theories (see Table 2.1).

In the second phase of this evaluation, all CCs, UCDPs, and specialist endocrinologists and physiatrists were presented with an overview of the evaluation's aims, design, and methodological approach in a team meeting and provided an opportunity to ask questions. Then the CCs and providers were approached for individual interviews to be completed in their respective offices. Written consent to participate and audio-record the interview was obtained from all individuals prior to the start of each interview. All participants were asked about intermediate trial outcomes, with questions tailored to each health care provider according to their particular role in the intervention. The interviewer explicitly asked about the role of contextual factors and how they influenced the implementation, functioning, and experience of the integrated care model.

The research was conducted from September 2016 to May 2017, with approvals from the respective Institutional Review Boards of Emory University, USA, and the All India Institute of Medical Sciences and Madras Diabetes Research Foundation, India.

Qualitative Data Preparation and Analysis

The primary sources of data for this evaluation were the provider interviews, therefore analysis began with these data. All interview audio-recordings were transcribed verbatim. Once a

transcript was complete, it was de-identified, and coded independently by two evaluation team members. The following steps were used to code the transcripts: (1) open code, (2) compare coding between coders, whereby common code names were agreed upon or a third-party from the respective study site offered additional insight to help reach a consensus, (3) independently cluster the codes into CMOCs, and (4) compare clustering of codes, with the help of a third-party if consensus could not be reached. Observation fieldnotes were coded based on the actors and implementation activities that they captured.

DS-EHR and Document Data Extraction Process

The DS-EHR system records patient health information, as well as provider-level data about the type of visit and whether individual treatment prompts were adhered to, modified, and why. In addition to using the DS-EHR, hard copy notes and files were maintained by CCs to document and coordinate processes not manageable with or integrated into the software. Evidence extracted from these data sources to be used for data triangulation included: rationale for treatment modifications, descriptive data on the types of patient visits, and the frequency and composition of case reviews.

Data Triangulation and Theory Refinement

Once all coding was completed, the process data extracted, and descriptive statistics calculated, the data were entered into an EXCEL spreadsheet with a specified tab for evidence related to each CMOC (see Table 2.4 for further information on how each tab was organized for data entry) and a separate spreadsheet for each study site. The spreadsheets, complete with both qualitative and quantitative data, were then used to compose individual case summaries for each site. These summaries facilitated a case comparison of observed outcome patterns and the contextual factors that (or do not) help trigger mechanisms contributing to those outcomes. The

synthesized evidence highlighting the identified CMOCs were then compared to the

hypothesized CMOCs in the initial program theory in order to produce a refined program theory.

Results

Across the two cases, there was evidence of the four, hypothesized CMOCs. These

CMOCs provide insight into what resources, contextual factors, and mechanisms promote

successful implementation of the INtegrating DEPrEssioN and Diabetes treatmENT care model

in India. Because provider interviews were conducted throughout the second half of the active

intervention year, participants often reflected on how circumstances evolved over the course of

the study. The CCs and health care providers described the ways these changes shifted their

approach to implementation, as reflected in changes in mechanisms over time.

A model of patient care that depicts all four CMOC's outcomes in relationship to one

another was developed based upon providers' descriptions of patient care and follow-up

procedures (see Figure 2.3). CCs are recognized as the primary link between all intervention

activities and actors. They work in tandem with the UCDPs and specialists to provide patient

care using the DS-EHR system. CCs identify and track patients' depressive symptoms, provide

counseling, and take DS-EHR treatment prompts to physicians for review and final prescription

decisions. Data from specific patients are later reviewed by the specialist endocrinologist(s),

psychiatrist, and CCs at regularly scheduled case reviews. Case reviews are facilitated by the

dashboards and access to information in the DS-EHRs. Following case reviews, CCs are

responsible for conveying any suggested treatment modifications to the UCDPs, following-up

with patients regarding treatment modifications, and scheduling additional interim visits so that

they can monitor patient health indicators using the DS-EHR system.

The following sections present findings relative to each CMOC (illustrated in Figures 2.4, 2.5, and 2.6). Each figure offers multiple detailed portions of the INDEPENDENT care model (Figure 2.3). Relevant actors for a given CMOC are located in the center of each spectrum of intervention activities. The mechanism associated with the adjacent actor and activity is listed as it occurred over the one-year active intervention period. The bottom box lists the intervention resources lacking at the start of the trial that contributed to the respective mechanisms. A change in mechanisms over time reflects the input of additional resources or the resolution of lacking resources, by means of acquiring additional experience or creating protocol modifications, over the course of the trial. Key contextual factors are presented on the outer ring emanating from the resources box.

CMOC 1—Care Coordinator-led Patient Care using the DS-EHR System

At the onset of implementation, the CCs experienced, as one CC described it, "teething issues because the [trial] was so new and [they] were doing things slightly differently than what [they] were doing in a regular practice or in an OPD practice." During the initial months of the trial, the CCs felt overwhelmed with their responsibilities of identifying patients in need of mental health treatment and counseling patients with various needs (Figure 2.4). When asked to reflect on the CCs' role and responsibilities, both psychiatrists expressed concern over burnout. One elaborated that a formal debriefing system for the CCs was lacking, while the other felt the CCs needed guidance on how to establish boundaries within their work in order to maintain confidence in their abilities, stating:

> And there are several social issues in India where we really can't change the
> situation. You have an alcohol dependent husband, you have 7-8 people to feed,
> you have immense poverty. Focus on where you can deliver. I help them to draw
> boundaries as to what they can do and what they can't do...So I make sure that
> [the CC] understands it and [the CC] can provide [counseling] without stress. And

to provide [the CC] some back-up support, because sometimes [the CC] feels very overwhelmed with issues that [the CC is] confronting.

The majority of patients reported feeling low or stressed due to family and/or financial struggles, matters that the CCs had a limited ability to address in their given role. Receiving support from the psychiatrist or another CC offered one way to cope with the stress and emotional burden of this position.

At the start of the trial, both sites had two CCs, but at the private clinic one CC resigned shortly after the trial commenced. The remaining CC acquired the entire patient case load for that site, requiring her to establish rapport with new patients and seek additional support from the off-site psychiatrist. The government clinic took a different approach, where both CCs met with each patient, when possible, so that they each had relationships with all of the patients and so that they could debrief challenging patient cases together. Despite having an in-house psychiatry department at the government clinic, the psychiatrist's schedule only permitted emergency consultations between case reviews.

One of the tools designed to help CCs identify high-risk patients, the DS-EHR system, had initial prompt malfunctions that reduced CCs' and physicians' trust in the software. Coupled with inconsistent access to the online software due to issues with internet access and speed, providers became more reliant on a paper version of the depression treatment algorithm. The site psychiatrists provided a training for the CCs and physicians on how to use the paper algorithm, and, over time, this became the default mental health treatment aid across both sites. The parallel use of the paper algorithm and software among CCs did, however, offer a unique educational opportunity. One CC recounted how she discovered the software malfunction:

> We had got that algorithm, the paper one, and it says that scores above 14 need to be prescribed certain anti-depressant. One or two cases it said 'no prompt found,' so then that was something we thought was not right. We won't know the exact

prompt. The exact SSRI or medication would not come up. We could guess that something was not right.

The CCs had to learn the thresholds for treating depression, based on the administered PHQ-9 screener, in order to recognize when the software failed to produce medication prompts; an extra layer of quality control.

The CCs were reliant on their site psychiatrist's feedback and the on-going technical assistance provided by TEAMcare investigators until they were more experienced in providing mental health counseling, and thus, more comfortable with their depression treatment-related responsibilities. In particular, all CCs noted that the training they received on motivational interviewing, after the start of the trial, made them feel more confident in their counseling abilities. The CCs described this counseling approach as a technique that takes the pressure off of the provider by putting the onus on the patients to come up with ways to address their problems. This was particularly valued when those problems fell outside of the realm of the CC's control (e.g., issues with family, work, finances). The longer the CCs worked with their patients and acquired a working knowledge of each individual's medical history and home life, the more equipped they felt to support them.

The CCs across these two sites all had backgrounds in nutrition sciences and were, therefore, more confident in their ability to counsel patients regarding diet than they were in their ability to provide mental health counseling. CCs did not often formally discuss depression with their patients because of fear of triggering stigma. As such, they reported wanting to first establish rapport with patients through several in-person visits. Over time, CCs noted what terminology the patients used to describe their state of mental health and engaged in conversation using those same terms or phrases. These terms referring to depression included "tension," "stress," "feeling heavy-hearted," "feeling low." Having in-person visits also enabled CCs to

maintain patients' attention when they administered questionnaires, and it allowed them to pick

up on behavioral indicators that patients may be depressed. The CCs all commented that over-

the-phone patient check-ins were limited in function. One elaborated:

> a lot of times we found out the person who is on the phone is either pre-occupied
> or they do not comprehend very well over the phone, or they are having to hang
> up because they are caught up with household calls and chores. So, we stopped
> taking the PHQs on phone unless the patient could not come in and we could not
> do it in-person.

Instead, brief phone calls not documented in the DS-EHR were used to maintain rapport with

patients and schedule appointments. A limitation of the DS-EHR system was not being able to

log these touch points with patients. An environmental barrier to discussing sensitive topics was

that both clinics lacked a private space for CCs to administer the PHQ-9 and counsel patients. As

a result of these contextual barriers, CCs largely avoided using the term depression and instead

inquired about patients' mental well-being using more colloquial terms (e.g., tension, stress,

feeling low or hopelessness).

Family involvement was a strategy used to increase rapport with patients, provide

enhanced counseling, and promote patient adherence to lifestyle modifications and medications

across both sites. The psychiatrist at one site promoted the involvement of family members:

> You are never going to get a handle on the diet until you see the person who
> actually cooks...As far as medication is concerned, a little more complex. And
> who pays for your medication, who buys your medication, because I would say a
> woman who is dependent on her son and she doesn't live with him, pretty much
> the last quarter of the month there will be no medication. So if it's the son who is
> paying for it, make sure you tell the woman 'make sure you have adequate money
> to buy the medication. Son is living in another part of the city, he is not going to
> send the money on time.' So they've understood the concept of medication more
> so from the social realities of India.

The other site involved family when the patients requested the presence of a family member. In

these instances, the process of involving family "released a lot of mental stress, pressure from

patient," in the words of one specialist endocrinologist, and provided information about why a patient was depressed or non-adherent.

CMOC 2—Usual Care Diabetes Physician-led Depression Treatment

Physicians described their increased confidence in prescribing anti-depressants (see Figure 2.4) as a response to how patients processed through the clinics and the frequency of case reviews (the other two spheres of intervention activities depicted in Figure 2.3 that are also outcomes of CMOC3). Patients met with the CC(s) and their UCDP on the same day at both sites. At the private clinic it was standard procedure to take biological samples, run labs, and consult both the CC and physician in one day, but at the government clinic, taking biological lab samples on the same day was a specific modification to the clinic flow to accommodate their low-income patients; the majority of whom had to travel long distances and forfeit wages to appear for clinic appointments. If, however, the reports came back and the patient had controlled or improving cardiometabolic risk factors and PHQ scores in the government clinic, then the patient only received counseling from the CC(s). The typical patient burden and wait time varied between clinical settings and ultimately altered how the physicians felt about adding depression treatment into their standard of care.

Though both clinics have high patient caseloads, the patient volume at the government clinic only allows for physicians to spend a few minutes consulting with each patient. In order to cover the A, B, C's (e.g., HbA1c, blood pressure, and cholesterol) of diabetes care, as well as depression treatment, CCs sat in on patient consultations to brief the physicians. CCs provided the patients' lab results and any treatment prompts produced by the DS-EHR system, then quickly highlighted any relevant circumstances, as discussed in the preceding counseling session, and recorded physician dictations for follow-up. As one physician summarized, "We shifted the fulcrum of care away from the physician to this care coordinator, who's essentially trying to do

both things: looking after global diabetes care, in terms of the traditional A, B, and C, and adding

a D." Physicians relied on the CCs to track and monitor patients' CVD risk factors and

depressive symptoms through the DS-EHR software and notify them when their PHQ-9 score

warranted a prescription of anti-depressants. The practice of having the CC sit in the patient

consultations was only done upon physician request at the private clinic because physicians had

more time to spend with patients, and therefore had more opportunity to confirm the presence of

depressive symptoms and provide additional counseling support. Because the majority of trial

participants were long-time patients of their respective clinics, the physicians at both sites were

already familiar with many of the patient's medical histories. As a result, most physicians noted

that this made it easier for them to pick up on behavior change and anticipate patient health

trends.

Physicians as a whole reported that it would stigmatize a patient to diagnose them with

depression or ask about the presence of depressive symptoms. This belief often led physicians to

avoid using the term depression and to avoid explicitly counseling patients regarding mental

health care. The psychiatrists made it known to the UCDPs that the process of deciding which

terminology was appropriate to use with patients when providing depression diagnosis and

treatment was complex. Many of the physicians interpreted this to mean that the safest method of

discussing depression was to not label it at all. The psychiatrist at one site recognized this

reluctance as a phenomenon common among physicians outside of their specialty: "sometimes

that stigma is sometimes in the doctors rather than the patient. We feel reluctant about it, but the

patient is fine talking about it so we need to get away from that." The concern remained that by

being sensitive to perceptions of patients' fear of being stigmatized for having depression,

providers may actually be helping to perpetuate it.

Because the only mental health treatment training physicians received as a part of this trial was on how to interpret and apply the paper version of the depression treatment algorithm, many of the physicians expressed being hesitant to prescribe anti-depressants at the onset of the trial. The UCDPs were endocrinologists (i.e., specialists in diabetes care) so they perceived their responsibility to be diabetes care, with the case reviews serving as the source of mental health treatment directives. Several physicians expressed fear of inappropriately prescribing anti-depressants, even with the algorithm as a reference, as captured in this physician's statement: "There have been many times wherein I have done dosage adjustments and the psychiatrist would tell me I can up-titrate this more. I'm a little more cautious about increasing the dose." With more case reviews, however, physicians picked up on patterns of care advised by the psychiatrists and felt more confident in their ability to prescribe anti-depressants and up-titrate doses. If concerns arose during a patient consultation in the private clinic, the off-site psychiatrist was called for guidance, while the physicians at the government clinic called emergency case reviews or convened case reviews at shorter intervals if such a need arose. Physicians modified DS-EHR depression treatment prompts due to variety of reasons, including DS-EHR malfunctions, a change in patient health or life circumstance, physician preference, or differential guidance from the psychiatrist (Table 2.5).

During the transitional period, wherein physicians developed confidence in their new role, the protocol for prescribing anti-depressants was temporarily modified. A CC describes this modification for physicians at the government clinic:

> Now if [physicians] see a patient's PHQ score is too high they usually prescribe [anti-depressants] on their own. Or they write the prescription and then they tell the patient not to buy it until the CC gives them a call...Then we have a case review meeting within a week or we have also done if it is not possible to have a case review meeting we go to the psychiatrist and we confirm.

In order to save patients from making several trips to the clinic, physicians found it easier to provide patients with prescriptions, confirm the dosage was appropriate with the psychiatrist after the appointment, and then have the patient fill the prescription once confirmed. These concerns were typically addressed in real time at the private clinic by calling the psychiatrist while the consultation was still taking place. Lastly, in cases where the DS-EHR system was unable to be accessed and prompts were not available for the physicians, the CCs were forced to generate a prompt at a later time and confirm the physician's treatment decision after the fact by comparing the prompt directives to the treatment provided.

CMOC 3—Case Review Meetings and Patient Follow-up Care

CCs received initial and on-going training on how to support and link patients, UCDPs, and the specialist psychiatrist and endocrinologist using the DS-EHR system. Because CCs are the central nodes in this care model, linking all other study components, these trainings sought to empower CCs to facilitate case reviews and coordinate patient care and follow-up. CCs reported feeling able to manage their responsibilities (Figure 2.5), however, they expressed mixed feelings about being able to exert control in their position. One coordinator explained:

> We can't [diagnose and treat patients] because [the psychiatrist] is the expert. [The psychiatrist] has a very important role to play. The entire project there is a primary treatment role, we are just bridging the gap between all the different components, but they are the experts.

CCs downplayed their role, often highlighting that, because the physicians and psychiatrist make the final treatment decisions and dictate follow-up schedules, their ability to control when patients come in for counseling was limited; especially since counseling appointments and physician consultations occurred on the same day in both clinics.

The physicians' ability to overrule the CCs decisions was something that the CCs were constantly aware of, but it was accepted by all providers that the CCs were the experts when it

came to knowledge about each patient's particular circumstances and successes or failures. The case reviews were, therefore, dependent on CC involvement. In reflecting on their role in these meetings, CCs felt, as one shared that "the entire spotlight is on [the CCs]" because "in case review meetings...all eyes are on us only, so what we say, based on that only psychiatrist is prescribing the anti-depressant." CCs felt under pressure to perform their duties to the highest standard, knowing that the psychiatrists' only connection to the patients was through them (Figure 2.5). Referencing their lack of expertise in mental healthcare, the CCs repeatedly expressed concern that patients would not receive proper depression treatment if they unknowingly left out an important aspect of the patient's life history; an aspect not captured in the DS-EHR system or notated in the individual patient care review sheets. This burden was lessened once CCs became accustomed to the types of questions the specialists asked in the case reviews and when they were provided with case review templates that helped structure and guide those discussions.

How CCs perceived their authority and power in their role was incongruent with how the physicians and specialists working with them viewed it. One physician stated, "if [the CCs] have a different opinion they might actually say this is what I think," demonstrating how, as CCs became more knowledgeable about treatment patterns and their patients' circumstances, they were more confident and able to express their opinions to the physicians. In the government clinic, the specialists felt that the CCs had almost equal power in identifying patient care needs because they spent more time with the patients, and therefore had more insight to offer on new and evolving issues in patient circumstances. Despite this, the CCs at this site reported feeling that they have less authority during case reviews. Whereas the private clinic allowed the CC to initiate and lead the case reviews, the government clinic structured the case reviews so that the

CCs initiated the discussion and then answered questions posed to them as the specialists reviewed the prepared case sheets for new or concerning patients.

The difference in CC experiences at case reviews was attributed to the fact that the UCDPs also served as the specialists in the case reviews at the government clinic. When asked about this dynamic one specialist physician stated, "The clinical physician will tell about the case because he is in charge of this case and will know more about the case," because in most cases the physicians have worked with the patients in the trial for many years and feel responsible for leading any discussions regarding their care. Still, the specialists relied on the CCs to provide updated case review sheets for patients and provide quick patient updates at these meetings in order to finalize treatment plans. CCs extracted patient data from the DS-EHR system for these forms because the WIFI connectivity and speed was unreliable, making the process of accessing information on the software's dashboard too time consuming to take place during the case reviews. CCs at the government clinic occasionally displayed the DS-EHR dashboard on a laptop at the case reviews, but with case reviews occurring at the psychiatrist's office off-site for the private clinic, this was not possible since the CC used a desktop computer in the clinic to access the DS-EHR system.

The CCs were also responsible for scheduling case reviews. While the protocol dictated that meetings be held bi-monthly, physician availability, namely the psychiatrists' availability, was the main determinant of when meetings were held. Case review logs show that while both clinics had variability in the length of time between meetings, the government clinic met, on average, once a month and the private clinic, on average, met twice a month. CCs elaborated that during the initial and final months of the trial, case reviews were held more frequently for shorter periods because there were not many active patients to discuss. However, at full enrollment

during the active intervention phase, the case reviews typically lasted one to two hours in the government clinic and two to three hours at the private clinic. These time demands aligned with the patient case load at those clinics, as the private clinic had nearly double the number of intervention patients.

Physicians requested when they wanted to schedule follow-up appointments with patients, but the CCs had to establish a flow of patients that enabled labs to be completed in a timely manner while meeting both patient and provider scheduling needs. The DS-EHR system does not have a scheduling component, so each site devised a separate calendar system for tracking patients based on whether they were on anti-depressants, needed new labs run, or were requested to meet with a physician within a certain window of time. CCs were mindful that they could only counsel a certain number of patients each day, in addition to bringing them to meet with a physician, so as they developed relationships with patients they assessed who needed more time and avoided scheduling those patients on the same day. With limited space in the waiting areas and long patient queues, the CCs aimed to expedite patients' time spent in the clinic by only scheduling two to three intervention arm patients on a given day. Despite these efforts, it was not uncommon to have no-shows or unscheduled patients arrive seeking appointments. At the government clinic, CCs also brought patients to the front of the non-trial patient queue when taking patients for their physician consultations. To reduce wait time in the private clinic, one physician was tasked with treating only intervention arm study patients, with supplemental support from other clinic physicians.

CMOC 4— Specialist Treatment Oversight

The psychiatrists were advocates for this model of care due to the shortage of trained mental health professionals in India. Both psychiatrists shared experiences with previous

training models they had been a part of, including distance-delivery care models and traditional

tiered training approaches used in academic institutions. The distinguishing factor between these

previous models and the current approach was that their previous experiences had allowed them

to meet the patients and/or work with medical professionals with some prior mental health

training.

The psychiatrists viewed their role in this integrated care model as mental health

educators whose responsibility was to develop and train less specialist and less experienced

providers on the use of a depression treatment algorithm and provide treatment oversight at the

case reviews. The specialist endocrinologist, who was not also an intervention study physician,

was comfortable providing oversight throughout the trial because all physicians were

endocrinologists whose usual care practices already aligned with the cardiometabolic risk factor

treatment prompts. This individual expressed that if the usual care physicians were not

specialized in diabetes care, then he might approach his role in the case reviews differently.

Despite recognizing the need to broaden the base of mental health care in India, the act of

providing feedback and overruling treatment decisions on cases where they had never met the

patient left the psychiatrists feeling uncertain about how to proceed in this unique role (see

Figure 2.6). As one psychiatrist expressed:

> You feel more confident when you are talking to a patient, because not everything
> can be captured in paper and pencil form. So that way, yes, some initial
> difficulties are there, because we [are] not used to do[ing] that. But I think one has
> to do it because that's the only way to get away from specialist care.

The inability to assess patients' body language, tone, and emotional state for themselves made

the psychiatrists value the input of the CCs all the more. Often at case reviews, this meant the

psychiatrists asked the CCs for details that were not on the patient case review sheets to better

understand how to proceed with treatment. One of the psychiatrists created a patient case review

template in an effort to better aid the CCs in distilling relevant patient information in a structured manner for the case reviews. The other site was provided the template and modified it for use at their clinic. The psychiatrists' primary concern in being disconnected from the patient was being too reliant on "the numbers," which can be misleading without a holistic understanding of the patient's situation. As this quick and efficient method for getting relevant information on patients fell into place at each site, the psychiatrists felt more comfortable providing advice on how to proceed with prescribing and altering anti-depressants and counseling patients. These lines of communication between the CCs and the psychiatrists were critical, given that the DS-EHR treatment prompts for depression were limited to the general advice to undertake 'behavioral interventions.'

Echoing the sentiments of one of the specialist endocrinologists, both psychiatrists shared the belief that a provider is better able to empathize with a patient when they have met face-to-face. One of the UCDPs reflected on how the lack of contact between a provider and her/his patient could result in a difference in the quality of care, stating, "Sometimes it affects how you respond. And it happens in chronic care—you are looking after somebody for years, you are more likely to empathize...there is a subtext, which in diabetes is sometimes as important as the text." The added information, or "subtext," offered by the CCs through their time spent with patients is considered essential by the physicians for providing quality diabetes and depression treatment and management. In fact, the only numbers used to supplement input from the CCs were the two most recent PHQ-9 scores broken down by domains. This layout and trajectory of scores helped the psychiatrist assess where improvements had been made and where new issues were developing, in addition to confirming that a suicide protocol had not been missed. This

method also helped quickly indicate if a patient needed medications aside from anti-depressants. For instance, if the patient was experiencing issues sleeping, a sleep aid might be prescribed.

Across both sites, there was a pervasive belief that having support from the clinic leadership, if not from higher levels of the health system, was critical for engaging and sustaining this model of care. It was believed to be the role of the clinic leadership to "integrate an important specialty [psychiatry] into mainstream medicine," as one psychiatrist put it. This requires those wielding the power to influence clinical practices in diabetes clinics to value the role of mental health practitioners and that they have a working knowledge of the relationship between diabetes and depression.

Discussion

Reviews of Medline and Google Scholar produced no other uses of realist evaluation accompanying a randomised controlled trial in India. This realist process evaluation provides insights into the dynamic interaction between intervention components of the INDEPENDENT trial and contextual features unique to the Indian health care setting. Causal mechanisms of complex interventions cannot be understood as independent components, in isolation of other intervention components and activities (Rosen & Proctor, 1978). Thus, the value of this evaluation is its ability to consider all provider-related components in relationship to one another when identifying capacity-building and contextual leverage points. Realist evaluation also recognizes that causation is bi-directional (Pawson & Tilley, 2004). In this study, this is demonstrated in the revised program theory wherein outcomes linked to responsibilities of the CCs served as context for the activation of physicians' confidence. Similarly, the provision of treatment oversight from the psychiatrist, in and out of the case reviews, was a contextual feature noted as important by both CCs and physicians.

A comparison of trial implementation at two contrasting clinics allowed for the identification of contextual elements that, alongside intervention inputs at the provider- and clinic-level, activated mechanisms that worked to accomplish implementation outcomes. The revised program theory (Figure 2.7) describes which inputs and contexts are critical for the INDEPENDENT care model to work in India, and other low-resource settings. Though the initial program theory largely hinged on providers' confidence in their ability to carry out their responsibilities, this evaluation found that CCs required additional training and support, adapted resources, and effective patient rapport-building strategies in place to be successful in their role. Because providers already had experience in diabetes care, the support of the CCs and psychiatrist in tackling the added dimension of depression treatment allowed them to remain confident and capable in their role. Lastly, the experience of providing oversight in a model of care where they could not assess the patients forced the psychiatrists to modify their approach before feeling comfortable in their role. Only one new mechanism was identified throughout this evaluation: there were mixed circumstances under which providers used the term depression when counseling patients and prescribing anti-depressants. Future research should seek to explore how providers discern when it is appropriate to use this term with a patient and how it influences a patient's willingness to accept treatment.

This study has several limitations including: (1) only evaluating two of the four trial sites, (2) having a small sample size for provider interviews, (3) potential response bias due to the interviews being carried out by LJ, who is an outsider to this study population as a non-physician public health researcher from the United States, and (4) the inability to quantify implementation outcomes for assessment of fidelity and dose. The short study timeline did not allow for the remaining intervention sites to be included in this evaluation, but the selected clinics offered the

greatest variability and contrast in answering the proposed research questions. One site had providers serving in multiple capacities and the other lost a CC at the start of the trial, which led to a smaller sample size. Despite these facts, all providers involved in implementation were interviewed and saturation of CMOCs was met upon converging interview data from all four provider types. To offset any potential response bias by LJ's carrying out the interviews as an outside evaluator, the initial fieldwork focused on observational data to inform the researcher's understanding of the Indian health care system and verify participants' answers. In addition, interview questions emphasized the appropriateness of sharing both positive experiences and critiques of the intervention. Due to limitations in process data available through the DS-EHR system and the nature of the trial (i.e., a patient-centered treatment approach), fidelity of intervention activities and dose of intervention components delivered could not be assessed in this evaluation.

The implications of each CMOC are described in detail below.

CMOC 1—Care Coordinator-led Patient Care using the DS-EHR System

The use of non-specialist health workers in the delivery of health services, an approach referred to as task shifting, is widely utilized in LMICs in order to overcome shortages of trained mental health professionals (van Ginneken et al., 2011). In the INDEPENDENT trial, both CCs and UCDPs were involved with mental health care, but CCs bore the burden of coordinating this responsibility. As a result, both the on-going support and technical assistance provided by the site psychiatrist and study investigators were essential in enabling CCs to successfully carry out their roles.

While a multitude of mental health care task shifting approaches have been advocated for and utilized in LMICs (Javadi, Feldhaus, Mancuso, & Ghaffar, 2017; Rebello, Marques, Gureje, & Pike, 2014), there is no consensus as to what types of education, training, and support

structures are needed to produce non-specialized health workers who can efficiently fill the void of mental health service providers (Joshi et al., 2014; Patel, Chowdhary, Rahman, & Verdeli, 2011; Patel et al., 2010; Patel et al., 2017). Short-term training with specialist mental health oversight and on-going supervision have been shown to improve workers' confidence and their ability to detect and treat mental disorders, but little is known about the sustainability of workers' knowledge and skills, or the type of guidance needed to support these workers (Kakuma et al., 2011; Armstrong et al., 2011). There is evidence that shifting complex tasks to health workers with minimal training can reduce the time needed to scale an intervention, but in doing so, it can also reduce the quality of care provided, due to a decline in motivation and performance over time (Fulton et al., 2011). Results from this evaluation demonstrate that having a tiered model of care, that offers untrained health providers various types of supervision and training opportunities at monthly intervals, is both feasible and seen as advantageous by all health care providers involved. It should be noted, that the time CCs spent trying to reach, schedule, and build rapport with patients is also a cost that has not been assessed in task-shifting models, and future interventions would benefit from doing so in order to understand both the full burden placed on care coordinators and the cost-effectiveness of this model of care.

CCs demonstrated improved knowledge and skills over time, according to physicians and psychiatrists, indicating that sustained informal educational support can actually improve the quality of care established with initial training programs. Guidance from the psychiatrist or peer support was used to counter feelings of being overwhelmed with identifying and counseling patients with mental health problems. This suggests that a more comprehensive initial training that incorporates training opportunities with actual patients (e.g., shadowing opportunities, discussions of real patient cases, mock counseling sessions with real patients), as well as routine

CC debriefing sessions, would benefit lay health workers with less confidence in their ability to provide mental health care. Future work to disseminate this model of care should seek to measure CCs' perceived self-efficacy, knowledge, and skill over of time, in order to better understand the role of sustained mentorship and supervision in care models using task shifting.

CMOC 2—Usual Care Diabetes Physician-led Depression Treatment

This study found that UCDPs relied heavily on the support of CCs and site psychiatrists when it came to providing mental health treatment because the UCDPs still did not feel comfortable treating mental illnesses on their own. Physicians also largely avoided the use of the term depression, unless PHQ-9 scores indicated that the prescription of an anti-depressant was warranted, as they were uncomfortable initiating conversations about mental health with patients. These findings are consistent with other studies examining physician perceptions on caring for patients with mental illness and co-morbid medical conditions (Loeb, Bayliss, Binswanger, Candrian, & deGruy, 2012; Welch, Litman, Borba, Vincenzi, & Henderson, 2015).

Loeb and colleagues (2012) identified physicians' lack of training and experience in the delivery of mental health care and discomfort communicating with patients about their mental illness as barriers to providing depression treatment among physicians treating patients with complex mental and medical illnesses. Having expressed similar barriers, the caution exhibited by UCDPs when prescribing anti-depressants in this evaluation could explain why rates of anti-depressant prescription (approximately 40% at the government clinic and 30% at the private clinic) were lower when compared with the depression treatment patterns of psychiatrists in India. Multi-center studies of diverse psychiatric care across India and other East Asian countries found that around 80% of patients with depression were prescribed anti-depressants by psychiatrists (Grover et al., 2013; Chen et al., 2015). Prescription patterns in this evaluation were, however, in line with a U.S. quality of care assessment examining primary care physicians'

recognition and treatment of depression among patients with diabetes (Katon et al., 2004). This U.S.-based study found 43% of patients with diabetes and comorbid major depression received one or more anti-depressant prescriptions (Katon et al., 2004), suggesting similar barriers exist for non-specialized physicians providing mental health treatment in other countries.

Although a physician's extent of psychiatric training may impact her/his willingness to prescribe anti-depressant medications, it is also possible that patients with complex, co-morbid chronic conditions pose additional treatment challenges in regard to disentangling their medical needs. A multi-country study which included India found that patients in good physical health, as rated by the physician, were significantly more likely to be prescribed anti-depressants by their general practitioner, compared to patients who were physically ill (Kisley, Linden, Bellantuono, Simon, & Jones, 2000). Anti-depressants were also prescribed twice as often when patient-centered models of care were used, where physicians had a continuing relationship with the patient and additional knowledge of their circumstances to determine a treatment plan, as opposed to non-client centered models where the physicians are more reliant on the presentation of symptoms to reach a diagnosis and treatment plan (Kisley et al., 2000). As was seen in this evaluation, when there is consistency in who provides care, physicians are better able to establish trust with patients. As a result, patients are better able to disclose contextual information that allows physicians to make informed treatment decisions. UCDPs were also more confident in making treatment decisions when they had seen a patient longer because it allowed them to better understand what was ailing a patient and how it might relate to new emergent symptoms.

For UCDPs to feasibly sustain responsibility for this added dimension of care, patients would have to be screened with the PHQ-9 instrument prior to physician consultation, especially when consultation times are brief. Physicians in this study preferred the hardcopy depression

treatment aid to the DS-EHR depression treatment prompts, despite the ability of the DS-EHR software to save them time.

Previous research has found that patients diagnosed with a co-morbid condition are more likely to seek treatment at a general hospital, when compared with those patients without comorbid conditions (Grover et al., 2013). These findings further highlight the importance of overcoming non-specialist physicians' barriers to providing mental health care and integrating depression treatment into the broader health care system in India.

CMOC 3—Case Review Meetings and Patient Follow-up Care

The utility of the DS-EHR system in this intervention was limited when used for care coordination and patient follow-up and varied in the support of case reviews. CCs were responsible for maintaining updated accounts of patients' progress and future appointments, yet found that several components that were needed to make this tracking possible (e.g., a scheduling function, dashboard of patients on anti-depressants; interim form for non-medical contact points) were missing from the software.

The use of the DS-EHR in the CARRS trial in India also required CCs to individualize their follow-up frequency with patients, but since case reviews were not utilized, the DS-EHR served more as a treatment aid in the CARRS trial (Ali et al., 2016). The inclusion of a case review in the INDEPENDENT trial was perceived as more beneficial than the care prompts provided by the DS-EHR, especially since the UCDPs were diabetes specialists and could consult a paper algorithm for the added mental health treatment component. For CCs, the DS-EHR provided a helpful at-a-glance color-coded snapshot of all clinic patients through the patient dashboard. Other visuals, such as health trend graphs, helped assess patient improvement, but navigating through individual patient files required more time than was available at case

reviews. Additional system modifications would be required to enhance and encourage use of the software in all arenas of patient care and follow-up.

CMOC 4— Specialist Treatment Oversight

According to the WHO, India is currently experiencing a mental health workforce shortage that leaves them unable to meet needs-based target levels of mental health care (Bruckner et al., 2011). In rolling out the District Mental Health Program (DMHP) to enhance mental health services in India, this workforce shortage threatens to stifle progress. In response, a manpower development scheme was established to support the DMHP and its service components being implemented across India (Sinha & Kaur, 2011). Psychiatrists in this evaluation referred to the DMHP as an underlying motivation for their involvement in efforts to support and train non-mental health specialists at the local level.

Evidence-based mental health interventions are not commonly implemented in LMICs, which has contributed to a scarcity of research testing whether these interventions, largely developed in Western countries, fit the cultural needs of diverse LMIC settings (Rathod et al., 2017). Psychiatrists in this study took time to adjust to the unfamiliar model of specialist oversight, but valued the ultimate goal of the approach. With additional experience in providing oversight without patient interaction, these specialists felt more adept at guiding anti-depressant prescription practices and guiding the CCs. Future dissemination of this care model would benefit from adding mentorship and support for the psychiatrists from other mental health professionals with experience training non-specialists and implementing variations of distance-delivered care.

Conclusion

Systems theory dictates that there is more than one way to reach an outcome (Bertalanffy, 1950), a notion mirrored in how realist evaluation's central constructs, context and mechanism, operate together and alongside other mechanisms to help or hinder implementation success (Pawson & Tilley, 1997). The contexts found to be necessary in this trial are not exhaustive, and mechanisms may change when additional contextual variations are introduced. The revised program theory offered here does, however, provide a solid foundation from which future efforts to disseminate and scale this integrated care model can build. These findings demonstrate that successful implementation of an integrated depression and diabetes care model is feasible in a low-resource setting. Future research should seek to refine the program theory in new contexts, both in India and other LMICs, in order to assess the transferability of the presented findings.

Figure 2.1 INDEPENDENT Care Process
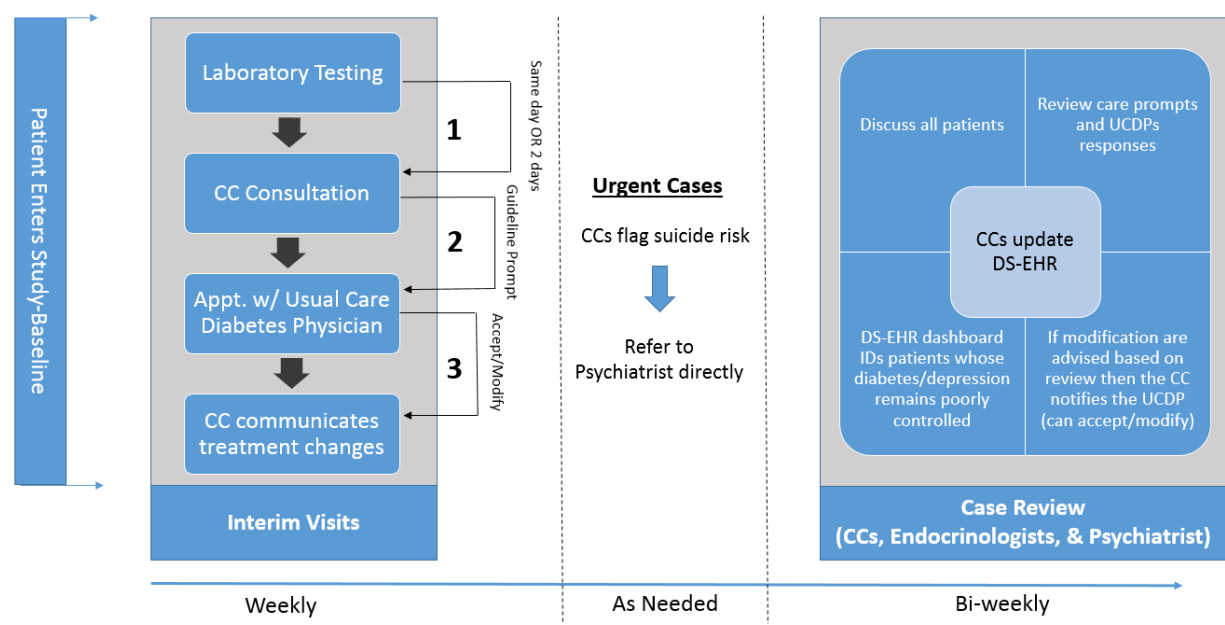
Key: CC: Care Coordinators   UCDP: Usual Care Diabetes Physician
      DS-EHR: Decision Support Electronic Health Record System

Figure 2.2 Logic Model of the INDEPENDENT Trial

Integrated Care Model for Depression and Diabetes in India
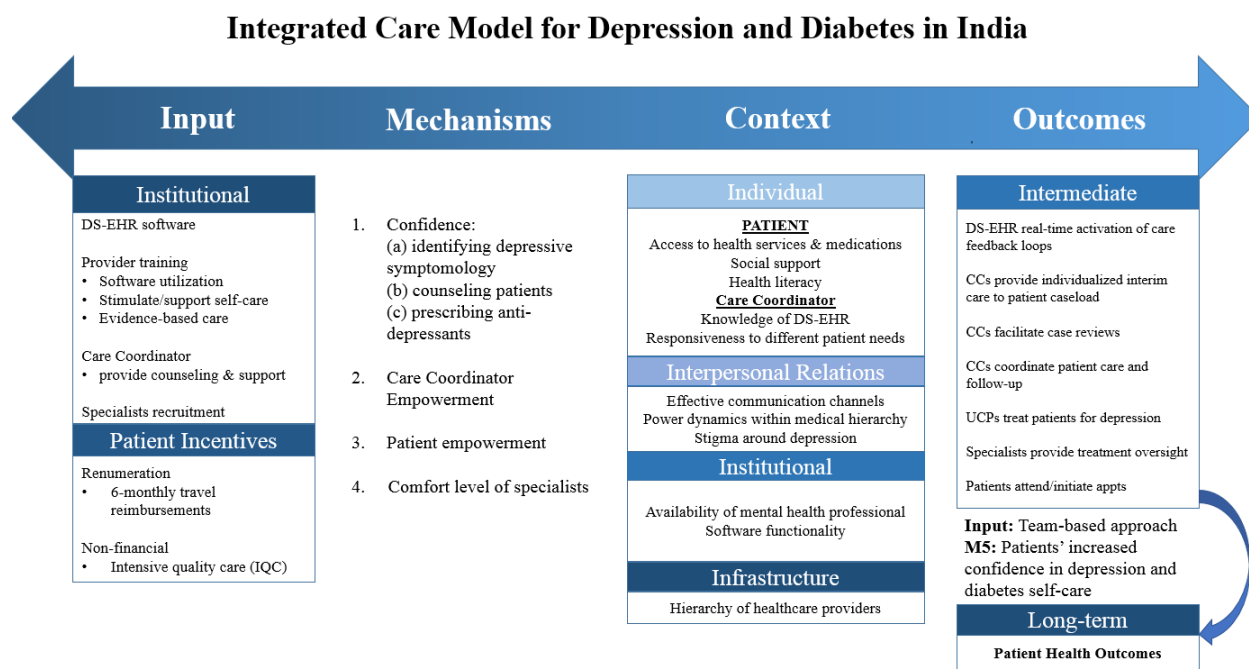
Table 2.1 Hypothesized Context-Mechanism-Outcome Configurations (CMOCs)

CMOC	Context	Inputs (I) and Mechanisms (M)	Outcomes
1	When the software is functioning, the care coordinator knows how to operate it and has the ability to respond to patient needs, and stigma around depression exists	If the DS-EHR is accessible and training on how to: (1) use the software, (2) identify depressive symptoms, (3) provide patient-centered care, (4) deliver behavioral interventions to support depression and diabetes self-care, and (5) monitor patient outcomes while serving as a link between patients and health care providers (I), then care coordinators will have the confidence (M)	To identify depressive symptoms, counsel patients regarding depression and diabetes self-care, and provide responsive, individualized care guided by the DS-EHR system
2	When the availability of trained mental health professionals is limited	If training on evidence-based mental health treatment is provided to usual care diabetes physicians (I), then physicians will have the confidence (M)	To identify depressive symptoms and prescribe anti-depressants
3	When care coordinators are non-physician providers working with physicians who are able to effectively communicate with patients and health care providers and feel heard by physicians	If initial and on-going training (I) are provided to care coordinators, then it will empower them (M)	To facilitate case reviews and coordinate patient care and follow-up
4	When the clinic set-up has a hierarchy of clinical staff and there is a need to broaden the base of mental health care	If a specialist psychiatrist and endocrinologist are recruited (I), then they will be comfortable (M)	Providing treatment oversight

Table 2.2 Study Phases with Respective Data Collection Methods and Analytic Approach

Phase 1: Formation of the Initial program theory

- Document review of published literature on the CARRS trial (Ali et al., 2016) and TEAMcare (Katon et al., 2010) [interventions forming the basis for the INDEPENDENT study]
- Document review of unpublished documents related to the development and implementation of the INDEPENDENT study
- Unstructured key informant interviews with program investigators (n=2) and study software (DS-EHR) designers (n=2)

Phase 2: Test program theories

- Intra-program case study (n= 2 sites)
- Observational data from clinic visits
- Semi-structured interviews with health care providers (n= 5,6 per site respectively)
- Extraction and review of process indicators from the DS-EHR and log books

Phase 3: Theory Refinement

- Conduct open coding of qualitative data
- Cluster codes into CMOCs
- Compose case summaries for each site using all data sources
- Compare patterns of outcome data across sites to establish the contexts that give rise to particular mechanisms
- Determine which CMOCs explain observed outcome patterns and compare to the original program theory
- Modify the program theory to reflect evaluation findings

Table 2.3 Health Care Provider Sampling

	GOVERNMENT (SITE 1)	PRIVATE (SITE 2)
CARE COORDINATOR	2	1
USUAL CARE DIABETES PHYSICIAN	(same as specialists)	3
SPECIALISTS		
ENDOCRINOLOGIST	2	1
PSYCHIATRIST	1	1
TOTAL	**5**	**6**

Table 2.4 Organization of EXCEL Analysis Spreadsheet

Column Headers	Related Columns Included
Stakeholder	• Participant identification number
Resource	• Data segment(s) • Code(s)
Mechanism	• Data segment(s) • Code(s)
Context	• Data segment(s) • Code(s)
Outcome	• Data segment(s) • Code(s) • Reflections on sustainability
Link to other CMOCs	• Relationship to other mechanisms and outcomes
Fieldnotes	• Observation data
Memos	• Methodological, Analytic, and Other

Figure 2.3 The Ways Implementation Actors are Involved with Intervention Activities

Composing the INDEPENDENT Care Model
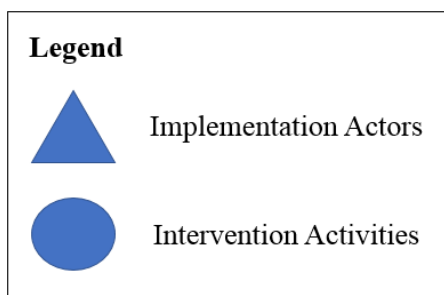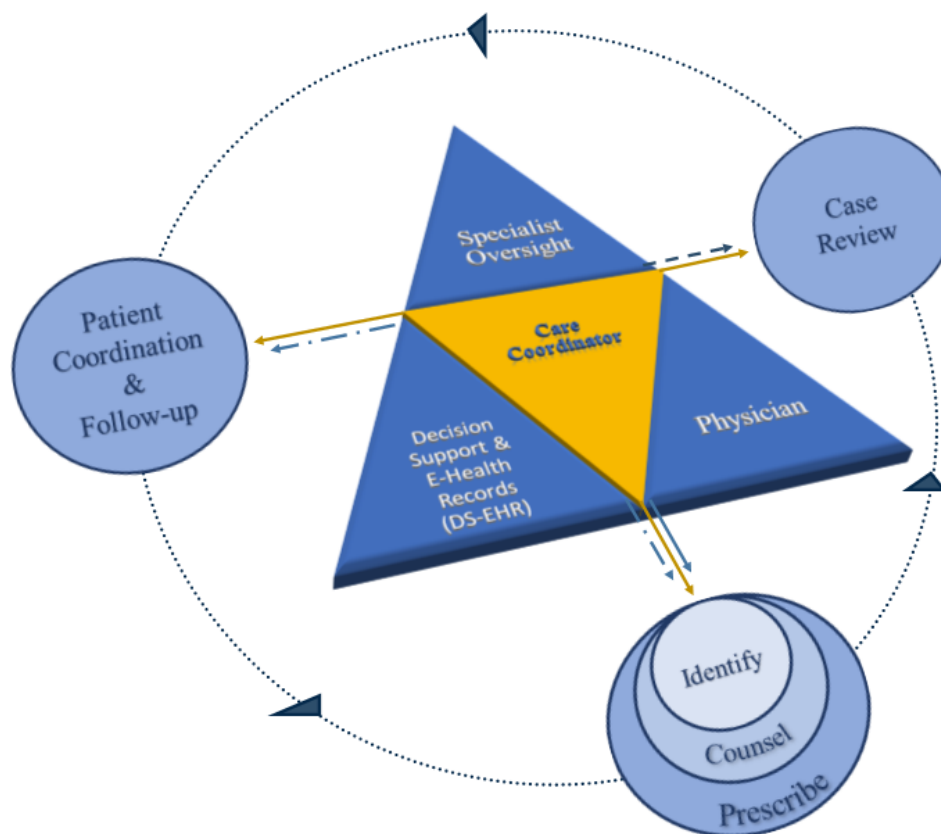
Data from this process evaluation are depicted above to illustrate which implementation actors played a dominant role in each intervention component of the INDEPENDENT care model. The activities are completed in a cycle, starting with the identification of patient health needs using the DS-EHR system, care coordinator-led patient counseling, and the prescription of medications and behavioral interventions by the physicians with guidance from the DS-EHR treatment prompts.

Figure 2.4 Mental Health Treatment Related Contexts, Mechanisms, and Outcomes
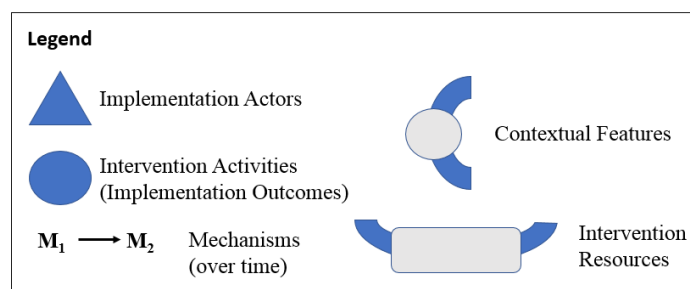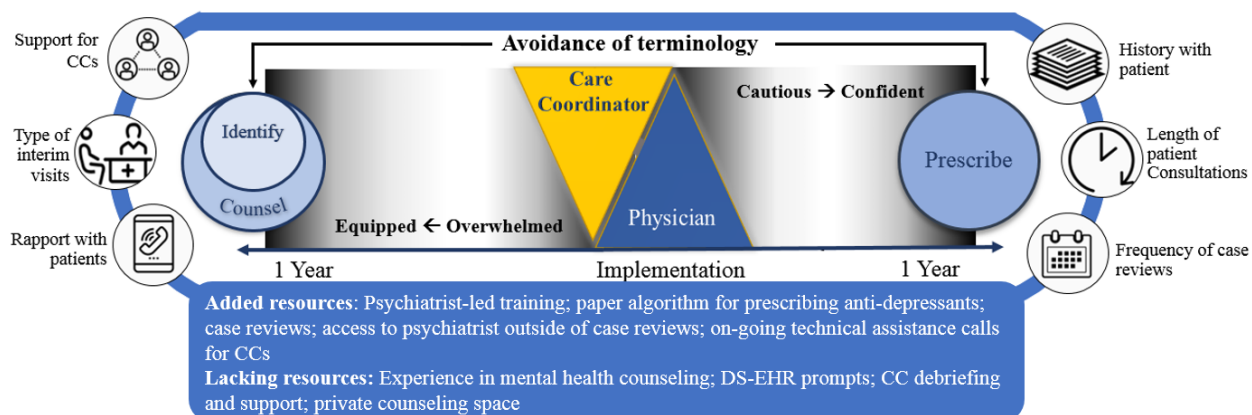
The evaluation data are depicted according to the realist evaluation concepts of contexts, mechanisms, and outcomes, as they change over the active intervention period. This diagram displays the contextual features and resources that determined (1) whether care coordinators felt equipped to identify and counsel patients with depressive symptoms, and (2) whether usual care diabetes physicians felt confident prescribing anti-depressants to patients with depression.

Figure 2.5 Case Review and Patient Follow-up Related Contexts, Mechanisms, and Outcomes
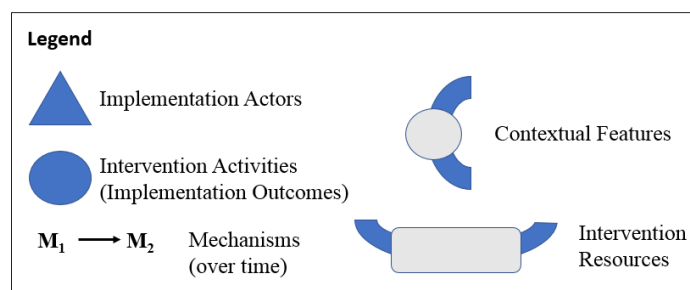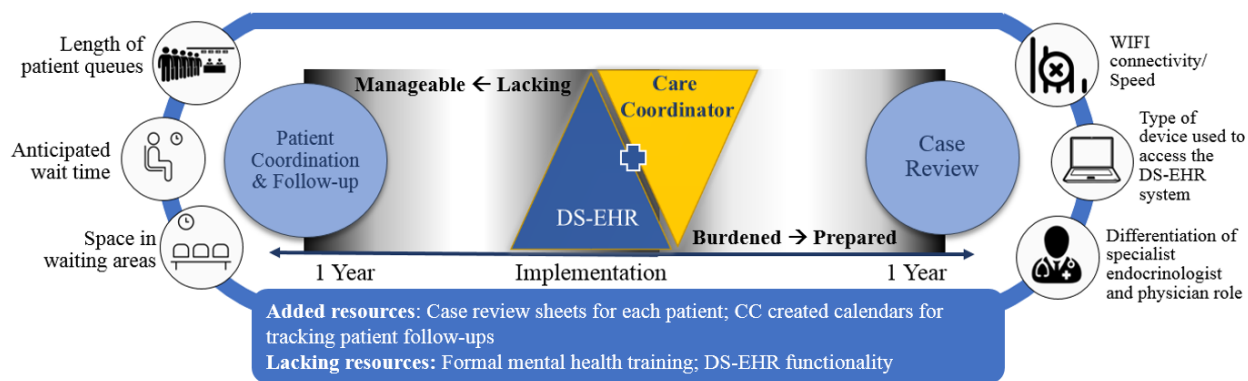
The evaluation data are depicted according to the realist evaluation concepts of contexts, mechanisms, and outcomes, as they change over the active intervention period. This diagram displays the contextual features and resources that determined whether the care coordinators felt their role was manageable and whether they were prepared to facilitate case review meetings.

Figure 2.6 Specialist Oversight Related Contexts, Mechanisms, and Outcomes
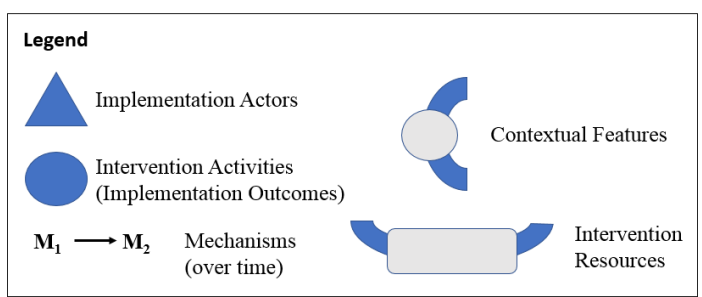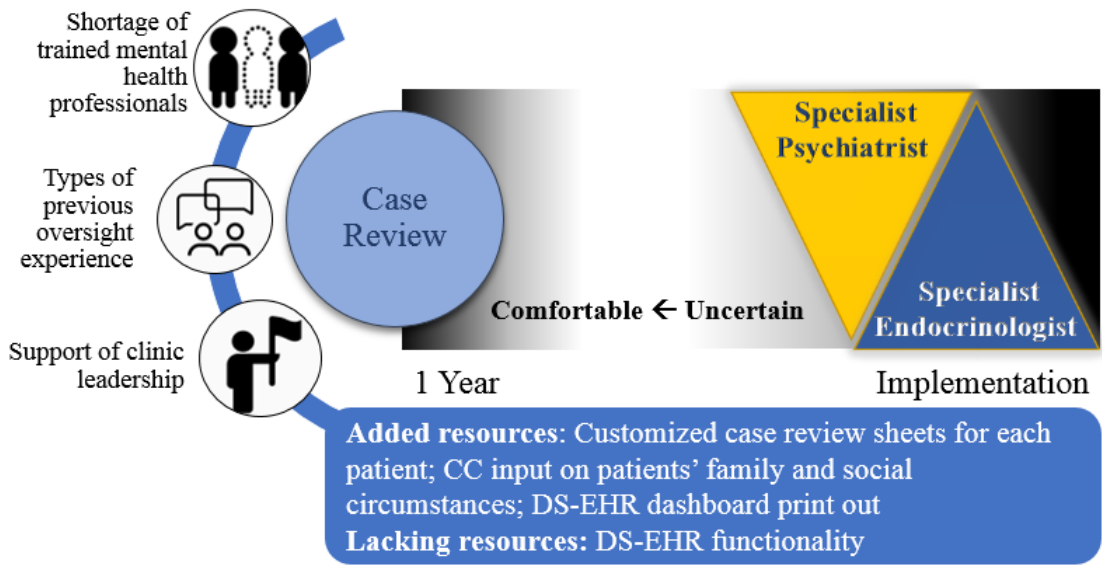
The evaluation data are depicted according to the realist evaluation concepts of contexts, mechanisms, and outcomes, as they change over the active intervention period. This diagram displays the contextual features and resources that determined whether the specialist psychiatrists was comfortable providing oversight in the case review meetings.

Table 2.5 Rationale for Anti-Depressant Treatment Prompt Modification

	Government (Site 1)	Private (Site 2)	Total
No therapy			
Physician prefers to reinforce lifestyle modification (continue behavioral therapy)	2	3	5
Physician interprets recent lab trends as improving	1	2	3
Patient discontinued therapy (PHQ-9 scores within limits)	--	1	1
Psychiatrist advised stopping medication as patient has improved	1	--	1
Maintain therapy			
Patient reluctant to increase therapies (maintain dosage)	--	3	3
Patient's circumstances preclude changing therapy (continue existing therapy or tweak with minor increase in dosage)	5	1	6
Patient too frail for aggressive therapy	--	1	1
Increase therapy			
Initiate drug therapy (prompt not produced)	6	2	8
PHQ - 9 scores have increased	--	1	1
Drugs for related conditions/side-effects of treatment are required (i.e., sleep disorder; pain)	3	--	3
Change therapy			
Physician prefers an alternative medication (change medication)	1	5	6
Patient is taking incorrect therapies/dosages	--	1	1

*Over the course of the active intervention, 17 of 40 patients (government clinic) and 19 of 60 patients (private clinic) were prescribed anti-depressants

Legend

■ High Preference (3-6 uses)

■ Low Preference (0-2 uses)

Figure 2.7 Revised Program Theory

Inputs, Mechanism, & Contexts

If the DS-EHR is accessible and functioning, or when a back-up protocol is in place, on-going training on all components of the CC position is provided, access to the psychiatrist outside of case reviews is made available, and private counseling spaces are available (I) and when the CCs feel supported, have regular in-person consultations with patients, and successfully establish rapport with patients (C), then CCs will feel equipped (M) to...[CMOC1]

If psychiatrists caution about the use of the term depression (I) because it is perceived to be a stigmatizing diagnosis for patients (C), then it will lead CCs and UCDPs to avoid using that term (M) when the providers seek to...[CMOC1/2]

If training is provided on evidence-based mental health treatment and how to use a paper version of the software's treatment algorithm (I) and when physicians have a history treating patients, longer consultations, and case reviews are held more frequently (C), then the physicians will have the confidence (M) to...[CMOC2]

If a patient scheduling tool is available (I) and patient lines and wait times are short in uncrowded waiting rooms (C) then it will be manageable for CCs (M) to...[CMOC3]

If a template for structuring the review of patient cases is provided (I) and the WIFI is functional, a computer is accessible, and CCs are the only provider attending case reviews who has met with patients (C) then the CCs will feel prepared (M) to...[CMOC3]

If a specialist psychiatrist is recruited (I), and clinic leadership supports the integration of mental health care, the psychiatrist has previous experience providing oversight when they cannot assess the patient, and there is a shortage of trained mental health professionals (C), then the psychiatrist will be comfortable (M) when they have to...[CMOC4]

Outcomes

Provide responsive, individualized care guided by the DS-EHR software

Identify depressive symptoms, counsel patients regarding depression, and prescribe anti-depressants

Coordinate patient care and follow-up

Coordinate and facilitate case reviews

Provide treatment oversight

Legend ⟶ Impact of contexts and mechanisms on outcomes

⇢ Impact of outcomes on contexts and mechanisms

Chapter 2 References

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Chapter 3: Factors that Facilitate Patient Activation in the Self-management of Diabetes and Depression

in India

Abstract

The aim of this study is to identify the factors that influence patients' motivation to engage in an integrated depression treatment model and self-manage both their diabetes and depressive symptoms. A total of 11 health care providers implementing the INDEPENDENT care model, and 62 patients receiving the intervention completed a semi-structured interview between September 2017 and May 2018. At the end of each interview, patients also completed the Client Satisfaction Questionnaire (CSQ-8). Using a realist evaluation approach, a hypothesized program theory for patient activation was tested and refined. The refined theory suggests that patients are activated through a cumulative process of being motivated to participate, being educated about how to self-manage diabetes, and being actively engaged in their disease self-management and treatment. In order for patients to practice self-management skills, patients needed assistance overcoming barriers to behavior change, and to sustain those behaviors they needed to be activated, rather than just engaged in the care model. Sources of motivation varied across participants, with shifts occurring over time as patients noticed the impacts of their treatment plan. The results of this study suggest that alternative forms of patient incentives should be used to initiate and sustain engagement in this care model, and that programs should prioritize counseling strategies that educate and engage patients and their family members about self-management practices, in order to achieve patient activation.

Introduction

Patient participation is essential to achieving and maintaining control over his or her diabetes and depression. Self-management refers to an individual's ability to manage the symptoms, treatment, health consequences, and lifestyle changes associated with chronic disease (Barlow, Wright, Janice, Turner, & Hainsworth, 2002). Self-management involves skill development, an understanding of available resources, and effective communication with healthcare providers and support persons (Wagner, Austin, & Von Korff, 1996; Wagner, Austin, Davis, Hindmarsh, & Schaefer, 2001).

According to the Association of American Diabetes Educators, diabetes self-management behaviors include physical activity, healthy eating, medication adherence, monitoring blood glucose, diabetes-related problem solving, and healthy coping (Association of American Diabetes Educators, 2008). While the central tenets of self-management still apply, there is no consensus on what constitutes self-management behaviors for depression (Houle, Gascon-Depatie, Belanger-Dumontier, & Cardinal, 2013). Collaborative care interventions do, however, sometimes include depression self-management components (e.g., identifying and practicing self-care activities, meditation, deep breathing exercises) in parallel with strategies for enhancing patients' self-management of other chronic conditions (Chang-Quan et al., 2009; Unutzer et al., 2002; Gilbody, Bower, Fletcher, Richards, & Sutton, 2006). A patient-centered care model with integrated depression self-management typically entails identifying depressed patients with a validated instrument, providing care with a multidisciplinary team of professionals, providing proactive follow-up, tracking depressive symptoms and medication adherence, and providing evidence-based treatment (Houle et al., 2013).

Collaborative care models integrating depression self-management into the diabetes care platform offer a way to reach high-risk patients in clinical settings where they are already seeking health care. There is evidence that integrating depression and diabetes treatment and support at the primary care level is effective in improving chronic disease self-management practices, such as diet and activity, among patients with co-morbid depression and poorly controlled diabetes or coronary heart disease (Rosenberg et al., 2014; Katon et al., 2010), thus suggesting that a similar care model may improve patient health outcomes and self-care behaviors if implemented within a diabetes care setting. In India, an estimated 72.9 million people live with diabetes (International Diabetes Federation, 2017), roughly 15.1% of which suffer from depression (Mohan, Sandeep, Deepa, Shah, & Varghese, 2007). Faced with barriers to accessing mental health treatment (e.g., the stigmatization of mental illnesses, distance to a psychiatric care facility, the limited number of trained mental health professionals) (Khandelwal, Jhingan, Ramesh, Gupta, & Srivastava, 2004; Hofmann-Broussard, Armstrong, Boschen, & Somasundaram, 2017; Gaiha, Sunil, Kumar, & Menon, 2014; Chadda, Agarwal, Singh, & Raheja, 2001; Patel et al., 2016; Patel, 2007), patients with depression living in India need more options for accessing treatment and acquiring chronic disease self-management skills.

In India, the INtegrating DEPrEssioN and Diabetes treatmENT (INDEPENDENT) care model was developed to address gaps in mental health care and improve diabetes care and management (Kowalski et al., 2017). While this approach largely focuses on quality improvements at the clinic-level, patient engagement and empowerment were considered key to cultivating patients' diabetes and depression self-management behaviors. Engagement broadly refers to the extent to which patients, and their support persons, are involved in healthcare decision-making processes (Gallivan, Kovacs Burns, Bellows, & Eigenseher, 2012). Patient

empowerment is achieved once patients' self-efficacy to facilitate their care is developed and patients feel capable making their own health care decisions (Aujoulat, Marcolongo, Bonadiman, & Deccache, 2008). The patient activation theory, which draws from the transtheoretical model (Prochaska & Velicer, 1997) and the concept of self-efficacy (Bandura, 1977), was developed to describe the gradual process through which patients take ownership of their health care management (Hibbard & Mahoney, 2010). According to this theory, patients are considered activated once they have the knowledge, skills, and confidence to take an active role in their health care and self-management (Hibbard & Greene, 2003). In addition to indicating patients' ability to self-manage their health and care, there is evidence that patient activation also contributes to patients' willingness to manage their conditions autonomously (Hibbard, 2003; Greene, Hibbard, Sacks, Overton, & Parrotta, 2015).

In India, where over 70% of health care costs are paid for out-of-pocket, health care consumers have flexibility in selecting where they seek medical treatment, and therefore, change providers if they are not satisfied with the care they receive (Balarajan, Selvaraj, & Subramanian, 2011). As such, it is important to examine what motivates patients to initiate care and what factors keep them engaged. Any efforts to improve patients' self-efficacy to self-manage their conditions will require continuity in care while patients receive counseling and support to actively manage their chronic conditions. In order to optimize diabetes and depression care for patients in India, it is critical to identify the mechanisms underlying, and the contextual factors informing, patients' willingness to engage in integrated depression treatment models and self-manage diabetes and depression. This study was designed to explore how patients responded to and experienced the INDEPENDENT care model, and how, through engaging with the model over time, patients altered their approach to chronic disease self-management.

Methods

Study Design

A realist evaluation was conducted alongside the INDEPENDENT randomised, controlled trial (Kowalski et al., 2017). Detailed study design, data collection, and planned analyses are described in a previous paper (Kowalski et al., 2017). The realist evaluation approach was chosen because the resulting program theory will inform the implementation of future integrated depression and diabetes care models, in part, by identifying the circumstances under which patients are motivated and empowered to engage in the management of their own health. This was accomplished through gaining a deeper understanding of contexts, mechanisms, and outcomes associated with the INDEPENDENT care model. Guided by the realist evaluation approach, contexts, mechanisms, and outcomes are expressed together as context-mechanism-outcome configurations (CMOCs) (Pawson, 2013). In this paper, only the CMOC pertaining to intervention patients' experiences is tested and refined using processes outlined by Pawson and Tilley's Realist Evaluation Framework (Pawson & Tilley, 1997). A detailed description of implementation activities linked to care coordinators (CCs) and health care providers is provided in Chapter 2.

This paper seeks to determine what mechanisms and contexts motivated patients to participate in the INDEPENDENT care model, with participation defined by clinic attendance, and to engage with the health care team to improve their health. The initial program theory, developed from key informant interviews and a document review in the initial phases of this realist evaluation (see Chapter 2), outlines the hypothesized causal mechanisms underlying how the INDEPENDENT care model works. The CMOC involving patient responses to the INDEPENDENT care model is summarized in Table 3.1. The refined patient-related program

theory will provide insight into what motivates patients to initiate and sustain participation in this form of care and demonstrate how the counseling and support offered by CCs influenced the likelihood of patients self-managing their depression and diabetes.

The RAMESES II reporting standards for realist evaluations was followed to ensure the study design, methodology and results are clearly reported in accordance with the realist evaluation framework (Wong et al., 2016).

The INDEPENDENT Care Model

The INDEPENDENT care model is a multi-component depression and diabetes care program that was culturally tailored for urban diabetes clinics in India. This care model combines the strengths of both the TEAMcare (Katon et al., 2010) collaborative care approach and the CARRS trial multi-component quality improvement strategy (Ali et al., 2016).

In keeping with the principles of collaborative care (AIMS Center, 2018), the INDEPENDENT care model provides evidence-based care while employing a measurement-based treatment to target approach (Kowalski et al., 2017). System generated care prompts were used to inform patients' usual care diabetes physicians (UCDPs) about patients' depressive symptoms and changes in cardiovascular (CVD) risk factors. These prompts were also used to guide the initiation or modification(s) of diabetes and depression pharmacotherapy and/or evidence-based behavioral interventions. The behavioral interventions were delivered by a CC, a trained health care worker without a prior background in mental health. The aim of the behavioral interventions was to support sustained depression and diabetes self-management among patients receiving the INDEPENDENT care model. Behavioral interventions used by the CCs included: motivational interviewing, behavioral activation, and problem-solving treatment strategies. Motivational interviewing was used to strengthen patients' commitment to behavior change through the use of reflective listening, reinforcement of positive statements, the

assessment of patients' readiness to change, and the affirmation of patients' self-direction throughout the process of behavior change (Miller & Rollnick, 2009; Rollnick & Miller, 1995). Behavioral activation strategies were used to engage patients in self-management by reinforcing positive environmental contingencies (Martell, Addis, & Jacobson, 2001; Lewinsohn & Grant, 1973). Lastly, structured procedures for problem-solving were used to address patients' difficulties systematically (Arean, Hegel, Vannoy, Fan, & Unuzter, 2008; Harpole et al., 2005).

      Participants. The INDEPENDENT trial took place between March 2015 and May 2018, with participants recruited from outpatient clinics and diabetes awareness camps in four cities in India. Eligible participants were adults (aged ≥ 35 years) with one or more poorly-controlled CVD risk factor(s) in the previous six months and newly-identified depressive symptoms. Only patients receiving the intervention at two of the trial sites were included in this evaluation: one government clinic in north India and one private clinic in south India. These sites enrolled 41 and 78 patients into the intervention arm of the trial, respectively.

      At baseline, patients receiving the intervention across both sites were similar with regards to several demographic characteristics, including age, sex, and education level. The mean age was just over 50 years, with female patients making up approximately 60% of the intervention group at each site. Over 65% of patients in both groups reported having only a primary or secondary education and about 5% reported having no formal education at all. Patients differed across sites in terms of income levels and use of private insurance. Only 5% of patients at the government clinic reported using private insurance, while 15% of patients at the private clinic reported having insurance. And while over 70% of patients across both sites reported earning a monthly income less than or equal to 30,000 INR (≤ 450 USD), a higher proportion of patients at the private clinic reported earning less than or equal to 10,000 INR (≤ 200 USD). A complete

sociodemographic profile of all INDEPENDENT trial participants is available in the INDEPENDENT trial's study design paper (Kowalski et al., 2017).

Interview Procedures

One-on-one interviews were conducted with the three CCs supporting patient care and depression and diabetes self-management across both sites in the INDEPENDENT trial, as well as with eight health care providers (i.e., usual care diabetes physicians, specialist endocrinologists and psychiatrists) in the study, as a part of a process evaluation of the INDEPENDENT care model (see Chapter 2). All provider interviews were completed in September 2017. Written consent was obtained from CCs and providers prior to starting the interviews and all interviews were audio recorded. Provider/CC interviews lasted from 1-1.5 hours and covered a range of topics including: providers'/CCs' roles and responsibilities, barriers to intervention implementation, and perceptions of patients' experiences and intervention impacts.

Two trained interviewers from the local communities (non-clinic staff members), one at each site, and LJ conducted a total of 62 two-on-one patient interviews across both sites (see Figure 3.1). The local interviewers were bilingual in English and the predominant local language (i.e., Hindi, Tamil) of their respective cities. Both interviewers completed a two-day training conducted by LJ on the intervention care model, the conduct of in-depth interviews, transcription practices, and the realist analytic approach, prior to starting data collection at either site. Interviews were conducted by the bilingual interviewers in order to keep interviews under an hour, but LJ directed probes throughout the interviews. Interviews at the government clinic, site one, were conducted from September to December 2016 and interviews at the private clinic, site two, were conducted from February to May 2017.

A semi-structured interview guide was used to provide flexibility as new topics emerged across interviews, and reflective probes were used to elicit nuanced patient perspectives (Hennink, Hutter, & Bailey, 2011). The interview guide was piloted and refined based on patient feedback and clinic observations conducted by LJ. Modifications were made to the interview guide after piloting the guide and conducting observations of the trial procedures. Questions on perceptions of privacy and the types of assistance provided by the CC(s) were added. The pilot phase also resulted in adjustments to word choice, particularly when inquiring about depression. Patients were asked to define depression and then describe their state of mental health, in order to identify terms patients were comfortable using to discuss their mental health for the last portion of the interview.

The final interview guide included a total of 3 main topic areas: motivation to participate, intervention experience, and health care communication. The interviewer explicitly asked what components of care and contextual factors influenced patient initiation and sustained engagement with the integrated care model. Patient interviews lasted 40-60 minutes in duration.

All patients in the intervention arm of the trial were first approached by a CC, who briefly explained the purpose of the evaluation and informed each patient of the interview time commitment. All interested patients were then referred to the interviewers for further information about the study. Informed consent was obtained by a written or thumbprint signature from all patients prior to participation and all interviews were audio-recorded. Participants were interviewed in a private room at each clinic. Because patients were not provided with additional incentives outside of those provided through the main trial, patients recruited to participate in the evaluation consisted of those individuals traveling to the main study sites for a physician

consultation or study visit. A sub-group of patients at site two lived outside of the city and sought care at another clinic branch and were therefore excluded from participation.

The study was approved by the Institutional Review Boards of Emory University, USA, and the All India Institute of Medical Sciences and Madras Diabetes Research Foundation, India.

Qualitative Data Preparation and Analysis

LJ transcribed verbatim all CC and health care provider interviews, while all patient interviews were translated and transcribed by the bilingual interviewer. In cases where translation was required, quality checks were carried out by a third-party staff member unaffiliated with the INDEPENDENT trial who read randomly-selected transcripts with the corresponding audio and noted any discrepancies. No major discrepancies were identified in this process. Once a transcript was complete, it was de-identified, and coded independently by two evaluation team members into an EXCEL spreadsheet organized into columns according to contexts, mechanisms, and outcomes.

Data collection and coding occurred simultaneously. This allowed for inductive and deductive code development (Hennink et al., 2011). Inductive codes were developed by exploring the data and identifying topics that were not explicitly asked about during the interview or anticipated based on the initial program theory outlined in the patient-related CMOC. Codes were then clustered into CMOCs, which were later compared to the hypothesized patient-related CMOC to produce a refined program theory regarding patient participation and self-management (see Figure 3.2).

Questionnaire Procedure and Analysis

At the end of each patient interview, participants were asked to provide general feedback regarding their satisfaction with the treatment they had received in the INDEPENDENT trial by

completing the eight-item Client Satisfaction Questionnaire (CSQ-8) (Nguyen, Attkinsson, &

Stregner, 1983). The total score is calculated by summing up each item's score. Scores range

from 8 to 32, where higher scores indicate higher satisfaction. Because the majority of patients

reported being illiterate or visually impaired, participants were administered the questionnaire

orally in either English, Hindi, or Tamil. The interviewer read each question and its

corresponding response options aloud, marked the participant's response, and then repeated the

selected response option back to the participant to ensure the correct response was recorded. This

questionnaire took approximately five minutes to administer. All survey data were entered into

an EXCEL spreadsheet where individual and group means and standard deviations were

calculated. These descriptive statistics were triangulated with qualitative findings related to

patient engagement to corroborate patients' expressed satisfaction with the care they received as

a part of the INDEPENDENT study.

Results

Patients receiving the intervention in the INDEPENDENT trial detailed how the added

support they received in this model of care influenced their willingness to continue participating

as well as their ability to self-manage their diabetes and depression. This study aimed to

empower patients, but patients revealed that while they felt confident in their ability to apply

their skills and knowledge, their inability to control numerous factors impacting their self-

management behaviors left them incapable of effectively self-managing their diabetes and

depressive symptoms. Instead, patients detailed a gradual progression through feeling motivated,

engaged, and educated about how to manage their conditions before first feeling confident in

their abilities to manage their conditions. The culmination of these responses resulted in patient

activation (see Figure 3.3). Each of the three contributing mechanisms individually (i.e.,

motivation, engagement, and education) contributes to one or both of the patient outcomes (i.e., clinic attendance and self-management), but the presence of all three mechanisms enabled patients to actively practice health behaviors to manage their conditions without the structure provided by the study. In a few cases, patients reported being engaged, but blindly followed guidance from the health care providers regarding attendance and self-management behaviors. In those cases, patients did not feel confident proactively seeking health care or sustaining self-management behaviors without the support of the CCs.

Across the interviews, patients emphasized how the CCs enhanced their ability to self-care by educating them about diet, exercise, and medication adherence, and through encouraging them to develop coping strategies for stressors encountered at home and/or work. Over time, patients' relationships with the CCs and UCDPs, and the noticeable improvements in their health and well-being, further motivated engagement with this model of care. Patients at the two sites were highly satisfied with the care they received. The average combined CSQ-8 score was 29.7 (SD: 2.16), with site one (mean: 30.03, SD: 1.87) demonstrating a similar mean to site two (mean: 29.35, SD: 2.35).

In Figure 3.3, the patients' described responses to care, or mechanisms, are depicted as merging to form one sustainable mechanism for generating the intended outcomes of participation (i.e., clinic attendance) and patient self-management, which work alongside the team-based approach to improve patients' health outcomes. Patients defined these care responses differently in terms of what motivated them to attend clinic appointments, what strategies were used to engage them in collaborative care, and the amount of time and resources it took for each of them to feel knowledgeable and capable of chronic disease self-management. Resources that patients consistently identified as barriers to self-management included not having a way to

monitor their blood sugar levels at home and not being able to fully engage with the provided educational materials, due to low literacy. As the study continued and CCs became aware of each patient's individual needs, low-income patients with uncontrolled diabetes received a glucometer, while supplies allowed. The supply of glucometers was determined by the clinics' resources as these supplies were not included in the resources provided by the INDEPENDENT study. Similarly, patients reporting poor adherence due to the cost of medications were either provided free medications from the clinic/hospital pharmacy or they were referred to an off-site pharmacy that provides free or low-cost medications. The contextual factors that determined if and how mechanisms were activated included a patient's community environment, co-existing health conditions, health literacy, social support, income level, and schedule. The following sections will provide detailed accounts of how each mechanism interacts with various contextual factors to impact patients' participation (i.e., clinic attendance) and self-management behavior.

Motivation

In this study, the travel reimbursements were hypothesized to motivate patients to continue attending study visits, with low-cost, quality, intensive care serving as a motivator for continued attendance at interim visits (i.e., visits between 6-monthly study visits). The majority of patients, however, reported the "VIP" treatment they received at interim visits was their main reason for continuing with this form of care. VIP treatment was broadly defined as having all counseling and medical care, and the accompanying logistics, handled with care and concern (see Table 3.2 for an expanded list and examples of defining characteristics). Care providers were aware of how patients responded to the perks of this care model. As one physician stated, "[these benefits of the study] are basically frills. And cutting the line—it is really harrowing to be standing in that line. So, these are all frills for them. This is actually what actually motivates

them to do better." Though many patients felt travel reimbursements should be provided for all clinic visits, including interim visits, in order to make this form of care accessible to patients of all socio-economic backgrounds, no one named this as a motivating factor for study participation. Patients did, however, identify cost of consultations, blood work, and medication as factors that influenced where they seek care. Nearly all patients mentioned that they had agreed to take part in the study in order to improve their health and quality of life.

For many patients, what distinguished this care approach from other health care experiences was feeling that their health care providers were deeply invested in their well-being, rather than viewing patient care as a business transaction. This sentiment is best captured by one patient who stated, "No one [in other clinical settings] used to care whether I take the medicine or not, whether my sugar level is going up or down, how I am living, or anything." Patients trusted their UCDP and CCs to act in their best interest because each patient had witnessed the staff's personal investment in and dedication to helping patients control their diabetes and/or reduce their depressive symptoms.

At the core of the trust established between patients and providers was that patients felt as if they were receiving treatment akin to what family members of physicians receive, one of the defining characteristics of VIP treatment. Expressing a cross-cutting theme, one patient summarized this notion when she stated, "[The CC] will look after me, treating me like her own mother or grandmother." Over time, patients reciprocated this bond, frequently referred to the CCs as family members and referenced them with affection and appreciation. One patient commented, "I consider them as my sisters and share personal talks. I consider them doctor, sister, and friend," highlighting how this pseudo-familial relationship between a patient and a CC helped establish rapport and improve the exchange of sensitive information. Another patient

concluded, "I consider them as my children." Familial dynamics were also used to capture the interaction between a patient and her/his physician. For example, one patient likened the interaction between a patient and her/his physician as that of a crying child and a parent, stating, "When you approach [the child] and innocently enquire about his problems, he stops crying. Although he does not understand what you are saying to him, he feels the affection and responds accordingly." Regardless of whether patients felt their physicians could truly understand the circumstances affecting their health, they felt comforted by the physicians' and CCs' genuine display of concern.

The formation of personal relationships with their health care providers was both highly valued among patients and named as one of the primary reasons patients continued to attend clinic appointments, even when it was an inconvenience due to conflicting family responsibilities or work schedules. The main impediment to attending clinic appointments was poor health resulting from another health condition(s) (e.g., Tuberculosis, Chikungunya), though as patients became engaged in their care, they were able to rebound from these set-backs with the help of their health care providers. Still, CCs noted that there were some patients who lacked the motivation to attend appointments and work towards improving their health. One CC noted, "And also, no matter how much you are doing, sometimes the patients are not motivated. So, in that case, it becomes very difficult," emphasizing how it is challenging to change individual habits and perspectives on health when patients will not even attend clinic appointments.

Education

Though many patients shared that they had family members or spouses who had diabetes, most reported learning about the disease through participation in this study. Patients valued the counseling provided by the CCs, as is best captured in one patient's comment, "The best thing

here is the facility of counseling. Since doctors don't have time to tell us about the precautions and other necessary information needed for better treatment, [CCs] fills that gap. And that, I think, that is the most important thing." Patients, however, varied in how well they understood their condition. A subset of participants across both sites were upset and confused by being the only person in their family with the disease. As expressed by one patient, "In my family, no one is having sugar. I don't know why it happened to me. It might be written in karma." There were also mixed understandings about the duration of diabetes. One patient stated, "You know that the diabetes will not be finished from my body. It will keep rolling up and down. So, it is going on like that only," while others expressed frustrations with not knowing how long they would have to maintain the advised diet and medications.

Patients were even less consistent in their understandings of depression, describing it as a natural and manageable phase of life, a temporary state of mind, a side effect of diabetes, or a psychological disease, which some thought may be permanent. Those patients who required anti-depressants described being counseled about depression at the time of their diagnosis, and how it helped them better understand the symptoms they were experiencing. One patient elaborated:

> I was totally ignorant about it. I used to think my mind has been disturbed, because of which I am not being able to sleep. I used to think like this only. But when I came here I got to know that I have been diagnosed with diabetes. After that they prescribed me medicines for that. I have heard that when someone has depression that does unexpected things. But I never thought that it would happen to me as well, as I think that I should have died. Or, sometimes, people start behaving like mad, so many other nonsensical things. Even I used to do all that. For example, waking up in the middle of the night, continuously walking, standing in the balcony for hours and so on. All that used to happen with me, as well. Now, I got to know that it is because of depression. Yes, it is because of the depression only.

Patients not only came to a deeper understanding about mental health, they learned how their diabetes and other health-related behaviors affect their mood and vice versa. One patient

explained, "My sugar level is under control, but any carelessness with the food makes it unbalanced. Then I take my medicines regularly and it gets controlled, but sometimes because of tension it gets increased." Patients recognized that their conditions influenced one another, which further motivated them to control each individually.

Patients learned more about their conditions with each additional counseling session. Though many patients felt they initially prioritized medication adherence, they found themselves equally or more concerned with diet and exercise (i.e., walking) by the end of their time in the active intervention. During the early counseling sessions, every patient received supplementary educational materials on diet and nutrition, though many were only able to use them if they had a family member who could read the materials to them. The CCs coupled these materials with extensive dietary guidance. As one patient recounts, "they keep telling me—eat less salt, eat timely, don't take fried food and so on." Though the majority of patients found altering their diet was the most challenging part of their self-management, nearly all patients echoed the following statement of one patient: "[the CC] makes me understand that I should control over my diet." Patients knew that they had to change their diet and they had clear examples of what those changes needed to consist of given their health status. Several patients expressed a desire to have counseling on exercise and weight loss, which they felt was lacking. The exercise advocated for by the physicians and CCs was walking, which many of the patients did not identify as a form of exercise.

The counseling sessions were also used to enhance patient adherence to medications, but this demanded problem-solving for the barriers to attaining medications, in addition to educating patients on the importance of medication adherence. One of the CCs shared an example of the complex relationship between patient education, income, and medication adherence:

[The patient] is not overweight or obese. To even get him to understand that he needs to take a lipid lowering drug was a challenge because he was, like, 'I am not fat, why should I take it?' Because he thought only if he's fat his cholesterol is bad. And then I think after a couple of interim visits, we understood that it's not really that he's fat or thin, but it's just that the statins are much more expensive than the metformin. The metformin is a little cheaper drug, where the statin drug is an expensive drug and he was not able to afford it. So we actually gave him half the dose of statin. It's little cheaper and he'll be able to buy and take it. And we were able to accommodate it. It takes some time for them to open up and tell. And only when they tell it we are actually able to work around what the issues are.

In sharing instances such as this, care providers stressed the importance of concurrently educating patients, building rapport, engaging patients and their family members in chronic disease management, and providing responsive and timely care as a means to empower patients to self-manage their conditions.

Engagement

Reflecting on their expectations at the start of the study, patients expressed a desire for a passive healthcare experience, but over time, the majority of patients became comfortable playing a more active role in managing their health. Numerous patients recounted situations where they were willing to call on the CC(s) to guide them regarding their diet or provide solutions during a medical emergency. One patient shared, "When I have a crisis situation, then I make call to the care coordinators and if they don't have solution for that, then they take me to the doctor. I keep them informed about my health." Patients' perceived the act of consulting a physician or CC as being active in one's health care and believed that healthcare decisions should only be made by the health care providers. Therefore, patients considered medication adherence to be the only necessary responsibility of the patient outside of the clinical setting prior to engaging in the INDEPENDENT care model.

Patients' resistance to taking a more active role in their health care was largely influenced by their available income and social support. The majority of patients had other health conditions

aside from diabetes and depression that demanded their attention. This left many patients in the position of having to pay for additional clinic fees and medications on a limited income, without even accounting for other family members' healthcare costs. The low-cost care offered at the sites in this trial allowed patients to more readily partner with the CCs to identify health goals and problem solve potential barriers to reaching those goals.

As CCs developed relationships with patients, they encouraged patients to brainstorm solutions to their own health challenges, which, beyond income, were often linked to a patient's schedule. Both men and women felt that work and family responsibilities hindered their ability to fully focus on their own health care needs. One man shared his daily schedule when elaborating on why he does not exercise more, stating, "I go to work at 10 am and return home by 10 pm and then have dinner and go to bed late and again wake up early to work—this is how my time is spent." Whereas men voiced concerns about not being able to support their families if they risked their job to take more time to eat healthy, exercise, and seek medical care, women typically reported finding it difficult to prioritize their health over that of other family members. For example, one woman shared how her health was suffering physically, mentally, and emotionally because she always put her husband's needs before her own:

> I can't take rest after doing my chores… [my husband] does not think that I have to sit and rest for a while… I should finish his work first. As soon as he comes I have to serve him with dinner and then, immediately after that, I have to make his bed and, immediately after that, I have to massage him with pain killer balm for his joints. He doesn't think about me at all, whether I have eaten or not… these things hurt my heart.

This patient felt safe sharing her situation with the CC and was able to identify small ways to improve her mood through exercise at home, such as "climb[ing] stairs up and down to sun dry washed clothes," in addition to taking her prescribed anti-depressants. Patients found it helpful to

recount their daily routines with the CC(s) and identify opportunities to build-in activities for self-care (e.g., yoga, prayer, time with family and friends).

A common strategy employed in this collaborative care approach was to involve patients' family members in counseling, in order to provide patients with support and positive reinforcements at home. In discussing with patients how they manage their conditions, it was almost inevitable that a patient would name one or more family members as critical to their health care and well-being. One woman succinctly stated, "[My son] takes care of me and buys me medication, sarees, basic necessities. He, only, takes care of me. If he ends up in any problem there is no one for me." Another man explained:

> My wife takes care of it. She is like a counselor, too. She would say that the counselor asked you to eat this, so, eat it… I must eat what she cooks. She will be present during counselling, right! She is the important person. She will make food that fits me. My wife takes care of everything. She is like a doctor to me because she injects insulin and I don't know about my medication, but she gives it to me.

Patients recognized that they were not only reliant on their health care providers for treatment, but that they needed the support of their family to manage their conditions. From taking an individual to her/his physician appointments to buying her/his medication, family played an important role in supporting patient self-management across both sites. CCs echoed the importance of family support when working with patients to set health goals. After sharing two different incidents, one where a patient did not receive family assistance to buy medications and another where a patient needed help accessing emergency care, a CC shared how engaging family members looks different for each patient, stating: "It depends on what the participant is dealing with, and then you set the short-term goals, thinking what is critical at that point of time." Friends were also seen as a source of support. Many patients recounted stories of sharing their symptoms with their friends, who then referred them to a particular physician or clinic.

Activation

Across both sites, the majority of patients felt confident that they could use the knowledge and skills that they learned in counseling sessions with the CCs to take responsibility for their diabetes and depression self-management. When asked how the CCs could better assist patients in achieving their health goals, every patient replied that it was the responsibility of the patient to apply her/his new-found knowledge and skills in order to improve her/his health. One patient captured those views, stating, "[The CCs] can't do more. Their job is to give patient right information and they are fulfilling their job nicely. If we are the one who is not working then in that, [the CCs] are not having any fault." In reflecting on how their health behaviors had changed since joining the study, patients contrasted prior instances of uncontrolled diets and non-existent exercise regimens to more consistent daily regimens including stricter diets, exercise routines, improved medication adherence, and attention to one's mood. One patient characterized the onus of patient self-management with the comment, "They guide me about my diet and I put control on myself," indicating that the health care providers may provide resources, but it is the patient who has to control her/his lifestyle in order to reap the health benefits. Another patient echoed the importance of self-control with the statement, "I hold control over myself and control over emotions, so that it doesn't affect my health." Despite feeling responsible for their health, patients remained dependent on the CCs, however, to facilitate their care and on the physicians to dictate their treatment decisions.

With additional health education, patients noted a greater awareness of the role of different behaviors in influencing their physiological health, as a result of changes in their health status over time. Those patients who showed improvements in their diabetes and depressive symptoms often recounted that they first recognized this connection when they disregarded the

lifestyle changes advised by their CC or physician. For example, one patient shared, "When my sugar level increased, that was all because of me only. I was careless. As I keep going out for outside dinner and other parties, then the next day it will be increased." Patients also expressed improvements in their self-confidence to self-manage their chronic conditions as a result of remaining engaged with the care model. The majority of patients expressed feeling confident in their ability to sustain their diabetes self-management. As one patient commented, "Earlier, I won't check my blood nor take medication properly, but here, I have come and gained confidence and am taking proper medication." Few patients referred to behavioral strategies for improving their mental health, with only one patient explicitly expressing more confidence in his ability to manage his depression moving forward. This individual put his current self-assurance in perspective by recounting his state of mental health and attitude towards self-care at the start of the study:

> Earlier I used to have negative thoughts about myself. My self-confidence was extremely low. I can't imagine that time. [I thought] about suicide and all. It was like there was nothing in my life after this disease, and living would be worthless.

Though patients had faith in their ability to self-manage their health, a number of contextual factors were identified as keeping patients from feeling fully capable of controlling their health care and self-management. Factors that limited patients' self-efficacy include income, additional health conditions, their community environment, and social support. Low income was described by the majority of patients as a factor that determined not only where a person could seek medical treatment, but the extent to which they could engage in the behavioral interventions. One patient shared that she was unable to follow the dietary guidelines provided by the CC due to the high price of fruit, stating, "I cannot afford it, I am not rich to follow those food patterns." For several patients,

purchasing anything more than tea and a staple grain was unrealistic. Having multiple medical conditions or illnesses on a limited income often resulted in patients only purchasing the cheapest prescribed medication. Having an additional health condition also impeded a patient's ability to exercise. Following an outbreak of Chikungunya, one patient explained how this one illness inhibited his exercise routine established as a part of his diabetes and depression self-management. In the patient's words, "It has been 1 month 20 days I had Chikungunya. You won't believe it is so painful that I am not being able to stand because of the severe joints pain." The availability of community spaces to walk, let alone time in one's schedule to maintain the practice, and menu options at restaurants all further limit patients' ability to control their depression and diabetes self-management. Unlike diabetes, which patients acknowledged was commonplace, patients felt they could only discuss their emotional and psychological problems with select family members, close friends, or their CC. As one physician explained, "That's a big stigma. Going to a psychiatrist—'oh I'm not mad, you can't send me to a psychiatrist!'" Patients perceived there to be few places to seek support when they were feeling depressed.

As patients became more confident and comfortable taking an active role in their health, any noticeable improvements in health and well-being were an added motivation to stay engaged in this model of care. One patient expressed, "I am sick and I am getting good treatment here. My health is improving, so I am coming." Even though it takes time to see marked improvements in CVD and depression indicators, particularly in terms of glycemic control, patients were encouraged by gradual improvements in their health. Many patients also expressed having better control over their emotions, noting that they

were not as quick to anger. It was common for patients to experience periods of

uncontrolled CVD risk factors or depressive symptoms as a result of specific events or

periods of travel that disrupted their established routines, but most patients viewed the

long-term reduction in symptoms and medications as an improvement in quality of life.

One physician elaborated on this by sharing his experience of following the treatment

guidelines when patients are unable to control their diabetes enough to reduce the number

of required medications:

> There are people who will say, 'I've done so much, I've brought it [LDL cholesterol] down so much and now you are asking [me to take more medication]?' Especially if you have put in a lot of effort they feel that they are being punished in spite of doing that. So he goes off of fried foods and he's cutting down on fat and he's done everything and his LDL has dropped so much, but it's not reached, so now you prescribe a statin. 'So give me another two months here. I've tried so hard and next time I will bring it down. Why do you want a statin now?' Now I ask him to take a drug for this and they feel they are medicalizing the problem. People don't like that.

The care providers understood that seeing improvements in their health motivated

patients to continue engaging in the integrated care model and to self-manage their

conditions. They also recognized, however, that there was a threshold for having patients

adhere to demanding treatment plans before patients no longer saw the added value of

behavior change. In a sub-group of patients, the perception existed that one only has to

control diet and exercise or medication adherence in order to see improvements in health.

Whether patients were motivated by improvements in health outcomes or demotivated by

unmet expectations and slow progress, this new source of patient motivation served as a

feedback loop to hinder or enhance patient engagement and activation.

Discussion

This realist evaluation explored a patient-based mechanism embedded in the

INDEPENDENT trial and showed that both patient participation and self-management were

triggered when patient activation was achieved, a process that requires enhancing patient motivation, engagement, and health literacy. These findings diverge from the initial program theory that provision of travel reimbursements and comprehensive, high-quality care would empower patients to control their depression and diabetes self-management and encourage participation. Instead, the analysis indicates that patients fall short of feeling empowered because they lack control over several key individual-, interpersonal-, and community-level determinants; all contextual factors that inhibit patient self-management. Additionally, patients expressed differences in what initially motivated them to participate in this form of care versus their source of continued motivation to engage with providers and seek to self-manage their diabetes and depression.

Patient self-management practices for chronic disease care have been found to vary by patients' level of health literacy, motivation, and engagement (Simmons, Wolever, Bechard, & Snyderman, 2014; Coventry, Fisher, Kenning, Bee, & Bower, 2014; Nielsen-Bohlman, Panzer, & Kindig, 2004), with results from this study reiterating these findings and further demonstrating that patient activation occurs when patients are motivated, educated about, and engaged in her/his treatment. Previous research has identified patient motivation is a precursor to patient engagement (Coventry et al., 2014). While this study is unable to determine how the three contributing factors relate to one another (i.e., any sequencing of factors or feedback loops in the pathway to patient activation and self-management), the results of this study indicate that there is a distinction between what motivates patients to initiate and continue participating in treatment versus what motivates patients to take an active role in their health care and engage in self-management practices. Health literacy has also been identified as a predictor of self-efficacy in self-care for patients with diabetes (Ishikawa, Takeuchi, & Yano, 2008), highlighting the

importance of assessing patients' knowledge of their medical conditions and self-management skills prior and throughout efforts to counsel and engage patients in their treatment and self-care.

The findings from this study contribute to the literature by illustrating the key elements involved in patient activation for depression and diabetes self-management. The gradual acquisition of relevant health education and engagement with health care providers through behavioral interventions, namely goal-setting and action planning, outlined in the revised patient-related program theory align with those patient responses anticipated across the first three levels of activation defined by the Patient Activation Measure (PAM) (Hibbard, Stockard, Mahoney, & Tusler, 2004; Insignia Health, 2018). According to PAM, self-efficacy is a component of patient activation that is inherent in the higher levels of activation, wherein patients take action and maintain behaviors (Hibbard et al., 2004). These findings also align with the Transtheoretical Model (Prochaska & Velicer, 1997), which shows that self-efficacy increases across the stages of change. Patients in this study reported feeling confident in their ability to maintain their motivation, with mixed feelings about the extent to which they could control their behavior, given the presence of social and environmental constraints. Further research is needed to examine the relationship between patient activation and empowerment, to assess whether empowerment is an element of activation or a separate mechanism promoting patient self-management. Among patients with diabetes there is evidence that high levels of patient activation are positively associated with high levels of self-care (e.g., regular exercise, eating more fruits and vegetables, smoking cessation, glucose tracking) and lower levels of fatalism about one's health (Hibbard et al., 2004; Zimbudzi et al., 2017). Therefore, efforts to trigger patient activation in an integrated care model targeting high-risk patients with diabetes may also promote depression-self-management.

Motivation and family engagement are critical elements supporting patient activation in the Chronic Illness Care Model (Bodenheimer, Lorig, Holman, & Grumback, 2002; Von Korff, Gruman, Schaefer, Curry, & Wagner, 1997), which is consistent with findings from this study. Patient activation strategies used by the CCs in the INDEPENDENT care model to engage patients in their health primarily focused on educating patients and their family members about the patients' health and involving both parties in making care decisions. Previous studies have found that for patients with diabetes, patient activation was affected by patients' emotional feelings regarding their health condition(s), the quality of the doctor-patient relationship, and physicians' comprehensive knowledge of their patients' health and life circumstances (Graffingna, Barello, & Bonanomi, 2017; Bilello et al., 2018). Many patients in this study attributed their depressive state to their diabetes, which has been found to indirectly affect diabetes self-management via patient self-efficacy (Devarajooh & Chinna, 2017). The CCs in this care model served as the repository for patient health and life circumstances from which the physicians and specialists could draw to treat patients. As such, patients prioritized the quality of their relationship with the CC over the physician whom they spent little time with in the entirety of the treatment process. Counter to previous findings (Bilello et al., 2018), care and concern in treatment was essential to the "VIP" treatment patients viewed as motivational to being active in their health care and self-management. The patient accounts of engaging with this model of care are in line with the documented levels of patient satisfaction from the CSQ-8. Due to limitations in the evaluation timeline and resources, control arm patients were not interviewed or surveyed about their experiences and satisfaction with care. As such, a comparison of CSQ-8 scores across groups was not possible. Future studies of integrated depression and diabetes care models in

India should seek to collect these data given that findings from this study point to contextually-bound differences in patient processes and care as a primary source of patient motivation.

The contextual features highlighted in this realist evaluation expands the evidence base on what micro-social processes impact diabetes self-management in India. A limited number of studies from India have provided evidence suggesting that economic, cultural, and social factors are important to diabetes self-management; only one of these studies focused on patients with diabetes and depression (Sridhar et al., 2007; Shobhana et al., 2003; Sridhar & Madhu, 2002; Sarkar & Mukhopadhyay, 2008; Weaver & Hadley, 2011). A systematic review of barriers and facilitators to diabetes management in South Asians found that patients preferred following their physician's guidance (Sohal, Sohal, King-Shier, & Khan, 2015), similar to what patients in this study expressed, prior to engaging in the CC-led counseling and coordinated care model. Additional barriers found in this review included communication barriers, social responsibilities to maintain a traditional diet, and misconceptions about exercise (Sohal et al., 2015). While the use of CCs helped improve patient-physician communication, identified barriers to maintaining a healthy diet and exercise regimen in this study found that patients were more concerned about the accessibility and affordability of healthier food options and that walking was essential to improving one's health, regardless of access to exercise facilities.

While a search of Google Scholar and Medline found no studies examining depression self-management in India, a recent UK study found that patients with depression desired improved information about how to access resources and develop self-management strategies, and that increased control over their care was important to instill hope, confidence, and motivation (Chambers et al., 2015). Given that these desired components are incorporated in patient-centered approaches to diabetes care, these findings point to the benefit of integrating

depression and diabetes care. Furthermore, the UK-based study suggests that the benefits of activation among patients with depression may create a feedback loop to enhance patient confidence and motivation. As seen in the revised program theory for this evaluation, these feedback loops operate to benefit self-management practices for both conditions.

Strengths. The use of a mixed qualitative and quantitative approach in this realist evaluation allowed for the exploration of patients' experiences of diabetes and depression self-management from a social-behavioral perspective. This study is strengthened by its inclusion of patient interviews as there is a notable lack of patient perspectives in existent evaluations of integrated care models. Though it is possible that response bias occurred due to the fact that patient interviews were conducted while some patients were still in the active portion of the intervention, the interviewer took time prior to each interview to stress that all responses would remain confidential and that patient care would not be affected in any way by the feedback provided. Because the INDEPENDENT trial was designed as an implementation trial, the clinical environment evaluated presents an accurate depiction of the clinic resources made available to patients at a government or private diabetes clinic, and thus, an accurate portrayal of patient barriers to self-management and strategies for overcoming those barriers in India. For example, patients in the intervention arm of the trial had to pay for all medical and transportation expenses outside of the six-monthly research-related clinic visits.

Limitations. Though a wide range of contexts were examined in this study, it is possible that other contexts not identified here may trigger mechanisms related to patient self-management. A challenge of this evaluation was differentiating between mechanisms associated with depression versus diabetes self-management. Because there is alignment between the lifestyle modifications used to support improved mental health and cardiometabolic outcomes

(Gelenberg et al., 2010; American Diabetes Association, 2018), CCs targeted both health outcomes with the same behavioral interventions, leveraged in different ways. The use of individualized approaches in this model of care, therefore, did not allow for the separation of self-management outcomes in this evaluation. While patients were specifically asked about changes in their health behaviors relative to diabetes and depression separately, as well as the resources and support that made those changes possible, this study is unable to determine if the functioning of the identified mechanisms would change if depression and diabetes self-management behaviors were examined as distinct outcomes. The investigator's ability to measure patient participation was limited due to technical issues experienced by CCs when using the decision support software and electronic health records (DS-EHR), the software used to record patient data at each visit. Without reliable records of the number of patient contact points over the intervention period, patient interviews could only be used to identify patients' self-reported attendance and patients' motivation to participate and sustain engagement. Additionally, because this study is limited to patients enrolled into the INDEPENDENT trial, it is possible that patients excluded from the trial may have different experiences if engaged in this model of care. Future work should explore how co-morbid conditions that impact cognitive and physical functioning (e.g., dementia, stroke, kidney disease) alter patients' strategies and present new barriers to or opportunities for accessing care.

Conclusion

Identifying the underlying mechanisms that motivate patients to engage in integrated depression and diabetes care will help promote its continued use, while outlining the patient activation process can help providers leverage influential contextual factors and supporting mechanisms to promote sustained behavioral change among patients. By identifying the

resources, both non-material and material, that support patient and provider engagement in the INDEPENDENT care model (e.g., patient case review sheets, provider support systems, access to reduced or free medications) the revised program theory presented can help in the allocation and optimization of clinic resources required in future efforts to implement integrated depression and diabetes care. While these findings reflect the operational context of urban diabetes clinics in India, the abstracted mechanisms within a realist program theory aim to be transferable to other settings with shared features (i.e., low-resource diabetes clinics seeking to integrate depression treatment using the INDEPENDENT care model) (Pawson & Tilley, 2004). The revised program theory presented provides a basis from which future studies on integrated depression and diabetes care, occurring in different contexts, can test and refine CMOCs linked to patient engagement and activation.

Table 3.1 Hypothesized Context-Mechanism-Outcome Configuration (CMOC)

CMOC	Context	Inputs (I) and Mechanisms (M)	Outcomes
1	When patients face barriers to health services and medication, lack social support, have limited health literacy, and depression is a stigmatized condition	If the patients are provided with 6-monthly travel reimbursements and intensive quality care at no additional cost (I), then patients will be empowered (M)	To attend clinic visits and self-manage one's conditions

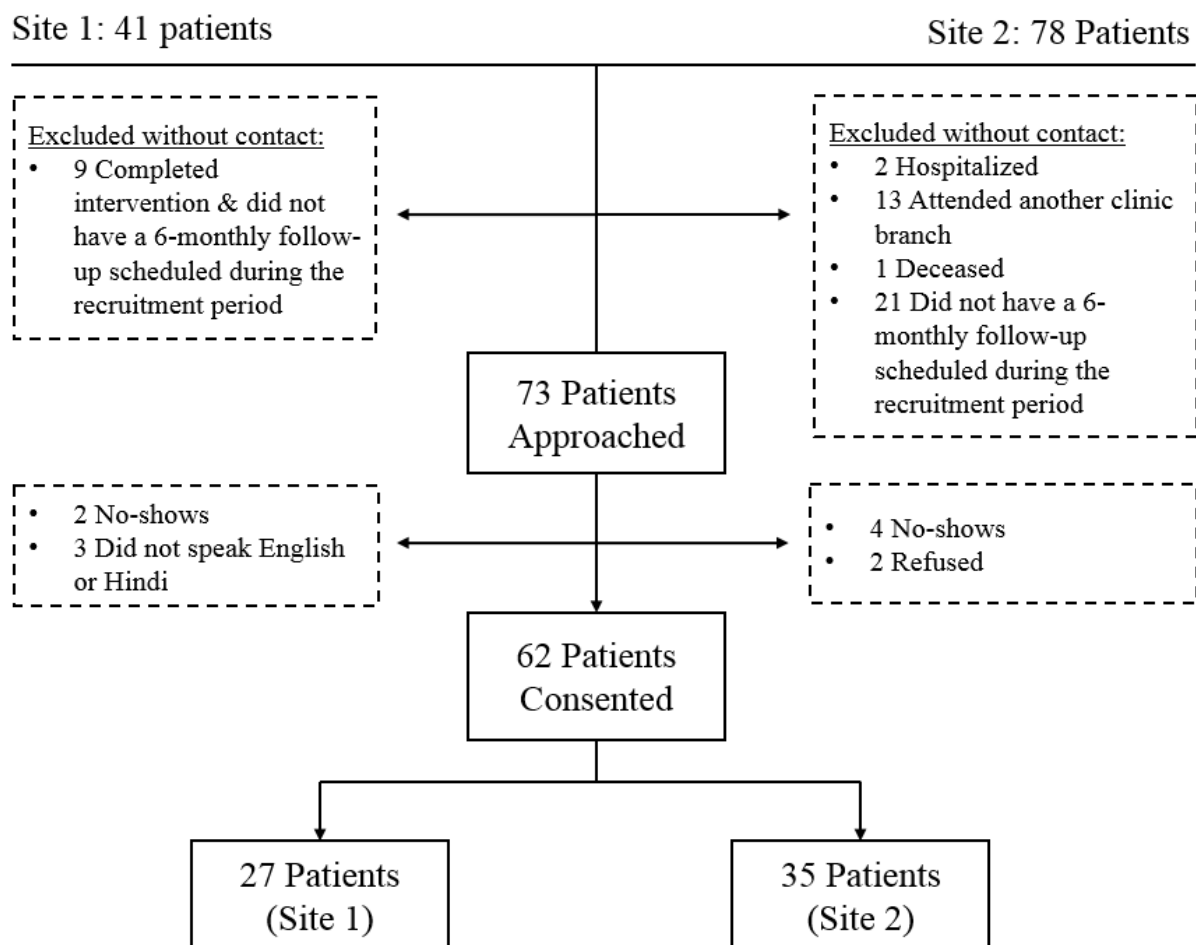Figure 3.1 INDEPENDENT Evaluation Study Recruitment

Figure 3.2 Revised Program Theory

Inputs, Mechanism, & Contexts

If CCs engage patients and their family members by including them in the process of setting health goals and identifying strategies to overcome barriers to attaining those goals (I) when patients have low income, limited social support, constraining schedules, and other health conditions (C), then patients will actively partner with CCs to (M)...

If the patients are provided with 'VIP' treatment, intensive quality care at no additional cost, and low-cost or free medication and glucometers (I), and patients do not have conflicting schedules or health conditions that restrict travel (C), then patients will be motivated (M)...

If comprehensive health education is provided (I) to patients with low health literacy (C), then patients will feel educated with the knowledge and skills to (M)...

If patients are motivated, engaged, and educated through counseling and coordinated care, then they will be activated and have the confidence to (M)...

If patients observe improvements in their health and well-being as a result of self-management behaviors and engagement in the integrated care model (I) when they previously had uncontrolled diabetes and depressive symptoms, and are satisfied with their medication regimen (C), then they will be further motivated to (M)...

Outcomes

To attend clinic appointments

To self-manage their depression and diabetes

Legend ⟶ Impact of contexts and mechanisms on outcomes

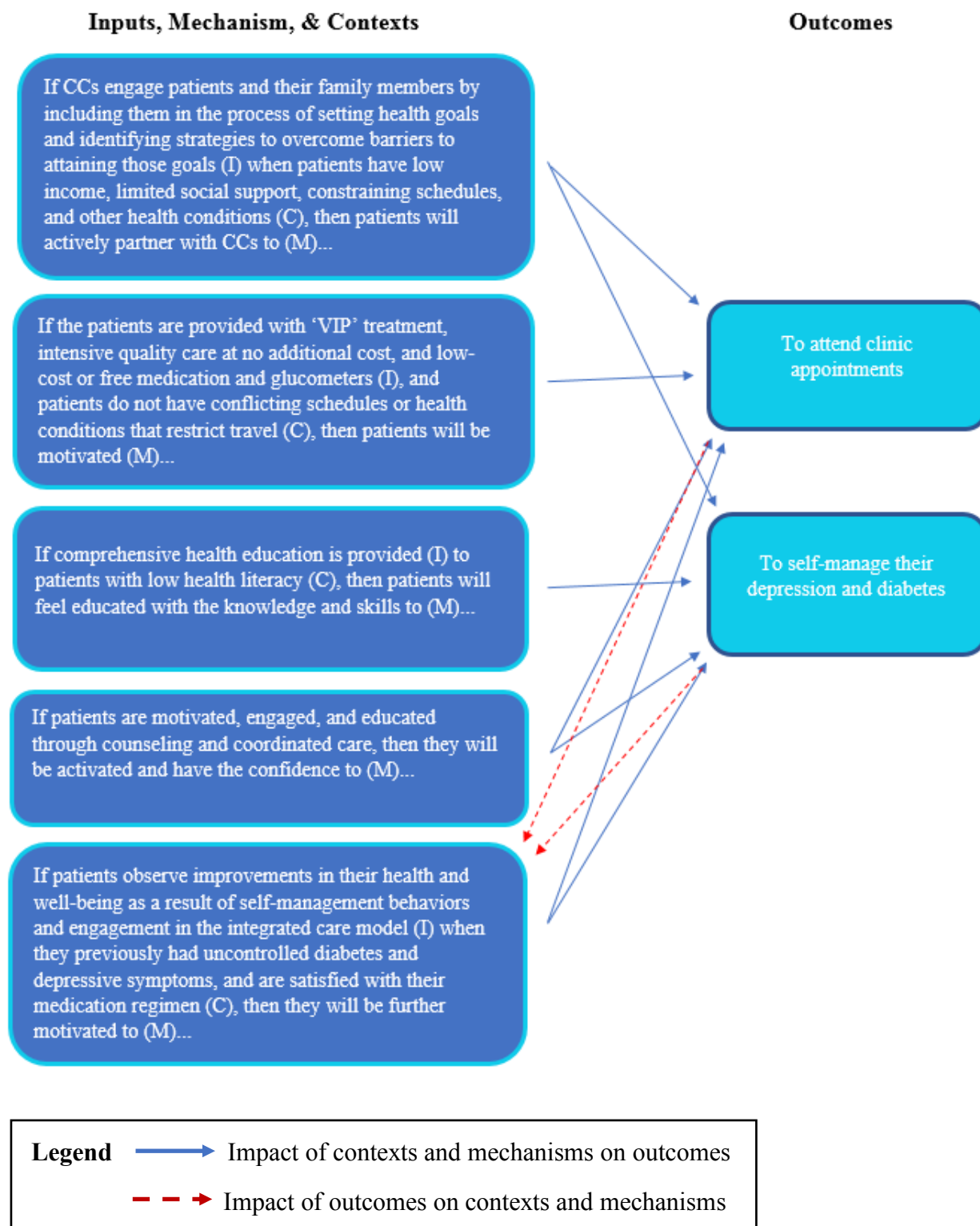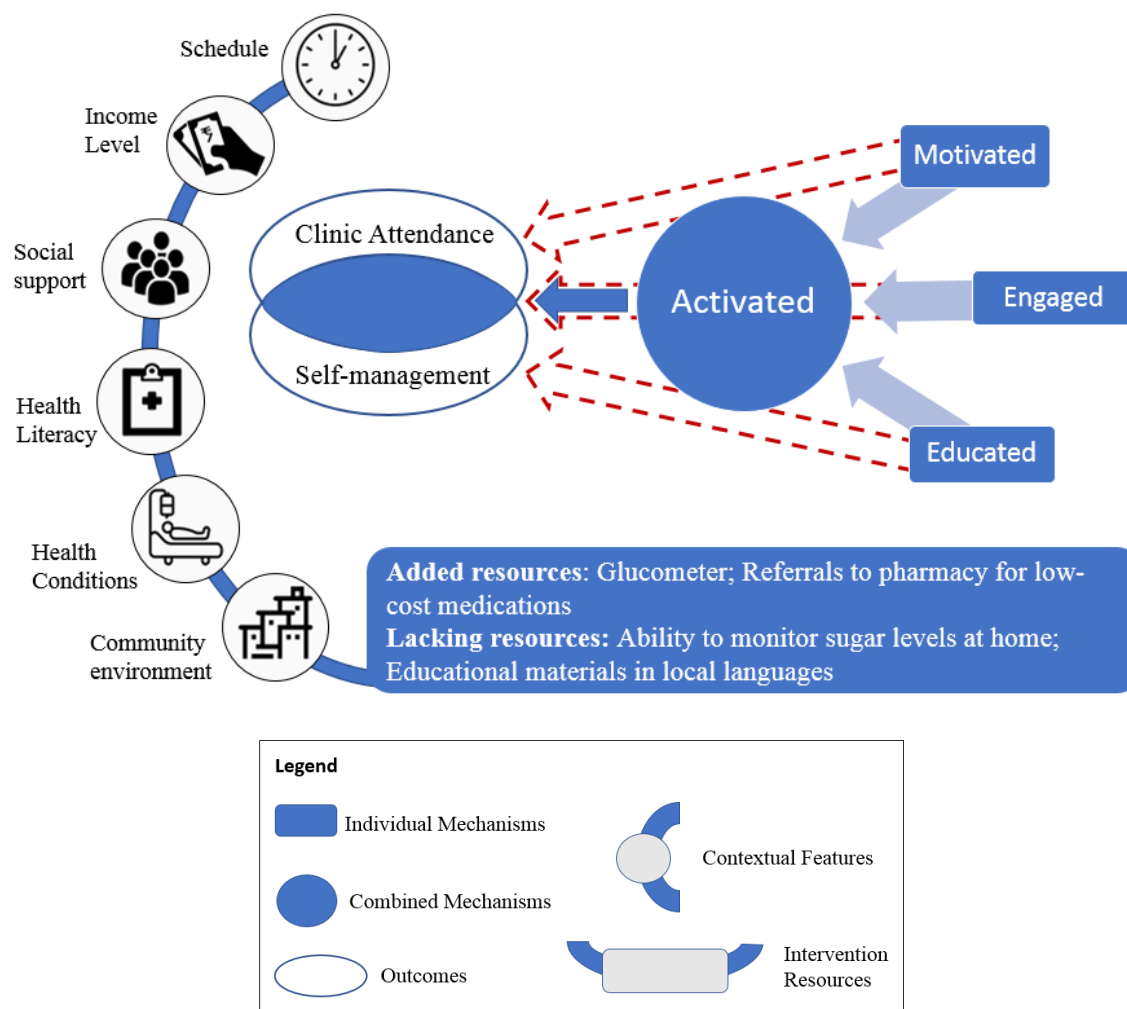⇢ Impact of outcomes on contexts and mechanisms

Figure 3.3 Patient Participation and Self-management Related Contexts, Mechanisms, and Outcomes

The evaluation data are depicted according to the realist evaluation concepts of contexts, mechanisms, and outcomes. This diagram displays the contextual features and resources that determined whether patients participate in the INDEPENDENT care model and self-manage their diabetes and depression.

Table 3.2 Characteristics of VIP Treatment

Characteristic	Site 1	Site 2
Cost effective	"Outside, the fees of doctors are more; the drugs are costly without any doubt. The hospitals are private. If one wants to get admit[ted] there, then charges are very high. It is governmental here; a small amount can get your work done."	"I will be treated freely here. If I get treated [at another clinic] I have to pay. As I am not wealthy enough I did not go [to another clinic]."
All-inclusive	"I don't have to roam around. I simply come here and take my treatment and they take care of me."	"For everything… kidney problem, lungs, eye pain, body pain, headaches, leg pain. Not just treating for one but for all."
Reduced wait time	"She takes me directly to the doctor and I don't have to be in the queue. I come here according to the appointment and with her help I meet the doctor in lesser time than others."	"Here they call us in prior and consult time with us ...so you are happy to meet doctor in scheduled time rather than waiting long."
Fixed appointments	"They call me at a regular time span for checkup. I don't have to worry about making calls to them and asking about my appointments. They are worried about my health more than myself."	"There I have to book an appointment, but here they call me and give appointment. Even if we don't follow up they will follow up… they give good care."
Comprehensive health education	"The best thing is they ask each and everything about my health. If they feel anything important they explain. If I mention anything which I have noticed problematic then they explain. They explain it to me till the time they are convinced that I have got whatever they said."	"From the blood reports they will counsel me what things to do and what should not do. I come here for this reason alone."
Patient advocacy	"Since we cannot speak English, we cannot fully convey our feelings to the doctor, but coordinators help us in that."	"When in doctor's room, she would help me. If I give wrong information, she corrects it."
Well-mannered approach	"They talk very nicely. You know, there are so many places people don't even talk softly. They will be talking to you in a very rude way, almost like scolding. Here it is not like that. I have never felt or faced anything of that kind. Sometimes they scold me, but for the sake of my best interest only. That happens only when I am not following their instruction."	"The patients are looked after with courtesy."

Provider accessibility	"Whenever I call them, whether it is early morning or late night, they pick up my calls. The never told me that it is their personal time or never gave any negative response. Every time they are there for help."	"I got severe pain at 3 am in the morning so I immediately called [the CC]. I didn't know where to go… at that time I got reminded of her and called her."
Outcomes oriented	"One good thing here in [site one] is that everything is monitored by the specialists whereas in other [hospitals and clinics], doctors are more interested in treating the symptoms. They only prescribe medicines to control the sugar level in a very superficial manner."	"If our blood sugar is high they would ask us to work towards reducing it in a good manner. Even if it is my mistake they would encourage me to stay controlled. We don't experience these things [other clinics]. This is also a major reason for being in study."
Family-treatment	"Even [the physician] used to listen to me very patiently...[the CCs] are just like my daughters."	"When they call us to visit [the clinic] I get a feeling of 'home'. They are behaving so humbly and lovingly. They don't treat patients as patients. They treat us like their family member."

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Chapter 4: Practices and Strategies that Differentiate Patients Who Achieved the Highest and Lowest

Reduction in Depressive Symptoms through Engagement in an Integrated Depression and

Diabetes Care Model

Abstract

There are few, if any, data from low- and middle-income countries regarding how patients respond to integrated care models that are aimed at improving self-care via counselling and treatment services. The aim of this study was to identify factors that enable patients receiving integrated depression and diabetes care in urban diabetes care centers in India to reduce their depressive symptoms. The study explored the personal experiences of patients who most (i.e., positively deviant) and least reduced their depressive symptoms during the active intervention phase of the INDEPENDENT trial. Seven patients who had most improved and six patients who had least improved were identified from among patients who were randomly assigned to participate in the INDEPENDENT care model at two trial sites. In-depth interviews and a treatment timeline review were conducted and analyzed using a realist approach to thematic analysis. Patient health data was extracted from the electronic health records system to compare baseline cardiovascular disease risk factors among patients. Positively deviant patients identified five factors that helped them effectively reduce their depressive symptoms: holistic diabetes self-management, knowledge about diabetes as a manageable disease, patient self-advocacy, employment of mental health coping strategies, and care coordinator support. Insights from the comparison group stress the importance of educating patients about the mind/body connection and how diet, exercise, and medication adherence are inter-related. Findings from this study suggest that efforts to reduce depressive symptoms among patients participating in this form of integrated care need to go beyond conventional self-management counseling. Care coordinators should make explicit the link between mental and physical health, aid patients in responding to misinformation about diabetes, and promote mental health coping strategies.

Introduction

There is evidence of a bi-directional relationship between diabetes and depression, indicating that individuals with diabetes are at risk for developing depression and that individuals with depression are at risk for developing diabetes, experiencing diabetes-related complications and treatment non-adherence (Mezuk, Eaton, Albrecht, & Golden, 2008; Pan et al., 2012; Yu, Zhang, Lu, & Fang, 2015; Rotella & Mannucci, 2013; de Groot, Anderson, Freedland, Clouse, & Lustman, 2001; Gonzalez et al., 2008). Among people with diabetes, it is estimated that 10% of people also have clinically significant depressive symptoms and nearly a third have subclinical depressive symptoms (Ali, Stone, Peters, Davies, & Khunti, 2006; Anderson, Freedland, Clouse, & Lustman, 2001; Hermanns, Kulzer, Krichbaum, Kubiak, & Haak, 2005). The growing global burden of diabetes poses challenges in determining how to effectively screen and treat depressive symptoms among patients, particularly those with uncontrolled cardiovascular disease (CVD) indicators (Shaw, Sicree, & Zimmet, 2010).

Integrating treatment approaches offers one solution to the challenges presented with the rise in co-morbid chronic conditions. Current evidence-based treatment guidelines for diabetes recommend comprehensive medical management (i.e., treating all cardiovascular disease risk factors together) paired with lifestyle modifications, such as physical activity, maintenance of a healthy diet, and medication adherence (American Diabetes Association, 2010). This aligns with the recommended long-term, patient-centered approach to depression treatment (Prince et al., 2007). Despite the knowledge that these diseases impact one another and that there is potential to combine treatment approaches for diabetes and depression, efforts to improve health outcomes among patients with diabetes and co-morbid depression often remain siloed within their respective medical specialties.

In India, the burden of diabetes continues to rise, with approximately 73 million people living with diabetes in 2017 (International Diabetes Federation, 2017). Because India also suffers from a shortage of trained mental health professionals (Bruckner et al., 2011), it serves as an ideal setting to test integrated treatment models that can expand access to mental health services, improving both cardio-metabolic and mental health outcomes among patients. This study seeks to identify what practices and strategies helped distinguish why some patients succeeded in improving their psychological wellbeing and others did not, among those engaged in the INDEPENDENT care model.

The INDEPENDENT Care Model

The INtegrating DEPrEssioN and Diabetes treatmENT (INDEPENDENT) care model provided depression treatment within the diabetes care platform in India. To be enrolled in the INDEPENDENT trial, patients had to present with clinically-significant depressive symptoms (Patient Health Questionnaire [PHQ-9] ≥10) and one or more poorly-controlled CVD risk factor(s) (HbA1c ≥8.0%, SBP ≥140 mmHg, or LDL-c ≥130 mg/dl) (Kowalski et al., 2017). Any patient who indicated a high risk of suicide (a "3" on the PHQ-9 suicide item) was excluded.

Depression management was tracked throughout the one-year active intervention period by administering the PHQ-9 at each interim patient visit; the depression results were used alongside laboratory results to determine individualized patient treatment plans. Using a web-enhanced decision-support electronic health record (DS-EHR) system, care coordinators (i.e., non-specialized health educators who are supervised by a psychiatrist) in the INDEPENDENT trial monitored patients' depressive symptoms and CVD indicators. This allowed care coordinators (CCs) and usual care diabetes physicians (UCDPs) to determine frequency of follow-up visits for each patient, in addition to highlighting what areas of patient chronic disease self-management (e.g., diet, exercise, medication adherence, glucose self-monitoring, and

smoking cessation) they should focus on with each patient. The DS-EHR also provided UCDPs with care prompts for medication intensification and signaled CCs to engage in behavioral therapy with patients. The DS-EHR care prompts were generated from evidence-based treatment algorithms, which the UCDPs could choose to accept or modify. Only those patients who indicated suicidal ideation were immediately referred to the site psychiatrist for intensive psychiatric care.

Based on formative work carried out for the INDEPENDENT trial, which revealed that patients may not be receptive to integrated counseling and treatment due to diabetes and depression-related stigma (Rao et al., 2016), it was hypothesized that not all patients in the INDEPENDENT trial would fully engage in mental health counselling or achieve reductions in their depressive symptoms. Since all patients received the same opportunity for diabetes and depression health education and individualized treatment through this trial, a positive deviance approach was selected to better understand how differences in mental health treatment outcomes arise when patients are engaged in depression treatment in a non-psychiatric specialty care setting.

The Positive Deviance Approach

The positive deviance approach involves studying uncommon cases of individuals' successes as models for how to achieve positive outcomes despite adversity (Lapping, March, & Rosenbaum, 2002). This methodology has been widely used to address health issues and achieve health services quality improvement across a variety of settings, with applications in low- and middle-income countries (LMICs) (Zeitlin, Ghassemi, & Mansour, 1990; Baxter, Taylor, Kellar, & Lawton, 2016). While this approach was initially used to identify group-level (e.g., family and community) characteristics that differentiate individual health outcomes (Lapping et al., 2002), it has since been used in HIV/AIDS research to study individual-level factors associated with risk

behaviors (Friedman, Mateu-Gelabert, Sandoval, Hagan, & Des Jarlais, 2008; Save the Children Federation, 2002). Additionally, a study conducted by Ma and Theall (2013) successfully used the positive deviance approach to explore factors that enabled immigrant women with mental disorders to access mental health services, compared to those who had mental disorders who did not utilize mental health services (Ma & Theall, 2013). These applications suggest that this approach is well suited for identifying points of intervention that could enhance access to and delivery of mental health services.

The flexibility of the positive deviance approach and its focus on identifying health promotion practices among high-performing individuals provides an opportunity to identify creative, contextually relevant solutions to current depression treatment barriers among a high-risk population in India. By investigating differences between those who stay depressed and those who reduce their depressive symptoms over time, this methodology can identify what circumstances, practices, and strategies enhance patients' ability to reduce their depressive symptoms while self-managing their diabetes. This study seeks to address the following research questions:

- *How do patients who have achieved the highest reduction in depressive symptoms during the INDEPENDENT trial differ from patients who have least improved?*

- *What factors enable the patients in the high-reduction group to reduce their depressive symptoms?*

Methods

In order to better understand the factors that promote depression management among patients with uncontrolled diabetes, this study employed a positive deviance approach. Interviews were conducted with patients who were successful in reducing their depressive

symptoms. Patients who demonstrated the lowest reduction in depressive symptoms were identified and interviewed as a comparison group. Patients from both groups were identified using interim patient health data from the DS-EHR software.

Sample

Recruitment. Patients were recruited from two INDEPENDENT study sites that differed in geographic location. Study implementation practices (i.e., the number of CCs employed, the frequency of case reviews, the level of involvement of the specialist endocrinologist and psychiatrist, and the degree of training and support made available to CCs and UCDPs) varied between the two locations. Patient experiences engaging in the integrated diabetes and depression care model also differed according to whether patients had lower waiting times, received low-cost or free medications, or were provided with a glucometer and/or literacy-appropriate educational materials.

Patients approached for participation in this study were identified separately at each of the two sites through the following procedures: (1) a complete patient list including baseline and the most recent PHQ-9 scores was generated from data recorded in the DS-EHR software, (2) for each individual patient a percent difference in PHQ-9 scores, from baseline to the most recent clinic visit, as of September 2016, was calculated, (3) patients were ranked according to the calculated scores, and (4) those patients in the top and bottom 10% were identified (i.e., approximately 4 from site one and 8 from site two) in order to recruit three patients in each category. Site two had another clinic branch outside of the main diabetes center where patients were seen as a part of the trial. Those patients were eliminated from the final list for this sub-study because they had a different clinical experience in the trial and potentially experienced different barriers and facilitators to accessing mental health counseling and treatment.

Once this process was completed, CCs attempted to contact the identified patients to invite them to participate in this study. Altogether, 16 patients were approached. Two patients refused participation due to lack of time and one patient was unable to be contacted in the selection process; all three of these patients were in the bottom 10% brackets at their respective clinics. If a patient refused to participate the CCs continued down the ranked patient list. All patients recruited for this study fell within the extreme arms of each site, and at least three patients were successfully recruited from each site's extreme arms. At site one, the top 10% bracket had four patients tied for the first ranking so all four were invited to participate. Figure 4.1 provides a breakdown of patient recruitment for this study across both sites.

Sample Description. Patients (n=13) were identified from within two of the four urban diabetes care centers participating in the INDEPENDENT trial, one government hospital in northern India (site one) and one private diabetes center in southern India (site two). Patients were categorized into two groups (referred to throughout as the extreme arms): (1) those patients demonstrating the greatest improvement in reducing depressive symptoms, as measured by the 9-item Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001; Spitzer, 1999), and (2) those patients demonstrating the least improvement in reducing depressive symptoms. Patients were eligible for selection if they were assigned to the intervention arm of the INDEPENDENT trial at either of the two aforementioned sites and had been enrolled into the trial for a minimum of three months, in order to ensure patients had been in the trial long enough to engage in the diabetes and depression counseling and treatment for more than one clinic visit. The average baseline PHQ-9 score among patients with the most improvement was 12.4 and among patients with the least improvement the average baseline PHQ-9 score was 11.83, with a combined average of 12 and scores ranging from 10-16.

Interview Procedures

Two interviewers who were non-clinic staff members were trained, one at each site. The interviewers were from the local communities of each site, and were bilingual in English and the predominant local language (i.e., Hindi, Tamil) of their respective cities. Both interviewers completed in a two-day training conducted by LJ on the intervention care model, the conduct of in-depth interviews, the realist evaluation framework, transcription practices, and qualitative coding procedures, prior to starting data collection at either site. Interviews were conducted by the bilingual interviewers with LJ present, and LJ provided guidance on how to probe using individualized patient treatment timelines throughout each interview. The total of 13 two-on-one interviews across both sites were conducted from September 2017 to May 2018.

Written consent to participate and audio-record the interview was obtained from all participants prior to the start of each interview. The interviews were broken into two segments. The first segment entailed completion of the process evaluation interview guide, inquiring about patients' experiences with the integrated care model (see Chapter 3). The second segment consisted of a timeline review of each patient's life events and health behaviors throughout the active intervention period up to the time of the interview. Patients were presented with a print out of their PHQ-9 scores over time created by the DS-EHR software. This timeline was used to direct conversations with patients about what was occurring in their lives between interim clinic visits (see Figure 4.2 for sample timelines). On average, it took patients 1-1.5 hours to complete both segments.

The research was conducted with approvals from the respective Institutional Review Boards of Emory University, USA, and the All India Institute of Medical Sciences and Madras Diabetes Research Foundation, India.

Qualitative Data Preparation and Analysis

All interview audio-recordings were transcribed verbatim directly from Hindi or Tamil into English. Once a transcript was complete, it was de-identified. A realist approach to thematic analysis was conducted whereby the focus of the coding was on capturing a hypothesized reality that is present in the data (i.e., that patients were responsive to the counseling and treatment plan provided by their respective CCs and UCDPs), in addition to identifying inductive topics (Pawson & Tilley, 1997; Pawson & Tilley, 2004). Two evaluation team members independently coded the data, first conducting open coding and then consolidating codes into succinct labels that relate to depression and diabetes self-management behaviors and treatment. All coded material was compared for discrepancies. While some variation in word choice for code names occurred, upon discussion, the coders found that they were using different terms to describe the same phenomenon. No discrepancies were identified that could not be resolved through this process. LJ then identified broader themes among groups of codes that provided insight into how and why patients differ, both between extreme arms and across study sites.

DS-EHR Data Extraction Process

The DS-EHR system records patient health information from both the 6-monthly study visits and the interim visits, which are scheduled on a patient-by-patient basis according to their individualized health needs. PHQ-9 scores were extracted from the software in order to select patients for this study. In addition, cardiovascular disease risk factors (i.e., blood pressure, A1c, and LDL) for each interviewed patient were extracted for a baseline comparison of patients across extreme arms.

Results

The mean age of participants was 52 (SD=6.1), with a minimum age of 41 and maximum of 62. Of the participants, 8 (61.5%) were male and 5 (38.5%) were female. Figure 4.3 displays

the PHQ-9 scores for all interviewed patients at baseline and their last clinic visit prior to initiating the patient selection process. The breakdown of patients in each extreme arm according to their depression, glycemic, lipid, and blood pressure control status at baseline is visually depicted in Figure 4.4. The assigned control statuses were designated by the treatment algorithms input into the decision support software. As a group, positively deviant patients had a greater proportion of patients with moderate depression (28.6% vs. 0%) and poorly controlled lipid levels (85.7% vs. 66.7%), while the comparison group had a greater proportion of patients with poorly controlled glycemic levels (100% vs. 85.7%) and poorly controlled blood pressure (33.3% vs. 14.3%).

Patient responses fell into two themes that varied by extreme arm: (1) self-management behavior, and (2) mental health treatment seeking and self-care practices. These themes are described in further detail in the below sections.

Self-Management Behavior

All positively deviant patients reported following the advised lifestyle modifications, which include maintaining a healthy diet, increasing physical activity (i.e., walking), and adhering to prescribed medications. Dietary restrictions posed the greatest challenge for all patients, though, as many reported festivals and weddings as occasions where it was difficult to avoid eating sweets. On a daily basis, positively deviant patients avoided eating food outside of the home (e.g., street vendors and restaurants) in order to reduce intake of oily, fried foods and sugar, namely from tea purchased from roadside shops, but public celebrations required them to alter their strategies for managing their diabetes. The primary strategies employed under those circumstances were to eat less food or only accept food items that comply with the recommended diet. One patient explained:

>After counselling, I eat only what I should, even at celebrations. Just two idly [rice cake] or one dosa [rice and black gram pancake] and sweet a little. I would just reject it. Even at my relative's wedding celebration I would ask them to serve me limited. I would not say that I have diabetes.

These individuals attributed their dietary compliance to self-control. Patients in the comparison group acknowledged that they often disregarded the advised diet in order to indulge in foods that they craved, despite knowing that they were detrimental to their health.

It was commonly understood among positively deviant patients that diet, exercise, and medication adherence collectively impact diabetes control. After explaining the importance of the provided diet chart, one patient shared, "It happens that if a person is on medication and if he is not following diet pattern then the medicines don't work," a notion that further motivated him to maintain a healthy and consistent diet. Because of the perceived relationship between these self-management practices, patients overcompensated in other aspects of their lifestyle modifications on those occasions where they did consume sugar. For example, one patient explained, "when I eat sweets I eat less next time and take a walk, in order to balance the ill effect of sweets." This was in contrast to patients in the comparison group who believed that they could eat anything because the medication would counteract the effects of a poor diet and lack of exercise. One patient in this group had recently come to learn that this was flawed logic, reflecting, "I also used to eat anything along with the treatment...this is the common attitude that [you can] eat everything and medicine too." The difference in patients' understanding of how medication works in relationship to diet and exercise altered how they approached their self-management practices.

Positively deviant patients were motivated to comply with the advised behavior changes because they were aware that their diabetes could be controlled. Similarly, patients in the comparison group also acknowledged this fact, however, only one patient in this group complied

with all of the recommended lifestyle modifications, while others either did not practice any or

complied only with medication adherence. Where extreme arms did vary was in how they

interpreted the fact that diabetes is a disease that can be managed, with positively deviant

patients differing in that they believed diabetes could be cured. One positively deviant patient

stated, "I have told my sister that there is cure for [diabetes]. I control [diabetes] by exercise and

weight loss," when elaborating on how she responds when people tell her that diabetes is a death

sentence. Disease self-management was understood among these patients as a part of the process

of curing diabetes. A number of patients across both extreme arm groups recognized that

diabetes is now common in India or considered it a condition that was fated. In those cases,

patients were open to sharing their diabetes diagnosis with friends and family. Several

individuals across both groups, however, had previous experiencing disclosing their diabetes

status in which individuals responded negatively and as a result did not feel comfortable telling

people that they were living with diabetes. Patients in the comparison group who could not hide

their condition because they were taking insulin simply chose to ignore that people treated them

differently. Positively deviant patients, however, let other people figure out that they had

diabetes and then educated those individuals who responded negatively based on misinformation.

One patient shared how she had to educate some of her relatives about the ways in which

diabetes can be controlled when they noticed she was avoiding sweets and guessed that she had

diabetes. She explained:

> People look at diabetic people differently. They say, 'You have diabetes? That's
> it, you can't survive it.' I have heard lots about it. If diabetes occurs then our life
> has ended. They would not know that we can control it. They don't know much,
> and hence, I don't attempt to share my diagnosis. Only the doctors and some of
> my relative is aware. I have told my sister that there is cure for it.

In order to overcome the stigma of a diabetes diagnosis, patients take on the onus of responsibility to educate those around them about the condition. Patients reported that they felt if they were more educated about diabetes they could be more forthcoming about their diabetes diagnosis. Additionally, after being educated about diabetes, some family members and neighbors were more observant of the individual's diet and scolded him/her if he/she deviated from the advised diet in their presence.

All patients were advised to walk daily for exercise, yet barriers to physical activity kept all but one patient in the comparison group from adopting this lifestyle change. Patients in this group suffered from other health conditions (e.g., chikungunya, arthritis, tuberculosis) that limited their mobility, had work schedules that kept them from exercising when they came home, or were deterred by the heat. Positively deviant patients overcame these obstacles by taking medications for pain management prescribed by their UCDP, integrating physical activity into their daily routines (e.g., taking the stairs, biking to work, walking to shops), and exercising outside before sunrise or after sunset. For example, one patient shared, "My life is very busy. If I work late till 2 in the night, the next morning I get up at 6 and, after morning walk, I again get back to work." After receiving counseling as a part of the INDEPENDENT trial, positively deviant patients had a new perspective on physical activity and described walking as a "compulsory" part of their day.

All but one patient stated that they adhered to their medication, with patients in the comparison group reporting that they took medications at the wrong time or skipped several days of a medication each month because one prescription ran out before their other prescriptions did. It was a common belief that medications were too expensive, although only one patient identified this as the reason he could not obtain medications. Positively deviant patients who encountered

this barrier informed their CC and/or UCDP so that their medication could be altered or a referral for free medication could be provided. One patient shared, "I told the doctor myself that the medicines he prescribed to me are very expensive and won't be able to afford them. So, he changed the prescription and gave some other medicines that are cheaper." Patients had to advocate for themselves in order to get accommodations made that would allow them to continue getting medications that they or their family members could not afford to purchase without the accommodations. The one patient in the comparison group who adopted all of the self-management behaviors reported doing so for her daughter's sake. This patient overcame financial barriers to purchasing medication by taking a loan out from the pharmacist. Cross-cutting issues that remained were medication adherence when patients traveled and taking medications at the correct times throughout the day when patients had to leave the house for work.

Mental Health Treatment-Seeking Behaviors and Self-Care Practices

While patients, overall, did not understand the link between diabetes self-management and depression, positively deviant patients expressed that there was a link between physical and mental health. As one patient who was successful in reducing his depressive symptoms summarized, "As long as my health is with me, I cannot be depressed." At the same time, these patients recognized that if they dwelled on their diabetes and resulting health complications then they would never be able to recover. These patients were, therefore, more open to taking medications that could help calm their mind in an effort to better control their diabetes. In recounting how she felt after starting to take anti-depressants, one patient exclaimed, "Now I am happy! Earlier I would not care much about me, even if head ache I would not take tablet for it. But now I take regular medication so that I could live." Patients who believed that there is a bi-

directional relationship between physical and mental health (i.e., positive deviants) actively

sought support from a healthcare provider and tried to use mental health coping strategies when

they felt low.

Patients across both extreme arms varied in how they approached mental health treatment

and self-care, largely based on how they defined depression. Patients considered depression to be

either a disease, or a naturally occurring state of mind that would resolve itself. Those patients

who classified depression as a disease were adamant that they had never suffered from

depression, while it was common among those that perceived it to be a natural form of mental

suffering to state that they had previously and/or currently experienced this state of mind.

Regardless of how people defined depression though, the majority of patients did not feel it was

appropriate to tell other people, many even refusing to confide in family members, if they were

struggling with feeling sad, low, or stressed. Patients felt that sharing their emotions with others

would not help them; therefore, disclosing this sensitive information would only make one

vulnerable to criticism and taunting. Positively deviant patients who did not rely on family

support found ways to distract themselves from whatever was triggering their poor mood (e.g.,

family crisis, financial loss, ailing health) because they believed if they could control their

emotions or forget their problems then their tension would pass without negatively affecting their

health. One patient shared that she exercised to keep from dwelling on negative thoughts,

explaining "When I go alone I will chant God's slogans and walk to omit such unnecessary

thoughts." Patients named exercise, prayer, meditation, television, and laughter as mental health

coping strategies. Patients in the comparison group were sometimes able to temporarily cope

with their depressive symptoms, but they most often reported dwelling on negative thoughts and

worrying about what would happen to them and their family members if their health failed in the future.

      None of the patients in either extreme arm reported having received educational materials or counselling specific to depression. When patients were asked to describe what depression was they often deferred to what they had heard others describe it as and used that as a basis for determining how it could be managed and whether medical treatment would prove effective. Positively deviant patients who did not identify as having depression had never considered seeking treatment for their tension prior to engaging in counseling with the CCs, while those in the group that did identify as having depression were motivated to join the trial because they anticipated learning mental health coping strategies. Though it was common among positively deviant patients to feel reluctant to engage in counseling at first, many reported that as they came to trust their CCs, they felt relieved when they could share their troubles with a health care professional who could advise them on how to problem-solve and calm their mind. By the end of the active intervention period, many echoed one patient's appreciation for the counseling provided through this trial: "When they do counseling I will pour out my heart. That one is good, quite relieving." Patients in the comparison group did not feel comfortable discussing their emotional issues with the CCs. Only one patient expressed a desire to meet with a psychiatrist because he felt the psychiatrist was more qualified to handle his mental health treatment. As a whole, those attending the clinic in northern India explained that seeking support for depression or tension was useless, because only the person suffering had the power to help themselves. On the other hand, patients attending the clinic in southern India did not feel the need to seek treatment for their depressive mood as they believed it was caused by the heat or fated; neither of which are modifiable.

Discussion

The positive deviance approach has previously been used to determine how to increase mental well-being (Ma & Theall, 2013; Singhal & Dura, 2017). This study contributes to this emerging body of literature by examining what barriers are present when patients are actively engaged in a depression treatment model and how patients and health care providers can respond to effectively overcome those barriers. Additionally, this study takes place within a context of integrated diabetes care, which provides contextual information that can aid in identifying missed opportunities for aligned depression treatment, problem-solving, and patient counseling.

Through this study, strategies and practices have been identified that help patients reduce their depressive symptoms while managing their diabetes. Figure 4.5 provides a summary of key characteristics that differentiate patient groups across the themes of patient self-management behavior and mental health treatment seeking and self-care practices. Overall, positively deviant patients differ from the comparison group in that they report engaging in diabetes self-management practices and depression self-care, and feel comfortable discussing mental health with CCs. Positively deviant patients avoided the stigma attached to diabetes by not sharing their diagnosis, when possible, and reframing negative perceptions of diabetes when encountered. Positively deviant patients largely avoided eating outside of the home and either limited their food intake during celebratory occasions if they did not want to have to disclose that they suffer from diabetes or were prepared to correct potential misinformation about living with diabetes if the topic were to arise. Informing and educating support persons about diabetes added another source of accountability for patients struggling to consistently practice diabetes self-management. All patients did, however, recognize diabetes as a life-threatening disease and, as such, believed medication adherence was vital. Positively deviant patients relied on available

support systems to ensure that they had the financial means to purchase their medication. Positively deviant patients also integrated exercise into their daily routine and made walking a priority. Lastly, these patients found activities that diverted their attention from their negative thoughts and came to view the CC as a trusted resource; one that was considered more accessible and appropriate to discuss family, work, and emotional problems with among their team of health care providers.

The findings from this study complements previous research on stress and depression in India by identifying the circumstances under which patients are not receptive to integrated mental health care and documenting ways in which patients have discovered to overcome barriers to depression management and treatment seeking. A multi-site pre-implementation study conducted to assess the acceptability of using non-specialist health workers to deliver mental health care in five LMICs, including India, found that service providers and potential users were receptive to community and primary care-level mental health care if supervision and medications were provided (Mendenhall et al., 2014). While the INDEPENDENT care model integrated depression treatment at the tertiary care level, there was a clear division between patient groups as to whether individuals were receptive to this model as a source for mental health treatment. With additional counselling about the link between physical and mental health, patients may be more receptive to engaging in mental health treatment in a non-psychiatric tertiary care setting.

Researchers have advocated for the consideration of social and cultural beliefs when examining diabetes self-care practices in India (Mendenhall, Narayanan, & Prabhakaran, 2012), and findings from this study demonstrate that diabetes self-management and mental health treatment-seeking behaviors are both impacted by cultural and religious beliefs regarding the role of God and fate in the on-set of illness. Patient education about depression in this context

requires acknowledging these beliefs and re-orienting individuals to health behaviors that can help them manage their condition. One potential tool to motivate patients to improve their mental health and CVD indicators is the treatment timeline graph used to conduct patient interviews in this study. While this tool was used to minimize recall bias, patients appreciated seeing their health trajectory and periods of progress. One patient even noted that their CC had previously shown him the graph of another patient who had started with the same poorly controlled glucose levels and yet had improved through strict self-management practices, which encouraged him to put more effort into his self-management practices.

This study was strengthened by the fact that baseline CVD indicator data were available on patients, alongside data on their trajectory of PHQ-9 scores. Patients who were less successful in reducing their depressive symptoms had worse baseline glucose levels. This may be attributable to the fact that hyperglycemia has been linked to the development of diabetic complications that adversely affect an individual's bodily functioning and quality of life (Ohkubo et al., 1995; UKPDS Groups, 1998), thus those with higher glucose levels had to overcome more challenging issues that arise from developing more severe complications. Alternatively, patients with the least improvement in depressive symptoms reported that having other health conditions negatively impacted their physical activity levels, which can result in higher depressive symptoms and poor blood glucose control (Dinas, Koutedakis, & Flouris, 2011; Strohle, 2009; American Diabetes Association, 2003). Though studies have found that exercise, including fast-paced walking, has positive effects on depression and blood glucose management (Colberg et al., 2016; Hu et al., 1999; Dinas et al., 2011), more research is needed on the optimal type, duration, and frequency needed to prove beneficial for patients based on their health condition and the presence of diabetes-related complications.

Future research should confirm this study's findings in a larger study, as these data could help narrow the process of identifying high-risk individuals most in need of mental health treatment within the diabetes care setting. The practices and strategies of positively deviant patients could then be used as a basis for enhancing patient counseling, since patients in both groups reported the same barriers to mental health treatment and diabetes self-management. Of the discussed self-management behaviors, medication adherence was perceived to be the most important across all patients. Studies of patients with diabetes in India have documented medication adherence rates between 47.9-57.7% (Mukherjee, Sharmasarkar, Das, Bhatacharyya, & Deb, 2013; Medi, Mateti, Kanduri, & Konda, 2015), with the top identified barriers to adherence being cost, forgetfulness, and being busy. While it was not possible to determine adherence rates for these patients, findings from this study of INDEPEDENT trial participants found the same primary barriers to taking medication. Positively deviant patients demonstrated that when patients actively self-advocate for themselves and tap into their support networks, medication adherence can be enhanced. Future studies should seek to identify patient strategies for taking medications on time and under the circumstances of busy schedules and travelling for long periods of time, since no patient in this study had managed these circumstances well.

This study was subject to several limitations related to the selection of participants and the examination of depression self-management practices. Because the INDEPENDENT trial recruitment occurred according to different timelines across and within the two sites, patients were not guaranteed to have been active in the intervention for the same period of time prior to being considered for participation in this study. Additionally, in a small number of cases the final patient study visit was conducted several months after the intended close out date, due to challenges getting the patients to return to the clinic. As a result, two of the least improved

patients had only been in the trial for six months or less, while the remaining patients had either nearly completed, completed, or were post-completion of the active intervention year. Because a patient's depressive symptoms are not static, it is possible that selecting patients at a different cut-off date could have resulted in different patient groupings. The PHQ-9 timelines for the selected patients who completed the active intervention period or who were near the end showed that the first several months in the trial had the greatest instability in depressive symptoms. This suggests that patients who were engaged in the care model for longer than three months would have likely been on the same positive or negative trajectory with only small deviations in PHQ-9 scores. While some patients may have fallen outside of the limits of the extreme arms if selected at different time points, the identification of common practices and strategies within the extreme arms demonstrates that these practices are likely shared more broadly among patients, based on whether they improved or not. Self-management of depression could not be explicitly discussed as different than diabetes self-management because patients were not counselled in that manner. Therefore, patients could not discuss how their mental health was impacted beyond having a counsellor who listened to them and helped problem-solve.

There are a number of considerations that arise from these findings. Despite having the same barriers as those patients who least improved their depressive symptoms, patients with the most improved depressive symptoms were able to identify and implement strategies that enabled them to self-manage their diabetes and practice mental health self-care. These strategies should be highlighted in future efforts to disseminate and scale an integrated depression and diabetes care model in urban diabetes care centers in India. Several modifiable provider- and clinic-level areas for improvement were also highlighted, offering points of intervention. UCDPs can provide pain-management options, when appropriate, to enhance patients' ability to maintain

their physical activity routine, in addition to identifying outlets for exercise aside from walking. CCs can inquire about a patient's need for reduced or free medications, so that a pharmacy discount can be applied or appropriate referrals can be provided. These medications should be prescribed as a monthly refill, with multiple medications being filled at the same time, when possible. Lastly, patient education can be enhanced to target misconceptions that promote poor chronic disease self-management and treatment-seeking behavior. Depression should be emphasized and described in relationship to diabetes self-management. In addition, the reinforcing relationship between different self-management behaviors should be explained and encouraged.

Conclusion

Much of the scientific literature on protective processes for mental health have, to date, focused on the concept of resilience (Davydov, Stewart, Ritchi, & Chaudieu, 2010). While similar in function to positive deviance, resilience research primarily focuses on identifying individual personality traits that contribute to resilience (Rutter, 1985; Masten, 2001), whereas positive deviance seeks to identify protective strategies and practices that provide modifiable points of intervention (Friedman et al., 2008). Through the process of assessing shared barriers and comparing patterns in chronic disease self-management and mental health treatment-seeking behaviors between patient groups, this paper provides concrete approaches to reducing depressive symptomology that can be highlighted in the diabetes care setting. Alternatively, the identified provider- and clinic-level barriers can be intervened upon directly. As the non-communicable disease burden continues to rise among low-income populations that are already impacted by infectious disease, a positive deviance approach has the potential to provide unique insight into how patients approach complex disease management produced by syndemic

suffering (e.g., patients with diabetes and co-morbid depression and one or more infections including chikungunya, tuberculosis, or malaria).

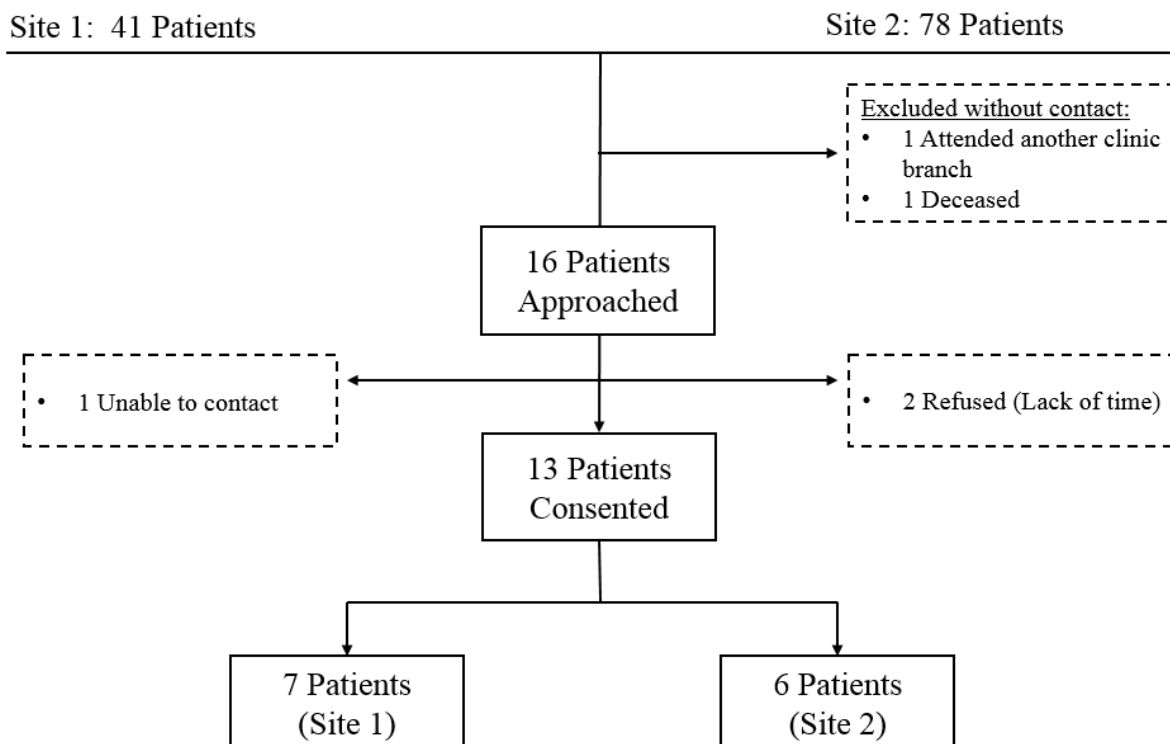Figure 4.1 Extreme Arm Patient Recruitment

Site 1: 41 Patients

Site 2: 78 Patients

Excluded without contact:
- 1 Attended another clinic branch
- 1 Deceased

16 Patients Approached

- 1 Unable to contact

- 2 Refused (Lack of time)

13 Patients Consented

7 Patients (Site 1)

6 Patients (Site 2)

Figure 4.2 Example Timelines for Extreme Arm Patients in Both Groups

1. Timeline for a patient who was least improved
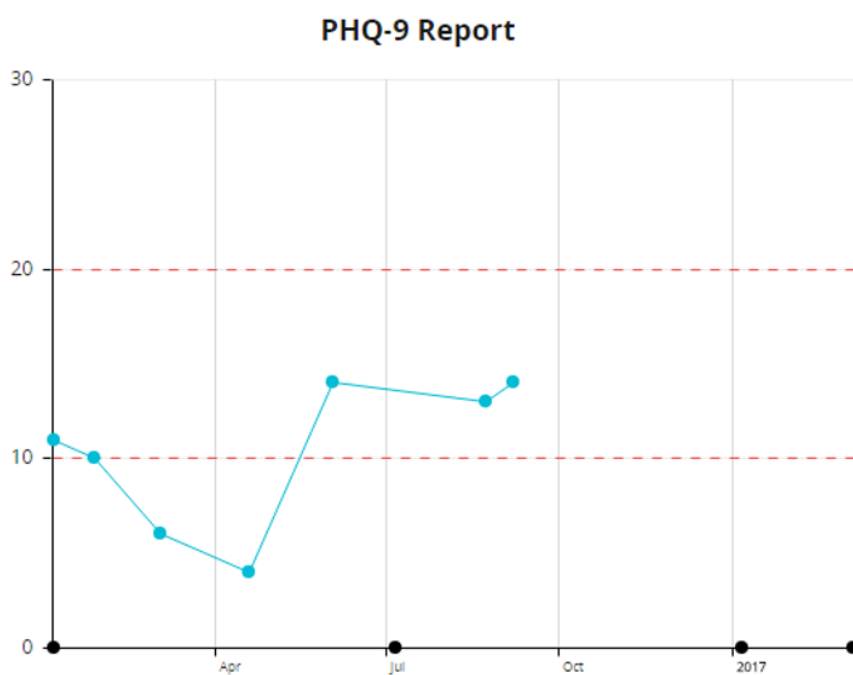
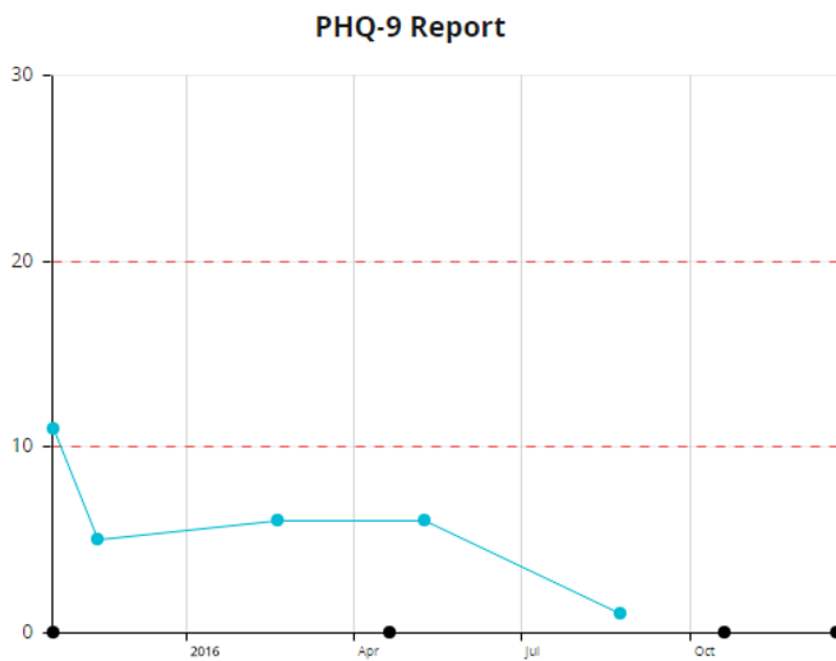**2. Timeline for a patient who was most improved**

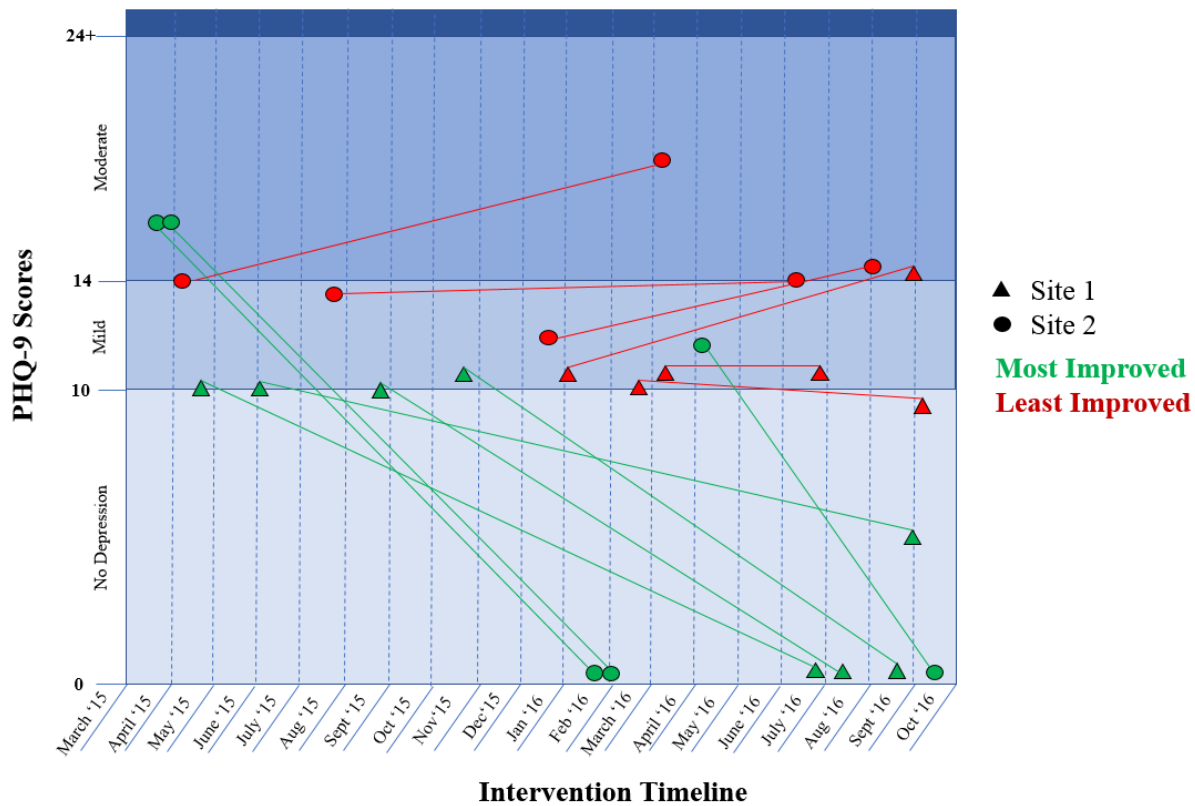Figure 4.3 Depressive Symptoms among Extreme Arm Patients Over Time

Figure 4.4 Patient Health Outcomes among Extreme Arms Patients across Both Sites at Baseline
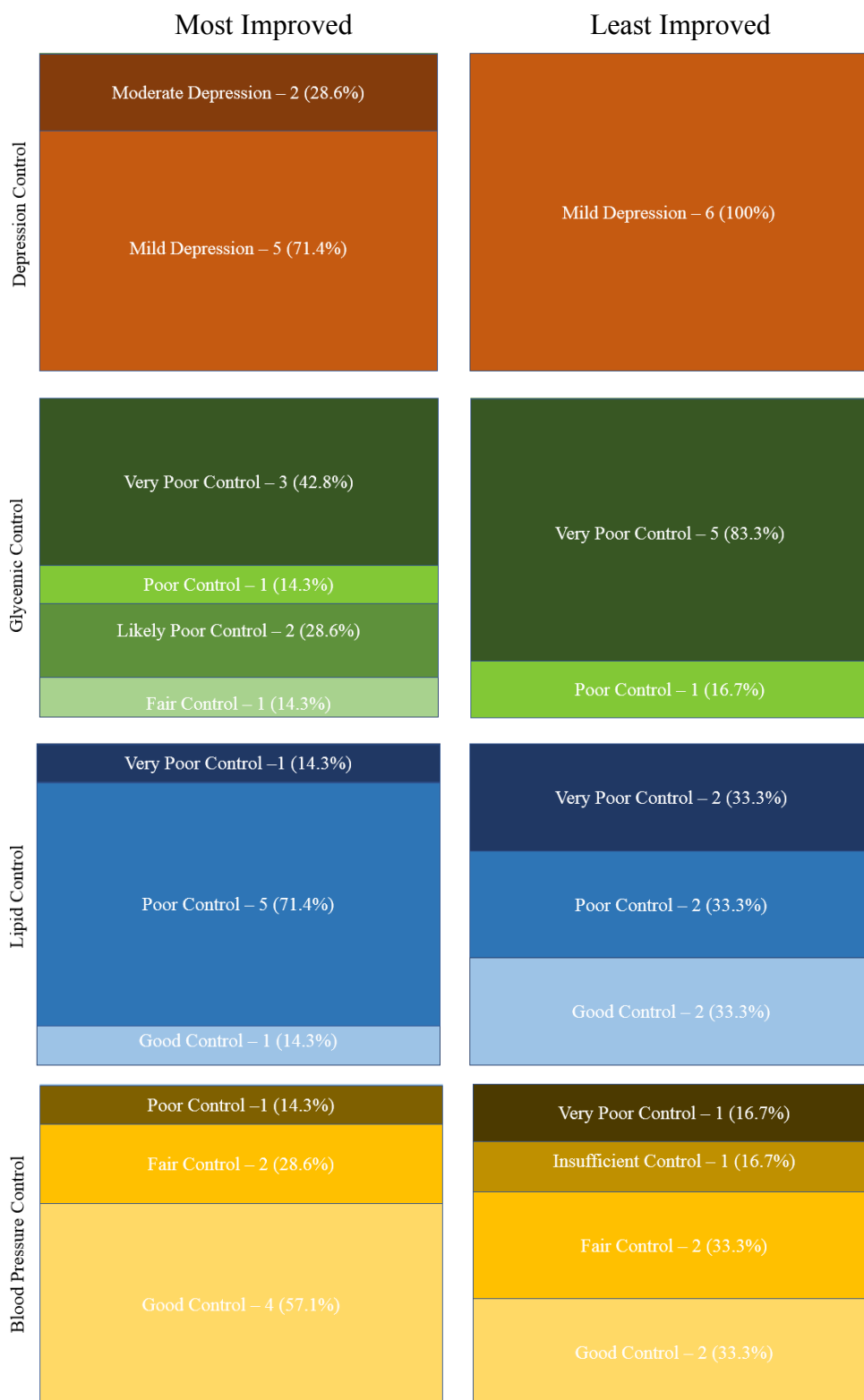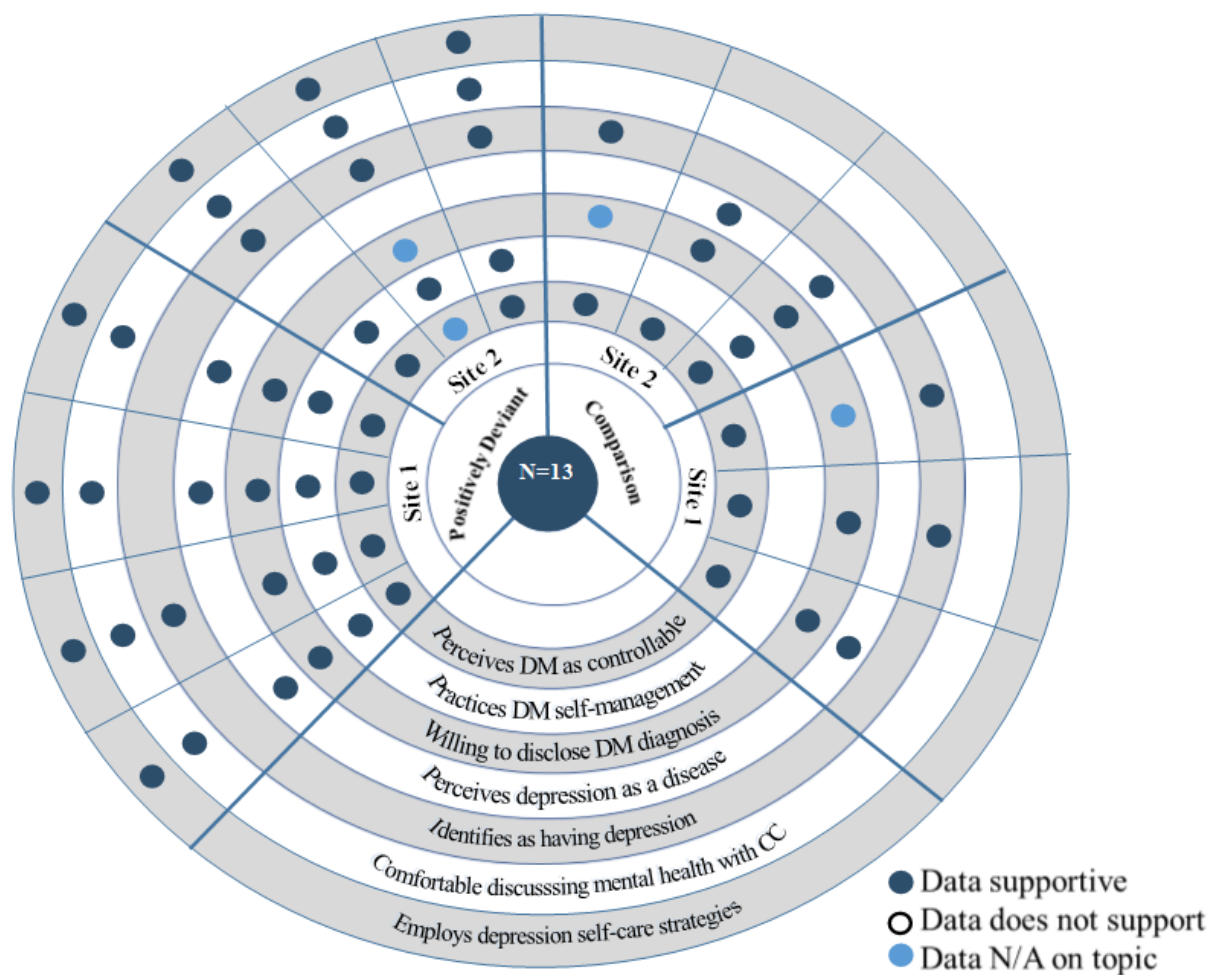
Figure 4.5 Spectrum Display of Data from Thematic Issues

Chapter 4 References

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Chapter 5: Overall Summary and Conclusions

There is a need to better understand how mental health care can be integrated into non-psychiatric care settings globally. With a growing mental health treatment gap in low- and middle-income countries (LMICs) (Patel et al., 2016; Patel, 2007; World Health Organization, 2015), many countries now seek to implement innovative task-shifting approaches that expand access to mental health services across a variety of care settings (World Health Organization, 2015; Patel et al., 2013; Rebello, Marques, Gureje, & Pike, 2014). In India, these task-shifting approaches largely occur in the community and primary care settings (Patel et al., 2011; Patel, 2008; Patel et al., 2010; Maulik et al., 2017; Nimgaonkar & Menon, 2015). Lay health workers either provide basic health education while identifying and referring individuals with psychiatric problems to a community hospital, or they operate in a stepped care model in which they are trained and supervised by a mental health specialist to provide psychosocial interventions (Patel et al., 2010; Patel et al., 2008; Cohen et al., 2011; Shinde et al., 2013; Arya, Flynn, Rojas, Fritsch, & Simon, 2006). In addition to this model of service integration at the primary care level, there are tertiary care settings that can be utilized to target patients who have a greater risk of developing depression because of their co-morbid health conditions.

The tremendous burden of diabetes in India creates one such opportunity to integrate mental health treatment where patients at risk of developing depression access care (Pan et al., 2012; International Diabetes Federation, 2017), and in doing so, improve their ability to self-manage their diabetes. To date, only one trial has sought to test the effectiveness of an integrated depression and diabetes care model in India, the INDEPENDENT trial (Kowalski et al., 2017). Variations of integrated depression and diabetes care have been tested, but exclusively in high-income countries, with no indication of how such a model would operate in low-resource settings (Katon et al., 2010; Katon et al., 2004; Katon et al., 2010; McGregor, Lin, Katon, 2011;

Coventry et al., 2012; Bogner & de Vries, 2010; Bogner, Morales, de Vries, & Cappola, 2012; Coventry et al., 2015). There is a general lack of evaluation linked to integrated care models (Shinde et al., 2013; Busetto, Luijkx, Huizing, & Vrijhoef, 2015; Knowles, Chew-Graham, Adeyemi, Coupe, & Coventry, 2015; Ling, Brereton, Conklin, Newbould, & Roland, 2012), leaving a limited understanding of how they are implemented, perceived by providers and users, and adapted for use. Gaining a deeper understanding of how different actors engage with the INDEPENDENT care model would ensure that this model of integrated mental health care is acceptable, manageable, and adaptive to the needs of different clinical settings in a LMIC.

The purpose of this dissertation was to increase the overall understanding of how transferrable a Western model of depression treatment was to the diabetes care platform in India. Convergent, parallel, mixed qualitative and quantitative methods were used to provide a comprehensive depiction of the implementation of the INDEPENDENT care model. Together, the three research aims forming the basis of this dissertation provide an in-depth portrayal of the INDEPENDENT trial from multiple stakeholder perspectives, each of which lends insight into the complexities of providing depression treatment in urban diabetes care centers in India. The results of this dissertation not only demonstrate that this model of care is feasible in low-resource settings where stigma around mental illness persists, it suggests that patients and health care providers are receptive to this form of mental health treatment, but must be provided the resources (e.g., peer support systems, health care communication training, wireless internet, laptop computers, private counseling areas, structured patient case review forms, integrated scheduling capability with the decisions support software) to overcome role-specific challenges to fully embracing this model of care. CCs' lack training on how to educate patients about depression within the context of the diverse religious and cultural beliefs that exist around mental

illness in India. Usual care diabetes physicians (UCDPs) do not have adequate training on how to communicate with patients about depression and other mental health conditions, while patients do not feel it is appropriate to waste physicians' time disclosing their reasons for feeling depressed, or discussing any barriers to diabetes self-management. It should also be noted that in this trial the CCs experienced several issues with the decisions support and electronic health records (DS-EHR) system that made this component a less prominent actor than was initially intended. Future work using decision support software should seek to improve functionality based on the findings from this study and examine how improved variations are received and integrated into clinic practice.

The three studies composing the body of this dissertation use a realist evaluation approach to examine the implementation of the INDEPENDENT trial (Chapter 2), patients' experiences engaging in the INDEPENDENT care model (Chapter 3), and how patients differ in their ability to overcome barriers to chronic disease self-management while receiving the INDEPENDENT care model (Chapter 4). The study presented in Chapter 2 identified the resources, mechanisms, and contextual factors necessary to integrate depression treatment into the diabetes care setting in India by interviewing the CCs, UCDPs, and specialist endocrinologists and psychiatrists involved in the INDEPENDENT trial. The study presented in Chapter 3 interviewed providers and patients receiving the INDEPENDENT care model to identify the factors that determine patients' motivation to engage in an integrated depression treatment model and self-manage both their diabetes and depressive symptoms. Triangulated with data from the DS-EHR, clinic observations, and patient satisfaction surveys, context-mechanism-outcome-configurations (CMOCs) related to UCDP and CC confidence, CC empowerment, psychiatrists' comfort providing treatment oversight, and patient participation

and self-management practices were tested and refined in Chapters 2 and 3. Lastly, the study

presented in Chapter 4 identified patient practices and strategies that enabled patients receiving

the INDEPENDENT care model to reduce their depressive symptoms and self-manage their

chronic conditions. Patients who had the most and least improvement in depressive symptoms at

the time of the study were identified and, together with extracted patient health data from the

DS-EHR, interviewed in order to compare self-management practices and strategies for

overcoming barriers to self-care. Together, these three studies provide a comprehensive process

evaluation of the implementation of integrated depression and diabetes care in urban diabetes

care centers in India.

Implementation of Mental Health Treatment

The study presented in Chapter 2 tests and refines the hypothesized causal mechanisms

underlying the INDEPENDENT trial in relationship to contextual factors present in the Indian

health care setting. This study found that the CCs took on a more active role in monitoring,

counseling, and finalizing mental health treatment plans for patients than was intended. This is

consistent with the findings presented in Chapter 3, where patients described the CCs as a

reliable source of support who listened to their problems, helped them identify solutions and

opportunities for self-care, and advocated for them to their UCDPs when they encountered

obstacles purchasing or taking prescribed medications. Though most of the focus was on diet and

exercise to improve patient's diabetes self-management, patients noted an improvement in mood

and outlook on life after being educated about diabetes and self-management practices. Chapter

4 further emphasizes that utilizing the CCs as a resource in times of medical crisis or stress is

critical to improving mental health outcomes, as it was one of the factors that differentiated

positively deviant patients from those who had least reduced their depressive symptoms. All

three studies identify the rapport building process between a patient and the CC as an essential, on-going process that continues to motivate and engage patients in their treatment plan.

The results of the study in Chapter 2 also suggest that CCs need private spaces to meet with patients in order to effectively administer the Patient Health Questionnaire (PHQ-9), inquire about personal health and family situations, and counsel patients about mental health coping strategies. CCs modified their patient data collection methods (i.e., used a combination of paper and electronic patient in-take forms) so that they were able to consult with patients in whichever available space offered the most privacy on a given day, despite the fact that this often created the need for double data entry. The impact of this clinic barrier to privacy was raised by patients in the study in Chapter 3. In cases where privacy was not able to be accommodated, patients expressed frustration that other patients and clinic staff could overhear their medical information and responses to the questions posed by the CC. This was particularly important when patients were accompanied by a family member to whom they did not feel comfortable disclosing their emotional problems or, in some instances, who were the source of their stress at home.

Impact of the clinical environment on patient motivation and engagement. Aspects of the clinic environments observed in Chapter 2's examination of mechanism triggers and enablers of implementation outcomes were also identified as factors that influenced patient motivation to participate in the INDEPENDENT care model. Specifically, patients were motivated to participate when they realized that they were able to avoid waiting in lengthy, crowded patient lines. Over time, they were further motivated by the familial relationships they established with the CCs. These findings support the results of studies of healing environments, which have found that the physical healthcare environment affects the well-being of patients (Dijkstra , Pieterse, & Pruyn, 2006). A study recently conducted in the United States found that

patients' overall satisfaction with their healthcare experiences was impacted by the quality of service delivery, atmospherics, physical design, and ability to navigate the facility (Suess & Mody, 2017).

Self-reported patient satisfaction, on average, was high across both study sites and patient interviews revealed that atmospherics of the healthcare environment and service delivery were two important factors that influenced both patient satisfaction and well-being. A patient's inability to physically sit or stand in line for hours posed challenges to accessing care. Physicians also noted negative patient responses when the active intervention was over, with patients exhibiting signs of distress at the prospect of having to return to the standard of care (i.e., having to schedule their own appointments and wait in the regular patient lines). This study furthers this body of literature by illustrating new dimensions to the domains of atmospherics, physical design, and service delivery that are characteristic of clinical settings in a LMIC. Atmospherics should assess crowdedness and physical design should capture perceptions of space and privacy. Considerations of service delivery have to go beyond whether the staff are perceived to be polite, helpful, and informative, and evaluate the quality of relationships staff have formed with patients.

Chronic Disease Self-Management

The results of the study in Chapter 3 suggest that patient motivation, engagement, and education, combined, enable patients to actively participate in their disease self-management and apply knowledge and skills that they acquired over the course of treatment and counselling. Results from Chapter 3 revealed that the focus on depression education was inconsistent across patients, but that problem-solving techniques were used to tackle broader issues that shaped patient experiences managing both their diabetes and depressive symptoms. The components of

motivation, education, and engagement align with how patient activation is described in the Patient Activation Measure (Hibbard & Greene, 2003; Hibbard, Stockard, Mahoney, & Tusler, 2004; Insignia Health, 2018), with an added emphasis on the importance of reducing various individual-, interpersonal-, and community-level barriers in order to build patient self-efficacy. With evidence that low self-efficacy strongly relates to low levels of self-management and diabetes-related quality of life (Glasgow, Toobert, & Gillette, 2001), counselling techniques focused on working around perceived barriers and obstacles, such as goal-setting and action planning, should be prioritized. It should be noted that the barriers identified across all three studies are not unique to LMICs. Patients' social support, health literacy, knowledge about their medical conditions, busy lifestyles, financial resources, co-morbidities, lack of disclosure about experiences of depression, environmental and cultural factors have all been identified as barriers to self-management among different patient populations living with multi-morbidities worldwide (Glasgow et al., 2001; Pamungkas, Chamroonsawasdi, & Vatanasomboon, 2017; Nam, Chesla, Stotts, Kroon, & Janson, 2011; Pun, Coates, & Benzi, 2009; Rustveld et al., 2009; Ward, Stetson, & Mokshagundam, 2015; Ridosh, Roux, Meehan, & Penckofer, 2017; Bayliss, Steiner, Fernald, Crane, & Main, 2003; Bayliss, Ellis, & Steiner, 2007). Health care providers' communication skills, resources, time, and confidence to provide support for patients' psychosocial needs are also documented barriers to supporting patients' chronic disease self-management (Nam et al., 2011; Russell et al., 2018). This body of work does, however, provide a conceptualization of how different mechanisms operate together and in the presence of one or more contextual features, as outlined in the revised program theories in Chapters 2 and 3.

Perceptions of the mind-body connection. A factor that shaped the development of effective mental health coping behaviors among positively deviant patients was the belief in a

mind-body connection. Patients received educational information regarding different components of self-care, but those patients who understood there to be a relationship between mental and physical health were inclined to try and maintain all self-management practices (i.e., diet, exercise, and medication adherence). Other integrated depression and diabetes programs have focused on the mind-body connection, using relaxation sessions, yoga sessions, and group discussions on the interrelationship between mental, physical, emotional, and spiritual health in their health programs, but have not assessed their impact on diabetes self-management practices (Anderson et al., 2007). Future integrated diabetes and depression interventions should stress the link between mental and physical health and seek to assess its value in promoting patient self-management practices.

Leveraging social support. The study in Chapter 3 notes that patients had mixed feelings about who was an appropriate source of emotional support, with varied perspectives on the role of family members in helping an individual suffering from depressive symptoms. A number of examples were provided by patients and CCs alike in the studies in chapters 2 and 3, documenting the added value of involving family members in patient counseling sessions on diabetes self-management. Patients occasionally requested the presence of a particular family member, such as the person who was in charge of cooking meals or buying medicines, so that self-management behaviors could be more easily followed in the home environment. While this has been shown effective in helping patients manage their diabetes (Pamungkas et al., 2017), and even advocated for by patients in the formative work conducted for the INDEPENDENT trial (Rao et al., 2016), results from this body of work show that family engagement, while effective in re-enforcing medication adherence and diet change, may not be appropriate for depression counseling. Patients felt that their condition was either fated or a burden that no one could help

them resolve. No patient reported having previously sought mental health treatment, but a number felt that being offered the opportunity to participate in this trial would provide them with mental health counseling that addresses the unique challenges faced patients with diabetes. CCs came to be recognized by most as people who would listen to her/his problems without judgement, as opposed to family, friends, and neighbors, who might perceive an individual with depression as weak or unstable. CCs in this trial worked closely with patients to establish trust and knowledge of their home life before inviting family members into counseling sessions, but were largely guided by the patients in deciding who it was appropriate to invite to the clinic for counseling and under what premise.

Health communication. The diversity in patient responses regarding depression diagnosis, disclosure, and treatment seeking behaviors captured in the study in Chapter 3 were further explored in Chapter 4, in order to identify patterns in patient behaviors and practices as they relate to patient mental health outcomes. The study presented in Chapter 4 provides clear distinctions between self-management strategies and treatment-seeking practices employed by patients who were most and least successful in reducing their depressive symptoms. The findings in Chapters 2 and 3, that depression education and self-care strategies were not explicitly named or differentiated from diabetes self-management practices in the provided counselling sessions, called for a closer examination of what patients' perceptions of diabetes and depression were and how they changed patients' approaches to self-management practices and treatment seeking behaviors. With known barriers related to stigma around diabetes and depression in India (Rao et al., 2016; Khandelwal, Jhingan, Ramesh, Gupta, & Srivastava, 2004; Hofmann-Broussard, Armstrong, Boschen, & Somasundaram, 2017; Gaiha, Sunil, Kumar, & Menon, 2014; Chadda, Agarwal, Singh, & Raheja, 2001), positively deviant patients were found

to be active in responding to misinformation about diabetes when it was negatively directed towards them, and seeking support from CCs in times of emotion distress. This proactive behavior was carried forward in patients' diabetes self-management strategies as patients advocated for reduced cost medications, sought medical consultations with their physicians when symptoms of other medical conditions inhibited self-care, and asked to have family members involved in diet counselling and education sessions. While the majority of patients across both groups reported that they had not shared their mental burdens with friends or family, only the positively deviant patients felt that the CCs could teach them ways to calm their mind if they participated in the trial. These patients were open with CCs when prompted with questions, and independently found ways to divert their minds from the sources of their stress outside of the clinic. Together with the finding from the study in Chapter 1 that UCDPs do not feel comfortable asking patients about their depressive symptoms, it is evident that neither the patients nor the providers wish to initiate conversations about mental health. To bridge this gap, future interventions need to address providers' communication strategies for engaging patients in conversation about mental health conditions and treatment.

Medication Adherence. The study in Chapter 4 found that patients with the least improvement in depressive symptoms reported only trying to self-manage their diabetes with medication, yet many were unable to overcome barriers to adherence. Findings from this body of work identified a number of barriers to medication adherence that are consistent with previous research on diabetes self-management. Financial constraints, obtaining refills, and comprehension of the treatment regimen and its benefits are recognized barriers that were also found to be applicable in this population and setting (Nam et al., 2011; Jerant, von Friederichs-Fitzwater, & Moore, 2005; Rubin, 2005; Odegard & Gray, 2008), though additional issues, such

as having family members with chronic health conditions and being a support person for extended family members, were raised by patients in this study. Whereas previous work has documented patients halving their dosages to reduce medication costs (Jerant et al., 2005), patients in this trial, as reflected in Chapter 3, frequently reported only purchasing what they perceived to be the most important medication when they could not afford all of their medications. Since many patients in this study had multiple conditions for which they took medication and had family members with the same conditions, the strategies for working around these recognized barriers differed.

The effective self-management strategies and practices outlined in Chapter 4 provide evidence that it is possible for patients to overcome barriers to diet, exercise, and medication adherence in order to self-manage their conditions. This is critical, given evidence that individuals with more severe depressive symptoms perceive greater barriers to medication adherence and that the odds of a depressed patient's being non-adherent are nearly two times the odds of a non-depressed person (Chao, Nau, Aikens, & Taylor, 2005; Grenard et al., 2011). The identified strategies offer points of intervention to strengthen patient health education. For example, this body of research adds to the literature on chronic disease self-management by pinpointing misconceptions about the function of medication as a de-motivator for self-management practices. Positively deviant patients understood that medication worked in conjunction with a healthier diet and exercise regimen to improve their physical health, which, in turn, improved their mood. In contrast, patients whose depressive symptoms did not change or worsened felt they could continue with their current lifestyle if they took their prescribed medications. The study in Chapter 2 examined patient motivation from the providers' perspectives and found that UCDPs were more concerned with influencing patients' perceptions

of the benefits of medication. UCDPs found it beneficial to delay medication initiation or

dosages increases if the patient had demonstrated substantial decreases in glycemic, lipid, or

blood pressure levels, as they had had patients stop following strict diabetes self-management

once they found out they were going to have to take medication regardless of their behavior

changes. Future integrated care models should move beyond demonstrating the benefits of

prescribed medications to educating patients about medication adherence in the context of other

self-management practices.

Implications for Future Research

The results of the study presented in Chapter 2 have considerable implications for

implementation research regarding integrated care models, particularly in LMICs. The study

suggests that CCs can assume the role of a mental health counselor, but they may experience

symptoms of secondary traumatic stress or compassion fatigue, as has been documented among

other mental health professionals (Cieslak et al., 2015; Cocker & Joss, 2016; Robinson,

Clements, & Land, 2003). This intervention did provide CCs with bi-monthly technical

assistance calls with TEAMcare implementers following an initial training and subsequent

refresher training. On-site supervision, however, was largely limited to interactions with the

psychiatrist at the case review meetings. Distance-delivery supervision and pyramid supervision

models have been used widely in task-shifting models of care (Patel et al., 2011; Yaya, Kouanda,

Kouyate, Hounton, & Adam, 2013; Agyapong, Osei, Mcloughlin, & McAuliffe, 2016; Zachariah

et al., 2009; Ogedegbe et al., 2014). However, given evidence that in taking on a counselling

role, CCs also become vulnerable to the same mental health consequences as those faced by

trained mental health professionals, this model of supervision may lead to poor mental health

outcomes among CCs, and as a result promote burnout (Cieslak, Douglas, Melville,

Luszczynska, & Benight, 2014). Shifting the fulcrum of mental health care to CCs requires a greater diversity in the mechanisms by which support is provided (e.g., sources of support, format of interaction, proximity, frequency, duration) in an integrated care model. Variations across the sites in how supplemental support was sought demonstrate, for example, that peer support provided on a daily basis can substitute for more recurrent, in-depth guidance from a trained mental health professional. Furthermore, interviews from the site psychiatrists found that psychiatrists are also unfamiliar with how to engage in this model of care and provide adequate support to CCs. Efforts to increase the role of the psychiatrists in supervising CCs outside of case reviews should focus on setting clear expectations and creating structured approaches to debriefing challenging cases.

The limitations of each of the three studies composing this body of research are outlined in their respective chapters, but there are overarching limitations as well. All three studies are subject to response bias. Patients and providers may have minimized negative experiences and overstated positive experiences of implementing or participating in the INDEPENDENT trial. Patients completed a client satisfaction survey and may have overstated their satisfaction with and endorsement of the INDEPENDENT care model. For the patient and provider interviews, participants may have altered their accounts of trial experiences in order to provide socially desirable responses that matched the stated aim of the research study. Patient and provider narratives contained a spectrum of experiences that included both positive and negative reflections on the care model, however, suggesting that the accounts were reflective of the participants' experiences and perceptions of those experiences. Additionally, the researcher's presence in the clinical setting where the observation data were collected may have caused the CCs to have more closely followed the study protocol because they knew they were being

observed. The duration of the observation period, however, allowed the CCs and patients to become accustomed to the presence of the researcher and return to their work routines. Another limitation of this body of work is that the data were collected from only two of the four trial sites, both of which are urban, tertiary diabetes care centers in India. This limits the generalizability of these findings to other urban diabetes clinics in low-resource settings. In this body of work, many of the barriers to chronic disease self-management named by patients are consistent with patient experiences in other care settings and countries (e.g., diabetes self-management in a primary care setting in the United States and in a community care setting in Kenya, chronic obstructive pulmonary disease self-management in a tertiary care setting in Taiwan) (Gleeson-Kreig, Bernal, & Woolley, 2002; Chen, Chen, Lee, Cho, & Weng, 2008; Abdulrehman, Woith, Jenkins, Kossman, & Hunter, 2016). Similarly, CC experiences mirror those of other lay health workers in task-shifting interventions (e.g., health workers with lower qualifications in Ghana, promotoras in Bolivia, community health volunteers in Taiwan) (Gau, Buettner, Usher, & Stewart, 2013; Okyere, Mwanri, & Ward, 2017; Grasso, 2015). These consistencies suggest that the refined program theory produced from Chapters 2 and 3, along with the qualitative findings from Chapter 4, are more broadly applicable.

Conclusion

The studies presented in this dissertation provide a basis for understanding the implementation of an integrated depression and diabetes care model in a low-resource setting. There is a severe lack of evidence in this area, and this body of work presents a comprehensive examination of how different patient, provider, and clinic factors operate together to promote patient chronic disease treatment and self-management, and mental health treatment seeking behaviors in the INDEPENDENT trial. Future integrated depression and diabetes care models

implemented in India, or other LMICs, should test and refine the program theories presented in Chapters 2 and 3, in order to effectively expand the provision of mental health services and improve the quality of integrated diabetes and depression treatment services. Researchers should also seek to explore additional contexts at the clinic and community level. Further research on patient-related factors identified across this body of work need to be examined to better understand patients' motivation and ability to self-manage their diabetes and depressive symptoms. Qualitative studies are needed on how patient rapport is developed by different groups of providers (e.g., CC vs UCDPs). Qualitative studies should also compare differences in patients' self-management practices and depressive symptomology between patient groups who do and do not feel stigmatized for having diabetes. This type of research would lend insight into how diabetes-related stigma may act as a barrier to self-management practices and worsen patient's depressive symptoms. Quantitative studies are also needed to identify the influence of characteristics of the health care environment and service delivery on patient satisfaction, motivation to engage in mental health treatment and counseling, and mental health outcomes. A quantitative study assessing the determinants of patient self-efficacy would also shed light on how to best support patients to be confident in their ability to self-manage their diabetes and depression without being reliant on the CCs. Building upon this dissertation with these types of studies would provide additional evidence that integrating depression and diabetes treatment is feasible and advantageous in improving both health outcomes, in addition to providing a more extensive evidence base from which to continue refining and adapting the INDEPENDENT treatment model for use in low-resource settings.

Chapter 5 References

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