BELIEFS IN MEDICATIONS AND TREATMENT COMPLEXITY AS PREDICTORS OF MEDICATION ADHERENCE AMONG ADULTS 18-65 YEARS OLD WITH INFLAMMATORY BOWEL DISEASE

by

DONNA BACCHUS

Presented to the Faculty of the Graduate School of

The University of Texas at Arlington in Partial Fulfillment

of the Requirements

for the Degree of

DOCTOR OF PHILOSOPHY

THE UNIVERSITY OF TEXAS AT ARLINGTON

December 2013

Acknowledgements

First I would like to acknowledge God Almighty through whom I experienced the miracle of faith in this journey. I also have profound gratitude for my chair, Dr. Jennifer Gray, whom I aspire to emulate. In other words, “When I grow up I would like to be like Dr. Gray.” I appreciate Dr. Lauri John, committee member, for her kindness, editorial expertise, and encouragement. Dr. Daisha Cipher, committee member, I extend my appreciation for her enthusiasm, advice, and ability to transform difficult statistical concepts into manageable ones.

My sincere thanks go to all my friends for their support and encouragement. I appreciate their confidence in me when I needed it. Penny Boyce and Jacqueline Williams, thank you for cheering me on to the finish line. Maxine Adegbola, I appreciate your words of wisdom and the many hours of your busy schedule that you spared to discuss how to succeed in this PhD journey. My gratitude goes to Gillian Ameerally for her strong faith in the Lord as well as her many words of wisdom. To my daughter Crystal Gomes, who was the inspiration for me to pursue this important topic. My hope is for a cure for IBD in the near future. I thank my mother Gwen Bacchus for her encouragement. My sincere gratitude goes to my sister June Sabbah for believing in me.

November 15, 2013

Abstract

BELIEFS IN MEDICATIONS AND TREATMENT COMPLEXITY AS PREDICTORS OF MEDICATION ADHERENCE AMONG ADULTS 18-65 YEARS OLD WITH INFLAMMATORY BOWEL DISEASE

Donna Bacchus, PhD

The University of Texas at Arlington, 2013

Supervising Professor: Dr. Jennifer Gray

Low adherence to medications in patients with inflammatory bowel disease (IBD) results in relapses and subsequently increased healthcare costs, poor quality of life, and increased comorbidities. In this correlational study, treatment complexity and beliefs in medications were tested to determine if they are predictors of medication adherence. Through convenience sampling, participants were recruited through face book, IBD organizations, and foundation websites (n = 369 final sample size). Females comprised the overwhelming majority (81.8%) of the sample.

Using the Morisky Medication Adherence Scale, approximately 56% were classified as nonadherent and 44% as adherent. Beliefs in medications were measured by four subscales: necessity, concerns, harm, and overuse. Treatment complexity was measured by a researcher-developed 5-item scale. The odds ratio for treatment complexity was .824 (95% CI = .768 - .884), $p < .05$, less than one, indicating that for every unit increase in treatment complexity, respondents were 18% less likely to be adherent (Pallant, 2009). The strongest predictor of adherence was specific necessity beliefs, 1.102 (95% CI = 1.062 - 1.143), $p < .05$, indicating that for every unit increase in beliefs in the necessity of medications, respondents were 11% more likely to be adherent (Pallant, 2009). Overall, demographic factors were not associated with adherence rates, but use of biologics and 5-ASA compounds, reports of depression and obesity, and

intravenous method of medication administration were all significantly associated with adherence.

Findings in this study were not dissimilar from those of previous studies in which conflicting results were found for some demographic variables and some consistencies for illness and treatment variables. Adherence rates can be improved when healthcare providers discuss beliefs in medications and treatment complexity problems with patients. This alliance can only result in clarification, education, and reinforcement of the importance of medication adherence: Ultimately, patients will have improved medication adherence.

Table of Contents

List of Illustrations

List of Tables

Chapter 1

Beliefs in medications and treatment complexity as predictors of medication adherence among adults 18-65 years old with inflammatory bowel disease

Introduction

Inflammatory bowel disease (IBD) is a chronic condition with unrelenting relapses and multiple co-morbidities. Two chronic gastrointestinal conditions, Crohn's disease (CD) and ulcerative colitis (UC) are collectively known as IBD (Sands, 2007). Nonadherence to medications in adults 18-65 years old with IBD is a health care problem because the disease frequently occurs in younger adults and requires a lifetime of adhering to medication therapy (Ediger et al., 2007). The potential for nonadherence is increased because the disease course is unpredictable with long periods of activity, and treatments can be cumbersome and difficult to follow. Currently, no cure exists, and nonadherence results in three outcomes: Increased disease activity, increased healthcare costs, and increased risk of dysplasia or cancer (Kane, 2008). In this study of adults with IBD, the researcher investigated beliefs in medications and treatment complexity for their potential to predict medication adherence. This chapter includes the background and significance of medication nonadherence in adults 18-65 years old with IBD, information on a common-sense model of self-regulation within the context of the study, and beliefs in medications and treatment complexity as predictors of medication adherence. The conclusion of the chapter includes propositions, purpose, research questions, and assumptions of the study. In this study, for the purpose of recruitment of a chronic illness population from social media, the term "adult" was used versus "patient" for more socially acceptable terminology. This population is subsequently referred to as patients in the remainder of the study.

Background and Significance

Adherence is the extent to which a patient acts in accordance with the prescribed interval, dose, and dosing regimen of medications (Cramer et al., 2008). Nonadherent behavior can be voluntary (intentional) or involuntary (nonintentional), both of which are associated with different patient characteristics (Sewitch, Leffondré, & Dobkin, 2004). In a systematic review of 17 studies on nonadherence to oral therapy in IBD patients, Jackson, Clatworthy, Robinson, and Horne (2010) found that nonadherence rates ranged from 7-72%, with an average between 30 and 45 percent. After decades of adherence research, the problem of nonadherence persists.

Clinical Significance

The overall estimate of Americans with IBD is one million across all age groups (Kappelman et al., 2007; Lakatos, 2009). Prevalence rates for UC and CD are 201 and 238 respectively (Kappelman et al., 2007). Despite advances in medical therapy, a significant increase has occurred in hospitalizations for persons with CD. Hospitalizations for UC have remained stable (Kappelman et al., 2007). In 2004, there were approximately 82,000 hospital admissions for UC and 141,000 for CD. Also in 2004, the most recent year for which data are available, outpatient visits rose to 1.1 million for CD and 716,000 for UC (Everheart, 2008). In addition, direct costs of IBD were 5.4 billion, and mean annual costs were $8,265 for 9,056 CD patients and $5,066 for 1,038 UC patients (Kappelman et al., 2008). In a literature review, Yu et al. (2008) found that the estimated direct medical costs per patient for CD were $18, 022 - $18,932 annually. Total CD related treatment costs were 3.6 billion dollars. In recent estimates, indirect and direct costs of CD resulted in an economic burden of $10.9-15.5 billion annually (Yu et al., 2008). Nonadherence to medications results in escalating costs due to increased hospitalizations and increased absenteeism from work and school.

Disease Course

IBD is chronic and unpredictable with predominant gastrointestinal symptoms such as diarrhea, rectal bleeding, and abdominal pain. Undesirable side effects of medications, invasive delivery methods, and complex and varying medication schedules disrupt adherence and management of IBD (Kane, Brixner, Rubin, & Sewitch, 2008; Lakatos, 2009). Over the long term, up to 75% of patients with CD and 25-33% of patients with UC will require surgery (Hanauer, 2005). Additionally, those patients with CD requiring surgery may need it more than once (Bewtra, Su, & Lewis, 2007). Although surgery may be curative for UC patients, it is only recommended when the disease course is refractory to treatment (Carter, Lobo, & Travis, 2004). On the other hand, surgical resections of the colon for CD patients are conservative because there is a high degree of reoccurrence (Carter et al., 2004); therefore, the initial treatment is medication therapy. After surgical intervention, long-term medication therapy is still necessary to prevent reoccurrence of symptoms, resulting in an overall potential increase of medication nonadherence (Carter et al., 2004).

Consequences of Nonadherence

In order to maintain remission, patients must adhere to medications, but ironically, periods of remission can result in poor adherence when individuals become complacent with the medication regimen (Ediger et al., 2007). In a study of UC patients in remission (n = 99), the adherence rate was 40% (Kane, Huo, Aikens, & Hanauer, 2003). When patients relapse, providers may change therapy or add adjunctive therapy based on the assumption that medications are not efficacious when, in fact, patients are nonadherent. Unfortunately, changing or adding medications results in more prescriptions and, consequently, increased cost and a greater risk of nonadherence. Pharmaceutical claims contributed approximately one third of the direct cost of IBD

Kappelman et al., 2008). Considering the 1.8 million prescriptions written for CD in 2004 and 2.1 million for UC, the probability of nonadherence is high in patients with IBD (Everheart, 2008).

Factors Related to Nonadherence

In the United States (US), Jackson et al. (2010) did the largest review of studies of medication adherence in IBD patients from 1980 to 2008. The purpose of the review was to determine factors associated with nonadherence in IBD patients. Psychological distress, patients' beliefs about medications, and patient-physician discordance were associated with nonadherence. Although few studies on beliefs in medication and adherence rates in IBD patients exist, studies in other chronic conditions indicate that beliefs is an important predictor of adherence. In a cross-sectional study of 24,017 patients with five chronic conditions, patients' beliefs of perceived need for medications were strong predictors of unintentional nonadherence (Gadarki, Pedan, Gowda, & McHorney, 2011). Phatak and Thomas (2006) studied beliefs in medication and adherence in 250 patients with chronic illnesses from a pharmacy data base in the US. Positive associations were found between beliefs about medication harm and nonadherence and between beliefs about medication necessity and adherence. Similar associations were found in two of the largest IBD studies to date (Ediger et al., 2007; Horne, Parham, Driscoll, & Robinson, 2009). The Horne et al. (2009) IBD study was conducted in England with 1,871 members of the National Crohn's and Colitis Foundation, and the Ediger et al. (2007) correlation study was conducted with 325 IBD patients of the Manitoba IBD cohort study. Other factors that may affect medication adherence in IBD patients such as dosing schedule and mode of medication delivery have been inconsistently associated with adherence (Ediger et al., 2007; Kane et al., 2008).

Medication nonadherence in IBD patients results in relapses and a disease course with potential morbidities such as increased risk of colon cancer in UC patients (Kane et al., 2003). Additionally, the burden of high economic cost and the serious consequences of nonadherence support the need for this study. In this study the researcher investigated whether medication beliefs and treatment complexity can predict nonadherence rates in IBD patients 18-65 years old in the US.

Framework

Levanthal and colleagues' common-sense model of self-regulation in health and illness provides the context of this study (Levanthal, Diefenbach, & Leventhal, 1992). Levanthal's model (Levanthal et al., 1992) incorporates three theories and one framework. Although the focus of Levanthal's model is use of common sense to understand treatment adherence and cognition interactions, it does not include how beliefs in medications and treatment complexity can predict adherence to medications in IBD patients. This study was based on a researcher-expanded model incorporating beliefs in medications and treatment complexity within Levanthal's model. In the expanded model, the researcher tested treatment complexity and beliefs in medications as predictors of adherence to medications among IBD patients.

Levanthal's Model

Levanthal's Model, known as the Common Sense Model (CSM), was developed from Levanthal and colleagues' beliefs that a patient's behavior in preventing and dealing with illness can be studied in terms of the patient's representation of the illness (Diefenbach & Levanthal, 1996). Fear Communication Theory, Social-Cognitive Theory, Self-regulation Theory of Health, and Illness Parallel Processing Framework were incorporated in Levanthal's Model. Earlier work on fear communication was the beginning of the development of the CSM of how affect (emotions) and cognition

influence beliefs and behaviors (Leventhal & Diefenbach, 1991). The key construct in Levanthal's Model is illness representation or the views lay persons have of their illnesses (Hale, Trihare, & Kitas, 2007). Patients use these representations and preconceived ideas about illnesses to make sense of their symptoms and guide coping actions. The three major constructs in the CSM are parallel processing, illness representations, and self-regulation.

Parallel Processing System

Within the model are two largely independent processing systems (Leventhal et al., 1992). One of the processing systems creates the psychologically objective or cognitive representation of the health threat; the other system creates the psychologically subjective or emotional representation of the health threat (Leventhal & Cameron, 1987). The patient is a problem-solver utilizing two parallel processes, cognitive and emotional. Parallel processing of the cognitive and emotional representation occurs in the development of the illness representation (Levanthal & Cameron).

Illness Representations

An illness representation is when persons are affected by external stimuli, such as diagnosis, or internal stimuli, such as pain, and they begin to formulate coping actions (Leventhal et al., 1992). Illness representation includes perceived identity of the health threat (symptoms), potential causes, possible consequences, and perceptions of how the health threat manifests over time (Leventhal & Cameron, 1987). Prior health and illness experiences also influence the illness representation (Diefenbach & Leventhal, 1996).

Self-regulation

In Levanthal's Model, patients are active problem solvers, and they attempt to close the gap between their perceived status from their illness representations and a health threat by implementing coping actions (Levanthal & Cameron, 1987). The self-

regulatory model is useful in the understanding of intentional nonadherence (Horne, 1996). Patients make decisions to follow treatment based on the representation of the illness and regulate responses to the threat (illness and treatment) to attain, or make "common-sense." The choice of a response to cope or not to cope is dependent on whether it makes sense based on the patient's illness representation (Leventhal and Cameron, 1987). Patients appraise the outcomes on how well they controlled the threat (fear); however, they may modify their actions to regulate the outcomes (Cameron & Levanthal, 2003). For example, they may modify their actions by following the prescribed regimen for medication therapy.

Emotional processes interact with illness representations, the patients' plan for coping, and the appraisal of the health threat (Levanthal et al., 1992). Emotional states are numerous and can influence illness cognition resulting in actions that may not be entirely based on cognitive levels (Levanthal & Diefenbach, 1991). For example, emotions may affect the patient's decision to adhere to medication therapy if there are adverse effects from the medications.

Expanded Model

The cognitive representation of the parallel processing system of Levanthal's CSM is an expansion to present the context of this study. The health threat is the diagnosis of IBD and the medication treatment. Within cognitive representations, patients develop a perception of treatment complexity and two groups of beliefs (general and specific) in medications. As a result of cognitive and emotional representations, patients develop an illness representation. Patients are more likely to be adherent if advice to take medications makes common sense to them (Levanthal et al., 1992). According to the self-regulatory theory, adherence is guided by beliefs about medications. Those

beliefs are about the nature, duration, causes, consequences, and potential for cure or control of the illness (Levanthal et al., 1992).

The focus of the Expanded model Illustration of concepts (Figure 1) was cognitive representation; therefore, arrows connect cognitive representation to treatment complexity and beliefs in medications. Coping actions are adherence or nonadherence that may be predicted by treatment complexity and beliefs in medications. Cognitive and emotional representations are illustrated to the left in solid rectangles and are the objective and subjective components respectively of the parallel processing arms. They are a result of the health threat. The CSM proposes that emotional representation and cognitive representation can have independent effects on the patient's behavior (Martin, Rothrock, Levanthal, & Levanthal, 2003). The emotional and cognitive representations may interact, but the extent of the interaction, if any, is unknown; therefore, a broken line connects each square. The emotional interactions were too numerous to measure in this model and were not addressed in this study. Represented in the middle of the model, patents' perceptions of treatment complexity and beliefs in medications depict illness representations of the health threat. They are in rectangles with broken lines, indicating that patients' perceptions of treatment complexity and medication beliefs are unknown predictors of medication adherence. In this model, beliefs in medications and treatment complexity are not causes of adherence but rather, predictors of adherence.

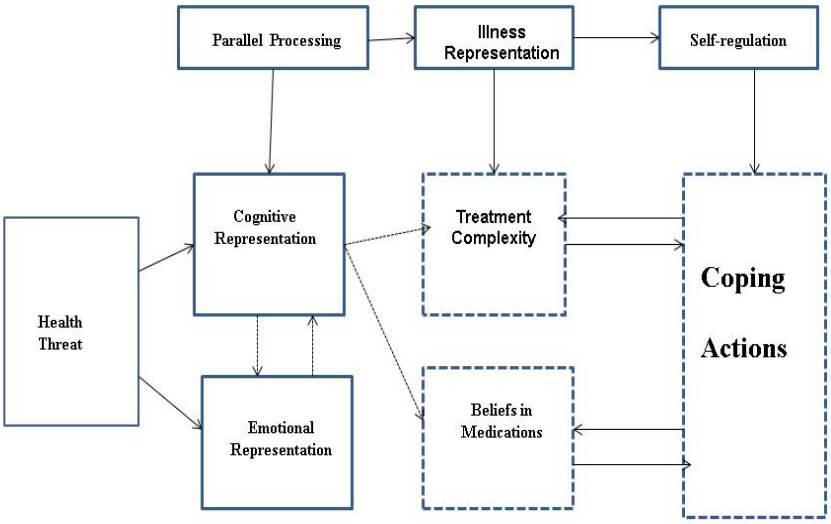

Figure 1 Expanded model: Illustration of concepts

Definitions of concepts used in this expanded model are described (Table 1). Coping, illustrated in the large rectangle with broken lines, depicts patients' self-regulatory actions to cope with the health threat. The lines of the rectangle are not continuous because the concept of coping or adherence will be measured. Arrows go in both directions, from coping to beliefs and from coping to treatment complexity, indicating that patients can self-regulate their coping actions after appraising the illness representations. This phase of self-regulation is dynamic.

Table 1 Definition of Concepts used in the Expanded Model

Concept	Definition
Cognitive representations	Individual's common sense definition of health-threat (Leventhal, Meyer, & Nerenz, 1980)
Treatment complexity	Factors that are likely to disrupt medication adherence and effective management of the disease (Lakatos, 2009)
Delivery	The manner in which a medication is administered to the body
Frequency	How often a medication is delivered in a given time frame
Availability	Whether a medication is present or ready for immediate use
Storage	A location for medications that preserves the integrity of the chemical components

Table 1 *Continued*

General Beliefs	Views about medication in the broad context of the practice of medicine, classified as overuse and harm (Horne et al., 1999)
Specific Beliefs	Views about specific medications prescribed for specific illnesses , classified as necessity and concern (Horne et al., 1999)
Overuse	Views that doctors tend to prescribe too many medicines (Horne et al., 1999)
Harm	Views that medications in general are harmful (Horne, et al., 1999)
Necessity	Views about the need for medications to maintain health (Horne et al., 1999)
Concern	Views that becoming dependent on a medication or long term use lead to adverse effects (Horne et al., 1999)
Adherence	The extent to which a patient acts in accordance with the prescribed interval, dosing, and frequency of medication (Cramer et al., 2008)

Treatment Complexity

The variables for treatment complexity are within broken lines as depicted in the Expanded model: Illustration of variables (Figure 2). Those variables related to the medication regimen are method of delivery, dosing frequency, availability, and storage requirements. It is an indication that method of delivery, dosing frequency, availability, and storage requirements vary among patients and for patients across the trajectory of the illness. The fact is that providers prescribe many formulations and types of medications for UC and CD. For the concept of coping, the researcher measured the variable of adherence, the focus of this study.

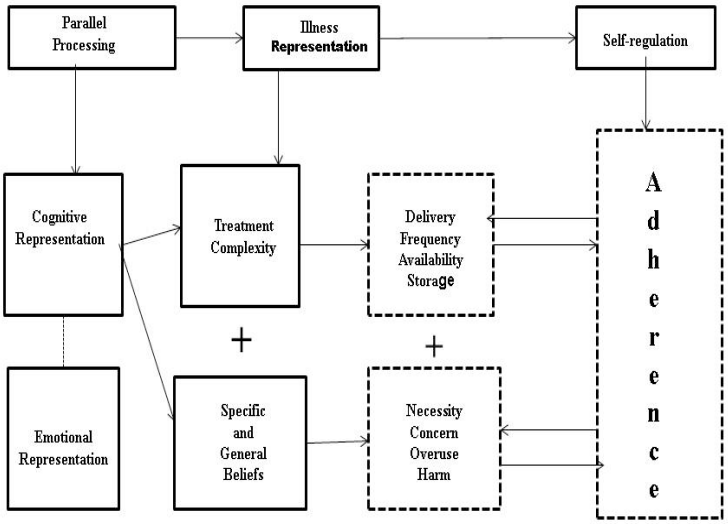

Figure 2 Expanded model: Illustration of variables

Beliefs in Medications

The variables related to the concept of beliefs in medications are in a rectangle with broken lines as depicted in the Expanded model: Illustration of variables (Figure 2). This illustrates that patients' beliefs in medications are unknown and will be measured. Two sub-concepts, specific beliefs in medications and general beliefs in medications are illustrated in the first rectangle. The researcher measured the variables, necessity and harm (specific beliefs) and overuse and concern (general beliefs).

Propositions

From a review of the literature and the conceptual framework (Figure 1), the following were the propositions for this study:

1. Treatment complexity as perceived by the patient is a predictor of adherence.

2. Patients' specific beliefs about their IBD medications are predictive of adherence.

3. Patients' general beliefs about medications are predictive of adherence.

As a result of a health threat (a diagnosis, symptom, relapse, or all of those conditions) for which medications are prescribed, patients develop a perception of the threat, cognitive representations. Cognitive representations develop from beliefs in medications and treatment complexity; therefore, to fulfill the purpose of this predictive correlation study the researcher explored whether beliefs about medications and treatment complexity are predictors of medication adherence among adults 18-65 years old with IBD. In the expanded model (Figure 2), beliefs in medications are categorized as specific beliefs and general beliefs. Specific beliefs about IBD medications are represented by both necessity and concern. General beliefs are about medications in general, whether they are perceived as harmful or overused by doctors. Treatment complexity is a combination of delivery, frequency, availability, and storage of medications (Figure 2). The four beliefs (overuse, harm, necessity, and concern) and treatment complexity are all potential predictors of adherence.

Questions

The researcher addressed the following two research questions in this study among adults 18-65 years old with IBD.

1. Which beliefs about medications are the strongest predictors of adherence to IBD medications?
2. Is treatment complexity a predictor of adherence?

Assumptions of the Model

Assumptions for this study, based on the researcher's recognition, are not exhaustive. They are within the conceptual framework, the study design, and interpretation of the findings (Burns & Groves, 2009).

1. Patients with IBD develop illness representations based on cognitive representation of the health threat.
2. Emotional representations may have unknown effects on illness representations.
3. Cognitive representations include treatment complexity and beliefs in medications.
4. Adherence is a behavior that patients are willing to report with honesty.
5. Treatment complexity may not be within the control of the patient.

Summary of Chapter

The significance of nonadherence to medication regimens includes serious economic and human costs. Patients are nonadherent, and not enough is known about how to improve adherence rates despite previous medication adherence studies. The purpose of this study was to explore beliefs about medications and treatment complexity as predictors of medication adherence within the conceptual framework. The assumptions about the medication adherence issue guided the study design and interpretation of the findings.

Chapter 2

Literature Review

Nonadherence to medications is a contributing factor to increased financial cost, increased hospitalizations, and increased risk of cancer among persons with IBD. Not enough is known, however, about how to increase adherence in these patients. Healthcare providers prescribe maintenance medications for patients and advise them to follow the directions to maintain remission and prevent exacerbations. The consequences of nonadherence are increased healthcare costs and increased morbidity resulting in poor quality of life in patients afflicted with chronic illnesses. In this review, the researcher examined adherence to medications in IBD patients. Specifically, the predictors examined were beliefs in medications and treatment complexity. It is important to define adherence and to explain the pathophysiology and treatment of IBD to facilitate an understanding of this complex health issue. The review includes data collection methods, theoretical emphasis, and methodological issues.

Background

Dimatteo's (2004) landmark review of medical adherence across diseases, including medication adherence, was conducted on 569 empirical studies done over a span of 50 years (1948-1998). Although these were not specifically IBD studies, gastrointestinal conditions were included in the review. The average nonadherence rate across these studies was 24%. Despite advances in medical therapy, a significant increase in hospitalization for CD has occurred, and hospital admissions for UC have not declined (Kappelman et al., 2008). Hospitalization rates for IBD increased between 1998 and 2004, resulting in a great increase in inflation-adjusted economic burden (Nguyen, Tuskey, Dassopoulos, Harris, & Brant, 2004). In the clinical course of IBD, relapses result in frequent hospitalizations and bowel surgeries.

In two systematic studies of IBD patients, most of the exacerbations that IBD patients experienced were attributed to medication nonadherence (Bergman & Parkes, 2006; Higgins, Rubin, Kaulback, Schonfield, & Kane, 2009). Additionally nonadherence was related to increased risk of dysplasia or cancer in patients with UC (Kane, 2008). In a retrospective claims analysis of CD patients, adherence with maintenance infliximab was associated with lower rates of hospitalizations and shorter hospital stays (Carter, Waters, & Smith, 2012). The cost of medical and surgical therapy for CD is about two billion annually although the prevalence of CD is low in comparison to other common gastrointestinal disorders (Lichtenstein, Hanauer, & Sandborn, 2009). Nonadherence to medications in IBD patients is an important healthcare issue that warrants attention and research.

Definitions of Adherence

Researchers use a variety of terminologies and definitions in medication adherence studies. Common terms include adherence, compliance, and persistence. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) defines “medication adherence” or “compliance” as the extent to which a patient acts in accordance with the prescribed interval and dose regimen (McDonald, Garg, & Haynes, 2002). The term “adherence” is preferred over “compliance” because the latter suggests that the patient is a passive participant in the treatment regimen and not involved in a contractual agreement with the provider (Osterberg & Blaschke, 2005). Medication persistence is the act of continuing the treatment for the prescribed duration (Cramer et al., 2008).

Medication compliance is considered by some to be synonymous with adherence and is the degree to which the patient conforms to timing, dosage, and frequency of the prescribed medication whereas medication persistence is the behavior of continuing the

medication for the prescribed duration (Karter et al., 2009). Although it is common to assume that nonadherence refers to discontinuation of the medicine, it is also associated with failure to follow the regimen, including under dosing, over dosing, or skipping doses (Ockene, Hayman, Pasternak, Schron, & Dunbar-Jacob, 2002).

Primary and Secondary Nonadherence

Nonadherence to medications can be further subdivided into primary and secondary nonadherence. Primary nonadherence is medication nonfulfillment, in which the patient does not fill the prescription, or early nonpersistence, whereby the patient does not refill a prescription (Karter et al., 2009). Secondary nonadherence is when the patient does not follow the medication regimen as prescribed. Secondary nonpersistence is discontinuing the medication at some point after the initial prescription has been filled (Karter et al., 2004).

Voluntary and Involuntary Nonadherence

Nonadherent behavior can be voluntary (intentional) or involuntary (nonintentional), both of which are associated with different patient characteristics (Sewitch et al., 2004). Nonintentional nonadherence, a passive process, is forgetting to take a medication, and intentional behavior is active (voluntary) and may be a decision based on an adverse effect of a medication, or inconvenience, or cost (Sewitch et al., 2004).

In a literature review on medication adherence conducted on studies done between 1996 and 2005, Cramer et al. (2008) found that researchers did not always differentiate between persistence and compliance. In IBD studies where the definition of adherence is similar, the method of measuring adherence differs (Bernal et al., 2006; D'Inca et al., 2008). Surveys used for IBD adherence studies were not always validated in patients with IBD or any other chronic illnesses (Baars et al., 2009; Bokemeyer et al.,

2007). In the majority of medication adherence studies in IBD patients, adherence was operationally defined as a rate of 80% or higher of adhering to medications (Baars et al., 2009; Bhatt, Patil, Joshi, Abraham, & Desai, 2007; Bokemeyer et al., 2007; D'Inca et al.).

Depending on the method of measurement, the designated adherence rate may vary as in the Kane and Dixon (2006) study in which 4% of UC patients not keeping appointments for intravenous infliximab was defined as nonadherent. Similarly, nonadherence to infliximab (biologic infusion) in CD patients was defined as a yearly rate of seven clinic attendances when 12 treatments are scheduled (Kane, Chao, & Mulani, 2009). The method of measuring adherence should be reflective of the operational definition of adherence, yet there is no consistency among studies on adherence definitions. Regardless of the definition of adherence and the numerous studies on medication adherence in patients with chronic illnesses, the problem of nonadherence remains (Osterberg & Blaschke, 2005).

Pathophysiology of Inflammatory Bowel Disease

IBD occurs at any age but is predominant among patients aged 15-30 years old, peaking with a smaller distribution in ages 50-70 years, although 10% of cases occur in individuals younger than 18 years old (Hanauer 2005). Possible complications of IBD include acute and sub-acute intestinal obstructions, secondary irritable bowel syndrome, gall stones, renal calculi, chronic pancreatitis, arthritis, iritis, and skin complications (Carter et al., 2004). Both CD and UC result in chronic inflammation of the gastrointestinal tract, marked by an abnormal response of the body's immune system (Hanauer, 2005).

Both CD and UC, classified as IBD, have a few distinct pathogeneses, complications, and medication regimens. CD may affect the entire intestine and all layers of the intestines, whereas UC affects the large bowel and fewer layers of the

gastrointestinal mucosa (Hanauer, 2005). According to Freeman (2009), several long-term studies have shown that CD evolves into a more complex disease with strictures and complications from penetrating disease complications. The course of UC is relapsing-remitting, with patients experiencing no or few gastrointestinal symptoms in between flare-ups (Kane, 2006). The unpredictable nature of IBD, whereby patients can become complacent about treatment, contributes to medication nonadherence. Although adherence to maintenance therapy decreases complications, frequent doses and multiple medications may add to the complexity of nonadherence.

Medication Therapy

Eight classifications of medications (Table 2) are recommended for the treatment of IBD (Bernstein et al., 2010). Mesalamine and five amino salicylic acids (5-ASA), two of the first class anti-inflammatory agents, are available in oral and rectal form, and they are ordered in combination with other drugs or as single therapy. Health care providers prescribe anti-inflammatories for flare-ups and maintenance of remission, but frequent doses may be required to ensure adequate drug intake (Bernstein et al.). Steroids are the second class of medications and are indicated for flare-ups to relieve IBD symptoms rapidly. They are given intravenously, rectally, or orally, and should not be used in long term therapy due to severe adverse effects. The third class, immunomodulators, is used for induction of remission or for an inadequate response to standard medications and may take up to three months to be effective. The fourth class, Anti-tumor necrosis factor (TNF) agents (biologics), given subcutaneously or intravenously, is prescribed for refractory UC, rescue therapy in severe cases, and second line therapy in Crohn's disease (Bernstein et al., 2010).

Another class is antibiotics, such as metronidazole and ciprofloxacin, which are most commonly used for complications like fistulas and bacterial overgrowth. Adjunctive

therapy classes include probiotic therapy, experimental agents, and supplements (Bernstein et al., 2010). When medication therapy fails in Crohn's patients, surgery is not curative, but removal of the colon in patients with UC will cure the disease (Hanauer, 2005). The difficult long-term medication regimen, including delivery, storage, frequency, and availability may contribute to nonadherence in IBD patients.

Table 2 Medication Therapy for Inflammatory Bowel Disease

Classification	Trade Names	Delivery Method	Use
5-ASA compounds Mesalazine	Sulfasalazine, mesalamine, olsalazine, balsalazide,	Oral and rectal enemas (liquid or foam) and suppositories	Colitis flare-ups and maintenance of remission in both UC and CD
Steroids	Methylprednisolone, hydrocortisone	Intravenously	Suppression of inflammation and rapid relief of symptoms in UC and CD acute flare-ups not responding to adequate doses of 5-ASA
	Prednisone, prednisolone, budesonide, dexamethasone	Orally Rectally (enema, foam preparations, suppository	
Immune Modifiers	Calcineurin inhibitors Thiopurines	Orally Intramuscular	UC CD
Anti-TNF agent (also known or referred to as biologics)	Infliximab, Adalimumab certolizumab	Intravenous Subcutaneous	CD; Infliximab is used as rescue therapy in steroid refractory severe UC
Antibiotics	Metronidazole and ciprofloxacin most commonly used	Intravenous and oral	CD complications
Probiotics	Strains of coli	Oral	No evidence are effective
Experimental agents	antiadhesion molecules, anticytokine therapies, anti-inflammatory proteins, Antiadhesion	Varied	UC CD

Table 2 *Continued*

Classification	Trade Names	Delivery Method	Use
	molecules, anticytokine, T-cell marker therapies, mesenchymal stem cells		
Supplements	Analgesics (acetaminophen), Nutritional supplementation, Vitamin B12, Vitamin D, multivitamins, iron	Oral	UC and CD

Methods of Measuring Adherence

In order to make clinical decisions, change therapy, and conduct research studies on adherence, it is vital to have the most accurate measures of adherence. Patients are classified as nonadherent based on a method of assessment. Healthcare providers use information about adherence assessment in order to make decisions about patient care. Adherence measures have methodological issues, advantages, disadvantages, and varying levels of concordance among the measures. The two main methods of measuring adherence to medications are the direct and indirect methods. The direct method of measuring adherence is the objective method, and the indirect method is the subjective method (Hawkshead & Krousel-Wood, 2007). In this review, biological assays are included as a direct method. Indirect methods include pill count, self-reports, medication electronic measures (MEMS), and pharmacy refill records.

Biological Assays Levels

Biological assays are measures of the concentration of a drug, its metabolites, and other compounds in the blood or urine of the patient. Measurement of other compounds includes detection of a biologic marker added to the formulation of the drug (Osterberg & Blaschke, 2005). Urine and serum biological assays are more objective

than self-report, but there are many factors such as rates of absorption, distribution, metabolism, and excretion of the drug that influence variability and metabolite levels of drugs (Partridge, Avorn, Wang, & Winer, 2002).

Assays are not frequently used as a measure of adherence but are sometimes used to validate other measures of adherence. Biological assays do not accurately detect adherence between clinic visits, and the drug level may not be a true measure of adherence to drug therapy (Hawkshead & Krousel-Wood, 2007). Immune modifiers (azathioprine) and aminocylcates (5-ASA) that are prescribed for IBD can be measured using assays. In three studies, immune modifiers were used successfully to treat CD, and validation of the effectiveness of those drugs was corroborated with biological assays (Belaiche, Desager, Horsmans, & Louis, 2001; Bokeymer et al., 2007; Wright, Sanders, Lobo, & Lenard, 2004). Patients who remained in remission over a two-year period had significantly higher thiogaunine levels than those experiencing exacerbations (Wright et al., 2004).

Patients can overestimate medication adherence in self-reports as evidenced by measures of biological assays of 5-ASA compounds. In a group of IBD patients, 2% admitted to total non-compliance, yet urinary drug analysis for 5-ASA metabolite was not detectable in 12% of the group (Shale & Riley, 2003). Similarly, IBD patients overestimated adherence in a study by Moshkovska et al. (2009) where adherence rates were 68% according to self-report and 60% according to urine analysis for 5-ASA metabolite. The two measures, self-report and 5-ASA metabolite, were not correlated ($\chi 2 = .12$, $p = .725$).

One disadvantage of biological assays as a measure of adherence is that they cannot determine the fluctuations of adherence between clinic visits. Another disadvantage is that assays do not account for the variability in the individual patient

metabolism and pharmacokinetics of the drugs (Hawkshead & Krousel-Woods, 2007). An advantage of assays is that finding a measured product in the blood or urine provides direct evidence that the patient has ingested the drug. Other advantages include verification of recent use and data on how responsive the patient is to the drugs (Garfield, Clifford, Elisson, Barber, & Willson, 2011). Use of biomarkers complicates patient adherence because it is an added burden for the patient to ingest a biomarker, further complicating the measure of adherence (Farmer, 1999).

Reliability of data is dependent on the accuracy of instruments; therefore, instruments must be checked for calibration (Waltz, Strickland, & Lentz, 2005). In the foregoing studies, biological assays may have been an accurate measure, but they may not correlate with other methods of measuring adherence. Use of bioassays to measure medication adherence is expensive and does not reflect adherence over a period of time. The patient may be adherent prior to testing in an effort to have satisfactory results.

Pill Count

Pill count is the second most common method used after self-report as a measurement of adherence (Osterberg & Blaschke, 2005). Adherence is usually reported as either a dichotomous variable (adherent versus nonadherent) or a continuous variable (a rate) varying from zero to 100% (Osterberg & Blaschke). When adherence is measured as a continuous variable, no consideration is made about whether the medications are taken on time or if the correct amount of medication is taken each time as prescribed. When adherence rates were measured by self-reports in IBD patients who were on 6-MP and 5-ASA, they were overestimated compared to pill count as a measure of adherence (Hommel, Odell, Sander, Baldassano, & Barg, 2008). In contrast, self-reporting correctly identified 66% of IBD patients labeled as noncompliant by 5-ASA urinary assay levels (Shale & Riley, 2003). Pill counts are non-invasive but may also be

impractical. Accuracy is questionable because patients may discard medications prior to a clinic visit or not ingest them once removed from a container.

Pharmacy Refill Methods

Pharmacy refill data can be obtained from self-reports or administrative data bases. Eleven methods of measuring adherence in pharmacy databases were found in a systematic review of studies from 1999 to 2006 of patients with chronic illnesses (Hess, Raebel, Conner, & Malone, 2006). In the first systematic report of medication non-fulfillment, Gadkari and McHorney (2012) reviewed 79 studies reporting non-fulfillment rates for medications prescribed for several chronic illnesses. Nonfulfillment rates across the studies varied from .5% to 57.1% and the nonfulfillment occurred at the patient level in 59 studies, at the pharmacy level in 20 studies, and at a combination of pharmacy and patient levels in six studies.

Three common methods for measuring adherence by pharmacy refill records are the medication possession ratio (MPR), continuous medication gap (CMG), and continuous single-interval medication availability (CSA) (Steiner & Prochazka, 1999). The MPR is the ratio of the number of days of medication supplied within the refill interval and number of days in the refill interval. CMG is the ratio of total days of treatment gap and total days to next fill (Steiner & Prochazka, 1999). CSA is calculated by dividing the number of days' supply obtained at a pharmacy fill by the number of days before the next pharmacy fill (Steiner & Prochazka, 1999).

Medication-total is a measurement of compliance over a long period of refill intervals (MED-TOTAL). MED-TOTAL formula is calculated as the total number of days of pills dispensed divided by the total number of days in the refill interval (Steiner, Koepsell, Fihn, & Inui, 1988). In a study of patients with quiescent UC, there was 60% non-adherence with MED-TOTAL (Kane, Cohen, Aikens, & Hanauer, 2001). An

adherence validation study on 116 IBD patients was done by correlating the Morisky 8-item adherence scale (MMAS-8) to prescription refill rates (Trinidade, Ehrilch, Kornbluth, & Ullman, 2011). The researchers used the MMAS-8 to identify 54 patients as low adherers and 56 patients as medium or high adherers. When measured by CSA, 85% of low adherers had non-persistent fill rates, and 11% were classified as moderate adherers.

Pharmacy refill methods are usually used in large database studies. The issue of non-fulfillment may be at the provider level when prescriptions are not renewed or not done in a timely manner (Gadkari & McHorney, 2010). At the pharmacy level, unavailability of medications may result in a delay of fulfillment. Additionally, problems with communication among pharmacies, health care providers, and patients combined with lack of consideration for changes in medication scheduling by healthcare providers lead to erroneous data collection. Pharmacy refill rates do not account for variations in the usual prescribed regimen, and they do not reflect changes made by physicians over a period of time (Farmer, 1999). Additionally, data can be incomplete with mail order pharmacies, or if patients switch pharmacies, data may not be captured.

Using databases to extract data requires time and statistical knowledge that may not be within the scope and budget of the researcher. The use of retrospective databases is challenging when different measures of adherence are included (Peterson et al., 2007). It is difficult to incorporate these results in clinical practice. In an attempt to improve the accuracy of measuring adherence, electronic monitors may be more accurate but present other challenges (Dunbar-Jacob, Sereika, Rohay, & Burke, 1998).

Electronic Monitors

Medication electronic measures (MEMS) are the incorporation of electronic devices into medication containers to record the date and time of usage (Osterberg &

Blaschke, 2005). Data can be stored for several months or up to one year, downloaded, and used for analysis (Dunbar-Jacob et al., 1998). A literature review was done to understand the association between self-reported questionnaires (SRQs) and MEMS (Shi et al., 2010). Of the 11 studies that qualified, the mean adherence by MEMS was 79.9% (range 53-4%-92.9%), as opposed to 84.0% (range of 68.35%-95%) by measure of SRQs. The correlation between adherence measured by MEMS and SRQs ranged from 0.24 to 0.87, demonstrating a modest correlation between MEMS and SRQs. In a 12 month clinical trial using MEMS to monitor adherence of patients in remission with UC, patients prescribed asacol daily were significantly more adherent than those prescribed three times a day dosing (Gillespie et al., 2011).

Medication ingestion is not recorded using the MEMS, but rather when and how often the patient opens the container. Individual variations in pill usage may not accurately reflect adherence such as when a patient removes medication and stores it in another container. MEMS are expensive, cumbersome, and may result in equipment failure. Assuming the medication is taken when a pill bottle is opened results in an overestimation of adherence. MEMS are useful in that they eliminate the “white-coat effect” and provide information on long-term behavior (Hawkshead & Krousel-Woods, 2007).

Self-reports

Self-reports are simpler methods of measuring adherence and include patient kept diaries, interviews, and responses to adherence questionnaires (Hawkshead & Krousel-Wood, 2007). These methods are simple and economical to use. Additionally, they provide information on behavioral and social factors that can affect adherence, including patterns and reasons for missed doses (Hawkshead & Krousel-Wood, 2007). In self-report methods, responses that require recall may be biased when participants

give socially accepted responses (Hawkshead & Krousel-Wood, 2007). Self-report methods may result in an overestimation of adherence.

In a literature review, Greenlaw, Yentzer, O'Neill, Balkrishan, and Feldman (2010) identified 11 self-report instruments for the measure of adherence in patients with chronic illnesses. Only four of the instruments were validated by the measure of MEMS. Number of items on instruments ranged from 4-30, of which the majority were dichotomous scales of yes or no answers. In another systematic review, however, Garfield et al. (2011) identified 58 available self-report measures of medication adherence in primary care settings for routine clinical use. Among the 58 measures reviewed, authors presented validation findings for 54 measures, reliability findings for 16 measures, and time for completion in six measures. Sample sizes varied from 22 to 1,985.

Morisky Medication Adherence Scale-8-Item

The Morisky Medication Adherence Scale, a four-item scale known as the MMAS-4, is the most commonly used adherence scale (Rolley et al., 2008). The scale is based on the belief that drug omission can occur when patients are forgetful, careless, stop taking the medication when feeling better, or stop when feeling worse (Morisky, Green, & Levine, 1986). The MMAS-8-Item was developed from the original MMAS-4-Item that was used in hypertensive patients (Morisky et al., 1986). The MMAS-8-Item, a revision of the original MMAS-4-Item, was tested in 1,367 hypertensive patients with blood pressure as the criterion standard (Morisky, Ang, Krousel-Wood, & Ward, 2008). Using the scale, blood pressure control was correctly classified on a dichotomous low versus high/medium level of adherence. The adherence rate was 83.3% with sensitivity and specificity of 93% and 53% respectively. For each of the eight items, the item total correlation was greater than .30 (Morisky et al., 2008). The underlying construct, failure to

adhere to the regimen, may be related to several factors, such as forgetting, complexity of the medication regimen, problems remembering, and feeling hassled about the regimen (Morisky et al., 2008). Morisky et al. (2008) examined the psychometric properties of the scale in patients with hypertension. A second level of criterion related validity for the MMAS-8-Item was established with validation against pharmacy level records in hypertensive patients (Krousel-Wood et al., 2009). Concordance between the MMAS-8-Item and pharmacy refill records was greater than 75% (Krousel-Wood et al., 2009).

The scale was later revised into an 8-item scale which has been used in two IBD studies to date (Kane, et al., 2012; Trinidade et al., 2011). Trinidade et al. (2011) grouped patients with scores of 6-8 and 8 as medium and high adherers and those with a score less than six as low adherers. Kane et al. (2012) classified patients as adherers (score 6-8 or 8) and nonadherers (score < 6). According to Morisky and DiMatteo (2011), adherence is a behavior, and sociocultural determinants such as social support are predictive of adherence. In this medication adherence construct, the focus of adherence assessment is the behavior and not the predictors or consequences (Morisky & DiMatteo, 2011). Each item on the MMAS-8-Item measures a behavior, as reported by the participant. The MMAS-8-Item was subsequently validated in a study of 110 patients using pharmacy refill records (Trinidade et al., 2011). A Cronbach's alpha was not calculated to determine the internal consistency of the MMAS-8-Item. In the Kane et al. (2012) study conducted with a similar population of IBD patients, scores from the MMAS-8-Item were correlated with refill rates of thiopurines, an immunomodulator ($n = 150$; $r = 0.26$, $p = .02$.).

All self-report tools do not measure the same domain in the same time frame. The quality of the questions, skill level of the interviewer, and literacy of the respondent

may all affect validity. In many of the measurement methods in adherence studies, researchers do not use standardized methods of measurement. Obtaining patient reports on the specific doses missed for a complex medication regimen is difficult because patients tend to generalize about medication adherence. Despite the disadvantages of self-report, the advantages are that the method is low cost, noninvasive, and easy to administer.

In the studies reviewed, researchers used many methods of adherence measurement, making it difficult to conclude what constitutes nonadherence and how to measure this concept. When healthcare providers change therapy, it is usually with the assumption that current therapy is not efficacious. This assumption may be inaccurate. The therapy may not be efficacious because the patient is not adhering to the regimen. Measuring adherence is very important as a factor in deciding whether to change therapy.

Theories in Adherence Studies

Few studies have utilized a framework to study medication adherence in IBD patients. Horne et al. (2009) conducted the largest cross-sectional survey of 1,871 IBD patients using the Beliefs in Medication Questionnaire (BMQ). The BMQ is based on the principles of the theory of planned behavior, CSM of health and illness, and the health belief model (Horne & Weinman, 1999). Other researchers used concepts from the BMQ in the design of adherence studies (Ediger et al., 2007; Horne et al, 2009; Moshkovska et al., 2009). Two studies were found to date in which Levanthal's CSM was used to test adherence to medications in IBD patients (Dorrian, Dempster, & Adair, 2009; Knowles, Wilson, Connell, & Kamm, 2011). In empirical studies on adherence in IBD patients, the majority of researchers used similar definitions for adherence (Bernal et al., 2006; D'Inca

et al., 2008; Kane et al., 2012; Lopez-SanRoman & Bermejo, 2006; Sewitch et al., 2003; Sewitch et al., 2004).

Theories used for studies in chronic illness management may be on individual health behavior, interpersonal health behavior, or community and group intervention models (Leventhal, Weinman, Levanthal, & Phillips, 2008). In creating theory, several facets of research are necessary: observational studies, intervention studies, and clarity on the predictors of medication adherence. The paucity of theories to study medication adherence in IBD patients may be due to the lack of research on these facets.

Methodological Issues with Adherence Studies

Researchers have used several different methods of measuring adherence among IBD patients (Table 3). In some studies, researchers used validated questionnaires such as the Morisky-8-item, Morisky-4-Item, and Medication Adherence Report (MARS) questionnaires. Others used various other nonvalidated questionnaires to determine adherence, designed for specific studies. In two studies, visual analog scales were used (Bokemeyer et al., 2007; Nahon et al., 2011).

Table 3 Methods of Measuring Medication among IBD Patients

Measurement Method of Adherence	**Source**	**Sample**
Study Specific Scales	Bernal et al. (2006)	CD and UC
	D'Inca et al. (2008)	CD and UC
	Moshkovska et al. (2009)	UC
Validated Measurement Scales		
Medication Adherence Report Scale (MARS)	Horne et al. (2009)	CD and UC
Morisky 8–item	Kane et al. (2012)	CD and UC
Pharmacy refill records	Kane et al. (2001)	UC
	Kane, Huo, & Magnanti (2003)	UC
Medication Adherence Report Scale	Sewitch et al. (2003)	CD and UC

Table 3 *Continued*

Measurement Method of Adherence	Source	Sample
Morisky 8–item	Trinidade et al. (2011)	CD and UC
Interviews	Cerveny, Bortlik, Vlcek, Kubena, & Lukas (2007)	CD and UC
	Nigro, Angeline, Grosso, Caula, & Satenga-Guidetti (2001)	CD and UC
	Shale & Riley (2003)	CD and UC
Urine Analysis	Cerveny, Bortlik, Kubena et al. (2007)	CD and UC
	Moshkovska et al. (2009)	UC
	Shale & Riley (2003)	CD and UC
Blood Analysis	Bokemeyer et al. (2007)	CD
Visual Analog Scale	Bokemeyer et al. (2007)	CD
	Nahon et al. (2011)	CD and UC
Patient Diary	Mantzaris et al. (2007)	CD
Medication possession ratio (MPR)	Carter et al. (2012)	CD
Rates of missing adalimumab doses	Billioud et al. (2011)	CD
No show rates	Kane & Dixon (2006)	UC
Failure to fill one prescription and MPR	Kane & Shaya (2008)	CD

Interviews with various questions were also used in a few studies. Biological assays used as an adherence measure included both blood and urine assays. In two studies, patient diaries were used as adherence measurement (Mantzaris et al., 2007; Waters, Jensen, & Fedorak, 2005). In a few studies, two types of measurements were used to assess adherence (Bokemeyer et al., 2007; Moshkovska et al., 2009; Shale & Riley, 2003). Researchers also used pharmacy refill records as a measure of adherence, but calculated adherence in various ways.

The development of newer biologics has changed the course of IBD therapy. Doctors prescribe injectable biologics more frequently for IBD (Clark et al., 2007). Research on adherence to newer biologics, especially the self-administered injectables, is lacking. In France, Billioud et al. (2011) evaluated adherence to injectable biologics among 108 CD patients using MPR. The MPR was defined as the ratio of the total days' supply of infliximab administered during a 12-month period. To date, Kane et al. (2012) are the only researchers who included IBD patients on injectable biologics in adherence studies in the United States. Previously, Kane and Dixon (2006) used records from patients on intravenous biologics to determine adherence rates by monthly clinic attendance. Recently, Carter et al. (2012) utilized a claims database to determine if Crohn's patients attended clinics for biologic infusions. Seventy-two percent met the adherence criteria.

A variety of study designs used to research the problem of medication nonadherence in IBD patients adds to the inconsistencies in findings. The methodologies vary from direct interviews to biological assays. Participants vary across the studies in terms of numbers of persons with UC and CD. The strength of the evidence in IBD adherence studies is weakened by small samples. The samples in the majority of the studies included less than 100 subjects. A few studies had larger samples, ranging from 153 to 187 (Bernal et al., 2006; D'Inca et al., 2008; Ediger et al., 2007).

Some similarities in medication treatment for both diseases exist, however the diseases have different pathologies, and generalizations may be inaccurate. Although the majority of medications in the studies consisted of oral ASA compounds, few studies included enemas, suppositories, injectables, and intravenous therapy. Patients were in varying stages of remission and exacerbations in the studies thereby affecting their adherence rates. The methodological inconsistencies make drawing conclusions difficult.

Researchers are challenged to identify a measurement method appropriate to a study question. Health care providers have limited evidence by which to adopt a screening method for measuring nonadherence among IBD patients in their practice.

Predictors of Medication Nonadherence

Researchers have identified several predictors of medication nonadherence and adherence in IBD patients. Because studies varied in design, participants, and outcomes, there is still a need to study predictors of medication adherence. In this review, the researcher will explore demographics, treatment complexity, disease history, psychosocial issues, beliefs in medications, and others as predictors of medication adherence in IBD patients.

Demographics

Male participants in IBD medication adherence studies had a higher rate of nonadherence (Bernal et al., 2006; Ediger et al., 2007; Kane, 2006; Kane et al., 2001; Lopez-SanRoman & Bermejo, 2006). In two other studies, gender did not make a difference in adherence rates (Cerveny, Bortlik, Kubena et al., 2007; Horne et al., 2009). Single status was significantly associated with nonadherence (DeWulf, Montiero, Passos, Vieira, & Troncon, 2007; Kane, 2008). Nahon et al. (2011) found that older age was associated with adherence, and in four studies, researchers found that younger age was associated with nonadherence (D'Inca et al., 2008; Ediger et al., 2007; Horne et al., 2009; Kane, 2008). Full time employment or a busy working life was associated with poor adherence (Bernal et al., 2006; D'Inca et al., 2008; Ediger et al., 2007). Full time employment was not associated with nonadherence in two studies of IBD patients (Cerveny, Bortlik, Kubena, et al., 2007; Horne & Weinman, 1999).

Treatment Complexity

Pill burden, described as more than one pill daily, is negatively associated with adherence rates (Kane et al., 2001; Kane, 2008; Shale & Riley, 2003). Contrary to that finding, Bernal et al. (2006) found that once daily dosing of azathioprine, an immunosuppressant, is associated with poor adherence. Inconsistent with the evidence, health care providers prescribe once daily dosing of immunosuppressant therapy (Carter et al., 2004); however, in a few studies, adherence to immunosuppressant therapy was better than to other medication types (Bokemeyer et al., 2007; Ediger at el., 2007; Kane, 2008). Higher adherence rates were found among IBD patients on once daily dosing of mesalamine, a 5-ASA compound (Sandborn, Feagan, & Lichenstein, 2007). Conversely, Ediger (2007) did not find any adherence differences in multiple dosing of ASA therapy compared to once daily regimens. Patients on oral 5-ASA therapy adhered better than patients prescribed 5-ASA rectal therapy (D'Inca et al., 2008; Kane et al., 2001).

Biologics are prescribed less frequently and dosing schedules range from every two weeks to every 2-3 months. In the Nahon et al. (2011) study, patients on injectable biologics reported good adherence whereas in the Billioud et al. (2011) study, biweekly biologic injections predicted injection delays in CD patients. The adherence rate for injectable biologics for IBD was associated with better adherence than other IBD medications (DeWulf et al., 2007; Kane et al., 2001; Mantzaris et al., 2007).

Patients with UC reported that safety and efficacy of medications had precedence over dosing regimen (Gray, Leung, & Scales, 2009). In the study by Horne et al. (2009), with CD and UC patients, however, speed of symptom relief and fewer side effects were also important, but less so than safety and efficacy. Patients' concerns about side effects of medications were present in three studies (Bernal et al., 2006; Gray et al., 2009; Horne et al., 2009). On the other hand, steroids were of serious concern,

and adherence rates were lower in two of those studies (Bernal et al., 2006; Horne et al., 2009).

Patients with chronic illnesses are unable to see immediate effects of their long-term medications. Long-term use of medications such as steroids may result in adverse effects that alter body image. It is challenging to predict what contributes to medication nonadherence. Treatment complexity as defined by challenges in adhering to medication therapy is a predictor that has not been examined frequently in IBD medication adherence studies.

Disease History

Long disease duration (greater than 5 years) was associated with poor adherence in several studies (Billioud et al., 2011; Horne et al., 2009; Kane et al., 2001; Lopez-SanJuan & Bermejo, 2006; Sewitch et al., 2003); however, disease remission was also associated with poor adherence (D' Inca et al., 2008). In two studies, nonadherent patients were in chronically active disease status or relapse (Cerveny, Bortlick, Kubena, et al., 2007; Cook, Emiliozzi, El-Hajj, McCabe, & Mischa, 2010). Recent diagnosis was also associated with poor adherence (D'Inca et al., 2008). In the ISSEO survey (Impact de la Situation Soci Economique sur L'Observance), conducted in France, a sample of 1,069 IBD participants was surveyed on nonadherence behavior (Nahon et al., 2011). There were no differences in type of IBD, disease activity and severity, and adherence rates. Similarly, Horne et al. (2009) did not find type of disease was a significant factor in adherence rates in IBD patients.

Psychosocial Issues

Social support and psychological variables may be associated with adherence yet were only investigated in two studies (Nigro et al., 2001; Sewitch et al., 2004). Nonadherence was significantly related to stress, anxiety, and depression (Nigro et al.,

2001; Sewitch et al., 2003; Shale & Riley, 2003). Groups of patients who reported moderate physical and mental health symptoms were least satisfied with their doctors' visits (Sewitch et al., 2004). In the same study, Sewitch et al. (2004) found that groups of IBD patients with poor communication were four times more likely to be more nonadherent than groups with better communication. Social support may have a significant role in preventing flare-ups of IBD participants in a behavioral self-management program (Keefer et al., 2011). Participants with social support were 57% less likely to flare than participants who did not have social support.

Beliefs in Medications

In a cross-sectional study of 178 adults with hyperlipidemia, hypertension, diabetes, hyperlipidemia, osteoporosis, and other cardiovascular conditions, McHorney and Gadkari (2010) found that persistence (continuation of medications) and non-persistence (ceasing medications without a physician's order) were associated with different perceptions and concerns about medications. They concluded that individual patients held different beliefs about medications to which they persist. Patients' perceptions and beliefs in medications determine different medication-taking behavior for different medications.

In a cross sectional study on adherence in four chronic illnesses (asthma, renal, cardiac, and oncology), higher scores on "believing medications are necessary" correlated with higher reported adherence rates, and higher concerns about medications correlated with lower reported adherence rates (Horne & Weinman, 1999). In that study, the BMQ was used to assess patients' beliefs in medications. During the development of the BMQ, a chronic illness patient sample (N = 529) completed a 37- item questionnaire on specific and general beliefs about medications. Horne et al. (1999) performed psychometric testing on the BMQ 37-item scale, resulting in core themes related to

beliefs in medications. Using principal confirmatory analysis, Horne et al. (1999) identified 18 items in a 4-factor structure that related to beliefs themes. Horne et al. (1999) categorized the scale into beliefs about the necessity of a prescribed medication for controlling illness and concerns about the potential adverse consequences of taking medications. Correlations between the BMQ scales and adherence assessed by the Reported Adherence to Medication Scale (RAM) demonstrated criterion-related validity (Horne et al., 1999). Additionally, expected correlations were obtained between BMQ scale scores and other measures of illness beliefs and medications beliefs (Horne et al., 1999). In a test of temporal stability, Porteus, Francis, Bond, and Hannaford, (2009) retested participants after four years from initial testing on the general beliefs in medication scale of the BMQ. They did not find any statistically significant differences in individual's scores, indicating stability of general beliefs

A study was done using grounded theory methods to explore perspectives and beliefs about medications and how they relate to medicine taking and other health related behavior in IBD patients (Hall, Rubin, Hungin, & Dougall, 2006). One of the key emerging themes, adapting to and accepting medication use, was linked to acceptance of IBD. The largest study to date on medication adherence and patients attitudes to medicines was conducted in England among 1,871 participants with IBD (Horne et al., 2009). The necessity scale and the concerns scale of the BMQ were used to assess attitudes about medications. The theme was verified in the Horne et al. (2009) study of patients' attitudes towards maintenance therapy in IBD. They found that among low adherers, 29% had doubts about the need for maintenance therapy, and 42% showed ambivalence.

Similarly, in another study, a significant association between self-reported nonadherence and doubts about personal need for medications persisted (Moshkovska

et al., 2009). Among the 48% who were concerned about maintenance therapy, 73% felt that long term effects existed and 53% felt that dependency was an issue. Sub-analysis of beliefs in medications and type of medications revealed some interesting results in the Horne et al. (2009) study. There were no significant differences in beliefs about the necessity of 5-ASA compounds, immunomodulators, and steroid therapy. Additionally, the BMQ was shown to predict adherence in a study of 242 hypertensive patients (Ross, Walker, & Macleod, 2004). Patients who believe in the necessity of medications were more likely to be compliant, OR = 3.06, p = .001, and those with high specific concern scores were less likely to be compliant, OR = .6, p = .028. General harm and general overuse beliefs were not significant predictors of adherence; those patients using steroids as monotherapy reported the highest concerns about medications.

Patients' beliefs and concerns about medications have a significant role in medication adherence. The beliefs and concerns are related to adverse effects that patients are currently experiencing. An investigation of patients' beliefs and concerns about medications in general may predict nonadherence whether they are experiencing adverse effects or not.

Other Predictors

Ediger et al. (2007) conducted a cross-sectional study using data from the largest population based IBD Cohort study in Manitoba, Canada. Analyses revealed differences in the predictors between genders. In a study of adults with IBD, South Asian participants were more likely to be low adherers compared to non-South Asians (Moshkovska et al., 2009). In a similar study on medication adherence, ethnicity (Hispanics) was a predictor of nonadherence (Trinidade et al., 2011). McHorney and Spain (2010) analyzed results for medication non-fulfillment and medication non-persistence from an internet based survey of 19,830 respondents with chronic illnesses.

Four reasons were cited for both types of nonadherence: financial hardship, fear or experience with side effects, generic concerns about medications, and lack of perceived need for medications. Sokol, McGuian, Verbugge, and Epstein (2005) did a retrospective cohort observation of 137,277 patients with chronic illnesses other than IBD. The rates of hospitalization were lower for patients with high medication adherence. In the McHorney and Spain (2010) study, the level of medication adherence was associated with lower disease-related cost. Three of the largest studies on IBD medication adherence occurred in Canada, France, and the United Kingdom (Ediger et al., 2007; Horne et al., 2009; Nahon et al., 2011).

Summary, Implications, and Discussions

Perhaps the single most important factor in adherence studies is the measurement of adherence and the determination of what constitutes adherence. Study designs are dependent on the measurement of adherence. In this review, designs ranged from cross-sectional surveys to retrospective studies. Researchers determined what constituted adherence. They rated patients as nonadherers, low adherers, poor adherers, and moderate adherers. Researchers do not always use validated methods of adherence measurement. The MMAS and the MARS are the only two adherence scales known to the researcher that has been validated in IBD studies.

Current data on predictors of nonadherence are limited and inconsistent. In a recent review, Jackson et al. (2010) analyzed 17 studies and found that nonadherence ranged from 7% to 72%. The demographic, clinical, or treatment variables were not consistently associated with nonadherence. Few studies investigated psychosocial issues and beliefs in medications. Research on availability, storage issues, dosing, and delivery of medications is lacking. Although a few studies were done to determine frequency as a predictor of nonadherence, the results are conflicting. Studies on

predictors such as race and gender are lacking. Clearly there is a need for studies using specific models for medication adherence specific for the IBD population. The other major gap in knowledge is the lack of research on adherence to medications other than 5-ASA compounds. Health care providers prescribe injectable biologics more frequently, and there is a need to determine how IBD patients are adhering to this new therapy.

Adherence to medications in IBD patients is a complex issue. Researchers have investigated various predictors of medication nonadherence in IBD patients. To date, no study has been done in which researchers investigated both general and specific beliefs in medications and treatment complexity (delivery, frequency, availability, and storage) as predictors of medication adherence measured with the MMAS-8 in IBD patients. The purpose of this predictive correlation study was to explore whether beliefs about medications and treatment complexity are predictors of medication adherence among adults 18-65 years old with IBD.

Although it is known that patients do not adhere to medications, the inconsistencies among healthcare providers in the use of screening tools and the lack of screening for nonadherence are major problems. If the predictors of medication adherence are known, the knowledge can be disseminated to healthcare providers. Healthcare providers may use the findings to identify nonadherers, teach, and encourage them to be consistent with medication therapy. IBD medication adherence research is lacking. This study has potential for providing additional information to the body of knowledge. This information may be useful in the development of a rapid adherence scale for use by healthcare providers in outpatient practice.

Chapter 3

Methods and Procedures

The focus of this chapter is on the methods and procedures that were used to explore whether beliefs in medications and treatment complexity were predictors of medication adherence among adults 18-65 years old with inflammatory bowel disease (IBD). This chapter includes discussions of the design, sample, measurement methods, and preparation of data for analyses. A discussion of the sample includes the criteria, sampling method, and planned sample size determined by power analysis. Demographic variables from a Demographic Survey (Appendix A) and treatment and illness variables from an Illness and Treatment Survey (Appendix B) were obtained. Ethical considerations are described along with a discussion of delimitations.

Research Design

A predictive correlational design was used in this study. This design was appropriate because to date no research had been conducted to determine if beliefs in medications and treatment complexity are predictors of medication adherence among patients with IBD using the BMQ formatted for this study (Appendix C), MMAS-8-Item (Appendix D) and Treatment Complexity Scale (Appendix E). Beliefs in medications and treatment complexity, the predictor variables, were tested for changes in adherence, the criterion variable (Gliner, Morgan, & Leech, 2009). The criterion variable was dichotomous because the scoring of the variable was whether the attribute (adherence) was present or absent. In a logistic regression model (Figure 3), the researcher identified which predictors determined the characteristic, adherence (Menard, 2002). This was not an experimental study; therefore, variables were not manipulated (Gliner et al., 2009). As a result, it was not possible to establish causality.

$$\hat{Y} = \frac{e^{A+B_1X_1+B_2X_2+B_3X_3+B_4X_4+B_5X_5}}{1+e^{A+B_1X_1+B_2X_2+B_3X_3+B_4X_4+B_5X_5}}$$

Legend

$\hat{Y}$ = Estimated probability of adherence (0-1)

A = Constant in the equation

B = Coefficient of predictors

X1 = Beliefs in medications: Specific concerns

X2 = Beliefs in medications: Specific necessity

X3 = General beliefs in medications: Overuse

X4 = General beliefs in medications: Adverse effects

X5 = Treatment Complexity

Figure 3 Logistic regression model

Study Variables

The predictor variable, beliefs in medications, was delineated into two domains: specific beliefs and general beliefs (Horne, 2000b). The two specific beliefs were concerns about the harmful effects of IBD medications and beliefs of the necessity and efficacy of IBD medications. General beliefs were views of overuse and adverse effects of medications in general (Horne, 2000a). The other predictor variable was treatment complexity, an assessment of availability, frequency, storage, discomfort, and delivery of IBD medications.

Sample

Sampling Criteria

The target population was adults 18-65 years old with IBD, and the accessible population was adults 18-65 years old with IBD who became aware of the study through the recruitment methods. The study sample consisted of participants who responded to

an electronic survey (Gliner et al., 2009). Other inclusion factors were English speaking participants who had access to the internet and were on IBD medications. Through the sampling method, the researcher sought to produce a sample more heterogeneous than a clinic-based sample. It was not within the scope of this study to determine if this sample was more heterogeneous than a clinic based sample. The goal of using electronic means of recruitment was to have a sample that represented a greater spectrum of the IBD population. The final sample was *n* = 369

Definitions

IBD represents two categories of diseases: CD and UC. In this study, an adult with IBD was a person who is 18 -65 years old who was diagnosed with IBD. IBD occurs at any age, but is predominant among persons 15-30 years old; peaking with a smaller distribution in ages 50-70. Selecting a sample 18 -65 years of age would capture the majority of IBD participants without Medicare and was appropriate for a web-based sample. In contrast, 10% of cases occur in individuals younger than 18 years old (Hanauer, 2005). The study methods would make securing parental consent for participants younger than 18 years old difficult.

Sample Size

The three parameters required for a priori determination of sample size for correlation research design using logistic regression are effect size, power, and alpha level (Huck, 2010). "The effect size in logistic regression may be interpreted as the odds ratio" (Tabachnik & Fidell, 2009, p. 463). The effect size was based on the odds ratio found in two studies with IBD patients with significant findings using the specific domain scales of the BMQ 19 as predictors of medication nonadherence. Low adherence rates were associated with doubts about personal need for medications *OR* = .56, $p < .001$, 95% CI [0.48-0.64] and concerns about adverse effects about medications were

associated with low adherence *OR* = 1.66, *p* < .001, 95% CI [1.42-1.94] in an IBD population (Horne et al, 2009). Similarly, low specific necessity scores and high specific concerns scores were associated with self-reported nonadherence *OR* = .506, p = .002, 95% CI [.329- .780] and *OR* = 1.565, *p* = .035, 95% CI [1.032-2.374] respectively (Moshkovska et al., 2009). Patients who had high specific concern scores were 1.5 times more likely to be nonadherent. A power analysis using G*Power (Version 3), for a moderate effect size of *OR* = .66, alpha = .05, and beta = .20 resulted in a calculated sample size of 362 (Buchner, Erdfelder, Faul, & Lang, 2009). The proposed target sample size was increased to 400 to allow for incomplete data.

Sampling Method

Several electronic entities were used to recruit participants (Table 4). Administrators of three organization websites, two Foundation websites, and six Facebook sites were contacted with a request to consider posting information about the study on their respective media (Appendix F). The administrators either posted the recruitment memo (Appendix G) with the embedded survey link or gave the researcher permission to post the same for potential participants. Alternate posts were created for Crohn's and Colitis Foundation (CCFA) website (Appendix H) and CCFA Facebook page (Appendix I). The researcher invited the participants to fill out the survey in a convenience sampling method. Methods for recruitment included posting of the survey on organization websites for IBD support groups, IBD support groups' sites on Facebook, and on IBD foundation websites. Memos of permission were obtained for IBD support groups: Crohn's Forum (Appendix J), IBD Support Group (Appendix K) and Healing Well

Table 4 Method of Participant Recruitment

Key Contact	Source of network participants	Method
Administrators of IBD support groups.	Crohn's Forum IBD Support Group Healing Well	The researcher contacted administrators of the IBD support groups and asked them to post survey link on the organization sites.
Administrators of Facebook IBD groups	Members of Facebook IBD sites CCFA Facebook page-National CCFA Facebook North Dallas Chapter; Ulcerative Colitis and Crohn's Disease; Ulcerative Colitis; Crohn's Disease, Ulcerative Colitis, Celiacs, and any IBD/IBS awareness; Crohn's and Ulcerative Colitis Worldwide Support Site	The researcher contacted administrators of the Facebook IBD sites and asked them to post survey link on the sites.
CCFA Foundation websites	Visitors to National CCFA Foundation website and North Dallas chapter of CCFA Foundation Website	The Researcher obtained approval from the IRB of CCFA after approval of the study from the University of Texas at Arlington IRB. The Researcher contacted contact persons for CCFA website-National and CCFA website – North Dallas Chapter

(Appendix L). Facebook sites were CCFA Facebook North Dallas Chapter (Appendix M); CCFA Facebook page-National (Appendix, I); Ulcerative Colitis and Crohn's Disease (Appendix N); Ulcerative Colitis (Appendix O); Crohn's Disease, Ulcerative Colitis, Celiacs, and any IBD/IBS awareness (Appendix P); and Crohn's and Ulcerative Colitis Worldwide Support Site (Appendix Q). Foundation websites were National CCFA

Foundation website (Appendix R) and North Dallas chapter of the CCFA Foundation Website. The potential participant became aware of the survey, read it, and made a decision to respond (Figure 4).

In a recent survey, 82% of Americans adults used the internet and 66% had a high speed internet connection at home (PEW Research Center, 2012). The gaps in internet usage between white non-Hispanics and black non-Hispanics and between white non-Hispanics and white Hispanics were 9% and 7% respectively. In that survey on internet usage, a 26% gap was found between low and middle-income wage earners, and a 30% gap between those without a high school diploma and those with a college education. As a result, the external validity may have been threatened by the differences by demographic characteristics having access to the internet. Conversely, this sample type had the potential to enhance external validity because it is representative of a specific population with a specific disease and was not limited to IBD patients in care and living in one geographic area (Gliner et al., 2009). Findings from this study can potentially be generalized to others within the same age range and with the same disease. In this sample type, however, there was no guarantee that it would be a true demographic representation of this specific population.

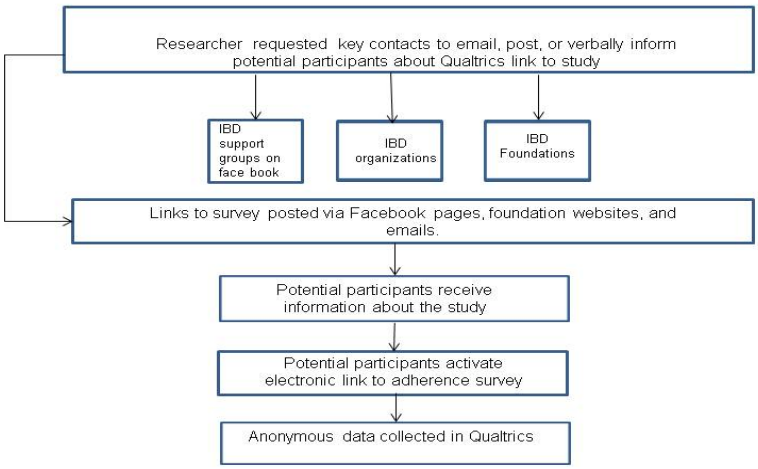

Figure 4 Data collection flowchart

Setting

The setting for this study was the location where the participant responded to the survey. Data were collected via a posted electronic link that provided participants with access to the survey presented through Qualtrics, a secure web-based electronic medium (Qualtrics, 2013). Participants had the choice to respond and complete the survey in their private setting, not respond, or respond but not complete the survey.

Measurement Methods

Three variables were measured in this study: adherence, beliefs in medications, and treatment complexity. Conceptual and operational definitions are provided in Table 5. Adherence was measured by the MMAS-8-Item, beliefs in medication measured by the BMQ, and treatment complexity measured by the Treatment Complexity Scale. This section includes discussion of the origin, theory, validity, and reliability of the instruments

used in the study. Cronbach's alpha value was computed to assess the degree of reliability of the three instruments used in this IBD population (Huck, 2010).

Table 5 Conceptual and Operational Definitions of Study Variables

Study Variable	**Conceptual Definition**	**Operational Definition**
Adherence	The extent to which a patient acts in accordance with the prescribed interval, dosing, and frequency of medication (Cramer et al., 2008).	Total scores on the MMAS-8-Item (Morisky et al., 2008).
Beliefs in Medications	People's views about medications in general and their views about specific treatments (Horne et al., 1999).	Four scales measuring four domains comprise the BMQ scale (Horne et al., 1999). Each domain scale is evaluated separately.
Specific Beliefs Concerns	The extent to which patients have concerns about specific medications for their illness leading to distrust and worry (Horne et al., 1999).	5-item scale scores of the BMQ scale (Horne et al., 1999).
Specific Beliefs Necessity	The extent to which patients' views on the necessity of their specific medicine for their illness is reflective of views that they are less likely to cope without it (Horne et al., 1999).	5-item scale scores of the BMQ scale (Horne et al., 1999).
General Beliefs Overuse	Views of how medicines are used by doctors (Horne et al., 1999).	4-item scale scores of the BMQ scale (Horne et al., 1999).
General Beliefs Harm	Patients whose views are that their medicines are intrinsically harmful would be more likely to avoid taking them (Horne et al., 1999).	4-item scale scores of the BMQ scale (Horne et al., 1999).
Treatment Complexity	Factors that are likely to disrupt medication adherence and effective management of the disease (Lakatos, 2009)	5-item scale represents method of availability, frequency, storage, and delivery of medications (Bacchus, 2013)

MMAS-8-Item

Permission was granted to use, adapt, and modify the MMAS-8-Item as needed (Appendix S) by the copyright holder of the instrument (D. E. Morisky, personal communication, May 15, 2011). In the MMAS-8-item, the level of measurement of the items is nominal. Seven of eight questions have a binary answer, where yes = 0 and no

= 1, with the exception of the response to question eight (Morisky et al., 2008). In the response to question eight, a choice of one of four numerical values, ranges from zero to four. The response is divided by four when calculating the summated score. The code response for question five was reversed in a positive direction. The summated score was a value on a 1-8 scale; patients were classified as high adherers (score = 8), medium adherers (score, 6 to < 8), and low adherers (score < 6). The MMAS-8 was easily scored and was not at an advanced reading level (D. E. Morisky, personal communication, May 15, 2011). In a study by Morisky et al. (2008), the scale evidenced high internal consistency of Cronbach's α = .83 and was significantly related to blood pressure control, $\chi 2 = 6.6$, $p < .05$. As in the literature review, a second level of criterion validity was established with hypertensive patients, and in IBD patients, MMAS scores correlated with medication refill rates. As in the Kane et al. (2012) study, the participants were classified as nonadherent if the scores were anything less than 6 and adherent for scores with a range of 6-8. MMAS-8-Item scale was chosen because the scale is brief, easily understood, economical, and previously validated in an adult IBD population. In this study, the KR-20 was .72.

Beliefs in Medications Questionnaire

The researcher received permission to use the BMQ (Appendix T). Over 50 groups of researchers have used one of eight translations of the BMQ (Horne, 2000a). The scale is comprised of two domain scales, general and specific. The BMQ-specific assesses patients' beliefs about their prescribed medicines, and the BMQ-general assesses general beliefs about all medications. The specific belief domain scale is composed of a necessity and a concern scale, and the general domain scale is composed of an overuse and a harm scale (Horne et al., 1999). The theoretical foundation of the BMQ was discussed in Chapter Two.

Internal consistency, as measured by Cronbach's alpha, was satisfactory for the specific beliefs scales and overuse scale of the BMQ (Horne et al., 1999). The specific belief domain scale has five items each for the necessity and concerns scales. Each item is rated on a 5-point Likert scale ranging from 1 = strongly disagree to 5 = strongly agree. Total scores for both scales range from 5 to 25 (Horne, 2000a). The general belief domain scale has four items in each of the two scales. Each item in both scales is rated on a 4-point Likert scale ranging from 1 = strongly disagree to 5 = strongly agree. Total scores range from 4-20 in each scale. Higher scores indicate a greater degree of belief in the specific variable. In patients with general medical conditions, reported Cronbach's alphas range from 0.51- 0.86 (Horne et al., 1999). In the Horne et al. (1999) study, the Cronbach's alpha for the Necessity, Concerns, Overuse, and Harm Scales were .90, .77, .81, and .76 respectively.

Treatment Complexity Scale

The Treatment Complexity Scale was developed by the researcher for this study to assess treatment difficulty. The first version consisted of four items to measure areas of difficulty related to availability of medications, frequency of doses, storage requirements, and method of delivery. These items were developed based on adherence literature and the researcher's personal experience and clinical knowledge. Members of the Nurse Initiatives Committee of the CCFA were asked for their input on the scale as content experts for readability, construction, and accuracy. They suggested a revision of the instructions for completion of the scale and the addition of one scale item to measure discomfort related to medication administration. In the second version of the scale, each item was rated on a 5-point Likert scale ranging from 1 = strongly agree to 5 = strongly disagree. Total scores for this scale can range from 5-25 points. Higher scores indicate a greater level of treatment difficulty as perceived by the participant. Item-total correlation

coefficients were computed to assess internal consistency. Additionally, a Cronbach's Alpha of .72 was calculated for the Treatment Complexity Scale: It is considered an acceptable value for internal consistency (Pallant, 2009).

Demographic Survey

Data were collected on the demographic variables using the Demographic Survey. The researcher collected demographic information based on the literature review and the researcher's knowledge and experience of IBD patients. In order to generalize results properly, obtaining demographic data was an essential consideration. Additionally, if other researchers would like to replicate this study, they will have a demographic description of the sample for comparison.

Illness and Treatment Survey

In order to make recommendations for practice and research, it was necessary to have illness and treatment information on the participants. The Illness and Treatment Survey was used to collect data on illness and treatment variables. The researcher collected information on illness and treatment variables based on the literature review and the researcher's knowledge and experience of IBD patients. As discussed in Chapter Two, previous studies reveal conflicting data on illness and treatment variables; however, not all of these variables have been researched in IBD patients. Information on variables such as frequency, methods of administration, type of medication, illnesses, and adverse effects were collected to add to the interpretation of the study results. The Treatment Complexity Scale measured complexity of methods, storage, availability, discomfort, and frequency. It was necessary to gather specific information on those variables for a richer interpretation of the study results. Due to the complex nature of the illness and treatment of IBD, many of the variables may be confounding factors. In this study, the researcher

did not include controlling for confounding variables in the statistical analyses, but interpretation may be more robust with a description of potentially confounding variables.

Procedure

Methods of Data Collection

Surveys were formatted for a secure web-based electronic survey. The researcher contacted several IBD Facebook sites, IBD organizations and several foundation websites. Potential participants received the attachment about the purpose of the study, the consent, and how long the survey would take to complete. In the requests, participants were directed to click on the link, which lead them to the consent form, (Appendix U) and the survey.

Data were collected using an electronic version of the MMAS-8-Item, BMQ, Treatment Complexity Scale, Demographic Survey, and Illness and Treatment Survey. The data collection process was followed as per the data collection flow chart (Figure 4). After the potential participant read the electronic message about the study, he or she had access to the survey link and consent form. Clicking to continue was equated with consent to participate in the research under the described terms and conditions. If the participant declined, closing the browser terminated the survey. No personal identifiers were collected, and responses were not linked to computer addresses, therefore, data collection was anonymous.

Ethical Considerations

Review Process

The researcher submitted the protocol to the Institutional Review Board (IRB) of University of Texas at Arlington (UTA) for exemption status for the use of human subjects. Names of participants and source of data were not identified, minimizing the potential risk of violation of confidentiality. The risk was minimal because there was no

requirement for written documentation of consent for this study. The opportunity to participate in the study was available to all potential participants who had access to a computer and the internet. The IRB of UTA agreed that the study was exempted and data collection was begun (Appendix V). Four revisions to the protocol were approved by the IRB of UTA (Appendix W, X, Y and Z).

Risk/Benefit

In this study, minimal risk to the participant for breach of confidentiality existed because no personal identifiers were generated from a secure web-based electronic survey. If the participants perceived the questions as intrusive, they had the option to terminate the study at any point without repercussions. A possible benefit was feeling they were contributing to the knowledge needed to alleviate one of the problems of IBD, adherence to medications. Because of this intrinsic motivation, participants may have believed that their contribution was worthy and may have responded to the questions honestly. The IBD population may benefit because healthcare providers will have data on medication adherence. Healthcare providers may be able to use this information to collaborate with patients to improve adherence rates. Information from this study may also be applicable to treatment in other chronic conditions.

Delimitations

A convenience sample of 369 participants who had access to the internet were included in the study. They were recruited by reading postings on IBD support groups on Facebook, IBD foundation websites, and free standing websites of which they are members. These participants are more likely to be proactive enough to be visiting websites, and, as a result, may be more knowledgeable about this disease.

Data Analyses

Preparation of Data for Analyses

Data were prepared for statistical analysis as depicted in Figure 5. The researcher downloaded data as per the online survey from Qualtrics into Microsoft Excel (2012) and recoded the variables. In Microsoft Excel, ordinal variables of the BMQ, MMAS-8-Item, and Treatment Complexity Scale were reversed and computed to reflect the scale values. New variables were created for total scores of the BMQ, MMAS-8-Item, and Treatment Complexity Scale. Following the recoding, the researcher downloaded the data from Microsoft Excel into the software Statistical Packages for Social Sciences (SPSS), Version 20, for statistical analyses. Data were recoded in SPSS to reflect the variable names and values. Participants with low adherence levels and those with medium and high adherence levels on the Morisky adherence scales were classified as nonadherent and adherent respectively.

Adherence, the criterion variable, was coded as one, representing the presence of the characteristic. Nonadherence was coded as zero, representing the absence of the characteristic. The scores of the four subscales of the BMQ and Treatment Complexity Scale were continuous, with higher scores indicating more of the variables. The demographic variables and the illness and treatment variables were collected through the online survey also. Data were cleaned and examined for missing components and statistical tests were subsequently conducted to answer the research questions.

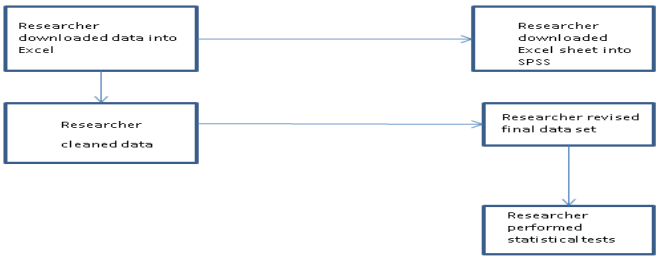

Figure 5 Data preparation for statistical testing

Data Cleaning

Four hundred and twenty-nine participants were recorded in Qualtrics. Frequencies and descriptive statistics from SPSS were used to detect correct coding of data names, outliers, and missing values. Participants, who did not proceed with the questionnaire, did not list medications, were less than 18 years old or did not identify a disease, were deleted from the sample. Of the remaining 410 participants, those with incomplete measurement variables were deleted from the sample. Surveys with missing data for nominal geographic variables other than age were accepted in the analysis. Missing data was determined to range from 0-1.9% for each item in the demographic and the illness and treatment surveys for the cases kept in the study with completed scales data. The final data set consisted of 369 cases. Participants were coded into 2 groups; those with complete data and those with incomplete data.

Statistics for Data Cleaning

Pearson chi-squares were calculated for nominal demographic variables to determine if the demographics (race, ethnicity, health insurance status, education, and gender) and type of illness of the deleted sample were similar to participants who were selected for the study. Data were computed only for variables with a cell count of 5 or

more to satisfy the assumption for Pearson chi-square analysis (Polit, 2010). No significant statistical differences were found between the two groups for gender, education, type of illness, and health insurance status (Table 6).

Table 6 Pearson Chi-square for Complete and Incomplete Cases

Variable	***df***	X^2	**Sig.(2-tailed)**
Gender	1	.528	.467
Education	1	.793	.373
Type of illness	1	.148	.700
Health Insurance status	1	.301	..582

Shapiro-Wilk, a test for normality, was computed to assess the distribution of age, .954; *df* 406, *p <.0001 (*Pallant, 2012*).* A significant value indicated violation of normality assumption. A Mann-Whitney U test was computed to compare age of complete cases and incomplete cases; no difference was found between the two groups Z = -.746, p = .456.

In logistic regression, normally distributed data are not necessary (Polit, 2010). Shapiro-Wilk statistics were calculated to determine the normality of the continuous variables of the BMQ and Treatment Complexity Scale. The continuous variables were entered in the regression regardless of significance because the criterion variable is dichotomous (Fields, 2005).

Assumptions

1. Logistic regression: No assumption of a linear relationship between the criterion variables and the predictors was made (Polit, 2010); therefore it was not necessary to have normally distributed variables. In this study, the outcome variable is categorical: adherent or nonadherent.
2. Multicollinearity: In the ideal situation, the predictor variables should be strongly related to the criterion variable, but not to each other (Pallant, 2009). In SPSS, collinearity diagnostic analyses were calculated and the coefficients

table analyzed for tolerance values and variance inflation factor (VIF) Tolerance values less than .20 or .10 indicate that the variable has high correlations with other variables in the model (Pallant, 2009). All the variables had tolerance values greater than 1.0 and were maintained in the regression model.

Data Analyses for Research Questions

Question one

Which belief about medications is the strongest predictor of adherence to IBD medications?

The proposed model (Figure 3) shows potential predictors of nonadherence to medications. Multicollinearity statistics, tolerance and VIF were calculated to determine the degree to which the predictor variables were related to each other. The logistic regression was calculated to determine which predictor variables (beliefs in medications) predicted the criterion variable (medication nonadherence). First, an initial model with only a constant in the equation was requested as per the entry method in a bivariate analysis (Field, 2005). The model was examined to see if it correctly predicted 100% accurately nonadherent participants. The Wald statistic was calculated to detect the variables that were statistically significant in the model (Polit, 2010). Hosmer-Lemeshow test was computed to determine how well the model fits the data. The confidence interval, a range of values, was reported as 95% confidence of the true value of the odds ratio (Huck, 2010). The variables were continuous, and it was possible to predict percentage likelihood of adherence for every unit increase in the predictor scales. The odds ratio was calculated to determine the predictive nature of each variable in the model (Huck, 2010).

Question Two

Is treatment complexity a predictor of nonadherence?

The research question was addressed by using logistic regression. Because the predictor was significant in the model, the odds ratio was examined to determine how much the odds of adherence were increased for every unit increase of the treatment complexity score (Polit, 2010). The confidence interval, a range of values, was reported as 95% confidence of the true value of the odds ratio (Huck, 2010).

Descriptive Statistics

In order to improve accuracy, participants were asked to list the names of their IBD medications. The researcher classified the medications into five categories: Immunomodulators, biologics, 5-ASA compounds, steroids antibiotics, and other. The researcher calculated frequencies and percentages of all demographic and treatment and illness variables. Frequency distribution of responses to each item of the four belief scales measured by the BMQ, responses to the MMAS-8-Item, and responses of the Treatment Complexity Scale were computed to understand the frequency of each item across the participants. This computation provided further insight into the construct of the five scales and presented the individual items for post-hoc analyses. Descriptive statistics including mean, range of scores, Shapiro-Wilk, skewness, and standard deviations were calculated for age, number of year with disease, and total scores of all predictor variables. Pearson chi-squares were calculated to explore the relationship of selected nominal variables and illness and treatment variables between the adherent and nonadherent groups.

Reliability of Scales

Cronbach's alphas were calculated on the four BMQ scales and Treatment Complexity Scales to assess the internal consistencies of the scales. K-R 20 was done to

assess the reliability of the dichotomous MMAS-8-Item. The Treatment Complexity Scale was also analyzed for item-total correlation because it was tested initially in this research.

Chapter Summary

In this chapter, methods and procedures for data collection were discussed along with specific plans to describe the demographic, illness and treatment variables, and instrument items. The research design, delimitations, ethical considerations, and preparation of data for analyses were also discussed. An outline of the methodology of answering the two research questions was discussed along with the reliability of the instruments.

Chapter 4

Results

In this chapter, findings of the study are presented. The chapter begins with descriptive characteristics for variables of the sample, followed by results of analyses for comparing complete cases (participants with complete measurement data) and incomplete case (participants with missing measurement data).

The results of the Illness and Treatment Survey, and the six measurement scales used in the study are described. The quantitative analyses are presented to answer the two research questions. Results comparing adherent and nonadherent participants on selected demographic and treatment and illness variables are presented followed by statistics on the reliability of the four measurement instruments.

Descriptive Statistics of Demographic Variables

The sample was primarily white, non-Hispanic, females (Table 7). Seventy-eight percent live in the US, and over 50% of participants were married or living together. Although less than 50% work full time, the majority (over 80%) has health insurance, and 23% of all participants reported that insurance covered all of their IBD medications. The majority of participants live with adults only, and of the entire sample, 87.7% was educated at a level higher than high school, and a majority (75%) learned of the survey through Facebook sites. The majority of participants were white and non-Hispanic. In Nguyen et al (2009) study, black IBD patients exhibited lower adherence compared to white counterparts. In this study, the number of black participants was too low to fulfill statistical criteria to examine differences between groups. Considering cultural differences for illness and treatment, generalizing to other populations must be done with caution.

Table 7 Descriptive Statistics Demographic Variables

Demographic Variable	Response	*n* (%)
Lives in the US (*n* = 369)	Yes No	289(78.3) 80(21.7)
Gender (*n* = 367)	Male Female	67(18.2) 301(81.8)
Race (n=368)	White Black/African American American Indian/Native Alaskan Asian Two or more races	345(93.8) 4(1.1) 1(0.3) 6(1.6) 12(3.3)
Ethnicity (*n* = 369)	Hispanic	15(4.1)
Marital status (*n*=369)	Unmarried Married/Living together Divorced Widowed	128(34.7) 208(56.4) 31(8.4) 2(0.5)
Employment Status (*n*=368)	Full time Part time Unable to work due to illness Retired Student Unemployed, but want to work	182(49.7) 52(14.2) 64(17.5) 9(2.5) 41(11.2) 18(4.9)
Highest level of education (*n*=368)	High School graduate or less Higher than high School	44(12) 324(88)
Health insurance (*n*= 367)	Yes No	309(84.2) 58(15.8
Degree to which insurance covers your Crohn's/ulcerative colitis medications (*n*=362)	All of it Portion of it None of it Not applicable	85(23.5) 209(57.7) 12(3.3) 56(15.5)
Living arrangement (*n*=369)	Alone With adults With children With adults and children	58(15.7) 173(46.9) 22(6.0) 116(31.4)

Table 7 *Continued*

Demographic Variable	Response	*n* (%)
Source of survey (*n*=368)	Facebook Organization Friend Flyer Other	277(75.3) 59(16.0) 4(1.1) 1(0.3) 27(7.3)

The participants were 18-65 years old with a mean age of 35.85, and they had been diagnosed for a wide range of years (Table 8). Skewness was positive for age and number of years participants reported having a diagnosis of IBD. Most respondents were younger and had less number of years with IBD. Shapiro-Wilk statistics for reported age of participants and number of years with IBD suggested violation of normality assumptions, $p < .0001$ (Pallant, 2009).

Table 8 Descriptive Statistics of Continuous Demographic Variables

Variables	Range	Mean	*SD*	Skewness	Shapiro-Wilk
Years with illness	1-49	10.82	10.82	1.37	.864, *df* 369; $p < .0001$
Age in years	18-65	35.85	35.85	.517	.959, *df* 369; $p < .0001$

Descriptive Statistics of Illness and Treatment Variables

Almost two thirds of the participants had Crohn's disease (Table 9). Approximately one-fourth of the sample viewed their current condition as controlled. Less than 10% considered their current condition severe. Respondents were asked to report all types, frequencies, and methods of medication administration; as a result, the parentages reported total > 100%. Of the sample of 369, one-third were on immunomodulators and steroids, and 50% were on biologics and 5-ASA compounds. The majority reported oral route, one-third subcutaneous, and approximately 20% rectal

and intravenous medications. Few participants had more than one or two doses per day. Although 53.7% reported side effects from medications, only 36% reported treatment for side effects related to IBD medications. Almost half reported taking medications for other illnesses. Slightly over one third of the respondents reported a change in IBD medications in the last three months, and about one-third reported a history of surgery for IBD. The most frequently reported illnesses were depression (31.7%), arthritis (27.9%), asthma (16.5%), obesity (11.4%), and hypertension (8.9%).

Table 9 Descriptive Statistics of Illness and Treatment Variables

Illness and Treatment Variables	**Response**	***n* (%)**
Type of illness	Crohn's Ulcerative colitis	237(64.2) 132(35.8)
View of current condition	Controlled Mild Activity Moderate Activity Severe Activity	91(24.7) 143(38.8) 108(29.3) 27(7.3)
Medications taken for Crohn's/ulcerative colitis	Immunomodulators Biologic ASA compounds Steroids Antibiotics Other	143(38.8) 171(46.3 199(53.9) 118(32) 15(4.1) 116(31.4)
Frequency of Medications	Daily More than once per day Every week Every 2 weeks Every month Every 3 months None as listed	186(50.4) 193(52.4) 33(8.9) 74(20.1) 33(8.9) 10(2.7) 36(9.8)
Methods by which medications are taken	Oral Subcutaneous Rectal Intravenous Other	312(84.6) 115(31.2) 66(17.9) 85(23.0) 6(1.6)

Table 9 *Continued*

Illness and Treatment Variables	Response	*n* (%)
Side effects with Crohn's/ulcerative colitis medications now	Yes	198(53.7)
Treated for side effects from Crohn's/ulcerative colitis medicine	Yes	133(36)
Surgery	Yes	121(32.8)
Change in Crohn's/UC medications in last 3 months	Yes	148(39.6)
Presence of other illnesses	Asthma Arthritis Cancer COPD Depression Diabetes Hyperlipidemia Hypertension Obesity Osteoporosis None of the above	61(16.5) 103(27.9) 3(0.8) 4(1.1) 117(31.7) 5(1.4) 4(1.1) 33(8.9) 42(11.4) 27(7.3) 156(42.3)
Taking medications for other illnesses	Yes No Not applicable	181(49.1) 168(45.5) 20(5.4)

Internal Consistency of Instruments

The Cronbach's alpha for the five independent scales were all at .70 or greater (Table 10). KR-20 was reported at .72 for MMAS-8-item.

Table 10 Internal Reliability Values for Instruments

Scale	Cronbach's alpha	KR-20
Beliefs in Medications Specific - Necessity	.90	
Beliefs in Medications Specific – Concern	.77	
Beliefs in Medications General – Overuse	.81	

Table 10 *Continued*

Scale	Cronbach's alpha	KR-20
Beliefs in Medications General – Harm	.76	
Complexity Treatment Scale	.73	
MMAS- 8 Item		.72

In the treatment Complexity Scale, the corrected item-total statistics were .357, .429, .498, .644 and .530 for items 1 to 5 respectively. The corrected item-total correlations show the extent to which each item correlates with the total score. According to Pallant (2009), a value less than .3 for an item indicates that it is measuring something different from the scale. The Cronbach's alpha is .73, usually acceptable, but values above .83 are preferable (Pallant, 2009).

Description of the Scales

Descriptive Statistics of Beliefs in Medication Questionnaire

Frequency distributions are presented for items of the 4 independent beliefs variables. According to the distributions of the responses to concerns scale, most respondents were concerned about the adverse long-term effects of their IBD medicines, and they expressed worry about taking their medications (Table 11).

Table 11 Frequency Distribution of Responses for the BMQ-Specific Concerns

Beliefs about specific concerns about medications	Strongly Agree *n* (%)	Agree *n*(%)	Uncertain *n*(%)	Disagree *n*(%)	Strongly Disagree *n*(%)
Having to take my Crohn's or ulcerative colitis medicines worry me	109 (29.5%)	128 (34.7%)	45 (12.2%)	66 (17.9%)	21 (5.7%)

Table 11 *Continued*

I sometimes worry about the long-term effects of my Crohn's/Ulcerative Colitis medicines	181 (49.1%)	125 (33.9%)	29 (7.9%)	26 (7.0%)	8 (2.2%)
I sometimes worry about becoming too dependent on my Crohn's/ulcerative colitis medicines	64 (17.3%)	108 (29.3%)	46 (12.5%)	101 (27.4%)	50 (13.6%)
My Crohn's/ulcerative colitis medicines are a mystery to me	19 (5.1%)	50 (13.6%)	50 (13.6%)	167 (45.3%0	83 (22.5%)
My Crohn's/ulcerative colitis medicines disrupt my life	47 (12.7%)	79 (21.4%)	62 (16.8%)	137 (37.1%)	44 (11.9%)

Although the majority of participants believed that medications were necessary, between 11-19% were uncertain as to their necessity (Table 12).

Table 12 Frequency Distribution of Responses to the BMQ-Specific Necessity

Beliefs about the necessity of medicines prescribed for Crohn's/ulcerative colitis	Strongly Agree *n* (%)	Agree *n* (%)	Uncertain *n* (%)	Disagree *n* (%)	Strongly Disagree *n* (%)
My health in the future will depend on Crohn's/ulcerative colitis medicines	147 (39.8%)	129 (35.0%)	72 (19.5%)	14 (3.8%)	7 (1.9%)
My health, at present, depends on Crohn's/ulcerative colitis medicines	195 (52.8%)	112 (30.4%)	43 (11.7%)	14 (3.8%)	5 (1.4%)
My life would be impossible without Crohn's/ulcerative colitis medicines	149 (40.4%)	116 (31.4%)	67 (18.2%)	32 (8.7%)	5 (1.4%)
Without Crohn's/ulcerative colitis medicines I would be very ill	187 (50.4%)	100 (27.1%)	63 (17.1%)	14 (3.8%)	5 (1.4%)
My Crohn's/ulcerative colitis medicines protect me from becoming worse	159 (43.1%)	147 (39.8%)	50 (13.6%)	11 (3.0%)	2 (0.5%)

The most frequently selected response to whether doctors overuse pharmaceuticals and medicines was “uncertain” (Table 13). Responses as to whether doctors place too much trust in medicines were distributed across the responses.

Table 13 Frequency Distribution of Responses to the BMQ-General Overuse

Beliefs about the way in which medicines are used by doctors	Strongly Agree *n* (%)	Agree *n* (%)	Uncertain *n* (%)	Disagree *n* (%)	Strongly Disagree *n* (%)
If doctors had more time with patients they would prescribe fewer medicines	31 (8.4%)	74 (20.1%)	129 (35.0%)	100 (27.1%)	35 (9.5%)
Doctors use too many medicines	57 (15.4%)	96 (26.0%)	109 (29.5%)	89 (24.1%)	18 (4.9%)
Doctors place too much trust on medicines	32 (8.7%)	102 (27.6%)	75 (20.3%)	123 (33.3%)	37 (10.0%)
Natural remedies are safer than medicines	26 (7.0%)	52 (14.1%)	141 (38.2%)	101 (27.4%)	49 (13.3%)

Most participants strongly disagreed or disagreed on all items of the General Harm Scale indicating that they did not believe medications in general were harmful (Table 14).

Table 14 Frequency Distribution of Responses to the BMQ- General Harm

Beliefs about the intrinsic nature of medicines in general	Strongly Agree *n* (%)	Agree *n* (%)	Uncertain *n* (%)	Disagree *n* (%)	Strongly Disagree *n* (%)
Most medicines are addictive	11 (3.0%)	14 (3.8%)	76 (20.6%)	172 (46.6%)	96 (26.0%)
Medicines do more harm than good	7 (1.9%)	27 (7.3%)	89 (24.1%)	175 (47.4%)	71 (19.2%)
People who take medicines should stop their treatment for a while every now and again	10 (2.7%)	22 (6.0%)	96 (26.0%)	141 (38.2%)	100 (27.1%)
All medicines are poisons	6 (1.6%)	19 (5.1%)	54 (14.6%)	140 (37.9%)	150 (40.7%)

Descriptive Statistics of Predictor Variables

The highest mean scores were for necessity, followed by concern, overuse, complexity and harm respectively (Table 15). The mean score for total complexity was closer to beliefs-harm than any other beliefs mean score. Although treatment complexity total scores were not negatively skewed, beliefs-necessity total scores and total concerns scores were negatively skewed, reflecting a clustering of scores on the higher range (Pallant, 2009). Total scores for harm, complexity and overuse were positively skewed indicating that the minority of respondents rated these two scales at a lower level. All of the Shapiro-Wilk values for the predictor variables are significant suggesting violation of normality assumptions, a criterion acceptable for logistic regression (Polit, 2010).

Table 15 Description of Predictor Variables Scores

Study Measures	Range	Mean Score	*SD*	Skewness	Shapiro-Wilk (*df* 369)
Beliefs in Medications Specific - Necessity	5-25	20.81	3.92	-1.026	.893; $p < .0001$
Beliefs in Medications Specific – Concern	5-25	16.14	4.32	-.237	.985; $p < 0001$
Beliefs in Medications General – Overuse	4-20	11.80	3.54	.251	.979; $p = .0001$
Beliefs in Medications General – Harm	4-19	8.44	2.90	.770	.948; $p < .0001$
Treatment Complexity	5-25	10.63	3.92	.329	.952; $p < .0001$

Descriptive statistics Treatment Complexity Scale

Most respondents indicated that their medication regimens were not complex (Table 16). The mean score was 10.63 (SD 3.92) on a possible range of 5 to 25.

Table 16 Frequency Distribution of Responses to the Treatment Complexity Scale

Degree of complexity of medications	Strongly Agree *n* (%)	Agree *n* (%)	Uncertain *n* (%)	Disagree *n* (%)	Strongly Disagree *n* (%)
It is difficult for me to take my medications because I do not always have my medications with me when I am scheduled to take them.	7 (1.9)	59 (16.)	16 (4.3)	169 (45.8)	118 (32.0)
It is difficult for me to take my medications because of how often they are prescribed.	12 (3.3)	59 (16.0)	20 (5.4)	164 (44.4)	114 (30.9)
It is difficult for me to take my medications because I have to store them in a special way.	4 (1.1)	40 (10.80	14 (3.8)	164 (44.4)	147 (39.80
It is difficult for me to take my medications because of how I have to take them.	16 (4.3)	61 (16.5)	18 (4.9)	152 (41.2)	122 (33.1)
It is difficult for me to take my medications because I have discomfort with the injections/suppositories/enemas/pills.	27 (7.3)	64 (17.3)	20 (5.4)	139 (37.7)	119 (32.2)

Descriptive Statistics of the MMAS--8-Item

Frequency distributions are presented for the MMAS-8-Item (Table 17). Scores were calculated as per Morsiky's instructions. Item five is a reverse of the score where a positive answer is a score of one. Approximately 50% of respondents reported that they sometimes forgot to take their medications, and 53% of participants felt hassled about taking their IBD medications.

Table 17 Frequency Distribution of Responses to the MMAS-8-Item

Item	***Yes* = *n* (%)**
1. Do you sometimes forget to take your medicine?	183(49.6)
2. People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medicine?	149(40.4)
3. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?	129(35.0)
4. When you travel or leave home, do you sometimes forget to bring along your medicine?	96(26)
5. Did you take all of your medicine yesterday?	286(77.5)
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	104(28.2)
7. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	197(53.4)
8. How often do you have difficulty remembering to take all of your medicine?	Frequency *Yes* = *n* (%)
Never/rarely	157(42.5)
Once in a while and sometimes	197(53.4%)
Usually and all the time	15(4.1)
Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095-1772.	

Categorization of adherence was based on the Kane et al (2012) study and the Trinidade et al (2011) study. The majority of participants rated themselves as having low and moderate adherence levels with high adherence accounting for only 9.5% of the sample (Table 18).

Table 18 Frequency Distribution for Levels of Adherence

Levels of Adherence	Frequency	Percent (%)
Low adherence	209	56.6
Moderate Adherence	125	33.9
High Adherence	35	9.5
Total	369	100.0

When adherence was reclassified as a categorical value the number of participants categorized as adherent or nonadherent were 160(43.4%) and 209(56.6%) respectively (Table 19).

Table 19 Levels of Adherence Reclassified into Groups

Groups	Frequency	Percent (%)
Nonadherent	209	56.6
Adherent	160	43.4
Total	369	100.0

Logistic Regression Analysis

The assumptions of logistic regression include multicollinearity (Table 20). The tolerance values were above .0001, the default for excluding a multicollinear variable in SPSS (Polit, 2010). Each variable in the model resulted in a VIF below three, the reciprocal of tolerance, and were kept in the logistic regression model.

Table 20 Collinearity Statistics of Predictor Variables

Model	Tolerance	VIF
Constant		
Beliefs in Medications Specific - Necessity	.793	1.261
Beliefs in Medications Specific – Concern	.585	1.710
Beliefs in Medications General – Overuse	.504	1.963

Table 20 *Continued*

Model	Tolerance	VIF
Beliefs in Medications General – Harm	.484	2.066
Treatment Complexity	.765	1.307

The results of the full model (Table 21) contain all the predictors: [X^2 (5, N = 369) = 66.14, p <.0001]. The model as a whole explained between 16% (Cox and Snell R square) and 21.9% (Nagalkerke R squared) of the variance in adherence and correctly classified 65.0% of the cases (Pallant, 2009). Hosmer-Lemeshow Test was 6.112 with a nonsignificant level of .624 supporting that the model was a good fit. The Wald statistic was only significant for two predictors (specific beliefs-necessity and treatment complexity) suggesting that these predictors contributed to the model statistically. The odds ratio for treatment complexity was .824 (95% CI = .768 - 884), p <.0001, which is less than one, indicating that for every unit increase in treatment complexity participants were 18% less likely to be adherent (Pallant, 2009). The strongest predictor of adherence was specific necessity beliefs, 1.102 (95% CI = 1.062 - 1.143), p <.0001, indicating that for every unit increase in necessity beliefs, participants were 11% more likely to be adherent (Pallant, 2009).

Table 21 Logistic Regression Predicting Likelihood of Reporting Adherence

Predictors	**Adjusted Odds Ratio**	**95% C.I. for EXP(B)**		**Sig**
	Exp(B)	**Lower**	**Upper**	**(*p* value)**
Specific Beliefs Concerns	.989	.925	1.058	.755
Specific Beliefs Necessity	1.102	1.062	1.143	<.0001*
General Beliefs Harm	1.015	.909	1.133	.795

Table 21 *Continued*

General Beliefs Overuse	.980	.902	1.066	. 644
Treatment Complexity	.824	.768	.884	<.0001*

* Significant at p < .05

Adherence and Demographic Variables

Only 37.5% of participants who do not live in the US reported adherence versus 45% of US residents (Table 22). For living arrangements, participants living with adults and children reported the lowest levels of adherence. Adherers and nonadherers did not have significant differences for gender, education level, possession of health insurance, or marital status. There were no significant differences in percentage of adherent and nonadherent participants from the US and outside the US; however, the results should be interpreted with caution because treatment factors may vary for medications as well as other treatment variables in other countries.

Table 22 Frequencies of Demographic Variables for Adherent and Nonadherent groups

Variables	**Adherent (*n*)%**	**Nonadherent (*n*)%**	**df**	X^2	***p***
Gender					
Male	31(46.3)	36(53.7)	1	.260	.610
Female	129(42.9)	172(57.1)			
Lives in US					
Yes	130(45)	159(55)	1	1.428	.232
No	30(37.5)	50(62.5)			
Health Insurance					
Yes	133(43.0)	176(57)	1	.063	.801
No	32(55.2)	26(44.8)			
Marital Status					
Unmarried	59(46.1)	69(53.9)	1	2.031	.154
Married/Living Together	87(41.8)	121(58.2)			
Divorced	13(41.9)	18(58.1)			
Widowed	1(50)	1(50)			

Table 22 *Continued*

Variables	Adherent (*n*)%	Nonadherent (*n*)%	df	X^2	*p*
Living Arrangement					
Alone	26(44.8)	32(55.2)			
With adults	82(47.4)	91(52.6)	3	4.629	.201
With children	11(50)	11(50)			
With adults and children	41(35.3)	75(64.7)			
Education					
Higher than high school	142(43.8)	182(56.2)			
High School	17(36.6)	27(61.4)	1	.425	.514

Illness and Treatment Variables

Participants who reported no adverse effects from IBD medications reported higher adherence rates than those who did (Table 23). Respondents on biologics reported being adherent more than subjects not on biologics. More respondents who reported depression were nonadherent versus those who did not report depression. Similarly, more participants on steroids and 5-ASA compounds reported not being adherent. Respondents who reported obesity were nonadherent versus those who did not report obesity. Pearson chi-square test for independence indicated significant association between adherence and reporting of depression, obesity, use of biologics and 5-ASA compounds, and intravenous method of medication administration.

Table 23 Frequencies of Illness and Treatment Variables Adherent and Nonadherent groups

Variables	Adherent (*n*)%	Nonadherent (*n*)%	*df*	X^2	*p*
Illness					
Crohn's	106(44.7)	131(55.3)	1	.503	.478
Ulcerative Colitis	54(40.9)	78(59.1)			
Surgery					
Yes	51(42.1)	70(57.9)	1	.130	.719
No	109(44.1)	138(55.9)			
Adverse Effects from Crohn's/UC medications					
Yes	79(39.9)	119(60.1)	1	2.084	.149
No	81(47.4)	90(52.6)			
Change in treatment					
Yes	63(43.2)	83(56.8)	1	.000	.986
No	96(43.2)	126(56.8)			
Treatment adverse effects					
Yes	56(42.1)	77(57.9)	1	.152	.697
No	103(44.2)	130(55.8)			
Biologics					
Yes	88(51.5)	83(48.5)	1	8.517	.004*
No	72(36.4)	126(63.6)			
One or more steroids					
Yes	45(38.1)	73(61.9)	1	1.928	.165
No	115(45.8)	136(54.2)			
5-ASA compounds					
Yes	73(36.7)	126(63.3)	1	7.841	.005*
No	87(51.2)	83(48.8)			
Immunologics					
Yes	62(43.4)	81(56.6)	1	.000	.999
No	98(43.4)	128(56.6)			
Intravenous Method					
Yes			1	5.204	.023*
No	46(54.1)	39(45.9)			
	114(40.1)	170(59.9)			
Depression					
Yes	40(34.2)	77(65.8)	1	5.869	.015*
No	120(47.6)	132(52.4)			

Table 23 *Continued*

Variables	Adherent (*n*)%	Nonadherent (*n*)%	*df*	X^2	*p*
Obesity					
Yes	8(19)	34(81)	1	1.40	.001*
No	152(46.5)	175(53.5)			
Arthritis					
Yes	42(40.8)	61(59.2)	1	.388	.533
No	118(44.4)	148(55.6)			
Asthma					
Yes	30(49.2)	31(50.8)	1	1.088	.315
No	130(42.2)	178(57.8)			
Hypertension					
Yes	12(36.4)	21(63.6)	1	.722	.395
No	148(44.0)	188(56.0)			
Osteoporosis					
Yes	16(59.3)	11(40.7)	1	2.998	.083
No	144(42.1)	198(57.9)			

* Significant at p < .05

Shapiro-Wilk statistics computed on the sample for age in years and number of years with IBD was significant suggesting violation of normality assumptions, $p < .0001$ (Pallant, 2009). A Mann U Whitney test indicated no significant differences between the nonadherent group and the adherent group for reported number of years with IBD and age; $Z = -.776$, $p = .458$; $Z = -.080$, $p = .936$ respectively.

Chapter Summary

In this chapter, descriptive statistics of all demographic, illness and treatment variables, and scale items were presented. Reliability analyses of instruments were discussed. Participants' beliefs in the necessity of IBD medications were greater than their beliefs in the overuse of medications in general, but less than beliefs in the harm of medications in general. Participants viewed their IBD treatment as more complex than their beliefs in overuse of medications in general but lower than beliefs in the harm of

medications in general. In the logistic regression computation, necessity belief was the only predictor of adherence among the four beliefs, and treatment complexity was a predictor of adherence. Significant associations were found between adherence and use of biologics and 5-ASA compounds, presence of depression and obesity, and intravenous method of medication administration.

Chapter 5

Discussions and Implications

This chapter includes a discussion of the major findings of the study. Strengths, limitations, and implications for research are presented. Findings of the logistic regression are integrated in the discussions along with implications for practice. In conclusion, recommendations are made on possible applications of the findings to improve medication adherence rates in IBD patients.

Discussion of Demographic Variables

Patients' characteristics of gender, disease type, and race were investigated in this study and other similar studies (Ediger et al., 2007; Trinidade et al, 2011). In this study, demographic factors were not significantly different among adherent and nonadherent groups; however several demographic factors are similar to findings in previous IBD studies.

In this study, diagnoses of CD and UC were not significantly associated with nonadherence, a finding similar to two other studies (D'Inca, 2008: Nigro et al., 2001). In an expert opinion review by Seliger, Robinson, and Leong (2011), the majority of IBD studies did not show any significant association for adherence with gender, marital status, employment status, and age. For those studies with significant findings, researchers found inconsistencies among the studies. Inconsistent findings in previous studies were similar to the findings in this study: Adherence was not associated with education, gender, living arrangement, insurance coverage, or marital status.

Discussion of Illness and Treatment Findings

Medications

The three major medicines for IBD therapy are immunomodulators, biologics, and 5-ASA compounds (Bernstein et al., 2010). In this study, no difference in adherence

rates for patients on immunomodulators were found, but significant association with adherence was found in two other studies (Ediger et al., 2007; Horne et al., 2009). Only those on a specific immunomodulators, thiopurines, had a survey score that correlated with adherence (Kane, 2012). Although specific immunomodulators were not analyzed in this study, generally immunomodulators were not significantly associated with adherence. Some immunomodulators are administered by injections weekly and can be painful; others are prescribed once daily (Nurse Practitioner's Prescribing Reference NPPR, 2013). Horne et al. (2008) and Ediger et al. (2007) recruited participants exclusively from the United Kingdom and Canada respectively.

As in this study, treatment with biologics was associated with good adherence in a group of IBD patients recruited through the French association of IBD patients (Nahon et al., 2010). Biologics must be stored under special conditions, are administered intravenously on an outpatient basis, or subcutaneously, and can cause discomfort (NPPR, 2013). Despite the complexity of biologics in both this study and the Kane et al (2012) study, biologics were significantly associated with adherence. A possible explanation for good adherence is that biologics are prescribed less frequently, every two weeks or every three months. Patients on biologics are monitored more frequently for blood work; therefore they may see providers more often than patients on 5-ASA compounds. Those patients on biologics may be more likely to be adherent. Additionally, biologics are also more efficacious, and providers are now prescribing biologics as first line therapy for a top down approach, resulting in faster remission rates (D'Haens & Geert, 2010

As a result of multiple daily frequencies of 5-ASA compounds, treatment complexity increases, a possible cause for why more nonadherent patients are on 5-ASA compounds (NPPR, 2013). In this study adherence was associated with the use of 5-

ASA compounds, conversely Ediger et al. (2007) did not find an association in the use of 5-ASA compounds and adherence. One possible explanation is that the participants in the Ediger et al. study are from a Canadian longitudinal cohort group and may be more likely to be adherent. Future adherence studies for 5-ASA compounds may result in different findings from those two studies because recent formulations of 5-ASA compounds are now prescribed daily.

For patients on steroids, adherence rates were lower in two studies (Bernal et al., 2006; Horne et al., 2009). In this study, adherence rates were not associated with steroids, but over one-third of participants reported steroid usage. Nonsignificance between the adherent and nonadherent groups may be attributed to the duration of steroid therapy. When patients relapse, or are diagnosed initially, steroids are prescribed for a short-term. Patients tend to take their steroid medications initially to decrease their symptoms but may stop before the treatment regimen ends due to the adverse side effects. In this study, there were no data collection and analyses of either duration of steroid therapy, or cessation of steroid therapy prior to the end of the regimen.

Illnesses

Eighty-eight percent of low adherers or nonadherers measured by the MMAS-8-Item scale reported a history of depression in a study by Trinidade et al. (2011), but in this study only 36.8% of all participants reported depression. This group of patients was recruited from social media sites: Perhaps IBD patients who use IBD support groups have less depression or depressed persons were less likely to respond. In the Nahon et al. (2011) online study on medication adherence in IBD patients, no significant differences in depression rates were found between adherent and nonadherent groups. The Nahon et al. study used members of the French Association of IBD Patients and this may account for the differences in depression rates in my study and that study.

In this study, the significant association between adherence and obesity should be interpreted with caution because this obesity can be a result of steroid usage. It is not uncommon for steroids to be prescribed when a patient relapses. A relapse may be associated with factors other than nonadherence. The fact that a patient is prescribed steroids does not necessarily mean that he or she was nonadherent. Additionally, adherent patients may be more likely to be consistent in maintaining weight versus nonadherent patients. Maintaining weight is suggestive of a characteristic that adherent patients possess, resulting in this association between adherence and obesity. More evidence is necessary before a conclusion can be offered. A high percentage of participants in this study reported skeletal conditions; 27.9% for arthritis and 7.3% for osteoporosis. Both conditions are co-morbidities of IBD, and steroid usage is also a contributory factor (Vatn, 2009).

Disease duration had no significant association with adherence in this study. Although shorter disease duration was associated with nonadherence in some studies (D'Inca et al., 2008; Nigro et al., 2001), it had no association in others (Bernal et al., 2006; Shale & Riley, 2003). Few studies have investigated the role of adverse effects from medications and adherence. In this study, no associations were found as in the other studies (D'Inca et al., 2008; Nigro et al., 2001; Shale & Riley, 2003).

In this study, significant association was found between intravenous method of medication administration and adherence. Thirty-nine percent were nonadherent in this combined study of both UC and CD versus two other studies of only CD patients in which 29% and 34% were nonadherent over a 12 month-period (Carter et al., 2012; Kane et al., 2009) respectively. In practice, intravenous medications are prescribed every 2-3 months (Bernstein et al., 2010). Patients who are on intravenous medications are usually on monotherapy and go to clinics for infusions. Nonadherence rates among those

patients are lower than the overall nonadherence rates in this study and in the majority of all other studies. Reminders from clinic staff may account for better adherence rates.

Discussion of Theoretical Framework

As a result of the health threat (diagnosis, relapse, adverse effects, or change in treatment) patients develop an illness representation. Many participants in this study reported comorbidities, side effects from IBD medications, or reported treatment from side effects of IBD medications. Perceptions of treatment complexity and beliefs in medications characterize the illness representation resulting from the health threat. The greater majority of participants reported that their IBD was controlled or characterized it as mild disease activity. Adherence is a behavior, a coping action, and patients self-regulate by adhering or not adhering. Close to 50% of participants reported adherence to IBD medications. In this study, the goals were to test which beliefs in medications were the strongest predictor of adherence and to test if treatment complexity is a predictor of adherence (Figure 1). The logistic regression demonstrated that beliefs in the necessity of IBD medications were the only predictor of adherence to medications, and treatment complexity (availability, frequency, discomfort, storage, and method of administration) was a predictor of adherence.

Discussion of Measurement Scales Findings

In the Jackson et al. (2010) systematic review of IBD adherence studies, 7-72% of participants were nonadherent: Adherence was measured by a variety of adherence tools. The adherence rate measured by the MMAS-8-Item in this study fell within that range and was similar to the Trinidade et al. (2011) study in which the MMAS-8-Item was used. In the Kane et al. (2012) study, the adherence rate was considerably higher, reported as two-thirds of the sample. This difference in adherence rate in the Kane et al. (2012) study may be attributed to the sampling procedure. In the Kane et al study,

participants were from an IBD center and may have had more contact with HCPs, thereby improving adherence rates versus the sample that was obtained in this study by use of social media

Treatment complexity includes method of delivery and dosing regimen. In Kane's (2006) systematic review of UC patients treated with 5-ASA compounds, patients reported that method of delivery and frequency dosing were negatively associated with adherence. In the Treatment Complexity Scale, the item that pertains to frequency showed that the majority of participants disagreed or strongly disagreed with this item. If the treatment regimen is less complex, maybe the adherence rates will be better. Adherence rates were inversely proportional to frequency of dosing in a variety of studies of patients with several types of chronic illnesses using various medications (Claxton, Cramer, & Pierce, 2001). In Ingersoll and Cohen's (2010) systematic review of over 18,000 studies using keywords dosing, pill burden, and regimen complexity in the PubMed data base, few studies addressed treatment complexity. To date, no known studies on storage and adherence rates have been done.

Beliefs in the necessity of medications have been associated with a higher rate of adherence (Horne et al., 2009; Moshkovska et al., 2009). Similarly, in this study, beliefs in the necessity of IBD medications were the only significant predictor of adherence. In this study, concerns about IBD medications were not a predictor of adherence, but in Moshkovska et al.'s (2009) study, specific concerns significantly predicted self-reported adherence with an *OR* = 1.56; however Moshkovska et al. had a different sample, patients with UC, and used self-report and urinary excretion of medication by products as measures for adherence.

Discussion of Measurement Scales

In this study, the KR-20 of the MMAS-8-Item scale was .72, which is higher than in other studies of IBD patients (Al-Qazaz et al., 2010; Korb-Savoldelli et al., 2012). The differences may be attributed to the fact that they were translated versions of the MMAS-8-Item scale. In both the Kane et al. (2012) and Trinidade et al. (2011) IBD studies, the reliability was not reported for the MMAS-8-Item scale. The Cronbach's alphas of BMQ (necessity and concerns) were .90 and .70 respectively in this study. Internal consisitency of the BMQ (overuse and harms) is higher than that found in a previous study (Brown et al., 2005). The difference may be attributed to the smaller sample size (*n*=192) of depressed patients in the Brown et al. (2005) study versus an IBD sample of *n*= 396 in this study (Nunnally & Bernstein, 1994). Post-coronary bypass graft patients were evaluated for adherence and beliefs in medications (Khanderia et al., 2008). Cronbach's alphas reported in that study were 0 .77 for the BMQ (Overuse) and 0.85 for the BMQ (Necessity). The Treatment Complexity scale was a researcher-developed scale indicating a need for continued testing and possible scale revisions.

Strengths and Limitations

One of the limitations of this study was using a convenience sample. Social media sites were used to recruit participants. Participants using IBD Facebook sites and IBD organizational websites are more likely to be actively involved in their treatment which may have affected the results. Persons with IBD who do not visit these websites were not recruited. An overwhelming majority of respondents were white which may be reflective of the type of users of IBD social sites. In a study of social media demographics, the average age of Facebook users was 38 years old (Hampton, Goulet, Rainie, & Purnell, 2011). Hampton et al. (2011) found that 58% of Facebook users in the US were females versus 43% of males, and 78% were whites, 9% black, 9% Hispanic,

and 12% other race. Although this study included 25% of participants who do not live in the US, it consists of an overwhelming number of white female participants who use Facebook. In multiple IBD studies, no differences have been found between the adherence rates for males and females (Ponder & Long, 2013). Although demographics and treatment variables were not controlled for in the logistic regression analysis, readers should consider these variables in the interpretation of the logistic regression results. Another limitation was the use of a new scale, Treatment Complexity, to measure this variable. It is the first time that it has been used; although it was a statistically significant predictor of adherence, the relationship can be improved.

One of the advantages is the fact that the participants recruited through IBD sites were knowledgeable about their disease. Strength is that internet method of recruitment did not limit the sample to any one geographic area. Remuneration was not offered for completing the study. Possibly participants had an intrinsic motivation to complete this survey; therefore, self-report of adherence, though lower than other IBD studies, may be more accurate. The participants took time to list multiple medications including up to six or more medications, demonstrating knowledge about their disease and an interest in facilitating research. Other strengths that the study had included a population of IBD patients with variable IBD medications, frequencies of taking medications, methods of taking medications, and views of current conditions.

To date, the researcher is aware that this is the only IBD study with the following factors.

1. Obesity was listed in the Illness and Treatment Survey and was found to be associated with adherence.

2. In this study, the BMQ 18 items and Treatment Complexity Scale were used to determine if they were predictors of adherence measured with the MMAS-8-Item scale.
3. This study is one of the largest studies originating in the US that investigated whether beliefs in medications and treatment complexity were predictors of medication adherence in IBD patients.
4. It is one of the few studies to use social media to recruit participants for a study on predictors of medication adherence in IBD patients.
5. It is a large social media study originating in the US in which patients on biologics had a significantly greater rate of adherence versus those not on biologics.

Conclusion

This novice researcher's quest to determine predictors of medication adherence in IBD patients using social media resulted in a rich experience with lessons learned and plans for future research. Although this sample was internet based, it provided opportunities for potential participants from anywhere in the US and the world to participate. It is noteworthy that all participants reported drugs that are commonly used in the US. Findings from the BMQ and MMAS-8-Item scales were similar to findings in previous IBD studies. The majority of participants were employed, not living alone, and had health insurance. These indicators of quality of life are desirable in the management of a population with a chronic illness.

More patients are nonadherent than adherent: The fact is, that IBD is a serious disease with many comorbidities resulting in great economic burdens. It was demonstrated that a large percentage of participants were uncertain about the harmful effects and overuse of medications in general and concerned about their IBD medications. HCPs should consider the fact that participants were willing to contribute to

this survey suggesting that they are also interested in their treatment for IBD. It is time for HCPs to view and change their relationship with patients to an alliance rather than a provider-dominated-punitive-relationship. This shift from compliance to adherence and now to alliance can only result in more dialogue and treatment choices for patients to truly believe in the necessity of their medications resulting in improved adherence.

Recommendations

Recommendations for Research

Researchers ought to be consistent in the measures of adherence and use multiple strategies to recruit heterogeneous groups of participants. As discussed in Chapter Two, many methods are available to measure adherence. In previous studies, a wide range of adherence rates have been reported. IBD treatments are complex, including multiple medication therapies and multiple scheduling. Because beliefs in the necessity of medications and treatment complexity were predictors of medication adherence, patients' beliefs and perceptions of treatment complexity should be addressed in future studies. The importance of treatment complexity may warrant development of a tool to combine its measure with specific beliefs about medications. Additionally, the Treatment Complexity Scale warrants use in additional studies to establish adherence.

Medications are only beneficial in those who use them. In the future, researchers should use recruitment methods with potentially more heterogeneous groups for race and gender. Studies for adherence ought not to place limitations on the adult age group. Despite the fact that studies on adherence rates and nonmodifiable factors have yielded controversial results, it is still important to investigate if there are any significant associations between adherence, culture, and ethnicity.

The sample quota was obtained from IBD sites during a 10-week period suggesting that participants were active on these sites and had the opportunity for social support. This fact is encouraging and provides the impetus for further studies to investigate use of social media and recruitment of IBD patients. Additionally, studies on the use of social media for social support may provide information to improve the lives of IBD patients. Sixteen percent reported asthma, a condition that is considered an immunological disease as is IBD. This finding provides an opportunity for further research on other immunological conditions and their association with IBD.

Recommendations for practice

Assessment of treatment complexity can be improved to be used as a screening measure to determine patients' perceptions. In order to lessen the complexity, healthcare providers can offer alternatives and management strategies to decrease complexity. In order to change behavior, potentially nonadherent patients must be identified to address factors such as patients' beliefs and their perception of treatment complexity. Use of a combined screening tool of beliefs in medications and treatment complexity will also be an opportunity to teach and clarify misconceptions about targeted medications. In conjunction with novel reminders, such as, electronic gadgets and emerging technology, the proposed approach could increase concern in improved adherent behavior, whereby patients have stronger beliefs about IBD medications and resources to deal with treatment complexity.

In this study, significant differences were found between adherence rates for patients who reported depression and obesity. One recommendation is for health care providers to screen patients for depression and make appropriate referrals. Although obesity may be the result of adverse effects of steroids, HCPs ought to be vigilant about this finding, screen, and treat this condition. A large percentage of patients reported

arthritis and osteoporosis: Healthcare providers ought to screen and treat for these conditions. Participants were very concerned about the long term effects of medications: It is important for HCPS to explore this topic with their patients.

Because participants seek information from social media, HCPs may be encouraged to volunteer as official monitors on these sites to assist with dissemination of information and correct fallacies about treatment and the disease process. It is also a forum for HCPs to learn how the IBD population truly views their disease and treatment, providing a better opportunity for improved patient provider encounters.

Chapter Summary

In this chapter a discussion of the major findings of the descriptive statistics of the demographics, treatment, and illness variables, the framework, and the measurement scales were presented. Findings of the logistic regression were integrated in the discussions. Strengths, limitations, and implications for research and practice are presented. Finally a summary integrating the model and the research findings were presented.

Appendix A

Demographic Survey

Demographic Survey

The following questions are designed to obtain information on your background such as age. Please read each question carefully and place a check mark next to the response that represents you. There is no right or wrong answers. Thank you for assisting with this research.

Do you live in the United States?
____Yes
____No

What is your gender?
____Male
____Female
____What is your age (in years) since your last birthday?

What is your ethnicity?
____Hispanic origin
____Not of Hispanic origin

What is your race?
____White
____Black or African American
____American Indian or Alaskan Native
____Asian
____Native Hawaiian and other Pacific Islander
____Two or more races

What is your marital status?
____Unmarried
____Married/Living together
____ Divorced
____Widowed

What is your employment status?
____Full time
____Part time
____Unable to work due to illness
____Retired
____Student
____Unemployed but want to work

What is the highest level of your education?

____High School graduate or less
____Higher than high school

Do you have health insurance?
____Yes
____No

If you have health insurance, does your insurance cover your Crohn's/ulcerative colitis medications?
____All of it
____Portion of it
____None of it
____Not applicable

What is your living arrangement?
____Alone
____With adults
____With children
____With adults and children

Where did you hear about this survey?
Facebook
___ Doctor's Office
____Other
____Organization Website

.

Appendix B

Illness and Treatment Survey

Illness and Treatment Survey

We know taking medications regularly can be difficult. We are asking for your help in determining what factors make it difficult to take medication as prescribed. Please read each question carefully and place a check mark next to the response that represents you. There is no right or wrong answer. Thank you for assisting with this research.

What type of Illness do you have?

____Crohn's
____ Ulcerative Colitis

How long have you had this condition to the nearest year?

____Years

How do you see your current condition?

____Controlled

____Mild Activity

____Moderate Activity

____Severe Activity

List the names of all the medications that you take for Crohn's/ulcerative colitis.

_____

_____

. List all the methods by which you take/get your medications.

____Oral (by mouth)

____Injection (Subcutaneous)

____Rectal (Suppository/enema)

____Intravenous (IV)

____Other

For all the Crohn's/ulcerative colitis medications prescribed by your doctor, how often were you told to take your medications. Check all that apply.

____Once a day_

____More than once a day

____Every week

____Every two weeks

____Once a month

____Every three months

____None of these _

Do you have side effects with Crohn's/ulcerative colitis medications now?

____Yes

____No

Were you ever treated for side effects from your Crohn's/ulcerative colitis medicine?

____Yes

____No

Has your doctor changed your Crohn's/ulcerative colitis medications in the last 3 months?

____Yes

____No

Have you had surgery for Crohn's/ulcerative?

____ Yes

____No

Place a check mark next to all of the following illnesses that you have

_____ Asthma

____Arthritis

____Cancer

____Cerebrovascular disease - History of stroke or TIA (transient ischemic attack)

____Chronic Renal Failure

____Congestive Heart Failure

____COPD

____Depression

____Diabetes

____Hyperlipidemia

____Hypertension

____Ischemic Heart Disease

____Obesity

____Osteoporosis

None of the above

Do you take medications for other illnesses?

____Yes
____ No
____ not applicable

.

Appendix C

BMQ

YOUR VIEWS ABOUT

CROHN'S/ULCERATIVE COLITIS MEDICINES PRESCRIBED FOR YOU

- We would like to ask you about your personal views about medicines prescribed for your Crohn's/ulcerative colitis
- These are statements other people have made about their medicines
- Please show how much you agree or disagree with them by ticking the appropriate box.

There are no right or wrong answers

We are interested in your personal views

Views about MEDICINES PRESCRIBED FOR YOU	**Strongly agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly disagree**
Having to take medicines worries me					
I sometimes worry about the long-term effects of my					
I sometimes worry about becoming too dependent on my					
My medicines are a mystery to me					
My medicines disrupt my life					
My health in the future will depend on medicines					
My health, at present, depends on medicines					
My life would be impossible without medicines					
Without medicines I would be very ill					
My medicines protect me from becoming worse					

YOUR VIEWS ABOUT

MEDICINES IN GENERAL

•These are statements other people have made about their medicines in general

•Please show how much you agree or disagree with them by ticking the appropriate box.

Views about MEDICINES IN GENERAL	**Strongly agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly disagree**
If doctors had more time with patients they would prescribe fewer					
Doctors use too many medicines					
Doctors place too much trust on medicines					
Natural remedies are safer than medicines					
Most medicines are addictive					
Medicines do more harm than good					
People who take medicines should stop their treatment for a while every now and again					
All medicines are poisons					

Horne, R., Weinman, J., & Hankins, M. 1999, "The Beliefs about Medicines Questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication", Psychology and Health, vol. 14, pp. 1-24

With permission adapted for this study

Appendix D

MMAS- 8--Item

©Morisky Medication Adherence Scale (MMAS-8-Item). This is a generic adherence scale and the name of the health concern can be substituted in each question item.

You indicated that you are taking medication(s) for your (identify health concern, such as "high blood pressure"). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your [health concern] medication.

(Please circle the correct number)

	No=1	Yes =0
1. Do you sometimes forget to take your [health concern] medication(s)?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [health concern] medication(s)?		
3. Have you ever cut back or stopped taking your medication(s) without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your [health concern] medication(s)?		
5. Did you take your [health concern] medication(s) yesterday?		
6. When you feel like your [health concern] is under control, do you sometimes stop taking your medication(s)?		
7. Taking medication(s) everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?		

8. How often do you have difficulty remembering to take all your med1cat10n(s)?

(Please circle the correct number)

Never/Rarely 4

Once in a while 3

Sometimes 2

Usually ..... ▮

All the time 0

Morisky Scale Continued

Morisky DE, Ang A, Krousel-Wood M, Ward H. Predictive Validity of a Medication Adherence Measure for Hypertension Control. Journal of Clinical Hypertension 2008; 10(5):348-354.

.

Appendix E

Treatment Complexity Scale

TREATMENT AND COMPLEXITY SCORING

Degree of complexity of medications	Strongly agree 5	Agree 4	Uncertain 3	Disagree 2	Strongly Disagree 1
It is difficult for me to take my medications because I do not always have my medications with me when I am scheduled to take them					
It is difficult for me to take my medications because of how often they are prescribed.					
It is difficult for me to take my medications because I have to store them in a special way.					
It is difficult for me to take my medications because of how I have to take them.					
It is difficult for me to take my medications because I have discomfort with the injections/suppositories/enemas/pills.					
Add scores from each column then total all scores for a final score					

Scale scores – Range form 5-25 where high scores indicate a greater degree of treatment complexity as reported by participant.

Appendix F

Letter of Request

UNIVERSITY OF TEXAS ARLINGTON | COLLEGE OF NURSING

Dear [*Insert name here*]

My name is Donna Bacchus and I am a PhD candidate at the University of Texas at Arlington. I am developing a research proposal for my doctoral dissertation at the University of Texas at Arlington, on beliefs in medications and treatment complexity as predictors of medication adherence in patients with inflammatory bowel disease. I am requesting your permission to invite members of your association/organization to participate in my study by completing an online survey.

I am not requesting email addresses, phone numbers, mailing addresses or any personally identifying information about the members of the association. Instead, I would like you to post/email my memo of invitation to complete the online survey, on my behalf, to all of the members of your association/organization. My survey does not ask for any personally identifying information. The study participant's identification will be completely anonymous.

I am not asking you to send the letter of invitation at this time. I have official approval from the Institutional Review Board of the University of Texas at Arlington to conduct this study. The intent of this email is to request your permission to invite members of your association/organization to complete my survey. Once I have your acceptance in writing (response by email is satisfactory), I will forward to you the actual letter of invitation for the members of your association/organization. I will ask you to email/post the letter with the embedded web-based secure electronic survey link on my behalf at that time to members of your association/organization.

If you are not the person in charge of approving this type of request I would very much appreciate if you would forward the name and contact information of the person with whom I should communicate. I would welcome the opportunity to discuss this with you by phone if that would be helpful. In addition, I would be happy to provide any further information you may require in order to make a decision. If you have any questions regarding this study, or would like additional information to assist you in reaching a decision about posting this study, please contact me at phone number (1-469-999-1356) or by email bacchus@uta.edu .You may also contact my supervisor, Dr. Jennifer Gray at 817- 272-2776 or by email jgray@uta.edu.

Thank you for your time.

Sincerely,

Donna Bacchus, MSN, RN, PhD Candidate

College of Nursing The University of Texas at Arlington B o x 19407 411 S. Nedderman Drive, Arlington, TX 76019-0407
T 817-272-2776 *F* 817-272-5006 www.uta.edu/nursing

Appendix G

Recruitment memo for participants

Are you between the ages of 18- 65 years-old, currently on medications, and have Crohn's or ulcerative colitis, then your input can help with improving medication adherence. Donna Bacchus, a PhD candidate at the University of Texas at Arlington, is conducting a research study to understand factors that affect the lives of individuals with IBD. It will take about 20-30 minutes to complete this anonymous survey. Information you provide will not be linked to your email, name, or any identifying information about you.

If you have any questions regarding this study, please contact me at 1-469-999-1356 or email bacchus@uta.edu Please click on the link below, or cut and paste the entire URL into your browser to access the survey *[Insert hyperlink here]* Thank you.

.

Appendix H

CCFA Foundation website post

Orna Ehrlich <oehrlich@ccfa.org>

Sent: Thursday, May 02, 2013 3:04 PM

To: Bacchus, Donna

Subject:RE: Application to post the survey.

Hi Donna,

I wanted to let you know that I received approval from our medical review committee with the following edit to the study objective to make it conform with the other postings on our Registry. Modified text so it reads: This on-line study seeks to gain information on patients' beliefs in medications and the complexity of the medication treatment. It is important for patients to take their medications to prevent complications and relapses. Beliefs and difficulties may predict if patients take or not take their medications.

Also, I had a follow-up question regarding the tracking ability (Q13) in your application. Do you have a question in the survey regarding how the user found out about the study or a way for Qualtrics to measure the referral source (i.e. the URL link that brought them to the survey) so we can better understand how many people took your survey as a result of seeing it on CCFA's Registry? Please let me know.

Below please find a link to preview your study posting on our Registry. It's best to open the link in IE and "show all content" or, if you use Google Chrome, you have to click on the security button and accept that you want to load unsecure components in order to properly see the posting.

https://cmsadmin30.convio.net/preview!www.ccfa.org/research/participate-in-research/find-studies-and-clinical-trials/beliefs-adherence.html?authToken=a5239aa50f5e0b41524b3cb0beff054169b57f93

.

Appendix I

CCFA Facebook site post

Are you between the ages of 18- 65 years old, currently on medications, and have #Crohn's or #ulcerative #colitis? If so, your input can help improve #medication adherence for other IBD #patients like you by simply completing this anonymous survey: [abbreviated link to: http://www.ccfa.org/research/participate-in-research/find-studies-and-clinical-trials/beliefs-adherence.html]. #research

The feedback you provide will not be linked to any of your personal information. Thank you!

.

Appendix J

Crohn’s Forum Permission memo

From: David Chapman [mailto:webmaster@crohnsforum.com]
Sent: Tuesday, May 07, 2013 9:32 AM
To: Bacchus, Donna
Subject: Re: Crohn's Disease Forum - Support group and forum for Crohn's Disease, Ulcerative Colitis, and other IBD Contact Us Form - Survey

Hi Donna,

Sorry for the delay responding. Your request to post the survey is approved. Here are the next steps:

1. Register an account at crohnsforum.com and reply here with the username so I can flag the account.
2. Once I let you know the account is flagged, you may post your thread in either the, "General IBD Discussion" or our Research forum.
3. You may bump the thread at most once every 7 days.
4. When you post the thread, please state in the post that, "David has approved this posting".

Regards,
David

.

Appendix K

IBD Support Group permission letter

From: IBD Support Group <ibd@ibdsupport.org>

Date: Wed, May 15, 2013 at 6:26 PM

Subject: Re: Response

To: Donna Bacchus <bacchd1958@gmail.com>

Dear Donna,

I'm sorry for the delay.

Please follow these instructions in order to post your study. Please remember to let me know what username you register.

http://www.ibdsupport.org/researcher

Thanks,

Jeffrey Roberts

Founder, IBD Support Group

.

Appendix L

Healing Well permission letter

From: healingwell@gmail.com on behalf of Peter Waite
To: Bacchus, Donna
Subject: Re: Survey
Date: Tuesday, April 23, 2013 11:37:41 AM

Yes, you may post this, please be sure to mention in your post that you obtained my prior permission so that one of our moderators does not inadvertantly remove it. Good luck with your research.

Peter

Peter Waite
HealingWell.com LLC
http://www.healingwell.com

Blog - http://blog.healingwell.com
Twitter - http://twitter.com/HealingWell
Facebook - http://facebook.com/HealingWell

Appendix M

CCFA Facebook North Dallas Chapter memo

From: Jacquelin Leech
To: Bacchus, Donna
Subject: Re: Thanks
Date: Wednesday, June 19, 2013 5:37:20 PM

Hi Donna
I am sorry that the link did not work. I will post on our chapter facebook page as well.

Thanks!
Jacquelin Way Leech
Community Development Director
Crohn's & Colitis Foundation of America
12801 N. Central Expressway, Ste 530
Dallas, Texas 75243
Phone: 972-386-0521

From: Bacchus, Donna [mailto:bacchus@uta.edu]
Sent: Wednesday, June 19, 2013 06:26 PM
To: Jacquelin Leech
Subject: Thanks

Hi Jacquelin,

I saw the promotion for the study. Thank you for posting it. The link does not open from the e newsletter from my end. However the awareness that it exists will help and promote the study.

Thank you very much

Donna Bacchus, MSN, RN, PhD Candidate

Clinical Instructor, College of Nursing

University of Texas at Arlington

411 S. Nedderman Drive

Arlington, TX 76019

(W) 817-272-2776 (F) 817-272-5006

.

Appendix N

Ulcerative Colitis and Crohn's Disease permission memo

From: Shari Coulton
To: Bacchus, Donna
Subject: Ulcerative Colitis.
Date: Monday, July 15, 2013 3:38:16 PM

Donna,
Permission granted to post study on adherence on Ulcerative Colitis and Crohn's disease Facebook page.

.

Appendix O

Ulcerative Colitis permission memo

From: Facebook [mailto:notification+kjdpuj1hk--i@facebookmail.com]

Sent: Monday, June 24, 2013 11:14 PM

To: Bacchus, Donna

Subject: New message from Behnam Nowrouzi-Kia

Behnam Nowrouzi-Kia

10:44pm Jun 24

thanks for the description.. Good luck with your study

Conversation History

improve adherence in persons with IBD.

View Conversation on Facebook • Reply to this email to message Behnam Nowrouzi-Kia.

This message was sent to bacchus@uta.edu. If you don't want to receive these emails from Facebook in the future, please unsubscribe.

Facebook, Inc., Attention: Department 415, PO Box 10005, Palo Alto, CA 94303

Appendix P

Crohn's Disease, Ulcerative Colitis, Celiacs, and any IBD/IBS awareness

Permission memo

From: Mindy Degnon
To: Bacchus, Donna
Date: Thursday, July 18, 2013 10:27:03 PM

Donna you can post adherence study on Crohn's Disease, Ulcerative Colitis, Celiacs and any other IBD/ibs awareness

Mindy Degnon

.

Appendix Q

Crohn's and Ulcerative Colitis Worldwide Support Site permission memo

From: Facebook [mailto:notification+kjdpuj1hk--i@facebookmail.com]

Sent: Friday, June 14, 2013 8:23 AM

To: Bacchus, Donna

Subject: New message from Dale Joseph

Dale Joseph

7:53am Jun 14

Hi Donna, yeah that's fine, would you like me to post it on your behalf? or do you want to do it?

Conversation History

View Conversation on Facebook • Reply to this email to message Dale Joseph.

Appendix R

National CCFA Foundation permission memo

Hi Donna,

Wonderful news! I have pushed the site live and it can be found at:
http://www.ccfa.org/research/participate-in-research/find-studies-and-clinical-trials/beliefs-adherence.html

We sincerely hope the posting will aid in your recruitment efforts. We will also plan to highlight the study in an upcoming CCFA e-newsletter in our Clinical Trials/Studies section. Please let me know if you have any other questions at this time.

Best wishes,

Orna G. Ehrlich, MPH
Director, Professional Education

CROHN'S & COLITIS FOUNDATION OF AMERICA

Crohn's & Colitis Foundation of America
National Headquarters
386 Park Avenue South, 17th Floor New York, New York 10016
Tel: (646) 943-7426
oehrlich@ccfa.org www.ccfa.org

vCard

Our Mission: To cure Crohn's disease and ulcerative colitis, and to improve the quality of life of children and adults affected by these diseases.

.

Appendix S

Permission to use MMAS-8–Item

Bacchus, Donna
From: DONALD E MORISKY <dmorisky@ucla.edu>
Sent: Monday, March 18, 2013 1:47 PM
To: Bacchus, Donna
Subject: Re: Signed consent 8 -item scale
Thanks Donna and best of success in your IBD research.
dmorisky
On Mar 16 7:01 PM, bacchus@uta.edu wrote:
From: Bacchus, Donna
Sent: Saturday, March 16, 2013 9:00 PM
To: Bacchus, Donna
Subject: RE: Re: Fw: 8-item scale Request
Hello Dr.Morsiky,
Attached please find the signed consent form to use the Morisky – 8 item scale. I thank you for your
generosity in allowing me to use this scale and will forward to you the results of my study.
Thank you
Donna Bacchus, RN, MSN, PhD Candidate
bacchus@uta.edu
--- On Sun, 5/22/11, Donald E. Morisky <*dmorisky@ucla.edu*> wrote:
From: Donald E. Morisky <dmorisky@ucla.edu>

Appendix T

BMQ permission

Dear Penny,

Here is the signed consent (attachment) as we discussed this morning. My plan is to use the scores of each BMQ domain – specific and general as independent variables in a logistic regression. As we discussed I plan to include a copy of the scale (proper copyright citation) in my proposal and dissertation. I plan to use the scale in Survey monkey for participants. The purpose is for research towards a PhD in nursing.

Thank you

Donna Bacchus

Donna Bacchus, MSN, RN. PhD Candidate
Clinical Instructor
University of Texas at Arlington, College of Nursing
411 S Nedderman Drive
Arlington, Texas 76019
T 817-272-277
F 817-272-5006

<BMQ permission.pdf>

.

Thanks Donna
That's fine. Permission granted. Good luck with your research
Best wishes
Rob

Sent from my iPhone

Rob Horne
Professor of Behavioural Medicine

Head of Department of Practice & Policy
Director, Centre for Behavioural Medicine
The School of Pharmacy, University of London

Correspondence Address:
School of Pharmacy, Mezzanine Floor, BMA House
Tavistock Square, London WC1H 9JP

Email: rob.horne@pharmacy.ac.uk Web: www.pharmacy.ac.uk
Direct line: + 44 (0) 207 874 1293

ADMINISTRATION
Penny Reed
cbm.admin@pharmacy.ac.uk
T +44 (0) 207 874 1281, Dept fax: + 44 (0) 207 387 5693

On 18 Sep 2012, at 19:49, "Bacchus, Donna" <bacchus@uta.edu> wrote:

From: Bacchus, Donna
Sent: Monday, September 17, 2012 7:49 AM
To: 'Penny Reed'
Subject: BMQ permission

Dear Dr. Horne,

I spoke to Penny yesterday and she advised that I send the memo (below) to you. I would like to report Cronbach's alpha also. Please advise since I am awaiting Penny to send a copy of the questionnaire ready for participants.

I really appreciate all your help and look forward to hearing from you.

Best Regards

Donna

.

Appendix U

Consent Form

UT Arlington

Informed Consent Document

RESEARCHER: Donna Bacchus, RN, MSN PhD Candidate

Email Address and Telephone Number: bacchus@uta.edu 469-999-1356

RESEARCHER SUPERVISOR: Dr. Jennifer Gray

Email Address and Telephone number jgray@uta.edu 817-272-2776

TITLE OF PROJECT:

Beliefs in medications and treatment complexity as predictors of medication adherence among adults aged 18-65 years old with inflammatory bowel disease.

This survey is for anyone aged 18-65 years old with Crohn's disease or ulcerative colitis who are currently taking medications. You are invited to be a part of a research survey.

The researcher is a doctoral student at The University of Texas at Arlington, College of Nursing. The information in this form describes what you will do for this study. If you have any questions about this survey, or you do not understand anything in this form, you are asked to contact the researcher.

WHAT IS THIS STUDY ABOUT?

The researcher wants to find out patients' beliefs about medications and how they take their medications. An understanding of the motivators and challenges of taking medications may help healthcare professionals understand patients' perspectives about their medications.

HOW LONG WILL THIS STUDY LAST?

It will take about 20-30 minutes to complete this study.

PROCEDURE

As a participant you will read this consent form and if you agree to participate you will complete surveys on personal information about yourself such as age, education, and illness. You will also complete surveys on beliefs in medications and difficulties with taking your medications. No information will be collected that will result in identifying you. You may discontinue participation at any time without penalty.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

It is anticipated that there will be 400 people in this study.

WHAT WILL YOU GAIN FROM THIS STUDY?

You will not be paid for participating in this study. Although you may not benefit directly from study, your participation in this study mayl help other patients with Crohn's, and ulcerative colitis as a whole and provide a better understanding of what may affect the lives of patients with inflammatory bowel disease..

IS THERE POSIBLE RISKS/DISCOMFORT FROM DOING THIS STUDY?

There are no foreseeable risks and/discomforts from doing this study. If, however, you are uncomfortable and unable to continue with the questionnaires, you can discontinue the study at any time.

WHO IS PAYING FOR THIS STUDY?

This study is funded by the researcher and a small dissertation fellowship award.

IS MY PARTICIPATION VOLUNTARY?

Your participation in this research study is voluntary and you have a right not to participate or stop at any time without any penalty.

WILL MY CONFIDENTIALITY BE PROTECTED?

Every attempt will be made to see that your study results are kept confidential. Your personal information will not be linked to the survey answers that you provide. All data collected from this study will be stored on a secure server at the University of Texas at Arlington for at least three (3) years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a participant. Additional research studies could evolve from the information you have provided, but your information will not be linked to you in anyway; it will be anonymous.

Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, the UTA Institutional Review Board (IRB), and personnel particular to this research have access to the study records. Your records will be kept completely confidential according to current legal requirements.

They will not be revealed unless required by law, or as noted above. The IRB at UTA has reviewed and approved this study and the information within this consent form. If in the unlikely event it becomes necessary for the Institutional Review Board to review your research records, the University of Texas at Arlington will protect the confidentiality of those records to the extent permitted by law.

APR 1 2 2013

APPROVED

APR 1 2 2014

Institutional Review Board

Appendix V

Permission Exempt Study

THE UNIVERSITY
OF TEXAS
AT ARLINGTON

Office of Research Administration
Box 19188
202 E. Border St., Suite 214
Arlington, Texas
76019-0188

T 817.272.3723
F 817.272.1111

http://www.uta.edu/research
Expertise at UT Arlington
http://www.uta.edu/expertise

April 22, 2013

Donna Bacchus
Dr. Jennifer r Gray
The University of Texas at Arlington
College of Nursing
Box 19407

EXPEDITED APPROVAL OF HUMAN SUBJECT RESEARCH WITH WAIVER/ALTERATION TO INFORMED CONSENT

IRB No.: 2013-0289
TITLE: *Beliefs in Medications and Treatment Complexity as Predictors of Medication Adherence among Adults aged 18-65 years old with Inflammatory Bowel Disease*
Effective Date: April 12, 2013
Expiration Date: April 12, 2014

Approved Number of Participants: 400(Do not exceed without prior IRB approval).

The University of Texas Arlington Institutional Review Board (UTA IRB) has made the determination that this research protocol involving human subjects is eligible for expedited review in accordance with Title 45 CFR 46.110(a)-(b)(1), 63 FR 60364 and 63 FR 60353, category (7). The IRB Chairman (or designee) approved this protocol effective April 12, 2013. IRB approval for the research shall continue until April 12, 2014.

APPROVED NUMBER OF PARTICIPANTS:
This protocol has been approved for enrollment of a maximum of 400 participants and is not to exceed this number. If additional data are needed, the researcher must submit a modification request to increase the number of approved participants **before** the additional data are collected. Exceeding the number of approved participants is considered an issue of non-compliance and will result in the destruction of the data collected beyond the approval number and will be subject to deliberation set forth by the IRB.

INFORMED CONSENT DOCUMENT:
The IRB approved and stamped informed consent document (ICD) showing the approval and expiration date must be used when prospectively enrolling volunteer participants into the study. The use of a copy of any consent form on which the IRB-stamped approval and expiration dates are not visible, or are replaced by typescript or handwriting, is prohibited. The signed consent forms must be securely maintained on the UT Arlington campus for the duration of the study plus a minimum of three years after the completion of all study procedures (including data analysis). The complete study record is subject to inspection and/or audit during this time period by entities including but not limited to the UT Arlington IRB, Regulatory Services staff, OHRP, and by study sponsors (if the study is funded).

HUMAN SUBJECTS TRAINING:
All investigators and key personnel identified in the protocol must have documented Human Subjects Protection (HSP) training or CITI Training on file with The UT Arlington Office of Research Administration; Regulatory Services. Completion certificates are valid for 2 years from completion date.

COLLABORATION:
If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federal wide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to: http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

CONTACT FOR QUESTIONS:
The UT Arlington Office of Research Administration; Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Robin Dickey at robind@uta.edu or you may contact the Office of Regulatory Services at 817-272-3723.

Sincerely,

Maria Martinez-Cosio

Digitally signed by Maria Martinez-Cosio
DN: postalCode=76019, o=The University of Texas at Arlington, street=701 South Nedderman Drive, st=TX, l=Arlington, c=US, cn=Maria Martinez-Cosio, email=mcosio@uta.edu
Date: 2013.04.25 13:39:48 -05'00'

Maria Martinez-Cosio, Ph.D.
Associate Professor
UT Arlington IRB Chair

.

Appendix W

First minor revision to protocol

THE UNIVERSITY
OF TEXAS
AT ARLINGTON

Office of Research
Administration
Box 19188
202 E. Border St., Suite 214
Arlington, Texas
76019-0188

T 817.272.3723
F 817.272.1111

http://www.uta.edu/research
Expertise at UT Arlington
http://www.uta.edu/expertise

April 22, 2013

Donna Bacchus
Dr Jennifer r Gray
College of Nursing
The University of Texas at Arlington
Box 19407

IRB No.: **2013-0289.1**

RE: Minor Modification Approval Letter

Title: *Beliefs in Medications and Treatment Complexity as Predictors of Medication Adherence among Adults aged 18-65 years old with Inflammatory Bowel Disease.*

The UT Arlington Institutional Review Board (UTA IRB) Chair (or designee) reviewed and approved the modification(s) to this protocol on **April 23, 2013** in accordance with Title 45 CFR 46. 110(b)(2). Therefore, you are authorized to conduct your research. The modification(s), indicated below, was/were deemed minor and appropriate for expedited review.

- Modification request to update the survey to include additional categories for Race and the diagnosis of Crohn's/ulcerative colitis was included in all items of the Morisky Medication Adherence Scale.

Pursuant to Title 45 CFR 46.103(b) (4) (iii), investigators are required to, "promptly report to the IRB ***any*** proposed changes in the research activity, and ensure that such changes in approved research, during the period for which IRB approval has already been given, **are not initiated without IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject."

The modification approval will additionally be presented to the convened board on May 14, 2013 for full IRB acknowledgment [45 CFR 46.110(c)]. All investigators and key personnel identified in the protocol must have documented Human Subjects Protection (HSP) training, *CITI* Training, or other approved training on file with the UT Arlington Office of Research Administration; Regulatory Services.

The UT Arlington Office of Research Administration appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Robin Dickey at robind@uta.edu or you may contact the Office of Regulatory Services at 817-272-3723.

Sincerely,

Judy R. Wilson, Ph.D.

Digitally signed by Judy R. Wilson, Ph.D.
DN: cn=Judy R. Wilson, Ph.D., o=University of Texas at Arlington, ou=Vice-Chair IRB, email=jrwilson@uta.edu, c=US
Date: 2013.04.25 15:24:37 -05'00'

Judy Wilson, Ph.D.
Associate Professor
UT Arlington IRB Vice-Chair

.

Appendix X

Second minor revision to protocol

THE UNIVERSITY
OF TEXAS
AT ARLINGTON

Office of Research
Administration
Box 19188
202 E. Border St., Suite 214
Arlington, Texas
76019-0188

T 817.272.3723
F 817.272.1111

http://www.uta.edu/research
Expertise at UT Arlington
http://www.uta.edu/expertise

May 10, 2013

Donna Bacchus
Dr. Jennifer Gray
Nursing
The University of Texas at Arlington
Box 19407

IRB No.: **2013-0289**

RE: Minor Modification Approval Letter

Title: *Beliefs in Medications and Treatment Complexity as Predictors of Medication Adherence among Adults aged 18-65 years old with Inflammatory Bowel Disease*

The UT Arlington Institutional Review Board (UTA IRB) Chair (or designee) reviewed and approved the modification(s) to this protocol on **May 9, 2013** in accordance with Title 45 CFR 46. 110(b)(2). Therefore, you are authorized to conduct your research. The modification(s), indicated below, was/were deemed minor and appropriate for expedited review.

- Include the study information and link on the inflammatory bowel disease support group sites
- Update the recruitment memo containing the link to participate

Pursuant to Title 45 CFR 46.103(b) (4) (iii), investigators are required to, "promptly report to the IRB ***any*** proposed changes in the research activity, and ensure that such changes in approved research, during the period for which IRB approval has already been given, **are not initiated without IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject."

The modification approval will additionally be presented to the convened board on May 14, 2013 for full IRB acknowledgment [45 CFR 46.110(c)]. All investigators and key personnel identified in the protocol must have documented Human Subjects Protection (HSP) training, *CITI* Training, or other approved training on file with the UT Arlington Office of Research Administration; Regulatory Services.

The UT Arlington Office of Research Administration appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Robin Dickey at robind@uta.edu or you may contact the Office of Regulatory Services at 817-272-3723.

Sincerely,

Judy R. Wilson, Ph.D.

Digitally signed by Judy R. Wilson, Ph.D.
DN: cn=Judy R. Wilson, Ph.D., o=University of Texas at Arlington, ou=Vice-Chair IRB, email=jrwilson@uta.edu, c=US
Date: 2013.05.16 16:06:23 -05'00'

Judy Wilson, Ph.D.
Associate Professor
UT Arlington IRB Vice-Chair

Appendix Y

First expedited modification review to protocol

Office of Research Administration
Regulatory Services
817-272-3723
regulatoryservices@uta.edu

June 5, 2013

Donna Bacchus
Dr. Jennifer Gray
Nursing
The University of Texas at Arlington
Box 19407

IRB No.: **2013-0289**

Title: *Beliefs in Medications and Treatment Complexity as Predictors of Medication Adherence among Adults aged 18-65 years old with Inflammatory Bowel Disease*

EXPEDITED PROTOCOL MODIFICATION APPROVAL

The UT Arlington Institutional Review Board (UTA IRB) Chair (or designee) reviewed and approved the modification(s) to this protocol on **June 4, 2013** in accordance with Title 45 CFR 46. 110(b)(2). Therefore, you are authorized to conduct your research. The modification approval will additionally be presented to the convened board on June 11, 2013 for full IRB acknowledgment [45 CFR 46.110(c)]. The modification(s), indicated below, was/were deemed minor and appropriate for expedited review.

- Use Twitter and Facebook as recruitment opportunities

MODIFICATION TO AN APPROVED PROTOCOL:
Pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB ***any*** proposed changes in the research activity, and to ensure that such changes in approved research, during the period for which IRB approval has already been given, are **not initiated without prior IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject." Modifications include but are not limited to: Changes in protocol personnel, number of approved participants, and/or updates to the protocol procedures or instruments and must be submitted via the electronic submission system. Failure to obtain approval for modifications is considered an issue of non-compliance and will be subject to review and deliberation by the IRB which could result in the suspension/termination of the protocol.

ADVERSE EVENTS:
Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to The UT Arlington Office of Research Administration; Regulatory Services within 24 hours of the occurrence or upon acknowledgement of the occurrence.

Office of Research Administration
Regulatory Services
817-272-3723
regulatoryservices@uta.edu

TRAINING
All investigators and key personnel identified in the protocol must have filed an annual Conflict of Interest Disclosure (COI) and have documented *Human Subjects Protection (HSP)* training on file with this office prior to protocol approval. HSP training certificates are valid for 2 years from completion date.

COLLABORATION:
If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to:
http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

CONTACT FOR QUESTIONS:
The UT Arlington Office of Research Administration; Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Robin Dickey at robind@uta.edu or Regulatory Services at regulatoryservices@uta.edu or 817-272-2105.

Sincerely,

Judy R. Wilson, Ph.D.

Digitally signed by Judy R. Wilson, Ph.D.
DN: cn=Judy R. Wilson, Ph.D., o=University of Texas at Arlington, ou=Vice-Chair IRB, email=jrwilson@uta.edu, c=US
Date: 2013.06.05 17:04:10 -05'00'

Judy R. Wilson, Ph.D.
Associate Professor
UT Arlington IRB Vice-Chair

Appendix Z

Second expedited modification to the protocol

Office of Research Administration
Regulatory Services
817-272-3723
regulatoryservices@uta.edu

July 03, 2013

Donna Bacchus
Dr. Jennifer Gray
College of Nursing
The University of Texas at Arlington
Box 19407

IRB No.: **2013-0289**

Title: *Beliefs in Medications and Treatment Complexity as Predictors of Medication Adherence among Adults aged 18-65 years old with Inflammatory Bowel Disease*

EXPEDITED PROTOCOL MODIFICATION APPROVAL

The UT Arlington Institutional Review Board (UTA IRB) Chair (or designee) reviewed and approved the modification(s) to this protocol on **July 3, 2013** in accordance with Title 45 CFR 46. 110(b)(2). Therefore, you are authorized to conduct your research. The modification approval will additionally be presented to the convened board on July 9, 2013 for full IRB acknowledgment [45 CFR 46.110(c)]. The modification(s), indicated below, was/were deemed minor and appropriate for expedited review.

- Update the Facebook message to include "hashtags", which link to Twitter trends and potentially reach a broader participant pool.

MODIFICATION TO AN APPROVED PROTOCOL:
Pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB ***any*** proposed changes in the research activity, and to ensure that such changes in approved research, during the period for which IRB approval has already been given, are **not initiated without prior IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject." Modifications include but are not limited to: Changes in protocol personnel, number of approved participants, and/or updates to the protocol procedures or instruments and must be submitted via the electronic submission system. Failure to obtain approval for modifications is considered an issue of non-compliance and will be subject to review and deliberation by the IRB which could result in the suspension/termination of the protocol.

ADVERSE EVENTS:
Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to The UT Arlington Office of Research Administration; Regulatory Services within 24 hours of the occurrence or upon acknowledgement of the occurrence.

Office of Research Administration
Regulatory Services
817-272-3723
regulatoryservices@uta.edu

TRAINING
All investigators and key personnel identified in the protocol must have filed an annual Conflict of Interest Disclosure (COI) and have documented *Human Subjects Protection (HSP)* training on file with this office prior to protocol approval. HSP training certificates are valid for 2 years from completion date.

COLLABORATION:
If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to:
http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

CONTACT FOR QUESTIONS:
The UT Arlington Office of Research Administration; Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Robin Dickey at robind@uta.edu or Regulatory Services at regulatoryservices@uta.edu or 817-272-2105.

Sincerely,

Judy R. Wilson, Ph.D.

Digitally signed by Judy R. Wilson, Ph.D.
DN: cn=Judy R. Wilson, Ph.D., o=University of Texas at Arlington, ou=Vice-Chair IRB, email=jrwilson@uta.edu, c=US
Date: 2013.07.11 13:48:58 -05'00'

Judy R. Wilson, Ph.D.
Associate Professor
UT Arlington IRB Vice-Chair

References

Al-Qazaz, H. K., Hassali, M. A., Shafie, A. A., Sulaiman, S. A., Sundram, S., & Morisky, D. E. (2010). The eight-item Morisky Medication Adherence Scale MMAS: Translation and validation of the Malaysian version. *Diabetes Research and Clinical Practice*, *90*, 216-221. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3109726/

Baars, J. E., Zelinkova, Z., Mensink, P. B., Markus, T., Looman, C. Kuipers, E. J., & Van, D. W. (2009). High therapy adherence but substantial limitations to daily activities amongst members of the Dutch inflammatory bowel disease patients' organization: A patient empowerment study. *Alimentary Pharmacology & Therapeutics*, *30*, 864-872. doi:10.1111/j.1365-2036.2009.04103.x

Belaiche, J., Desager, J. P., Horsmans, Y., & Louis, E. (2001). Therapeutic drug monitoring of azathioprine and 6-mercaptopurine metabolites in Crohn's disease. *Scandinavian Journal of Gastroenterology, 36*, 71-76. doi: 10.1080/00365520120315)

Bergman, R., & Parkes, M. (2006). Systematic review: The use of mesalazine in inflammatory bowel disease. *Alimentary Pharmacology & Therapeutics, 23*, 841-855. doi: 10.1111/j.1365-2036.2006.02846.x

Bernal, I., Domènech, E., Garcia-Planella, E., Marín, L., Mañosa, M., Navarro, M., . . . Gassull, M. A. (2006). Medication-taking behavior in a cohort of patients with inflammatory bowel disease. *Digestive Diseases and Sciences, 5*, 2165-2169. doi: 10.1007/s10620-006-9444-2

Bernstein, C., Fried, M., Krashius, J. H., Cohen, H., Eliakam, K., Fedail, S.,… Gearry, R. (2010). World Gastroenterology Organization practice guidelines for the

diagnosis and management of IBD in 2010. *Inflammatory Bowel Diseases, 16,* 112-124. doi: 10.1002/ibd.21048

Bewtra, M., Su, C., & Lewis, J. D. (2007). Trends in hospitalization rates for inflammatory bowel disease in the United States. *Clinical Gastroenterology and Hepatology, 5,* 597-601. doi:10.1016/j.cgh.2007.01.015

Bhatt, J., Patil, S., Joshi, A., Abraham, P., & Desai, D. (2009). Self-reported treatment adherence in inflammatory bowel disease in Indian patients. *Indian Journal of Gastroenterology, 28,* 143-146. doi: 10.1007/s12664-00900050-z

Billioud, V., Laharie, D., Filippi, J., Roblin, X., Oussalah, A., Chevaux, J., B.,… Peyrin-Biroulet, L. (2011), Adherence to adalimumab therapy in Crohn's disease: A French multicenter experience. *Inflammatory Bowel Diseases, 17*, 152–159. doi: 10.1002/ibd.21491

Bokeymer, B., Teml, A., Roggel, C., Hartmann, P., Fischer. C., Schaeffeler, E., & Schwab, M. (2007). Adherence to thiopurine treatment in outpatients with Crohn's disease, 26(2), 217-225. *Alimentary Pharmacology & Therapeutics, 26,* 217-225. doi:10.1111/j.1365-2036.2007.03365.x

Brown, C., Battista, D. R., Bruehlman, R., Sereika, S. S., Thase, M. E., & Dunbar-Jacob, J. (2005). Beliefs about antidepressant medications in primary care patients: Relationship to self-reported adherence. *Medical Care, 43*(12), 1203-1207.

Buchner, A., Erdfelder, E., Faul, F., & Lang, A. (2009). G*Power (Version 3.1.2) [Computer program].

Burns, N., & Grove, S. K. (2009). Introduction to quantitative research. In L. Henderson (Ed.), *The practice of nursing research: Appraisal, synthesis, and generation of evidence* (6th ed., pp. 33-49). St. Louis, MI: Saunders.

Bursac, Z., Gauss. H. C., Williams, D. K., & Hosmer, D.W. (2008). Purposeful selection of variables in logistic regression. *Source Code for Biology and Medicine, 3,* doi:10.1186/1751-0473-3-17

Cameron, E., & Levanthal, H. (2003). Self-regulation, health, and illness: An overview. In E. Cameron & H. Levanthal (Eds.), *The self-regulation of health and illness behavior* (pp. 1-13). New York, NY: Routledge.

Carter, M. J., Lobo, A. J., & Travis, S. P. (2004). Guidelines for the management of inflammatory bowel disease [supplement V]. *GUT, 53*, V1-V6. doi: 10.1136/gut2004.043372

Carter, C.T., Waters, H.C., & Smith, D. (2012). Effect of a continuous measure of adherence with infliximab maintenance treatment on inpatient outcomes in Crohn's disease. *Patient Preference and Adherence, 6*, 417-426. doi: 10.2147/PPA.S31115

Cervený, P., Bortlík, M., Kubena, A., Vlcek, J., Lakatos, P. L., & Lukás, M. (2007). Nonadherence in inflammatory bowel disease: Results of factor analysis. *Inflammatory Bowel Diseases, 13*, 1244-1249. Retrieved from http://www.strevni-zanety.cz/dokumenty/nonadherence.pdf

Cerveny, P., Bortlik, M., Vlcek, J., Kubena, A., & Lukás, M. (2007). Non-adherence to treatment in inflammatory bowel disease in Czech Republic. *Journal of Crohn's and Colitis, 1*, 77-81. doi 10.1016/j.crohns.2007.08.002

Clark, M., Colombel, J., Feagan, B. C., Fedorak, R. N., Hanauer, S. B., Kamm, M. A., . . . Vermeire, S. (2007). American Gastroenterological Association consensus development conference on the use of biologics in the treatment of inflammatory bowel disease. *Gastroenterology, 133*, 312-339. doi: 10.1053/j.gastro.2007.05.006

Claxton, A. J., Cramer, J., & Pierce, C. (2001). A systematic review of the associations between dose regimens and medication compliance. *Clinical Therapeutics*, *23*(8),1296-1310.

Cook, P., Emiliozzi, S., El-Hajj, D., McCabe, T., & Mischa, M. (2010). Telephone nurse counseling for medication adherence in ulcerative colitis: A preliminary study. *Patient Education & Counseling, 81*, 182-186. doi:10.1016/j.pec.2009.12.010

Cramer, J. A., Roy, A., Burrell, A., Fairchild, C. J., Fuldeore, M. J., Ollendorf, D. A., & Wang, P. K. (2008). Medication compliance and persistence: Terminology and definitions. *Value in Health, 11*, 44-47. doi:10.1111/j.1524-4733.2007.00213.x

Dewulf, N. D. L. S., Monteiro, R. A., Passos, A. D. C., Vieira, E. M., & Troncon, L. E. A. (2007). Compliance to drug therapy in inflammatory bowel diseases outpatients from a university hospital. *Arquivos De Gastroenterologia, 44*, 289-296. doi:10.1590/S1413-81232012000700028

D'Haens, Geert R. (2010) "Top-down therapy for IBD: Rationale and requisite evidence." *Nature Reviews Gastroenterology and Hepatology, 7,* 86-92. doi:10.1038/nrgastro.2009.222

Diefenbach, M. A., & Levanthal, H. (1996). The commonsense model of illness representation: Theoretical and practical considerations. *Journal of Social Distress and Homelessness, 5*, 11-37. doi:10.1007/BF02090456

DiMatteo, M. R. (2004). Variations in patients' adherence to medical recommendations. *Medical Care, 42*, 200-209. doi:10.1097/01.mlr.0000114908.90348.f9

D'Incà, R., Bertomoro, P., Mazzocco, K., Vettorato, M. G., Rumiati, R., & Sturniolo, G. C. (2008). Risk factors for non-adherence to medication in inflammatory bowel disease patients. *Alimentary Pharmacology & Therapeutics, 27*, 166-172. doi: 10.1111/j.1365-2036.2007.03555.x

Dorrian, A., Dempster, M., & Adair, P. (2009). Adjustment to inflammatory bowel disease: The relative influence of illness perceptions and coping. *Inflammatory Bowel Diseases, 15*, 47-55. doi:10.1002/ibd.20583

Dunbar-Jacob, J., Sereika, S., Rohay, S. S., & Burke, R. J. (1998). Electronic methods in assessing adherence to medical regimens. In D. Krantz & A. Baum (Eds.), *Technology and methods in behavioral medicine* (pp. 95-113). Mahwah, NJ: Erlbaum.

Ediger, J. P., Walker, J. R., Graff, L., Lix, L., Clara, I., Rawsthorne, P., . . . Bernstein, C. N. (2007). Predictors of medication adherence in inflammatory bowel disease. *American Journal of Gastroenterology, 102*, 1417-1426. doi:10.1111/j.1572-0241.2007.01212.x

Everheart, J. E. (2008). Inflammatory Bowel Disease. In The Burden of Digestive Diseases in the United States (NIH Publication No 09-6443). Retrieved from http://www3.niddk.nih.gov/Burden_of_Digestive_Diseases/index.shtml#CHAPTER25

Farmer, K. C. (1999). Methods for measuring and monitoring medication regimen adherence in clinical trials and clinical practice. *Clinical Therapeutics, 21*, 1074-1090. doi:10.1016/S0149-2918(99)80026-5

Fields, A. (2005). *Discovering statistics using SPSS* (2nd ed.). London, England: Sage

Freeman, J. (2009). Long-term natural history of Crohn's disease. *World Journal of Gastroenterology, 15*, 1316-1318. doi:10.3748/wjg.15.1315.

Gadkari, A. S., & McHorney, C. A. (2012). Medication nonfulfillment rates and reasons: Narrative systematic review. *Current Medical Research and Opinion, 26*, 683-785. doi:10.1185/03007990903550586

Gadkari, A. S., Pedan, A., Gowda, & McHorney, C. (2011). Survey non-responders to a Medication-beliefs Survey have worse adherence and persistence to chronic medications compared with survey responders. *Medical Care, 49,* 956–961. doi:10.1097/MLR.0b013e3182204503

Garfield, S., Clifford, S., Eliasson, L., Barber, N., & Willson, A. (2011). Suitability of measures of self-reported medication adherence for routine clinical use: A systematic review. *BMC Medical Research Methodology, 11*,(149), 1-9. doi:10.1186/1471-2288-11-149

Gillespie, G., Hood, K., Williams, A., Stenson, R., Probert, C, & Hawthorne, A. (2011). The use of the medication event monitoring system (MEMS) for assessing medication adherence for chronic conditions: Use and results from a 12-month trial of patients in remission with ulcerative colitis (UC). *Trials, 12* (Suppl. 1), S130. doi: 10.1186/1745-6215-12-S1-A130

Gliner, J. A., Morgan, G. A., & Leech, N. L. (2009). *Research methods in applied settings*. (2nd ed.). New York, NY: Taylor & Francis.

Gray, J. R., Leung, E., & Scales, J. (2009). Treatment of ulcerative colitis from the patient's perspective: A survey of preferences and satisfaction with therapy. *Alimentary Pharmacology & Therapeutics, 29*, 1114-1120. doi:10.1111/j.1365-2036.2009.03972.x

Greenlaw, S.M., Yentzer, B.A., O'Neill, J.A., Balkrishnan, R., & Feldman, S.R. (2010). Assessing adherence to dermatology treatments: A review of self-report and electronic measures. *Skin Research and Technology, 16*, 253–258. doi:10.1111/j.1600-0846.2010.00431.x

Hale, E. D., Trihare, G. J., & Kitas, G. D. (2007). The common-sense model of self-regulation of health and illness: How can we use it to understand and respond to

our patients' needs? *Rheumatology, 46*, 904-906. doi:10.1093/rheumatology/kem060

Hall, N., Rubin, G., Hungin, A., & Dougall, A. (2006). Medication beliefs among patients with inflammatory bowel disease who report low quality of life: A qualitative study. *BMC Gastroenterology, 7*(20), 1-8. doi:10.1186/1471-230X-7-20

Hampton, N.H, Goulet, L.S., Rainie,, L. & Purcell, K. (2011). Social networking sites and our lives. *Pew Research Center: Pew Research Center's Internet & American Life Project*. Retrieved from http://pewinternet.org/Reports/2011/Technologyandsocialnetworks.aspx

Hanauer, S. (2005). Inflammatory bowel disease: Epidemiology, pathogenesis, and therapeutic opportunities [supplement]. *Inflammatory Bowel Diseases, 12,* S1-S9.

Hawkshead, J., & Krousel-Wood, M. A. (2007. Techniques of measuring adherence in hypertensive patients in outpatients setting: Advantages and limitations. *Journal of Clinical Hypertension, 9*, 179-186. doi:10.1111/j.1751-7176.2010.

Hess, L. M., Raebel, M. A., Conner, D. A. & Malone, D. C. (2006). Measurement of adherence in pharmacy administrative databases: A proposal for standard definitions and preferred measures. *Annals Pharmacotherapeutics, 40*, 1280-1288. doi:10.1345/aph.1H018

Higgins, P. D., Rubin, D. T., Kaulback, K., Schonfield, P. S., & Kane, V. S. (2009). Systematic review: Impact of non-adherence to 5-amonosalicyclic acid products on the frequency and cost of ulcerative colitis flares. *Alimentary Pharmacology and Therapeutics, 29*, 247-257. doi:10.1111/j.1365-2036.2008.03865.x

Hommel, K. A., Odell, S., Sander, E., Baldassano, R. N., & Barg, F. K. (2011).

Treatment adherence in pediatric inflammatory bowel disease: Perceptions from adolescent patients and their families. *Health & Social Care in the Community, 19,* 80-88. doi:10.1111/j.1365-2524.2010.00951.x

Horne, R. (1996). Representations of medication and treatment: Advances in theory and measurement. In K. Petrie and J. Weinman (Eds.). *Perception of health and illness* (pp. 155-88). Amsterdam, Netherlands: Harwood Academic.

Horne, R (2000a). Nonadherence to medications: Causes and Implications for care. In Paul R. Gard (Ed.). *A behavioral approach to pharmacy practice* (pp. 111-130). Oxford, UK: Blackwell Science.

Horne, R. (2000b). Assessing perceptions of medication: Psychological perspectives. In McGlavock (Ed.). *Handbook of drug research methodology* (pp. 299-315). New Castle, UK: UK Drug Utilization Group.

Horne, R., Parham, R., Driscoll, R., & Robinson, A. (2009). Patients' attitudes to medicines and adherence to maintenance treatment in inflammatory bowel disease. *Inflammatory Bowel Diseases, 15*, 837-844. doi:10.101002/ibd.20846

Horne, R., & Weinman, J. (1999). Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *Journal of Psychosomatic Research, 4,* 555-567. doi:10.1016/S0022-3999(99)00057-4

Horne, R., Weinman, J., & Hankins, M. (1999). The Beliefs about Medicines Questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. *Psychology and Health, 14*, 1-24. doi:10.1080/08870449908407311

Huck, S. W. (2010*). Reading statistics and research*. Boston, MA: Allyn & Bacon

Ingersoll, K. S., & Cohen, J. (2008). The impact of medication regimen factors on adherence to chronic treatment: A review of literature. *Journal of Behavioral Medicine, 31*(3), 213-224 doi:10.1007/s10865-007-917-y

Jackson, C. A., Clatworthy, J., Robinson, A., & Horne, R. (2010). Factors associated with nonadherence to oral medication for inflammatory bowel disease: A systematic review. *Clinical Reviews*, *The American Journal of Gastroenterology, 105*, 529-539. doi:10.0138/ajg.2009.685

Kane, S. V. (2006). Systematic review: Adherence issues in the treatment of ulcerative colitis. *Alimentary Pharmacology & Therapeutics, 23,* 577-585. doi:10.1111/j.1365-2036.2006.02809.x

Kane, S. V. (2008). Strategies to improve adherence and outcomes in patients with ulcerative colitis. *Drugs, 68*, 2601-2609. Retrieved from http://link.springer.com/article/10.2165/0003495-200868180-00006

Kane, S., Becker, B., Harmsen, S., Kurian, A., Morisky, D., & Zinsmeister, D. (2012). Use of a screening tool to determine nonadherent behavior in inflammatory bowel disease. *American Journal of Gastroenterology, 107,* 154-160. doi:10.1038/ajg.2011.317

Kane, S. V., Brixner, D., Rubin, D., & Sewitch, M. (2008). The challenge of compliance and persistence: Focus on ulcerative colitis [supplemental material]. Journal of *Managed Care Pharmacy, 14,* S1-S20. Retrieved from http://www.amcp.org/

Kane, S., Chao, J., & Mulani, P. M. (2009). Adherence to infliximab maintenance therapy and health care utilization and costs by Crohn's disease patients. *Advances in Therapy, 10*, 936-946, doi:10.1007/s12325-009-0069-7

Kane, S. V., Cohen, R. D., Aikens, J. E., & Hanauer, S. B. (2001). Prevalence of nonadherence with maintenance mesalamine in quiescent ulcerative colitis. *The*

American Journal of Gastroenterology, 96, 2929-2933. doi: 10.1111/j.1572-0241.2001.04683.x

Kane, S., & Dixon, L. (2006). Adherence rates with infliximab therapy in Crohn's disease. *Alimentary Pharmacology & Therapeutics, 24*, 1099-1103. doi:10.1111/j.1365-2036.2006.03092.x

Kane, S., Huo, D., Aikens, J., & Hanauer, S. (2003). Medication nonadherence and the outcomes of patients with quiescent ulcerative colitis. *The American Journal of Medicine, 114,* 39–43. doi:10.1016/S0002-9343(02)01383-9

Kane, S., Huo, D., & Magnanti, K., (2003). A pilot feasibility study of once daily versus conventional dosing mesalamine for maintenance of ulcerative colitis. *Clinical Gastroenterology and Hepatology, 1,* 170-173.doi:10.1016/S1542-3565(03)70032-9

Kane, S.V., & Shaya, F. (2008). Medication nonadherence is associated with increased health care costs. *Digestive Diseases and Sciences, 53*, 1020-1024. doi:10.1007/s10620-007-9968-0

Kappelman, M., Rifas-Shiman, S., Porter, C., Ollendorf, D., Sandler, R., Galanko, J., & Finkelstein, J. (2008). Direct health care costs of Crohn's disease and ulcerative colitis in US children and adults. *Gastroenterology, 135,* 1907-1913. doi:10.1053/j.gastro.2008.09.012

Kappelman, M., Rifas-Shiman, S., Kleinamn, K.., Ollendorf, D., Bousvaros, A., Grand, R. J., & Finkelstein, J. A. (2007). The prevalence and geographic distribution of Crohn's disease and ulcerative colitis in the United States. *Clinical Gastroenterology and Hepatology*, *5,* 1424-1428. doi:10.1016/J.cgh.2007.07.012

Karter, A. J., Parker, M. M., Moffet, H. H., Ahmed, A. T., Schmittdiel, J. A., & Selby, J. V.

(2009). New prescription medication gaps: A comprehensive measure of adherence to new prescriptions. *Health Services Research, 44,* 1640–1661. doi:10.1111/j.1475-6773.2009.00989.x

Keefer, L., Kiebles, J. L., Martinovich, Z., Cohen, E., Van Denburg, A., & Barrett, T. A. (2011). Behavioral interventions may prolong remission in patients with inflammatory bowel disease. *Behaviour Research & Therapy, 49,* 145-150. doi:10.1016/j.brat.2010.12.005

Khanderia, U., Townsend, K. A., Erickson, S. R., Vlasnik, J., Prager, R. L., & Eagle, K. A. (2008). Medication adherence following coronary artery bypass graft surgery: assessment of beliefs and attitudes. *The Annals of Pharmacotherapy, 42*, 192-199. doi:10.1345/aph.1K497

Knowles, S. R., Wilson, J. L., Connell, W. R. and Kamm, M. A. (2011), Preliminary examination of the relations between disease activity, illness perceptions, coping strategies, and psychological morbidity in Crohn's disease guided by the common sense model of illness. *Inflammatory Bowel Diseases, 17*, 551–2557. doi:10.1002/ibd.21650

Korb-Savoldelli, V., Gillaizeau, F., Pouchot, J., Lenain, E., Postel-Vinay, N., Plouin, P. F., ... & Sabatier, B. (2012). Validation of a French Version of the 8-Item Morisky Medication Adherence Scale in Hypertensive Adults. *The Journal of Clinical Hypertension, 14,*, 429-434. doi:10.1111/j.1751-7176.2012.00634.x

Krousel-Wood, M., Islam, T., Webber, L., Re, R., Morisky, D., & Muntner, P. (2009). New medication adherence scale versus pharmacy fill rates in seniors with hypertension. *American Journal of Managed Care, 15,* 59-66

Lakatos, P. L. (2009). Prevalence, predictors, and clinical consequences of medical adherence in inflammatory bowel disease. *World Journal of Gastroenterology, 15,* 4234-4239. doi:10.3748/wjg.15.4234

Leventhal H., & Cameron L. (1987) Behavioral theories and the problem of compliance. *Patient Education Counseling, 10*, 117–138. doi:10.1016/0738-3991(87)90093-0

Levanthal, H., & Diefenbach, M. (1991). The active side of illness cognition. In J. A. Skeleton, & R. T. Croyle (Eds.), *Mental representations in health and illness* (pp. 247-272). New York, NY: Springer-Verlag.

Leventhal, H., Diefenbach, M., & Levanthal, E. (1992). Illness cognition: Using common-sense to understand treatment adherence and affect cognition interactions. *Cognitive Therapy & Research, 16,* 143-163. doi: 0.1007/BF01173486

Leventhal, H., Meyer, D., & Nerenz, D. (1980). Common sense representation of illness danger. In S. Rachman (Ed.), *Contributions to medical psychology* (pp. 17-30). New York, NY: Pergammon.

Leventhal, L., Weinman, J., Leventhal, E. A., & Phillips, L. A. (2008). Health Psychology: The search for pathways between behavior and health. *Annual Review of Psychology, 59,* 477-505 doi:10.1146/annurev.psych.59.103006.093643

Lichtenstein, G. R., Hanauer, S. B., Sandborn, W. J. (2009). Practice Parameters Committee of American College of Gastroenterology. Management of Crohn's disease in adults. *American Journal of Gastroenterology, 10,* 465-483. doi:10.1038/ajg.2008.168

López-SanRomán, A., & Bermejo, F. (2006). Review article: How to control and improve adherence to therapy in inflammatory bowel disease. *Alimentary Pharmacology & Therapeutics, 24,* 45-49. doi:10.1111/j.1365-2036.2006.03060.x

Mantzaris, G. J., Roussos, A., Kalantzis, C., Koilakou, S., Raptis, N., & Kalantzis, N. (2007). How adherent to treatment with azathioprine are patients with Crohn's disease in long-term remission? *Inflammatory Bowel Diseases, 13*, 446-450. doi:10.1002/ibd.20041

Martin, R., Rothrock, N., Leventhal, H., & Leventhal E. (2003). Common sense models of illness: Implications for symptom perception and health-related behaviors In J. Suls and K. Wallston (Eds.), *Social psychological foundations of health and illness* (pp. 199-219). Malden, MA: Blackwell.

McDonald, H. P., Garg, A. X., & Haynes, R. (2002). Interventions to enhance patient adherence to medication prescriptions. Scientific review. *Journal of American Medical Association, 288*, 2868-2879. doi:10.1001/jama.288.22.2868

McHorney, C., & Gadkari, A. (2010). Individual patients hold different beliefs to prescription medications to which they persist vs nonpersist and persist vs nonfulfill. *Patient Preference and Adherence, 4*, 187-195.

McHorney, C., & Spain, C. (2010). Frequency of and reasons for medication non-fulfillment and non-persistence among American adults with chronic diseases in 2008. *Health Expectations, 14,* 307-320. doi:10:1111/ j.1369-7625.2010.00619.x

Menard, S. (2002). *Applied logistic regression analysis* (2nd ed), Sage: Thousand Oaks, Ca.

Morisky, D. E., Ang, A., Krousel-Wood, M., & Ward, H. J. (2008). Predictive validity of a medication adherence measure in an outpatient setting. *The Journal of Clinical Hypertension, 10,* 348-354. doi:10.1111/j.1751-7176.2008.07572.x

Morisky, D.E., & DiMatteo, M.R. (2011). Improving the measurement of self-reported medication nonadherence: Final response. *Journal of Clinical Epidemiology, 64,* 262-263. doi:10.1016/j.jclinepi.2010.09.010

Morisky, D.E., Green, L.W., & Levine, D.M. (1986). Concurrent and predictive validity of a self-reported measure of medication adherence. *Medical Care, 24,* 67-74.

Moshkovska, T., Stone, M. A., Clatworthy, J., Smith, R. M., Bankart, J., Baker, R., . . . Mayberry, J. F. (2009). An investigation of medication adherence to 5-aminosalicylic acid therapy in patients with ulcerative colitis, using self-report and urinary drug excretion measurements. *Alimentary Pharmacology & Therapeutics, 30,* 1118-1127. doi:10.1111/j.1365-2036.2009.04152.x

Nahon, S., Lahmek, P., Saas, C., Durance, C., Olympie, A., Lesgourgues, B., & Gendre, J. (2011). Socioeconomic and psychological factors associated with nonadherence to treatment in inflammatory bowel disease patients: Results of the ISSEO survey. *Inflammatory Bowel Diseases, 17,* 1270-1276. doi:10.1002/ibd.21482

Nguyen, G. C. Tuskey, A. Dassopoulos, T. Harris, M. L., Brant, S. R. (2004). Rising hospitalization rates for inflammatory bowel disease in the United States between 1998 and 2004. *Inflammatory Bowel Diseases*, 13, 1529-1535. doi:10.1002/ibd.20250

Nguyen, G. C. LaVeist, T. A., Harris, M. L., Datta, L. W., Bayless, T. M., & Brant, S. R. (2009). Patient trust-in-physician and race are predictors of adherence to medical management in inflammatory bowel disease. *Inflammatory Bowel Diseases, 15*(8), 1233-1239.doi:10.1002/ibd.20883

Nigro, G., Angelini, G., Grosso, S. B., Caula, G., & Sategna-Guidetti, C. (2001). Psychiatric predictors of noncompliance in inflammatory bowel disease: Psychiatry and compliance. *Journal of Clinical Gastroenterology*, 32, 66-68.

Nurse Practitioners' Prescribing Reference (NPPR). (2013, Summer). New York, NY: Haymarket Media.

Nunnally, J.C., & Bernstein, I.H. (1994). *Psychometric theory*, (3rd edition). McGraw-Hill: New York, NY.

Ockene, I. S., & Hayman, L.L., Pasternak, R. Schron, E., & Dunbar-Jacob J. (2002). Task force #4—adherence issues and behavior changes: Achieving a long-term solution. 33rd Bethesda Conference. *Journal American College of Cardiology, 40,* 630-640. doi:10.1016/S0735-1097(02)02078-8

Osterberg, L., & Blaschke, T. (2005). Adherence to medication. *The New England Journal of Medicine, 353*, 487-497. doi:10.1056/NEJMra050100

Pallant, J. (2009). *SPSS Survival Manual: A step-by-step guide for data analysis using SPSS for Windows* (3rd ed.). Berkshire, England: McGraw-Hill

Partridge, A. H., Avorn, J., Wang, P. S., & Winer, E. P. (2002). Adherence to therapy with oral antineoplastic agents. *Journal of the National Cancer Institute, 94,* 652-661. doi:10.1093/jnci/94.9.652

Peterson, A. M., Nau, D. P., Cramer, J. P., Benner, J., Gwardy, F., Nichol, M. (2007). A checklist for medication compliance and persistence studies using retrospective databases. *Value in Health, 10,* 3-11. doi:10.1111/j.1524-4733.2006.00139.x

PEW Research Center. (2012). Use and home broadband connections: Demographics. *PEW Internet and American Life Project*. Retrieved from http://www.pewinternet.org/Infographics/2012/Internet-Use-and-Home-Broadband-Connections.aspx

Phatak, M. H., & Thomas, J. (2006). Relationships between beliefs about medications and nonadherence to prescribed chronic medications. *The Annals of Pharmacotherapy, 40,* 1737-1742. Retrieved from http://www.theannals.com/

Polit, D. F. (2010). *Statistics and data analysis for nursing research* (2nd ed.). Upper Saddle River, NJ: Pearson.

Ponder, A. & Long, M. D. (2013). A clinical review of recent findings in the epidemiology of inflammatory bowel disease. *Dove Press, 5*(1), 237-247. doi:10.2147/CLEP.S33961

Porteous, T., Francis, J., Bond, C., & Hannaford, P. (2009). Temporal stability of beliefs about medicines: Implications for optimizing adherence. *Patient Education and Counseling, 79,* 225-230. doi:10.1016/j.pec.2009.07.037

Qualtrics Research Suite (Version 2013) [Computer Software]. Provo, Utah

Rolley, J. X., Davidson, P. M., Dennison, C. R., Ong, A., Everett, B., & Salamonson, Y. (2008). Medication adherence self-report instruments: Implications for practice and research. *Journal of Cardiovascular Nursing, 23,* 497-505. doi:10.1097/01.JCN.0000338931.96834.16

Ross, S. S., Walker, A. A., & MacLeod, M. J. (2004). Patient compliance in hypertension: Role of illness perceptions and treatment beliefs. *Journal of Human Hypertension, 18*, 607-613. doi:10.1038/sj.jhh.1001721

Sands, B. E. (2007). Inflammatory bowel disease: Past, present, and future. *Journal of Gastroenterology, 42,* 16-25. doi:10.1007/s00535-006-1995-7

Sandborn, W. J., Feagan, B. G., Lichtenstein, G. R. (2007), Medical management of mild to moderate Crohn's disease: Evidence-based treatment algorithms for induction and maintenance of remission. *Alimentary Pharmacology & Therapeutics, 26,* 987–1003. doi:10.1111/j.1365-2036.2007.03455.x

Selinger, C. P., Robinson, A., & Leong, R. W. (2011). Clinical impact and drivers of non-adherence to maintenance medication for inflammatory bowel disease. *Expert Opinion on Drug Safety, 10*, 863-870 doi:10.1517/14740338.2011.583915

Sewitch, M. J., Abrahamowicz, M., Barkun, A., Bitton, A., Wild, G. E., Cohen, A., & Dobkin, P. L. (2003). Patient nonadherence to medication in inflammatory bowel

disease. *American Journal of Gastroenterology, 98*, 1535-1544. doi:10.1016/S0002-9270(03)00304-6

Sewitch, M. J., Leffondré, K., & Dobkin, P. L. (2004). Clustering patients according to health perceptions: Relationships to psychosocial characteristics and medication nonadherence. *Journal of Psychosomatic Research, 56,* 323-332. doi:10.1016/S0022-3999(03)00508-7

Shale, M. J., & Riley, A. (2003). Studies of compliance with delayed-release mesalamine therapy in patients with inflammatory bowel disease*. Alimentary Pharmacology and Therapeutics, 18,* 191-198. doi:10.1046/j.l365.2003.01648.x-2036

Shi, L., Liu, J., Fonseca, V., Walker, P., Kalsekar, A., & Pawaskar, M. (2010). Correlation between adherence rates measured by MEMS and self-reported questionnaires: A meta-analysis. *Health and Quality Life Outcomes, 8,* 1-7. doi:10.1186/1477-7525-8-99

Sokol, M. C., McGuian, K. A., Verbugge, R. R., & Epstein, R. S. (2005). Impact of medication adherence on hospitalization risk and healthcare cost. *Medical Care, 43,* 521-530.

Steiner, J. S., Koepsell, T. D., Fihn, S. D., & Inui, T. S. (1998). A general method of compliance assessment using centralized pharmacy records: Description and validation. *Medical Care, 26*, 814-823

Steiner, J. F., & Prochazka, A. V. (1999). The assessment of refill compliance using pharmacy records: Methods, validity, and applications*. Journal of Clinical Epidemiology, 50*, 105-116

Tabachnik, B. G., & Fidell, L. S. (2007). *Using multivariate statistics* (5th ed.). New York, NY: Pearson.

Trindade, A. J., Ehrlich, A., Kornbluth, A., & Ullman, T. A. (2011), Are your patients taking their medicine? Validation of a new adherence scale in patients with inflammatory bowel disease and comparison with physician perception of adherence. Inflammatory *Bowel Diseases, 17*, 599–604. doi:10.1002/ibd.21310

Vatn, M. H. (2009). Natural history and complications of IBD. *Current Gastroenterology Reports, 11*, 481-487. doi:10.1007/s11894-009-0073-8

Waltz, C. F., Strickland, O. L., & Lenz, E. R. (2005). *Measurement in nursing and health research*. New York, NY: Springer

Waters, B. M., Jensen, l.,& Fedorak, R. N. (2005). Effects of formal education for patients with inflammatory bowel disease: A randomized controlled trial. *Canadian Journal of Gastroenterology, 19*, 235-244. doi:10.3748/wjg.15.4234

Wright, S., Sanders, D. S., Lobo, D. J., & Lenard, L. (2004). Clinical significance in azathioprine active metabolite concentrations in inflammatory bowel disease. *GUT*, 53, 1123-1158. doi:1136/gut2003.032896

Yu, A.P., Cabanilla, L. A., Wu, E.Q., Mulani, P. M., & Chao, J. (2007). The costs of Crohn's disease in the United States and other Western countries: A systematic review. *Current Medical Research and Opinion, 24*, 319-328. doi: 10.1185/030079908X260790)

Biographical Information

Donna Bacchus graduated from the University of Ottawa, Ottawa Canada in 1980 with a Baccalaureate of Science in Nursing. She worked in Toronto, Canada as a staff nurse in a variety of critical care areas as well as a clinical nursing instructor at Centennial and Seneca Colleges in Toronto Canada. In 1991 she moved to South Texas where she worked part time as a clinical Instructor at the University of Texas Pan American. Additionally, she worked as a CNE coordinator, ICU nurse, Nurse Practitioner, recovery room nurse and an outpatient cardiology nurse. In 1993 she graduated from the University of Texas Health Sciences Center at Houston Texas with a Masters in Nursing, role specialization as Clinical Nursing Specialist in Critical Care. She continued with her education and graduated with a post masters from Family Nurse Practitioner program at Texas A & M, Corpus Christi, Texas. She moved to North Texas in 2005 where she continued to work as a clinical nursing instructor at UTA at Arlington. She also worked part-time as a Quality Improvement Coordinator at two major metropolitan hospital systems in the DFW metroplex.

Her research interests are patients with inflammatory bowel disease: Adherence to medications, improving quality of life, transitional issues that late adolescent to young adults encounter and excellence in practice for providers taking care of IBD patients. She is a member of the Nurse Initiatives Committee of the Crohn's and Colitis Foundation of America and has presented posters and seminars on inflammatory bowel disease. Her future plans include the development of a tool to assess adherence to treatment and medications. She believes that a rapid assessment tool will empower healthcare providers to work collaboratively with patients to improve adherence to medications. The ultimate goal is for healthcare providers to facilitate adherence, form partnerships and therefore improve the quality of life in patients with inflammatory bowel disease.