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Disease Self-Management Capacity, Patient Burden, and Medication Adherence in African American Adults with Type 2 Diabetes and Hypertension

Michelle Gaddis

ACCEPTANCE

This dissertation, DISEASE SELF-MANAGEMENT CAPACITY, PATIENT BURDEN, AND MEDICATION ADHERENCE IN AFRICAN AMERICAN ADULTS WITH TYPE 2 DIABETES AND HYPERTENSION by Michelle R. Gaddis was prepared under the direction of the candidate's dissertation committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing in the Byrdine F. Lewis College of Nursing and Health Professions, Georgia State University.

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ABSTRACT

DISEASE SELF-MANAGEMENT CAPACITY, PATIENT BURDEN, AND MEDICATION ADHERENCE IN AFRICAN AMERICAN ADULTS WITH TYPE 2 DIABETES AND HYPERTENSION

by

Michelle R. Gaddis

African American (AA) adults are disproportionately affected by type 2 diabetes (T2D) and hypertension, with greater prevalence and disease-related complications. Disease complications may be prevented or delayed with adequate disease self-management (DSM). The literature indicates greater patient activation and health literacy and lower treatment burden and illness burden are associated with improved DSM, but AAs with comorbidities were underrepresented in these studies. The purpose of this study was to examine associations among patient activation, health literacy, treatment burden, illness burden, medication workloads, and medication adherence for AA adults with T2D and hypertension. This study also explored the perceived impact of COVID-19 on medication management.

A non-experimental, predictive, correlational design was used. Participants were recruited using social media and flyers distributed via email. Data were collected via surveys administered through Qualtrics® and telephone/online interviews. Spearman's correlations and hierarchical regression analyses were conducted to examine relationships among the study variables.

Participants (*N* = 91) ranged in age from 25 to 73 years (*M* = 39.6), were mostly male (66%), college-educated (71%), and earning incomes of $30,000 or more (66%). Most were diagnosed with T2D and hypertension for less than five years (respectively, 64% and 75%) and averaged four (±1.3) prescribed medications.

On average, participants had high patient activation scores, low health literacy scores, and moderate levels of treatment and illness burden. Overall, medication adherence scores (*M* = 2.4) indicated the presence of non-adherence; 66% were classified as non-adherent. The model, including all predictor variables, was significant in predicting medication adherence, accounting for 19% of the variance. However, patient activation was the only significant contributor; for each one-point increase in patient activation, medication adherence improved by .03.The perceived impact from the COVID-19 pandemic on medication management was moderate, with participants feeling worried about leaving their homes (e.g., to get medications) and paying for medications.

In this sample of mostly younger AA men with T2D and hypertension, medication adherence was inadequate, but was only partially explained by patient activation. Further research is needed on DSM in AAs with T2D and hypertension to identify additional factors that may promote or hinder their medication adherence.

DISEASE SELF-MANAGEMENT CAPACITY, PATIENT BURDEN, AND MEDICATION ADHERENCE IN AFRICAN AMERICAN ADULTS WITH TYPE 2 DIABETES AND HYPERTENSION

by

MICHELLE GADDIS

A DISSERTATION

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“Every good gift and every perfect gift is from above…”

-James 1:17

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LIST OF ABBREVIATIONS

AA	African American
ADA	American Diabetes Association
AHA	American Heart Association
CCM	Cumulative Complexity Model
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
DBP	Diastolic blood pressure
DSM	Disease self-management
HbA_{1c}	Hemoglobin A_{1c}
HL	Health literacy
IIRS	Illness Intrusiveness Ratings Scale
MTBQ	Multimorbidity Treatment Burden Questionnaire
NVS	Newest Vital Sign
PA	Patient Activation
PAM ®	Patient Activation Measure ®
SBP	Systolic blood pressure
T2D	Type 2 diabetes

CHAPTER I

INTRODUCTION

Diabetes is the 7th leading cause of mortality in the United States (Centers for Disease Control and Prevention [CDC], 2018a). The CDC (2017a) reports that greater than 30 million individuals in the United States have diabetes, with 95% having Type 2 Diabetes (T2D). The prevalence of diabetes continues to increase rapidly, with a projected rise in prevalence to more than 54 million individuals in the US by the year 2030 (Rowley et al., 2017). Adults with diabetes have an increased susceptibility to the development of comorbidities and associated health complications, along with a 50% greater risk of death from any cause as compared to adults without diabetes (Rowley et al., 2017).

Most adults with diabetes have at least one coexisting chronic condition (Lin et al., 2015). One of the more prominent comorbidities for individuals with diabetes is hypertension (CDC, 2018c). According to national estimates, about 68% of individuals with diabetes also have hypertension (CDC, 2018c). In a cross-sectional analysis including 161,174 adults (63% White, 20% Black, 2% "other", and 13% unidentified) with T2D, 36% of the sample had one to two comorbidities, with 65% having hypertension (Lin et al., 2015). Five of the six most common multiple morbidity clusters observed in the study included hypertension.

Background

Individually, Type 2 diabetes (T2D) and hypertension are associated with elevated risks for several vascular complications including coronary artery disease, myocardial infarction, congestive heart failure, peripheral artery disease, retinopathy, nephropathy, neuropathy, stroke and heart disease (CDC, 2018b; Long & Dagogo-Jack, 2011; National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2017). When diabetes and hypertension coexist, the risks for associated vascular complications greatly increases (American Heart Association [AHA], 2015; CDC, 2018b; Long & Dagogo-Jack, 2011; NIDDK, 2017; Petrie et al., 2018). Hypertension has been identified as a significant risk factor in the accelerated development of vascular complications and the progression of cardiovascular disease for individuals with diabetes (Petrie et al., 2018). The AHA (2015) reports that the presence of comorbid diabetes and hypertension doubles the risk of developing cardiovascular disease compared to having only one of the diseases.

T2D and hypertension are also associated with higher rates of unplanned healthcare utilization (e.g., emergency room visits) resulting from complications of these diseases (CDC, 2017b; Lynch et al., 2015). Reportedly, emergency room (ER) visits for individuals with chronic disease(s) have continued to rise over the last decade, particularly for individuals with diabetes and hypertension (McNaughton et al., 2015). The heightened use of unplanned healthcare services for individuals with T2D and hypertension coincides with the estimated national expenditure ($375 billion) for managing both diseases (ADA, 2018a; CDC,

2016a). Additionally, on average, more than half of the total medical costs related to diabetes management are attributed to hospital inpatient care and prescription medications (ADA, 2018a).

Many of the disease-related complications for individuals with T2D and hypertension can be prevented or delayed with appropriate disease management (AHA 2016a; CDC, 2017c). Supplementary to the clinical aspect of disease management, managing T2D and hypertension involves a significant amount of self-management activities. Disease self-management (DSM) activities are recommended actions for patients to take, typically on a regular basis, and independent of their healthcare provider's direct assistance. DSM activities that may be recommended to patients with T2D and hypertension include healthy eating, physical activity, monitoring blood glucose and blood pressure, taking prescribed medications, and solving problems relating to disease management (e.g., calculating insulin doses; Byers et al., 2016; Powers et al., 2015). DSM activities collectively form an individual's DSM workload. Adhering to the recommended DSM activities within the DSM workload has been associated with increased glycemic and blood pressure control, reductions in T2D and cardiovascular complications, and fewer unplanned hospitalizations (Byers et al., 2016; CDC, 2018b). The escalating number of hospitalizations for individuals with T2D and hypertension may be associated with deficiencies in their DSM abilities and potentially overwhelming burdens in performance of DSM activities (CDC, 2017b; Fingar et al., 2017; McNaughton et al., 2015).

One prominent DSM activity for adults with T2D and hypertension is the management of prescribed medications. It has been estimated that roughly 85% of people with T2D and 70% of people with hypertension are prescribed medications for management of their disease (CDC, 2016b; CDC, 2019), indicating a heavy medication workload for individuals with these diseases. Adhering to prescribed medications is essential in achieving improvements in patient care outcomes and reducing the potential of associated disease-related complications (e.g., heart failure, stroke, and mortality) for individuals with T2D and hypertension (Brown & Bussell, 2011; CDC, 2018b; NIDDK, 2017). Adhering to prescribed medication regimens can be a complex and burdensome DSM activity, as it requires time, resources, knowledge, skills, and motivation. Thus, this study aimed to examine factors that had the potential to impact medication adherence and the DSM workload associated with managing prescribed medications for AA adults with T2D and hypertension.

Problem

African American (AA) adults are disproportionately affected by T2D and hypertension with higher prevalence rates and complications that result from these diseases (ADA,2018b; CDC,2017a; Gebregziabher et al., 2018). Currently, there is a greater prevalence of T2D among AAs (11.7%) than non-Hispanic Whites (7.5%; CDC, 2020e). Additionally, AAs have a greater number of diabetes-related comorbidities than other racial and ethnic groups (Lin et al., 2015). For example, Lynch et al. (2015) conducted a retrospective cohort study of 892,223 veterans to identify multiple morbidity patterns across ethnicities. The

sample included 12% AAs, 61% Whites, 13% Hispanics, and 12% identified as "other". There were 32% of AA participants with three or more comorbid conditions as compared to 27% of Whites, 26% of Hispanics, and 14% of the group labeled as "other". Hypertension, a commonly associated comorbidity of T2D, further increases and accelerates the risks for clinical complications (e.g., stroke and heart disease), especially for AAs (AHA, 2016a; CDC, 2019b). Similar to T2D, the prevalence of hypertension is greater for AA adults (40.3%) than non-Hispanic Whites (27.8%) (CDC, 2017d).

AAs have also been frequently identified as having an increased risk and higher rates of associated complications from T2D, compared to other racial/ethnic groups (CDC, 2017d; CDC, 2019b; Lin et al., 2015; Office of Minority Health [OMH], 2016). The age-adjusted death rate per 100,000 attributed specifically to diabetes is higher among AA adults (38.7) as compared to non-Hispanic White adults (18.8) and all other race/ethnicity groups (21.5; CDC, 2019b). The CDC (2019b) also reports that the age-adjusted death rate per 100,000 from hypertension for AA adults (17.1) is higher than for non-Hispanic White adults (8.0). Higher mortality rates for AAs with T2D and hypertension are potentially due to the disproportionate challenges in medication adherence, leading to uncontrolled blood glucose and blood pressure (CDC, 2017d; OMH, 2016).

Management of T2D and hypertension involves a multifaceted approach, with self-management activities having a large role. Managing both conditions is more challenging than managing either alone. For example, there may be more

medications prescribed, additional self-monitoring tasks to complete (e.g., blood glucose and blood pressure monitoring), and additional diet restrictions to follow. DSM in T2D and hypertension requires patients to have adequate DSM capacity: relevant knowledge, motivation, and skills (Beck, 2018; Powers, 2015). This claim is supported by previous studies that demonstrated patient activation (i.e., knowledge, motivation, and skills for managing health) and health literacy (i.e., the skill needed to obtain, process, and understand basic health information to make decisions) were associated with DSM performance (Beck, 2018; Bolen et al., 2014; Mayberry et al., 2010; Powers, 2015; Weld et al., 2008; Ylitalo et al., 2018). People with T2D and hypertension who have limited DSM capacity (i.e., patient activation and health literacy) may perceive their DSM activities as too complex, leading to inadequate performance and lack of glycemic and blood pressure goal attainments (Egan et al., 2014).

Additionally, DSM activities for T2D and hypertension, particularly managing prescribed medications, may become overly burdensome leading to poor adherence. The burden in performance of DSM may stem from the complexity of the prescribed treatment plan (i.e., treatment burden) or from the symptomology associated with the illnesses being treated (i.e., illness burden), collectively described as patient burden. The performance of DSM activities may be further complicated during a major crisis, such as what may occur during a global pandemic. Presently, there is a worldwide pandemic that could be impacting the performance of DSM activities for AAs with T2D and hypertension. The Coronavirus Disease 2019 (COVID-19) is a life-threatening public health

situation that is currently impacting individuals on a global scale. The incidence and mortality for COVID-19 continue to climb at alarming rates. Recent reports indicate that there have been more than one million cases of COVID-19 identified in the U.S., with 68,279 deaths reported (CDC, 2020a). The CDC (2020b) states that during a pandemic such as with COVID-19, individuals may experience large amounts of stress which may subsequently create difficulty in concentrating (e.g., carrying out DSM activities) and worsen chronic health problems. The CDC (2020c) also reports that individuals with diabetes may be at a higher risk of experiencing a greater severity of illness from COVID-19 and have greater difficulty in recovering from the illness. Furthermore, AAs may be disproportionately impacted by COVID-19, with recent reports indicating that COVID-19 related hospitalizations and death rates are higher for AAs as compared to other ethnicities (CDC, 2020d). Thus, it is important to explore individuals' perceived impact of the COVID-19 pandemic on their abilities to manage their prescribed medications.

Although literature describing the benefits of DSM exists, some individuals with diabetes and hypertension still demonstrate poorly executed DSM (e.g., poor medication adherence), even with already having experienced a cardiovascular event (Beck et al., 2018; Brown & Bussell, 2011; Fox et al., 2015; Powers et al., 2015; Shrivastava et al., 2013; Weller et al., 2017). Considering that AA adults have a higher prevalence of uncontrolled T2D and hypertension, this may potentially indicate that AAs have significant DSM capacity deficiencies and overwhelming burdens in DSM (ADA, 2018b; CDC, 2017d; OMH, 2016).

There are no known studies that examine the combined impact of DSM capacity and patient burden (i.e., treatment burden and illness burden) on the performance of any DSM activities for AA adults with T2D and hypertension. The heightened health risks associated with comorbid T2D and hypertension (e.g., stroke, heart disease) are further magnified in this vulnerable population when appropriate DSM behaviors are absent (CDC, 2018b). The apparent disparity in health outcomes for AA adults with T2D and hypertension suggests a need to investigate factors that may impact their performance of DSM. Additionally, as managing medications is a prominent DSM activity for individuals with T2D and hypertension, it is also important to examine the relationships of DSM capacity and patient burden within the context of medication adherence. Furthermore, as no known studies have examined any DSM activities for T2D and hypertension during a pandemic, valuable information was also gained from exploring individuals' perceptions of the impact of COVID-19 on their ability to manage their prescribed medications.

Significance of the Study for Healthcare Professionals

This study is significant because it addressed existing gaps in the literature by investigating underexamined factors potentially associated with medication adherence for AA adults with T2D and hypertension. Healthcare professionals are essential in providing self-management support to patients with T2D and hypertension through the provision of education, encouragement, and empowerment strategies relating to the performance of DSM tasks, specifically adherence to prescribed medication regimens. This study provides a gateway to

clinical practice improvements, specifically in the provision of care for AA adults with T2D and hypertension. First, this study highlights factors that associate with medication adherence (i.e., DSM capacity and patient burden). Additionally, this study strengthens the validity and reliability for measures of DSM capacity (i.e., health literacy and patient activation) and patient burden (i.e., treatment burden and illness burden). By gaining a better understanding of factors that associate with medication adherence and having valid methods to assess those factors, healthcare professionals can be better equipped to identify individuals at risk for poor medication adherence and enhance the effectiveness of the treatment plans developed for AA patients with T2D and hypertension. Ultimately, discoveries from this study can facilitate the development of novel strategies in patient care delivery, resulting in improved patient outcomes and reduced health care costs.

Purpose

The purpose of this study was to examine associations among patient activation, health literacy, treatment burden, illness burden, medication workload, and medication adherence for AA adults with comorbid T2D and hypertension. This study also explored the perceived impact of COVID-19 on the management of prescribed medications.

Research Questions

For AA adults 18 years of age or older with comorbid T2D and hypertension who have been prescribed medications for blood pressure and glycemic control:

RQ1: Are higher levels of illness burden associated with lower levels of patient activation and health literacy?

RQ2: Are higher levels of treatment burden associated with a higher number of prescribed medications and greater perceived difficulty in managing prescribed medications?

RQ3: Do patient activation, health literacy, treatment burden, and illness burden significantly predict medication adherence?

RQ4: Which aspects of medication management are the most challenging?

RQ5: What is the perceived impact of the COVID-19 pandemic on medication management?

Theoretical Framework

The Cumulative Complexity Model (CCM), developed by Shippee et al., 2012, was used to guide the selection and analysis of variables in this study (See Figure 1). The CCM provides a patient-centered framework for exploring the complexity of disease management by illustrating: (1) how treatment burden and illness burden impact the interaction between workload of demands and capacity, (2) the potential imbalances that occur between individuals' workload of demands and their abilities to manage their workloads, and (3) how imbalances between workloads and capacities indirectly impact health-related outcomes (Shippee et

al., 2012). The CCM provides a mechanism for understanding the complexity of patient care by illustrating how clinical and social factors accrue and interact, complicating patients' disease management experiences (Shippee et al., 2012).

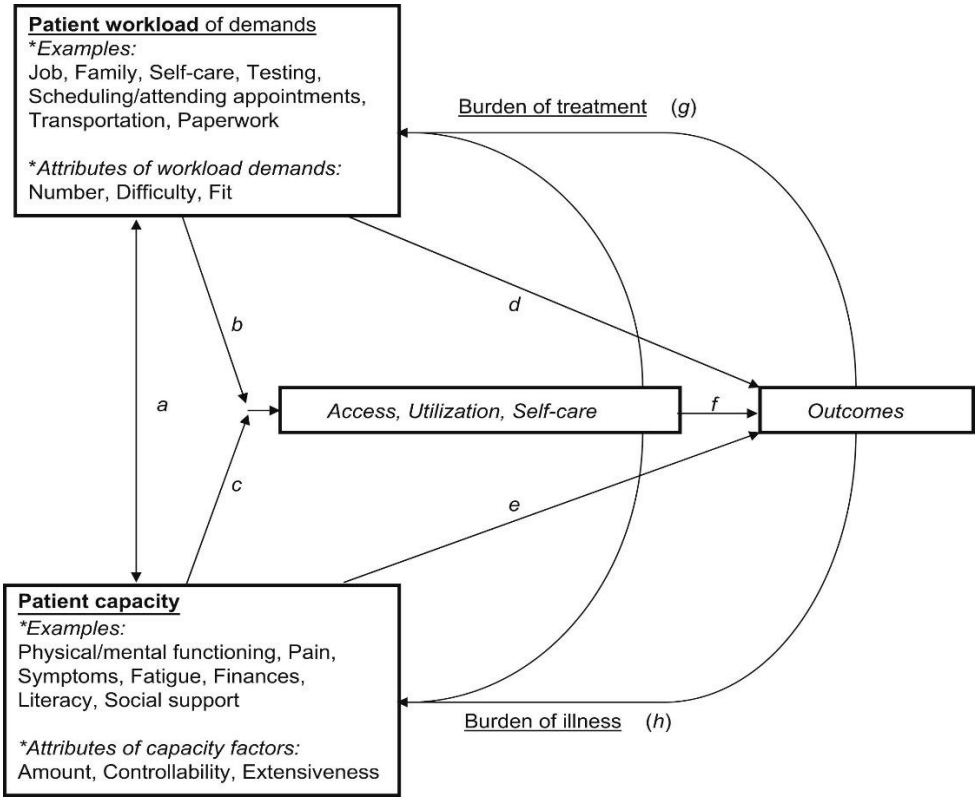
The CCM incorporates interrelating concepts with feedback loops to display disease management complexity and the ongoing consequences of workload-capacity imbalances (Shippee et al., 2012). There are four primary constructs within the model: workload, capacity, burden of treatment, and burden of illness (Shippee et al., 2012). Workload is described as a collective of all the demands (e.g., DSM, family obligations, work obligations) individuals have in their lives (Boehmer, Shippee, et al., 2016). Capacity is defined as the abilities and resources individuals have in meeting the demands of their workload (Boehmer, Shippee, et al., 2016). Burden of treatment is the level of perceived difficulty individuals have in meeting their workload demands (Rogers et al., 2017). Lastly, burden of illness refers to the perceived level of disruption in aspects of day-to-day life that is attributed to a pre-existing disease process (Shippee et al., 2012).

The CCM posits that when there is an imbalance between workload and capacity, specifically when capacity fails to meet the demands of the workload, individuals are more likely to have deficiencies in their disease management performance (Boehmer, Shippee, et al., 2016). Performance deficits (e.g., poor medication adherence) are associated with unfavorable health outcomes such as illness leading to unplanned hospitalization (Fox et al., 2015; Leppin et al., 2015; Shrivastava et al., 2013). Poor health outcomes may lead to greater treatment

and illness burdens (Bodde et al., 2013; Shippee et al., 2012;). The increased burdens subsequently increase the demands of the workload and decrease the capacity in meeting the increasingly demanding workload (Boehmer, Shippee, et al., 2016).

Figure 1

Cumulative Complexity Model



Applicability of the Cumulative Complexity Model

The CCM can be applied to studies examining medication adherence for individuals with chronic diseases, as it provides a framework to categorize patient capacity and burden factors and examine how DSM capacities and burdens interact. The CCM also reflects how certain attributes of a medication workload

(i.e., number, difficulty, and route) can highlight the complexity that individuals encounter when attempting to meet the DSM workload demand of managing prescribed medications. The model has been used in previous studies involving individuals with chronic illness (e.g., stroke survivors, patients on dialysis) to explore DSM capacity (Boehmer, Shippee, et al., 2016; Gallacher et al., 2018). Gallacher et al. (2018) conducted a qualitative study to explore patient burden and patient capacity for stroke survivors. Findings from the study indicated a cyclical relationship among patient workload, patient capacity, and deficiencies in performance of DSM activities. Additionally, clinical practice implications from the study included the need for healthcare professionals to review clinical guidelines and healthcare delivery models, as these also have an impact on a patient's capacity and burden. In a cross-sectional study of adults receiving dialysis treatments, Boehmer, Shippee, et al. (2016) sought to explore patients' perceived burdens from dialysis and their individual capacities in coping with the associated burdens. Findings from the study indicated that deficits in physical, emotional, and financial capacities were the most significant factors associated with a disruption in disease management. The CCM has also been used as a framework for the development of a self-report tool which facilitated communication between patients and clinicians, highlighted patients' conflicts in managing competing priorities in DSM, and in some cases, led to changes in treatment plans (Boehmer, Hargraves, et al., 2016). To date, the model has not been utilized in a study specifically for AA adults with T2D and hypertension nor as a framework for predicting medication adherence.

Overview of Concepts

Workload

An individual's workload is the summation of all their competing, personal demands (Shippee et al., 2012). Examples of workload demands include maintaining or acquiring employment, completing disease self-management activities, and managing household duties (Shippee et al., 2012). Workloads can vary in several ways including in the following attributes: number of demands, difficulty of demands, and how well each of their demands fit into an individual's life among their other demands (Shippee et al., 2012). In this study, "workload" was adapted to "DSM workload" for AA adults with T2D and hypertension. DSM workload is defined as the DSM demands that individuals have in managing their illness(es). For T2D and hypertension, demands may include the activities involved in exercising, acquiring and consuming healthy foods, communicating with healthcare providers, and managing prescribed medications (Gallacher et al., 2018). One specific DSM workload demand of interest, managing prescribed medications, was examined in this study. The specific attributes of this DSM workload demand that were examined in this study are *number* (i.e., the number of medications prescribed), *difficulty* (i.e., the perceived difficulty in managing the workload demand), and *route* (i.e., the routes prescribed for medication administration). These attributes were collectively described as "medication workload" and were used to gain additional insight into the workload demand of managing prescribed medications for AA adults with T2D and hypertension.

Capacity

Capacity refers to the abilities and resources individuals possess in order to manage their workload responsibilities. Capacity includes any physical, mental, social, financial, personal, and environmental resources, all of which may change over an individual's lifespan (Leppin et al., 2014). In this study, "capacity" was adapted to "DSM capacity" and was defined and measured through two functions: patient activation and health literacy. Patient activation is an individual's perceived knowledge, motivation, and DSM skills relating to managing healthcare activities (Bolen et al., 2014). Health literacy is defined as the ability to obtain, process, and understand health and healthcare service information (Weld et al., 2008).

Treatment Burden

Treatment burden refers to the amount of difficulty and effort individuals perceive is involved in meeting DSM workload demands (Boehmer, Shippee, et al., 2016). Treatment burden is impacted by the amount and complexity of the DSM workload demands an individual has been tasked with completing. Treatment burden can also be impacted (positively or negatively) by other clinical and social factors (e.g., healthcare access, presence of social support, financial resources, physical functioning). The concept of treatment burden emphasizes the need to consider the impact that prescribed DSM activities have on individuals' functioning or well-being (Boehmer, Shippee, et al., 2016).

Illness Burden

Illness burden refers to the perceived level of disruption in day-to-day life that is associated with an existing disease (Shippee et al., 2012). Illness burden may be impacted by symptoms (e.g., fatigue and pain), deterioration of functional status, and an assortment of other health impairments relating to an individual's morbidity (Devins, 2010).

Conceptual Outcomes

DSM in T2D and hypertension can be very demanding for the individuals who have these diseases, requiring completion of numerous DSM activities, including the management of prescribed medications (Rogers et al., 2017). When individuals with comorbid T2D and hypertension do not have the level of capacity (e.g., adequate health literacy and patient activation) necessary to manage their DSM demands, this may result in poor execution of DSM (e.g., poor medication adherence). Individuals who demonstrate poor medication adherence are at risk of experiencing negative health outcomes and may be further impacted by diminished health and additional prescribed DSM workload demands, adding to burdens that are likely already overwhelming (Rogers et al., 2017).

In this study, the attributes of one specific DSM workload demand (i.e., managing prescribed medications) was examined (i.e., number of prescribed medications, perceived difficulty in managing prescribed medications, and the routes prescribed for medication administration). Additionally, the relationships among DSM capacity (i.e., patient activation and health literacy), patient burden (i.e., treatment burden and illness burden), and medication adherence for AA

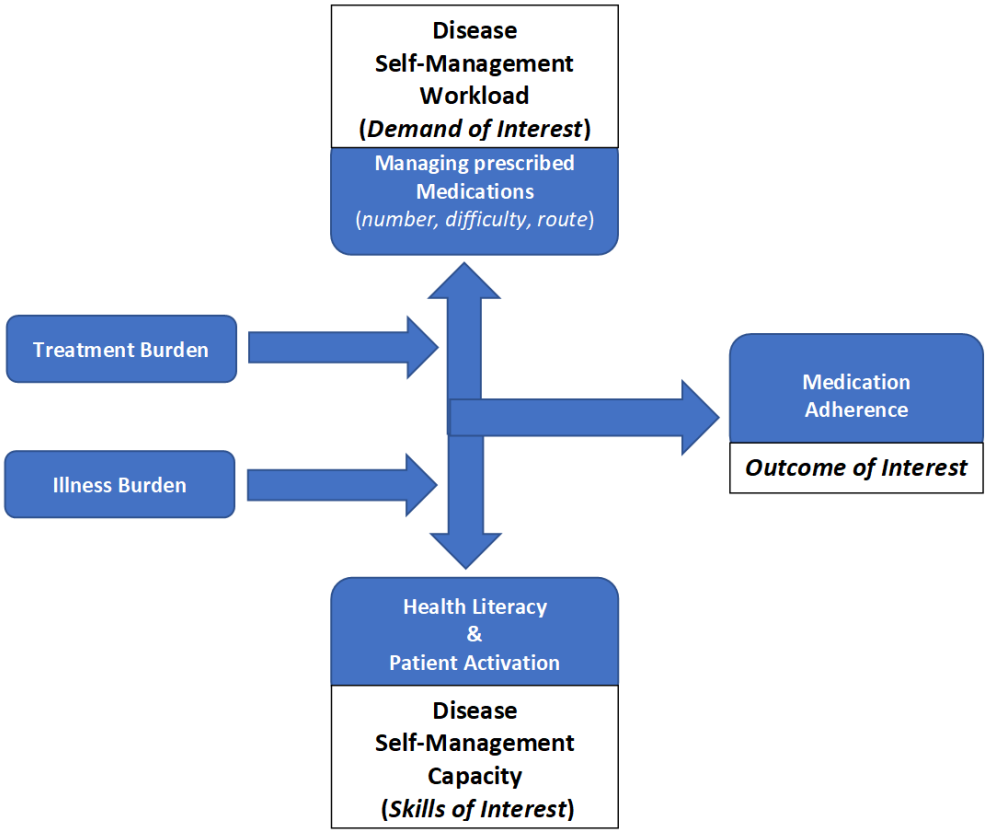
adults with T2D and hypertension was examined. Greater illness burden was expected to associate with lower DSM capacity. Greater treatment burden was expected to associate with higher number of prescribed medications and greater perceived difficulty in managing prescribed medications. The routes of medication administration (e.g., oral, injection, topical) were also examined in this study. An attribute of DSM workload demands is the "fit" of the workload demands in individuals' day-to-day lives (Shippee et al., 2012). As the specific DSM workload demand in this study was the management of prescribed medications, examining the routes prescribed for medication administration provides insight into additional challenges in medication management. For the outcome of interest in this study (i.e., medication adherence), individuals with poorer medication adherence were expected to have higher patient burdens (i.e., treatment burden and illness burden) and/or lower levels of DSM capacity (i.e., patient activation and health literacy).

An adapted CCM model was developed to highlight the relationships that were anticipated among the selected study variables (see Figure 2). Without appropriate interventions, individuals who do not have the DSM capacity to manage their DSM workload demands or have patient burdens too heavy to overcome, may demonstrate poor medication adherence and have greater risks of experiencing poor health outcomes. Poor health outcomes may create additional treatment burdens and illness burdens, subsequently having additional negative impacts on future health outcomes. As this study did not examine the impact of DSM performance (e.g., health status, hospitalizations), researchers

may benefit from exploring the cyclical nature of the original CCM by conducting longitudinal studies that include objective measures of health status (e.g., glucose levels, HbA_{1c}, blood pressure readings) and DSM performance, how increased treatment burden impacts the DSM workloads, and how changes in illness burden effect DSM capacity.

Figure 2

Adapted Cumulative Complexity Model



Note. This model was adapted for medication adherence among African American adults with type 2 diabetes and hypertension. Adapted from Shippee et al., 2012.

Assumptions

The following are assumptions inherent in the Adapted Cumulative Complexity model:

1. Managing prescribed medications is a prominent disease self-management workload demand for African American adults with Type 2 diabetes and hypertension.
2. The number of prescribed medications, perceived difficulty in medication management, and the prescribed route(s) for administration of prescribed medications are attributes that define the disease self-management workload demand of managing prescribed medications.
3. Patient activation and health literacy are essential aspects of disease self-management capacity that quantify individuals' abilities to meet the disease self-management workload demand of medication management.
4. Treatment burden and illness burden are specific patient burdens that may complicate individuals' abilities to meet the disease self-management workload demand of medication management.
5. Treatment burden, illness burden, and disease self-management capacity collectively impact an individual's ability to manage their prescribed medications and shape their medication adherence.

Summary

Although several national initiatives have been implemented to facilitate reductions in complications from T2D and hypertension, the complications from these diseases continue to threaten the well-being of individuals living with them,

particularly AA adults. This study used an innovative model to examine a DSM workload demand (i.e., managing prescribed medications), DSM capacities (i.e., patient activation and health literacy), patient burdens (i.e., treatment burden and illness burden), and medication adherence for AA adults with T2D and hypertension. Considering that managing prescribed medications is a prominent DSM workload demand for AA adults with T2D and hypertension, it is essential to examine underexplored factors that may have a great impact on patients' abilities to meet this DSM workload demand.

Examination of patient activation, health literacy, and patient burden factors provided insight into the challenges that AAs face in meeting their DSM workload demand of managing prescribed medications. As this entire study was conducted remotely, this study also provides support for the feasibility of using the respective measures as risk assessment tools in remote settings, such as during telemedicine visits. In addition, findings from this study could potentially be translated into enhanced clinical practice guidelines, with the goal being to improve patients' DSM capacities, decrease patient burdens, and improve patients' medication adherence. Ultimately, improvements in medication adherence for AA adults with T2D and hypertension may lead to improvements in overall minority health and a reduction in health disparities for a currently vulnerable population.

CHAPTER II

REVIEW OF THE LITERATURE

This study aimed to examine the relationships among disease self-management capacity, patient burden, and medication adherence for AA adults with comorbid T2D and hypertension. The perceived impact of COVID-19 on management of prescribed medications was also examined in this study. This chapter presents an overview of the literature relating to the concepts that were examined in this study. The first section of this chapter provides context for the disease self-management workload in Type 2 diabetes and hypertension, including the specific workload demand of managing prescribed medications.

Disease Self-Management Workload in Type 2 Diabetes and Hypertension

T2D and hypertension are chronic diseases that often require lifelong disease management (AHA, 2016; Powers et al., 2015). Disease management in both T2D and hypertension is largely conducted through performance of disease self-management (DSM) activities (AHA, 2016; Powers et al., 2015). DSM activities are the specific DSM workload demands an individual must meet in managing their chronic conditions and preventing disease-related complications (Beck et al., 2018). Previous reports indicate that adhering to recommended DSM activities (e.g., medication adherence) is essential in achieving favorable health outcomes and reducing risks for long term disease-related complications (Fox et al., 2015; Powers et al., 2015; Shrivastava et al., 2013). Although

recommended DSM activities are tailored to meet individualized needs, general guidelines for DSM have been established and reported (Powers et al., 2015). A joint position statement from the American Diabetes Association (ADA), the American Association of Diabetes Educators (AADE), and the Academy of Nutrition and Dietetics (AND) indicates that healthy eating, physical activity, glucose monitoring, taking prescribed medications, problem-solving, and healthy coping are general recommended DSM activities for individuals with diabetes (Powers et al., 2015). Furthermore, the ADA affirms that the DSM aspect of diabetes care also encompasses management of comorbidities, namely hypertension (de Boer et al., 2017). ADA recommendations for inclusion of hypertension for individuals with diabetes highlights the importance of home blood pressure monitoring and medication adherence (de Boer et al., 2017).

Previous studies have highlighted the significance of DSM performance. Weller et al. (2017) conducted a mixed-methods study to determine if the DSM practices of adults with T2D were linked to glycemic control outcomes. A total of 56 participant interviews (29% AA) were retained from the larger study to conduct a qualitative comparative analysis. The study revealed key themes relating to glycemic control. Participants were then divided into three groups: good glycemic control was indicated by HbA_{1c} of <7.0%, fair control by a HbA_{1c} from 7.0% to 8.0%, and poor control by a HbA_{1c} of >8.0%. Individuals with good glycemic control performed self-monitoring of blood glucose, rarely skipped or missed medication doses, and followed dietary recommendations. More specifically, individuals with good glycemic control, as compared to those with poor control,

were less likely to report skipping medications (5% vs. 33%) and more likely to monitor dietary sodium intake (53% vs. 6%).

Schmitt et al. (2016) also found associations between diabetes self-management behaviors and glycemic control. The researchers conducted a study to compare the efficacy of two self-report measures of diabetes self-management in predicting variations in HbA_{1c} levels. The self-report tool of primary interest, the Diabetes Self-Management Questionnaire (DSMQ), incorporated essential measures of disease self-management: dietary control, medication adherence, blood glucose monitoring, physical activity, and maintaining recommended physician contact. Using a sample of 430 patients with diabetes (T2D patients = 182), the researchers found that the DSMQ explained 28% of the variance in glycemic levels, with higher DSMQ scores (i.e., better DSM performance) associating with lower HbA_{1c} levels (-0.46, $p < .001$). These results highlight the importance of DSM performance in chronic disease management. Essentially, better DSM performance lead to greater improvements in glycemic control.

Medication Workload

An important DSM workload demand for individuals with T2D and hypertension is managing prescribed medications. It has been estimated that roughly 81% of individuals with T2D and 70% of individuals with hypertension are prescribed medications for management of their disease (CDC, 2016b; CDC, 2019b). In 2018, antidiabetic medications ranked sixth out of the top 20 therapeutic classes of dispensed prescriptions, with 214 million prescriptions

(Aitken et al., 2019). In that same year, antihypertensives ranked first for dispensed prescription medications, with 674 million prescriptions (Aitken et al., 2019). The combined costs for both therapeutic classes of medications accounted for greater than $67 billion in non-discounted U.S. spending during 2018 (Aitken et al., 2019). Furthermore, while the percentage of oral or insulin therapy was consistent between AA and non-Hispanic White groups (respectively 47% vs 50%), AAs with diabetes were reported to have an almost two-fold prevalence of dual pharmacologic therapy consisting of insulin and pills as compared to their non-Hispanic White counterparts (respectively 25% vs. 13%; CDC,2019). These data indicate a hefty DSM workload demand for managing prescribed medications exists for AAs with T2D and hypertension.

Managing prescribed medications can be very complex, as it may require numerous skills (e.g., health literacy, problem-solving skills). This complexity may create challenges in meeting this DSM workload demand, leading to poor medication adherence (Brown & Bussell, 2011; Greene et al., 2015; Ylitalo et al., 2018). Deficiencies in DSM capacities and overwhelming burdens may exist for individuals who demonstrate difficulty in performance of DSM. There is evidence that knowledge deficits, the complexity of T2D management, and managing comorbid conditions such as hypertension, create additional challenges in performance of daily DSM activities (Akohoue et al., 2015; Bockwoldt et al., 2017; Utz et al., 2006). While a few studies were identified that examined DSM performance in AAs with diabetes (Al Sayah et al., 2015; Bains et al., 2011; Bockwoldt et al., 2017; Davis et al., 2006; Skolasky et al., 2011; Weller et al.,

2017), only one study was found that examined DSM solely in the AA population (Bockwoldt et al., 2017) and no studies were found that examined DSM performance exclusively in AAs with diabetes and comorbid conditions (e.g., hypertension). This study aimed to examine factors that potentially impact the performance of DSM activities for AA adults with T2D and hypertension. Additionally, the individual medication workloads (i.e. number of prescribed medications, perceived difficulty in managing prescribed medications, prescribed routes for medication administration) for AA adults with T2D and hypertension were examined. By gaining a better understanding of how the capacity and burdens of AAs with comorbid T2D and hypertension relate to performance of a specific DSM activity (i.e., managing prescribed medications), it may be possible to develop strategies that could improve medication adherence, and potentially, improve health outcomes for this population.

Disease Self-Management Capacity

Individuals must have adequate DSM capacity to take the necessary actions in meeting the demands of their DSM workloads (CDC, 2018d; Powers et al., 2015). DSM capacity relates to the abilities and resources an individual has in meeting disease management workload demands (Boehmer, Shippee, et al., 2016). Considering that DSM capacity encompasses physical, mental, social, financial, personal, and environmental resources, there are several factors potentially related to an individual's capacity to perform DSM activities (Leppin et al., 2014). Multiple studies have reported on the influence of personal attributes, physical and cognitive abilities, support networks, socioeconomic status, and

culture on performance of DSM for individuals with chronic diseases (Akohoue et al., 2015; Byers et al., 2016; Gallacher et al., 2018; Osborn et al., 2013; Rovner et al., 2013). While other studies have found that even when facing substantial challenges relating to disease management (e.g., low socioeconomic status), some individuals maintained the capacity to remain engaged in DSM activities (Greene et al., 2015; Keene et al., 2018). These findings highlight the importance of exploring attributes of DSM capacity for individuals with T2D and hypertension to gain a better understanding of factors that possibly enhance patients' performance of DSM activities.

Patient activation and health literacy levels were used as measures of DSM capacity in this study. Patient activation and health literacy represent an individual's capacity (i.e., knowledge, motivation, and skills) to manage health-related activities, with both patient activation and health literacy being previously linked with the performance of DSM activities, including adhering to prescribed medication regimens (Greene et al., 2015; Skolasky et al., 2011; Ylitalo et al., 2018). Both measures have been used frequently in studies exploring DSM performance for individuals with chronic diseases, and together, patient activation and health literacy encompass the various skills required of individuals with T2D and hypertension to perform prescribed DSM activities (Bolen et al., 2014; Fowles et al., 2009; Greene et al., 2015; Hibbard at al., 2008; Lubetkin et al., 2010; Mayberry et al., 2010; Weld et al., 2008; Ylitalo et al., 2018).

Patient Activation

Patient activation represents individuals' perceptions of their knowledge, motivation, and skills in managing their health (Bolen et al., 2014). Patient activation has four levels, with higher levels indicating greater patient activation: Level 1 reflects individuals who have not realized the importance of their role in the management of their health, Level 2 indicates individuals who lack the knowledge and confidence to take action in managing their health, Level 3 reflects individuals who are beginning to engage in recommended health DSM behaviors, and Level 4 reflects individuals who have a proactive approach to managing their health and are engaging in most, if not all, recommended DSM activities (Greene et al., 2015). High patient activation levels are associated with greater competency in carrying out appropriate prevention measures, adequately managing chronic conditions (e.g., adhering to prescribed medication regimens) and having the ability to make sound decisions regarding health and health services (Greene et al., 2015; Lubetkin et al., 2010; Skolasky et al., 2011). For example, Skolasky et al. (2011) found in their cross-sectional study of 855 multimorbid participants (46% AA) that a 10-point increase in patient activation scores yielded a 13% increase in odds of having increased medication adherence (p = .025). The study used the number of missed doses to calculate medication adherence (self-reported). No data on the specific chronic diseases the participants had were reported.

Several other important associations have been reported for patient activation. In a cross-sectional study, Mayberry et al. (2010) examined 48 adults

with T2D to determine the relationships among patient activation, self-reported DSM behavior (i.e., confidence in diabetes self-management and summary of diabetes self-care), and glycemic control. The races of participants were only stratified into two categories: White and non-White (14.6%). The 13-item Patient Activation Measure® (PAM®) was used, with higher scores indicating greater patient activation. The scores range from 0 to 100, signifying the degree of an individuals' active role in managing their health. Self-management behavior was measured using a revised 13-item subscale based on the transtheoretical model of stages of readiness for behavioral change, with higher scores indicating greater self-management. Glycemic control was determined by the participants' most recent HbA_{1c} levels (i.e., $HbA_{1c} > 7\%$ = uncontrolled diabetes; $HbA_{1c} \leq 7\%$ = controlled diabetes). The researchers found a significant positive association between DSM behavior and patient activation scores. However, this correlation was stronger for individuals whose glycemic levels were under control ($r = 0.73$, $p = .01$) than among patients with uncontrolled glycemia ($r = 0.48$, $p < .001$). Additionally, there was no significant association found between patient activation scores and glycemic control (*OR* 0.99; 95% CI: 0.94–1.03; $p > .05$). A potential explanation offered for the lack of association between glycemic control and patient activation was that some T2D patients potentially need to be at the highest stage of activation (stage 4) to achieve glycemic control. Stage four of patient activation indicates consistency in adequate DSM performance even when DSM becomes problematic. Additionally, the small sample size of the study

may have impacted the power to detect correlations between patient activation and glycemic levels.

The effectiveness of patient activation interventions for adults with T2D (*N* =33,124) was examined in a systematic review of 138 randomized control trials (Bolen et al., 2014). The systematic review focused on intermediate outcomes (i.e., HbA_{1c}, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, systolic blood pressure, or bodyweight). Results indicated patients receiving the patient activation interventions experienced greater reductions in HbA_{1c} (weighted mean differences [WMD] = −0.37; 95% CI: −0.45, −0.28; I^2 = 83 %), systolic blood pressure (WMD = −2.2; CI: −3.5, −1.0; I^2 = 72 %), body weight (WMD = −2.3; 95% CI: −3.2, −1.3; I^2 = 64 %), and triglycerides (WMD = −8.5;95% CI: −15.0, −2.3; I^2 = 64 %) than patients randomized to the control groups. It is important to note that although the studies yielded moderate reductions in HbA_{1c}, a reduction as small as 1% in HbA_{1c} is associated with a 21% reduction in mortality for individuals with T2D (Bolen et al., 2014). Additionally, the studies that had higher baseline means in HbA_{1c}, systolic blood pressure, and cholesterol levels had greater reductions in these outcomes as compared to lower baseline means. This finding emphasizes that individuals with the greatest need for improvements in glucose and blood pressure control may benefit substantially from the implementation of patient activation strategies.

Patient activation encompasses attributes considered essential to the performance of DSM (i.e., knowledge, motivation, skills). Therefore, widening the

breadth of knowledge on patient activation's role in medication adherence for AA adults with T2D and hypertension is imperative. Patient activation has been previously described as a modifiable risk factor for poor health outcomes, particularly for individuals with chronic diseases (Mitchell et al., 2014). For patients with T2D and hypertension, an examination of patient activation can provide supplementary assessment data potentially used to facilitate improvements in patients' DSM performance, and more specifically, in their medication adherence. Likewise, health literacy can be considered a modifiable risk factor for patients with chronic diseases and the DSM workload demand of managing prescribed medications. Many activities involved in DSM, including managing prescribed medications, require adequate health literacy to perform properly. Exploration of health literacy provides further insight into medication adherence for individuals with T2D and hypertension. Although much can be gained from assessing patient activation levels, measuring patient activation is currently highly subjective. The examination of health literacy provided the opportunity to use more objective measures in examining patients' DSM capacities.

Health Literacy

Health literacy is the ability to obtain, process, and understand basic health and service information needed to make wise decisions about healthcare (Weld et al., 2008). Health literacy encompasses multiple skills including visual literacy (i.e., ability to understand visual information), information literacy (i.e., ability to obtain and apply relevant information), numeracy (i.e., ability to

calculate numbers), and oral language skills (i.e., ability to articulate health concerns, ask pertinent questions, and understand verbalized information and instructions; CDC, 2019c; Dastani & Sattari, 2016). Several DSM activities for individuals with T2D and hypertension necessitate adequate health literacy. For example, DSM for individuals with T2D and hypertension may involve reading and comprehending prescription instructions, interpreting blood pressure readings and glucose levels, and calculating medication doses.

Previous studies have described associations between health literacy and DSM activities. In a cross-sectional study of 343 adults (83% AA), Al Sayah et al. (2015) sought to determine associations between health literacy, behavioral indicators (i.e., depressive symptoms, diabetes knowledge, diabetes self-efficacy, diabetes self-care, and self-reported medication adherence), and cardiometabolic parameters (i.e., HbA_{1c}, systolic blood pressure, and body mass index) in individuals with T2D. Health literacy was measured using three screening questions that assessed difficulty understanding written information, confidence in filling out medical forms, and frequency of needing assistance reading hospital materials. Medication adherence was assessed with Morisky Medication Adherence Scale (MMAS), a self-report medication adherence tool. Diabetes self-care was assessed with the Summary of Diabetes Self-Care Activities questionnaire, another self-report tool. The researchers found that summative health literacy scale only had significant associations with knowledge (r = -0.34, $p \leq .05$) and self-efficacy (r = -0.16, $p \leq .05$). One item within the health literacy scale, “difficulty understanding written information”, was

significantly associated with lower diabetes knowledge (r = 0.26, $p \leq .05$.), lower diabetes self-efficacy (r = 0.24, $p \leq .05$), and worse medication adherence (r = -0.14, $p \leq .05$). However, there were no significant associations between any health literacy screening questions and any cardiometabolic parameters. The researchers discussed that this lack of association might have resulted from the health literacy measure used. The brief health literacy screening questions had high specificity but were not as effective as expected in identifying individuals with marginal health literacy due to the low sensitivity of the screening questions (area under the ROC curve 0.62; 95% CI: 0.53, 0.72; Chew et al., 2004).

In another cross-sectional study, Bains et al. (2011) examined associations among health literacy, diabetes knowledge, frequency of diabetes self-care activities, medication adherence, and glycemic control. The sample consisted of 125 adult patients with diabetes (AA = 71.4%). No data on comorbidities was provided. The Revised Rapid Estimate of Adult Literacy in Medicine (REALM-R) was the health literacy measure used in the study. Diabetes knowledge was assessed with the Diabetes Knowledge Questionnaire (DKQ). The Summary of Diabetes Self-Care Activities scale was used to measure the frequency of diabetes self-care activities (i.e., diet, foot care, glucose testing, and exercise). Medication adherence was measured using the MMAS. HbA_{1c} was the measure used to determine glycemic control. The researchers found that higher health literacy scores associated with better diabetes knowledge (r = 0.446, $p < 0.001$). Also, better diabetes knowledge was associated with glycemic control (β = 0.12; 95% CI [0.01, 0.23], $p < 0.05$).

However, no associations between health literacy and medication adherence, frequency of diabetes self-care activities, or glycemic control were found. There are several potential explanations for the lack of associations between health literacy and the disease management variables (i.e., diabetes self-care activities, medication adherence, and glycemic control). First, it is possible that other unexamined factors have a mediating role between health literacy and performance of DSM activities and glycemic control (e.g., patient burden). Secondly, the study used self-report measures for all variables except for glycemic control. Inclusion of objective measures for performance of DSM activities would possibly provide more data on associations with health literacy. Lastly, the study utilized the REALM-R, a health literacy measure that does not assess numeracy or reading comprehension. By using a health literacy tool measure that incorporates assessment of numeracy and document literacy (e.g., The Newest Vital Sign), more insight can be gained into the health literacy skills necessary in the performance of DSM activities for individuals with diabetes.

Another study conducted found associations between health literacy and other DSM activities. Ylitalo et al. (2018) found that the number of missed medical office visits was significantly greater for patients with limited health literacy (M = 9.8, SD = 10.4) as compared with individuals with adequate health literacy (M = 5.0, SD = 5.7; $p < .001$). Additionally, the number of prescribed medications for patients with limited health literacy (M = 10.5, SD = 7.3) was significantly greater than for patients with adequate health literacy (M = 8.1, SD = 5.6; $p = .03$). This finding potentially indicates that individuals with limited health

literacy had poorer DSM performance, requiring the need for additional medications to sufficiently manage their disease. This phenomenon of the accumulation of treatments for individuals who struggle with managing initial treatments is a principal feature of the CCM. Polypharmacy is particularly concerning for individuals with insufficient health literacy, as Davis et al. (2009) found that the risk for misinterpreting prescription instructions was greater for individuals with low literacy (adjusted risk ratio [RR] 2.70; 95% CI: 1.81,4.03; $p <$ .001) than those with adequate literacy.

While no studies were found that examined the role of health literacy in any DSM activities (e.g., managing prescribed medications) in an exclusive sample of African Americans with T2D and hypertension, previous studies have been conducted that explored the health literacy of AAs. Overall, AAs tend to have lower healthy literacy levels than other racial/ethnic groups (Gwynn et al., 2016; Kutner et al., 2006; Osborn et al., 2011; Rothman et al., 2004; Shiyanbola et al., 2018). Ylitalo et al. (2018) conducted a cross-sectional study of 406 patients (39% had diabetes; 41% non-Hispanic Blacks) to assess health literacy in a low-income adult population. The researchers used the Newest Vital Sign (NVS) and a single-item screening question (i.e., “How confident are you filling out medical forms by yourself?”) to measure health literacy. The NVS is a 6-item assessment tool that incorporates a nutritional label and corresponding questions, with scores of four or higher indicating the likelihood of adequate health literacy. After adjusting for several covariates (i.e., age, sex, self-rated health, BMI, diabetes status, number of medications, healthcare utilization, and

confidence completing medical forms), findings indicated that non-Hispanic Black patients were more likely to have inadequate health literacy (NVS<4) compared to non-Hispanic White patients (*OR* 7.32, 95% CI [2.41, 22.16], $p < .001$). Additional studies have also reported similar findings supporting the disparity in health literacy for AAs with diabetes (Gwynn et al., 2016; Osborn et al., 2011; Rothman et al., 2004; Shiyanbola et al., 2018). Therefore, it is imperative to conduct further exploration of health literacy for AAs with T2D and hypertension and the potential impact on medication adherence.

Concurrent Examination of Patient Activation and Health Literacy

Individually, patient activation and health literacy are distinct, measurable components of DSM capacity that provide insight into medication adherence for individuals with T2D and hypertension. However, previous research suggests the enhanced knowledge to be gained from examining patient activation and health literacy simultaneously. For example, Gwynn et al. (2016) examined 225 adults (67% Black) using data from a randomized controlled trial to determine the relationships between race, health literacy, and patient activation. The researchers also tracked participants' number of comorbidities, which ranged from none to more than two. No data were provided on the participants' specific types of comorbidities. Health literacy was measured with the short version of the Test of Functional Health Literacy in Adults (S-TOFHLA). The S-TOFHLA is a validated health literacy test designed to evaluate an individual's ability to read and understand health-related information, with higher scores indicating higher literacy levels (Housten et al., 2018). The 21-item PAM® was used to measure

patient activation. Health literacy was found to have a greater influence on patient activation levels for individuals with greater comorbidities (path coefficient = 0.420; $p < .001$) as compared with those with fewer comorbidities (path coefficient = 0.119; $p = .18$). The researchers also found that low health literacy was significantly higher among AA participants (54%) compared to non-Hispanic White participants (12%); $p < .0001$. Furthermore, health literacy was found to mediate the negative impact of race/ethnicity on patient activation (indirect effect −0.139, SE = 0.036; $p < .001$).

Additional studies have yielded results that further support an association between patient activation and health literacy. Lubetkin et al. (2010) conducted a cross-sectional study to explore the relationship between patient activation and health literacy. The researchers used a convenience sample of 454 patients (34% Black) receiving care from one of three health centers. No data were gathered on chronic disease status for the patients. However, patients provided self-rated health status data (excellent: 7%; very good: 23%; good: 38%; fair: 22%; poor: 9%). The 13-item PAM® was used to measure patient activation, and health literacy was measured with the S-TOFHLA. Lubetkin et al. (2010) found that patients with adequate health literacy were more likely to achieve the highest level of patient activation (i.e., Level 4; 44%) and had significantly higher patient activation scores ($M = 64.8$) compared to patients with borderline or inadequate health literacy (21%; $M = 55.7$ $p < .01$).

Mitchell et al. (2014) obtained similar results in their secondary data analysis. Health literacy was measured by the Rapid Estimate of Adult Literacy

Measure (REALM). Significant associations were found between patient activation and health literacy. Specifically, patients in the lowest health literacy category (Grade 6 and below) were more likely to be at the lowest level of patient activation (level 1; 16%) as compared with patients at the highest patient activation level (level 4; 9%), $p < .01$. Previous research has indicated that as little as a four-point difference in patient activation scores can create a meaningful impact on DSM behavior sustainability (Fowles et al., 2009; Hibbard at al., 2008).

In a different study, Sheikh et al. (2016) reported on the association between patient activation and health literacy. The researchers conducted a cross-sectional pilot study with a sample of 108 adult patients (63% AA) to examine patient activation and health literacy during emergency room visits. The 13-item PAM® and the REALM were used to measure patient activation and health literacy, respectively. Higher health literacy was significantly associated with higher levels of patient activation ($r_S = 0.30$; $p = .001$).

In summary, there is insufficient evidence of the associations among patient activation, health literacy, patient burden, and medication adherence. While three studies found higher patient activation was associated with higher health literacy (Gwynn et al., 2016; Lubetkin et al., 2010; Sheikh et al., 2016), none of the studies were conducted among patients with comorbid T2D and hypertension or focused on AAs, a group at great risk for low health literacy and poorer health outcomes from diabetes and hypertension. A single study found a positive relationship between patient activation and better DSM behaviors (i.e.,

self-reported confidence in diabetes self-management and summary of diabetes self-care) but did not include measures of the actual performance of any DSM activities (Mayberry et al., 2010). A different cross-sectional study discovered positive associations between patient activation and medication adherence but did not specifically analyze the association in a sample of AA adults with comorbid T2D and hypertension (Skolasky et al., 2011). A systematic review of randomized controlled trials involving individuals with T2D resulted in the discovery of the association between patient activation interventions and improved health outcomes (i.e., < HbA_{1c}, <systolic blood pressure). However, the researchers did not study medication adherence (Bolen, 2014).

Four studies discussed associations between health literacy and DSM activities. One study including AA adults with diabetes examined associations between health literacy and attending healthcare appointments as scheduled. The researchers found that lower health literacy associated with greater frequency of missing medical appointments (Ylitalo et al., 2018). Another study found the risk for misinterpreting prescription instructions was greater among individuals with low literacy. The remaining two studies examined health literacy along with medication adherence, with both studies including samples of AAs with diabetes. One study examined health literacy, DSM indicators (i.e., diabetes knowledge, diabetes self-efficacy, and depressive symptoms), self-reported medication adherence, and health outcomes (i.e., HbA_{1c}, systolic blood pressure, and body mass index). No relationship between health literacy and health outcomes were found, potentially due to the low sensitivity of the health literacy

measured used. However, one item within the health literacy scale used, “difficulty understanding written information”, was significantly associated with lower diabetes knowledge and worse medication adherence (Al Sayah et al., 2015). The other study examined associations among health literacy, diabetes knowledge, frequency of diabetes self-care activities, medication adherence, and glycemic control. No associations between health literacy and medication adherence, frequency of diabetes self-care activities, or glycemic control were found, potentially due to unexamined factors (e.g., patient burden) and exclusion of measures of numeracy and reading comprehension from the health literacy tool used in the study (Bains et al., 2011). Moreover, of the studies that examined health literacy, only one study used literacy measures that assessed the numeracy skills of the participants (Ylitalo et al., 2018) and no studies examined the patient burden of participants. Numeracy relates to an individual’s ability to process numeric information (Housten et al., 2018). For patients with T2D and hypertension, numeracy skills are essential. Additionally, patient burden provides insight into how some individuals with adequate health literacy or high patient activation do not demonstrate expected DSM performance (e.g., good medication adherence).

Overall, there is limited literature that suggests a relationship between patient activation and health literacy, particularly for AAs with chronic conditions. Moreover, the literature that describes associations among patient activation, health literacy, and the management of prescribed medications, specifically for AA adults with T2D and hypertension, is non-existent. Several reports indicate

lower health literacy levels for AA adults as compared to non-Hispanic White adults (Gwynn et al., 2016; Osborn et al., 2011; Rothman et al., 2004; Shiyanbola et al., 2018; Ylitalo et al., 2018). However, no studies reported the inclusion of patients with comorbid T2D and hypertension. Higher levels of patient activation and health literacy were found to associate with improved DSM abilities: self-efficacy in diabetes care, interpreting prescription instructions, attending scheduled medical appointments (Al Sayah et al., 2015; Davis et al., 2009; Mayberry et al., 2010; Ylitalo et al., 2018)), but the limited research conducted to examine the role of patient activation and health literacy in the actual performance of DSM activities (e.g., managing prescribed medications) is conflicting (Al Sayah et al., 2015; Bains et al., 2011; Skolasky et al., 2011) . Therefore, more research is needed. This study addressed the gaps in literature by investigating patient activation, health literacy, and medication adherence for AA adults with T2D and hypertension. The patient burden (i.e., treatment burden and illness burden) reported by AA adults with comorbid T2D and hypertension was also examined. The following section describes the potential role of patient burden (i.e., treatment burden and illness burden) in DSM.

Patient Burden

Individually, T2D diabetes and hypertension are burdensome chronic diseases (AHA, 2016; Powers et al., 2015; Rowley et al., 2017). When these diseases co-exist, the patient burden is further compounded (CDC, 2018b; NIDDK, 2017). Individuals with chronic diseases often experience illness and treatment burden. These burdens stem from the physiological impact of the

diseases and the complexity of treatment regimens prescribed for disease management (Brod et al., 2009; Eton et al., 2012; Gupta et al., 2016). Individuals with comorbidities, namely T2D and hypertension, may have DSM workloads that include completion of daily activities (i.e., taking medications), creating daily treatment burdens for patients to overcome (Eton et al., 2012). Considering the typical DSM workload that patients with comorbid T2D and hypertension encounter, it is very probable that many of these patients experience treatment burden. As treatment burden potentially impacts DSM productivity, such as what is needed for medication adherence, it is essential to examine this burden for patients with T2D and hypertension (Rogers et al., 2017). The following sections describe the specific aspects of patient burden of interest in this study, treatment burden and illness burden.

Treatment Burden

The burden of treatment has been defined as an individual's DSM workload and the impact that the workload has on well-being (Eton et al., 2012). A DSM workload consists of prescribed therapies and individualized DSM demands, which are essential activities in the effective management of T2D and hypertension (Byers et al., 2016; CDC, 2018b; Shippee et al., 2012). Although the benefits of proper management of T2D and hypertension are well known (e.g., decreased risks of heart disease and stroke), the prescribed DSM activities to manage these comorbidities can be burdensome for patients (AHA, 2016; Brod et al., 2009; CDC, 2017c). The ADA recommends that healthcare professionals consider patients' overall treatment burden when engaging in

shared decision-making with patients to establish glycemic and blood pressure control targets (de Boer et al., 2017). The integration of minimally disruptive medicine into patient care is an attempt to address the concerns regarding treatment burden for patients (Eton et al., 2012). Minimally disruptive medicine refers to the development of treatment plans and the provision of services that are designed to facilitate patients' healthcare goal attainments while limiting the healthcare burden patients experience. A key aspect of effectively implementing minimally disruptive medicine is to establish patients current and potential treatment burdens.

Few studies have specifically explored the treatment burdens experienced by individuals with chronic disease. Findings from two qualitative studies described how managing prescribed medications along with other factors may lead to increased treatment burden (Eton et al., 2012; Gallacher et al., 2018). Gallacher et al. (2018) conducted a qualitative study to explore patient burden and patient capacity for stroke survivors (N = 29). Findings from the study indicated that treatment burden arose from the participants' healthcare workloads or the occurrences of care deficiencies. Within participants' healthcare workloads, several factors that added to chronic disease management treatment burdens were reported as: (1) understanding symptoms and treatments, (2) problem-solving, (3) goal setting and prioritizing, (4) routine appointments, and (5) managing medications. Additionally, specific care deficiencies that added to treatment burdens were: (1) difficulty with understanding provided information, (2) poorly timed information, (3) information not tailored to the individual, (4)

complicated medication regimes, and (5) poor long-term follow-up from health care providers. In a similar study, Eton et al. (2012) conducted semi-structured interviews of thirty-two adults who had at least one chronic condition and were tasked with DSM activities (i.e., taking multiple medications and monitoring their health, diet, and exercise), to understand the perspectives of patients regarding their treatment burden. Twelve of the participants were previously diagnosed with diabetes and fourteen were diagnosed with hypertension. Findings revealed several themes for treatment burden, similar to the Gallacher et al. study, including medication adherence challenges, financial challenges, and confusion about medical information.

In a secondary analysis of a quantitative cross-sectional study, Rogers et al. (2017) examined 120 adults (AA = 22) with diabetes and at least one other comorbid condition (hypertension =85% of the sample) to examine the associations between treatment burden and disease-related outcomes. Of the associations examined in the study, the associations between treatment burden and two outcome measures: chronic condition distress and perceived competence in managing health conditions are of primary interest. Treatment burden was measured with the 48-item Patient Experience with Treatment and Self-Management (PETS) questionnaire, with higher scores on each subscale indicating greater perceived treatment burden in the corresponding domain. Chronic condition distress was positively associated with multiple treatment burden subscales: medical information burden ($r_S = 0.56$), medication burden ($r_S = 0.53$), monitoring health burden ($r_S = 0.50$), health care expenses burden ($r_S =$

0.48), medical appointments burden ($r_S = 0.44$), and bothersome medication side effects ($r_S = 0.39$); $p < .001$ for all associations. These findings imply that individuals who felt more overwhelmed with their health conditions (i.e., experienced greater illness burden) also experienced greater treatment burdens related to managing their chronic conditions. Additionally, perceived competence in disease self-management was negatively associated with several treatment burden subscales: monitoring health burden ($r_S = -0.50$; $p < .001$), physical and mental health exhaustion ($r_S = -0.47$), medical information burden ($r_S = -0.46$), healthcare expenses burden ($r_S = -0.39$), medication burden ($r_S = -0.33$); all with $p < .001$. Based on these findings, it appears that individuals who had lower perceived competence (e.g., lower DSM capacity) in completion of DSM activities also experienced greater treatment burdens. Therefore, by exploring factors associated with patients' DSM capacity (e.g., patient activation and health literacy) in addition to treatment burden, strategies can be developed that could enhance patients' DSM capacities and reduce their treatment burdens, subsequently improving their chances of meeting the demands of their DSM workloads.

In addition to the factors previously described in regard to treatment burden, some of the burden patients experience stems from changes to patients' treatment regimens. For example, according to clinical practice guidelines, diabetic patients who have elevated HbA_{1c} during a hospital admission are prescribed a more intense outpatient treatment regimen, as compared to the regimen received during hospitalization (Umpierrez et al., 2012). Thus,

individuals who have poorly controlled diabetes are likely to have even greater treatment burdens following a hospitalization. Griffith et al. (2012) conducted a retrospective cohort study to examine how pre-hospital admission medication prescriptions for 1,359 Veteran Affairs patients (AA = 19%) differed from the prescribed outpatient regimen following hospital discharge. Of the 2,2025 admissions that occurred during the study period (indicating that there were repeat admissions for some patients), 22% (*n* = 454) of the encounters involved a change to the post-discharge treatment regimen. The most frequent changes in treatments included initiating a new insulin medication (44%), initiating a non-insulin medication (17%), change from one insulin medication to another (12%), and increasing medication dosages (34%).

Individuals who are overly burdened with their treatment regimen may struggle with completing DSM activities (i.e., managing prescribed medications), leading to partial or complete nonadherence to prescribed DSM activities (Eton et al., 2012; Lin et al., 2015; Shippee et al., 2012). For example, greater treatment burden has been found to associate with poorer medication adherence (Rogers et al., 2017). As nonadherence to prescribed DSM activities places patients at a greater risk for negative health outcomes, healthcare providers may respond with the implementation of additional treatments, further increasing the complexity of patients' disease management and intensifying treatment burdens (Eton et al., 2012; Rogers et al., 2017).

Along with treatment burdens, patients with T2D and hypertension may also experience illness burdens. Even with adequate disease management,

individuals with T2D and hypertension may still experience daily illness burdens as a result of associated disease symptomatology. As such, an examination of potential illness burdens alongside treatment burdens is necessary to achieve a greater understanding of patient burden.

Illness Burden

Comparable to treatment burden, illness burden reportedly has negative associations with the performance of DSM activities. Illness burden refers to the perceived disruption in a person's life attributed to symptoms (e.g., pain) and functional limitations (e.g., amputation) that occur as a result of disease (Adriaanse et al., 2016; Boehmer, Shippee, et al., 2016). The presence of more than one chronic condition is associated with poorer health, decline in functional status, lower quality of life, and higher mortality (Adriaanse et al., 2016; Boehmer, Shippee, et al., 2016; Payne et al., 2013; Rogers et al., 2017). People with chronic diseases, such as T2D and hypertension, may suffer from numerous disease-related symptoms and/or functional challenges, ultimately leading to considerable illness burdens. Rogers et al. (2017) also found that chronic illness distress was significantly associated with greater medication burden (0.53, $p < .001$).

In a cross-sectional study, researchers evaluated the illness burden for 255 patients (AA = 19%) with diabetes who also had diabetic peripheral neuropathy (Gore et al., 2006). Neuropathy is one of the most common diabetes complications that causes pain, numbness, and potentially leads to permanent disabilities (CDC, 2017c). Most of the sample had T2D (86%) and 52% reported

taking at least two prescription medications specifically for management of neuropathic symptoms (Gore et al., 2006). Many participants reported declines in home productivity (59%) and diminished ability to perform activities of daily living (86%) due to the pain experienced from diabetic neuropathy. For participants who worked at least part-time (n = 73), 64% reported missing work (M = 13 days), leaving work early, and decreased work productivity as a result of diabetic neuropathy pain.

Examples of illness burden were also found among people with kidney disease, a major complication that can result from poorly managed diabetes and/or hypertension. Boehmer, Shippee, et al. (2016) conducted a cross-sectional study of 137 adult dialysis patients to discover associations between domains of patient capacity and disruptive of illness (i.e., illness burden). The Illness Intrusiveness Scale was used to measure illness burden. The results indicated that illness intrusiveness (i.e., perceived impact of illness burden on daily life) had significant negative associations with capacity measures: self-efficacy (-0.4, $p < .001$), mental capacity (-0.6, $p < .001$), and financial capacity (-0.5, $p < .001$). They also found that specific illness burden factors had significant positive associations with overall illness intrusiveness scores: pain (0.5, $p < .001$) and fatigue (0.6, $p < .001$).

In a retrospective population-based cohort study of 530,771 adults with chronic kidney disease (CKD), it was found that participants with one concordant comorbid condition (e.g., diabetes and hypertension) had a greater occurrence of acute myocardial infarctions (HR 1.2; 95% CI: 1.13, 1.19; $p < .05$) and mortality

(HR 1.8; 95% CI: 1.73, 1.93; $p < .05$) than participants without a concordant comorbidity (Tonelli et al., 2015). Diabetes and hypertension were listed as concordant comorbidities in the study, as they have been indicated as having a similar pathophysiological profile as CKD, similar care management strategies, and in many cases, are major contributing factors in the development of CKD (Aga et al., 2019; Tonelli et al., 2015).

The burden of illness for individuals with diabetes and hypertension also includes indirect costs stemming from the inability to acquire or maintain employment due to disease-related disabilities and increased absenteeism from work due to disease-related symptoms and/or hospitalizations (ADA, 2018a). AAs with T2D and hypertension reportedly have greater costs associated with hospital inpatient visits and higher rates of disease-related mortality as compared with non-Hispanic White patients, indicating a greater burden of illness in this population (ADA, 2018a; CDC, 2019a; CDC, 2019b). The disparity in illness burden for AAs may be explained by the higher rates of chronic disease noted in this population. Gebregziabher et al. (2018) analyzed differences in multimorbidity magnitude and patterns among a national sample of more than three million Veterans (n = 1,263,906 for participants with diabetes, 13% AA). They found that urban non-Hispanic Blacks had an elevated risk of multimorbidity when compared to urban non-Hispanic Whites (RR 1.05; 95% CI: 1.05, 1.05; $p < .001$). Other reports have also supported the higher prevalence of diabetes-related comorbidities and disease-related complications for AAs as compared to other racial and ethnic groups (CDC, 2017d; CDC, 2019b; Lin et al., 2015; Lynch

et al., 2015; Mathur et al., 2011; OMH, 2016), further highlighting the illness burden for the AA population.

In summary, multiple studies have reported on the illness and treatment burden experienced by individuals with chronic disease (Brod et al., 2009; Eton et al., 2012; Gallacher et al., 2018; Griffith et al., 2012; Gupta et al., 2016; Rogers et al., 2017; Rowley et al., 2017; Shippee et al., 2012; Umpierrez et al., 2012) and others have highlighted the added burden that occurs in the AA population (CDC, 2017d; CDC, 2019b; Lin et al., 2015; Lynch et al., 2015; Mathur et al., 2011; OMH, 2016) and with the presence of more than one chronic disease (Adriaanse et al., 2016; Aga et al., 2019; Boehmer, Shippee, et al., 2016; Gebregziabher et al., 2018; Lin et al., 2015; Payne et al., 2013; Tonelli et al., 2015). Few associations among treatment burden, illness burden, and performance of DSM activities have been reported (Gore et al., 2006; Rogers et al., 2017). Only one study was found that discovered associations between illness burden and DSM capacity measures, with greater illness burden associating with lower self-efficacy and mental capacity (Boehmer, Shippee, et al., 2016). However, no studies were found that examined associations among patient burden, patient activation, health literacy, and medication adherence, specifically for AA adults with T2D and hypertension.

Considering that multimorbidity has been associated with poor health outcomes and greater risks of mortality, it can be reasonably inferred that the AA population with multimorbid conditions (i.e., T2D and hypertension) potentially experience elevated burdens as compared to other ethnic groups

(Gebregziabher et al., 2018; Tonelli et al., 2015). Therefore, the examination of illness burdens and treatment burdens for AA adults with T2D and hypertension reveals important factors involved in DSM for this population, ultimately providing a foundation for the development of methods to address the notable disparities in patient burden.

Another potential factor that has a role in individuals' inabilities to meet their DSM workload demands relates to managing DSM activities in the presence of catastrophic global public health challenges, such as the current COVID-19 pandemic. This study explored the perceived impact of the COVID-19 pandemic on DSM performance, including the management of medications for AA adults with T2D and hypertension. The following section describes DSM performance in the context of the COVID-19 pandemic.

Potential Impact of the Coronavirus Disease 2019 Pandemic

The Coronavirus Disease 2019 (COVID-19) is a life-threatening infectious disease with no specific vaccines or treatments (World Health Organization [WHO], 2020). Although many individuals who become infected with COVID-19 may experience only mild symptoms, certain individuals (e.g., individuals with underlying cardiovascular disorders or diabetes) are more likely to develop more serious illnesses from COVID-19 and have greater challenges in recovery (AHA, 2020a; CDC, 2020c; WHO, 2020). Additionally, AAs are disproportionately impacted by COVID-19, as the hospitalizations and death rates related to COVID-19 are higher for AAs as compared to other ethnic groups (CDC, 2020d).

The COVID-19 pandemic has presented many potential challenges in performance of DSM activities. During a pandemic such as with COVID-19, individuals may have increased levels of stress. This increased stress may reduce their ability to concentrate on routine activities, including performance of DSM. Additionally, since the declaration of pandemic status for COVID-19, the U.S. has experienced a drastic rise in unemployment rates, with rates increasing from 3.6% in January 2020 to 14.7% in April 2020 (U.S. Bureau of Labor Statistics, 2020). This surge in unemployment is likely a consequence of COVID-19 related business closures, massive layoffs, and furloughs. Potential challenges are also presented from changes in patient access to routine healthcare visits, as many organizations were driven to either postpone non-urgent care visits or transition to telemedicine services, per public health recommendations (AHA, 2020b). Moreover, the developing nature of COVID-19 has led to uncertainty relating to performance of DSM activities (e.g., managing medications). For example, Schroeder (2020) discussed erroneous speculations that the use of angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs), both of which are medications used to treat high blood pressure, increase the risk of illness from COVID-19. Although there have been no studies that confirm associations between COVID-19 illness and these medications, the uncertainty of risks and fear of illness may lead individuals prescribed these medications to stop taking them.

The potential financial strain, changes in access to non-urgent healthcare services (e.g. telemedicine), and the need to navigate a sea of new and

potentially conflicting information relating to COVID-19, may present additional challenges in managing medications for individuals with T2D and hypertension. There is limited information on how COVID-19 impacts DSM activities for individuals with chronic disease. Additionally, no studies were found that examined performance of DSM in the context of COVID-19. Therefore, exploration of the perceived impact that the COVID-19 pandemic has had on performance of DSM, namely managing prescribed medications, is of great importance.

This study examined the associations among DSM capacity (i.e., patient activation and health literacy), patient burden (i.e., treatment and illness burden), and medication adherence for AA adults with T2D and hypertension. Additionally, the perceived impact of the COVID-19 pandemic on the management of prescribed medications was explored. The importance of DSM, the specific DSM activity of managing prescribed medications, and factors that influence DSM performance (i.e. capacity and burden) for individuals with comorbid T2D and hypertension have been described. The remaining review of literature describes the dependent variable of this study, medication adherence.

Medication Adherence

Medication adherence is defined as the extent to which an individual's medication usage parallels with the prescribed medication regimen (World Health Organization [WHO], 2003). Medication adherence is a DSM activity that is of great importance for individuals with T2D and hypertension, as it has been reported as a vital factor in the prevention of health complications for individuals

with chronic conditions (Brown & Bussell, 2011). Adhering to medication prescribed specifically for management of T2D and hypertension has been associated with reduction in the risk of diabetes complications (e.g., kidney disease) and reductions in the risk of stroke and heart disease (CDC, 2018b).

Inconsistent medication adherence in the management of T2D and HTN is associated with failing to achieve glycemic and blood pressure control and increased risks of cardiovascular disease (CDC, 2018b; Dragomir et al., 2010). Poor medication adherence has also been found to associate with high perceived treatment burden (Rogers et al., 2017). More specifically, medication adherence was poorer for individuals who reported feeling more overwhelmed by medical information (*OR* 0.94; 95% CI: 0.90 -0.99) and for individuals with greater perceived medication burden (*OR* 0.96: 95% CI: 0.92 -0.99), $p < 0.001$ (Rogers et al., 2017). Reportedly, from 2017-2018 approximately 13% of adults diagnosed with diabetes in the U.S. did not take diabetic medications as prescribed (Cohen & Cha, 2019). Other reports have indicated that nationwide measures of medication adherence have varied for individuals with hypertension and diabetes, from 50% in some states among Medicaid recipients to 85% for those covered by Medicare Part D (Aitken et al., 2019).

Taking medication as prescribed for T2D and hypertension requires health literacy skills (e.g., numeracy and reading comprehension), which creates a level of complexity that may be difficult for some individuals to manage. This complexity may lead higher occurrences of poor medication adherence (Brown & Bussell, 2011; Greene et al., 2015; Ylitalo et al., 2018). For example, in a cross-

sectional study of 395 adult primary care patients (AA = 47%), the abilities of the patients to understand and demonstrate instructions found on container labels of common prescription medications were explored (Davis et al., 2006). While 70% of patients with low literacy were able to verbalize the instructions, only 30% were able to accurately demonstrate the instructions, implying a lack of comprehension for some of the patients. Davis et al. (2006) also found that misunderstanding prescription instructions was more likely to occur for individuals taking three or four prescription medications (*adjusted RR* 3.22; 95% CI: 1.53–6.77; $p < 0.001$) and for individuals with low literacy (*adjusted RR* 2.32; 95% CI: 1.26, 4.28; $p < 0.001$).

Previous studies have explored factors that contributed to medication adherence, or lack thereof. Weller et al. (2017) found in a qualitative comparative analysis of 56 adults (AA = 29%) with T2D that there were specific medication-taking behaviors participants identified that might have influenced glycemic control outcomes. Individuals with good glycemic control reported greater use of memory aids to assist with complexity of adherence (e.g., a pillbox organizer), indicating the use of problem-solving skills in managing the complexity of medication management. Forgetting to take medications, stopping prescribed medications to try alternative therapies, and not comprehending medication administration instructions contributed to poor medication adherence (Weller et al., 2017). Eton et al. (2012) also described several challenges individuals had with taking medications including experiencing side effects of medications, being confused about medication administration (e.g., not knowing the purpose and

timing of medication administration), managing multiple medications, and dealing with the interference in daily routines caused by managing medications. Similar to the Weller et al. study, participants also reported improving medication adherence by organizing and preparing medications with a pill box.

In another qualitative study, Bockwoldt et al. (2017) explored the medication-related experiences of fifteen AA adults with T2D to identify factors that influenced their adaptation to medication adherence. Participants reported that acute physical changes (e.g., residual effects from a stroke), acquisition of new knowledge relating to DSM, and changes in life status (e.g., death of a family member) led to a greater sense of accountability and improved adherence to their medication regimen. Additionally, the study revealed health promoting and health impairing factors involved in medication adherence. Health promoting factors (i.e., factors that facilitated medication adherence) included self-confidence in performance of DSM, belief in the value of medication adherence, assuming responsibility for their health, development of a routine for medication adherence, and maintaining positive relationships with the healthcare team. Some participants reported coordinating their medication administration with mealtimes and/or making lifestyle adjustments to improve adherence. Health impairing factors (i.e., factors that impeded medication adherence) included feelings of powerlessness, self-blame, and fear relating to taking medication. Some participants with inconsistent medication adherence reported not taking prescribed medications due to being fearful of the medication side-effects, while others reported taking medications only when physical symptoms were

experienced (Bockwoldt et al., 2017). Kennedy et al. (2008) reported similar findings from a quantitative study of 1.6 million Medicare beneficiaries. Results of the study indicated that greater than 4% of the total sample failed to fill or refill at least one prescription, with the most common reasons being not finding the medication necessary (18%) and fearing the medication side effects (12%).

In summary, previous studies have reported findings that support the role of medication adherence in achieving improved disease management outcomes (Brown & Bussell, 2011; Dragomir et al., 2010; Weller et al., 2017). Individuals who adhere to prescribed medication regimens have lower risks in the development of disease-related complications such as neuropathy, kidney disease, stroke and heart disease (CDC, 2018b). Problem-solving skills and literacy have been identified as important aspects in adhering to prescribed medications (Bockwoldt et al., 2017; Brown & Bussell, 2011; Eton et al., 2012; Greene et al., 2015; Rogers et al., 2017; Weller et al., 2017; Ylitalo et al., 2018).

A few studies were found that examined factors that facilitated and hindered medication adherence. Individuals who demonstrated poor medication adherence were found to experience greater perceived treatment burden, have poorer health literacy, have more difficulty in carrying out written instructions, fear the medication side effects , and feel more overwhelmed by medical information and managing their prescribed medications (Bockwoldt et al., 2017; Davis et al., 2006; Kennedy et al., 2008; Rogers et al., 2017; Weller et al., 2017). Additionally, individuals with poor medication adherence reported difficulty in managing multiple medications, remembering to take their medications, understanding

medication administration instructions, and managing the disruption in daily routines caused by taking prescribed medications (Eton et al., 2012; Weller et al., 2017). The use of memory aids, acquiring DSM knowledge, having greater confidence in performance of DSM, and developing a routine for medication management were found to increase individuals' potentials for good medication adherence (Bockwoldt et al., 2017; Weller et al., 2017). However, no studies were found that examined medication adherence among in a sample of AA adults with T2D and hypertension. Additionally, none of the studies examined medication adherence during a global public health crisis.

Taking medications as prescribed can be complex process, thus it is imperative to examine factors that potentially impact individuals' abilities to manage this DSM activity. In this study, medication adherence was examined along with DSM capacity (i.e., patient activation and health literacy), patient burden (i.e., illness burden and treatment burden), and the potential impact of COVID-19 on medication management. Considering the complexity of adhering to a prescribed medication regimen and the high prevalence of prescribed medications for individuals with T2D and hypertension, this study provides valuable medication adherence associations. These associations may be key in the development of strategies to improve health outcomes for AAs with comorbid T2D and hypertension.

Summary

In this chapter, multiple studies were presented that reinforced the need for further exploration of DSM capacity and patient burden for AA adult patients

with T2D and hypertension. The existing literature supports the role of DSM performance in disease management and prevention of disease-related complications (Beck, 2018; Powers, 2015; Weller et al., 2017). However, the literature examining medication workloads, DSM capacity, patient burden, and medication adherence for AAs with T2D and hypertension is fragmented and, in some cases, non-existent.

This study addressed several gaps in the literature. First, existing literature describing the role of DSM capacity in DSM performance (Al Sayah et al., 2015; Bolen et al., 2014; Davis et al., 2009; Greene et al., 2015; Gwynn et al., 2016; Lubetkin et al., 2010; Mayberry et al., 2010; Ylitalo et al., 2018), provide limited evidence on associations among patient activation, health literacy, and medication adherence, particularly for adult AAs with both T2D and hypertension.

Secondly, research on patient burden (Adriaanse et al., 2016; Boehmer, Shippee, et al., 2016; Eton et al., 2012; Gallacher et al., 2018; Gebregziabher et al., 2018; Gore et al., 2006; Griffith et al., 2012; Payne et al., 2013; Rogers et al., 2017; Ylitalo et al., 2018), has provided limited information on associations with patient activation and health literacy. Furthermore, the studies that were found on patient burden did not compare associations of illness and treatment burden with medication workloads, DSM capacity, and medication adherence, for patients with comorbidities. Treatment and illness burdens have both been described by participants in previous studies as being barriers to performance of DSM activities (Eton et al., 2012; Gore et al., 2006).

Third, the literature on medication adherence for patients with chronic disease provides some insight on associations among health outcomes, health literacy, and treatment burden (Aitken et al., 2019; Davis et al., 2006; Dragomir et al., 2010; Rogers et al., 2017; Weller et al., 2017). However, only one study was found that examined the associations between an aspect of treatment burden (i.e. medication burden) and illness distress (Rogers et al., 2017). A few studies reported on factors that promote and hinder medication adherence has been described (Bockwoldt et al., 2017; Davis et al., 2006; Eton et al., 2012; Kennedy et al., 2008; Rogers et al., 2017; Weller et al., 2017). However, little is still known on how medication adherence associates with patient activation, medication workload, or illness burden within the target population.

Lastly, no studies were found that explored medication adherence in the context of the COVID-19 pandemic. This study extends the current knowledge of DSM by examining patient activation, health literacy, treatment burden, illness burden, and medication adherence. The perceived impact of the COVID-19 pandemic on the performance of DSM was also explored.

Managing prescribed medications is an important DSM workload demand for individuals with T2D and hypertension. Guided by the Cumulative Complexity Model, the study adds to the body of knowledge for underexamined and potentially significant factors associated with medication adherence in T2D and hypertension, specifically for AA adults. By developing a more thorough understanding of specific DSM capacity factors and the patient burdens from prescribed treatments and disease symptomatology, additional insight was

gleaned on the identification of risks for poor medication adherence and strategies to improve medication adherence for vulnerable populations.

CHAPTER III

METHODOLOGY

This chapter describes the methodology that was used for this study. The sections included in this chapter are organized as follows: study design, setting, sample, recruitment, measures and instruments, data collection procedures, data management, data analysis procedures, potential challenges, and the protection of human subjects.

Study Design

A non-experimental, predictive, correlational design was used to examine relationships among disease self-management capacity measures (i.e., patient activation and health literacy), patient burden measures (i.e., treatment burden and illness burden) and medication adherence for AA adults with T2D and hypertension. This study also explored the workload and perceived impact of COVID-19 in the context of managing prescribed medications.

Setting and Sample

All aspects of this research study were conducted remotely. A non-random sample of 91 AA adults who met the inclusion criteria were recruited for this study. Inclusion criteria for this study were: (1) self-identify as African American/Black, (2) adult aged 18 years or older, (3) diagnosis of T2D and hypertension for at least one year, (4) ability to read,

understand, and speak English and provide informed consent, (5) prescribed at least one medication for diabetes and one for hypertension treatment, (6) ability to access the study surveys online or receive the surveys via a physical mailing address, and (7) ability to participate in a scheduled online or telephone session with the student Principal Investigator (student PI) following completion of online or mailed surveys. The exclusion criterion for this study was inability to independently carry out two or more activities of daily living (i.e., eating, bathing, getting dressed, and toileting). As the ability to perform mental and physical tasks were examined in this study, participants needed to meet minimum mental and physical capacity levels, limiting the potential impact of covariates.

Sample Size Calculation

Using an online sample size calculator by Soper (2020), a priori statistical power analysis for hierarchical multiple regression was conducted to determine an adequate sample size for this study. The results indicated that a sample size of 69 participants was needed for a medium effect size of 0.15, an alpha level of 0.05, a statistical power of 0.80, with two primary predictor variables (set A) and two secondary predictor variables (set B) (Soper, 2020). Because no similar studies that provided effect sizes could be identified, the student PI used the ranges and SD reported previously by similar studies (Boehmer, Shippee, et al., 2016; Huang et al., 2018; Sheikh et al., 2016; Weiss et al., 2005) to provide an estimate of the variability and an estimate of the potential effect size for this current study (Schmidt & Hollestein, 2018). The SDs were all

approximately one-third of their respective ranges, therefore, a medium effect size appears to be an appropriate selection for this study. An additional sample size calculation was performed to ensure an adequate sample size for the analyses that was conducted to detect correlations for variables not included in the hierarchical regression model. Using the G*Power calculator 3.1.9.2 to determine an a priori sample size for bivariate correlation analyses, a sample size of 84 participants was needed to have 80% power in detecting a moderate association, with an alpha level of .05. A moderate association was anticipated based on findings from two studies (Eton et al., 2012; Gallacher et al., 2018) that found the management of medications, and specifically the management of multiple medications, were key factors in the treatment burden participants reported. Based on these findings, the larger target sample size calculation of 84 was used for this study.

A survey completion rate of 85% was anticipated based on the lowest response rate observed in a review of previous studies with a similar target population and variables (Al Sayah et al., 2015; Ylitalo et al., 2018). Therefore, oversampling to the amount of 99 participants was determined to yield the needed sample size for this study (*N*=84 complete survey sets).

Recruitment

Upon receipt of study approval from Georgia State University's Institutional Review Board (IRB), participants were recruited remotely from online settings via a digital recruitment flyer (See the Recruitment Flyer in Appendix A). Flyers were posted to social media outlets (i.e., Facebook, Instagram, LinkedIn,

and Pinterest) and disseminated via email and text messaging to individuals within the student PI's networks of healthcare professionals (See email/text messaging script in Appendix B). The Flesch-Kincaid grade level for the email/text messaging script was 7.3. The student PI created profiles on each of the identified social media outlets for the specific purpose of providing study information and facilitating recruitment (e.g. posting the recruitment flyer). The recruitment flyer included a description of the study, criteria for inclusion eligibility, honorarium information, directions for accessing the study information online, how to receive printed versions of the study surveys if preferred, and the contact information for the student PI. The Flesch-Kincaid grade level for the recruitment flyer was 7.4. Participants were recruited and enrolled until the sample size of 84 with complete surveys was acquired.

Measures and Instruments

Data collected via online surveys included demographic data, contact information for participants, and participants' responses to measures of medication workload, patient activation, treatment burden, illness burden, medication adherence, and perceived impact of COVID-19 on medication management. Data collected via scheduled telephone calls (n = 22) or online sessions via Zoom Video Conferencing (n = 69) were participants' responses to the health literacy measure. The Flesch-Kincaid grade level for all survey instruments used in this study was 8th grade or below, with the exceptions of two surveys (i.e. health literacy and

treatment burden measures). The total estimated time of completion for all the surveys that were used in this study was 35 minutes. Descriptions of the survey instruments that were used in this study are provided in this section.

Demographic Variables

Using a demographic survey developed by the student PI, fifteen items were assessed: age, sex, race/ethnicity, level of education, employment status, household income, marital/relationship status, length of time since diagnosis of diabetes and hypertension, most recent HbA_{1c} value, most recent blood pressure, list of any additional comorbidities, insurance status, primary care provider status, presence of social support, and activities of daily living status (See Appendix C). The Flesch-Kincaid grade level for the demographic survey was 5.9. The estimated time of completion for this survey was three minutes.

Independent Variables

Measures of medication workload, DSM capacity, patient burden, and perceived impact of COVID-19 on management of medication were independent variables in this study. A description of each variable and how each variable was measured is provided below.

Medication Workload

The attributes of individuals' medication management (i.e. number, difficulty, route) were examined with the Medication Workload Survey (See Appendix D). The survey consists of 10 questions that assessed the following: (1) the number of medications taken for diabetes, hypertension, and other health issues (e.g. cholesterol), (2) if medications must be taken at separate times each

day, (3) the difficulty in managing medications at separate times, (4) the routes prescribed for medication administration (i.e., oral, topical, and or injection), (5) the difficulty in administering medications via the prescribed routes, (6) if medication dose(s) had to be adjusted based on glucose or blood pressure levels taken at home and their perceived difficulty in performing the necessary assessments and dosage adjustments, (7) if their healthcare provider made any changes to their medications in the last 90 days and their perceived difficulty in managing the changes that were made, and (8) the difficulty they had with eight situations relating to medication management (i.e., remembering to take their medications, paying for medications, opening medication containers, getting refills on time, reading the instructions on medication containers, taking medications at inconvenient times, understanding what their medications are for, and dealing with the side effects from their medications). The Flesch-Kincaid grade level for the Medication Workload Survey was 6.9. The estimated time of completion for this survey was five minutes.

For the items that assessed level of difficulty, participants selected a response option from a 3-point Likert scale that corresponded to their perceived difficulty in dealing with the respective situation. The 3-point Likert scale consisted of the following options: *not hard, a little hard,* and *very hard*. Responses were scored from 0-2, with higher scores indicating greater perceived difficulty in the respective situation. Total workload difficulty scores were calculated by summing the individual scores of all

items that assessed perceived difficulty in specific aspects of medication management (total of 13 items). Scores range from 0-26, with higher scores indicating a greater perceived difficulty in medication workload management. The questions within this survey were developed by the student PI using the Cumulative Complexity Model and the Brief Medication Questionnaire as a framework (Shippee et al., 2012; Svarstad et al., 1999). The Medication Workload Survey was reviewed prior to implementation in this study by healthcare professionals and educators with healthcare backgrounds and demonstrated good face validity. However, the Medication Workload Survey had not been administered prior to this study. Therefore, the initial internal consistency reliability for this measure was assessed during the data analysis portion of this study.

Disease Self-Management Capacity

Two measures (i.e., patient activation and health literacy) were used in this study to assess participants' capacities to complete disease self-management activities. The Patient Activation Measure® (See Appendix E) and the Newest Vital Sign (See Appendix F) were the specific instruments used to measure patients' activation and health literacy, respectively.

Patient Activation. The Patient Activation Measure® (PAM®) is a 13-item questionnaire that assessed participants' beliefs, motivation, knowledge, and skills in managing their diseases and preventing disease-related complications (Hibbard et al., 2004). The PAM® is a Guttman-like scale, with each question having one of the following response options: *disagree, strongly disagree, agree,*

strongly agree, or *not applicable (N/A*). The measure incorporates a 0-100 scoring method, with higher scores indicating greater patient activation. Insignia Health has rights to the PAM® *and* does not share the specific methods used to score individual patient activation items. To obtain PAM® scores for this study, licensing was purchased to use the PAM® scoring spreadsheet. Participants' responses were keyed into the spreadsheet. The spreadsheet has built-in formulas that analyze participants responses and yield a corresponding activation score. PAM® scores indicate if individuals: (1) believe that the patient role is important, (2) have the confidence and knowledge necessary to take necessary action, (3) take steps to maintain and improve personal health, and (4) stay adherent to disease self-management even under stressful circumstances. Scores are categorized into one of four patient activation levels. Level one (scores = 0-47) is the lowest level of patient activation and indicates that individuals possibly lack the belief that they have an important role to play in their health and lack basic knowledge about their condition and their care. Patients at level two (scores = 47.1 - 55.1) of patient activation have the knowledge and confidence necessary to manage their health. Level three (scores = 55.2 - 72.4) patient activation indicates that patients are not only knowledgeable and confident, but also take the initiative to perform health promotion and illness prevention activities. Level four (scores = 72.5 - 100), the highest level of patient activation, involves maintaining performance of DSM activities even under stressful circumstances

(Greene et al., 2015; Hibbard et al., 2004). The Flesch-Kincaid grade level for this document was 4.0. The estimated time of completion for this questionnaire was five minutes.

The instrument has been used to measure self-management abilities across differing levels of health status, age groups, racial groups (including AAs), and different chronic illnesses including T2D (Bolen et al., 2014; Greene and Hibbard, 2012; Lubetkin et al., 2010; Mayberry et al., 2010; Mitchell et al., 2014; Skolasky et al., 2011). Previous literature has indicated that individuals with higher levels of patient activation had significantly lower rates of emergency room visits and days of hospitalization, supporting criterion validity of the PAM® (Greene et al., 2015; Mitchell et al., 2014). A Cronbach's alpha range of 0.81 - 0.87 has also been reported from studies that included samples of AA adults, individuals with varying health statuses (including chronic illness), and adequate and low health literacy levels (Lubetkin et al., 2010; Prey et al., 2016). Thus, the PAM® has demonstrated very good internal consistency reliability.

Health Literacy. The Newest Vital Sign (NVS) is a 6-item questionnaire that evaluated participants' health literacy by: (1) assessing their understanding of words and numbers and (2) examining their ability to apply reading and numeracy skills (Weiss et al., 2005). The instrument involved each participant reviewing a nutritional facts label and answering six corresponding questions. The NVS was administered by the student PI over the phone or via a Zoom meeting. For phone administration, participants were emailed the nutritional label. For Zoom meetings, the student PI shared the screen to display the

nutritional label. Participants were then asked questions about the nutritional label and participants responded verbally with their answers. The NVS has not yet been tested as a self-administered tool. Scores were calculated on a 0 to 6 scale, with the lowest scores (i.e., 0 to 1) suggesting a high likelihood (50% or more) of limited literacy, middle scores (i.e., 2 to 3) indicating the possibility of limited literacy, and higher scores (i.e., scores of 4 or more) high likelihood of adequate literacy (Weiss et al., 2005). The Flesch-Kincaid grade level for the nutritional label participants were expected to read and comprehend is 10.5. The target grade reading level of this study's population was eighth grade. Although the reading level for this instrument was above the 8th grade level, the nutritional label reflects real life occurrences that potentially require higher levels of literacy skills to manage. The estimated time of completion for this questionnaire was three minutes.

The NVS has been previously used to assess health literacy in the AA population, including AA patients with diabetes (Ylitalo et al., 2018). The NVS has also been compared to other validated instruments considered as gold standards for health literacy measurement (Ylitalo et al., 2018). The NVS demonstrated good criterion validity when compared with the Test of Functional Health Literacy for Adults (TOFHLA; $r = 0.59$, $p < .001$). The TOFHLA is an instrument used to measure health literacy and has been used often in healthcare research. However, the TOFHLA requires a longer administration time (18-22 minutes) as compared to the

NVS (three minutes), making the NVS a more appealing health literacy assessment tool for the inpatient setting (Weiss et al., 2005). Another study examining a sample of 170 patients with T2D (no report of participant's races/ethnicities), indicated that the NVS was useful in predicting risks for complications from diabetes (e.g., neuropathy; *OR* 2.3, 95% CI [1.05,5.2], p = 0.037), based on comparisons of individuals with varying health literacy levels (Mann et al., 2019). Cronbach's alpha coefficients have been adequate ranging from 0.76 – 0.91 in samples of AAs, individuals with T2D, and individuals who were prescribed medications for diabetes management (Huang et al., 2018; Miser et al., 2013; Weiss et al., 2005). Therefore, the NVS has demonstrated good internal consistency and was an appropriate variable to include in this study as a potential predictor of medication adherence.

Patient Burden

In this study, measures of treatment burden and illness burden were used to assess patient burden. The Multimorbidity Treatment Burden Questionnaire (See Appendix G) and the Illness Intrusiveness Ratings Scale (See Appendix H) were the specific instruments used to measure treatment burden and illness burden, respectively.

Treatment Burden. The Multimorbidity Treatment Burden Questionnaire (MTBQ) was used to measure treatment burden in this study. The MTBQ is a 13-item questionnaire that measures patients' perceived effort in self-management of their medical conditions (e.g., managing medication adherence) and the impact that effort has on their daily well-being (Duncan et al., 2018). Each

question involves scaled response choices relating to level of difficulty: *extremely difficult, very difficult, quite difficult, a little difficult, not difficult,* or *does not apply*. The scores range from 0-100, with higher scores indicating greater perceived treatment burden. In a study of 143 adults with multimorbidity (predominantly White with no report of AA participants; 44% had diabetes), the instrument had good content validity and construct validity demonstrating a negative association between MTBQ and quality of life (r −0.36, $p<0.0001$) and self-rated health (r −0.36, $p<0.0001$) (Duncan et al., 2018). The Cronbach's alpha reported for the MTBQ was 0.83 demonstrating internal consistency reliability (Duncan et al., 2018). The Flesch-Kincaid grade level for this document was 10.7. The estimated time of completion for this questionnaire was five minutes.

Illness Burden. The Illness Intrusiveness Ratings Scale (IIRS) was used to measure illness burden in this study. The IIRS has been previously used to assess illness burden among AAs and individuals with varying chronic diseases including diabetes (Boehmer, Shippee, et al., 2016; Devins, 2010; Molzon et al., 2013). The IIRS is a 13-item measure that assessed participants' perception of the degree of interference in his/her life attributed to disease (Devins, 2010). The IIRS measured intrusiveness in the following life domains: health, diet, work, active recreation, passive recreation, financial situation, relationship with partner, sex life, family relations, other social relations, self-improvement/self-expression, religious expression, and community and civic involvements.

Participants rated the intrusiveness of their illness from one to seven, with one symbolizing *not very much* and seven symbolizing *very much*. Scores range from 13 to 91, with higher scores indicating greater perceived illness intrusiveness (i.e., illness burden). Good convergent validity has been reported for the IIRS, as predicted differences in scores were observed for individuals with differing observable burdens (Devins, 2010). The Cronbach's alpha coefficients previously reported for the IIRS were obtained from samples of individuals with diabetes (0.88) and for AAs with chronic disease (0.93) support reliability of the IIRS and its usefulness in examining illness burden in a sample of AA patients with chronic disease (Devins, 2010; Molzon et al., 2013). The Flesch-Kincaid grade level for this document was 7.2. The estimated time of completion for this questionnaire was four minutes.

Dependent Variable

The specific outcome measured in this study was medication adherence. A description of how this dependent variable was measured is provided below.

Medication Adherence

Medication adherence was assessed using the Extent of Adherence Survey (See Appendix I). This survey consists of two scales totaling fourteen items. The first scale includes six items that assess self-reported medication adherence over the prior 30 days. Participants responded with their level of agreement to medication adherence statements (e.g., "I missed or skipped at least one dose of my diabetes medications"), with *strongly disagree, disagree, neutral, agree,* and *strongly agree* as response options. Possible scores for each

item range from one (strongly disagree) to five (strongly agree), with items numbered one and two being reverse scored. To be considered adherent to their medication regimens, participants needed to respond with the highest level of agreement to adherence behaviors and highest level of disagreement to non-adherence behaviors. For example, participants needed to respond with *strongly agree* to "I took all doses of my diabetes medications" and *strongly disagree* to "I missed or skipped at least one dose of my diabetes medications." Participants were considered nonadherent if they received a score of ≥ two on any item. A total score reflecting adherence was calculated by averaging responses to the six items. While higher scores indicated greater levels of nonadherence, lower scores indicated greater levels of adherence (Voils et al., 2012).

The second scale in the survey assessed reasons for non-adherence. The eight questions of the reasons for non-adherence scale presented situations that potentially led to missing or skipping doses of medications (Voils et al., 2012). Participants responded to each situation using a Likert-scale with the following options: *not at all*, *a little*, or *a lot*. Scores for each situation ranged from zero through two, with higher scores indicating that the situation was perceived to contribute more greatly to non-adherence. Participants were also presented with an opportunity to report additional reasons that were not already listed for their non-adherence. In a study of 202 veterans with hypertension (50% Black), the Extent of Adherence Survey had good internal consistency

reliability, Cronbach's alpha = 0.84 (95% CI: 0.80, 0.87). Concurrent validity was also demonstrated by correlations between the extent measure, systolic (r=0.27, p<.0001) and diastolic (r=0.27, p<.0001) blood pressure (Voils et al., 2012). The Flesch-Kincaid grade level for this document was 7.8. The estimated time of completion for this survey was five minutes.

Exploratory Variable

COVID-19 Impact on Medication Management

The perceived impact of the COVID-19 pandemic on the management of medications was measured with the COVID-19 Impact Survey. The 10-item survey assessed participants' beliefs on how much the COVID-19 pandemic has changed situations relating to their medication management. Using a Likert-scale, participants responded with one of the following options: *strongly disagree, disagree, neither agree nor disagree, agree,* or *strongly agree* to the survey questions. Response item scores range from one through five, with higher scores indicating a greater belief that the presence of the COVID-19 pandemic has negatively impacted that specific aspect of their medication management. Total scores range from 10-50, calculated by summing the individual scores, indicating the overall perceived impact of COVID-19 on their medication management. Participants were also provided with the option of reporting additional details on how COVID-19 has affected their medication management (See Appendix J).

The questions within this survey were developed by the student PI using the Extent of Adherence and previous COVID-19 related literature (AHA, 2020b; Schroeder, 2020; Voils et al., 2012). The COVID-19 Impact Survey was reviewed by healthcare professionals and educators with healthcare backgrounds and demonstrated good face validity. However, the COVID-19 Impact Survey was not administered prior to this study, therefore, reliability measurements were not available. Internal consistency reliability for this measure was assessed in the data analysis portion of this study. The Flesch-Kincaid grade level for this document was 7.6. The estimated time of completion for this survey was five minutes.

Data Collection Procedures

Upon IRB approval from Georgia State University, the student PI began posting, emailing, and text messaging digital recruitment flyers. Potential participants were directed to the Qualtrics survey page developed by the student PI to determine their eligibility for the study. If a participant met inclusion criteria and did not have any exclusion criteria, they moved on to the informed consent process. The informed consent process was conducted via the Qualtrics survey. Informed consent included: (1) an explanation of the purpose of the research study, (2) the duration of the research study, (3) a description of the procedures that were followed, (4) how data confidentiality was maintained, (5) any potential risks to the participants, (6) an explanation that participants would not receive any direct benefits from the research findings, (7) whom

participants would contact if they had questions regarding the research study, (8) circumstances that required the participant's termination from the study, (9) how the data from the study would be used, (10) incentive details, and (11) a statement that participation in the study was voluntary and participants had the choice to withdraw from the study at any point they decided to do so. The Flesch-Kincaid grade level for the informed consent was 7.2.

The informed consent process was conducted online. Consent information was provided in the Qualtrics survey. Eligible participants independently read the consent form. The student PIs contact information was provided on the Qualtrics survey if participants had questions about the consent information or the study. All eligible participants were informed that their participation was voluntary and could be terminated at any time if they chose to do so. Once the informed consent document was reviewed, eligible participants responded to the following question, "Do you have any questions about this form or this study?". If "yes" was selected, eligible participants were directed to the contact information for the student PI and the survey ended. If "no" was selected, the eligible participants proceeded to a true or false question to assess their understanding of the information within the consent form. Individuals who did not respond correctly were redirected to the consent form along with a reminder that the student PI could be contacted with any questions. They also had the opportunity to respond to the question again. If answered incorrectly for a second time, eligible participants were directed to the student PI contact information to assist them with understanding the details of the study and the survey ended. Eligible

participants who responded correctly proceeded to selection of one of the following statements in the Qualtrics survey, “I consent, begin the study” or “I do not consent, I do not wish to participate.”, with the first statement indicating their desire to proceed with the survey.

The Qualtrics survey was set up to assign random identification numbers to all participants following their consent to the study. The identification numbers were used for data tracking purposes and protection of participants’ identities. There was no waiting period between participants providing consent and initiating their participation in the study. Once was provided, eligible participants proceeded to the survey portion of the study. For eligible participants who elected not to consent, the survey ended. A copy of the consent form was made available to each participant.

For eligible participants who indicated interest in the study but lacked access to the online documents, a paper version of the consent was offered to be mailed to them along with an addressed and stamped envelope for them to return the document. By returning the surveys, participants would indicate that they were consenting to participate. Eligible participants who opted to receive a paper version of the study documents were also provided with the student PI’s contact information in the event they had any questions or concerns regarding the consent process or study.

Once consent was provided, participants proceeded to the

demographic survey portion of the Qualtrics survey. The demographic information obtained from participants included age, sex, race/ethnicity, level of education, employment status, household income, marital/relationship status, length of time since diagnosis of diabetes and hypertension, list of any additional comorbidities, insurance status, primary care provider status, presence of social support, and activities of daily living status. The student PI also obtained participants' contact information (i.e., telephone numbers, email addresses, and mailing addresses) per participants' preferences. The contact information collected from participants via the Qualtrics survey was used to conduct the scheduled telephone or online session of the study (i.e., administer the NVS survey) and as a method for disseminating incentives. For participants who elected to receive telephone communications, they were asked to provide their preferred time(s) for contact, the name the student PI should use to address the participant in telephone communications, and if it was acceptable to leave voicemail messages.

Following the collection of demographic data and contact information, participants were asked to complete the Medication Workload Survey, PAM®, IIRS, MTBQ, Extent of Adherence Survey, and COVID-19 Impact Survey. While participants had the option to pause the survey and come back to complete at a later time, participants were encouraged to complete their surveys within 48 hours of initiating the survey process. Upon completion of the online surveys, participants were notified via a message in Qualtrics that they would be contacted within 72 hours, via their preferred contact method, to schedule

completion of the final survey (i.e., NVS). The completion of the NVS for each participant took place within one week of them completing the online surveys. During the scheduled session for completion of the NVS survey, the student PI reassessed participants for inclusion/exclusion criteria. Each participant was asked to confirm that they were (1) an AA adult with T2D and hypertension, (2) diagnosed with T2D and hypertension for at least one year, (3) prescribed at least one medication for T2D and at least one medication for hypertension, and (4) able to perform activities of daily living independently. Additionally, participants were asked to provide any responses missing from the online survey. Participants were also asked how they found out about the study for recruitment analysis purposes. Although the intent was to conduct this study primarily online, alternative methods of data collection were used when necessary. However, each participant needed to have access to at least a telephone to complete the NVS survey. Upon completion of the NVS survey, each participant was sent a digital gift card of $25. Upon acquiring the required sample of 84 participants with complete survey sets, the Qualtrics survey was closed to new participants. Participants who started the survey process but had not completed their surveys and had not had any survey activity for 48 hours prior to acquiring the sample of 84 completed survey sets, were informed of the study closure and thanked for their time. Participants that had activity within the prior 48 hours were notified of the time they had remaining to complete their study surveys. An additional seven

participants completed their survey sets and scheduled interviews, resulting in a total sample size of 91. Participants were advised if they did not complete all aspects of the study upon study closure they would not receive an incentive.

Data Management

The student PI collected data using self-report measures and one survey that was administered via a scheduled online or telephone session (i.e., NVS). Prior to data collection, the student PI developed a code book for the study variables and two tracking sheets. The code book was created in Microsoft Word and contained no identifying participant information. The code book was used to maintain the scoring methods for each of the variables used in this study. Microsoft excel was used to develop a spreadsheet to track each participant's responses on surveys. The student PI maintained a separate spreadsheet which consisted of participants' identification numbers, participants' contact information, a log of the dates and number of times participants were contacted, the scheduled dates for the administration of the NVS, a log of how the participants found out about the study, and the record for distribution of incentives. This list was also maintained on a password protected excel spreadsheet.

All surveys were administered in one of two ways: (1) via an online Qualtrics survey or (2) through scheduled online or telephone sessions based on participant preference and instructions from the developers of the instruments being used in the study. Each survey used in this study was labeled with a unique identification number in lieu of using participants' names. Survey responses were primarily collected online via Qualtrics. The Qualtrics data were

password protected. Upon obtaining the completed surveys and contact information from participants, the student PI transferred the data from the surveys into a password protected Microsoft excel sheet on a duo password protected tablet equipped with a 15-minute inactivity timeout, data storage encryption, automatic data wiping after 10 consecutive failed login attempts, and ability to remotely wipe the device.

The NVS survey was administered via a scheduled session, per instructions from the NVS developers. For participants who chose to complete the NVS via telephone, the nutritional label was emailed or texted to them. For online sessions, the nutritional label was displayed via a screen share for them to view. The online platform used included microphone capability so that the student PI and participant could communicate verbally. The student PI transcribed participants' responses on an electronic copy of the document, labeled with the participant's study identification number, and stored on the password protected tablet.

Upon completion of all surveys, the student PI assessed them for missing responses and followed up with participants as appropriate. All identifiable information was removed from the study data before reporting the study results. As this study had exempt status, signatures were not required on informed consent forms and therefore, did not need to be retained for three years, in accordance with regulations (U.S. Department of Health & Human Services [HHS], 2017). The data collected from participants via the Qualtrics survey were password protected and only

accessible by the PI (i.e., Dr. Dawn Aycock) and student PI (i.e., Michelle Gaddis). No study documents were distributed or collected via mail, therefore, no hard copies needed to be stored in this study. Any data shared via the student PI's dissertation defense, research conferences, or publications was deidentified prior to disseminating.

Data Analysis

IBM SPSS Version 25 software was used to conduct the statistical analyses for this study. Prior to inputting data into the SPSS database, the data were assessed to identify errors and missing values. Upon transferring data into SPSS, the data were rechecked for errors, missing values, and normality. Errors were corrected and missing values were handled by following up with the participants to acquire the missing information. Normality was assessed by using descriptive statistics then assessing for kurtosis or skewness. Outlier values were identified by using frequencies, minimum, and maximum. For data that deviated from a normal distribution, appropriate transformations were conducted. For variables that did not achieve normality, non-parametric tests were used. The data were also examined to ensure assumptions to perform the inferential data analysis were met (i.e., linearity, independent errors, homoscedasticity, and multicollinearity). Internal consistency reliability was assessed for each of the scales within the Medication Workload Survey, PAM®, NVS, MTBQ, IIRS, the Extent of Adherence Survey, and COVID-19 Impact Survey using Cronbach alpha test. Descriptive statistics (i.e., frequencies, percentages, measures of central tendency and variability) were used to summarize the demographic

characteristics of the sample, independent variables, outcome variable, and the exploratory variable. The data were also analyzed for potential covariate variables. As potential covariates were identified during data analysis, the appropriate steps were taken to control for their effects. The literature indicated that the following demographic variables were potential covariates for the concepts in this study: age, sex, and socioeconomic status (Akohoue et al., 2015; Boehmer, Shippee, 2016; Byers et al., 2016; Gallacher et al., 2018; Osborn et al., 2013; Rovner et al., 2013). In this study, income and level of education were the measures used to assess socioeconomic status. The data analyses for addressing the research questions are described next.

Data Analysis for Research Questions

The research questions were analyzed as follows:

For AA adults 18 years of age or older with comorbid T2D and hypertension who have been prescribed medications for blood pressure and glycemic control:

RQ1: Are higher levels of illness burden associated with lower levels of patient activation and health literacy?

RQ2: Are higher levels of treatment burden associated with a higher number of prescribed medications and greater perceived difficulty in managing prescribed medications?

The plan for answering the first and second research questions was to use Pearson's correlation test if the assumptions were met (e.g., normality) and if not, a non-parametric alternative (e.g., Spearman's rank-order correlation) would be

used. As the variables did not achieve normal distribution upon multiple transformation attempts, the non-parametric alternative was used to answer questions one and two. The correlation matrix provided an indication of the direction of relationships (i.e., either positive or negative correlations), the strength of the relationships among the variables, and if any of the correlations were significant.

RQ3: Do patient activation, health literacy, treatment burden, and illness burden significantly predict medication adherence?

To answer the third research question, a linear regression analysis was performed. Multiple linear regression analysis uses a model composed of multiple independent variables (X) to explain or predict variance in one dependent variable (Y) at a time. Therefore, one linear regression analysis was performed to test the model consisting of patient activation, health literacy, treatment burden, and illness burden in predicting the variance in medication adherence. Hierarchical entry was the method used for the regression analysis, with potential covariates entered first (i.e., age, sex, income, and level of education), patient activation entered second, health literacy third, treatment burden fourth, and illness burden entered last. The decision for hierarchical entry and the order in which variables were entered was based on the amount of literature found to support each of the independent variables' associations with the dependent variables. The level of significance used for the data analysis was $\alpha = 0.05$. The model summary indicated whether the model that included patient activation, health literacy, treatment burden, and illness burden significantly

predicted variance in the dependent variables. The coefficients table displayed each independent variable's contribution to predicting the variance in the dependent variables and the significance of those predictions.

RQ4: Which aspects of medication management are the most challenging?

The fourth research question was addressed by analyzing: (1) the frequencies of the responses to questions five, seven, eight, nine, and 10 of the Medication Workload Survey to identify the aspects of managing medications most frequently identified as being a challenge, and (2) the modes for the Likert-scale responses to question #s five, seven, eight, nine, and 10 of the Medication Workload Survey to determine the extent of the challenge created by medication management activities. The same analysis was conducted for questions four and five of the Extent of Adherence Survey. For both analyses, items with higher frequencies in level 1 and level 2 scale responses (i.e., *A little* and *A lot* on the Medication Workload Survey; *A little hard* and *Very hard* on the Extent of Adherence Survey) indicated they were the more commonly identified challenges. Items that had modes of zero indicated the situations that were the least challenging, modes of one indicated situations that were perceived as a little challenging, and modes of two indicated situations that were found to be the most challenging in managing medications and medication adherence.

RQ5: What is the perceived impact of the COVID-19 pandemic on medication management?

To answer the final research question, (1) the frequencies of the responses to questions from the COVID-19 Impact Survey were analyzed to

identify the aspects of managing medications most frequently identified as being impacted by COVID-19, and (2) the modes for the Likert-scale responses to questions one through 10 of the COVID-19 Impact Survey to determine the extent of the perceived impact of COVID-19 on medication management activities. Items with higher frequencies in level four and level five scale responses (i.e., *Agree* and *Strongly agree*) indicated they were the more commonly identified activities believed to have been impacted by COVID-19. Items that had modes of zero through three indicated situations that were not perceived to be impacted by COVID-19, items with modes of four indicated situations perceived to have been impacted by COVID-19, and modes of five indicated situations relating to medication management that were found to be the most impacted by the presence of COVID-19.

Priori Identification of Study Challenges

Prior to conducting the study, potential situations that could cause challenges in the study were identified. These potential challenges have been outlined below. Any additional situations that were not identified prior to the study were addressed as they arose during the study.

Recruitment Challenges

This study was conducted entirely remotely. Potential participants could have been uncertain in determining that this study's recruitment efforts were legitimate, that it was safe to participate in the study, that they were not being spammed, and that they were not targets of fraudulent attempts to gain access to their information. To address these problems, the contact information for the

student PI was included on all recruitment materials (i.e., social media posts, recruitment flyer, emails, text messages). The recruitment flyer that was disseminated also included a picture of the student PI. Potential participants who contacted the student PI were provided with the study details along with the informed consent form to review. The consent form included contact information for the PI, student PI, and GSU IRB. The student PI allowed adequate time for them to review the consent form and answered any questions they had for making their decision to participate. Participants were informed of the privacy protection and data security measures that were in place. At any point that a potential or active participant indicated that they no longer desired to be contacted, the student PI terminated all future contact with that individual. The student PI conducted weekly analyses to evaluate the recruitment flow and detect any additional unanticipated challenges with recruitment.

Completion of Study Surveys Questionnaires

There was a total of eight surveys (i.e., Demographic survey, COVID-19 Impact Survey, Medication Workload Survey, PAM®, NVS, MTBQ, and IIRS) that participants were asked to complete during this study. The estimated completion time for all surveys in this study was 35 minutes. For participants who unintentionally skipped questions or left out information, the student PI evaluated the participants' responses to the surveys at least every 72 hours to determine if the participants demonstrated having difficulty in providing their responses. The student PI

assisted participants in the completion of their questionnaires during each scheduled 1:1 session as needed, while ensuring any actions to assist participants did not conflict with the administration guidelines provided for the study instruments. As indicated in the informed consent, participants had the right to skip questions at any time of their choosing. If any participants intentionally skipped questions for reasons that could not be resolved, the student PI honored the participant's choice to not respond.

Additionally, as most of the questionnaires relied on self-reported data, there was potential for response bias from the participants. To address this issue, participants were informed of the importance of providing honest responses to the surveys. Participants were also reminded that the information they provided in the study would be de-identified prior to sharing any results.

This study involved a small incentive for participants. As such, some participants possibly attempted to complete the study more than once. To address this potential issue, the Qualtrics survey was equipped with a "prevent ballot stuffing" feature, which deterred individuals from joining the study more than once. Additionally, as this study involved a scheduled telephone or online session prior to receiving incentives, the student PI also monitored for repeated attempts to participate in the study.

Retention of Study Participants

As this study involved a scheduled session (i.e., administration of the NVS survey), for which scheduling took place within 72 hours after completion of the online surveys, potential problems with retention of participants were anticipated.

To address potential retention issues, the student PI included information about the required scheduled session in the informed consent. The student PI also provided participants with reminders for the session. Additionally, the student PI planned for oversampling to the amount of 99 to increase the potential of acquiring the completed set of surveys for 84 participants.

Protection of Human Subjects

Prior to initiating this study, IRB approval was obtained from Georgia State University, in accordance with Human Research Protection regulations. This study posed no more risks than participants would experience in a normal day. However, as this study involved participation of human subjects, the student PI acknowledged potential ethical concerns. In addition to the activities described in the data management section regarding protection of participant data (e.g., password protection of surveys, assignment of Participant ID numbers, locked file cabinet for hard copy documents), the following human subjects' protection activities were performed. The student PI completed required research training provided by the Collaborative Institutional Training Initiative (CITI) program for studies involving human subjects. The student PI obtained informed consent from all study participants. Participants were informed that their participation was voluntary, and they had the option to withdraw from the study at any time, even if consent to participate in the research study was already provided. The student PI ensured that the approved study

procedures were followed, including assigning participant identification numbers in lieu of using names on study documents, to maintain participants' privacy and confidentiality of the information study participants provided.

CHAPTER IV

RESULTS

The results of this non-experimental, predictive, correlational study of disease self-management capacity, patient burden, and medication adherence in African American adults with type 2 diabetes and hypertension are outlined in this chapter. More specifically, this chapter contains a description of the recruitment and retention outcomes, demographic characteristics of the sample, and the reliability of the scales used to quantify the study variables. The descriptive statistics for all study variables and the results of the analyses of five research questions are also presented.

Recruitment and Survey Completion Results

A total of 498 Qualtrics survey entries were received from July 4, 2020 to August 1, 2020 (See Figure 3). Of the 498 entries, 62 (12%) potential participants did not proceed past the informed consent. Fifty-six (11%) potential participants indicated they had questions following the review of the consent but did not call or email the student PI as instructed nor did they provide their contact information. Two did not pass the assessment for understanding the elements of the study following the informed consent and were directed via Qualtrics to contact the student PI for assistance. Neither contacted the student PI to discuss options for reentry into the study and therefore were not included. Lastly, four potential participants declined to participate in the study.

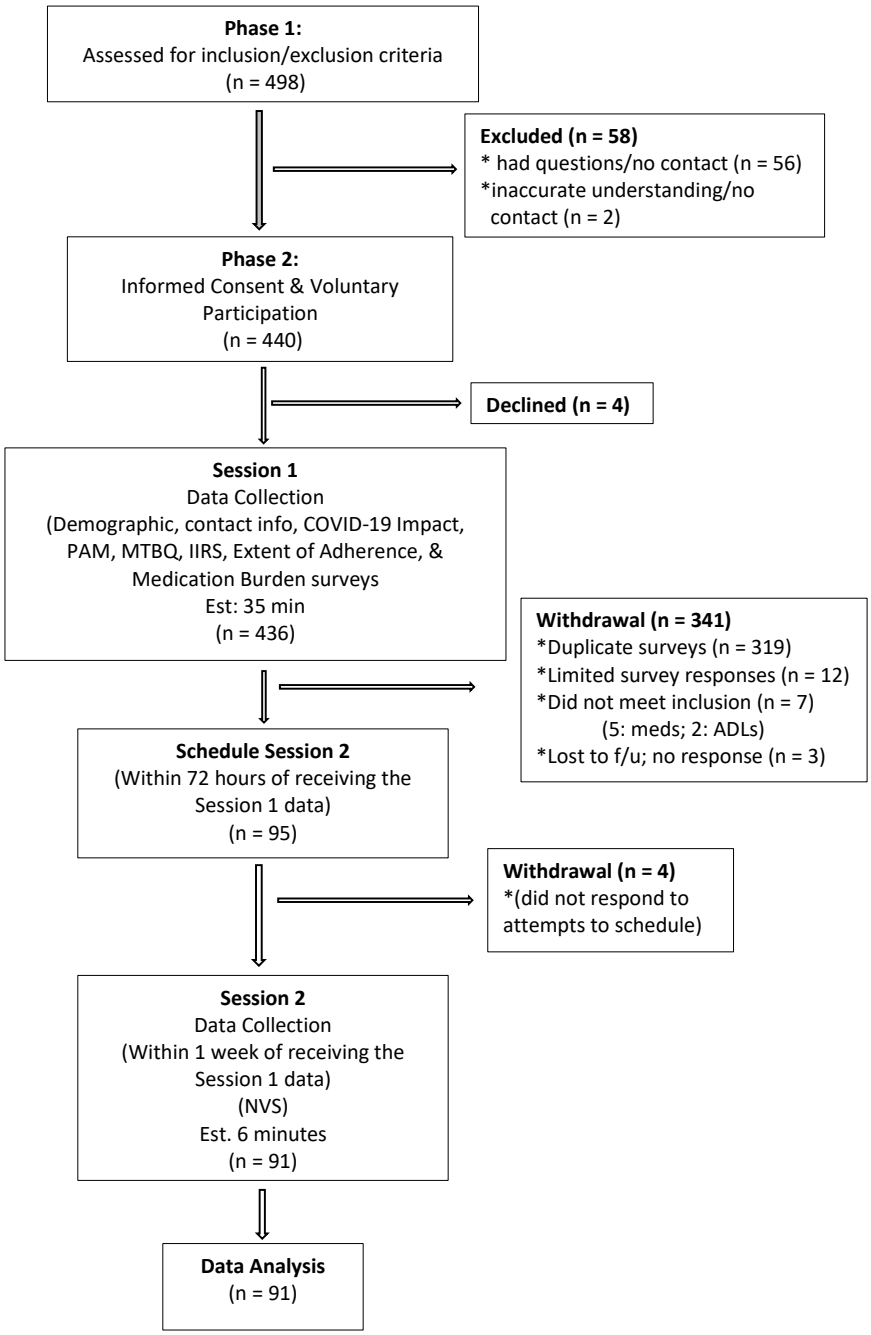
Although 436 consents were received, 319 were found to be duplicate survey entries and were removed. Duplications were identified by examining the individual survey responses and by examining the re-captcha and relevant ID duplicate scores provided by Qualtrics. Of the remaining 117 participants who provided informed consent, 12 did not complete their online surveys and did not provide contact information for follow up. Three participants did not complete their online surveys, and although contact information was provided, they did not respond to the student PI's attempts to reach them. Seven participants upon reassessment of eligibility criteria, were found to not meet the criteria and therefore were excluded; five participants indicated on the question that asked how many medications do they take for T2D and hypertension that they were not prescribed medications for both T2D and hypertension and two participants indicated that they were not able to independently carry out activities of daily living (i.e., eating, bathing, getting dressed, and toileting). Of the remaining 95 participants who completed the online surveys and proceeded to the scheduling of session two (i.e., telephone/Zoom interview), four were excluded for not returning emails or calls to schedule the session.

The final sample consisted of 91 African American adults with T2D and hypertension who completed both data collection sessions, meeting the required sample size indicated by the priori statistical power analysis (n = 84). The retention rate for this study, excluding the duplicate responses and potential participants who consented but did not qualify for the study, was 83% (91/110). More than half of the sample (51%) were recruited via a social media platform

(i.e., Facebook). The remainder of the sample were recruited via referrals from friends, relatives, and co-workers of the participants as indicated by the results of the survey question that assessed how participants found out about the study.

Figure 3

Flow Diagram for Dissertation Study



Data Cleaning

Upon acquiring completed survey sets from 91 participants, the data from the completed surveys were transferred from Qualtrics to SPSS and checked for accuracy. All study variables were analyzed for errors and missing values. Outlier values were assessed using frequencies, minimum, and maximum. Normality was also assessed by examining the variables for kurtosis or skewness.

The data were free from errors and excluding "do not apply" items, there were 13 missing responses. Specifically, nine responses were missing for HbA_{1c}. The remaining four responses were missing from two participants who did not provide a recent SBP and DBP. During their health literacy interviews, the 13 participants were asked to provide responses for the missing data (i.e., SBP, DBP, and/or HbA1c), however, the participants were unable to recall their levels. Therefore, pairwise deletion was the method used for managing the missing data for HbA_{1c}, SBP, and DBP. Pairwise deletion involves running the analyses on the data available for each case. The cases with missing data were not considered in the analyses for HbA_{1c}, SBP, and DBP. As these variables were not considered major variables in any of the correlation or regression analyses, this was an appropriate method for managing these missing variables. All data sets needed to answer the research questions in this study were complete.

All of the demographic and theoretical variables were skewed. Skewness was notable (i.e., skewness values greater than one or less than negative one) for age. The kurtosis measure for several variables (i.e., perceived difficulty in

managing medication workload, health literacy, medication adherence, and perceived difficulty in medication adherence) were also out of range. There was a total of 12 noteworthy outlier values for the major study variables. Outliers were identified by assessing the box plots for patient activation, health literacy, treatment burden, illness burden, medication adherence, total number of prescribed medications, total difficulty in managing medications, and COVID-19 impact scores. While there were 4 outlier values ranging from 27 through 36 for treatment burden, only one outlier (i.e., 36) was not within one standard deviation of the mean treatment burden score. Another four outliers ranging from 77 through 88 were found within the illness burden scores, all of which were outside of one standard deviation of the mean illness burden score. The remaining four outliers (i.e., four scores of 10) were from the COVID-19 impact scores, with the scores being more than two standard deviations below the mean COVID-19 impact scores. Shapiro-Wilk tests were conducted on the major study variables to determine whether the distributions of the variables were significantly different from a normal distribution. The results indicated that all of the variables significantly differed from normality based on an alpha of 0.05. Logarithmic, square root, and reciprocal transformations were conducted on these variables, but normal distribution was only achieved for illness burden ($W = 0.97$, $p = .066$). Therefore, non-parametric alternatives were used for the analyses, as appropriate.

Descriptive statistics (i.e., frequencies, percentages, measures of central tendency and variability) were used to summarize the demographic

characteristics of the sample, independent variables (i.e., patient activation, health literacy, treatment burden, and illness burden), outcome variable (i.e., medication adherence), and the exploratory variable (i.e., perceived impact of COVID-19 on medication management). The next section describes the characteristics of the study sample.

Description of the Sample

For the 91 African American adults with T2D and hypertension who participated in this study, ages ranged from 25 to 73 years (M = 39.6; SD = 11.9). The majority of the sample were male (n = 60; 66%), had a college degree (71%), were employed part-time (53%), had an income of $30,000 or more (66%), and were married (64%). Additionally, 89% of the sample reported having some form of health insurance, with the most prevalent being employer-sponsored (37%) and Medicare/Medicaid (33%). Most participants also reported having a primary health care provider (78%) and social support (80%).

For clinical characteristics of the sample, most reported having T2D and HTN for less than five years (respectively, 64% and 75%) and denied having additional health issues (79%). Most participants ($\geq$ 91%) were able to self-report their most recent HbA_{1c}, SBP, and DBP levels. The mean HbA_{1c} value was slightly above 7.0 % (7.4 %; SD = 1.8), indicating the potential for elevated risk of vascular complications among participants (American Diabetes Association [ADA], 2020). Though the mean reported SBP (139; SD = 18.7) and DBP (82; SD = 10.4) were below the general blood pressure target of 140/90 recommended by the ADA for individuals with T2D and low risk for

cardiovascular disease, the mean blood pressure in this study was above 130/80 which has been indicated as the BP target for individuals at higher risk for cardiovascular disease, such as AAs, who may require more intensive blood pressure control (ADA, 2019; Passarella et al., 2018; Saab et al., 2015; Whelton et al., 2018). See Table 1 for the full demographic characteristics of the sample.

Table 1

Characteristics of the Sample (N = 91)

Variables	*M (SD)*	Minimum	Maximum
Age (years)	39.6 (11.9)	25	73
Time Since Diabetes Dx (years)	4.3 (3.2)	1	18
Time Since Hypertension Dx (years)	4.4 (5.7)	1	47
HbA_{1c} (%) [a]	7.4 (1.8)	5.0	14.7
SBP (mmHg) [b]	139 (18.7)	100	187
DBP (mmHg) [c]	82 (10.4)	50	98
Variables	*n* (%)		
Sex			
Female	31 (34.1)		
Male	60 (65.9)		
Level of Education			
High school graduate	15 (16.5)		
Trade school graduate	11 (12.1)		
College: Undergraduate degree	30 (33.0)		
College: Graduate degree	35 (38.5)		
Employment Status			
Full-time	32 (35.2)		
Part-time	48 (52.7)		
Unemployed	5 (5.5)		
Retired	6 (6.6)		
Household Income			
< $30,000	31 (34.1)		
≥ $30,000	60 (65.9)		
Marital Status			
Single	17 (18.7)		
Married	58 (63.7)		
Separated	10 (11.0)		
Divorced	4 (4.4)		
Widowed	1 (1.1)		
Domestic Partnership	1 (1.1)		

[a] n = 82; [b] n = 89; [c] n = 89.

Table 1

Characteristics of the Sample Cont'd (N = 91)

Variables	n (%)
Other Health Issues	
Obesity	5 (5.5)
High cholesterol	4 (4.4)
Arthritis	4 (4.4)
Anxiety	3 (3.3)
Depression	3 (3.3)
Pain	2 (2.2)
Heart disease	2 (2.2)
Kidney disease	1 (1.1)
Gout	1 (1.1)
Allergies	1 (1.1)
Ulcers	1 (1.1)
Insurance status	
None	10 (11.0)
Private	16 (17.6)
Employer-sponsored	34 (37.4)
Medicare/Medicaid	30 (33.0)
Other (not described)	1 (1.1)
Primary healthcare provider	
Yes	71 (78.0)
No	20 (22.0)
Presence of social support	
Yes	73 (80.2)
No	18 (19.8)

Descriptive Statistics of Study Variables

The descriptive statistics for the major study variables (i.e., patient activation, health literacy, treatment burden, illness burden, medication adherence, total difficulty in managing medications, total number of prescribed medications, and perceived impact of COVID-19) are reported in Table 2. The Cronbach's alpha coefficients are also provided, as appropriate. The NVS was scored based on correct or incorrect responses, thus, Kuder-Richardson (KR) 20 is the recommended method for reliability testing for this measure. In SPSS, the

Cronbach's alpha is reported as providing the same result as the KR 20 value. All coefficient alphas were above .75, indicating adequate internal consistency reliability of all scales.

Table 2

Descriptive Statistics for Major Study Variables (N = 91)

Variables	*M (SD)*	Observed Min - Max	Possible Min - Max	α
Patient activation	78 (13.3)	54 - 100	0 – 100	.87
Health literacy	2.6 (2.0)	0 - 6	0 - 6	.81
Treatment burden	20.6 (14.7)	0 - 69	0 - 100	.87
Illness burden	46 (15.8)	13 - 88	13 - 91	.91
Total # of prescribed medications	4 (1.3)	2 - 8	≥ 2	-
Medication adherence (overall)	2.4 (0.9)	1 - 4	1 - 5	.78
Total perceived difficulty in managing medications	10.5 (6.8)	0 - 29	0 - 42	.92
Perceived COVID-19 impact	30 (8.8)	10 - 44	10 - 50	.89

Patient Activation

The Patient Activation Measure ® has a possible score range of 0 - 100 and the mean score was 78 (*SD* = 13.3), indicating a high level of patient activation within the sample. Of the four patient activation levels, most participants' (63%) were categorized at level four, the highest level of patient activation (scores of 72.5 – 100), indicating they perceived themselves as being more proactive and engaged in recommended health behaviors. Table 3 reflects the distribution of patient activation levels in the sample.

Table 3

Participants Categorized by Patient Activation Levels (N = 91)

Patient activation levels	N	%
PA Level 1: Disengaged and overwhelmed (scores = 0 – 47)	0	0
PA Level 2: Becoming aware but still struggling (scores = 47.1 – 55.1)	2	2
PA Level 3: Taking control and gaining control (scores = 55.2 – 72.4)	32	35
PA Level 4: Maintaining behaviors and pushing further (scores = 72.5 – 100)	57	63

As reflected in Table 4, for the individual item responses, s*trongly agree* was the most frequently observed response, supporting the high patient activation mean score. The items with the highest prevalence of disagree and strongly disagree responses were patient activation items number eight (i.e., I understand my health problems and what causes them; 19%), number 12 (i.e., I can figure out solutions when new health problems arise; 18%), and number nine (i.e., I know what treatments are available for my health problems; 13%).

Table 4

Distribution of Patient Activation Measure® Responses (N = 91)

PAM® Questions	Level of Agreement				
	Strongly agree n(%)	Agree n(%)	Disagree n(%)	Strongly disagree n(%)	Not applicable n(%)
1. I am responsible for my health.	53(58)	38(42)	-	-	-
2. Taking an active role is the most important thing that affects my health.	57(63)	31(34)	3(3)	-	-
3. I can help prevent/reduce my health problems.	49(54)	38(42)	4(4)	-	-
4. I know what my prescribed medications do.	43(47)	40(44)	5(6)	3(3)	-
5. I know what I can handle and when I need to see the doctor.	44(48)	41(45)	6(7)	-	-
6. I can tell a doctor about my concerns without being prompted.	45(49)	40(44)	5(6)	1(1)	-
7. I can follow through on medical treatments at home.	44(48)	42(46)	5(6)	-	-
8. I understand my health problems and what causes them.	30(33)	44(48)	15(17)	2(2)	-
9. I know what treatments are available for my health problems.	26(29)	53(58)	11(12)	1(1)	-
10. I have maintained positive lifestyle changes.	34(37)	48(53)	8(9)	1(1)	-

Table 4

Distribution of Patient Activation Measure® Responses Cont'd (N = 91)

PAM® Questions	Level of Agreement				
	Strongly agree n(%)	Agree n(%)	Disagree n(%)	Strongly disagree n(%)	Not applicable n(%)
11. I know how to prevent health problems.	30(33)	53(58)	7(8)	1(1)	-
12. I can figure out solutions when new health problems arise.	24(26)	51(56)	15(17)	1(1)	-
13. I can maintain positive lifestyle changes even during stressful times.	42(46)	40(44)	8(9)	1(1)	-

Health Literacy

On average, participants completed the NVS measure by phone or web-based interview within the anticipated time frame of six minutes (*M* = 5.53 minutes, *SD* = 2.2). The possible score range for the NVS health literacy measure is 0 - 6.The mean score for health literacy was 2.6 (*SD* = 2.0), indicating low health literacy within the sample. Participants were grouped by literacy scores as level one (score = 0 - 1), level two (score = 2 - 3), or level three (score ≥ 4), with higher scores indicating higher levels of health literacy. Health literacy levels varied, but the most frequently observed level was a high likelihood of poor health literacy (40%), followed by a high likelihood of adequate health literacy (32%), then possibility of limited literacy (29%). Most participants answered questions one through four incorrectly, indicating low numeracy and document literacy. Conversely, most participants provided the correct answers to questions

five and six, indicating high prose literacy. Table 5 displays the frequencies and percentages of correct vs. incorrect responses for each of the six health literacy questions.

Table 5

Distribution of Newest Vital Sign (NVS) Responses (N = 91)

Health Literacy Questions	Correct n (%)
1. If you eat the entire container, how many calories will you eat?	18 (19.8%)
2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?	42 (46.2%)
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?	34 (37.4%)
4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?	29 (31.9%)
Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.	
5. Is it safe for you to eat this ice cream?	65 (71.4%)
6. Why not?	47 (51.7%)

Note: Items one through four assess document literacy and numeracy. Items five and six assess document literacy and prose literacy.

Treatment Burden

The Multimorbidity Treatment Burden Questionnaire has a possible score range of 0 – 100. The mean score for participants' treatment burden (M = 20.6, SD = 14.7) indicated a moderate level of perceived burden from treatment for this sample. Based on treatment burden scores, nine participants (10%) were found to have no burden (score = 0), 12 (13%) had low burden (score <10), 34 (37%) had medium burden (score 10 – 22), and 36 (40%) had high burden (score > 22). Most participants reported *no or little difficulty* in several aspects of their treatment. For example, monitoring medical conditions (n = 83, 91%), getting clear and up-to-date information about their condition (n = 82, 90%), collecting prescription medications (n =81, 89%), making recommended lifestyle changes (n = 73, 80%), and getting healthcare in the evenings or weekends (n = 71, 78%). Conversely, there were some activities that a number of participants found *quite difficult, very difficult, or extremely* difficult. For example, taking lots of medications (n = 46, 51%) and seeing lots of healthcare providers (n = 29, 32%), indicating a potentially heavy perceived medication burden for half of the participants and a provider burden for one-third of the participants. Frequencies and percentages of participants' responses to the treatment burden questions are presented in Table 6.

Table 6

Distribution of Multimorbidity Treatment Burden Questionnaire (MTBQ)

Responses (N = 91)

Variable	Level of Difficulty				
	Extremely difficult n(%)	Very difficult n(%)	Quite difficult n(%)	A little difficult n(%)	Not difficult/ Does not apply n(%)
1. Taking lots of meds	9(10.0)	10(11.0)	27(29.6)	23(25.0)	22(24.0)
2. Remember to take meds	-	4(4.4)	16(17.6)	29(31.9)	42(46.2)
3. Paying for meds	-	8(8.8)	14(15.4)	29(31.9)	40(44.0)
4. Collecting meds	-	-	10(11.0)	32(35.0)	49(53.8)
5. Monitoring medical conditions	1 (1.1)	2(2.2)	5(5.5)	29(31.9)	54(59.3)
6. Arranging appointments	-	1(1.1)	10(11.0)	38(41.8)	42(46.2)
7. Seeing lots of healthcare providers	5(5.5)	7(7.7)	17(18.7)	26(28.6)	36(39.6)
8. Attending appointments	1(1.1)	5(5.5)	14(15.4)	29(31.9)	42(46.2)
9. Getting healthcare in evenings/weekends	2(2.2)	4(4.4)	14(15.4)	23(25.3)	48(52.7)
10. Getting help from community services	2(2.2)	5(5.5)	11(12.0)	29(31.9)	44(48.4)
11. Getting clear/up-to-date info about condition	-	1(1.1)	8(8.8)	35(38.5)	47(51.6)
12. Making recommended lifestyle changes	3(3.3)	2(2.2)	13(14.3)	25(27.5)	48(52.7)
13. Having to rely on help from family and friends	1(1.1)	2(2.2)	15(16.5)	29(31.9)	44(48.4)

Illness Burden

Score on the Illness Intrusiveness Ratings Scale may range from 13 – 91. On average, total illness burden scores for this sample were moderate (*M* = 46, *SD* = 15.8), suggesting the existence of illness burden for participants, but not excessively high levels of burden (See Table 7). Participants reported the highest scores of illness intrusiveness (i.e., illness burden) in health (*M* = 5.2, *SD* = 1.6), diet (*M* = 4.7, *SD* = 1.6), and financial situation (*M* = 4.5, *SD* =1.9). The factors that were the least impacted by participants' illnesses were religious expression (*M* = 2.6, *SD* = 1.7) and social relationships (*M* = 2.9, *SD* = 1.6).

Table 7

Mean Scores for Illness Intrusiveness Ratings Scale (IIRS) Responses (N = 91)

Variables	*M*	*SD*	Observed Min - Max	Possible Min-Max
Perceived interference in:				
Health	5.23	1.59	1-7	1-7
Diet	4.69	1.60	1-7	1-7
Work	3.73	1.67	1-7	1-7
Active recreation	3.69	1.64	1-7	1-7
Passive recreation	3.29	1.78	1-7	1-7
Financial situation	4.47	1.86	1-7	1-7
Relationship w/ sig. other	2.98	1.83	1-7	1-7
Sex life	3.23	2.21	1-7	1-7
Family relationships	2.92	1.80	1-7	1-7

Table 7

Mean Scores for Illness Intrusiveness Ratings Scale (IIRS) Responses Cont'd (N = 91)

Variables	*M*	*SD*	Observed Min - Max	Possible Min-Max
Social relationships	2.88	1.64	1-7	1-7
Self-improvement	2.93	1.88	1-7	1-7
Religious expression	2.57	1.68	1-7	1-7
Community involvement	3.38	1.65	1-7	1-7
Total illness burden	45.99	15.84	13-88	13-91

Number of Prescribed Medications

As shown in Table 8, the total number of prescribed medications in this sample ranged from 2 - 8 (*M* = 4, *SD* = 1.3). The number of prescribed medications for diabetes and blood pressure ranged from 1-3 per medication type. Most participants reported taking two medications for diabetes (*n* = 53, 58%) and two medications for blood pressure (*n* = 48, 53%). Thirty-three (36%) participants reported taking medications for health issues other than diabetes or blood pressure, with one additional medication being the most frequently observed response.

Table 8

Distribution of Prescribed Medications (N = 91)

# of prescribed medications	Diabetes n(%)	Blood pressure n(%)	Other medications n(%)	Total n(%)
0	-	-	58(63.7)	-
1	27(29.7)	39(42.9)	16(17.6)	-
2	53(58.2)	48(52.7)	13(14.3)	13(14.3)
3	11(12.1)	4(4.4)	2(2.2)	19(20.9)
4	-	-	1(1.1)	28(30.8)
5	-	-	-	18(19.8)
6	-	-	1(1.1)	9(9.9)
7	-	-	-	3(3.3)
8	-	-	-	1(1.1)

Medication Adherence

The mean medication adherence score was 2.4 (*SD* = 0.9), indicating the potential for a lack of adherence within the sample. The possible range of scores was 1 – 5, with actual medication adherence average scores ranging from 1 – 4. Participants were grouped by average medication adherence scores as adherent (scores < 2) or non-adherent (scores ≥ 2). The majority of the sample (66%) were classified as non-adherent. For this measure, any participants who do not indicate the highest level of agreement (i.e., strongly agree) for questions one and two and the lowest level of agreement (i.e., strongly disagree) to the remaining four questions, are considered non-adherent.

Most participants *agreed or strongly agreed* to taking all of their diabetic (*n* = 64, 70%) and blood pressure (*n* = 68, 75%) medications over the prior 30 days. These responses aligned with the low level of agreement to questions which assessed whether they were “unable” to take all of their diabetes and hypertension medications. However, responses to whether they missed or skipped a dose, somewhat conflicted with the level of adherence questions. For example, 42 (46%) participants disagreed or strongly disagreed to missing or skipping any of their diabetic medications and only 46 (51%) participants *disagreed or strongly disagreed* to missing or skipping any of their blood pressure medications. This was a difference of 22 conflicting responses for both diabetes and blood pressure medication adherence. Table 9 displays the frequencies and percentages of responses to each of the six medication adherence questions.

Table 9

Distribution of Extent of Adherence Responses (N = 91)

Medication Adherence Questions	Level of Agreement				
Over the past 30 days:	Strongly agree n(%)	Agree n(%)	Neutral n(%)	Disagree n(%)	Strongly disagree n(%)
1. I took all of my diabetes medications.	19(20.9)	45(49.5)	15(16.5)	12(13.2)	-
2. I took all of my blood pressure medications.	24(26.4)	44(48.4)	8(8.8)	14(15.4)	1(1.1)
3. I missed or skipped a dose of my diabetes medications.	2(2.2)	31(34.1)	16(17.6)	20(22.0)	22(24.2)
4. I missed or skipped a dose of my blood pressure medications.	2(2.2)	22(24.2)	21(23.1)	21(23.1)	25(27.5)
5. I was unable to take all of my diabetes medications.	3(3.3)	20(22.0)	11(12.1)	34(37.4)	23(25.3)
6. I was unable to take all of my blood pressure medications.	3(3.3)	21(23.1)	11(12.1)	32(35.2)	24(26.4)

Perceived Difficulty in Managing Prescribed Medications

Total difficulty in managing medication scores were determined by aggregating the difficulty scores from participants' responses on the Medication Workload Survey (i.e., difficulty in attributes of the medication workload) and the Reasons for Non-adherence Scale within the Extent of Adherence Survey (i.e., barriers in medication adherence). The measure has a possible score range of 0 – 42. As reflected in Table 10, total scores for level of difficulty in managing medications ranged from 0 to 29, with a mean score of 10.4 (*SD* = 6.9). This

finding indicates that participants experienced some difficulty in overall medication management and further supports the presence of medication burden indicated by the treatment burden measure. Both instruments measured difficulty in different aspects of medication management on a three-point scale, with a maximum difficulty score of 2 for each of the 21 items. Additionally, as some of the medication difficulty questions from the workload survey did not apply to some participants, there are fewer responses noted for those questions.

Table 10

Mean Scores for Perceived Difficulty in Managing Prescribed Medications Scales (N = 91)

Variables	*M*	*SD*	Observed Min-Max	Possible Min - Max
Perceived difficulty in:				
Medication workload	5.8	4.2	0-22	0-26
Medication adherence	4.6	3.4	0-12	0-16
Managing medications (Total)	10.4	6.9	0-29	0-42

Medication Workload Difficulty

The mean medication workload difficulty score was 5.8 (*SD* = 4.2), indicating a low perceived difficulty in managing aspects of the medication workload (e.g., routes of administration, timing of medications, changes to medication regimen, etc.) among participants. Although overall workload difficulty was low, 83 participants (91%) reported some level of difficulty in managing certain aspects of their medication workload. As indicated by frequencies of *not hard*, the easiest aspects of participants' medication workloads, were opening

medication containers (*n* = 77, 85%), reading medication labels (*n* = 72, 79%), and understanding what prescribed medications are for (*n* = 72, 79%). The most difficult aspects of the medication workload, as indicated by higher frequencies of *very hard*, were paying for medications (*n* = 19, 21%), dealing with side effects (*n* = 12, 13%), and getting refills on time (*n* = 7, 8%). The sample responded equally with *not hard* and *a little hard* on how difficult it was to manage taking medications at inconvenient times (*n* = 43, 47%). Participants reported taking medications orally (*n* = 91,100%), topically (*n* = 5, 6%), via self-injection (*n* = 47, 52%), pump (*n* = 11,12%), and through other routes (*n* = 1,1%). Thirty-six participants (40%) reported some level of difficulty with administering their medications via the prescribed routes.

Sixty-two (68%) participants reported having to alter their blood pressure or diabetes medications based on blood pressure and glucose readings they obtain at home. Of these participants, about half indicated they experienced *difficulty* in checking their blood pressure and glucose levels at home and in figuring out how to adjust their dose based on the blood pressure and glucose readings. Of the 48 participants who indicated their healthcare provider made changes within the last 90 days to their medication regimens, 40% (*n* = 19) reported having difficulty with managing those medication changes. The distribution of responses to the questions that assessed difficulty in medication workload are displayed in Table 11.

Table 11

Distribution of Difficulty in Medication Workload Responses (N = 91)

Medication Workload Difficulty Questions	Levels of Difficulty		
	Not hard n(%)	A little hard n(%)	Very hard n(%)
1. Taking meds at different times [a]	30(46)	31(48)	4(6)
2. Administering meds via prescribed route(s)	55(60)	31(34)	5(6)
3. Checking blood pressure/glucose levels [b]	29(47)	31(50)	2(3)
4. Figuring out med doses [c]	30(48)	28(45)	4(7)
5. Managing med changes [d]	29 (60)	19(40)	-
6. Remembering to take meds	57(63)	31(34)	3(3)
7. Paying for meds	31(34)	41(45)	19(21)
8. Opening med containers	77(85)	13(14)	1(1)
9. Reading med containers	72(79)	17(19)	2(2)
10. Getting refills on time	35(38)	49(54)	7(8)
11. Taking meds at inconvenient times	43(47)	43(47)	5(6)
12. Understanding purpose of meds	72(79)	16(18)	3(3)
13. Dealing with side effects from meds	33(36)	46(51)	12(13)

[a] $n = 65$; [b] $n = 62$; [c] $n = 62$; [d] $n = 48$.

Difficulty in Medication Adherence

Overall, the sample reported relatively low perceived difficulty in managing barriers to medication adherence, with a mean difficulty score of 4.6 (*SD* = 3.4). However, the majority had some level of non-adherence attributed to the medication adherence barriers on the scale (*n* = 75, 82%). As displayed in Table 12, the most prevalent contributors to non-adherence were being busy (*n* = 52, 57%), cost (*n* = 51, 56%), and taking medications more than once a day (*n* = 48, 53%). Most participants reported that adherence to their medication regimens was not impacted by feeling too ill to take their medications (*n* = 60, 66%), feeling that they did not need their medications (*n* = 57, 63%), running out of medications (*n* = 54, 59%), or having a blood glucose or blood pressure that was too low to take their medications (*n* = 52, 57%) . Although 64% of participants reported some level of difficulty with side effects on the workload survey, for medication adherence, only 48% reported that side effects impacted their adherence.

A total of six participants shared comments on additional reasons for non-adherence. One participant reported they “ran out of money” and could not pay for their prescriptions. Another participant commented they were “too tired” to get up from bed once they realized they had forgotten to take their medications. Two participants indicated they overslept and were not able to take their medications at the scheduled times. Lastly, two participants reported that their travel plan conflicted with them taking their medications as scheduled. One of the two

participants reported forgetting to pack their medications in their luggage before departing.

Table 12

Distribution of Reasons for Medication Non-Adherence Responses (N = 91)

Reasons for Non-Adherence	Levels of Contribution		
In the past 7 days, how much did each situation contribute to you missing a dose of your diabetes or blood pressure medication?	Not at all n(%)	A little n(%)	A lot n(%)
1. I was busy	39(43)	42(46)	10(11)
2. They caused some side effects	47(52)	34(37)	10(11)
3. They cost a lot of money	40(44)	35(38)	16(18)
4. I felt I did not need them	57(63)	28(31)	6(6)
5. I had to take them > once a day	43(47)	30(33)	18(20)
6. I ran out of medication	54(59)	28(31)	9(10)
7. My blood pressure/glucose was too low	52(57)	31(34)	8(9)
8. I was feeling too ill to take them	60(66)	23(25)	8(9)

Impact of Coronavirus Disease 2019 on Medication Management

Participants were asked how much they believed the Coronavirus disease 2019 (COVID-19) impacted 10 aspects of their medication management. Participants' COVID-19 impact scores ranged from 10 – 44, with a mean score of 30 ($\pm$8.8), indicating that COVID-19 was perceived to have had a moderate impact on medication management activities. The items with the most prevalent

responses of *strongly agree* and *agree* to COVID-19's impact on medication management were worrying about leaving their homes to get medications, get supplies, or see their healthcare providers (*n* = 62, 68%), getting prescription refill orders from healthcare providers (*n* = 58, 64%), paying for medications (*n* =57, 63%), and getting help from others (*n* = 53, 58%). In contrast, the items with the least prevalent responses of *strongly agree* and *agree* to COVID-19's impact on medication management were checking their blood pressure and glucose levels (*n* = 22, 24%), remembering to take their medications (*n* = 23, 25%), and feelings of uncertainty regarding which medications they should or should not take (*n* = 23, 25%). See Table 13 for the frequencies of responses on the COVID-19 Impact survey.

Table 13

Distribution of COVID-19 Impact Survey Responses (N = 91)

COVID-19 Impact Scale	Level of Agreement				
	Strongly agree n(%)	Agree n(%)	Neither agree nor disagree n(%)	Disagree n(%)	Strongly disagree n(%)
1. Remembering meds	3(3)	20(22)	8(9)	35(38)	25(28)
2. Paying for meds	16(18)	41(45)	8(9)	15(16)	11(12)
3. Getting prescription orders	13(14)	45(50)	10(11)	11(12)	12(13)
4. Getting refills	7(8)	44(48)	10(11)	18(20)	12(13)
5. Talking with healthcare provider	8(9)	38(42)	11(12)	22(24)	12(13)
6. Getting help from others	9(10)	44(49)	11(12)	13(14)	14(15)

Table 13

Distribution of COVID-19 Impact Survey Responses (N = 91)

COVID-19 Impact Scale	Level of Agreement				
	Strongly agree n(%)	Agree n(%)	Neither agree nor disagree n(%)	Disagree n(%)	Strongly disagree n(%)
7. Getting supplies	7(8)	45(50)	10(11)	15(16)	14(15)
8. Checking blood pressure and glucose levels	1(1)	21(23)	8(9)	28(31)	33(36)
9. Uncertainty about which meds I should take	1(1)	22(24)	14(15)	30(33)	24(27)
10. Worry about leaving the house	20(22)	42(46)	9(10)	10(11)	10(11)

Relationships among Major Study Variables

Bivariate correlations between select demographic characteristics (i.e., age and level of education) and major study variables (i.e., patient activation, health literacy, treatment burden, illness burden, medication adherence, total number of prescribed medications, total difficulty in managing prescribed medications, and perceived COVID-19 impact on medication management) were examined. Due to the lack of normality among the study variables, a non-parametric correlation analysis was performed (i.e. Spearman's rho correlation). The variables met all assumptions for conducting Spearman's rho correlation analyses (i.e. levels of measurement, paired observations, and monotonic relationships).

Table 14 displays the Spearman's rho correlation coefficients. Both increasing age and higher level of education were associated with greater treatment burden and more difficulty with managing medications. Increasing age was also associated with lower levels of patient activation and taking more prescribed medications. Due to the assumptions for Spearman's rho correlation, age and education were the only demographic variables appropriate for inclusion in the correlation analyses.

As an exploratory measure, independent t-tests were performed to examine the major study variables for significant differences by participants' sex. Men reported significantly higher levels of illness burden (M = 48, SD = 15.3) than women (M = 41, SD =15.9; $t(89) = 2.056$, $p = .04$). Men also had significantly higher COVID-19 Impact scores $t(84) = 2.601$, $p = .01$, (M = 31, SD = 9.5) than women (M = 27, SD = 6.3; $t(84) = 2.601$, $p = .01$). There were no significant differences found between men and women for patient activation, health literacy, treatment burden, number of prescribed medications, total medication difficulty, or medication adherence.

The correlation analyses also revealed a significant, negative correlation between patient activation and health literacy. Patient activation was also negatively correlated with treatment burden and total difficulty in managing medications. The negative correlation between patient activation and medication adherence indicates that as patient activation goes up, the scores on the medication adherence measure decrease. Lower scores on the medication adherence measure indicates better medication adherence. The variables

significantly associated with medication adherence were treatment burden, patient activation, total difficulty in managing medications, and COVID-19 impact.

Table 14

Spearman's rho Correlation Coefficients among Study Variables (N = 91)

Variables	1	2	3	4	5	6	7	8	9	10
1. Age	-									
2. Education	-.07	-								
3. Patient Activation	-.33**	-.01	-							
4. Health Literacy	.09	.02	-.22*	-						
5. Treatment Burden	.24*	.22*	-.31**	.08	-					
6. Illness Burden	-.17	.17	.07	-.29**	.18	-				
7. Medication Adherence	.03	-.05	-.39**	.21	.24*	-.10	-			
8. Total # of prescribed medications	.22*	-.04	.07	-.04	.14	.25*	-.02	-		
9. Total difficulty in managing medications	.24*	.21*	-.48**	.09	.69**	.20	.35**	.29**	-	
10. COVID-19 Impact	-.12	.15	-.16	.12	.45**	.01	.22*	.16	.56**	-

Note. *$p < .05$. **$p < .01$.

Data Analyses for Research Questions

Research Question 1: Are higher levels of illness burden associated with lower levels of patient activation and health literacy?

To answer research question one, results from the Spearman's correlation analyses (Table 14) were examined to determine the correlations between (1) illness burden and patient activation and (2) illness burden and health literacy. Cohen's standard was used to evaluate the strength of the relationships, where coefficients between .10 and .29 represent a small effect size, coefficients between .30 and .49 represent a moderate effect size, and coefficients above .50 indicate a large effect size. A significant negative correlation was observed between illness burden and health literacy (r_s = -0.29, p = .005), indicating that as illness burden increases, health literacy decreases. No significant correlation was found between illness burden and patient activation.

Research Question 2: Are higher levels of treatment burden associated with a higher number of prescribed medications and greater perceived difficulty in managing prescribed medications?

To answer research question two, Spearman's rho correlation coefficients (Table 14) were examined to determine the associations between treatment burden and (1) number of prescribed medications and (2) total perceived difficulty in managing prescribed medications scores. A significant positive correlation was observed between treatment burden and perceived difficulty in managing medications (r_s = 0.69, p = .000) indicating as treatment burden increases, perceived difficulty in managing medications also increases. The correlation coefficient of 0.69 indicated a large effect size. No significant correlation was found between treatment burden and number of prescribed medications.

Research Question 3: Do patient activation, health literacy, treatment burden, and illness burden significantly predict medication adherence?

To answer research question three, a hierarchical regression analysis was conducted to test the model consisting of patient activation, health literacy, treatment burden, and illness burden in predicting the variance in medication adherence. The order of entry for the variables was based on existing literature on the concepts. Several assumptions for this statistical analysis were confirmed. All predictor variables and the dependent variable were measured at the interval level. The demographic variables included in the model as covariates were age, sex, income, and education. Although age and education were the only demographic variables appropriate for inclusion in the correlation analyses, sex and income were identified in previous literature as potential confounding influencers on the major study variables. As such, the regression analyses conducted in this study adjusted for these potential covariates as well. Age was measured as a continuous variable. Sex and income were categorical variables with each having two categories (i.e., $30,000 or ≥ $30,000, male or female). Each category for the two variables were designated scores of 0 and 1, respectively. Education was measured as an ordinal variable. As such, dummy coding was used for each of the education levels assessed, excluding the reference category (i.e., high school or lower). A sample size of 91 was determined to be adequate based on the priori analysis performed. Adequate variance of the predictor variables was determined by examining the descriptive statics. There were no predictor variables that had the same values for all

participants. All Variance Inflation Factor values were < 10 and all Tolerance statistics were > .2, indicating that none of the predictor variables were excessively correlated with each other and that the assumption of multicollinearity was met. Examination of residual and scatter plots indicated the assumptions of normally distributed errors, linearity, and homoscedasticity were satisfied. Results of the Durbin-Watson test indicated that the assumption of independent errors was met, as the value of 1.5 is an acceptable value for indicating non-autocorrelation. Lastly, Cook's distances were examined. All values were found to be less than one, indicating that none of the observations for the predictor variables appeared to have excessive influence on the regression line.

A five-step hierarchical linear regression was conducted with medication adherence as the dependent variable. For step one, age, income, education, and sex were entered as predictor variables into the null model. This was done to control for their potential confounding impact. Patient activation was added as the first predictor variable in the model at step two. Health literacy was added into the model at step three, treatment burden was added at step four, and illness burden at step five.

As reflected in Table 15, the results of the hierarchical regression analysis indicated that the full model (i.e., Model 5) that included all of the independent variables was significant in predicting medication adherence [$F(10, 90) = 3.11$, $p = .002$)], accounting for 19% of the variance. Although model 4 explained more variance in medication adherence (19.6%) than model 5 (19%), model 5 is being

highlighted because this study sought out to follow the cumulative complexity model and determine if the model with all four predictor variables would significantly predict medication adherence. However, of the four predictors, only patient activation was a significant individual contributor in predicting medication adherence as indicated by a t-statistic of -3.73 (p = .000). Additionally, interpretation of the unstandardized beta coefficient indicated that for each one-point increase in patient activation, medication non-adherence decreases by .03 (*SE* = .008; 95% CI: -.047, .014). These results indicate that while patient activation is a significant predictor of medication adherence, adding the other variables (i.e., health literacy, treatment burden, and illness burden) to the model only provided a minimal change (i.e., highest amount of change in adjusted R^2 after model 2 was $\leq$.023) in helping to explain the variance in medication adherence. Additionally, the demographic variables (i.e., age, income, education, and sex), did not have a significant contribution in explaining medication adherence.

Table 15

Results of Hierarchical Regression Analysis Predicting Medication Adherence in African American adults with T2D and Hypertension (N = 91)

	B	*SE B*	β	*T*	R^2	Adj. R^2	R^2 Δ	*F*
Model 1					.027	-.042	.027	.392
Sex	-.344	.245	-.168	-1.404				
Income	.011	.226	.005	.048				
Age	-.003	.010	-.039	-.334				
Grad	-.084	.315	-.042	-.266				
Undergrad	-.082	.321	-.039	-.254				
Trade	-.028	.401	-.009	-.069				
Model 2					.236	.172	.209	3.665**
Sex	-.315	.219	-.153	-1.440				
Income	.211	.206	.103	1.023				
Age	-.015	.009	-.177	-1.637				
Grad	-.288	.284	-.144	-1.014				
Undergrad	-.408	.294	-.197	-1.389				
Trade	-.317	.363	-.106	-.874				
Patient Activation	-.037	.008	-.495	-4.764***				
Model 3					.254	.181	.017	3.481**
Sex	-.286	.218	-.139	-1.310				
Income	.261	.208	.127	1.255				
Age	-.014	.009	-.175	-1.621				
Grad	-.284	.282	-.142	-1.006				
Undergrad	-.439	.293	-.212	-1.498				
Trade	-.272	.362	-.091	-.751				
Patient Activation	-.035	.008	-.470	-4.479***				
Health Literacy	.068	.049	.140	1.383				

Table 15

Results of Hierarchical Regression Analysis Predicting Medication Adherence in African American adults with T2D and Hypertension Cont'd (N = 91)

	B	*SE B*	β	*T*	R^2	Adj. R^2	R^2 Δ	*F*
Model 4					.276	.196	.023	3.436**
Sex	-.258	.217	-.126	-1.188				
Income	.321	.209	.156	1.532				
Age	-.015	.009	-.185	-1.731				
Grad	-.368	.285	-.184	-1.292				
Undergrad	-.500	.293	-.241	-1.707				
Trade	-.236	.360	-.079	-.656				
Patient Activation	-.032	.008	-.429	-4.008***				
Health Literacy	.077	.049	.159	1.582				
Treatment Burden	.011	.007	.166	1.597				
Model 5					.280	.190	.004	3.111**
Sex	-.249	.218	-.121	-1.139				
Income	.306	.211	.149	1.449				
Age	-.017	.009	-.202	-1.827				
Grad	-.345	.288	-.173	-1.200				
Undergrad	-.478	.296	-.231	-1.615				
Trade	-.177	.373	-.059	-.474				
Patient Activation	-.031	.008	-.413	-3.736***				
Health Literacy	.068	.051	.141	1.335				
Treatment Burden	.012	.007	.185	1.705				
Illness Burden	-.005	.007	-.074	-.642				

Note. $^{**}p < .01$. $^{***}p < .001$.

Research Question 4: Which aspects of medication management are the most challenging?

To answer research question four, the responses from the Medication Workload Survey and the Reasons for Non-Adherence Scale from the Extent of Adherence Survey were examined. The five most challenging aspects of medication management, listed in order of most challenging to least challenging were (1) paying for medications, (2) dealing with side effects, (3) getting refills on time, (4) managing medication schedules (i.e., preventing a busy schedule from interfering with medication adherence, taking medications at different and/or inconvenient times), and (5) managing medication dosing (i.e., taking a prescribed medication more than once a day and figuring out medication doses).

Research Question 5: What is the perceived impact of the COVID-19 pandemic on medication management?

To answer research question five, responses to the COVID-19 Impact Survey were examined. From greatest to least perceived impact, participants reported the following impact of COVID-19 on medication management: (1) worrying about leaving their homes (68%), (2) getting refill orders from their healthcare providers (64%), (3) paying for medications (63%), (4) getting help from others (59%), (5) getting supplies (58%), (6) getting refills from the pharmacy (56%), (7) talking with their healthcare provider about their medications (51%), (8) being uncertain about what medications they should or should not take (25%), (9) remembering to take their medications (25%), and (10) checking their blood pressure or blood glucose levels (24%).

Eight participants shared additional details about how COVID-19 impacted situations relating to their diabetes and hypertension. Four participants described how COVID-19 impacted their income sources, making it more difficult to pay for medications and supplies. One participant also described how they had to rely more on the financial support from family and friends. Two participants described how COVID-19 impacted their daily routines. One described how working from home, due to COVID-19 public health concerns, created additional difficulty in remembering to take medications as scheduled. The participant described how physically going into work created a daily structure for them, helping them with remembering to take their medications. The other reported that the restrictions relating to COVID-19 public health concerns impacted their ability to continue with their normal exercise routine at the gym. Another participant described how they are consistently worried about their potential for becoming ill from COVID-19. Lastly, a participant described how they had recently suffered from a stroke and during their hospital admission discovered that they were positive for COVID-19. During their admission, their healthcare provider prescribed a medication for management of their diabetes. The medication was one that the participant had previously taken and one that created unpleasant side effects. The participant reported that they decided to take the medication, however, they reduced the daily dosage of the medication in hopes that it would reduce the side effects from the medication.

Summary

In this study of young to older African American adults with Type 2 diabetes and hypertension, most were male, college graduates, employed part-time, and had health insurance and a primary care provider. The time since diagnosis of diabetes and hypertension averaged four years each and most were able to provide their recent HbA_{1c}, SBP, and DBP levels. All of the scales used to measure the major study variables in this study demonstrated adequate internal consistency reliability, with Cronbach's alpha coefficients of >.70.

On average, participants had high levels of patient activation. Their health literacy scores were somewhat split over the three health literacy categories, but the highest prevalence indicated a high likelihood of poor health literacy. The mean number of medications taken by participants was four, with a range of two to seven prescribed medications. The overall treatment burden was low; however, the medication burden aspect of the treatment burden scale was high for about one-third of the sample. Illness burden was moderate, with the highest impacts reported for health, diet, and financial status. The majority of the sample was found to be non-adherent to their medication regimen based on adherence scores ≥ 2, although the majority responded with some level of agreeance to taking all of their diabetic and blood pressure medications over the prior 30 days.

The major demographic variable of interest was participant age, and increasing age was significantly associated with lower patient activation and greater treatment burden, greater number of prescribed medications, and increased difficulty in managing medications.

Five research questions were answered in this study. Illness burden was significantly associated with health literacy but not with patient activation, while treatment burden was significantly associated with perceived difficulty in managing medications but not with the number of medications prescribed. The results of the hierarchical regression analysis revealed that the model explained 19% of the variance with patient activation being the only predictor variable significantly explaining the variance in medication adherence. The participants' total perceived difficulty in managing prescribed medications on average was low. The aspects of medication management that participants found the most challenging were paying for medications, dealing with side effects, getting refills on time, managing medication schedules, and managing medication dosing. The mean COVID-19 impact score indicated a moderate perceived impact among participants. Most participants reported that paying for medications, getting refill orders, getting medications from the pharmacy, and getting supplies were harder to do than they were prior to the rise of the COVID-19 pandemic in March 2020. Additionally, participants shared how the changes from the COVID-19 pandemic created disruptions in their routines, making it more difficult to remember to take their medications.

CHAPTER V

DISCUSSION AND CONCLUSIONS

The purpose of this non-experimental, predictive correlational study was to examine relationships among disease self-management capacity, patient burden, and medication adherence in African American adults with T2D and hypertension. This study also explored the perceived impact of the COVID-19 pandemic on the management of medications. This chapter provides a discussion of the study findings, study limitations, and strengths. The implications for practice and recommendations for future research are also described followed by the conclusion.

Recruitment and Characteristics of the Sample

Targeted advertising facilitated recruitment efforts for this study. Approximately half of the participants (n = 46) were recruited from a social media platform (i.e., Facebook). Potentially more people being at home due to the COVID-19 pandemic and greater accessibility and use of computers and cell phones may have also contributed to the successful online recruitment rates. In general, this sample was composed of mostly college-educated, males. Social media may also explain why the sample was composed of more college-educated and younger participants than anticipated.

Based on the employment-to-population ratio for males aged 25 – 54 (81.5%) in comparison to females in the same age group (68.7%), the U.S.

workforce has a greater representation of males (U.S. Department of Labor., 2020). Thus, the greater number of male participants in this study may be due to a greater prevalence of increased availability during the pandemic (e.g., COVID-19 related employment challenges). Furthermore, the use of social media vs. traditional recruitment settings (e.g., clinics or doctor's offices) may have provided greater opportunity to recruit AA males in this study, as AA males have been found to be less likely than AA females to have a usual source of healthcare (Stewart et al., 2019).

Most participants (≥91%) were able to self-report their most recent HbA_{1c}, SBP, and DBP levels, which may be explained by participants being mostly young and college educated. Average HbA_{1c} readings (*M* = 7.4%) were above recommended levels (CDC, 2018e). Though the mean SBP (139; *SD* = 18.7) and DBP (82; *SD* = 10.4) were below the general blood pressure target of 140/90 recommended by the American Diabetes Association (ADA) for individuals with T2D and that have lower risks for cardiovascular disease, the mean blood pressure in this study was above 130/80 (ADA, 2020). A target BP goal of < 130/80 has been suggested as a more favorable BP target for individuals at higher risk for cardiovascular disease, such as AAs, who may require more intensive blood pressure control (ADA, 2020; Passarella et al., 2018; Saab et al., 2015; Whelton et al., 2018). These findings support the presence of blood pressure levels and T2D that may lead to an increased risk for cardiovascular and neurological complications among these participants (AHA, 2015; CDC, 2018b; NIDDK, 2017; Petrie et al., 2018).

Few participants reported having additional health issues other than T2D and hypertension. This may be due to the sample's low average for years since diagnosis of T2D (*M* = 4.3) and hypertension (*M* = 4.4) and low mean age (39.6). The mean age in this study is lower than what was found in similar studies that included AAs with T2D and/or hypertension (Rogers et al., 2017; Skolasky et al., 2011; Ylitalo et al., 2018). This mean age supports the previous research indicating that AAs tend to develop these diseases at earlier ages than other racial or ethnic groups, and as a result experience cardiovascular diseases, stroke and other complications at earlier ages.

Of the participants (n = 19) that reported additional health issues (n = 19), obesity (*n* = 5), high cholesterol (*n* = 4), and arthritis (*n* = 4) were the most frequently identified. These additional health issues are in line with previous studies, as Lin et. al (2015) found that obesity, hyperlipidemia, and arthritis were some of the most common components of the multiple morbidity clusters for individuals with T2D and hypertension. However, in a sample of adults with both T2D and hypertension, it was anticipated that there would be higher rates of obesity. The low rates of obesity in this sample may be related to underreporting. Participants may not be fully aware of their body mass index levels or perceive themselves to be "obese", and as such, may not have reported this health issue. A previous study also found that participant report of obesity was low, as only 22.2% of obese women and 6.7% of obese men were able to correctly classify themselves as obese (Truesdale & Stevens, 2008). Future studies should include

inquiries of waist circumference or waist-to-hip ratio to help with determining rates of obesity.

Illness Burden, Heath Literacy, and Patient Activation

Illness burden was significantly associated with health literacy but not with patient activation; the higher the illness burden, the lower the level of health literacy. As illness burden has been described as being a barrier to performance of DSM activities in previous studies, findings in this study suggest that challenges created by illness burdens may be offset by greater health literacy (Eton et al., 2012; Gore et al., 2006). Additionally, Boehmer, Shippee, et al. (2016) found that greater illness burden related to diminished mental capacity. This further supports the link between health literacy and illness burden and emphasizes the importance of providing additional health literacy support to AA with co-morbid T2D and hypertension.

Previous studies also reported that increased illness burden related to diminished ability to perform activities of daily living, decreased productivity, and less self-efficacy (Boehmer, Shippee, et al., 2016; Gore et al., 2006). As these are functions similar to those measured in this study with patient activation, it was anticipated that higher illness burdens would be related to lower patient activation. This was not found and may indicate that individuals who have greater patient activation, but not adequate health literacy, may not have the same ability to overcome challenges from the illness burden they experience.

Treatment Burden and Medication Workload

While increased treatment burden related to greater perceived difficulty in managing medications (r_s = 0.69, p = .000), no association was found between treatment burden and number of prescribed medications. These findings indicated that while individuals perceived increases in their treatment burden and greater difficulty in managing medications, the number of medications they reported taking did not largely factor into their overall perceived treatment burden. Additionally, as a high level of patient activation was found in this study and patient activation was significantly associated with treatment burden, it is possible that greater activation eased the impact from taking a greater number of medications in overall treatment burden.

Although no association was found between number of medications and treatment burden, taking more medications was associated with greater difficulty in managing medications. As a high level of medication burden was found for some participants in this study, the association between number of medications and difficulty in medication management implies that individuals taking multiple medications may need more guidance on managing their medication workload.

Application of the Adapted Cumulative Complexity Model in Predicting Medication Adherence

As proposed by the adapted CCM, the regression model that included all of the independent variables (i.e., patient activation, health literacy, treatment burden and illness burden) was significant in predicting medication adherence; explaining 19% of the variance. However, only patient activation provided a

significant individual contribution in predicting medication adherence. This finding suggests that individuals who perceived themselves as more capable in managing their DSM workloads (i.e., higher patient activation) also perceived that they were more adherent to their prescribed medication regimens (i.e., had lower scores on the Extent of Adherence Survey). Skolasky et al. (2011) also found in their cross-sectional study of 855 multimorbid participants (46% AA) that higher patient activation related to improved medication adherence.

Based on the available literature, it was anticipated that health literacy would also provide a significant contribution in predicting medication adherence. Al Sayah et al. (2015) found that a health literacy item that measured difficulty understanding written information was significantly associated with worse medication adherence (Al Sayah et al., 2015). Additionally, Ylitalo et al. (2018) examined health literacy using the Newest Vital Sign (NVS) among 406 patients (39% had diabetes; 41% non-Hispanic Blacks) and found attending scheduled medical appointments was significantly lower for patients with limited health literacy as compared with individuals with adequate health literacy. Although attending office visit appointments is a different activity than adhering to medication, the study provided support that health literacy is linked with performance of disease management activities. A different study (Bains et al., 2011) reported that they did not find associations between health literacy and medication adherence, however, the lack of association in that study was thought to be due to that study not using a tool such as the NVS that measures numeracy and reading comprehension.

The lack of contribution from health literacy in the regression model may be related to response bias of participants. While health literacy examined actual ability to solve numerical problems and make decisions based on written information, the medication adherence tool captured participants perceived level of adherence. Essentially, participants may have overestimated their adherence to their medication regimens. Additionally, it is possible that by modifying the medication adherence tool to capture adherence over the prior 30 days, instead of the original 7 days, may have created challenges for participants to accurately recall their adherence.

Patient burden (i.e. illness burden and treatment burden) also did not significantly contribute to explaining the variance in medication adherence. This finding suggests that while individuals who demonstrate poor adherence may also be experiencing higher levels of treatment burden, other factors or relationships should be considered in explaining adherence to their medication regimen. Possibly, focusing more on the burden of their medication workloads rather than their entire disease-related burden may be beneficial.

Additionally, although burden was not significant in the model, in bivariate correlation analysis, greater treatment burden was significantly associated with poorer medication adherence, but not illness burden. Individuals who believed their prescribed treatments were less burdensome (i.e., lower treatment burden scores) perceived themselves as being more adherent to their medication regimens. Rogers et al. (2017) also found significant associations between treatment burden and medication adherence. The negative bivariate correlation

observed between patient activation and treatment burden provides further support for the CCM, as it posits that patient burdens (e.g., treatment burden) work against capacity factors (e.g., patient activation) in an individual's attempt to carrying out DSM activities. Therefore, by addressing an individual's burden, increases in patient activation may be observed leading to greater medication adherence.

Exploratory Findings

Two concepts examined in this study but were not included in the model explaining medication adherence were difficulty in managing medications and the impact of COVID-19 on managing medications. Examination of how attributes of individual medication workloads (e.g., level of perceived difficulty) provided additional insight into the workload demand of managing prescribed medications for AA adults with T2D and hypertension and highlighted situations that add to the complexity individuals encounter when attempting to meet the DSM workload demand of managing prescribed medications. Additionally, as this study considered factors that may create challenges in individual medication workloads, it was fitting to also incorporate an exploration of the potential impact of the COVID-19 pandemic on medication management.

Perceived Difficulty in Managing Medications

Overall, participants reported little perceived difficulty in their medication management (i.e., difficulty in managing prescribed medication workloads and overcoming potential barriers to medication adherence). However, 45% of participants had total perceived difficulty scores that exceeded the sample mean.

The challenges in medication management that participants generally perceived the most difficult related to managing medication costs, side effects, getting refills, taking medications at inconvenient times, and medication frequency (i.e., taking medications more than once a day). These findings are in line with previous studies that also found participants with T2D and/or hypertension had challenges in their medication management relating to the side effects they experienced, being confused about medication administration (e.g., timing of medication administration), managing multiple medications, and dealing with the interference in daily routines caused by managing medications (Bockwoldt et al., 2017; Eton et al., 2012; Rogers et al., 2017; Weller et al., 2017). Additionally, studies have examined how feelings of powerlessness and fear can hinder individuals from taking their medications as prescribed (Bockwoldt et al., 2017; Kennedy et al., 2008). Considering that dealing with side effects was one of the more challenging aspects of medication management for participants, it is very possible that the fear from experiencing side effects lead to inconsistencies in their medication management.

Managing prescribed medications require various skills. This complexity potentially created challenges for participants in meeting their medication workload demands (Brown & Bussell, 2011; Greene et al., 2015; Ylitalo et al., 2018). Of the participants in this study who had to self-monitor their blood pressure and glucose at home, 53% reported having some difficulty in self-monitoring their blood pressures and glucose levels (53%). Also, 52% of this same group reported difficulty in adjusting their medication dosing based on

those levels. In these situations, participants must use technical skills (i.e., operating blood pressure and glucose monitoring equipment, handling an insulin syringe), health literacy skills (e.g., reading and interpreting medication instructions), and problem-solving skills (e.g., what to do if they run out of medications, supplies, etc.). Individuals who have deficiencies in the skills needed to manage these tasks (i.e., deficient DSM capacity) likely have greater challenges in carrying out their medication workload activities and achieving their blood pressure and glucose goals.

Of the participants that had provider-initiated changes to their medication regimen, 40% of them reported difficulty in managing those changes. These findings indicate that participants also need skills in adapting to medication changes. Previous studies have found that diabetic patients who have elevated HbA_{1c} during a hospital admission are typically prescribed a more intense outpatient medication regimen, as compared to what they receive during hospitalization (Umpierrez et al., 2012). Griffith et al. (2012) also found that the most frequent changes in patients medication regimens were initiating a new insulin medication (44%), initiating a non-insulin medication, change from one insulin medication to another, and increasing medication dosages. These findings highlight the importance of assessing individual abilities in managing medications, providing clear instructions on managing changes to their medication regimens, and providing them with resources for managing their medication management challenges.

Perceived Impact of the COVID-19 Pandemic

The mean COVID-19 impact score indicated participants perceived a moderate impact on their medication management. Participants felt most strongly about COVID-19 impacting their abilities to get prescription refill orders from their healthcare providers, pay for medications, and receive help from others. Most participants also reported worrying more about leaving their homes to get medications and supplies and to see their healthcare providers. Considering that COVID-19 is life-threatening infectious disease, transmitted through contact with infected individuals, and has no specific vaccines or treatments, it is understandable that individuals would have concerns with performing activities that may increase their potential for contracting the illness (World Health Organization [WHO], 2020). In line with the impact on pay reported by participants, a review of U.S. unemployment reports indicated a dramatic rise, with rates increasing more than threefold from January 2020 to April 2020 (U.S. Bureau of Labor Statistics, 2020). The additional stress and concerns that come from the presence of the COVID-19 pandemic may have created additional challenges for individuals in performing their DSM activities (e.g., managing their medication workloads). The activities that the participants reported were least impacted by COVID-19 (i.e., monitoring blood pressure and glucose levels, remembering to take their medications, and having uncertainty regarding which medications they should or should not take), were activities that did not typically require them to leave their homes or interact with other individuals.

Furthermore, although only a small portion of the sample, 10% of participants indicated not believing they could maintain positive lifestyle changes during stressful times. Considering the current presence of the COVID-19 pandemic, these participants may have great difficulty in carrying out the DSM activities necessary for their T2D and hypertension. This concept is further supported by the results of the correlation analysis performed in this study which indicated that greater perceived impact from COVID-19 associated with greater treatment burden and poorer medication adherence. Although the COVID-19 impact was not included in the adapted CCM, this finding suggests the potential impact that the COVID-19 pandemic may have on the existing burden individuals with T2D and hypertension experience and on their abilities to carry out their DSM workload activities. Additionally, as the perceived COVID-19 impact as well as illness burden were found to be significantly greater for men as compared to women, this may indicate that men with T2D and hypertension may need greater support (e.g., emotional support, financial support) in managing their diseases including meeting their medication workload demands.

The Cumulative Complexity Model

The Cumulative Complexity Model (CCM) guided the selection of variables for examination of associations among DSM capacity (i.e., patient activation and health literacy), patient burden (i.e., treatment and illness burden), and a DSM outcome measure (i.e., perceived medication adherence) for AA adults with T2D and hypertension. The abilities individuals have in meeting the demands of their workload were examined with patient activation and health

literacy measures. The burdens that individuals experience in meeting their workload demands and the perceived level of disruption in aspects of day-to-day life attributed to their chronic diseases were measured with treatment burden and illness burden measures. Imbalances between medication workload and DSM capacity, specifically when capacity fails to meet the demands of the workload, individuals are more likely to have deficiencies in their disease management performance, such as poor medication adherence (Boehmer, Shippee, et al., 2016). As poor medication adherence may lead to poor health outcomes, greater illness and more burden of treatment is likely to ensue (Bodde et al., 2013; Shippee et al., 2012;). An explanation of the findings from the application of the CCM in this study are described next.

Disease Self-Management Capacity

Disease self-management capacity is an individual's ability to complete the activities involved in their individual disease workload (e.g., taking prescribed medications). Patient activation (i.e., an individual's perceived knowledge, motivation, and DSM skills relating to managing healthcare activities) and health literacy (i.e., the ability to obtain, process, and understand health and healthcare service information) were measures used to examine the disease self-management capacity of the participants in this study.

Patient Activation

Overall, mean patient activation (PA) scores were high (M = 78, SD = 13,3), with the majority (63%) of the sample categorized in the highest level of patient activation (level 4). Level 4 patient activation indicates that individuals

proactively engage in recommended disease self-management (DSM) behaviors, such as medication adherence (Greene et al., 2015). The mean patient activation scores were similar to those found in previous studies examining patient activation, with mean scores ranging from 66 – 80 in diverse samples, some of which included AAs and individuals with T2D (Fowles et al., 2009; Hibbard et al., 2008; Mayberry et al., 2010). The high level of patient activation reported in this study may be explained by the younger age of participants. This finding is supported by previous studies that found a correlation between lower patient activation scores and older age in diverse populations (Chubak et al., 2012; Gerber et al., 2011; Gleason et al., 2016; Hendricks & Rademakers, 2014). Essentially, participants may feel less confident in performing some of their DSM activities as they age.

Despite the high levels of PA, there were survey items for which participants generally reported lower levels of agreeance (e.g., understanding their health problems and what causes them, knowing what treatments were available for their health problems, figuring out solutions when new health problems arise). This suggests there are opportunities to enhance PA among AAs with T2D and hypertension. Several studies have reported differences in DSM behaviors and patient outcomes as PA scores change (Bolen et al., 2014; Fowles et al., 2009; Greene et al., 2015; Hibbard at al., 2008; Lubetkin et al., 2010; Mayberry et al., 2010; Skolasky et al., 2011). For example, individuals who had increases in PA scores have been found to have greater reductions in systolic blood pressure, body weight, and cholesterol (Bolen et al., 2014).

Health Literacy

In general, participants had low health literacy scores; 69% did not demonstrate a high likelihood of adequate health literacy (NVS scores <4). The mean NVS score of 2.6 was lower than scores in previous studies of AAs from diverse age groups, ranging from 3.2 to 3.7 (Huang et al., 2018; Miser et al., 2013; Weiss et al., 2005). The lower health literacy scores found in this study may be related to the low mean years for time since diagnoses of T2D (M_{years} = 4.3) and hypertension (M_{years} = 4.4). Although no studies could be found that examined associations between health literacy and the amount of time since diagnosis of any chronic disease, it is possible that the amount of time individuals have to adjust to DSM tasks plays a role in their development of health literacy skills.

The majority of incorrect responses in this study were for questions that assessed numeracy and document literacy. Numeracy and document literacy are essential components of the health literacy skills individuals with T2D and hypertension need to adequately carry out their DSM activities. For example, numeracy skills are needed when performing quantitative tasks (e.g., figuring out insulin dosage based on glucose levels or calculating carbohydrates) and document literacy skills are needed to search for and comprehend information presented in non-continuous text such as what may be found on medication or food labels (National Assessment of Adult Literacy [NAAL], n.d.). Although 71% (*n* = 65) of participants demonstrated prose literacy by correctly answering the prose-related question (i.e., Is it safe to eat the ice cream?), 48% (*n* = 44) were

not able to answer the corresponding question correctly (i.e., Why not?). This indicates that participants likely were unable to comprehend the information presented in the ingredients section (i.e., demonstrate document literacy skills) and instead, considered factors outside of the scenario (e.g., potential impact the ice cream may have on their glucose or blood pressure levels) to determine the appropriateness of consuming the food product. Although it is promising that the participants considered the impact of their choices on their health, failure to identify the rationale for their decisions leaves an opening for misinterpretation of instructions or lack of compliance in DSM activities. For example, a prescription may provide information on interactions with food or drug items and if participants are unable to comprehend this information, they may inadvertently create additional complications in their health. Individuals may also have instructions that direct them to take their medications with food. Inadequate interpretation of this information may lead individuals to decide that they should skip a medication dose because they did not eat, rather than eating so they can take their medications.

Overall, the sample had insufficient disease self-management capacity in regard to patient activation and health literacy. Although patient activation scores were high, there was area for improvement, and average health literacy scores were less than adequate. Inadequate health literacy has been found to associate with less disease-related knowledge, greater risk of misinterpreting prescription instructions, and worse medication adherence (Al Sayah et al., 2015; Davis et al., 2009). Interventions are needed to improve knowledge and critical thinking skills

for individuals with T2D and hypertension, particularly those with inadequate health literacy. Adequate health literacy and having a good understanding of health problems, prevention measures, and problem-solving are essential components to DSM. Interventions that enhance these components may further support efforts in reducing health complications associated with the presence of T2D and hypertension.

This study also examined the relationship between patient activation levels and health literacy. As these variables were measures of DSM capacity, with higher scores indicating greater capacity, and based on previous research (Gwynn et al., 2016; Lubetkin et al., 2010; Mitchell et al., 2014; Sheikh et al., 2016) it was anticipated that they would be positively associated. In contrast with previous studies, patient activation and health literacy had a negative correlation in this study. This unanticipated finding may be related to the use of a different health literacy measure in this study (i.e., NVS) than what was used in the previous studies (i.e., Rapid Estimate of Adult Literacy in Medicine and the Short Test of Functional Health Literacy in Adults). The major difference between the NVS and the Rapid Estimate of Adult Literacy in Medicine (REALM) is that the latter does not incorporate measures of numeracy (Dumenci et al., 2013). While the Short Test of Functional Health Literacy in Adults (S-TOFLA) indicates that numeracy is examined, a previous study found that there were limitations in the S-TOFLA identifying individuals with poor numeracy as compared to other tools (Housten et al., 2018). This suggests that other measures of health literacy should be explored when examining DSM capacity in this population.

Patient Burden

Disease self-management capacity can be impacted by the burden that patients experience. In this study, burden was measured in respect to participants' treatment burden and illness burden. Research has demonstrated that while having high levels of patient activation is beneficial, if high levels of burden are also present, individuals may have considerable challenges in managing their medication workloads (Boehmer, Shippee, et al., 2016).

Treatment Burden

There was a moderate level of perceived treatment burden among participants; 40% had scores above 22, indicating a high level of treatment burden. The item response with the highest burden score was "taking lots of medications". This was similar to previous studies (Eton et al., 2012; Gallacher et al., 2018; Rogers et al., 2017), that found one of the most substantial aspects of greater treatment burden is taking multiple medications. The mean number of medications taken by participants in this study was 4 with a range from 2-8; half reported taking two medications for T2D and two for hypertension.

The number of prescribed medications reported in this study was not associated with medication adherence. However, a previous study by Davis et al. (2006), found that misunderstanding prescription instructions was more likely to occur for individuals taking three or four prescription medications. As misinterpretation of prescriptions may lead to poorer adherence, individual's perceived difficulty in managing their number of medications should be considered. Greater treatment burden was found to associate with greater

difficulty in medication management and worse medication adherence. These findings suggest that higher perceived treatment burden may impact DSM productivity (e.g. medication adherence), warranting the need to incorporate measures to reduce this burden when possible for patients (Rogers et al., 2017).

Illness Burden

Overall, the perceived illness burden in this sample was moderate and comparable with other studies that examined illness burden in samples of primarily White individuals with chronic disease (Boehmer, Shippee, et al., 2016; Molzon et al., 2013). The highest levels of illness burden reported were for health, diet, and finances, indicating a greater perceived disruption in these aspects of the participants' lives related to their diseases. This is not surprising as patients with two major chronic diseases, such as T2D and hypertension may perceive their overall health poorer than others and have dietary restrictions (e.g. reduced carbohydrate and sodium). Previous studies have reported that illness burden arises from the presence of more than one chronic disease and the symptoms that coincide with those comorbidities (Adriaanse et al., 2016; Aga et al., 2019; Boehmer, Shippee, et al., 2016; Gebregziabher et al., 2018; Lin et al., 2015; Payne et al., 2013; Tonelli et al., 2015). Illness burden was potentially intensified for some participants in this study, as 21% reported having a health issue other than T2D and hypertension.

Additionally, the higher reports for intrusiveness in finances were likely related to the associated costs of living with these diseases (e.g., paying for multiple medications). Furthermore, the ADA (2018b) described how individuals

with greater illness burden may be financially impacted, as they may have challenges in acquiring or maintaining employment due to their disease-related complications. The majority of participants in this study reported being employed part-time (n = 48; 53%); this underemployment further supports the presence of financial challenges for participants.

Religious expression and social relationships were the least impacted factors in illness burden. Although no previous studies were found that examined the impact of these concepts on illness burden in AAs with chronic disease, these factors may serve as buffers to illness burden and warrant additional exploration.

While illness burden did not associate with medication adherence, greater illness burden was found to associate with a higher number of prescribed medications. This is similar to the findings reported by Rogers et al. (2017) that greater illness burden associates with greater medication burden. Overall burden among participants in this study was moderate. Identifying strategies to reduce the burdens of living with co-morbid T2D and hypertension may improve DSM and patient outcomes.

Disease Self-Management: Medication Adherence

The primary outcome for this study of disease self-management was medication adherence. On average, medication adherence scores were above two, indicating the presence of medication non-adherence among participants. Based on the medication adherence grouping, 66% of participants were classified as not adhering to their medication regimens. The level of non-

adherence found in this study falls within the range of non-adherence (15% - 85%) reported by previous studies that examined medication adherence among AAs with T2D (Al Sayah et al., 2015; Weller et al., 2017) and in diverse samples (Aitken et al., 2019; Brown & Bussell, 2011). Non-adherence to medication has been found to associate with not achieving glycemic and blood pressure control goals, increased risk for disease-related complications, and greater treatment burden (CDC, 2018b; Dragomir et al., 2010, Rogers et al., 2017). The mean Hba1c readings in this study were above recommended levels, potentially due to the lack of medication adherence among participants.

Participants' reporting on the Extent of Adherence tool indicated that 70% had taken all of their prescribed diabetic medications and 74% took all of their prescribed anti-hypertensive medications in the prior 30 days. However, when asked if they missed or skipped any of their prescribed medications, 53% indicated that they may have missed some of their diabetic medications and 49% said they potentially missed or skipped taking some of their anti-hypertensives. These percentages for missed or skipped medications were greater than what was anticipated based on the high reports of taking all medications. The higher percentages of missed or skipped medications in this sample suggests that while participants may have had a higher level of confidence in reporting that they were adhering to their medication regimens, they felt less certain about whether they may have missed or skipped a dose. The reports of missing or skipping medications may also be higher than anticipated due to participants including the medications they skipped in accordance with medication instructions (e.g.,

medication instructions that advise not to take the medication if their glucose is below a certain level). The number of participants who missed or skipped medication doses based on their medication instructions was not tracked in this study. Future studies should delineate between participants who missed or skipped doses per medication instructions and those who did so for other reasons (i.e., side effects relating to sexual performance).

Associations of Demographic Characteristics with Capacity, Burden and Medication Management

Of the demographic characteristics assessed in this study, age correlated with the most study variables. Associations were found between age and one of the capacity variables (i.e., patient activation), one of the burden factors (i.e., treatment burden), and attributes of the DSM workload (i.e., number of prescribed medications and difficulty in managing medications). Associations were also found between level of education and two of the major study variables (i.e., treatment burden and total difficulty in managing medications). When examining differences by sex, males had significantly higher illness burden than females. Previous studies with diverse samples have found similar associations with age, socioeconomic status (e.g., income, level of education), and sex, identifying these demographic characteristics as confounding variables (Akohoue et al., 2015; Boehmer, Shippee, 2016; Byers et al., 2016; Gallacher et al., 2018; Neto et al., 2019; Osborn et al., 2013; Rovner et al., 2013). These findings suggest that age, sex, and level of education may impact the cumulative complexity of managing a DSM workload and should be taken into consideration

when developing treatment plans for individuals who are older and have lower education attainment.

Limitations

This study had limitations that affect generalizability and should be considered when interpreting the findings. The first limitation relates to the sample selection. Convenience sampling was the recruitment method used in this study, with a large number of participants being recruited from a social media platform. Participants also self-screened and self-identified as being AA, having T2D and hypertension, and taking prescribed medications for their T2D and hypertension. It is possible that some participants may have provided inaccurate information. To reduce the amount of false or inaccurate information, the student PI conducted daily quality checks on the data. Any information that appeared erroneous was reviewed with participants during their follow up call and revised as applicable. Prior to the conclusion of each participant's interview session for administration of the NVS, the student PI verified eligibility of the participants by having them confirm their chronic disease status, age, the number of medications and the names of the medications they were taking.

A second limitation is that, during the time of recruitment for this study, the effects of COVID-19 on employment and financial status were likely very present. The perceived impact of COVID-19 on medication management was explored in this study and found that there was an overall moderate perceived impact reported by participants. It is possible that participants who chose to volunteer for

this study may have been motivated more greatly by the small financial incentive as compared to times prior to the pandemic.

A third limitation was that most of the instruments used in this study were self-report measures which created a space for recall and response bias. Potentially, participants may have intentionally, or unintentionally, provided inaccurate responses to some of the study questions (e.g., most recent blood pressure reading or whether they took all of their T2D and blood pressure medications). Incorporating more objective measures may have provided verification of the potential of recall and response bias and greater clarity into the accuracy of the reports provided by participants.

Strengths of the Study

While limitations of this study were observed, there were several strengths as well. This study adds to the limited body of literature describing disease-self management for AAs with comorbidities. This is the first known study that examined associations among patient activation, health literacy, treatment burden, illness burden, medication workload, and medication adherence for AA adults with comorbid T2D and hypertension. Also, the perceived impact of a pandemic on the management of prescribed medications was explored. The ability to recruit younger participants and male participants is also a major strength of this study. Furthermore, there was limited missing data and each instrument used in this study was found to have adequate internal consistency reliability.

Implications for Nursing Practice

Nurses have essential roles in supporting patients' DSM efforts. The findings from this study suggest several implications for nursing practice in furthering the support provided by nurses to patients who have DSM responsibilities. First, this study highlighted factors that created burdens and also counteracted burdens in medication management for AA adults with T2D and hypertension. Lower patient activation was primarily associated with worse medication adherence, but treatment burden and difficulty in medication management may contribute to nonadherence directly or through patient activation.

Assessing levels of patient activation may provide useful information for healthcare professionals, as patient activation was found to predict medication adherence. The patient activation tool used in this study provides an assessment measure and also a framework for implementing strategies to assist patients in achieving the highest level of activation. For example, a patient who is at the lowest level of patient activation (i.e., level one) would likely benefit most from receiving basic knowledge about their condition and their treatment plan and establishing with them the role they have in improving their health (Greene et al., 2015; Hibbard et al., 2004).

Without a basic understanding of their condition and their treatment plan, the patient may make choices that they believe will have positive outcomes, but not have an adequate understanding of how certain decisions may impact their health. Therefore, it is essential that patients are not just instructed on how to

carry out their medication management tasks, but also on why certain tasks must be performed. For example, when instructing patients about taking their medications at certain times of day, providing them with rationales as to why the medications need to be taken as prescribed may be beneficial in fostering their desire and abilities to adhere to their medication regimens.

To boost activation, patients may also benefit from having problem-solving strategies incorporated into the education they receive from their healthcare providers. For example, patients could be presented with various scenarios that may occur as they navigate their medication management tasks alongside their other responsibilities. This will create an opportunity to identify potential challenges patients have in their medication management as well as facilitate discussions that can empower them to overcome those challenges.

Additionally, as both treatment burden and difficulty in managing medications were associated with medication adherence, using measures to assess the more burdensome and/or difficult areas in managing medications for patients may provide guidance on how to best facilitate individualized adherence to medication regimens. For example, more than half of the sample reported difficulty in taking medications at inconvenient times. These individuals may benefit from receiving assistance for incorporating strategies in their day such as structuring their mealtimes to coincide with their medication times or mapping out their daily routines to incorporate the times for their scheduled medications. Additionally, the patient's daily routine could be considered when healthcare providers are prescribing their medication regimen, thereby reducing the level of

inconvenience experienced with their medications and potentially improving their medication adherence. Helping patients identify strategies that facilitate better medication management may promote a greater sense of accountability for them in their medication management and increase the likelihood of them achieving their treatment goals.

When educating patients, healthcare providers should consider those characteristics that increase patients' risk for poor disease self-management in relation to the CCM. This study suggests that patients who are older in age, male and less educated may need greater support in building capacity and reducing perceived burden including workload. Health literacy was low in this sample. Although health literacy was not found to correlate with medication adherence, a clinical practice implication remains for assessing health literacy, as individuals who have poor health literacy may have difficulty in other aspects of disease self-management. Additionally, participants in this study found the financial aspect of their medication workloads, particularly in the face of the COVID-19 pandemic, to be one of the most difficult aspects of managing their medications. As such, these participants could benefit from healthcare policy that provides financial support or reduced costs for the purchasing of prescriptions and/or supplies needed for management of T2D and hypertension.

Recommendations for Future Research

Although several significant correlations were found in this study, more research is needed on DSM among AAs with T2D and hypertension. All of the instruments in this study demonstrated good internal consistency reliability, thus,

future research may benefit from using the measures in studies that examine other DSM activities (e.g., healthy eating habits). Additionally, future studies could include more objective measures of capacity, and medication adherence. For example, in addition to assessing participants' self-reported patient activation and perceived level of adherence, studies could incorporate administrative refill data to substantiate participants' perceptions. Furthermore, studies may benefit from using the S-TOFHLA and/or the REALM as measures of health literacy to examine if either of these measures significantly predict medication adherence. The different aspects of health literacy (e.g., reading comprehension, numeracy, document literacy) could also be incorporated in the regression analyses to examine how those specific elements of health literacy correlate to other independent variables and outcome measures.

Future studies should include inquiries of waist circumferences or waist-to-hip ratios for examining adiposity and to help determine rates of obesity more accurately. While cardiometabolic variables were assessed in this study, they were also through self-report and only the most recent reading for blood pressure and HbA1c. Longitudinal studies that assess trends in blood pressure and HbA_{1c} to determine correlations with capacity and burden measures may provide more insight into the impact that DSM performance has on treatment goals. Further research is also needed in examining DSM capacity, patient burden, and DSM outcomes among AA adults with chronic comorbid conditions in various situations (e.g., following a hospital discharge) and settings (e.g., rehabilitation facility).

Lastly, the findings from this study suggest that there may be benefit in further exploration of differences in age, sex, length of time since diagnoses, religious practices, and social relationships among AA adults with chronic disease. Further exploration of these variables may provide greater insight into DSM performances, intervention designs, and potential outcomes for this population.

Conclusions

In this study of AA, mostly educated, younger men, self-reported glucose and blood pressure readings were elevated. Non-adherence to medication may help to explain this finding as more than half of the sample reported skipping or missing medications within the prior 30 days. While low levels of health literacy, moderate treatment burden, and moderate illness burden were found in this study, only patient activation significantly contributed to predicting medication adherence, explaining only a small percentage of variance. This finding suggests that while patient activation may be an effective tool for identifying AA patients at risk for poor medication adherence, additional concepts for DSM capacity and burden should be considered for this population, as the model that incorporated all measures only accounted for 19% of the variance in medication adherence.

Greater illness burden was associated with lower health literacy, while greater treatment burden was associated with lower patient activation and higher perceived difficulty in managing medications. These findings imply that certain aspects of capacity may counteract the burdens from illness and treatment in this population. Paying for medications, dealing with side effects, getting refills on

time, managing medication schedules, and managing medication dosing were the most challenging aspects of medication management for this sample.

Additionally, COVID-19 had the greatest perceived impact on getting refill orders, paying for medications, getting medications from the pharmacy, and getting supplies. These findings suggest the need for DSM support services that emphasize reduction of financial burdens, adequate management of side effects, efficient acquisition of medication refills, and minimization of disruptions from medication schedules. By considering the various factors that may hinder or promote medication adherence, strategies can be implemented to help this vulnerable population, particularly older, male and less educated AAs improve their adherence, achieve their treatment goals and ultimately, live longer and healthier lives.

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Appendix A

Recruitment Flyer

Georgia State University | Byrdine F. Lewis College of Nursing and Health Professions

VOLUNTEERS NEEDED FOR A STUDY OF AFRICAN AMERICANS WITH TYPE 2 DIABETES AND HYPERTENSION

A PhD nursing student at Georgia State University is working on a research study to learn more about skills and burdens of African American/Black adults with diabetes and hypertension.

Seeking African American/Black adults who have had Type 2 diabetes and hypertension for at least 1 year.

You will be asked to complete online surveys about how you manage your diabetes and hypertension. You will also be asked to take part in a short phone call or online chat to assess your skills. It may take a total of 45 minutes for you to complete this study.
You will receive a $25 electronic gift card for completing this study.

- Have you had Type 2 diabetes and high blood pressure for 1 year or longer?
- Are you African American/ Black?
- Are you 18 or older?
- Do you take medications for diabetes **and** high blood pressure?

If so, you may be able to participate in this study.

Interested?
Please visit https://gsu.qualtrics.com/jfe/form/SV_bCJr1YY9mcNET2Z for more information

If you have any questions about this study or prefer to receive printed copies of the surveys, please contact:

Michelle Gaddis, MSN-ED., RN-BC
at **404-855-0815**
or **mgaddis1@gsu.edu**

Appendix B

Email/Text Message Script

Dear [*name will be inserted here*],

My name is Michelle Gaddis and I am a PhD student at Georgia State University. I am writing to invite you to join a research study. The purpose of this study is to find out about the skills, burdens, and medication practices of African Americans with diabetes and hypertension. The total estimated time for you to complete this study is 45 minutes. Your email (or phone number) was obtained from [source will be inserted here] because of your potential interest in the study.

You may be eligible for this study if you:

- Are African American
- Are 18 years or older
- Have Type 2 diabetes and high blood pressure for 1 year or longer
- Take at least 1 medication for diabetes and 1 medication for high blood pressure

If you decide to join this study, you will:

- Complete an online consent form
- Complete seven short online surveys
- Complete a 10-minute phone call or online chat to assess your skills
- Receive a $25 electronic gift card once you have completed the study

If you do not have access to complete the online surveys, please call or email Michelle Gaddis. It may still be possible for you to join the study. *Remember, this study is voluntary. You can choose to be in the study or not.* If you'd like to join the study, you can visit the following link to get started:

https://gsu.qualtrics.com/jfe/form/SV_bCJr1YY9mcNET2Z

If you have any questions about the study, please contact Michelle Gaddis*:*
phone at 404-855-0815 or email mgaddis1@gsu.edu

If you know of anyone else that may be interested in this study, please provide them with my contact information.

Thank you very much.

Sincerely,
Michelle Gaddis
Student Investigator
Georgia State University
Study Title: Disease Self-Management Capacity, Patient Burden, and Medication Adherence for African American adults with Type 2 Diabetes and Hypertension

Appendix C

Demographic Survey

ID: _____ **DATE:** _____

(1) **Age** _____

(2) **Sex/Gender**
- □ Female
- □ Male
- □ Other (please describe) ____

(3) **Race/Ethnicity** (select all that apply)
- □ Black/African American
- □ Other (please describe) _____

(4) **Highest level of education completed**
- □ Did not attend school
- □ Elementary school
- □ Middle school
- □ High school
- □ Trade school
- □ College

(5) **Employment status**
- □ Fulltime
- □ Part-time
- □ Unemployed
- □ A homemaker
- □ Military
- □ Retired
- □ Unable to work

(6) **Household income**
- □ < 30,000
- □ ≥ 30,000

(7) **Marital status**
- □ Single (never married)
- □ Married
- □ Separated
- □ Widowed
- □ Divorced
- □ Domestic partnership

(8) **When did you find out that you had:**

Diabetes? _____

Hypertension? _____

(9) **Most recent HbA_{1c} value** _____

(10) **Most recent blood pressure** _____

(11) **Other health issues**

_____

(12) **Insurance status**
- □ No insurance
- □ Private insurance
- □ Employer-sponsored insurance
- □ Medicare/Medicaid
- □ Other (please describe) _____

(13) **Do you have a primary health care provider?**
- □ Yes
- □ No

(14) **Do you have social support in doing the things you need to do to manage your health?** (For example, a friend, church member, or family member who drives you to your doctor visits.)
- □ Yes
- □ No

(15) **Are you *able* to complete three or more of the following activities of daily living on your own: eating, bathing, getting dressed, or toileting?**
- □ Yes
- □ No

Appendix D

Medication Workload Survey

ID: _____ **DATE:** _____

Your responses to the questions in this survey will help us learn about the work that goes into managing your medications.

How many medications do you take for diabetes? _____

How many medications do you take for high blood pressure? _____

Do you take medications for things other than diabetes or high blood pressure? (For example, do you take medications for cholesterol, pain, or any other health issue).

- □ Yes
- □ No

How many different medications do you take for these other health issues? (Do not include your diabetes and hypertension medications in this count).

_____

Do you have to take any of your medications at separate times each day?

- □ Yes
- □ No

How hard is it for you to take medicines at different times? [Select one response]

Not hard	A little hard	Very hard
□	□	□

The list below includes different ways you might have to take your medications. Which of the following describe how you take your medicines? [Select all that apply to you]

- □ Oral (For example, pills or liquid)
- □ Topical (For example, creams or ointments)
- □ Injection (For example, you have to give yourself a shot through your skin)
- □ Pump (For example, an insulin pump)
- □ Other (please describe) _____

How hard is it for you to take your medication in the way(s) you listed? [Select one response]

Not hard	A little hard	Very hard
□	□	□

Do you have to change the amount of medication you take based on blood sugar or blood pressure levels you check at home? (For example, you might have to check your blood sugar level each day and give yourself a certain amount of insulin based on your blood sugar).

- □ Yes
- □ No

(By responding "yes", the following two questions will be displayed)

a. How hard is it for you to check your blood pressure and/or blood sugar levels at home? [Circle one response]

Not hard	A little hard	Very hard
□	□	□

b. How hard is it for you to figure out the amount of medication you should take based on the levels you check at home? [Select one response]

Not hard	A little hard	Very hard
□	□	□

Has your healthcare provider made changes in the last 90 days to the medications you take?

- □ Yes
- □ No
- □ Does not apply to me (Select this one if you do not have a primary healthcare provider)

(By responding "yes", the following question will be displayed)

How hard has it been for you to deal with the changes made to your prescriptions? [Select one response]

Not hard	A little hard	Very hard
□	□	□

How hard is it for you to deal with the following situations?
[Select one response for each situation]

	Not hard	A little hard	Very hard
Remembering to take my medications	□	□	□
Paying for my medications	□	□	□
Opening my medication containers	□	□	□
Reading the words on the medication containers	□	□	□
Getting my refills on time.	□	□	□
Taking medication at inconvenient times	□	□	□
Understanding what my medications are for	□	□	□
Dealing with the side effects from my medications.	□	□	□

Appendix E

Patient Activation Measure® (PAM®)

ID	
Date	

Below are statements people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally.

Circle the answer that is most true for you today. If the statement does not apply, select N/A.

1.	When all is said and done, I am the person who is responsible for taking care of my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
3.	I am confident I can help prevent or reduce problems associated with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
4.	I know what each of my prescribed medications do.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
8.	I understand my health problems and what causes them.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
9.	I know what treatments are available for my health problems.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
11.	I know how to prevent problems with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
12.	I am confident I can figure out solutions when new problems arise with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
13.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

(Hibbard et al., 2004)

Appendix F

Newest Vital Sign (NVS)

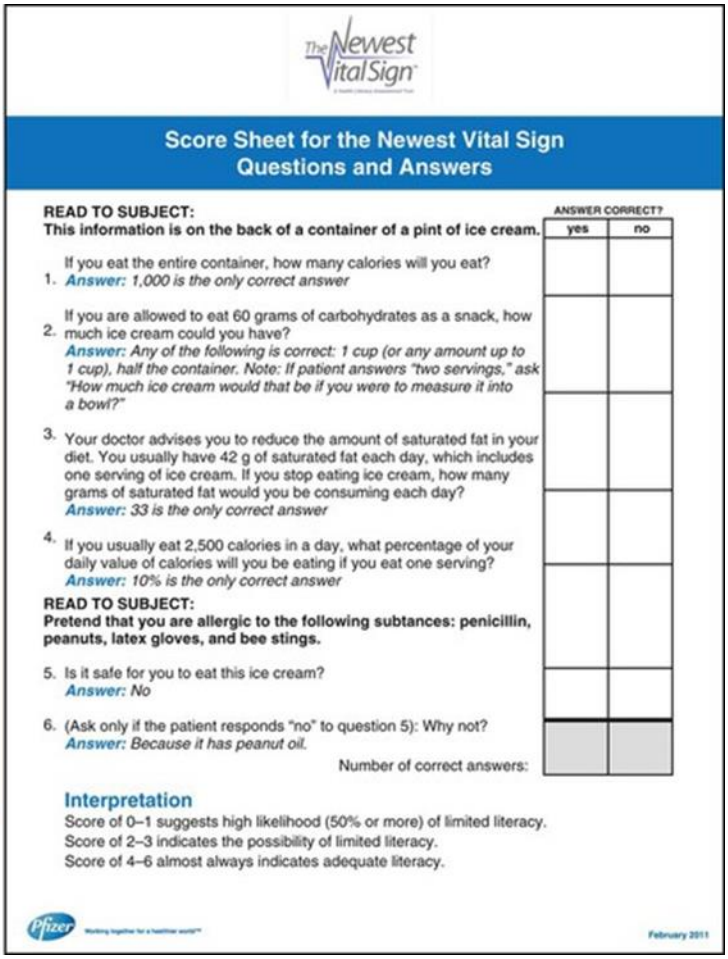
PARTICIPANT ID: _____ **DATE:** _____

Nutrition Facts

Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.



The Newest Vital Sign

Score Sheet for the Newest Vital Sign Questions and Answers

READ TO SUBJECT:
This information is on the back of a container of a pint of ice cream.

	ANSWER CORRECT? yes	no
1. If you eat the entire container, how many calories will you eat? *Answer: 1,000 is the only correct answer*		
2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have? *Answer: Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you were to measure it into a bowl?"*		
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day? *Answer: 33 is the only correct answer*		
4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving? *Answer: 10% is the only correct answer*		

READ TO SUBJECT:
Pretend that you are allergic to the following subtances: penicillin, peanuts, latex gloves, and bee stings.

5. Is it safe for you to eat this ice cream? *Answer: No*		
6. (Ask only if the patient responds "no" to question 5): Why not? *Answer: Because it has peanut oil.*		
Number of correct answers:		

Interpretation

Score of 0–1 suggests high likelihood (50% or more) of limited literacy.
Score of 2–3 indicates the possibility of limited literacy.
Score of 4–6 almost always indicates adequate literacy.

Pfizer

February 2011

(Weiss et al; 2005)

Appendix G

Multimorbidity Treatment Burden Questionnaire (MTBQ)

PARTICIPANT ID: _____ **DATE:** _____

THE EFFORT OF LOOKING AFTER YOUR HEALTH

We are interested in finding out about the effort you have to make to look after your health and how this impacts on your day-to-day life.
Please tell us how much difficulty you have with the following:
(Please tick the box that most applies to you)

	Extremely Difficult	Very Difficult	Quite Difficult	A little Difficult	Not Difficult	Does not apply
1. Taking lots of medications	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
2. Remembering how and when to take medication	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
3. Paying for prescriptions, over the counter medication or equipment	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
4. Collecting prescription medication	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
5. Monitoring your medical conditions (e.g. checking your blood pressure or blood sugar, monitoring your symptoms etc.)	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
6. Arranging appointments with health professionals	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
7. Seeing lots of different health professionals	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
8. Attending appointments with health professionals (e.g. getting time off work, arranging transport etc.)	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
9. Getting health care in the evenings and at weekends	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
10. Getting help from community services (e.g. physiotherapy, district nurses etc.)	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
11. Obtaining clear and up-to-date information about your condition	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
12. Making recommended lifestyle changes (e.g. diet and exercise etc.)	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$
13. Having to rely on help from family and friends	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$	☐$_0$

(Duncan et al; 2018)

Appendix H

Illness Intrusiveness Ratings Scale (IIRS)

PARTICIPANT ID: _____ **DATE: _____**

The following items ask about how much your illness and/or its treatment interfere with different aspects of your life. **Please circle the one number that best describes your current life situation. If an item is not applicable, please circle the number one (1) to indicate that this aspect of your life is not affected very much. Please do not leave any item unanswered.** Thank you.

How much does your illness and/or its treatment interfere with your:

1. **Health**
Not Very Much 1 2 3 4 5 6 7 Very Much

2. **Diet** (i.e., the things you eat and drink)
Not Very Much 1 2 3 4 5 6 7 Very Much

3. **Work**
Not Very Much 1 2 3 4 5 6 7 Very Much

4. **Active recreation** (e.g., sports)
Not Very Much 1 2 3 4 5 6 7 Very Much

5. **Passive recreation** (e.g., reading, listening to music)
Not Very Much 1 2 3 4 5 6 7 Very Much

6. **Financial situation**
Not Very Much 1 2 3 4 5 6 7 Very Much

7. **Relationship with your spouse** (girlfriend or boyfriend if not married)
Not Very Much 1 2 3 4 5 6 7 Very Much

8. **Sex life**
Not Very Much 1 2 3 4 5 6 7 Very Much

9. **Family relationships**
Not Very Much 1 2 3 4 5 6 7 Very Much

10. **Other social relationships**
Not Very Much 1 2 3 4 5 6 7 Very Much

11. **Self-expression/self-improvement**
Not Very Much 1 2 3 4 5 6 7 Very Much

12. **Religious expression**
Not Very Much 1 2 3 4 5 6 7 Very Much

13. **Community and civic involvement**
Not Very Much 1 2 3 4 5 6 7 Very Much

(Devins, 2010)

Appendix I

Extent of Adherence Survey

PARTICIPANT ID: _____ **DATE: _____**

Please rate your agreement with the following statements.

Over the past 30 days…

1. I took all doses of my diabetes medications.	Strongly disagree ○	Disagree ○	Neutral ○	Agree ○	Strongly agree ○
2. I took all doses of my blood pressure medications.	Strongly disagree ○	Disagree ○	Neutral ○	Agree ○	Strongly agree ○
3. I missed or skipped at least one dose of my diabetes medications.	Strongly disagree ○	Disagree ○	Neutral ○	Agree ○	Strongly agree ○
4. I missed or skipped at least one dose of my blood pressure medications.	Strongly disagree ○	Disagree ○	Neutral ○	Agree ○	Strongly agree ○
5. I was not able to take all of my diabetes medications.	Strongly disagree ○	Disagree ○	Neutral ○	Agree ○	Strongly agree ○
6. I was not able to take all of my blood pressure medications.	Strongly disagree ○	Disagree ○	Neutral ○	Agree ○	Strongly agree ○

Reasons for Nonadherence

Situations come up that make it difficult for people to take their diabetes and blood pressure medications as prescribed by their doctors. Below is a list of those situations. We want to know how much these situations contributed to you missing a dose of your medication. Only one of these situations may apply to you, or many may apply to you.

In the past 7 days, how much did each situation contribute to you missing a dose of your diabetes or blood pressure medication?

	Not at all	**A little**	**A lot**
1. I was busy	○	○	○
2. They caused some side effects	○	○	○
3. They cost a lot of money	○	○	○
4. I felt I did not need them	○	○	○
5. I was supposed to take them more than once a day	○	○	○
6. I ran out of medication	○	○	○
7. My blood pressure or blood sugar was too low	○	○	○
8. I was feeling too ill to take them	○	○	○

Were there other reasons why you missed taking your medications?

- □ Yes
- □ No

If you selected “yes” in question #8, please use the space below to list other reasons for why you did not take your diabetes or blood pressure medications.

(Voils et al., 2012)

Appendix J

COVID-19 Impact Survey

ID: _____ DATE: _____

We want to know how COVID-19 has changed how you are able to manage your diabetes and hypertension. Please select a response for how much you believe the COVID-19 (coronavirus) pandemic has changed the following situations for you. [Select one response for each statement]					
During the COVID-19 pandemic…					
	Strongly Disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly Agree**
1. It has been harder to remember to take my medications.	o	o	o	o	o
2. It has been harder to pay for my medications.	o	o	o	o	o
3. It has been harder to get refill orders from my healthcare provider.	o	o	o	o	o
4. It has been harder to get my medications from the pharmacy.	o	o	o	o	o
5. It has been harder to talk with my provider about my medications.	o	o	o	o	o
6. It has been harder to get help from others (family, friends, community) .	o	o	o	o	o
7. It has been harder to get the supplies I need (e.g. alcohol, needles, etc.) .	o	o	o	o	o
8. It has been harder to check my blood pressure or blood sugar levels.	o	o	o	o	o
9. I am more uncertain about what medications I should or should not take.	o	o	o	o	o
10. I worry more about leaving the house to pick up medications, get supplies, or see my healthcare provider.	o	o	o	o	o

Are there any other details you would like to share about how COVID-19 has affected situations relating to your diabetes and hypertension medications? o **Yes** o **No**

Please use the space below to write any details you would like to share.