Minimally Disruptive Medicine;
State of the Science and Plan for the Future

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By

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"Long live the walls we crashed through. How the kingdom lights shined just for me and you. I was screaming long live all the magic we made, and bring on all the pretenders; I'm not afraid. Long live all the mountains we moved. I had the time of my life fighting dragons with you."

Long Live, Taylor Swift

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Dedication: Perceptions and reality

People think strength comes from holding on
But it comes from stopping full speed ahead
Blades scraping ice, pushing outside edge
Friction creating grace

People think vision is born center stage
But it comes from the balcony
Atop pointed toes, symphony of bodies
Mistakes creating space

People think joy comes from perfection
But it comes from losing it all
Conditioned, yet physical strength giving out
Adversity creating wholeness

People think love is born at first sight
But it is forged in the trenches
Weight lifted, repetition building physique
Imperfection creating closeness

People think the end of life is death

But truly it is the culmination of living to its fullest
Years of training, at its peak
The end creating new beginnings

People think faith is born in churches
But it is forged in the cold, dark, quiet of morning
Weary soul, ready to go for it again
Nothingness creating everything

You see my friends, this journey’s been long
And while my expertise has increased
These are the real lessons I’ve learned
And whose stories are held within

Abstract

Background

Patients living with multiple chronic conditions, or multimorbidity, represent a growing portion of the adult population. One in four adult Americans, three in four over the age of 65, live with multimorbidity. This population experiences unique challenges, many of which are driven by the way healthcare is delivered. Specifically, patients must cope with the work of being a patient. For patients with a single condition to follow recommended guidelines, the work amounts to approximately two hours per day. However, with multiple chronic conditions, this can quickly become a part- or full-time job for patients and their families. The ability to cope with this work rests on patients' capacity, which is a result of their interactions with their biography, resources, environment, patient and life work, and social network. When this capacity is overwhelmed by the work of being a patient, problems accessing and using healthcare and enacting self-care arise, which if unaddressed can have negative impacts on patients' health outcomes and quality of life. Minimally Disruptive Medicine (MDM) is a philosophy of care, supported by a conceptual model and multiple theoretical frameworks, that seeks to address and remedy problems of patient workload-capacity imbalance. To date, chronic care remains unexamined in light of the principles of MDM, and MDM remains untested.

Aims

Therefore, the aims of this dissertation were to:

1) Conduct a systematic review and synthesis of recent interventions using the Chronic Care Model to examine the extent to which MDM had been adopted within those interventions;
2) Evaluate the implementation process of a six-month pilot of an MDM-driven intervention, *Capacity Coaching*, in primary care using focused ethnographic observations and in-depth interviews; and
3) Propose a detailed protocol to implement and test MDM using a proven culture-change curriculum.

Methods

We conducted a systematic review and qualitative thematic synthesis of reports of Chronic Care Model (CCM) implementations published from 2011 – 2016, a focused ethnographic study, which included the synthesis of written artifacts, nine hours of clinic observation, and nine interviews with ten key stakeholders, and propose a mixed-methods, cluster-randomized trial to test MDM using a culture-change approach.

Results

CCM implementations examined were mostly aligned with the healthcare system's goals, condition-specific, and targeted disease-specific outcomes or healthcare utilization. No CCM implementation addressed patient work. Few reduced treatment workload without adding additional tasks. Implementations supported patient capacity by offering information, but rarely offered practical resources (e.g., financial assistance, transportation), helped patients reframe their biography with chronic illness, or assisted them in engaging with a supportive social network. *Capacity Coaching's* implementation,

however, addressed most of these shortcomings of past chronic care interventions, including being available to patients living with any chronic condition(s), acknowledging and seeking to reduce patient work, and supporting patient capacity holistically across all constructs described in the Theory of Patient Capacity. Its implementation was successful in getting many individuals on the healthcare team to understand the purpose of the program and the ways in which it was distinguishable from other programs and in getting a small group of dedicated champions to drive implementation of the program forward. However, implementation struggled to get a broader group of individuals across the clinic involved in the program and to build in evaluation of the program's success. These challenges are ones specifically addressed in the Leadership Saves Lives culture-change curriculum.

Conclusion

MDM offers a unique lens to meet the needs of the growing population living with multimorbidity. However, recent chronic care interventions have not implemented most MDM principles. *Capacity Coaching* is a novel intervention that uses MDM principles and when implemented showed promise in overcoming past chronic care shortcomings. Its pilot implementation highlighted challenges in enrolling the full healthcare team to drive MDM forward. The LSL program offers promise to overcome these challenges, but deserves large-scale testing.

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List of Abbreviations

BREWS – Theory of Patient Capacity Constructs: Biography, Resources, Environment, Work, and Social

CCM – Chronic Care Model

CuCoM – Cumulative Complexity Model

ESRD – End-Stage Renal Disease

IC – Interstitial Cystitis

MDM – Minimally Disruptive Medicine

NPT – Normalization Process Theory

LSL – Leadership Saves Live

Introduction

Maria Louisa

Maria Louisa is the 83-year-old grandmother of a colleague. She is originally from Peru, but now lives with her son and his family in Alaska. Maria Louisa lives with a box of medications to manage her conditions, and spends half of her day, three days a week at a dialysis unit. More importantly, Maria Louisa doesn't speak English, and feels socially isolated, particularly during dialysis. She misses the cultural familiarity of home not just because of her language barrier. Additionally, she feels isolated from her beloved Peruvian foods, now restricted from her low-sodium, low-phosphorus diet. She longs for the rich flavors of home and the hundreds of native Peruvian potatoes.

Kasey Rebekah

I am Kasey Rebekah, 28-year-old wife, mother, daughter, and researcher working at Mayo Clinic attending school for my doctoral degree at the University of Minnesota. Growing up, I had asthma and a heart condition, but these chronic conditions were fairly easy to manage with practice. Yet in my first year as a PhD student, I developed mysterious, debilitating pelvic pain over the span of a few weeks. Months later, I was diagnosed with interstitial cystitis (IC), a chronic painful bladder condition that is underdiagnosed and lacks a strong body of evidence on how to treat it.[1] Surveys of patients with IC suggest that it negatively impacts travel, employment, leisure activities and sleeping in more than 80% of patients, with the majority of these patients living on permanent disability.[2] Despite decreased wage-earning abilities, patients with IC face high costs of care. The average yearly cost for patients with IC is $4000 per year greater than age-matched controls, largely driven by pharmaceutical costs,[3] as the cash price for Elmiron, the only FDA approved drug specifically for IC is approximately $750 per month. My cost for Elmiron is $250 a month, even with good employer-sponsored insurance.

My daily routine to manage interstitial cystitis, asthma, and heart condition includes 18 pills, daily exercise, and at least seven to eight hours of sleep. I also receive acupuncture every few weeks and must carefully monitor my stress levels. I have a strong social network, including nearby parents, husband, five year-old son, and many friends from work as well as outside of work. From my personal experience, the most problematic part of managing interstitial cystitis is the restricted diet. I must carefully monitor my intake of bladder-irritating acidic foods. During the six months following diagnosis, while stabilizing my medication regimen, I needed to eliminate certain foods and drinks completely. These included things like citrus fruits or citrus derivatives used as preservatives, tomatoes, strawberries, vinegars, soy sauces, and most importantly, my beloved black tea. Even today, I must take care to avoid too much of these foods, despite traveling often and sometimes internationally for work, and maintaining a peanut-free, dairy-free, gluten-free diet due to other allergies and food intolerances.

The Work of Being a Patient

Maria Louisa and I, despite our 55-year age gap have something in common: the work of being a patient. The work of being a patient has been described using the Normalization Process Theory (NPT), and includes four activities.[4] First, sense-making work is that which patients must do in order to understand instructions, find and interpret medical information, and discern how these tasks might fit into their daily lives.[5, 6] Next, patients must plan the work and enroll others where they cannot do the work alone.[5, 6] Third, patients engage in the work itself, making it happen daily.[5, 6] Finally, patients must continually appraise whether this work is actually worth doing in their daily lives.[5, 6] For patients with conditions that are regularly symptomatic, like my own, the appraisal process is intuitive. I must continually appraise my pain levels and the way in which daily activities or choices correspond with increased or decreased pain. However, for patients with chronic conditions that remain mostly asymptomatic until later progression of the disease, such as diabetes, appraisal is less concrete. Patients must appraise whether the continual investment in medical interventions, tests, monitoring, appointments, and administrative hassles is worth the proposed potential for less suffering down the road in time. By understanding “non-adherence” through a lens of the patient work activities required for self-care, one can understand why non-adherence may be logical in some cases (e.g. during periods of few or no symptoms) or forced in other cases (e.g., due to lack of funds to pay for medications).

Treatment Burden

The work of being a patient is the discrete activities that patients must do to manage their health conditions. However, each patient subjectively experiences this work differently, leading to different levels of *treatment burden*. Considerable scholarly work has occurred in the area of treatment burden in the last five years. Treatment burden has been defined as “the workload of health care and its impact on patient functioning and well-being.”[7] Tran et al., used an international survey to create a taxonomy for the burden of treatment, which included “the tasks imposed on patients by their diseases and by their healthcare system; the structural, personal, situational, and financial factors that aggravated the burden of treatment; and patient-reported consequences of the burden, such as poor adherence to treatments, financial burden, and its impact on professional, family, and social life."[8] Treatment burden has been studied using qualitative methods broadly across conditions including, stroke, heart failure, diabetes, respiratory diseases, among others, and has similar elements across conditions and healthcare systems.[5-12] It is now measureable using two different disease-agnostic measures,[13, 14] and numerous disease-specific measures.[15]

Patient Capacity

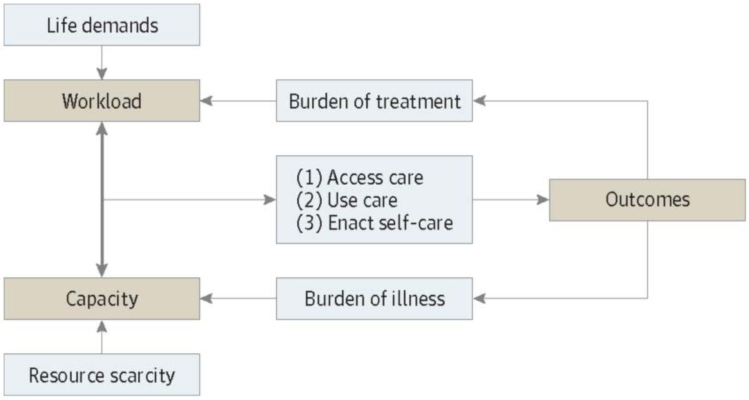
The subjectively different experience of treatment burden can be explained, in part, by the differing capacity for each patient to take on treatment workload alongside life's work. Capacity can be summarized as "the abilities and resources a patient has to take on the work of being a patient."[16] Capacity is a complex phenomenon. Boehmer et al., through a qualitative systematic review and thematic synthesis proposed a descriptive Theory of Patient Capacity.[17] This theory proposes that patient capacity is a complex interaction of people with five constructs in their lives: Biography, Resources, Environment, Work, and Social, known by the pneumonic of the constructs (BREWS).[17]

Briefly, **B**iography encompasses who the patient fundamentally is in their life – their life's hopes, dreams, responsibilities, and roles. Chronic illness interrupts this biography, and some patients reinvent their biography to include that of their illness. Others get stuck in the reframing process and struggle with downstream consequences on their ability to self-care.[17] The **R**esources construct covers not simply the resources that exist in a patient’s life, but patient’s ability to access and mobilize those resources.[17] Patients’ **E**nvironment, particularly the healthcare environment where they receive care, can serve to positively or negatively impact patients’ capacity. For example, patients who were met with disbelief by their clinical team or struggled to get access to the care they felt they needed had deteriorated capacity. On the other hand, patients who were met with careful consideration of their circumstances and available healthcare had improved capacity.[17] Interestingly, the **W**ork of being a patient does not always deteriorate patient capacity; in fact, it can contribute to patients’ capacity. However, patients needed the correct amounts of work, rather than an overwhelming plate of healthcare tasks all at once. “The cognitive, emotional, and experiential results of successfully completing the work serve to fuel patient capacity.”[17] Finally, the **S**ocial construct describes patients’ social functioning in the world, both properties of their own personal ability to be social and the properties of their social networks to be supportive in caring for their chronic illnesses.[17]

Workload-Capacity Balance

The interaction between the concepts described in the previous sections can be described using the Cumulative Complexity Model (CuCoM) (**Figure 1**), which illustrates that the balance of workload to capacity affects patients’ ability to access and use self-care and enact self-care.[16] In turn, it also affects their health and quality of life outcomes.[16] What the CuCoM also calls attention to is the fact that from the healthcare team’s standpoint, the information that is fed to clinicians and other care team members are patients’ *outcomes*.[16] Teams receive information on markers such as blood pressure, HbA1c, and phosphorus levels. When these outcomes worsen, the automatic

Figure 1: The Cumulative Complexity Model (from Leppin A et al. JAMA IM 2014).



response is to intensify treatment in order to bring the values back into normal ranges. However, there is a danger in this response for overwhelmed patients living with chronic illness. If this response is actually the incorrect action to respond to an *undiagnosed workload-capacity imbalance*, the vicious cycle will continue where patients have more work than they can handle with their current capacity, while they continue to feel worse, further deteriorating capacity.[16]

Minimally Disruptive Medicine

Minimally Disruptive Medicine is a philosophy and model of care that seeks to rectify this problem of undiagnosed workload-capacity imbalances by acknowledging and minimizing the work of being a patient, as well as acknowledging, supporting, and growing patient capacity.[18] Minimally Disruptive care is guided by considering patients' clinical problems in light of the CuCoM and other middle-range theories described above like BREWS and NPT, using existing tools and strategies such as the ICAN Discussion Aid, Shared Decision Making tools, and *Capacity Coaching*, yet whole-scale implementation of MDM appears elusive.[19-22]

Dissertation Contribution

For Maria Louisa, her struggles were met with Minimally Disruptive Medicine thanks to her granddaughter, Ana, who happened to encounter MDM during her research and medical training prior to residency. First, Ana recognized that not being able to eat her beloved Peruvian foods was a tremendous loss for Maria Louisa. By connecting Maria Louisa with a nutritionist that was familiar with Peruvian food, she was able to ensure that her diet met her cultural norms as well as her health restrictions. Second, Ana worked with her dialysis team to change her dialysis time to the evenings, which allowed her to spend more time with her loved ones during the day when she had energy. That change had an unexpected positive consequence. On the evening shift, most nurses spoke fluent Spanish, unlike the day nurses. This change opened Maria Louisa's social world greatly, and she felt less lonely and isolated.

For me, Minimally Disruptive care was achieved by my own advocacy and the advocacy on my behalf by my social circle, many of whom are physicians and nurses willing to jump in and help navigate the complex healthcare system at a moment's notice. IC is a rule-out condition, meaning that conditions with similar symptoms must be ruled out prior to diagnosis. The specialists that saw me, in a much faster time frame than the months-long waits I would have otherwise experienced, were either friends or friends of friends. When we narrowed in on the IC diagnosis, I was fortunate enough to have a clinician in my social network who was an urogynocologist, willing to see me when my condition was otherwise not treated locally. He began treatment with oral therapies right away and checked in a few weeks later to assess my symptoms. We were able to remove one medication, but in discussing my own personal treatment burden with him, we came to a shared understanding that the primary treatment burden that I experienced was not from the pills, but the restricted diet. I was able to voice my preferences to take more medication if it meant living my life in a less-restricted way.

These examples of tailored, minimally disruptive care are accidents; the prevalence of these examples pales in comparison to the prevalence of overwhelmed patients. This dissertation is intended to serve as a guiding light for the future of MDM, such that in the future, examples of minimally disruptive, maximally supportive care are not accidents but the norm. To do that, this dissertation features three stand-alone manuscripts that serve distinct purposes on their own, but are tied together by the concepts and theories supporting MDM and the overarching theme of moving from past to present to future.

Manuscript One evaluates chronic care as described in the existing literature that follows the historically implemented Chronic Care Model to assess the extent to which it accounts for the needs of patients with multimorbidity, including those needs described by MDM and its supporting conceptual model and theories. Manuscript Two uses focused ethnography and in-depth interviews to examine a recently-implemented program of MDM, Capacity Coaching, in a clinical practice. The purpose of this exploration is to evaluate what worked well, what needs further support, and the extent to which the small pilot influenced practice at the clinic more broadly. Finally, Manuscript Three sets forth a detailed protocol to test, using mixed-methods, cluster-randomized trial, a strategy of MDM implementation that leverages the curriculum and lessons learned from an evidence-based culture-change curriculum, Leadership Saves Lives (LSL). An R18 grant proposing the protocol outlined in Manuscript Three has been resubmitted, after being scored in the 25th percentile on the first submission. In conclusion, the body of work represented within these three manuscripts, ties a decade of past experience and learnings from present implementation to a vision for the future of Minimally Disruptive Medicine and research to support its practice.

Manuscript One: Does the chronic care model meet the emerging needs of people living with multimorbidity? A systematic review and thematic synthesis

Introduction

In the 1990s, Wagner and colleagues developed the evidence-based Chronic Care Model (CCM). The CCM had significant advantages over the primarily acute-care model of primary care at the time. Namely, it responded to the need for the healthcare system to change structurally how it addressed the needs of patients with chronic illness.[23] The CCM oriented primary care's shift to proactive management of chronic conditions.[24] Two decades later, the CCM has been packaged into toolkits[25, 26] and widely adopted. In that time, though, the landscape of chronic care has further changed.

In 2009, a new problem in the care of patients with multimorbidity, i.e., the coexistence and interaction of *multiple chronic conditions* (MCC); a growing public health problem that affects 3 in 4 Americans 65 and older,[27, 28] was recognized. Some patients were unable to complete all tasks assigned to them because of the way care was organized and delivered. Usual care was transferring to these patients more work than what their capacity could enact. A solution, Minimally Disruptive Medicine (MDM),[18] proposed that health care should account for patient work, should work to make it fit in the context of living, and seek to achieve patient goals while minimizing the burden of treatment. In the past eight years, this model has begun to gain traction.[29] Supported by a conceptual and theoretical foundation,[4-6, 16, 17, 30, 31] MDM is responsive to the accumulation of chronic conditions that is increasingly prevalent. Its main contribution is to orient healthcare, to correctly size the work delegated to the patient, and support the patient’s capacity to enact it.[18]

MDM builds on the CCM to address two of its weaknesses. First, the CCM describes what elements should be implemented to support patients with chronic conditions, but not how these implementations should handle multimorbidity. Conceivably, the CCM could simply be applied to handle multiple individual conditions. However, there is a growing body of evidence that shows that disease and treatment interactions, and interactions between the biomedical and the socio-personal context of each patient, make it unwise to care for each condition separately (i.e., as when each one is handled by uncoordinated specialists) and call for whole-person primary care for patients with multimorbidity.[32-37] Such patients and their caregivers may become overwhelmed by chronic care that ignores the accumulation of tasks, all recommended in the care of each condition.[5, 6, 9-11]

Second, in its original conception, components of the CCM were assembled based on favorable experience with each component independently, rather than to respond to the tenets of a conceptual or theoretical framework. The sum of the components may not preserve their advantages or achieve synergies. MDM’s theoretical and conceptual frameworks may guide the implementation of CCM’s elements to patients with MCC. An additional advantage is that interventions that seek to apply theoretical and conceptual foundations may be more effective.[38]

MDM has a conceptual model, the Cumulative Complexity Model (CuCoM), and two middle-range theories relevant to this manuscript: the Normalization Process Theory (NPT) and the Theory of Patient Capacity (known by its pneumonic, BREWS). CuCoM describes the cumulative work of implementing healthcare and self-care tasks for patients with multimorbidity, and how without consideration of patients' other conditions and of their life situation, this work can overwhelm the capacity (i.e. abilities and resources)[16] of patients and their caregivers to enact treatment plans.[5, 6, 18, 31, 39] Practically, this translates into a choice between enacting and adhering to treatment or engaging in life duties, roles and activities; in choosing the latter, as most patients do,[18] patients may delay or cancel healthcare tasks, becoming labeled as "noncompliant".

NPT offers a more in-depth explanation of the nature of patient work. This includes making sense of the work required (e.g., reading pamphlets, thinking through how to adhere to the treatment regimen), enrolling others to help and planning the work, conducting the work (e.g. attending the appointments, successfully adhering to treatment), and appraising, continuously, whether the work is worth the effort.[4-6, 30] For patients with chronic conditions, many of which are asymptomatic, the appraisal is complicated by the absence of or delayed feedback from the condition. Patient work was described before the CCM's genesis[40] and has been described in later qualitative research specifically relating to multimorbidity,[41] but its importance was not acknowledged in the original CCM[23] or in later versions of the model.[42] Finally, the Theory of Patient Capacity puts forth that patients' capacity to take on the self-care tasks are resultant of their interactions with their **B**iography and their ability to incorporate their illness and its care into that biography, **R**esources, **E**nvironment, experiential learning from the **W**ork of being a patient, and **S**ocial network (BREWS).

The Present Review

To date, no review of the literature addresses the extent to which the elements of MDM, namely those constructs described in the CuCoM, NPT, and BREWS, have guided the implementation of the CCM. Thus, we sought to critically appraise reports of the implementations of the CCM to address this knowledge gap.

Methods

To explore the extent to which MDM constructs are present in the reporting of current CCM implementations, we conducted a systematic review and thematic synthesis following the ENTREQ reporting guidelines.[43]

Study Eligibility

We included English-language studies published within the last 5 years (July 2011- July 2016) describing implementations of the CCM using any study design. We chose the past 5 years to capture contemporary practice rather than historical trends, and to give time for implementers to consider MDM (its first description was published in 2009). Eligible studies had to state that their intervention was based on the CCM, and to describe implementing at least one of the five components of the original CCM: 1) the use of evidence-based, planned care and protocols; 2) practice redesign to meet the needs of patients with chronic conditions, in terms of additional time and close follow-up; 3) patient self-management and behavioral change support; 4) ready access to clinical expertise; and/or 5) supportive information systems.[23] We excluded protocol papers for planned studies; however, if an included study had an available protocol (as an appendix to the study or as a standalone publication), we reviewed the methods reported in all these sources.

Search Strategy

An expert reference librarian (P.E.) created and conducted the initial search from July 2011 to July 2016 using the Ovid MEDLINE and Scopus databases (See Appendix 1 for full search strategies). We also reviewed the references of included studies and of systematic reviews for potentially eligible studies.

Selection of studies

Prior to beginning screening for study eligibility, two reviewers (K.B. and M.G.) were trained regarding the purpose of the review and eligibility criteria. They conducted abstract and full text screening in duplicate, with disagreements at abstract screening included in full-text screening. Full-text screening disagreements were resolved by discussion and consensus.

Data Extraction and Quality Assessment

We extracted in duplicate pertinent study characteristics, CCM components targeted in the intervention and any additional theoretical frameworks used, using a systematic review software, Distiller SR (EvidencePartners, Ottawa, Canada). Quality was assessed in duplicate using the "Template for Intervention Description and Replication" (TIDieR) checklist.[44] This checklist is designed to assess the completeness of intervention descriptions, the clarity of the proposed mechanisms for change, and how well the intervention was implemented.[44] All disagreements were resolved by consensus.

Data Analysis

Articles were imported into qualitative data analysis software (NVivo® qualitative data analysis Software; QSR International Pty Ltd. Version 10, 2014). In order to synthesize the overarching themes of current CCM implementations, we conducted an inductive thematic synthesis.[45] Traditionally, this method has been applied to synthesize textual findings during systematic reviews of qualitative studies without *a priori* expectations. Because we aimed to synthesize textual information slightly different in nature, about how interventions were enacted, but without preconceived *a priori* expectations, we selected this method. Ultimately, thematic synthesis is “the process of taking concepts from one study and recognising the same concepts in another study, though they may not be expressed using identical words,”[45] which facilitates a summary of what is happening across many interventions. Using previously described thematic synthesis methods,[45] two coders (K.B., M.A.) first coded five studies line-by-line to create the initial list of codes. During this process, each segment of text is described by a “code” (e.g., adherence, coaching, patient skill building). The coders then met to discuss and refine this list, deleting duplicate codes, combining similar ideas into individual codes, and resolving coding discrepancies. They then coded three additional studies in duplicate using the refined coding list, and added additional codes that emerged during the process. They again met to discuss this process and finalize the coding scheme. Reviewers completed coding the remainder of studies individually, and met weekly to discuss any newly emerging codes and questions. Once the coding was completed, K.B. synthesized codes into overarching themes.

K.B. then compared intervention characteristics and themes that emerged from analysis with the tenets of MDM, using the CuCoM, NPT and BREWS.[4, 16, 17, 30]

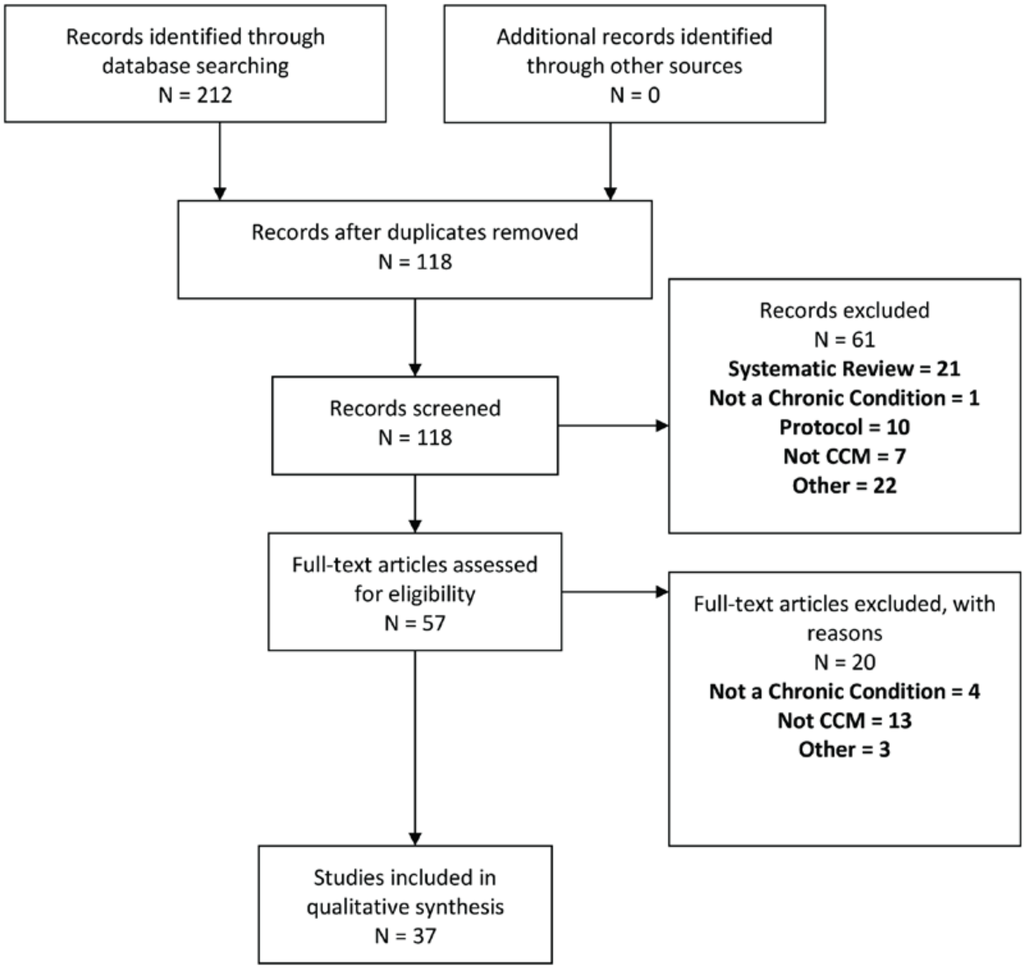
Using the CuCoM,[16] each study was categorized as adding patient work (+), subtracting patient work (-), neutral to patient work (N), meaning it both added and subtracted patient work, or as having an unclear effect. Using NPT,[4, 30] we identified if the intervention assisted patients with sense-making work (S), enrolling others to help, and planning the work (E), enacting the patient work (W), or appraising the work (A). Using BREWS,[17] we identified if each intervention supported patients’ capacity by helping them reframe their biography with chronic illness (B), provided or assisted in accessing resources (R), improved the environment in which patients received care (E), promoted experiential success in managing the work of healthcare and life (W), or supported the patients interaction with their social network (S).

Results

Identification of Studies

The initial search yielded 118 potentially eligible articles, of which 37 reports of 29 studies were included with sufficient chance-adjusted inter-rater reliability (κ = 0.78; **Figure 2**)

Figure 2: PRISMA Study Eligibility and Inclusion Process



Summary of Included Studies

Table 1 describes the included studies. Most articles described quantitative analyses (n=24) of implementations focused on a single condition (e.g., chronic obstructive pulmonary disease, asthma, chronic kidney disease), most commonly type 2 diabetes, and implemented patient self-management support and practice redesign. Very few addressed patients with comorbidities (n=3) or were condition agnostic (n=4).

Table 1: Study Characteristics											
Author	**Year**	**Type**	**Conditions**	**EBP**	**Redesign**	**SMS**	**Expertise**	**SIS**	**Duration**	**Framework**	**Conflicts**
Austin	2013	Quant	Type II Diabetes			**X**			4 weeks; support group for 12 months	None	No
Bissonnette	2013	Quant	Chronic Kidney Disease	**X**	**X**	**X**	**X**		3.5 years	None	No
Bojadzievski	2012	Quant	Type II Diabetes/Hyperlipidemia					**X**	Unclear	None	No
Britto	2014	Quant	Asthma	**X**	**X**	**X**		**X**	4 years	None	No
Collinsworth	2014	Qual	Type II Diabetes		**X**	**X**			18 months	none	No
Comín-Colet	2014	Quant	Heart Failure	**X**	**X**	**X**	**X**	**X**	6 years	None	no
Crabtree	2014	Mixed	Hypertension		**X**	**X**			unclear	Model for Improvement	No
Cramm	2014	Mixed	Type II Diabetes/Heart Failure/Comorbidities/COPD/Cardiovascular Disease	**X**	**X**	**X**		**X**	1 year	none	No
Cramm	2014	Quant	Type II Diabetes/Depression/Heart Failure/Comorbidities/COPD/Cardiovascular Disease/Stroke/Eating Disorders	**X**	**X**	**X**		**X**	2 years	none	No
Cramm	2012	Quant	Type II Diabetes/Depression/Heart Failure/Comorbidities/COPD/Cardiovascular Disease/Stroke/Eating Disorders/Psychotic Disorders	**X**	**X**	**X**	**X**	**X**	1 year	None	No
Dickinson	2014	Quant	Type II Diabetes	**X**	**X**	**X**	**X**	**X**	6-18 months	Complexity Theory; Model for Improvement	No
Dickinson	2014	Quant	Type II Diabetes		**X**			**X**	12-18 months	None	No
Farley	2014	Quant	Tuberculosis	**X**	**X**	**X**	**X**	**X**	6 months	PRECEED-PROCEED	No
Goldwater	2014	Qual	Type II Diabetes/Hypertension/Hyperlipidemia/Tuberculos	**X**				**X**	Unclear	None	No

			is								
Halladay	2014	Quant	Type II Diabetes	**X**		**X**		**X**	13+ months	none	No
Hariharan	2014	Quant	Type II Diabetes	**X**	**X**	**X**	**X**	**X**	3 years	none	No
Heinelt	2015	Mixed	Not Targeted		**X**		**X**	**X**	unclear	none	No
Holm	2014	Qual	Depression		**X**	**X**			12 months	none	No
Holtrop	2015	Mixed	Type II Diabetes		**X**	**X**		**X**	9 months	Macrocognition Framework	No
Ku	2015	Mixed	Type II Diabetes	**X**	**X**	**X**		**X**	28 months	none	No
Ku	2014	Quant	Type II Diabetes	**X**	**X**	**X**			22 months	none	No
Langwell	2014	Mixed	Type II Diabetes			**X**			4 years	none	No
Mackey	2012	Quant	Type II Diabetes	**X**	**X**	**X**	**X**	**X**	Unclear	None	No
Martin	2016	Quant	Not Targeted			**X**			Unclear	Bandura's Social Cognitive Theory	No
Massoud	2015	Quant	HIV		**X**	**X**		**X**	Unclear	Systems theory; Model for Improvement	No
McGough	2016	Quant	Depression/Anxiety	**X**	**X**	**X**	**X**	**X**	44 months	none	No
Noel	2014	Quant	Type II Diabetes	**X**	**X**	**X**		**X**	12 months	None	No
Parchman	2013	Quant	Type II Diabetes	**X**	**X**	**X**	**X**	**X**	1 year	None	No
Philis-Tsimikas	2014	Qual	Type II Diabetes		**X**	**X**		**X**	Varying	None	No
Pilleron	2014	Quant	Type II Diabetes	**X**	**X**	**X**	**X**	**X**	3 years	none	No
Roland	2012	Quant	COPD or Not Targeted		**X**	**X**		**X**	6 months	None	No
Sack	2012	Quant	Inflammatory Bowel Disease	**X**	**X**	**X**	**X**	**X**	5 months	None	No
Schauer	2013	Qual	Not Targeted	**X**	**X**	**X**	**X**	**X**	Unclear	None	No
Smidth	2013	Qual	COPD	**X**	**X**	**X**		**X**	25 months	Medical Research Council's framework	No

Smidth	2013	Quant	COPD	**X**	**X**	**X**		**X**	25 months	None	No
Tu	2013	Quant	HIV	**X**	**X**	**X**	**X**	**X**	3 years	None	Yes
Van Durme	2015	Mixed	Not Targeted	**X**	**X**	**X**	**X**	**X**	15 days - 36 months; mean 6 months	Complexity Theory	No

Protection from Bias and Reporting of Methods

With few exceptions, most studies used methods warranting trustworthy results (Appendix 2). However, intervention fidelity assessments were rare. For example, studies that included patient self-management support sessions did not assess the extent to which the curriculum was covered or patients attended the sessions. Several studies described poorly how the intervention was delivered, i.e., in-person or online, or how to access the materials used.

Major Themes

The inductive thematic synthesis highlighted four high-level themes: intervention aims, practice assessment mechanisms, intervention alignment with different healthcare stakeholders, and the ways in which practices assisted patients with self-management. Each of these could be broken down into subthemes (**Table 2**).

Table 2: Themes of CCM Implementation with Examples

Theme	Sub-Themes	Representative Quotes
Aims	Adherence to treatment; implemeting behavioral changes; improving disease-specific outcomes; reducing healthcare utilization; improving functional status or overall well-being; quality of life	• *"The RNs provided outreach for continued motivation and adherence and providers integrated the information from each patient's HBPM diary into their treatment strategy."* Crabtree, 2014 • *"The health coach describes this: "I help keep them compliant . . . make sure they're seeing their doctor on time, they're keeping their appointments, they, they get a wellness check and they get a physical each year. . . to make sure they're doing that. If you are diabetic, I'm making sure that you are doing what you're supposed to—getting your A1Cs, checking blood sugar on time, taking any meds.""* Shauer, 2013
Alignment	Healthcare system; community; patients; clinicians	• *"Defy Diabetes! created a unique collaborative partnership between Seton Health, CDEs, faith community nurses and churches, and a number of other key partners such as other medical centers, the local ADA chapter, several colleges and universities, and Cornell Cooperative Extension to impact diabetes in the community."* Austin, 2013
Assessment	EHR; patient registries; quality ratings, patient satisfaction	• *"The presence and use of an electronic patient record and a registry, including a list of beneficiaries of the projects and reminders to providers to plan care were important facilitators of the process."* Van Durme, 2015
Assisting	Care coordination; collaboration with other clinical teams and community agencies; team-based care; financial assistance; patient education; overcoming patient barriers; changing the flow and feel of the care environment; coping support	• *"[Diabetes self-management education] DSME sessions focused on: information on diabetes and diabetes medications, adoption of self-care behaviour, gaining control over the condition through problem solving skills and goal setting."* Ku, 2014 • *"Scheduled phone follow-up for any patient with symptoms at routine clinic visits and post hospital discharge to ensure resolution (pre-empting any deterioration whilst awaiting next routine visit)."* Sack, 2011 • *"The social worker also assessed the patient during the clinic visit reviewing advanced care directives, financial, or social support issues identified during the interaction. The social worker assessed the patient's overall coping response to his or her chronic kidney disease and inquired*

about any major life changes (e.g., death, job loss, etc.).” Woodend, 2013

The primary aims of CCM interventions were: understanding characteristics of successful or unsuccessful implementation, improved adherence to therapy, behavioral changes, decreased healthcare utilization, improvement in disease-specific outcomes, and in a few cases, patient-reported outcomes such as quality of life, functional status, wellness, or coping. Most studies aligned their aims with the healthcare system administration as the primary stakeholder. Only the few studies that involved patients, the community, or practicing clinicians as stakeholders in the development and implementation of CCM interventions aligned their aims with them.

The primary method for assessing the success of the intervention included collection of data in the electronic medical record or patient registries. A small number of studies used quality improvement methods, such as rating systems. The rest used the number of patients receiving or referred to specific services, patient satisfaction, and the score on the Assessment of Chronic Illness Care, a measure of organizational alignment with the CCM, reported by clinicians and health professionals at an institution.

Current CCM Implementation versus the Principles of MDM

Constructs of MDM that were described in the CCM implementations are reported in **Table 3**, using the CuCoM, NPT, and BREWS.[4, 16, 17, 30]

Table 3: Study-by-Study look at the inclusion of MDM constructs and study outcome reporting						
Author	Workload	NPT (normalizing the workload)	Capacity	Outcomes Reported (Y/N)	Outcome Focus	Outcomes
Austin	+	**S**EWA	B**REW**S	Y	Both	N
Bissonnette	N	**SE**WA	**BREW**S	Y	System	+
Bojadzievski	+	SEWA	BREWS	N	N/A	N/A
Britto	N	**SEWA**	**BREWS**	Y	Both	+
Collinsworth	N	**SEW**A	B**REWS**	N	N/A	N/A
Comín-Colet	N	**SEW**A	B**REWS**	Y	System	+
Crabtree	+	**S**EWA	B**R**E**W**S	Y	System	N
Cramm	+	**S**EW**A**	B**REW**S	Y	Patient	N
Cramm	+	**S**EW**A**	B**REW**S	Y	System	+
Cramm	+	**S**EW**A**	B**REW**S	Y	System	N
Dickinson	+	SEWA	BREWS	N	N/A	N/A
Dickinson	Unclear	SEWA	BREWS	N	N/A	N/A
Farley	Unclear	SEWA	BR**E**WS	Y	System	+
Goldwater	+	**S**EWA	BREWS	N	N/A	N/A
Halladay	Unclear	**S**EWA	BREWS	Y	System	N
Hariharan	+	**S**EWA	B**RE**WS	Y	System	+
Heinelt	-	**SEW**A	B**RE**WS	N	N/A	N/A
Holm	Unclear	SEWA	BREWS	N	N/A	N/A
Holtrop	unclear	**S**EWA	B**RE**WS	Y	System	N
Ku	+	**S**EWA	B**R**EWS	Y	System	+

Ku	+	**SE**WA	B**R**E**W**S	**Y**	**Both**	**N**
Langwell	+	**S**EWA	B**RE**WS	**N**	**N/A**	**N/A**
Mackey	+	**S**EWA	B**R**EW**S**	**N**	**N/A**	**N/A**
Martin	+	**S**E**W**A	B**R**E**W**S	**Y**	**Patient**	+
Massoud	-	S**EW**A	B**REW**S	**Y**	**System**	+
McGough	**N**	**SE**WA	B**REW**S	**Y**	**System**	+
Noel	+	**S**EWA	B**R**EW**S**	**N**	**N/A**	**N/A**
Parchman	+	**S**EWA	B**R**EW**S**	**Y**	**System**	+
Philis-Tsimikas	**N**	**SEW**A	**BREWS**	**N**	**N/A**	**N/A**
Pilleron	+	**SE**WA	B**REW**S	**Y**	**System**	**N**
Roland	-	S**EW**A	B**REW**S	**Y**	**Both**	**N**
Sack	-	**S**E**WA**	B**RE**W**S**	**Y**	**System**	+
Schauer	+	**S**EWA	B**REW**S	**N**	**N/A**	**N/A**
Smidth	**N**	**SEWA**	**BREWS**	**N**	**N/A**	**N/A**
Smidth	**N**	**SEWA**	**BREWS**	**Y**	**System**	**N**
Tu	+	**SE**WA	**BRE**W**S**	**Y**	**System**	+
Van Durme	**unclear**	SEWA	BR**E**WS	**N**	**N/A**	**N/A**

Workload Analyzed Using the Cumulative Complexity Model (CuCoM)
+ = transferring work to patients
- = removing work from patients
N = both transferring work to patients but providing support

Normalization Process Theory (NPT)
S = sense-making work
E = enrolling others and planning the work
W = enacting the work

Theory of Patient Capacity (BREWS)
B = biography support R = resource support
E = supportive healthcare environment
W = workload support
S = support of the social network

Outcomes Reported = Yes or No - studies that primarily focused on reporting implementation characteristics or lessons learned, and/or did qualitative analysis only are recorded as "No"
Outcome Focus = Patient-focused outcomes (e.g., quality of life,

A = appraising the work	involvement in decision making, confidence in managing conditions, etc.); System-Focused Outcomes (e.g. ACIC, laboratory values, % patients meeting guideline targets, etc.); or both <u>Outcomes</u> + = all or majority positive outcomes from intervention - = no studies reported completely negative outcomes N = mixed results; some outcomes positive, others negative or null

Patient Work

No CCM studies acknowledged patient work or the impact of life's work on patient health or healthcare. In six studies, the work asked of patients by the intervention was unclear, and in eight it was neutral – they asked patients to enact work, but also provided support to help patients carry out this work. Most studies (n=19) transferred work to patients by asking them to attend more classes, more appointments, or appointments on specifically scheduled days, and by intensifying treatment. Only four studies actually took work off the patient's plate without adding any additional work.[46-49] Examples of how to reduce patient work can be gleaned from these studies. One intervention changed the role of paramedics, such that they conducted regular home visits with patients, rather than having patients come to clinic unless absolutely warranted.[46] Another traced patients lost to follow-up by conducting home visits, and for patients unable to travel to the clinic, they introduced outreach visits.[47] Roland et al., described the evaluation of multiple pilots for care of elderly patients, which offloaded work from patients through intensive team communication about patients most at risk for admission to the hospital and rapid follow-up by phone or home visits as needed for patients.[48] In many of these pilot sites, community and social services and home-care services were deployed.[48] Finally, in a program for patients with inflammatory bowel disease, the healthcare team made a 24-hour nurse line available to all patients, so that they would not need to seek care elsewhere for urgent questions.[49] Additionally, they proactively followed-up by phone with patients who had medication changes, were on certain therapies, or who were discharged recently from the hospital, ensuring patients did not need to do the work of navigating how best and with whom to follow-up.[49]

Interventions that supported patient work most commonly supported sense-making activities or activities required to enroll others to help and to plan the work. This was accomplished through patient education, referrals to outside agencies, or with home visits. Few interventions helped patients accomplish the work or appraise whether the work was worth the effort. One way in which patients were helped to appraise their self-management actions was to set-up regular coaching calls with the patient to monitor goals and symptoms, and to change action plans as needed based on this feedback loop.[50]

Patient Capacity

Patient capacity was most often supported through the provision of resources required to carry out the work of being a patient, namely patient education materials and courses. Few implementations provided other resources or support, such as transportation or financial assistance. The next most supported element was improvement in the care environment to make it more patient-centered, typically by implementing team-based care to provide more holistic care. Very few studies supported the patients’ reframing of their biography in the face of chronic disease. Patients with chronic illness often lose the potential to fulfill important obligations and dreams in their life including the ability to care for family, work, and partake in pleasurable activities. This loss of taken-for-granted perceptions of self is called biographical disruption.[51] Furthermore, few studies supported productive interactions with the patients’ social network.

Only three studies supported all constructs of patient capacity, and these studies deserve attention as potential exemplars for future work. To highlight how supporting all elements of patients’ capacity might be accomplished consider, Smidth et al.,[52] which reported on a program for patients with COPD. They supported patient capacity through their exploration of **B**iography with illness in conversations that took an “appreciatory approach with dialogue between the patient and the health professional about the patient’s range of choices and opportunities, available treatment options and the patient’s readiness to change habits.”[52] Additionally, self-management course content supported overcoming biographical disruption through “knowledge and insight into their own psychological and physical situation, discuss and provide new inspiration for sexual life.”[52] They provided **R**esources such as a simple action card with information on exacerbations and steps to take. They improved the care **E**nvironment by encouraging a team-based approach to caring for patients with COPD, and by creating manuals for health professionals to ensure no tests were duplicated, which would have caused more work for patients. To support patients in accomplishing the **W**ork of being a patient they included regularly scheduled group self-management sessions that placed emphasis on “participatory activities with dialogue-based knowledge exchange to aid development of competences to act.”[52] Finally, they “wanted to inspire and encourage family, friends and patients to talk openly about the disease by providing disease-specific knowledge and therefore developed a webpage with information about the following issues: COPD; the support, help and aid provided by the municipality; local support groups and the general practices.”[52] This supports patients’ capacity to interact with their **S**ocial network about caring for their illness. As this exemplar demonstrates, however, even the best applications of elements of MDM tend to focus on the care of a single condition.

Outcomes

The CuCoM postulates that if care is aligned such that patient workload and capacity are balanced, patients will be better able to access and use healthcare and enact self-care, which in-turn, should improve outcomes.[16] In line with this, we examined whether reports included any outcomes, whether the focus of those outcomes were on the patient (e.g., their confidence in managing their condition or their quality of life) or on the system (e.g. patients' adherence to guidelines, surrogate markers, chronic care implementation efforts). Approximately two-thirds of reports included some outcome reporting. The majority of reports included system-focused outcomes only. All studies that reported outcomes reported mixed or positive results, and none had entirely negative findings. There did not appear to be a clear association between included MDM components and outcomes; however, this type of synthesis was difficult given the heterogeneity of study designs included (e.g., implementation, observational, intervention pre- post-, RCTs, etc.) and the heterogeneity of the interventions (e.g. practice facilitation vs. care manager implementation).

Discussion

Our analysis uncovered four important findings:

1) Very few implementations of the CCM are agnostic to chronic condition type or target patients with multiple chronic conditions.

2) The primary aims of these interventions were to improve disease-specific outcomes or reduce healthcare utilization, and most were conducted in alignment with the healthcare system's goals. Few studies focused on patient-centered outcomes, such as functional status, coping skills, or quality of life.

3) Studies primarily supported patient capacity through the provision of information resources. Few provided practical resources such as transportation or financial assistance, helped patients reframe their biography, or fostered productive interactions with their social network.

4) None of the included articles specifically mentioned patient work. Most implementations were either unclear in their impact on patient work or added to patient workload. Very few articles took work away from patients without adding new tasks.

Implications for Practice and Policy

Studies evaluating the CCM reveal that they, for the most part, have not incorporated the contributions of MDM. Specific problems for complex patients with multimorbidity that could be better incorporated into CCM implementations include considering the compound effects of conditions and treatments and their interaction with the demands of life, the administrative and financial complexity of attending to multiple conditions, and the additional coordination and communication with and amongst clinicians required to care for a patient with multiple conditions.[53, 54] Incorporating the MDM construct of "treatment burden," the impact that healthcare workload has on patient wellbeing,[9] could build on CCM implementations to better address the needs of patients with multimorbidity in whom work accumulates and often overwhelms. Treatment burden has been well documented across a number of conditions and is an important factor that can lead to nonadherence.[5-8, 10, 11] Furthermore, the burden of multimorbidity, and its associated increases in treatment work, falls more often on patients of lower socioeconomic status, often times without increased clinical care or clinical funding to areas of high social deprivation.[55, 56] We saw little focus specifically on implementing the CCM specifically for patient populations of low SES, with only approximately one-third of the papers using SES as a rationale for their study or conducting their research in low-resource settings. Another one-third of papers briefly mentioned SES somewhere or adjusted for it in their analyses, and the final one-third make no mention of SES variables or considerations.

Additionally, CCM implementations could be further tailored to incorporate the MDM construct of patient capacity in order to better support patients. Patients most disrupted by their illness and care are those with limited physical, emotional, and financial capacity,[57] suggesting, at minimum, interventions should pay attention to the resources needed to support these capacities. Most implementations sought to support patient capacity through the provision of education. However, a few tried to overcome problems like financial burdens, transportation, and problematic access hours, which are well documented problems for patients with chronic conditions.[5, 6, 8, 10, 11, 39] More interventions should seek to incorporate these elements to support patient capacity.

Additionally, the implementations of the CCM in the literature did not report supporting patients as they reframed their biography with chronic illness and or supporting their interactions with their social network. While this may be a limitation in detailed reporting of intervention components, it still deserves attention. Supporting the reframing of biography is emerging as a critical component of care as it may affect many other elements of capacity such as the ability to mobilize existing resources or to gain experiential learning from successfully carrying out patient and life work.[17] Patients' biographies include *who* the person is (e.g., a working grandmother) and *what* is most important to them (e.g., gardening and playing with grandkids). Biographical disruption is caused by *how* illness and treatment disrupt those important roles and activities (e.g., time away to attend medical appointments and pain inhibiting paid work). Chronic care can support biographical reframing by reducing the disruption caused by healthcare itself and supporting patients in conversation with health professionals and peers about changes caused by illness and strategies to cope and thrive. Of note, the American Geriatrics Society has called for at least incorporating this type of information into treatment decision making by putting forth as their first guiding principle of care for older adults with multimorbidity eliciting and incorporating patient preferences into medical decision-making.[58] However, it is also worth considering that the population of patients living with multimorbidity includes patients who are not yet geriatrics patients, as well as the apparent need for supporting the patients' biographical reframing beyond the inclusion in care decisions alone.

Finally, patients' capacity depends in part on acting in collaboration with their social network. When the social network fails to recognize the importance of this help, understand practically what needs to be done, or is non-existent, patients struggle to mobilize capacity.[17] The Burden of Treatment Theory states: "*Interventions that maximize collective competence in enacting practical tasks, distributing help and exploiting local resources, and effect increased confidence in healthcare processes and outcomes, are therefore likely to reduce inappropriate demands on healthcare services.*"[31] Three quarters of the literature examined on current implementations of the CCM did not report maximizing this collective competence, missing a critical opportunity to potentially support patient quality of life while simultaneously reducing the demands on the healthcare system. The quarter that did seek to draw on social support for patients did so by implementing group visits, promoting support groups, and tailoring education material for the social network of the patient, not just the patient individually. These strategies could be used in more CCM interventions to improve the collective competence of the patient and their social network. This recommendation is strengthened by additional reports of caregiving difficulties in caring for patients with multimorbidity, including caregivers' frustrations with the work associated with accessing and coordinating care,[59] and higher caregiver strain for caregivers with greater numbers of caregiving tasks and lower self-efficacy.[60]

Implications for Research

The CCM has modernized healthcare to respond proactively to the common occurrence of patients with chronic illness. The model tell us what to implement (e.g., clinical information systems), but the orientation of the CCM components to better the care of complex patients with multimorbidity may benefit from the contributions of MDM. Our review demonstrates that this potential awaits evaluation. Researchers must rigorously design interventions with strong theoretical underpinnings, which are sensitive to the issues highlighted in this review. In particular, to the care patients can use to flourish through careful consideration of the complexities of care and life and the interplay of workload and capacity. Interventions with theoretical underpinnings are more likely be effective, allow replication, and to allow better identification of the components of complex interventions that actually are responsible for their effects.[38] It is important that future evaluations look at outcomes important to a variety of stakeholders, most importantly, patients, and measure not only disease-specific metrics or utilization, but also patient-centered outcomes such as treatment burden, quality of life, and functional status. The recommendation of more inclusive measures is strengthened in light of the Cochrane systematic review on interventions specifically designed for multimorbidity, where still only one-half of included studies included patient-reported outcome measures.[61] In regards to other outcomes, studies that included depression as a co-morbid condition did show consistent improvements in depression-related outcomes.[61] Otherwise, the review illustrated mixed effects or no effects of interventions specifically for multimorbidity across a variety of other outcomes including clinical outcomes, healthcare utilization, medication use and adherence, and health-related patient behaviors,[61] highlighting the need to consider new approaches for this population.

Strengths and Limitations

Our findings are limited by what we could access from published reports, their protocols, and supplemental material, and in this, the provision of insufficient details about how the interventions were implemented and with what fidelity. Additionally, MDM is only one lens by which we can view multimorbidity, and to-date, whole-scale interventions that seek to implement all components of MDM within a healthcare system to reduce treatment burden and support patient capacity have not been implemented or tested. Despite these limitations, this systematic review fills important gaps in the current literature. First, while most reviews of the CCM have explored process and disease-specific outcomes,[62-66] this review critically evaluates *how* the CCM has been implemented. Furthermore, the CCM has not faced comparisons with emerging models that detail more specifically how to deliver care to patients with multimorbidity. This review accomplishes this by examining CCM implementations in light of MDM. In doing so, we have identified critical leverage points for changes in clinical practice, policy, and research that build on the substantial contributions of the CCM. Specifically, policy designers must acknowledge the cumulative work of being a patient and support critical elements of patient capacity. Based on the conceptual and theoretical underpinnings of MDM, one should expect that these changes would lead to healthcare that patients are better able to access and use, and self-care tasks that can be carried out within their existing capacity and life context.[16] Ultimately, these should translate into better patient outcomes and health system performance.

Conclusion

As highlighted in this review, current interventions that deliver the components described in the CCM may need modifications in how they are delivered to meet the needs of the growing population with chronic multimorbidity. MDM provides a lens to consider these modifications. Specifically, interventions should be agnostic to condition type and accommodate the coexistence and interactions typical of multimorbidity. They must acknowledge patient work and its dynamic interaction with the work of everyday life. Interventions should also support patient capacity, including supporting patients' ability to reshape their biography in chronic illness and to draw from their social networks. Implementation of interventions informed by MDM should be evaluated considering their ability to influence patient-centered outcomes, the experience of care for those receiving and those providing it, and the resource invested in their implementation.

Manuscript Two: Capacity Coaching: A qualitative evaluation of a novel intervention pilot

Background

The prevalence of chronic conditions is growing. Epidemiologic studies show that by middle-age, one-half of the population already lives with one chronic condition and one-third already have two or more chronic conditions.[28] While living with chronic conditions was once a problem of the elderly, it is now a reality for many working-age adults. With this shift in the age of the population living with multimorbidity, a unique problem surfaces for many of these patients – the competing priorities of life. Two key issues often left unacknowledged or unaddressed in clinical practice lie behind the failure to implement care in patient daily routines.

First, there is significant, underappreciated, patient work necessary to implement health interventions. Attending appointments, taking medications, shopping for and preparing healthy food, enacting an active lifestyle, dealing with administrative tasks related to insurance, and self-monitoring all take time, effort, sense-making, and attention.[5, 6] Second, patients must invest *capacity* - effort, time, emotion, help, and attention - to implement this work. Yet, patients' capacity to manage the tasks required to care for their condition(s) is the same capacity that they must draw on to work, participate in their community, care for children or older parents, and enjoy life with friends and family.[16, 39] This capacity can quickly become overwhelmed, and this pressing problem is often unacknowledged in healthcare settings. Even if recognized, current practice rarely has the time, skills, or resources to address the growing need to support patients’ capacity or to tailor care in such a way that it can be effectively implemented in patients’ busy routines.

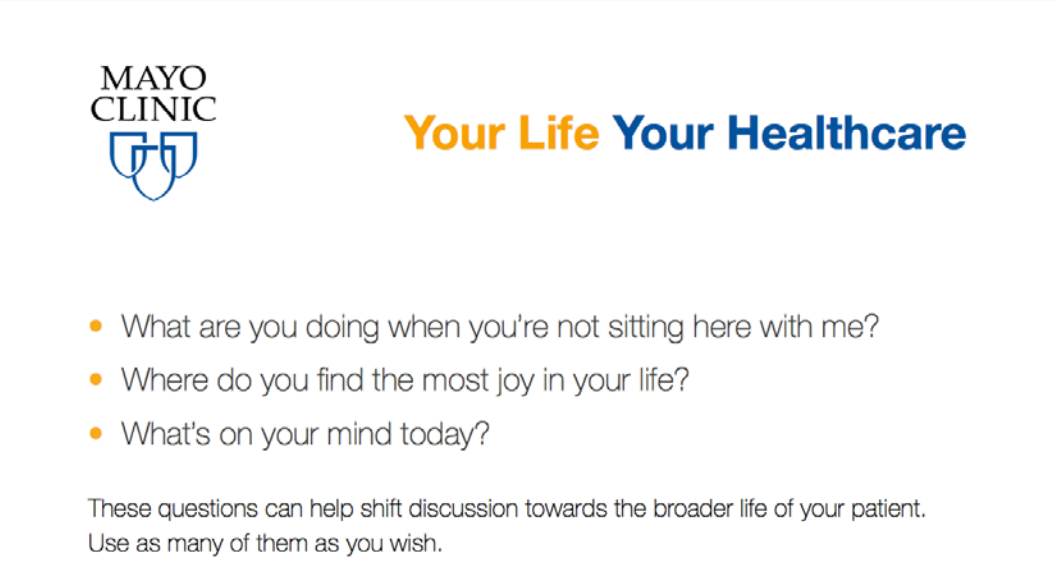
Healthcare seldom (a) assesses the available capacity patients have to enact new medical and lifestyle interventions, (b) prioritizes these interventions, or (c) identifies when patients require additional support. Actions of uncoordinated healthcare team members, working in different settings, worsen the situation. When patient work exceeds patient capacity, nonadherence ensues.[16]

For example, in response to a persistently elevated HbA1c (8-8.5%) related to her diabetes, Ms. Jones’ clinician added a new medication and referred her, as part of a disease management program, to a personal trainer. The goal was to improve her diet and implement “150 min/week of moderate-intensity aerobic physical activity, at least 3 days/week with no more than 2 consecutive days without exercise.”[67] She dropped out after two training sessions. The 3-month HbA1c remained high. Unknown to clinician or trainer, the patient shuttles her 3 children to different sporting events and practices 5 times/week. Game times vary making it hard to commit to training sessions or regular gym times. On these nights, she and her children eat convenience food while in transit, impairing her ability to remember to take pills prescribed to be taken with food.

Capacity Coaching is an intervention that has been designed to address the need of supporting and growing patient capacity, while ensuring their care is also best tailored to be implemented in patients’ lives. Briefly, the *Capacity Coaching* intervention, fully described and differentiated from other styles of coaching elsewhere, is designed to: 1) increase patient capacity for self-care through one-on-one coaching with a *Capacity Coach* trained in the principles of Minimally Disruptive Medicine, the Theory of Patient

Capacity, and coaching practices such as Appreciative Inquiry and SMART Goal Setting; and 2) help tailor patient care plans to their current life situations through interactions between the *Capacity Coach* and the primary care team. [20] Additionally, an important component of *Capacity Coaching* is that it begins the first coach-patient conversation with the ICAN Discussion Aid to fully understand what is going on in patients' lives, what they have been asked to do to care for their health by all their clinicians, and how life and healthcare are working together or not working together. The ICAN Discussion Aid is depicted in **Figure 3 and 4.**

Figure 3: ICAN Discussion Aid Clinician/Coach Questions



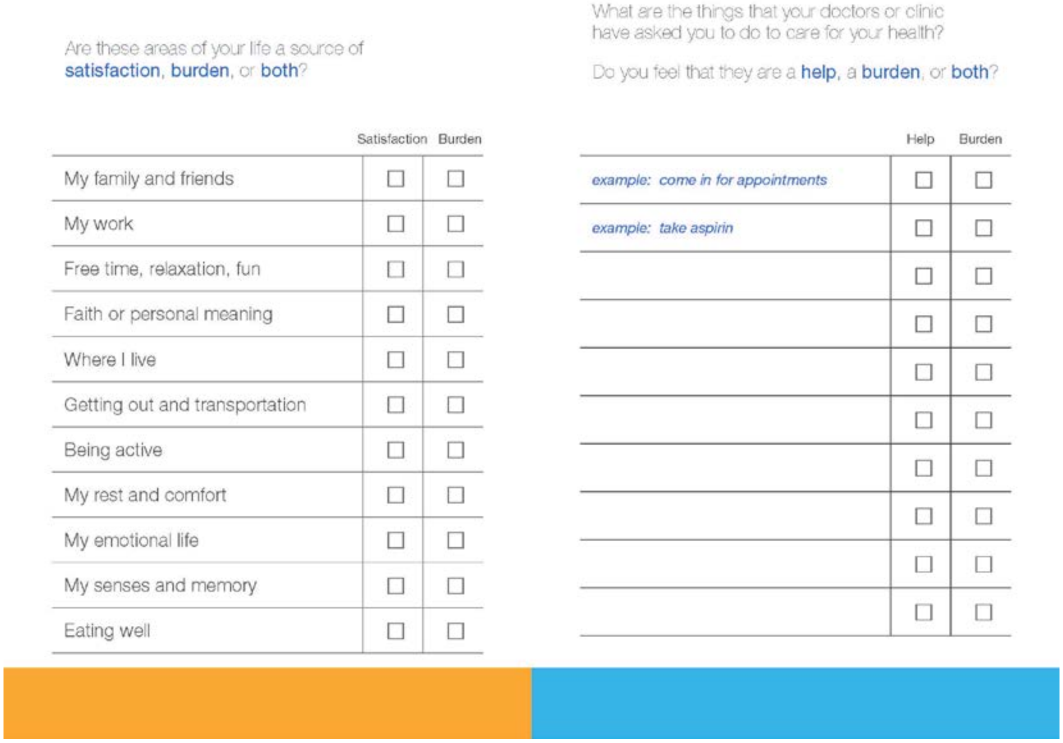
MAYO
CLINIC

Your Life Your Healthcare

- What are you doing when you're not sitting here with me?
- Where do you find the most joy in your life?
- What's on your mind today?

These questions can help shift discussion towards the broader life of your patient.
Use as many of them as you wish.

Figure 4: ICAN Discussion Aid Patient-Filled Questions



Are these areas of your life a source of **satisfaction**, **burden**, or **both**?

	Satisfaction	Burden
My family and friends	☐	☐
My work	☐	☐
Free time, relaxation, fun	☐	☐
Faith or personal meaning	☐	☐
Where I live	☐	☐
Getting out and transportation	☐	☐
Being active	☐	☐
My rest and comfort	☐	☐
My emotional life	☐	☐
My senses and memory	☐	☐
Eating well	☐	☐

What are the things that your doctors or clinic have asked you to do to care for your health?

Do you feel that they are a **help**, a **burden**, or **both**?

	Help	Burden
example: come in for appointments	☐	☐
example: take aspirin	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Aim

To date, *Capacity Coaching* remains novel and untested. It is unknown how it can actually be implemented into primary care practice, nor if implementation is successful, how it would impact patient outcomes. The purpose of this study was to understand the first unknown regarding *Capacity Coaching* – can it be translated from a novel idea into real-life clinical practice? We aim to determine what promise it holds to potentially impact patient outcomes and what lessons can be learned for future implementation projects.

Methods

Two Veterans' Administration (VA) Medical Centers in the Midwest sought to implement *Capacity Coaching* as a quality improvement pilot initiative in their Patient-Aligned Care Teams (PACT). These teams include physicians, nurses, social workers, pharmacists, nutritionists, and peer-support specialists. The teams were trained during a one-day workshop, and following the workshop, they independently planned and implemented the program in their own setting according to their own local settings' needs.   Following the closure of the implementation period, we returned to one clinic which led the initiative to understand the program's implementation successes and challenges. We used focused ethnographic methods to accomplish our aims. Focused ethnography is similar in its methods to traditional ethnography, but instead focuses on answering specific questions in micro-cultures that exist within larger cultures. [68]

Sample and Data Sources

Participants were employees of a VA medical center in the Midwest who worked in the Women's Health Clinic during the Capacity Coaching implementation period. Patients were not participants in the study, as we sought only to understand the healthcare team's implementation of the program. Participants were notified via email from their clinic leadership that a trained researcher would be coming to visit approximately one-month prior to the site visit. Four sources of data were collected: observations, interviews, a focus group, and artifacts. Participants were allowed flexibility to partake in as many or few data collection activities as their schedules allowed. Some participants took part in all activities on-site, whereas others only took part in one activity (e.g. an observation or interview only). All participants provided oral consent for participation in the study. Ethics approval and oversight were provided by the Mayo Clinic IRB.

Data Collection

The data collection period took place over three days on-site as well as a number of preparatory phone meetings and email exchanges leading up to the three days on-site visit. Nine in-person interviews of ten key individuals, one focus group with the current Women's Health Clinic team, and nine hours of observation were conducted.

Observations occurred during clinic on- and off- hours. Observations were conducted in the teaming room of the Women's Health Clinic, in the mental health clinic, and in another primary care clinic where pharmacy consultation services were provided. We conducted observations in areas beyond the Women's Health Clinic, which was the primary location of the *Capacity Coaching* pilot, because staff caring for female veterans in the Women's Health Clinic are not all currently located in the same area of the center all days of the week. Detailed observation notes were collected in the field, and at the end of each day, further written notes summarizing all data collection activities were completed.

Focus group data was collected using a semi-structured interview guide informed by the Normalization Process Theory (NPT). [30] Briefly, NPT can be used to describe how healthcare innovations are taken up or fail to be taken up in healthcare. It focuses on four key domains: *coherence*, how participants make sense of the work required to take up the innovation; *cognitive participation* to enroll others and plan the work; *collective action* of the team to enact the work of implementing the innovation; and *reflexive monitoring*, to continually appraise if the innovation is worth the time and effort. [30]

Individual interview data was collected using an unstructured interview format, beginning with a "grand tour" of the reason for the interview: to fully understand the experience of implementing *Capacity Coaching* in their practice and inviting them to begin by telling their experience. [69] After letting the participants talk as long as they liked, follow-up questions were asked about the experience they described. Probes were used to get deeper information from participants' stories, such as asking about the influence of the program on their practice following the pilot period, detailed information about changes in their day-to-day work, and sensitive group dynamic information, which was unlikely to emerge in the focus group discussion. All focus groups and interviews were audio recorded on a digital audio recorder and were transcribed verbatim.

Reflexivity

The practice of reflexivity "involves being deliberately aware of oneself, one's responses, and one's internal state in relation to a specific situation."[68] The primary researcher collecting the data kept a reflexivity journal during time onsite and during the analysis period, tracking initial impressions, state of mind, and thoughts about ideas that need to be subjected to follow-up interview questions, observations, and discernment.

Data Analysis

All data sources including transcripts, artifacts, and observation notes, hereafter referred to as "source documents" were imported into Nvivo 11 for analysis. The analysis process used procedures guided by Roper and Shapira's process for ethnographic analysis. [68]

First, the lead author (K.B.) and two trained research assistants (P.O., A.T.) listened to the audio recorded data and read all source documents to get a feel of the data. Then, we coded source documents inductively using line-by-line coding to develop a code book. We used this process on three source documents, meeting two to three times weekly to discuss newly emerging codes and codes that should be combined or reconciled. We deemed the codebook complete at the conclusion of coding the third source document, as no new codes were emerging from the data. We continued to meet twice weekly as we coded the remaining source documents using the codebook to address discrepancies or potentially new codes; two new codes emerged from the later data and were added to the codebook. In addition to our inductive codes we included *a priori* codes related to NPT: coherence, cognitive participation, collective action, and reflexive monitoring.

After coding all source documents, K.B. began to aggregating descriptive codes into themes using grouping and matrix functions in Nvivo 11. Coders reviewed results from the analysis to ensure that interpretations of the data remained close to the data. K.B. summarized all data into key themes found in the culture of the clinic, using constructs from MDM's conceptual model and middle-range theories: the CuCoM, BREWS, and NPT. In the case of this manuscript, CuCoM helps us understand the path from workload-capacity imbalance to difficulties accessing and using healthcare or enacting self-care, and the impact on patients' outcomes;[16] BREWS sheds light on the domains of patient capacity to be supported;[17] and NPT helps explain how teams can take up innovation.[4] Finally, synthesis of the data was closely examined in the context of a systematic review on current practice using the Chronic Care Model.[70] This review highlighted deficits in current practice such as interventions' inflexibility to deal with multiple chronic conditions, lack of acknowledgement of the work of being a patient, and limited to no support of patient capacity through tangible resources (e.g., transportation or financial), assistance in overcoming biographical disruption from chronic illness, or support in how to work with their social networks to manage their illness.[70]

Results

Summary of Capacity Coaching Intervention Delivered

K.B. delivered the original one-day workshop to introduce the concepts of MDM and *Capacity Coaching*. The workshop covered MDM, its underlying conceptual and theoretical frameworks, work-to-date, training on how to use the ICAN Discussion Aid to support minimally disruptive practice, *Capacity Coaching* tenets, basic coaching skills, and an overview of leadership in complex systems. The workshop was delivered to a large group including physicians, nurses, fellows, pharmacists, social workers, and peer-support specialists. Following the workshop, K.B. had very little contact with either VA site; two calls occurred approximately one month after the workshop and one year after the workshop, when the pilot began. A core group of individuals championed the *Capacity Coaching* intervention forward. This group included the medical director of the clinic, the social worker affiliated with the clinic, and a project coordinator. These individuals met regularly and other clinicians and health professionals met with them periodically, particularly in the planning phases. The planning phase lasted approximately a year and the pilot implementation lasted six months. At the conclusion of the pilot, the team developed a freely-available *Capacity Coaching* toolkit that describes lessons learned and how other VA's can implement the program in their PACT teams. The toolkit is available to VA sites through an internal network, and will soon be made available to the public on minimallydisruptivemedicine.org.

Alignment with Cumulative Complexity Model

There was evidence that the pilot *Capacity Coaching* program was in alignment with the principles of MDM, as described in the CuCoM. Specifically, there was considerable evidence that those most involved in the pilot and the work with patients in the pilot focused on reducing the work of being a patient.

"I hate swallowing pills, always have – gummy vitamins were a lifesaver for me [laughs]. My capacity coach suggested I talk to the pharmacist. The pharmacist worked with my doctor to adjust some of the doses I was on so I wouldn't have to take so many pills. She also told me which ones I could put in applesauce to make them easier to swallow. It's still not as good as my gummies, but it makes taking my meds so much easier." – Toolkit, Patient Success Story

"And I think that that is an opportunity again because if they're coming here for an appointment it kinda puts on that hat again of I'm here for my health, I'm here for this. And you know, I'm not sure if, you know, part of them not coming to appointments is because they don't like to be here. So um, you know, the phone visits are helpful, like I said, if they're busy and they have other commitments." –Staff Member 6, Pharmacist

Additionally the data revealed that very little work was added to patients' plates by delivery of the program. The primary work added by the program was the actual act of engaging with the coach during coaching visits. However, there was evidence that even this work was carefully engineered to be as minimal as possible. For example, the implementation team explored getting patients video cameras for remote video-calling with coaches as well as iPads, allowing the coach to meet with patients off-site, and doing warm hand-offs to the coach so that the first visit could occur immediately rather than being scheduled at a later date.

While formal outcomes were not collected from the program's implementation, participating staff and the toolkit did reflect success stories in patients' ability access and use healthcare and enact self-care, as well as their outcomes and quality of life.

"Like that particular veteran, I feel like her self-care did improve. She's making her appointments. She was more on top of managing her health care." –Staff Member 2, Capacity Coach

However, despite the program's clear impact on the practices of the individuals exposed to it and those who drove it forward, there was no clear evidence from ethnographic observations that the program's impact had trickled beyond those individuals to others working in the Women's Health Clinic, or to other Primary Care Clinics in the same center.

"While I was waiting, I noticed a sign on the wall that said 'We need your help reducing our no-show rate. Each no-show costs $118." –Observation Notes

"They focused on her weight quite a bit as she was overweight and recently gained weight. The patient mentioned that she had been really consistent with one of the programs the VA offered, but then the person she connected with that was delivering the program left. She did not feel like she had the same connection and motivation from the new person delivering the program, so she had quit going. This felt like a traditional

clinician-driven conversation focused on weight rather than addressing whether that was one of the patient's goals." –Observation note

Alignment with Theory of Patient Capacity

Participant's stories and artifacts illustrated that the implementation of the *Capacity Coaching* program positively acted upon each construct of the Theory of Patient Capacity. **Table 4** describes the ways in which this occurred as well as representative quotes.

Table 4: Program Alignment with Theory of Patient Capacity

Construct	**Positive Impact**	**Representative Quotes**
Biography	While the capacity coach was originally the team's social worker, they eventually transferred the coach role to a peer female-veteran. The program allowed patients to express their stories, the changes in their lives because of their conditions, and work through how to discuss those with their doctors.	*"And that was another reason we thought [peer] would be a good match, because she's a mother; she had a lot of face validity. She wasn't just like a single female talking to somebody that is a caregiver and is juggling a zillion and one things. I mean she's a veteran. She's had those challenges and she's a mom." – Staff Member 1, clinician* *"Back in the day, I used to play all sorts of sports: Field hockey, soccer, volleyball, you name it, I'd try it. I actually liked boot camp: I loved challenging my body like that. On my second tour to Iraq, the jeep I was in was overturned by an IED. Broke both my legs. Healing and rehab took forever. I got really depressed and even when I was good enough to walk and do stuff again, I just didn't want to. I gained a lot of weight and have zero motivation to do anything about it. About a year ago, I was diagnosed with diabetes. I'm ashamed to see my doctor. She didn't know me when I was healthy; all she's gonna see is someone who's fat and lazy and not managing her diabetes very well. A friend of mine suggested I see this gal at the VA, a capacity coach. She told me about an online support group for women that helps them advocate for themselves with providers. Now I rehearse what I'm going to say and how I'm going to say it before I see my doctor. It's helped me a lot. – Toolkit, Patient Success Story*
Resources	The capacity coach and social worker worked collaboratively, with the social worker supervising the coach and the two meeting weekly to discuss cases. This pairing worked well, and they were able to connect patients to resources in the VA or their community	*"There was one person who she broke her leg and she needed a wheelchair and I was like 'Okay. Hmm. I can come and help a little bit'… And they were able to get the things that they needed and they were like 'oh, that was so helpful.' I recommended, you know, going to a senior center to that same person, and her partner really was appreciative of the things that I was coming to them with." – Staff Member 2, Capacity Coach* *"So she was with us probably five hours a week on Monday and Tuesday mornings. And we would touch base if not both days, um, one day. And we could go through her cases and updates, and I could say 'Hey, that person would be great for OT lifestyle coaching' or 'Hey, let's connect that person to the pharmacist.'" – Staff Member 4, Social Worker*
Environment	The program shifted the way in which the healthcare team was interacting with patients, as well as the way they worked together as a team to support patients.	*"My capacity coach gave me this journal with some stickers. I've been using it to track my moods, sleep, food cravings…stuff like that. I write my blood sugar readings in it, too. It's helped me figure out some stuff out, make some connections. When I went to the doctor last week, my A1c was much better. My doctor was so happy! She asked if she could tell the team, and I said sure, and then everyone applauded, right there in the clinic! It was really nice to be recognized like this, to feel that positivity." –Toolkit, Patient Success Story*

		"When I first met her, my first encounter with her, she had just found out that she had breast cancer. … She went inpatient in August. Because she had a reaction to the chemo, and it was a serious reaction. She was in palliative care – from August to December she was in there, and I would go and visit her, and 'how you doin'?' You know, and she would say - sometimes you know, uh, sometimes she might not have been in the best moods, but that is understandable. But other times I would go in, I'd visit her and she would say 'You know what? I'm so glad that you came today. I'm gonna get out of the bed now. I feel better. I'm gonna walk around. I'm gonna take a shower.'" – Staff Member 2, Capacity Coach
Work	The Capacity Coach was able to work with patients towards setting small, achievable goals that were in line with their values, preferences, and context.	*"[Peer] was awesome at doing goal setting and following up with them every week and meeting with them every week or every other week so she would do that, and she could leave the clinic which is really nice." - Staff member 4, Social Worker* *"My Capacity Coach told me about this phone app that reminds me to drink water, get up and stretch every 20 minutes, and park farther from my destination: It's really motivating!" – Toolkit, Patient Success Story*
Social	Some of the toughest challenges patients encountered in caring for their health that the staff highlighted was balancing self-care with caregiving for others. The Capacity Coach was often able to support them in working through this balance as well as working productively with their social network.	*"My sister, god bless her, is always needin' my car for this, that, and everything. I don't mind helping her out, but now I can't get to the grocery store when I need to, so I just pop in at the convenience store on my block for stuff, and all they've got is junk food. My capacity coach is helping me work out some ways to talk nicely to my sister about getting my car back." – Toolkit, Patient Success Story* *"So just it seems like there's always like some other outside influence. There was another lady who she had lots of medical issues and a spouse who was not doin' what he needed to be doin'. And she was so worried about tryin' to keep thinks intact that her care fell off and right now… and she's in like a rehabilitation center." –Staff Member 2, Capacity Coach discussing the biggest barriers she had to help patients overcome*

Implementation Successes and Challenges

Beyond the impact of the program and its alignment with the fundamental principles of MDM, the remainder of the data was primarily focused on stories that were illustrative of the success and the challenges of implementation. These can be broken down into the four constructs of NPT: coherence, cognitive participation, collective action, and reflective monitoring. **Table 5** describes the successes and challenges in each domain. As is visually apparent from **Table 5**, the primary success of the implementation was seen in the domains of coherence and collective action, whereas a significant number of the challenges occurred in cognitive participation and reflexive monitoring.

Table 5: Implementation Success and Challenges

Construct	**Success**	**Challenge**
Coherence	The workshop getting everyone on the same page initially. *“Um, so that was really important. And that’s why everybody came to your workshop. And so, everybody had the same, basic understanding.” –Staff Member 3, Clinical Champion* Human-Centered Design and continuous iteration of the program until they felt they achieved success. *“Um, and once we switched over from [social worker] to [peer] as the capacity coach, [it changed] completely. And then [social worker] supervised [peer] but, um, yeah, she connected completely differently with our women.” – Staff Member 3, Clinical Champion* Describing patients that might be a good fit for the program. *“PSS [Peer-Support Specialist] informs PACT members and supervisor about what type of patient might benefit from meeting with her and participating in HCD-[human-centered design] driven Capacity Coaching, such as no shows, patients with multiple chronic conditions, polypharmacy issues, and patients who were doing well until ‘life happened’ (e.g., experienced a crisis).” – Toolkit, description of appropriate patients* The program’s distinguishability from other programs offered. *“I finally got it and said, you know, ‘ these are not difficult patients. These are women with difficult lives.’ … I think that labeling as difficult patients, people, you know, that fits into like a lot of our mental health patients who don’t take their medicines, so they’re definitely not taking their other meds. But there’s kind of a different category. … We were trying to reach out more to the women whose lives fell apart for a little bit.” –Staff Member 3, Clinical*	Conveying changes about the program to others. *“And when we started out, it was just for diabetics, and like, I didn’t know that they went into other stuff.” – Staff Member 9, Nurse* Building validity of the peer as Capacity Coach. *“[Peer] was also [clinician]’s patient. So, I think that was a barrier and a uniqueness to it as well – like conflict of interest kinds of things maybe.” – Staff Member 4, Social Worker “Yeah I wasn’t gonna say anything. Yes, I think it was.” –Staff Member 11, clinician*

	Champion Modifying existing structures (templates, supervision logs, etc.) to fit the new program. *“These are the templates we use that we created for all the peers. And how do you take that and then we can change the template to have the capacity coaching pieces in there, which was fine, but those were all things that just hadn’t been considered.” – Staff Member 1, Clinician*	
Cognitive Participation		Getting people involved clinically and throughout Women’s Health. *“I don’t really know what she [social worker] did because I wasn’t involved. But then eventually, the idea came out- came down from somewhere to use the peer support person.” – Staff Member 8, Program Manager* A select few individuals driving the program forward. *“Uh I think some people were more aware than others, and I think if we – when we would remind them, they’d say ‘Oh, yeah!’ but then it quickly dissipates. [Clinical Champion] and [Clinical Champion] were better about it.” – Staff Member 4, Social Worker* Clarifying and creating a streamlined referral process from clinic to coach. *“Not the providers.” –Staff Member 12, Nurse “Really? I have never done it.” –Staff Member 13, Nurse* The amount of time to get all the logistics worked out to implement the program. *“Cause the infrastructure wasn’t there. If we did six months now, it would look completely different because you would be comin’ out of the gate running. Because things needed to- we used to go back and we’ll say ‘Okay, let’s uh, strengthen this piece here and do somethin’ different here.” Staff Member 1, Clinician* Balancing planning logistics and focusing on the big picture of the program’s intended impact. *“On the one hand, it’s nice just sort of be in the presence of people that are sort of big picture thinkers, but on the other hand, it’s like okay, at some point, we have to just, you know,*

		decide and do something." – Staff member 5, Project Coordinator Co-location, visibility, and marketing of the capacity coaching program. *"I think [peer] needed to be in the clinic or like have space so that- for me, a lot of things are out of sight out of mind." –Staff Member, Social Worker "Yeah 'cause it woulda been nice if you woulda – you know, if we would've – if you woulda walked in the nurses and say 'hey, have you been doing this?" –Staff Member 12, Nurse*
Collective Action	Appropriate patients were referred to the program. Five hours Monday and Tuesday were dedicated for the capacity coach to be in the primary care clinic. Individual's practices with patients did change because of the intervention. *"I think it was just having a little bit more focus on, you know, 'cause my practice I kinda of had to figure it out those barriers, I needed to focus on those, um, before we had the training. But like how to approach focusing on them, and being more approachable to my patients, the veterans, um, on how to you know, get that out of them. And be a little bit more nurturing so to speak about how we get to that point, and maybe even having a better structure of how we facilitate doing that." –Staff Member 6, Pharmacist* When the program transitioned the capacity coaching role from social worker to peer, the coach and social worker had a productive working relationship with each other and with patients. *"[Peer] is awesome at coaching and has, like, all of those skill sets. So she, I think, did a lot better job and really brought the program to life more than I could." –Staff Member 4, Social Worker* Capacity coaching notes were entered into the electronic medical record with a summary of the visit and next steps. These were signed by coach, social worker, and the referring clinician.	The referrals to the program were primarily driven by a few champions of the program. *"I'm surprised we didn't get more referrals is the other thing. Um, because I know how many people that I see whether they're male or female could've been helped." Staff Member 6, Pharmacist* Limited flexibility of the Capacity Coach's time due to the fact she was shared with another program. *"Her supervisor was really strict on, like, 'You're there Monday and Tuesday morning from like, 10 to 12' kind of deal, but that doesn't work. Like that is a really small window, so she was able to give herself some more flexibility, which I really appreciated, and she would kind of weave people into her other schedule." –Staff Member 4, Social Worker*

	The Capacity Coach successfully used the workshop curriculum to work with patients. *"I made, uh, some really good connections through the capacity coaching. And I was a little saddened that it ended." –Staff Member 2, Capacity Coach* The implementation team put out a Capacity Coaching toolkit for other VA Medical Centers to use, and it will be shared with 31 other sites. *"I think there are 31 sites that have – that now have, um, peer support people in primary care. And none of the sites reached out, but I reached out to the directors of those programs. As it's through the directors of those programs that allowed access to be able to put this on. It's called TMS, and it's a teaching program. They get credit for it to go through the webinars. So they're extending that out. And I think he sad that they have five sites that they really wanted to pilot [capacity coaching] with." Staff Member 3, Clinical Champion* ICAN Implementation was straightforward. *"I like how it's more conversational. 'What's on your mind today?' Those three [questions] are really strong." Staff Member 1, Clinician*	
Reflexive Monitoring	Participants involved in championing the program found value in it, making it worth continuing. *"It definitely, um, helped with frequency of um, well, shorter intervals of follow up and just going a little bit more in details about those things that I don't have the time to do and realistically, I don't think anyone in the PACT team has time to do with the patients." –Staff Member 10, Clinical Champion* Participants highlighted that the male population might also have benefitted from the program. *"Well, because, I mean, we're [women] 7% of the population here, right? 7%, I mean that is tiny. And it's really easy to just have it*	Failure to build in robust evaluation into the pilot. *"And sometimes I'm kind of like, it's so – I feel like it's sort of untested, 'cause we didn't do the formal evaluation. And they're all like 'oh yeah, sure we'll [other peer support specialists] do this.' And I'm like 'Okay,' so there's a little trepidation there. It's like, well, I don't really, you know, have any p-values or anything." –Staff Member 7, Project Coordinator* *"They could actually say 'what was the system burden?' would be the way to do it just like in our – in mental health they look at like how many people are comin' in usin' ED services gotten acute services. You probably – especially with a longer pilot – you could say how did [capacity coaching] save them money because this person now is*

	sort of dismissed or forgotten about. But if you include men, um, men are more interested in being involved and working on it." –Staff Member 8, Program Manager	*actually using their meds and they're not coming in and they're not having a long hospital stay and those outcomes would be the way to sell it." –Staff Member 1, Clinician* Failure by referring clinicians to check back in with patients on the value they found from the program. *"I think it would've been a good idea if I did ask some of those patients 'well, how is that going?' But I, as a provider, didn't necessarily do that." –Staff Member 10, Clinical Champion* Lack of planning regarding the sustainability of the program beyond the grant funding period.

Transferability of Capacity Coaching Curriculum

A surprising finding that emerged outside of the conceptual models and theories described above was the applicability of the *Capacity Coaching* curriculum beyond patients living with chronic conditions. One participant highlighted the ways in which she took the skills learned in the workshop and applied it to working with nursing students in another role.

"Yeah, so that – this is real – I really like it. Actually, I do something similar with students … I, you know, sometime we only look at the student's GPA, you know, their grades, like you know 'You're struggling in this class,' but you know they have a lot more. They have a college life. They have a life besides, you know, go to school. They are working and they have a you know, family and then – so I actually really use that concept, trying to understand a little better." –Staff Member 6, Fellow

Discussion

Summary of Findings

To summarize, this ethnographic exploration of the first attempt to implement the novel *Capacity Coaching* program into clinical practice uncovered four key points:

1) The program was feasible in clinical practice.
2) Its implementation achieved changes in clinical practice that were aligned with Minimally Disruptive Medicine.

3) The program’s implementation strengths were in participants making sense of the intervention (coherence) and working collectively to enact the program in the pilot period (collective action).
4) The program’s implementation challenges were in planning the work of implementation and enrolling a diverse coalition of clinical staff to expand referrals to the program (cognitive participation), and in evaluating the impact of the program on outcomes that upper leadership was interested in to continue the program beyond the grant funding period (reflexive monitoring).

Limitations and Strengths

The results of this evaluation cannot be interpreted without considering it in light of its strengths and limitations. There are two key limitations. First, this evaluation was conducted after the program pilot had ceased and there were no continued *Capacity Coaching* activities during the time the data was collected. This means the robustness of the evaluation relies somewhat on participants’ memories of the previous two years and likely captures only key highlights of the successes and challenges that occurred. Second, the evaluation was entirely qualitative, which means the impact of the program on patients’ health outcomes and quality of life relies entirely on anecdotal cases documented by staff engaged in the pilot. This limitation exists because of the narrow scope of the grant funding that supported implementation of the program to test feasibility, as well as the heterogeneous nature of the small patient population that participate in the pilot.

Implications for Research and Practice

Importantly, even in this brief pilot of the *Capacity Coaching* program, it satisfied the components of MDM, and addressed key needs of patients living with multimorbidity not addressed by other recent chronic care interventions.[70] These key features included: being agnostic to the chronic condition(s) patients were living with, acknowledging and reducing work required of patients for healthcare, and supporting patients' capacity across all constructs described in the Theory of Patient Capacity. Given these differences in the intervention compared to recently evaluated interventions for chronic conditions, *Capacity Coaching* deserves broader testing to understand its impact on patient health outcomes, quality of life, and healthcare utilization.

Capacity Coaching is novel not only in its application of the principles of MDM, but also in that it combines two types of interventions that have typically been used individually for populations of patients living with chronic illness – intensive team-based management and coaching.

Positive changes in a variety of outcomes have been elusive when testing team-based management interventions for multimorbidity.[71] Across studies of this nature, multiple saw no effect on measures of utilization, health outcomes, or caregiver- or patient-reported outcomes (e.g., quality of life, caregiving burden). [72-74] One of these interventions was even specifically implemented within VA PACT teams. [74] However, participants exposed to the *Capacity Coaching* program could clearly articulate the difference between it and other programs at the VA, including one for intensive management of patients with chronic conditions and numerous programs offered through Mental Health. This distinguishability suggests it should not be immediately lumped with past programs that have had limited impact, but rather tested to assess its outcomes in comparison to past interventions. Importantly, the fidelity of the program's adherence to MDM principles should be monitored closely in future research, as it appears to be a distinguishing and potentially impactful factor when compared to previously tested interventions.

The coaching literature lacks clarity in defining different types of coaching.[75] However, the most recent systematic review of health coaching interventions in chronic conditions indicated statistically significant changes in patients psychological, behavioral, physiological, and social outcomes across 11 of 13 studies examined.[76] Furthermore, a recent compendium of health and wellness coaching interventions indicated mostly positive results for patients living with cancer, diabetes, heart disease, hypertension, and obesity.[77] Finally, in a recent systematic review of health coaching for cancer survivors, patient capacity was supported across four of the five constructs of the Theory of Patient Capacity (Biography, Resources, Work, and Social).[78] These previous studies also point to the potential impact of capacity coaching, particularly when integrated with the rest of the primary care team.

It is important that future research of *Capacity Coaching* and other MDM-driven interventions incorporate the implementation learnings gleaned from this study. First, implementation was a complex process of integrating this new way of working into the primary care team, and that task filled much of the 6-month pilot period. There was little time to enroll others and plan to expand the program further or to build in evaluation of the program. Second, critical challenges in the cognitive participation of the full primary care team included difficulties with role definition, investing in management capacity, and building accountability within the team, which resulted in a limited footprint of the cultural changes concordant with MDM in other areas of the clinic or VA center. These challenges can potentially be addressed in the future by using a two-year culture-change curriculum, Leadership Saves Lives (LSL) to implement *Capacity Coaching* and other MDM-driven interventions. [79] This curriculum was previously applied in acute care, focused on the problem of post-heart attack mortality. [79] In the testing of the LSL, the researchers found significant changes in culture across hospitals and in decreased post-heart attack mortality rates in hospitals that demonstrated the greatest changes in their culture. [80] Therefore, there is potential to use LSL as a facilitation strategy to overcome the key implementation challenges faced when piloting *Capacity Coaching.*

Conclusion

This study represents the first implementation and evaluation of the novel, MDM-driven, *Capacity Coaching* program in primary care clinical practice. The ethnographic observations and qualitative interviews demonstrated that the program was indeed feasible to implement in team-based primary care practice. Additionally, we saw delivery of the program in such a way that it positively impacted clinical practice, bringing in elements of MDM not seen in other chronic care interventions. Finally, we saw significant success of the implementation in participants making sense of the intervention (coherence) and working collectively to enact the program in the pilot period (collective action). Implementation challenges occurred in planning the work of implementation and enrolling a diverse coalition of clinical staff to expand referrals to the program (cognitive participation), and in evaluating the impact of the program on outcomes that upper leadership was interested in to continue the program beyond the grant funding period (reflexive monitoring). These challenges suggest the potential positive impact of incorporating an existing culture-change curriculum, LSL, to facilitate implementation that is robust and far-reaching.

Manuscript Three: Minimally Disruptive Medicine: A cultural approach to optimizing care for people living with chronic conditions

Background

Multimorbidity, the coexistence of *multiple chronic conditions* (MCC), affecting 3 in 4 Americans 65 and older, is a growing public health problem.[27, 81] Patients living with multimorbidity deal with a large burden of illness and a complex, long-term self-care regimen.[5, 6] Traditional healthcare may increase the burden of managing the illnesses in the lives of people with MCC, as guidelines typically focus on managing individual conditions and not the patient as a whole,[82] potentially overwhelming patients and their families.[39] For people with MCC, healthcare often requires unsustainable self-management strategies while offering treatment in an uncoordinated fashion and out of line with patients' resources and abilities to handle complexity.[18, 31] When this occurs, non-adherence and self-care exhaustion are increasingly likely. [13, 16]

Minimally Disruptive Medicine (MDM) is a philosophy of care designed to ensure treatment plans do not overwhelm patients by bridging the gap between evidence-based, disease-specific treatment guidelines and the personal context of patients living with multimorbidity. MDM comprises tools and practices to pursue patient goals while reducing the burden of treatment for patients and caregivers, resulting in sensible care plans that patients can feasibly implement and sustain.

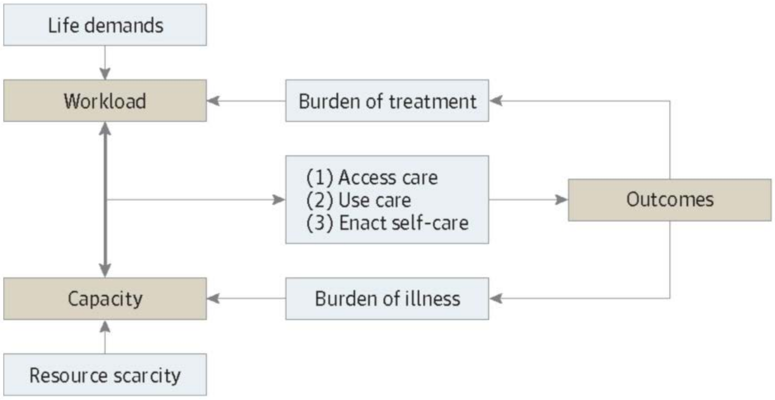
The application of MDM may be highly valuable for a specific population of patients, those on dialysis, where many caring for this patient population have called for a more patient-centered focus.[83-85] Patients with advanced End-Stage Renal Disease (ESRD) requiring long-term hemodialysis treatment count among the patient groups with the highest comorbid burden (56-86% patients with chronic kidney disease have co-morbidities, such as diabetes and heart failure[86, 87]) and treatment workload. Patients face considerable treatment workload including the time-consuming regimen of at-center hemodialysis, generally three days weekly, as well as strict medication and diet regimens that they must enact at home. These include taking an average of 6-10 medications daily, and adhering to fluid and dietary restrictions - specifically eating a diet high in protein and low in sodium, potassium, and phosphorus.[88-90] Because guidelines often do not consider patients' other conditions, their overall treatment burden, or their personal and social contexts, patients and their caregivers are frequently faced with uncoordinated and overwhelming work that is sometimes contradictory in nature and difficult to organize and implement in daily life.[34, 82] The stakes of nonadherence are high, including increased symptom burden, emergency department visits, hospitalizations and death.[91] Patients on dialysis have mortality and symptom burden similar to that of cancer patients,[92] and two-thirds of patients receiving hemodialysis do not survive five years.[91]

Despite the considerable potential benefit to implementing MDM, first described in 2009 and now widely recognized as one of the most important medical ideas in the last 20 years,[29] in the care of patients on dialysis, a key challenge remains: the required cultural shift in the way clinicians and healthcare organizations deliver care to patients with MCC. To date, no healthcare system to our knowledge has applied MDM as a comprehensive model of care.[93, 94]

Past Work and Conceptual Foundation

This study draws upon the Cumulative Complexity Model (CuCoM) (**Figure 5**), which conceptually drives proposed MDM practice, and a previous culture-change intervention, Leadership Saves Lives (LSL). In the CuCoM, patient complexity arises when the burden of work from treatment and life overwhelms the capacity of patients and caregivers. For some patients, workload and capacity are balanced, and they are able to meet all demands. Yet for others, they become imbalanced: patients must choose to adhere to treatment or to respond to important life demands. When workload and capacity become imbalanced, patients may experience breakdowns in their ability to access and use healthcare and enact self-care, ultimately affecting outcomes. Also, declining outcomes are often met with efforts by the healthcare team to ramp up treatment while the patient's capacity continues to diminish from the burden of illness, establishing a vicious cycle of imbalance and complexity.[16]

Figure 5: The Cumulative Complexity Model (from Leppin A et al. JAMA IM 2014).



Yet the application of MDM guided by CuCoM requires cultural change for healthcare teams to think in this manner with each patient and to drive this change across clinics and systems. Specifically, systems must create a culture that recognizes patient work and supports patient capacity. In a clinical culture that has typically worked to reduce work, waste, and cost to improve its own efficiency and value rather than the efficiency and value in patients' lives, this requires a whole-scale change in thinking. Because organizations face implementation fatigue already, and clinician burnout is high, the culture-change process needs careful support.[95, 96]

Leadership Saves Lives (LSL) is a culture-change intervention that was originally applied to the problem of reducing 30-day mortality after an acute myocardial infarction (AMI).[79] LSL was implemented in ten large and unique health systems, subscribing members of the Mayo Clinic Care Network.[79] LSL was originally designed as an intervention to promote the uptake of five specific strategies, including creative problem solving, and five domains of organization culture associated with reduced AMI mortality[79, 97, 98]. Building on a decade of prior work [99-104], the LSL intervention included three key components: (1) the formation of a multidisciplinary guiding coalition to undertake the tasks required to implement culture change, (2) facilitated workshops with the guiding coalition over a two-year period, and (3) an annual convening of representatives from each guiding coalition. Culture change was measured across five domains: (a) senior management support [105] (b) learning environment [106] (c) psychological safety [107] (d) commitment to the organization, [108] and (e) time for improvement efforts.[107]

At the conclusion of the LSL intervention, two years later, the research team observed statistically significant positive culture change overall, primarily driven by changes in the learning environment and leadership support. [79] Recently published results from LSL have also shown that culture change was associated with decreases in patient risk standardized mortality rates.[109] This is a significant finding as it suggests that culture change can improve health outcomes of individual patients.

The Current Study

The current study seeks to extend the LSL intervention to the ambulatory care setting, i.e., dialysis centers, and if successful, will facilitate the first change of health system culture to implement an MDM model of care. Specifically, we hypothesize that through application of the LSL intervention, we will see positive cultural shifts that improve senior management support, learning environment, psychological safety, commitment to the organization, and time for improvement efforts, and that these changes in culture will result in care that improves its alignment with MDM by reducing patient work and supporting patient capacity. Second, we expect that in clinics where the intervention positively impacts culture change will see a positive impact on triple aim outcomes: health outcomes, experience of care, and cost.

Methods

Study Design

We will use a cluster-randomized, mixed-methods convergent design to evaluate the culture change at the clinic-level and patient-important outcomes at the patient level. This study design uses both quantitative and qualitative data collection across all time points, analyzed simultaneously, and presented as a rich mixing of results to explain both what happened and why. The timeline for the study activities are shown in **Figure 6**.

Figure 6: Study Timeline

Tasks	**Year 1**				**Year 2**				**Year 3**				**Year 4**			
Quarter	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Study Preparation/IRB	■															
Baseline QoL, Symptom Burden, PACIC, Illness Intrusiveness Surveys		■	■													
Baseline adherence, utilization data collected		■	■													
My Healthcare Grid collection and synthesis				■	■											
Staff Organizational Culture Surveys					■											
Observations of Culture during workshops									■				■			
LSL Annual Meetings					■				■				■			
LSL Workshops – 4 per intervention site					■	■	■	■	■	■	■	■				
Follow-up QoL, Symptom Burden, PACIC, Illness Intrusiveness Surveys													■	■		
Follow-up adherence and utilization data													■	■		
Mixed-Methods Analysis														■	■	
Reports/ manuscripts															■	■

Study Sample

The study will be conducted at eighteen diverse dialysis centers, distributed nationally. These centers are administratively owned and operated by a single healthcare organization or by an independent dialysis company with the healthcare organization's medical directorship. Sites will be categorized by size, geography, and payer, allocated into pairs with similar centers, and then randomly allocated within pairs to either LSL or to usual care (control). If selected as the intervention site, the leadership at the site will form a guiding coalition of clinic staff consisting of 4-12 members. Center staff (physicians, nurses, physicians' assistants, social workers, and dieticians) will be introduced to the project during existing standing breakfast- or lunch-hour staff meetings and will be consented as participants in the study. Patients receiving care at participating clinics will be consented for participation if they are participating in study activities.

Intervention

We have developed an LSL intervention that harnesses the core components of the original intervention designed for hospital-based care and incorporates the theoretical underpinnings of MDM as well as the ethnographic findings of early-adopters of the principles in care. The intervention is described briefly here, and a full online intervention manual can be found online.[22] The intervention has three key components: 1) a multi-disciplinary guiding coalition, appointed by clinic leadership; 2) LSL bi-annual workshops; and 3) annual meetings of guiding coalition members at a central location.

Clinics randomized to participate in LSL will establish a guiding coalition of 4-12 clinic staff members across disciplines tasked with participating in four LSL workshops hosted at their site, and three annual meetings hosted onsite at one of the participating clinics. Cross-clinic collaboration will be facilitated through the use of Basecamp®, a project management and information sharing platform, previously used to support the original LSL intervention. This coalition, tasked by center leadership with being the key problem-solvers and intervention leaders will be responsible for bringing the intervention into the dialysis center practice. The guiding coalition will work throughout the two-year intervention period to solve the problem of burdensome care for patients. They will be guided in their work by the My Healthcare Grid synthesis and the LSL workshops, both described in more detail below.

LSL workshops will be held for the selected guiding coalition at each of the nine LSL dialysis centers once every six months, for four total workshops over a two-year period. LSL workshops are designed to build a culture that supports creative problem solving to tackle the problem of burdensome care for patients. The curriculum of the LSL workshops to support MDM will have the same curriculum as the previously successful LSL workshops to support practice change regarding mortality following acute myocardial infarction. The curriculum will:

- Prepare coalitions to **bring the right perspectives to the table** by providing instruction and learning experiences related to role clarity,[110] working across boundaries,[111, 112] and working with hierarchy.[113, 114]
- **Pursue full engagement** as guiding coalition members contribute their unique skills and perspectives to a common objective by providing instruction and learning experiences related to leadership and followership,[115] representational

groups,[116-118] psychological safety,[119] group decision making,[120] levels of analysis[121, 122]

- **Promote progress** by providing instruction and learning experiences related to managing conflict[123] and building accountability[124] within the group
- Introduce strategies to **facilitate Minimally Disruptive Medicine**. These strategies include the application of the ICAN Discussion Aid, regular measurement of treatment burden, de-prescribing for overwhelmed patients with polypharmacy, refill synchronization by time or by family, registries of patient capacity resources in the community, and *Capacity Coaching* – a unique style of health coaching that focuses on rightsizing workload-capacity balance rather than coaching toward specific guideline-recommended behaviors.[14, 20, 125-127] Additional novel strategies are expected to arise as sites reflect on the My Healthcare meta-grids, described below, and as part of the strategic problem-solving approach.
- Facilitate the coalition through the **strategic problem-solving approach** (defining the problem of disruptive care, setting and measuring progress toward shared objectives for MDM, identifying and prioritizing of root causes of disruption, and generating and pursuing strategic solutions).[128]

Finally, a key part of the LSL strategy includes annual meetings of the guiding coalitions for co-learning across sites. These yearly gatherings will draw on the curriculum from the original LSL experience. The first annual meeting will cover topics such as: introducing the MDM and LSL teams, the current evidence and theoretical base for MDM, and the platform for co-learning across sites between meetings (Basecamp®).

Additionally, breakout sessions during the meeting will cover current MDM strategies, ensuring the right members are on the guiding coalition, and study expectations. The second annual meeting will include presentations by individual centers regarding their current progress, challenges, and lessons learned, and will also include breakouts by discipline to facilitate co-learning by role at sites (i.e., social workers, nurses, physicians at each site). The third annual meeting will include presentations by individual clinics to summarize their experience of participating in the intervention and to share site-based organic innovative tools and protocols. This sharing across sites at the conclusion of LSL participation was a highlight in the first LSL intervention, and we expect to see similar cross-learning in chronic care as well. At each annual meeting, members from the visiting clinics will be allowed to tour the hosting clinic to learn about local context and the way in which they are seeking to apply MDM given their unique population's needs.

Quantitative Data Collection and Measurement

Quantitative data will be collected at the clinic-level and at the patient-level. Quantitative data will be collected at both intervention and control sites.

Clinic-level: We will measure culture as reported by staff at each clinic using the 31-item survey instrument “Underlying Aspects of Organizational Culture” (see Appendix), administered at baseline, mid-point (12 months), and completion (24 months). This instrument has been validated and was used as a key outcome measure in the previous LSL study.[79, 80] The measure examines five key domains of organizational culture: 1) Learning and Problem Solving; 2) Psychological Safety; 3) Senior Leadership Support; 4) Commitment to the Organization; and 5) Stress/Pressure in the System. Questions are asked on a 5-point Likert Scale and ask respondents the extent to which they agree or disagree with statements such as “There is good ***coordination*** among the different clinical units involved with the care of patients receiving hemodialysis” and “In this work environment, people value new ideas.” Surveys will be administered by email. Non-responders will be sent an email reminder at one week and will be sent a paper copy of the survey at three weeks if the email survey has still not been completed. Overall culture scores and average scores for each of the five domains will be computed and reported back to each site. In addition to the scores’ application to continuous improvement as part of the intervention, change in culture scores from baseline to completion, will be used as an outcome measure.

Patient-level: We will measure the extent to which the intervention impacts the triple aim: patient health outcomes, patient and healthcare teams’ experience of chronic care, and the cost of care to the healthcare system.[129] We hypothesize that clinics that are more successful in affecting culture change, as measured by clinic-level quantitative data, and triangulated with qualitative data, will see positively correlated changes in patient-level outcomes.

We will consider three patient-level health outcomes. *Quality of Life* will be measured using EQ5D, one of the most commonly used generic measurement tool for health-related quality of life (HRQOL). It takes a holistic view of health, including medical definition and independent physical, emotional and social functioning. The concept of health in EQ-5D also encompasses both positive aspects (well-being) and negative aspects (illness). The EQ-5D is short, easy to use and flexible. This 5-item measure has been shown to be valid and reliable[130] across a range of countries and conditions. We expect that sites that implement MDM will have, on average, higher quality of life scores than control sites. *Symptom burden* will be measured using a modified Edmonton Symptom Assessment System (ESAS). This 10-item measure has been shown to be valid and responsive to changes in symptom burden over time. The questionnaire asks patients to rank a number of common symptoms, such as pain and fatigue, on a scale of 1-10. In cancer, the minimal meaningful difference should range from 1.1–1.8 units.[131] We expect that sites that implement MDM will have, on average, lower symptom burden scores than control sites. *Adherence to prescribed pharmacologic therapy* during the previous six months will be measured as Percent Days Covered from pharmacy fill profiles. We have experience using profiles and this outcome measure as a trial outcome.[132, 133] Polypharmacy is likely to be the norm in this population, which will be accounted for in this analysis. We expect MDM to lead to more feasible treatment plans and better medication adherence.

We will measure the patient-level care experience using two measures. First, p*atient care experience* will be measured using Glasgow's 20-item Patient Assessment of Chronic Illness Care (PACIC). Higher PACIC scores have been shown to be positively correlated with patient-reported self-management behaviors.[134] The 20-item scale measures goal setting, coordination of care, decision support, problem solving, and patient activation and prompts the patient to reflect with items such as: "Over the past 6 months, when I received care for my chronic conditions, I was: helped to make a treatment plan that I could carry out in my daily life." We expect patients at MDM sites will feel supported in exactly this way, increasing PACIC scores, compared to control sites. *Illness intrusiveness* will be measured using the Illness Intrusiveness Scale [135, 136] a tool originally developed in the dialysis population, but also used widely in testing the Chronic Disease Self-Management Program.[137] This identifies the extent to which the treatment regimen interferes with life by asking “How much does your illness and/or its treatment interfere with...” things like “your work, including job, house work, chores, or errands?” MDM implementation should lead to care that better fits the context of patients and therefore, be associated with less Illness Intrusiveness.

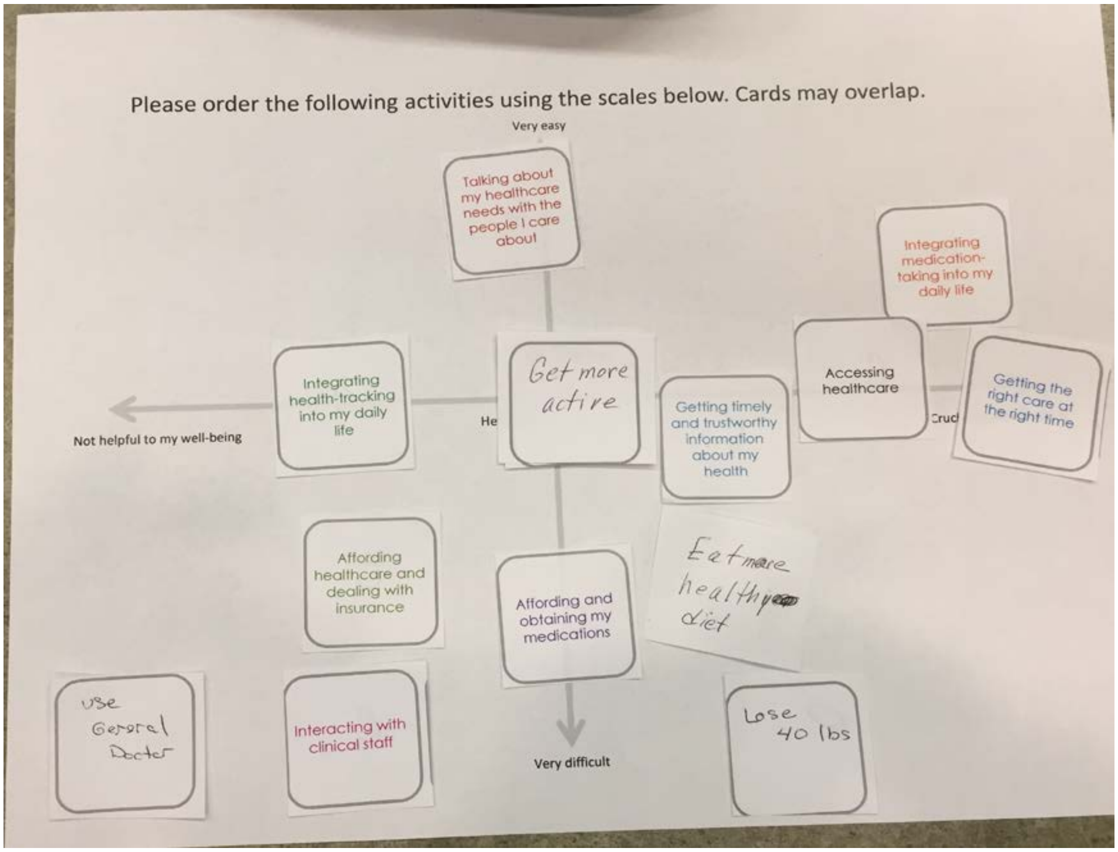
Finally, we will measure healthcare costs using patient emergency department (ED) visits, resource-intensive ED visits, and hospitalized days. Data collected will include the typical data elements included in administrative claims including diagnoses, dates of services and payments for services. We have recently published on hospitalizations in the ESRD population using U.S Renal Data System.[138] We have shown that 19% of patients receiving hemodialysis average fewer than 2.5 dialysis sessions per week, compared to the recommended 3-4 sessions per week. These patients are at higher risk for ED visits, ED visits that require more intensive intervention, and greater numbers of hospitalized days.[139] We hypothesize that MDM sites will have higher adherence to dialysis sessions, resulting in fewer ED visits, intensive ED visits, hospitalizations, and total spending.

Qualitative Data Collection

Qualitative data will also be collected at the patient level and the clinic level. Qualitative data collection will only occur at intervention sites.

Patient Level: Previous work developing the ICAN Discussion Aid has informed the development of the My Healthcare Grid (**Figure 7)** that is part of the modified LSL intervention. Whereas the ICAN Discussion Aid brings to light patient context and treatment burden during the clinical encounter, the LSL intervention brings a complementary and necessary focus of treatment burden at the <u>practice level</u>, orienting the guiding coalition tasked with improving these issues by implementing MDM.

Figure 7: My Healthcare Grid



After consenting, patients will be assisted in completing the My Healthcare Grid. Patients will first “write down the things that you have been asked to do to care for your health” into empty squares. Then, they will be asked to place these on the grid, which divides the space into four quadrants: 1) “Not helpful to my well-being/Easy” 2) “Not helpful to my well-being/Difficult” 3) “Crucial to my well-being/Easy” and 4) “Crucial to my well-being/Difficult.” After placing their own squares, they receive nine prefilled squares, and asked to place these in the quadrants as well. As they are placing the squares, patients will be asked to talk to the facilitator about the reasons for these placements. Clinic staff at each site will complete the same exercise, based on their perception of what patients at their center would experience. A filled My Healthcare Grid, completed by a member of our KER Unit Patient Advisory Group is depicted in **Figure 7**.

Clinic Level: At baseline, mid-point, and conclusion of the intervention, we will collect observation notes using traditional ethnographic methods.[140] We will tour the clinic with members of the guiding coalition, asking them to show us the space in which care is taking place and to point out things that they have been excited by or struggled with since beginning the LSL intervention. In addition to the observations occurring while touring the clinic, we will bring an additional research personnel member to collect observation notes during the facilitated workshop. We use an observation guide modeled off of the original LSL one used to generate observation notes (**Table 6**). We will also conduct qualitative interviews with guiding coalition members at the beginning, mid-point, and end of the intervention. These interviews will be semi-structured and designed to understand the current culture of patient-centered care. All interviews will be audio-recorded and transcribed verbatim.

Table 6: Sample Observation Guide	
Physical Environment/ Context	• What is the space like? • Cluttered/Neat? Quiet/Loud? Energetic/Relaxed? Bright/Dim? Other? • What artifacts of culture do you observe?
Actors/ Participants	• Who is doing what? • What are the relationships between participants? o Who interacts with whom? o Who empowers or silences whom? o How is power and authority exercised? • Who is missing?
Timing	• What is the timing of your visit (morning/evening, busy/slow, shift change, tied to other cyclical patterns?
Informal Factors	• What non-verbal cues do you observe? • What visual cues to you observe? • What symbols or symbolic acts do you observe?

Quantitative Data Analysis

Both quantitative and qualitative data will be used for reporting outcomes of the study, but will also be used for the continuous cultural innovation at participating intervention sites.

The trial conduct and analysis will follow the intention-to-treat principle. Data will be analyzed using techniques appropriate for pragmatic cluster-randomized trials. Baseline characteristics will be summarized at the site within each trial arm, providing counts and frequencies for categorical variables and means with standard deviations and ranges for continuous variables. We will test the null hypothesis of no difference between arms in baseline characteristics using t-tests and chi-square tests adjusted for clustering by practice.[141]

The patients' follow-up responses will be modeled using Hierarchical Generalized Linear Models (HGLMs), each outcome assessed for the correct distribution and for meeting assumptions. As with the clinic staff analysis, the pairing of the sites will be treated as a random effect at the first level. As the amount of overlap between patients at baseline and follow-up is unknown, to account for this, patients will be treated as a random effect at the second level. The baseline effect will be averaged per site within a pair and the difference calculated. The model will then be adjusted by arm and the average difference for the outcome of interest will be calculated between arms. In essence, we will conduct a difference-in-difference analysis.

Sample Size Considerations: Across the 18 eligible dialysis centers there are nearly 1.839 eligible patients based on last year's annual census. The outcomes of interest to power the study will be based on patient outcomes. As the key outcomes for patients are collected at the 24-month follow-up, the recruitment period of interest per center is the two-week follow-up, where we estimate we will be able to approach half of the center patients for enrollment. With a 70% acceptance rate, we could potentially enroll 642 patients, as the burden of involvement is minimal, and we have historical experience to support this.[57] As data collection is to be conducted at time of enrollment, loss to follow-up may mostly be a factor in the adherence (pharmacy) outcome. Assuming an intracluster correlation coefficient of 0.1 (conservative) and alpha of 0.05 with a two-sided test we will have 80% power to detect a difference of 0.5 standard deviations (i.e., a moderate-sized difference) for a continuous outcome. We have successfully obtained pharmacy records for 80% of trial participants in previous studies in similar populations.[132, 142, 143] Reasons for not having complete data are due to lack of pharmacy response and patient refusal to provide consent to obtain these records. This has little impact on the power changing the detectable difference to just over a half of a standard deviation (51%).

Missing data: Every effort to avoid missing data will be undertaken. Because our data collection for patient-level survey data will primarily occur in-person, study coordinators will be ideally positioned to ensure fully completed surveys. The inclusion of patient consent to review EMR data will allow for the collection of patient ER and hospitalization data when it is missing from administrative data. Patients with missing outcome data will be assessed in that outcome by using appropriate techniques per current recommendations.[144] We will report rates of missing data for each outcome by study arm and known reasons for missing data. For data elements that are used to adjust study comparisons we will use multiple imputation to account for any that are missing at random (MAR), and conduct sensitivity analyses to compare outcomes with imputed data to those calculated, excluding patients with missing outcome data.

Qualitative Data Analysis

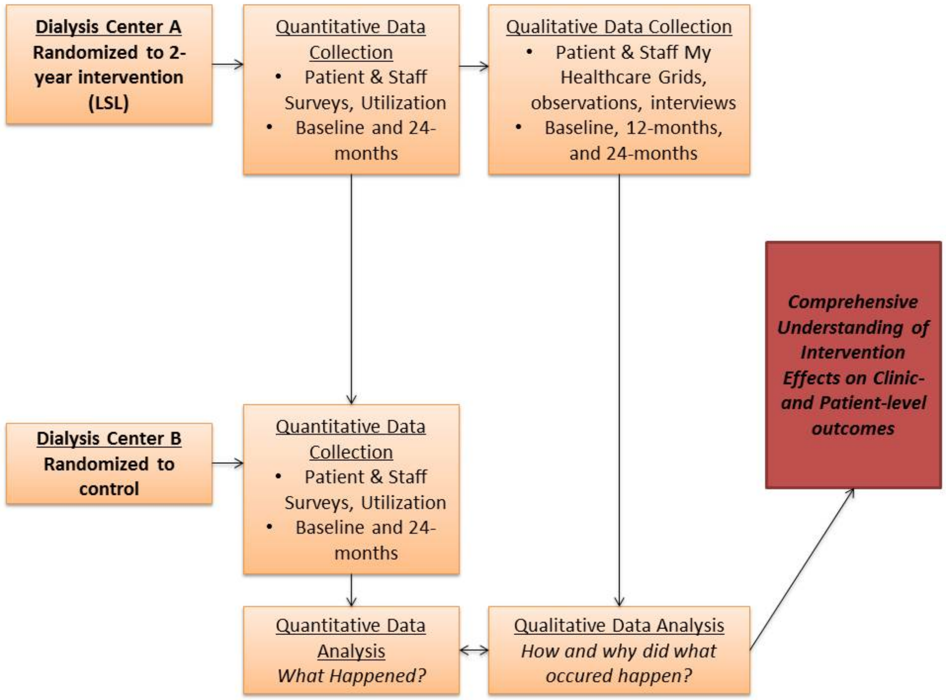
Patient My Healthcare Grid conversations with the researcher will be recorded and transcribed verbatim for analysis. Completed grids will be photographed by the researcher for data analysis. We will conduct a thematic synthesis using the photos of completed grids and the transcribed conversations to create two meta-grids which will be presented to clinic staff. One meta-grid will represent the location of each healthcare activity square most consistent with the largest number of patients. The other meta-grid will represent the location of each healthcare activity square consistent with the largest number of staff. In both cases, outliers will be noted. If certain squares are equally split between distinctly different quadrants, this will be accounted for by duplicating squares and discussing the reason for this double placement during presentation to the guiding coalition.

Observation notes and interview transcripts will be uploaded to Nvivo 11 and synthesized by using constant comparison methodology as used in the original LSL research study[109, 145, 146] where “each transcript was coded independently by at least three analysts, with discrepancies reconciled through negotiated consensus. Iterative coding and analysis occurred across each wave of data collection, with refinement and review by the full team.”[109, 145, 146] This process will be repeated “until a final code structure [is] established and reapplied to the full data set.”[109, 145, 146]

Integration of Quantitative and Qualitative Data

Data will be integrated using a convergent mixed-methods design, which contributes to a rich understanding of a single research phenomenon.[147] As described, quantitative and qualitative data will be collected in a parallel, ongoing manner throughout the project. Quantitative data and qualitative data will be analyzed separately and the results will be triangulated. The quantitative data will contribute to our understanding of what occurred, and provide effect sizes of change (e.g., to what extent patient quality-of-life did or did not differ in sites implementing LSL compared to control), whereas the qualitative data will contribute to our understanding of why that may be the case (e.g., nurses tailored their supportive practices for patients at LSL sites). Additionally, as illustrated by the original LSL study, the qualitative data can help better describe differences amongst intervention sites. For example, hospitals that demonstrated significantly more culture change (particularly in the areas of changes in the learning environment, senior management support, and psychological safety) showed significant changes in risk standardized mortality whereas their counterparts missing this culture-change phenomenon did not.[109] **Figure 8** illustrates the convergent mixed methods design of the study.

Figure 8: Convergent Mixed Methods Design



Discussion

Strengths and Limitations

Limitations to our study include the relatively small-scale nature of conducting this work in dialysis centers. Compared to the original LSL intervention that occurred in large hospital settings that required culture change across multiple departments (e.g. emergency departments, cardiology, ICUs, and outside transport companies), dialysis centers are fairly isolated units of ambulatory care. However, the intervention may shed lights on ways in which dialysis centers need to be better connected to other points of care in the healthcare system and community in order for their care to be minimally disruptive to patients and their families. Furthermore, this study represents a proof-of-concept that culture-change interventions can impact patient-level outcomes in the outpatient setting, as was demonstrated in the inpatient setting. Success in the intervention could catalyze similar changes at a larger scale, such as in patient-centered medical homes. Strengths of the study design include randomization, which did not occur in the original LSL study, and the convergent mixed methods design to ensure robust and transferable findings.

Potential to Impact the Practice

Patients living with ESRD on dialysis need to undertake self-care practices that are restrictive and potentially overwhelming. When patients become overwhelmed, they are increasingly at risk for non-adherence to their medical regimens, which can have fatal consequences for patients on dialysis. The organization of healthcare can be maximally supportive for these patients, and reduce the chances of non-adherence by minimizing the disruption to patients in the way healthcare is delivered in dialysis centers. However, clinics’ ability to change their practices in this way requires careful cultural support that promotes the examination of the way care is currently given to patients and their families. MDM provides a lens through which to view the problem of non-adherence as one of the imbalance of workload to patient capacity, and it offers tools and strategies to correct this imbalance. LSL is a culture-change curriculum, which supports teams through the treacherous work of making systemic changes within healthcare settings. The marriage of MDM and LSL represents an opportunity to fully test the idea of MDM and to expand LSL’s contribution beyond the in-patient setting. The proposed mixed methods research will provide both evidence of the success or failure of this interventional approach, as well as key contributors to its success or failure.

Conclusions

In conclusion, patients with ESRD on dialysis represent a population in need of minimally disruptive care in order to reduce the chance of high-risk non-adherence. MDM is a conceptual foundation with tools and strategies to assist this population, and LSL is a culture-change intervention to support the sustainable application of MDM within clinics. The application of the LSL intervention to MDM will be tested in a cluster randomized trial that includes a mixed-methods convergent design. The outcome of this research study will provide evidence of the intervention’s effect, as well as generate hypotheses regarding its applicability to the outpatient setting and transferability to other populations and settings.

Conclusion

Summary of Findings

This dissertation looks to the past and the present to plan for the future. Maria Louisa and Kasey Rebekah's care should not be accidents; care should look careful and kind across patients, clinicians, and healthcare systems. Minimally Disruptive Medicine (MDM) and its underlying conceptual and theoretical constructs offer a lens by which we can imagine that reality. Yet at the outset of this dissertation, the current state of chronic care had not been reflected upon to examine its alignment or misalignment with MDM, a team-based MDM intervention had not been implemented anywhere in the country, and it was unclear exactly what was needed to move this field forward. Yet at the conclusion of this dissertation, we have three concrete manuscripts that bring clarity to the previously unexecuted and unknown.

Manuscript One carefully examined the current state of chronic care in light of the past decade of MDM's existence. That exploration revealed that recently implemented chronic care interventions on the whole failed to meet the unique needs of patients living with multimorbidity, namely: most of them were disease-specific in their aims and outcomes, few focused on patient-centered outcomes, patient capacity was not supported holistically and focused mostly on educating patients, and none of the examined interventions acknowledged the work of being a patient. Manuscript Two was a logical next step, the evaluation of a MDM-driven intervention, *Capacity Coaching*, to understand the extent to which it met the needs of patients not met by previous chronic care programs. That exploration revealed that the program, as implemented, did indeed offer patients unique support, specifically: it acknowledged and sought to reduce the work of being a patient, it was available to all patients regardless of condition(s), and it provided holistic support for patients' capacity, covering all constructs in the Theory of Patient Capacity. Yet the implementation of *Capacity Coaching* had challenges that can be improved upon in the next implementation of the program and other MDM-driven interventions. Manuscript Three is the proposition for those implementation endeavors inspired by the *Capacity Coaching* learnings and is the protocol for an AHRQ-submitted R18 funding proposal. This protocol proposes to take the principles of MDM and combine them with the curriculum of a culture-change intervention, Leadership Saves Lives. This research is proposed in a national network of dialysis centers, which serve patients with a high rate of multimorbidity and high levels of healthcare work, those living with end-stage renal disease. This combination should encourage team-driven culture change within clinics and overcome some of the implementation challenges discussed in Manuscript Two.

Limitations

Limitations for each individual manuscript are discussed within. However, it is worth considering limitations to MDM as a whole. These limitations can be classified into two categories: research and clinical practice. From a research standpoint, MDM has a strong theoretical and conceptual foundation, but the ability to measure constructs described in foundational work is problematic. For example, if we consider the constructs described in the CuCoM, we have the ability to measure treatment burden, illness burden, use of healthcare, and patient health outcomes and quality of life. However, we lack clarity on how to measure patient work, patient capacity, and access to healthcare. Patient work could be interpreted as the number of hours spent caring for health, the number of prescriptions a patient is taking, the number of conditions a patient has to manage, or some compilation of these, yet no single definitive measurement exists. Patient capacity lacks a holistic measure that can paint a picture of each construct in the Theory of Patient Capacity (Biography, Resources, Environment, Work, and Social). And finally, access to care can be captured from patients who make it to the healthcare system for treatment and monitoring, but how can we measure those that fail to ever walk through the healthcare system's doors simply because access is too problematic?

Another research limitation is that the way in which we have historically conducted research and structured our research institutions accordingly is by each condition or each specialty that treats a specific set of conditions (e.g. heart failure or cardiology). Yet, as multimorbidity continues to grow, this path makes little sense, since patients with one condition are likely not patients with only one condition. As researchers, we have a great deal that can be learned by bridging the gap between conditions and specialties, and synthesizing the experience of patients and health professionals across living with and treating different conditions. New innovations could follow from considering problems facing the healthcare system and patients from the perspective of many, rather than few and in silos. Interestingly, the National Institutes of Nursing Research is the only institute within the NIH that is not condition-specific, and why MDM fits incredibly well within the body of nursing research.

Clinically two significant challenges face MDM becoming a reality: time and quality metrics. Manuscript Two highlighted ways in which people become too busy to remember one more thing, including MDM interventions, yet this is highlighted in the work everywhere we go to discuss MDM. Clinicians are overwhelmed by the number of tasks they are asked to do, and finding time to conceptually realign one's practice with a new way of thinking often simply isn't there. Furthermore, sense-making with patients to understand their nuanced individual situations in order to construct minimally disruptive plans of care takes time, which ten to fifteen minute visits may not support.

Quality metrics also pose significant problems for MDM, as minimally disruptive plans of care may favor patient-important outcomes over healthcare-important outcomes. Manuscript Two highlighted the frustration with the difficulty in measuring the way *Capacity Coaching* impacted metrics decision-makers typically cared about. For example, patients may prioritize their quality of life, which to them means less disruption from checking their blood sugars. However, this may clash with quality metrics that flag patients with HbA1cs above a certain level.

Future Directions

Again each manuscript points logically to immediate next steps, and Manuscript Three points to concrete next steps for a specific unexplored path in this work. However, to address the above limitations there remain bigger picture next steps to consider as well. From a research standpoint, future projects should focus less on conceptual definitions, and more on developing measures that help us measure constructs already described within MDM's body of work. This will ensure that as we implement MDM-driven interventions, we can accordingly test their impact on outcomes that should change as a result of their implementation. Additionally, researchers should seek to think less in condition-specific ways, but rather in ways that explore the experience of living with and treating multiple chronic conditions. We have a great deal to learn from these syntheses that can move both research and clinical practice forward.

Clinically, we need healthcare leadership to consider abandoning time constraints and quality metrics, at least for brief periods in which we can study the impact of these deviations from the standard protocol. While certainly, some will gasp at the potentially negative impact this could have on the profits or sustainability of the healthcare system, the potentially negative impacts are an assumption. It is possible that with more time, patients and clinicians might be able to work carefully to make sense of the patient's situation and craft care that makes emotional, intellectual, and practical sense. One hypothesis might be that care like this actually requires patients to use the healthcare system less often and less urgently, since they would not need to return due to confusion or frustration. This undoubtedly requires bold leadership that is willing to try risky ideas and iterate on new programs in order to achieve the best outcomes for patients, their families, and clinicians giving care.

One thing is certain, a single grant or project will not change the world; it will take many more to ensure careful and kind care for all patients living with multimorbidity. The work represented here represents only a small portion of a much larger body of work that I remain committed to continuing as faculty at Mayo Clinic's Knowledge and Evaluation Research (KER) Unit. In closing, I would like to highlight funded projects that I am leading within that body of work, and move us incrementally onward towards a path of MDM. These include:

- A mixed-methods exploration of patients living on dialysis to understand practices that differ between patients experiencing low treatment burden compared to patients experiencing high treatment burden with the intention of developing interventions to assist patients with high treatment burden.

- A mixed-methods multi-site cluster randomized trial testing the ICAN Discussion Aid, a conversation tool that can assist in beginning conversations grounded in minimally disruptive, maximally supportive care.
- A design-research driven effort to develop an implementation toolkit for the ICAN Discussion Aid, available for free to the public, to assist a wide-variety of healthcare professionals and healthcare teams in taking up and implementing ICAN in their clinical practices.
- An in-depth qualitative exploration into the patient experience of living with chronic illness and having difficulty accessing and using healthcare services.
- An in-depth qualitative exploration of the patient experience of living with difficult-to-treat chronic conditions.

Additionally, I serve as the course director for the annual Minimally Disruptive Medicine Workshop, which brings a diverse set of clinicians and researchers from across the world together for two days. The curriculum changes yearly and is infused with the findings of the latest MDM research.

This dissertation looks at the past and the present to plan for the future to ensure minimally disruptive and maximally supportive care does not happen by accident. It lays a foundation for not only my future research career but pathways for other researchers and clinicians committed to kind and careful care of patients living with multimorbidity. This dissertation illuminates pathways for exploring ways toward Minimally Disruptive Medicine ensuring its future is bright with possibility.

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Appendix 1: Search Strategy

Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

#	Searches	Results	Type
1	"chronic care model".mp.	800	Advanced
2	1 and og.fs.	301	Advanced
3	1 and implement*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	350	Advanced
4	2 or 3	510	Advanced
5	..l/ 4 lg=en and yr=2012-2017	227	Advanced
6	remove duplicates from 5	167	Advanced
7	5 and implement*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	160	Advanced

Scopus:
"chronic care model" AND (implementing OR redesign*)) AND SUBJAREA (mult OR agri OR bioc OR immu OR neur OR phar OR mult OR medi OR nurs

OR vete OR dent OR heal OR mult OR arts OR busi OR deci OR econ OR psyc OR soci) AND PUBYEAR > 2011 = 61

Appendix 2: Methods reporting and bias protection based on TIDieR Checklist Criteria

Author	Year	Brief Name	Why	Materials	Procedures	Who Provided	How	Where	When and How Much	Tailoring	Modifications	Planned Fidelity Assessment	Actual Fidelity Assessment
Austin	2013	Yes	Yes	Partially	Partially	Yes	Yes	Yes	Partially	No	No	No	No
Bissonnette	2013	Yes	Yes	Partially	Yes	Partially	Yes	Yes	Partially	Yes	No	No	No
Bojadzievski	2012	Yes	Yes	No	No	No	No	No	No	No	No	No	No
Britto	2014	Yes	Yes	Partially	Yes	Partially	Yes	Yes	No	Yes	Yes	No	No
Collinsworth	2014	Yes	Yes	No	Yes	Yes	Yes	Partially	Partially	Partially	No	No	No
Comín-Colet	2014	Yes	Yes	Partially	Yes	yes	No	Yes	Partially	No	No	No	No
Crabtree	2014	Yes	Yes	Partially	Yes	Yes	Yes	Yes	Partially	No	Yes	No	No
Cramm	2014	Yes	Yes	No	No	No	No	Partially	No	Partially	No	No	No
Cramm	2014	Yes	Yes	No	Yes	Partially	No	Partially	No	No	No	No	No
Cramm	2012	Yes	Yes	No	Partially	Partially	No	Partially	No	No	No	No	No
Dickinson	2014	Yes	Yes	No	Partially	Partially	Partially	Yes	Partially	Partially	No	No	No
Dickinson	2014	Yes	Yes	Partially	Yes	Partially	Yes	Yes	Partially	Yes	No	No	No
Farley	2014	Yes	Yes	Partially	Yes	Yes	Yes	Partially	Yes	No	Yes	Yes	Partially
Goldwater	2014	Yes	Yes	Partially	Yes	No	No	Yes	No	No	No	No	No
Halladay	2014	Yes	Yes	Yes	Yes	Partially	No	Yes	No	No	No	No	No
Hariharan	2014	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partially	Yes	No	No	No
Heinelt	2015	Yes	Yes	No	Yes	yes	Yes	Yes	Partially	Yes	No	No	No
Holm	2014	Yes	Yes	No	No	yes	No	Partially	No	No	No	No	No
Holtrop	2015	Yes	Yes	No	Yes	No	Yes	Yes	No	Partially	No	Yes	Yes
Ku	2015	Yes	Yes	No	Yes	No	No	Yes	Yes	No	No	No	No
Ku	2014	Yes	Yes	Partially	Yes	Partially	Yes	Yes	Partially	Yes	No	No	No
Langwell	2014	Yes	Yes	Yes	Yes	yes	Yes	Yes	Yes	Yes	Yes	No	No
Mackey	2012	Yes	Yes	No	No	Partially	No	Yes	No	No	No	No	No
Martin	2016	Yes	Yes	Partially	Yes	Partially	Yes	Yes	Partially	no	No	Yes	Yes

Massoud	2015	Yes	Yes	Partially	Partially	No	Partially	Partially	No	Yes	No	No	No
McGough	2016	Yes	Yes	Partially	Yes	Partially	Partially	Yes	Partially	Yes	No	No	No
Noel	2014	Yes	Yes	Partially	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes
Parchman	2013	Yes	Yes	Partially	Yes	Partially	Yes	Yes	Partially	Yes	No	No	No
Philis-Tsimikas	2014	Yes	Yes	Partially	Partially	Partially	Partially	No	No	Yes	No	No	No
Pilleron	2014	Yes	Yes	Partially	Yes	Yes	Yes	Partially	No	No	No	No	No
Roland	2012	Yes	Yes	Partially	Yes	Partially	No	Yes	No	Yes	No	No	No
Sack	2012	Yes	Yes	Partially	Yes	Yes	Yes	Yes	Partially	Yes	No	No	No
Schauer	2013	Yes	Yes	No	Partially	No	Partially	Yes	No	Yes	No	No	No
Smidth	2013	Yes	Yes	Yes	Yes	Partially	No	Yes	Partially	Yes	No	No	No
Smidth	2013	Yes	Yes	Yes	Yes	yes	Yes	Yes	Yes	Yes	No	No	No
Tu	2013	Yes	Yes	Partially	Yes	Partially	Partially	Yes	No	Yes	No	No	No
Van Durme	2015	Yes	Yes	Partially	Partially	Partially	Partially	Partially	Partially	Partially	No	No	No