

COST AS A FEATURE OF MEDICATION MANAGEMENT COMMUNICATION
IN MEDICAL VISITS

Ashley J. Beard

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Approved by,

Betsy Sleath, Ph.D.
Susan Blalock, Ph.D.
Mary Roth, Pharm.D., M.H.S.
Morris Weinberger, Ph.D.
Gail Tudor, Ph.D.

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ABSTRACT

ASHLEY J. BEARD: Cost as a Feature of Medication Management Communication
in Medical Visits
(Under the direction of Dr. Betsy Sleath)

Little is known about how patients and physicians discuss medication costs in medical visits, if such discussions impact decision making, and if patients are more satisfied with their medications if they discuss cost. The predominance of medication therapy, the need for continuous treatment, and the variation in medication costs make it especially important to examine the extent to which rheumatoid arthritis (RA) patients discuss issues related to medication costs, how they manage their medications with their physicians, and how this relates to patient-reported medication satisfaction.

This is a cross-sectional secondary analysis of survey and clinic visit audiotape data that were collected in North Carolina from 2003 to 2005 from 8 rheumatologists and 200 of their adult patients with RA. Qualitative analyses were conducted to examine the content of communication about medication costs and management in routine rheumatology clinic visits. Quantitative analyses employing multivariable models were conducted to examine the influence of patient, physician, and medication characteristics on visit communication about medication costs, management, and satisfaction.

Results revealed that 34% of medical visits contained medication cost communication and the content centered on insurance coverage and strategies to reduce patient out-of-pocket medication expenses. Quantitative results revealed that patients identifying as White/Caucasian and those with no prescription drug coverage were significantly more likely to discuss medication costs. Results revealed that medication cost communication and disclosure of patient-initiated regimen changes were significantly,

positively associated with one another. In over 20% of visits, patients disclosed self-initiated changes to their medication regimens and the communication demonstrated that patients were active managers of their medications. Patients disclosed taking more, less, and substituting medications for those prescribed. Almost unanimously, the regimen changes reduced their total RA medication cost burden. However, neither communication about medication costs nor patient medication management significantly predicted medication regimen changes in the medical visit and no factors reliably predicted patient-reported medication satisfaction.

These findings have implications for conceptualizing medical visit communication about medication costs and management. Better understanding of these topics provides guidance for the development of conceptual frameworks and interventions to improve communication, and thereby improve care.

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LIST OF ABBREVIATIONS

| | |
|-------|---------------------------------------|
| ACR | American College of Rheumatology |
| AWP | Average Wholesale Price |
| DMARD | Disease Modifying Anti-Rheumatic Drug |
| FCS | Fully conditional specification |
| NSAID | Non-Steroidal Anti-Inflammatory Drug |
| OOP | Out-of-pocket |
| OTC | Over-the-counter |
| RA | Rheumatoid Arthritis |

CHAPTER ONE: INTRODUCTION

“It is not to see something first, but to establish solid connections between the previously known and hitherto unknown that constitutes the essence of specific discovery.”
(Selye, 1956)

The cost of prescription medication in the United States is a critical health and policy issue. Americans, especially those with chronic conditions, are not only paying more for medications, but they are also using more prescription medications than ever (Alexander, Casalino, & Meltzer, 2005; Alexander, Casalino, Tseng, McFadden, & Meltzer, 2004; Heisler, Langa et al., 2004). While it is generally agreed that medication costs should be taken into account in prescribing decisions, little is known about how patients and physicians discuss medication costs in medical visits, if such discussions impact medical decision making, and if patients are more satisfied with their medications if they discuss cost issues with physicians (Alexander, Casalino, & Meltzer, 2003; American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines, 2002).

The predominance of medication therapy, the need for continuous treatment, and the variation in medication costs make it especially important to examine the extent to which RA patients discuss medication cost issues and how they manage their medications with their physicians. RA is a chronic disease primarily treated through long-term continuous use of prescription medications. Out-of-pocket (OOP) costs incurred by patients for RA medications vary widely from just a few dollars per month to thousands per month (Lapsley et al., 2002). With medication regimen changes occurring in as many as 90% of rheumatology clinic visits, examining discussions of medication cost provides insight into management strategies employed by patients and whether discussing such issues improves

patient satisfaction with their medications (Chewning et al., 2001; Piette, Heisler, & Wagner, 2004a).

To address the issues outlined above, the objective of this research study was to examine routine medical visit communication about medication costs and medication management between patients with RA and their rheumatologists and assess the impact of such communication on medication satisfaction. This study is a cross-sectional, secondary analysis of data that were collected as part of an ongoing National Institute on Aging funded study examining patient-physician communication about quality of life and medication concerns in rheumatology visits. The data were collected in North Carolina from March 2003 to December 2005. Study data include clinic visit audiotapes, patient interviews, medical records, and questionnaires. The three aims of the investigation were to: (1) qualitatively examine the content of discussions regarding medication costs and medication management between RA patients and rheumatologists, (2) describe relationships among patient characteristics, physician characteristics, medication characteristics, and medical visit communication about medication costs and management, and (3) examine how discussions of medication cost and management in routine medical visits affect patient-reported medication satisfaction.

The broad, long-term objective is to improve physician-patient communication about medication costs and medication regimen management in an effort to improve patient medication satisfaction and subsequent medication adherence. Medication satisfaction has been shown to be predictive of subsequent medication adherence (Bultman & Svarstad, 2000). Further, satisfaction with medication and health care more broadly can also be considered an indicator of quality care (Cleary & McNeil, 1988).

This study addresses the need to better understand patient-physician communication about medication costs and medication management during rheumatology visits and the impact of such communication on medication satisfaction. This will be one of the first

studies to examine actual discussions between patients and physicians about medication cost and management (Alexander et al., 2004; Chewing & Sleath, 1996; Schafheutle, Hassell, Noyce, & Weiss, 2002). The findings from this study can be used to educate physicians and patients about ways they can optimize communication about medications during rheumatology visits to improve patient outcomes.

This dissertation is organized around the three primary research aims described above. Chapter 2 includes a review of the literature on RA, medication costs, discussions of medication costs between patients and providers, patient medication management, and patient satisfaction with medications. The chapter provides a description of how this literature informed the specific aims and conceptual framework underlying the dissertation. Chapter 3 describes the conceptual framework that guides the study. Chapter 4 details the research methods describing the study setting, patient eligibility, the study data, measurements, and analyses by aim. This is followed by the study results in Chapter 5. Finally, Chapter 6 summarizes the major findings from the research, discusses the implications, presents a revised conceptual framework, and suggests possible directions for future research.

CHAPTER TWO: BACKGROUND AND SIGNIFICANCE

Overview

Few published studies have examined the content of patient-physician communication about medication costs as part of medication regimen modification discussions in medical visits (Richard & Lussier, 2006; Tarn et al., 2006). To the best of my knowledge, there has been no published work examining communication about medication costs between rheumatologists and patients with RA. RA is a chronic, systemic disease characterized by inflammation of the joints which can lead to irreversible joint damage (Brus, van de Laar, Taal, Rasker, & Wiegman, 1999). Current estimates indicate a 1% population prevalence of RA (DeWitt, Glick, Albert, Joffe, & Wolfe, 2006). Medication is the dominant therapy for RA patients and recent advances in medication therapy have provided patients and physicians with new options in treating RA. These new biologic agents have demonstrated efficacy and are being increasingly used in clinical practice (Maradit-Kremers, Nicola, Crowson, O'Fallon, & Gabriel, 2006). However, the use of biologic medications has driven up the medical costs of RA, with patients taking biologics subject to disproportionately greater costs (Michaud, Messer, Choi, & Wolfe, 2003). While some of these medication costs may be offset by health insurance and prescription drug coverage, RA patients in the United States generally incur a portion of the total cost as OOP medication costs. While patients may be increasingly burdened by these OOP medication costs, little is known about the frequency and content of communication about medication cost as part of medication management communication in medical visits (Heisler, Langa et al., 2004). Therefore, the purpose of this research is to examine actual RA patient-rheumatologist communication

about medication costs and medication management in routine clinic visits, the patient, physician, and medication characteristics that influence such communication, and the impact these factors have on patient reported medication satisfaction.

The following section examines relevant literature on RA, medication costs, discussions of medication cost between patients and providers, patient medication management, and patient satisfaction with medications.

Rheumatoid Arthritis

RA is a chronic, systemic disease characterized by inflammation of the joints. The disease is incurable and while the inflammation is reversible it can lead to irreversible joint damage (Brus et al., 1999). Current estimates indicate that there is an overall 1% population prevalence of RA and approximate 2% population prevalence of RA among individuals age 60 and older in the United States, meaning nearly 10 million US adults age 60 and older are affected by RA (DeWitt et al., 2006; Rasch, Hirsch, Paulose-Ram, & Hochberg, 2003). RA is generally more prevalent among women, persons with less education, and older persons (Rasch et al., 2003).

Recommended treatments for RA include physical exercise, ergonomic measures, disease-modifying antirheumatic drugs (DMARDs), nonsteroidal anti-inflammatory drugs (NSAIDs), and glucocorticoids (Maradit-Kremers et al., 2006). Treatment with medication is the dominant therapy for RA patients. The use of medications in the treatment of RA is particularly important because the medications have the potential to reduce and prevent joint damage and preserve joint integrity and function. Treatment with DMARD therapy is prescribed to change the disease process, and should be used continuously. However, effects of this therapy on the disease, and consequently symptoms, can be expected only after weeks or months (Brus et al., 1999). Response to the medications can be highly individual with certain patients experiencing potentially serious side effects or receiving little

to no benefit, especially over the long term (Maradit-Kremers et al., 2006; Neame & Hammond, 2005). Notably though, recent advances in medication therapy have provided patients and physicians new medication options in treating RA. These new biologic agents have demonstrated efficacy and are being increasingly used in clinical practice (Maradit-Kremers et al., 2006).

Medication Costs

In 1999, \$100 billion was spent on prescription drugs and the Health Care Financing Administration (HCFA) has predicted that pharmaceutical costs, which accounted for 9.4% of health care expenditures in 1999, will increase to 12.6% per year on average over the next decade (Iglehart, 2001). Older adults often have to spend significant portions of their incomes on prescription drugs. A study by Hwang, Weller, Ireys, and Anderson (2001) using 1996 Medical Expenditure Panel Survey data found that OOP spending increased with age. Study results indicated that persons 80 years-old and over spent more than 5 times that of those from birth to 19 years. For US adults with multiple chronic illnesses, OOP prescription medication expenditures can be well over one thousand dollars a year (Heisler, Langa, Eby, Fendrick, Kabeto, & Piette, 2004). Even in countries with more generous prescription drug coverage than the United States, many patients face financial pressure from OOP medication costs and generally report being cost-conscious about their prescription medications (Atella, Schafheutle, Noyce, & Hassell, 2005; Ess, Schneeweiss, & Szucs, 2003; Krobot et al., 2004; Noyce et al., 2000).

For patients with RA, medication costs are an especially salient issue. The increasing use of biologic medications combined with the predominance of medication therapy has driven up the medical costs of RA. The mean total annual direct medical care cost in 2001 for an RA patient was calculated as \$9,519, an approximate \$4,000 increase over the 1998 estimate (Michaud et al., 2003). Of the \$9,519, medication costs accounted

for 66% or \$6,324. RA patients taking biologic medication agents were subject to mean total annual direct costs of \$19,016 per year, while the cost to those not taking biologics was \$6,164. While some of these medication costs may be offset by health insurance and prescription drug coverage, RA patients in the United States generally incur a portion of the total cost as OOP medication costs.

Discussions of Medication Cost between Patients and Physicians

A nationally representative survey of over 4000 chronically ill adults found that of those individuals who restricted their medication use, only 33% reported that they had told their doctor that they planned to use fewer medications because of cost in the previous 12 months (Piette, Heisler, & Wagner, 2004b). A recent examination of actual visit communication between patients and physicians about the cost of newly prescribed medicines found that among a sample of family physicians, internists, and cardiologists medication cost was only discussed for 12% of newly prescribed medications (Tarn et al., 2006). Alexander et al. (2004) found that 11% of patients and 20% of physicians were able to recall a time they wanted to talk about cost but did not. Both patients and physicians report numerous barriers to discussing medication costs during medical visits (Alexander et al., 2005; Alexander et al., 2004; Piette et al., 2004b; Schafheutle et al., 2002). Patient-reported barriers to medication cost discussions are: discomfort discussing OOP costs, insufficient time, belief that the physician did not have a viable solution to offer, and concerns regarding the impact of discussion on quality of care. Physician-reported barriers to discussing medication costs in medical visits have included: insufficient time, belief that they did not have solution to offer, discomfort discussing medication cost, and fear of compromised quality of care.

Despite reported barriers to communication of medication cost between patients and physicians, patients who talk with their physicians about medication costs have rated these conversations 'helpful' (Piette et al., 2004b). Physicians have reported employing a number of strategies to address issues of medication cost-related restriction when they are aware that it is an issue for patients. Physician reported strategies to assist patients who were burdened by OOP medication costs included: switching patients from brand-name to generic drugs, providing patients with medication samples, critically reviewing patients' medication list and discontinuing nonessential ones, switching to different brand name drugs in same medication class, and expressing sympathy (Alexander et al., 2005; Piette et al., 2004b).

Medication Management

Discussions of medication cost can be viewed in the larger context of medication management. Generally, patients are required to manage their medication regimens immediately following the interaction with their physician. Specifically, medication management refers to the set of decisions and behaviors patients engage in to evaluate and revise, at their discretion, their medication regimens (Chewning & Sleath, 1996). Patients have been shown to be active in managing their medication regimens and, yet, this has been an often-overlooked element in patient-physician communication about medications (Chewning & Sleath, 1996).

For chronic-conditions like RA, patient medication management has a potentially large impact on the disease experience. RA medications have the potential to reduce pain, prevent joint damage, and preserve joint integrity and function. Medication therapy is prescribed to change the disease process, and should be used continuously. However, the medications used to treat RA can potentially be harmful to patients and may only be partially effective (Neame & Hammond, 2005). With variability in the side effects and effectiveness

of medications, as well as the painful and highly somatic nature of RA, there is a need for constant medication calibration (Chewning et al., 2001). RA patients must make decisions about the amount, timing, and quantity of medication to take based on a number of personal factors, including the cost of their medications. In this way, medication cost is a feature of medication management, and medication management is something that may or may not be discussed in medical visits. The presence or absence of discussion about medication management may have several implications. Without discussion and understanding of how patients conceptualize or monitor their RA, physicians are at a disadvantage for understanding patients' judgments and medication decisions (Chewning & Sleath, 1996). If physicians and patients discuss medication management strategies during the medical visit, they may agree on a regimen that is tailored on the basis of patients' financial status. For example, insurance coverage might be discussed and physicians might select preferred medications with lower co-payments. If such discussions do not take place, patients may be less satisfied with their medications and may modify their regimens without the input of the physician.

Patient Satisfaction with Medication

Patient satisfaction has become an increasingly important health outcome and can be used to evaluate the quality of care as well as identify particular factors of care, such as medications, that need to be changed to improve satisfaction (Jackson, Chamberlin, & Kroenke, 2001). Satisfaction has been conceptualized as an attitudinal response to value judgments that patients make about their clinical encounters (Kane, Maciejewski, & Finch, 1997). From this, medication satisfaction can be conceptualized as patients' attitudes and judgments about the medications they are taking or are supposed to take. Assessing satisfaction with medication as an outcome of communication about medication cost and management is especially pertinent since satisfaction has been shown to be associated with

the nature of patient-physician communication and with medication adherence (Bultman & Svarstad, 2000). A meta-analysis of 41 studies examining objectively measured patient-physician behaviors in medical encounters and satisfaction indicated that greater satisfaction had statistically significant associations with physician provision of more information, greater conversation about topics not directly medical, and more physician engagement of patients in decision making (Hall, Roter, & Katz, 1988). Looking specifically at RA, a study of 1,041 patients with RA found that patients who reported greater involvement in medical decision-making were significantly more satisfied with their treatment than patients who reported being less involved in decision-making (Kjeken et al., 2006). Therefore, patients who communicate with their physicians about medication cost and medication management may be more likely to perceive their physicians as providing more information and engaging them more in medical decision making and are more likely to be satisfied with the medications they are supposed to take.

Summary and Significance of the Project

In sum, the proposed research will give insight into discussions of medication cost and medication management between patients and providers and the effect that such discussions have on medication satisfaction. Examining actual patient-physician communication about medication costs and management is important because it is within this context that patients obtain their medications and their level of satisfaction with these medications has important implications for their subsequent adherence. This will be one of the first studies to examine actual discussions between patients and physicians about medication cost and management (Alexander et al., 2004; Chewing & Sleath, 1996; Schafheutle et al., 2002). The findings from this study can be used to educate physicians and patients about ways they can optimize communication about medications during rheumatology visits to improve patient outcomes.

CHAPTER THREE: CONCEPTUAL FRAMEWORK

Overview and Conceptual Model

While communication between patients and physicians has been studied for over fifty years, examination of communication about medication costs between patients and physicians is relatively new and, as such, so is development of conceptual frameworks to understand such communication and its impact (Parsons, 1951; Piette, Heisler, Horne, & Caleb Alexander, 2006). Since much of the focus of this research is on the nature of communication between physicians and patients, typologies of patient-physician interaction as well as the antecedents and outcomes of typologies of interaction guide the conceptual framework in this study.

The entry of patient and physician into an exchange, as occurs in medical visits, denotes the start of a relationship between the two participants predicated on the expectations that each has for the other (D. Roter & Hall, 2006). Patient and physician enter into a fluid system of expectations, roles, and outcomes based on their mutual influence on each other within medical visit interactions. In this way, the medical visit and the interacting partners are a dynamic system of interaction of cause and effect, recognizing the primacy of the individual positions of patient and physician in interactions (Lewin, 1935). The individual positions that patient and physician assume often take the form of defined roles. These roles influence medical visit communication and have implications for the provision of care, satisfaction, and outcomes. The assumption of defined roles by patient and physician in medical visit interactions are the foundation of relationship typologies.

Patient-physician interaction typologies are based on the level of physician authority and patient autonomy where both elements exist along a spectrum and must be negotiated in the patient-physician relationship (Parsons, 1951; D. Roter & Hall, 2006). These typologies are played out in the course of communication and, as conceptualized, can be thought of as four hypothetical models of varying levels of control of the interaction on the part of the participants. The expression of power and the dynamics of negotiation have been described as assuming the four paradigms of the patient doctor-relationship: paternalism, consumerism, mutuality, and default (D. Roter & Hall, 2006). Table 1 displays the typologies and associated levels of physician and patient control.

Table 1. Patient-physician relationship typologies as presented in Roter & Hall, 2006.

| Patient Control | Physician Control | |
|-----------------|-------------------|-------------|
| | Low | High |
| Low | Default | Paternalism |
| High | Consumerism | Mutuality |

The upper right quadrant of Table 1 presents the archetype of *paternalism*. It is characterized by physician domination of medical visit agenda setting, treatment negotiation, and overall control of information and services. In this model the patient has little control in the visit and often has little to no participation in communication.

Consumerism, in the lower left corner of Table 1, represents the opposite of paternalism. Patients have primary responsibility for goal setting, negotiating, and decision-making in the consumerism relationship model. In medical visits characterized by consumerism, patients make demands for information and services that are obliged by the physician. This view is often thought of in economic marketplace terms where consumers demand goods and services, physicians supply care, and transactions are conducted accordingly.

In the lower right quadrant of Table 1, *mutuality* represents the middle ground between paternalism and consumerism. In this relationship model, both patient and physician exercise high control over the interactions. Insofar as is possible, the power is balanced between patient and physician and agenda setting happens jointly, both participate in negotiation, and decision-making happens jointly. Joint decision-making and negotiating happen through meaningful dialogue between patient and physician in relationships characterized by mutuality. Patients explicitly communicate about their condition, values, and preferences. Physicians respond by exploring those views with patients, providing thorough information, and actively involving them in treatment decisions. Through these exchanges, the experiences and inherent expertise of both participants are validated.

Mutuality relationships have important implications for decision-making about medications because it is under conditions of mutuality that concordance is likely to be achieved (Elwyn, Edwards, & Britten, 2003). Concordance has been defined as, “an agreement reached after negotiation between a patient and health care professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken. Although reciprocal, this is an alliance in which the health care professional recognizes the primacy of the patient’s decisions about taking the recommended medications (Royal Pharmaceutical Society of Great Britain, 1997).” Exchanges about medications in which patients provide information on their feelings and preferences about taking medications, physicians ask questions, they provide patients with the pros and cons of taking and not taking medicine, and both parties agree on a decision meet the criteria for both concordance and mutuality.

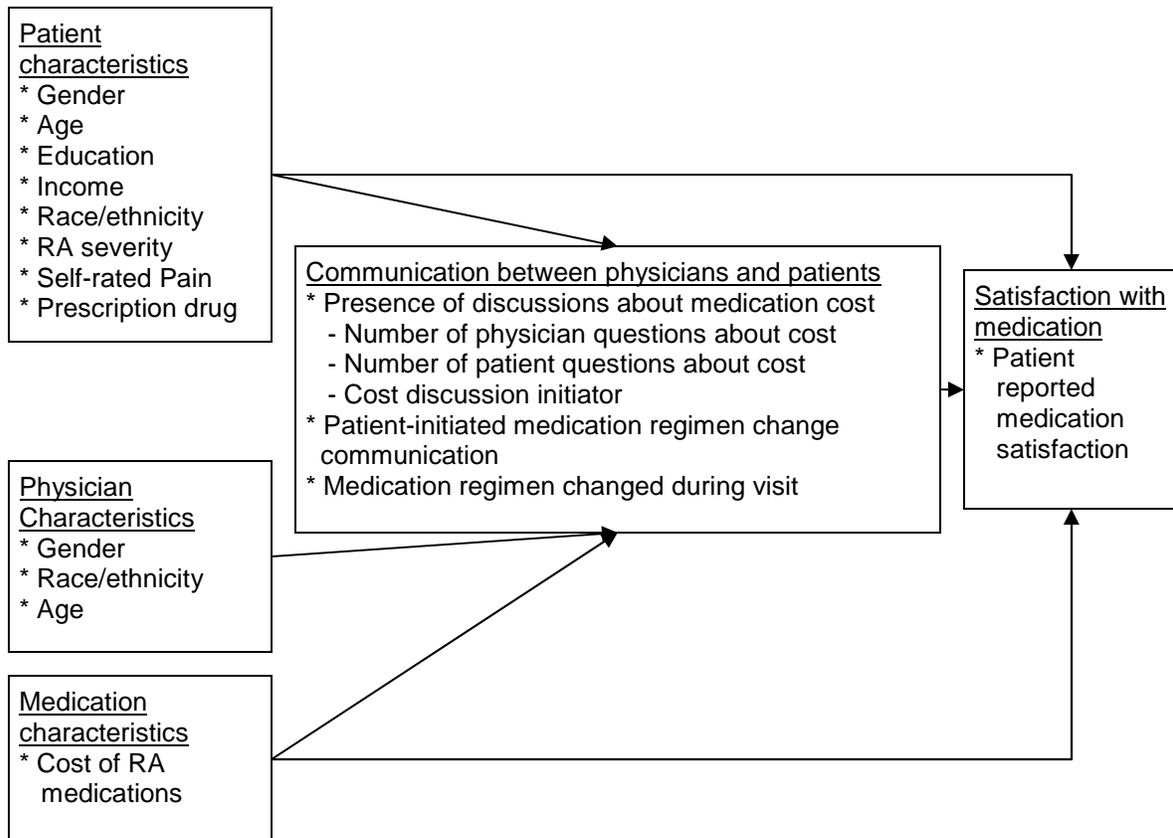
When the relationship is difficult to negotiate, both parties are functionally absent in decision-making, and neither participant in the medical visit exercises high levels of control the relationship is *default*, which is shown in the upper-left quadrant of Table 1. The

relationship is considered default because it assumes a practical dysfunction as neither party exercises control to move interactions or the relationship forward. Patients in default relationships may become angry and frustrated and make time and service demands that are impossible for the physician to meet. Patients may subsequently discontinue care with the physician because of failed expectations for interactions and treatment (D. Roter & Hall, 2006).

To a certain extent these typologies of the patient-physician relationship may represent separate poles within which actual relationships and communication exist. However, understanding the foundations and boundaries within which the patient-physician relationship exists facilitates understanding the continuum of communication. In addition, these typologies provide a framework for analyzing interactions between patients and physicians. Also important to recognize, patient-physician relationships are influenced by numerous factors beyond communication. Characteristics of the patient and the physician may alter their relationship preferences, as well as their communication and its outcomes (Lewis, DeVellis, & Sleath, 2002).

Figure 1 outlines the conceptual framework for this application, which draws on typologies of patient-physician interaction and the mutual influence of the interacting partners in the patient-physician dyad (Lewis et al., 2002; Parsons, 1951; D. Roter & Hall, 1992). In addition, the medical communication literature has shown that particular physician and patient demographic factors, patient disease status, and medication characteristics influence patient-physician communication and, therefore, may influence communication about medication cost and management (Chewning & Sleath, 1996; Cooper-Patrick et al., 1999; Sleath, Roter, Chewning, & Svarstad, 1999; Sleath & Rubin, 2002). Each of these factors, in turn, has the ability to affect patient-reported satisfaction with medications. The following sections examine each of the components of the conceptual framework.

Figure 1: Conceptual framework for understanding the impact of physician-patient communication about medication cost and medication management on medication satisfaction



According to the model, predisposing patient, physician, and medication factors directly influence patient-physician communication. Patient-physician communication then influences patient satisfaction with medications. In addition, patient and medication factors also exercise a direct influence on medication satisfaction.

Patient Characteristics

Patient age, income, and education level have all been found to characterize more active physician-patient relationships (Lewis et al., 2002). Studies investigating the influence

of patient gender on communication in the medical visit show that female patients generally receive more information, ask more questions, and have more collaborative relationships with physicians than male patients (Cooper-Patrick et al., 1999). Further, several studies suggest that younger patients prefer to be more involved in medical decision-making as do patients with higher incomes, higher educational levels, and higher occupational levels (Chewning & Sleath, 1996). Disease severity also has the potential to influence communication because patients with more severe disease may be more likely to discuss medications and ask questions than patients with less severe disease (Chewning & Sleath, 1996). Self-rated pain, as a measure of disease activity, is likely to influence communication about medication regimens and cost; patients experiencing higher levels of pain are less likely to be satisfied with their current medications and, therefore, may be more likely to communicate about their medication regimens and subsequent medication costs with their physicians than patients with lower pain levels (Jackson et al., 2001; Kjekken et al., 2006). Prescription drug coverage is also likely to influence communication about medication cost in regimen discussions. Patients with very generous prescription drug coverage may not be as motivated to discuss medication costs as patients with less generous coverage. Physicians who are aware that patients have generous insurance coverage are also likely to be unmotivated to discuss medication costs. Research has shown distinct differences in the frequency of communication about medication costs at practice sites with different dominant prescription drug plans (Tarn et al., 2006). Taken together, these determinants suggest that communication about medication cost and medication management are likely to be affected by patient gender, age, race, ethnicity, education, income, disease severity, self-rated pain, and prescription drug coverage.

Patient characteristics also are expected to have a direct effect on patient reported satisfaction with medications. Research literature has demonstrated that older patients and those who report better health status are more satisfied with their health care and specific

aspects of care than younger patients or those reporting their health status as poor (Jackson et al., 2001; Kane et al., 1997). It can be expected that patients with more severe RA and those experiencing more pain are less likely to be satisfied with their medications. Study results have indicated associations between satisfaction and female gender, social class, and race; however, the existence of contradictory and inconsistent findings make it difficult to make a clear determination of direction of association (Jackson et al., 2001). With prescription drug coverage playing a role in access to certain medications, it is expected that prescription drug coverage type may affect patient assessment of medication satisfaction since access has been shown to be an important element in determinations of satisfaction (Cleary & McNeil, 1988).

Physician Characteristics

The medical communication literature has shown that female physician gender is associated with more patient and physician talking during visits including more discussion of social issues, and more active enlistment of patient input (Cooper-Patrick et al., 1999; D. L. Roter, 2003). Beyond the impact of physician gender on interaction in medical visits, the literature has found that physician race and ethnicity matter, especially when patients and physicians are of the same race and ethnicity (Saha, Komaromy, Koepsell, & Bindman, 1999). Some research has suggested that physician age may affect communication style with patients, with older physicians less likely to use participatory decision-making styles than younger physicians (Epstein, Alper, & Quill, 2004). This literature suggests that physician age, gender, race, and ethnicity may all affect the likelihood that medication management and medication costs are or are not discussed in medical visits.

Medication Characteristics

The characteristics of the medications under consideration and discussion in the medical visit may play a role in whether medication cost or medication management is brought up. The research literature has shown that patients are more cost sensitive to symptom relieving medications than disease modifying medications. A recent analysis of medical communication in primary care demonstrated different rates of cost communication by medication type (Piette, Heisler, Horne et al., 2006; Tarn et al., 2006). Therefore, the relative cost of the RA medications being prescribed is likely to influence discussion. In addition, the cost of medication is likely to influence patient ratings of medication satisfaction. Studies that have examined costs of medical products and services have found that the higher the cost, the lower the satisfaction (Cleary & McNeil, 1988). Given the potential impact on reported medication satisfaction, knowing the types of medications discussed in the visit and their relative cost will be important variables to control for in the analyses.

Communication between Physicians and Patients

A recent examination of visit communication between patients and physicians about the cost of newly prescribed medicines found that among a sample of family physicians, internists, and cardiologists medication cost was only discussed for 12% of newly prescribed medications (Tarn et al., 2006). Alexander et al. (2004) found that 11% of patients and 20% of physicians were able to recall a time they wanted to talk about cost but did not. Both patients and physicians report numerous barriers to discussing medication costs during medical visits (Alexander et al., 2005; Alexander et al., 2004; Piette et al., 2004b; Schafheutle et al., 2002). Despite reported barriers to communication of medication cost between patients and physicians, patients who talk with their physicians about medication costs have rated these conversations 'helpful' (Piette et al., 2004b). Physicians have

reported employing a number of strategies to address issues of medication cost-related restriction when they are aware that it is an issue for patients (Alexander et al., 2005; Piette et al., 2004b).

Discussions of medication cost can be viewed in the larger context of medication management. Specifically, medication management refers to the set of decisions and behaviors patients engage in to evaluate and revise, at their discretion, their medication regimens (Chewning & Sleath, 1996). Patients have been shown to be active in managing their medication regimens and, yet, this has been an often-overlooked element in patient-physician communication about medications (Chewning & Sleath, 1996).

For chronic conditions like RA, patient medication management has a potentially large impact on the disease experience. RA medications have the potential to reduce pain, prevent joint damage, and preserve joint integrity and function. Medication therapy is prescribed to change the disease process, and should be used continuously. However, the medications used to treat RA can potentially be harmful to patients and may only be partially effective (Neame & Hammond, 2005). Because of variability in the side effects and effectiveness of medications, as well as the painful and highly somatic nature of RA, there is a need for constant medication calibration (Chewning et al., 2001). RA patients must make decisions about the amount, timing, and quantity of medication to take based on a number of personal factors, including the cost of their medications. Once patients leave physicians' offices they must make decisions about the medicines they have been prescribed. Patients may choose not to have a prescription filled because of the cost of the medication, may substitute less expensive over-the-counter (OTC) medicines for prescription medications, or they may alter the timing or dosing of medication to make it last longer between prescription fills. In this way, medication cost is a feature of medication management, and medication management is something that may or may not be discussed in medical visits. More remains to be learned about the frequency and content of patient disclosures to physicians

about their self-initiated medication regimen changes. The presence or absence of discussion about patient-initiated medication regimen management may have several implications. Without discussion and understanding of how patients monitor or conceptualize their RA, physicians are at a disadvantage for understanding patients' judgments and medication decisions (Chewning & Sleath, 1996). If physicians and patients discuss medication management strategies during the medical visit, they may agree on a regimen that is tailored on the basis of patients' financial status. For example, insurance coverage might be discussed and physicians might select preferred medications with lower co-payments. If such discussions do not take place, patients may be less satisfied with their medications and may modify their regimens without the input of the physician.

In the proposed study, discussions of medication cost, patient-initiated medication regimen changes, and discussion of modifying the medication regimen are variables of interest in assessing the impact of physician, patient, and medication characteristics on physician-patient communication. Patient initiated-medication regimen change communication and medical visit discussion of modifying the medication regimen can be conceived of as aspects of medication management communication in medical visits. Both variables will be measured to confirm that they represent distinct constructs and to assess the relationship of medication cost communication with each.

In addition, patient and physician questions about cost and the cost discussion initiator are viewed as important variables. In general, physicians asking about medications is important because it allows physicians to assess patients' educational needs and understanding of the treatment rationale, how treatment should be used, treatment goals and preferences, side effects, contraindications, and barriers to adherence (Sleath, Rubin, & Huston, 2003). Question-asking can also be a sign of a more collaborative communication style because, by its very nature, physician question-asking engages the patient in conversation through required response (D. Roter & Hall, 1992). However, physicians often

fail to ask their patients questions and there may be differential characteristics of physicians who do and do not ask questions of their patients (Sleath et al., 2003). Previous studies have found patients are reluctant to ask questions about medications during medical visits (Sleath et al., 2003). There are patient characteristics in question-asking that may be important: research has shown older patients were significantly more likely to ask about their medications. Additionally, patients were significantly more likely to ask questions of younger physicians (Sleath et al., 1999).

In addition to question-asking, assessing who initiates discussions about medication cost and medication management is important because it provides information about the nature of such communication and also it may have an impact on patient rated medication satisfaction. In a primary care and cardiology setting in California, physicians overwhelmingly initiated medication cost and insurance coverage conversations (Tarn et al., 2006). However, it is unknown whether this varies by medical specialty or geographic area. Knowing more about patient and physician characteristics associated with question asking about medications costs and the initiator of conversations about cost can help inform interventions that improve communication about medication costs.

Medication Satisfaction

Satisfaction is an increasingly important health outcome and can be used to evaluate the quality of care as well as identify particular factors of care, such as medications, that need to be changed to improve satisfaction (Jackson et al., 2001). Medication satisfaction can be conceptualized as patients' attitudes and judgments about the medications they are taking or are supposed to take (Kane et al., 1997). Assessing satisfaction with medication as an outcome of communication about medication cost and management is especially pertinent since satisfaction has been shown to be associated with the nature of patient-physician communication and with medication adherence (Bultman & Svarstad, 2000). A

meta-analysis of 41 studies examining objectively measured patient-physician behaviors in medical encounters and satisfaction indicated that greater satisfaction had statistically significant associations with physician provision of more information, greater conversation about topics not directly medical, and more physician engagement of patients in decision making (Hall et al., 1988). Looking specifically at RA, a study of 1,041 patients with RA found that patients who reported greater involvement in medical decision-making were significantly more satisfied with their treatment than patients who reported being less involved in decision-making (Kjeken et al., 2006). Therefore, patients who communicate with their physicians about medication cost and medication management may be more likely to perceive their physicians as providing more information and engaging them more in medical decision making and are more likely to be satisfied with the medications they are prescribed.

Assessing satisfaction has been a recommended outcome measurement for medical visit communication about medication cost between patients and physicians (Alexander et al., 2003). With discussions about medication cost and management in medical visits centering on medications, assessment of patient-rated medication satisfaction is the most specific outcome and measurement match to the communication under study (Shikiar & Rentz, 2004). Patient ratings of medication satisfaction are likely to be affected by communication with the physician and by properties of the medication (Shikiar & Rentz, 2004). Physicians who discuss medication costs and ask patients how they manage their RA medications may be more likely to prescribe medications that fit within the budget and lifestyle of patients. This would likely positively impact patient medication satisfaction ratings. Conversely, in medical visits where physicians and patients do not discuss medication costs, patients may be less satisfied with their medications due to cost factors or reactions to the perceived omission of such information by the physician. Because medication satisfaction has demonstrated association with the nature of patient-provider

communication, monitoring satisfaction may help identify situations in which communication is not optimal (Bultman & Svarstad, 2000; Cleary & McNeil, 1988).

CHAPTER FOUR: METHODS

Overview

This study is a cross-sectional secondary analysis of data that were collected as part of an ongoing National Institute of Aging funded study examining patient-physician communication about quality of life and medication concerns in rheumatology visits. The data were collected from March 2003 to December 2005. The study sample includes 200 patients and eight rheumatologists from North Carolina. Study data include clinic visit audiotapes, patient interviews, medical records, and questionnaires. The University of North Carolina Institutional Review Board approved this study.

Study Setting

The study includes eight rheumatologists practicing in academic and non-academic clinic settings in North Carolina. Data were collected from four rheumatology practices, three academic affiliated clinics and one non-academic. Physicians were chosen based on whether they were rheumatologists who saw patients who were age 45 and older with RA. Written consent was obtained from each participating physician. The physician sample was a convenience sample. Eleven rheumatologists were approached to participate and eight (72.7%) agreed to participate. Of the three physicians who refused to participate in the study, two were female, two were White/Caucasian, and one was Black/African American.

Examining medication cost and medication management communication among patients seeing rheumatologists rather than primary care physicians is advantageous because such patients are likely to have more complex RA disease than would be found among patients seeing primary care physicians. These patients, therefore, are likely to be

taking more medications, which may be more expensive than patients with less severe RA (Neame & Hammond, 2005). Given this, examining data from rheumatologists and their patients is especially appropriate because they are particularly likely to be affected by the medication cost issues discussed above.

Patient Eligibility

Patients were eligible for the study if they were 45 years of age and older, had a physician-confirmed diagnosis of RA, did not have a terminal illness, were able to speak English, and were mentally competent to participate. Potentially eligible patients were identified by rheumatology clinic staff and were asked about their willingness to be contacted by study research assistants. Research assistants administered the Mental Status Questionnaire to determine whether patients were mentally competent to participate (Fillenbaum, Heyman, Williams, Prosnitz, & Burchett, 1990). Of the pool of 290 potentially eligible research subjects identified by clinic staff, 38 were excluded from study participation prior to the informed consent process. Reasons for exclusion from study participation were diverse and are included in Table 2. The mean age of excluded patients was 59.3 years (SD = 7.94 years), 25 (65.8%) were female, and 20 (52.6%) were White/Caucasian. Examination of participants and excluded patients revealed no statistically significant differences in age, gender, or race.

Table 2. Reasons for patient exclusion from study participation, frequency, and percent.

| Reason for exclusion | Frequency | Percent |
|---|------------------|----------------|
| Patient not mentally capable of participating | 9 | 23.7 |
| Physician felt patient not a good candidate | 8 | 21.1 |
| Patient enrolled in another study | 6 | 15.8 |
| RA diagnosis not definitive | 5 | 13.2 |
| Patient did not speak English | 3 | 7.9 |
| Patient too sick to be enrolled | 3 | 7.9 |
| Patient unable to read | 1 | 2.6 |
| Patient not returning to clinic | 1 | 2.6 |
| Patient can not hear | 1 | 2.6 |
| Patient too distressed | 1 | 2.6 |
| Total | 38 | 100.0 |

After exclusions, 252 patients were eligible for study enrollment and were willing to be contacted by study research assistants at their routine medical visits. Research assistants obtained written consent from each patient at the time of the clinic visit. For each physician, eligible consenting patients were enrolled sequentially at baseline. Of the 252 potential participants that were approached, 52 of them refused leaving a total of 200 enrolled for baseline and a participation rate of 79.4%. Of the 52 participants that refused to participate in the study, the mean patient age was 60.8 (SD = 10.13 years), 39 (75.0%) were female, and 34 (65.4%) were White/Caucasian. Comparison of means and cross tabulations of patients that refused to participate and study participants revealed no statistically significant differences in patient age, gender, race, or ethnicity.

While potentially eligible patients were identified and enrolled based on whether they were seeing a study physician, patient enrollment across physicians was not even. Table 3 provides the frequency and percent of patients enrolled by participating study rheumatologists. Differences in enrollment can be attributed to several possible sources. First, not all study physicians were enrolled at the outset of the study and not all physicians

remained in the study for the full duration. Second, some physicians had limited clinic schedules so they saw fewer patients overall or had clinic hours that made it difficult to enroll patients. Third, some physicians saw more patients with confirmed diagnoses of RA while others tended to see more patients with other types of rheumatic diseases. Beyond differences in patient diagnoses, the patient case-mix of physicians differed by age, language spoken and other factors that affected enrollment. In the study analyses, methods were used to try to account for differences in enrollment by physician as well as differences in the patient case-mix by physician.

Table 3. Patient enrollment by study rheumatologist.

| Physician | Number of Patients Enrolled | Percent |
|------------------|------------------------------------|----------------|
| 1 | 3 | 1.5 |
| 2 | 5 | 2.5 |
| 3 | 8 | 4.0 |
| 4 | 11 | 5.5 |
| 5 | 42 | 21.0 |
| 6 | 42 | 21.0 |
| 7 | 42 | 21.0 |
| 8 | 47 | 23.5 |
| Total | 200 | 100.0 |

Data Overview

The data come from five primary data sources: (1) patient medical records, (2) clinic visit audiotapes, (3) patient interviews, (4) self-report questionnaires, and (5) physician report. To audiotape, a research assistant set up a digital tape recorder and microphone in the exam room as patients entered, started the recorder as the physician entered, exited the exam room, and collected the recorder at the end of the consultation. Following the audio taped visit, patients were interviewed either in the exam room or in the clinic waiting room about their self-rated pain and medication satisfaction. Patients then completed brief questionnaires reporting their: gender, age, education, income, race, and ethnicity. Patients

independently completed the majority of questionnaires at the conclusion of the research assistant-led interview, but in a few cases patients were given questionnaires with self-addressed, stamped envelopes to complete and return by mail. Patients who did not complete and return the demographic information in the study questionnaire were contacted at follow-up visits to complete that information. At study enrollment, physicians completed demographic self-report questionnaires that asked them to report: gender, age, race, and ethnicity. At the end of each patient's medical visit, the physician was asked to record his/her perception of the patient's RA disease severity.

Medical Record Data

To complement the existing data and obtain important information on patient prescription drug coverage and prescribed medications, patient medical records were abstracted in the course of this research. Medical record data collection was approved by the Institutional Review Board and all patients in the study consented to have information abstracted from their medical records. Medication and insurance information was successfully abstracted from rheumatology records for all 200 patients. A medical record abstraction form was developed to facilitate the retrieval of information from the records (Appendix 1). The purpose of the abstraction form was to obtain detailed information on the medications that patients were supposed to be taking at the time of their recorded medical visit, the number of prior visits with the physician in the study, patient weight, and patient health insurance information.

Using the 2002 American College of Rheumatology *Guidelines for the Management of Rheumatoid Arthritis* as a foundation, the first page of the abstraction form listed the major medications used to treat RA within each medication category (i.e. NSAIDs, DMARDs, Glucocorticoids) with check boxes next to the medications to ease the recording burden of abstractors (American College of Rheumatology Subcommittee on Rheumatoid Arthritis

Guidelines, 2002). In addition to checking off the RA medication that patients were supposed to be taking before seeing the physician on the day of the recorded medical visit, the form instructed abstractors to record the medication dose, frequency of administration, and dates of medication start and, if applicable, stop.

Further, for each medication the form contained spaces to record chart-noted changes in the medication regimen, notes on adherence, and notes related to medication costs. Chart-noted changes in the medication regimen were recorded if they occurred during the recorded medical visit through one year of follow-up medical visits. For chart notes on adherence, abstractors were instructed to record any notes that referred to patient adherence or non-adherence to medications that were recorded on the date of the recorded medical visit. Abstractors were also instructed to record any notes from the chart that referred to medication cost or issues with insurance or medication assistance programs that would affect cost. Abstractors were instructed to record verbatim any physician notes on adherence and medication cost. In addition to the medication information contained on the first page, abstractors were instructed to record the number of prior visits the patient had with the physician who saw them on the date of the recorded medical visit, as well as chart noted patient weight in pounds or kilograms from the recorded medical visit.

The second page of the abstraction form contained a table for abstractors to record information about the other medications patients were supposed to be taking that were not covered in the listing of RA medications on page one. Abstractors were instructed to record all medications, regardless of whether they were used to treat RA. In the table abstractors were supposed to record: (a) medication name, (b) dose, (c) route of administration, (d) frequency of administration, (e) start and, if applicable, stop date, and (f) reason for stopping if noted in the record. There was variability in the depth of information in each record, especially regarding non-RA medications, and abstractors were instructed to record as much of the applicable information as possible on each medication. Below the table on

other medications, was a box for abstractors to circle the type of health insurance noted in the medical record from the date of the audio-recorded medical visit. Further details on the categories of health insurance and conceptualization of this variable are provided in the measurement section of this chapter. Abstractors were instructed that if they had any trouble discerning the appropriate type of health insurance that they should record verbatim what was in the record. Further, medical record abstractors were instructed to write down any information provided about the patients' prescription drug plan or prescription drug assistance programs included in the record.

Once the medical record abstraction form was created, it was iteratively tested using a random sample of 5% of the medical records. Through the iterations, the abstraction form was revised to facilitate completion. The principal investigator and a clinical pharmacist who specializes in medication management for older adults reviewed the form and 10 initial abstractions jointly. The clinical pharmacist provided instruction and background detail to the principal investigator about information contained in the abstractions as well as ways to improve the reliability and validity of future abstractions.

To improve the quality of data abstracted from patient medical records the principal investigator and a pharmacy student familiar with medications for treating RA double-abstracted 30 (15%) of the 200 medical records. The information from the abstractions was compared and revealed that abstractors were in full agreement on all medication information and mostly agreed on the relevant notes from the records. Discrepancies on the abstracted notes, although minor, were discussed and the abstraction instructions were adjusted accordingly. Following final review of the form by fellow investigators, the principal investigator completed the medical record abstractions. At sites that had both electronic and paper medical record information the paper records were checked against electronic data for consistency and to complete information that might have been missing from one of the sources.

Medical Visit Audiotape Data

In the larger research project upon which this study was based, the researchers developed a coding tool to capture information on discussion of medications, issues such as side effects, and quality of life. The coding tool was developed in conjunction with detailed coding rules and tapes were reviewed and coded by trained research assistants. Calculated inter-rater correlations and percent agreement among 6 coders based on the same 41 tapes was 0.71 or greater for the 45 items on the main coding tool. While information on medications and changes to the medication regimen were captured in the main coding tool, important information for this study on communication about medication costs and management were not collected.

To facilitate audiotape review and to measure the specific features of patient-physician communication of interest in this study, a detailed coding instrument was designed to measure patient-physician communication about medication management and medication cost. The tapes were coded for: (a) whether medication cost is brought up during the medical visit (e.g. prescription insurance coverage or OOP medication costs), (b) the number of patient questions about medication cost, (c) the number of physician questions about medication cost, (d) cost discussion initiator, (e) times of medication cost discussions, (f) patient initiated changes to the medication regimen, (g) description of the patient initiated changes to the regimen, and (h) times of discussion of patient initiated regimen changes. The details of the coding tool are discussed more fully in the measurement section of this chapter and the actual coding tool can be found in Appendix 2. Explicit rules were developed to guide the coding of each item. The coding rules can be found in Appendix 3. The coding tool and rules were developed drawing on principles used previously in coding patient-physician medical visit interactions for specific content areas (Sleath et al., 2008; Sleath, Svarstad, & Roter, 1998).

The coding instrument and rules were pre-tested and revised several times using randomly selected audiotapes. To further test the robustness of the coding tool, the instrument was used to code a random selection of medical visit audiotapes from rheumatologists and patients with RA drawn from a different patient sample. The principal investigator and a second, experienced coder participated in pre-testing and actual coding of the audiotapes. The second coder was blinded to study hypotheses. The principal investigator and second researcher coded a 10% random sample of the tapes throughout the coding period and met biweekly to discuss discrepancies. In the initial coding and testing phase, all disagreements between coders were resolved by consensus and the coding rules were subsequently modified until coders and study investigators agreed upon the final coding rules.

When the coding instrument and rules had been finalized, the principal investigator coded all of the actual study audiotapes and a new group of 35 randomly selected tapes were double-coded by the second researcher. After the 35 tapes were double-coded, the inter-rater reliability was calculated using Pearson correlation coefficients for continuous variables and percent agreement for dichotomous variables, as well as, Cohen's kappa to correct for chance in assessing agreement between the raters (DeVellis, 2005). Results of inter-rater reliability indicated a Pearson correlation range from 0.42 to 1.00 for 35 tapes coded by two independent coders. On categorical items, Cohen's kappa ranged from 0.62 to 1.00. Pearson correlation coefficients and kappa statistics of 0.61 to 0.80 are considered good and those that are between 0.81 and 1.00 are considered very good. The two items that had the lowest correlation were the counts of patient questions about cost ($r = 0.48$) and physician questions about cost ($r = 0.42$). Examination of the data revealed that coders did not differ on whether questions were asked in a particular visit but on how many questions were asked. Analysis of any versus no questions asked for patients revealed a Pearson correlation of 0.82 and a kappa of 0.80 and for any versus no questions asked for

physicians there was perfect agreement. Since the question asking variables were transformed into 'any' versus 'no' cost questions asked for patients and physicians for the analysis and coders had high agreement on these variables, the low correlations on the original variables were not seen as an analysis issue.

Measurement

This section defines and describes all of the variables used in the analysis. It follows Figure 1 moving from outcomes to predictors in the conceptual model with the major categories: satisfaction with medications, characteristics of communication between physicians and patients, patient characteristics, physician characteristics, and medication characteristics. Table 4 contains a listing of each of the variables within each category, the measure, source, and type or range. The following sections provide detailed information on each of the variables.

Table 4. Measures, sources, and types of variables

| Variable | Measure | Source | Type/Range |
|--|------------------------|-------------------------|---|
| Satisfaction with Medications | | | |
| Medication Satisfaction | Self-report | Patient interview | 1 = not at all 2 = a little 3 = somewhat 4 = very 5 = totally |
| Communication Characteristics | | | |
| Presence of discussion about medication cost | Coding tool | Medical visit audiotape | 1 = yes 0 = no |
| Number of physician questions about cost | | | Ratio |
| Number of patient questions about cost | | | Ratio |
| Cost discussion initiator | | | 1 = physician 0 = patient |
| Patient-initiated regimen change communication | | | 1 = yes 0 = no |
| Discussion of modifying regimen | Main-study coding tool | Medical visit audiotape | 1 = yes 0 = no |
| Patient Characteristics | | | |
| Gender | Self-report | Patient questionnaire | 1 = female 0 = male |
| Age | | | Continuous |
| Education | | | 1 = 8 th grade or less 2 = some high school 3 = high school graduate 4 = some college 5 = college graduate 6 = any post-graduate work |
| Income | | | 1 = less than \$20,000 2 = \$20,000 - \$39,999 3 = \$40,000 - \$59,999 4 = \$60,000 - \$79,999 5 = \$80,000 or more |
| Race | | | 1 = Black/African American 2 = White/Caucasian 3 = Asian/Oriental or Pacific Islander 4 = American Indian/Alaskan Native 5 = Other |
| Spanish/Hispanic | | | 1 = yes 0 = no |
| Marital status | | | 1 = married 2 = widowed 3 = separated 4 = divorced 5 = never married |

| Variable | Measure | Source | Type/Range |
|-----------------------------------|---|-------------------------|--|
| RA severity | American College of Rheumatology Classification of Global Functional Status | Physician report | 1 (low) to 4 (high) |
| Self-rated pain | Visual analog scale | Patient interview | 0 (no pain) to 10 (worst pain ever) |
| Prescription drug coverage | | Medical records | 1 = no coverage 2 = partial drug coverage 3 = generous drug coverage |
| Physician Characteristics | | | |
| Gender | Self-report | Physician questionnaire | 1 = female 0 = male |
| Race | | | 1 = Black/African American 2 = White/Caucasian 3 = Asian/Oriental or Pacific Islander 4 = American Indian/Alaskan Native 5 = Other |
| Spanish/Hispanic | | | 1 = yes 0 = no |
| Age | | | Continuous |
| | | | |
| Medication Characteristics | | | |
| Cost of RA medications | | Medical records | Continuous |

Satisfaction with Medications

Medication satisfaction: A single-item assessing patient satisfaction with medications was asked of all patients in the patient interview immediately following the medical visit. Patients were asked to respond to the item, “How satisfied are you with the medications you are supposed to take until your next visit?” by selecting one of the following five response categories: ‘Not at all’, ‘A little’, ‘Somewhat’, ‘Very’, or ‘Totally’. Previous research has demonstrated that asking about overall medication satisfaction is associated with patient-physician communication and subsequent medication adherence (Bultman & Svarstad, 2000).

Characteristics of Communication between Physicians and Patients

Presence of discussion about medication cost: This dichotomous variable was measured from the coding tool that was created to accompany the audiotape. Presence of discussion about cost was coded as ‘yes’ if during the visit either the patient or physician discussed direct medication costs (e.g. OOP costs incurred by patients) or indirect medication costs (e.g. prescription drug assistance programs or prescription drug insurance coverage). While multiple discussions of medication costs may have occurred during a single visit, one conversation was sufficient for the item to be coded ‘yes’.

Number of physician questions about medication cost: The number of questions the physician asks about medication costs was measured using the created audiotape-coding tool. A count was recorded for each distinct question the physician asks about direct or indirect medication costs. These questions may have been open or closed-ended but all were related to the medication cost discussion. Questions that were framed as statements or semi-questions where it was still clear that the physician was inquiring

about medication costs were also counted. As mentioned in the medical visit audiotape data section, this variable was transformed into a dichotomous ‘any’ versus ‘no’ questions asked variable for analysis.

Number of patient questions about medication cost: This variable was assessed using the same methods as physician question asking except it counted distinct medication cost questions asked by patients. This variable was also transformed into a dichotomous ‘any’ versus ‘no’ questions asked variable for analysis.

Cost discussion initiator: This dichotomous variable was measured from the created audiotape-coding tool. Initiation of medication cost discussion was coded as ‘physician initiated medication cost discussion’ if the physician brought up a medication cost topic, either direct or indirect, *before* the patient in the medical visit (i.e. if the physician asks a question about prescription drug insurance coverage or gives details about a medication cost before the patient asks a question or makes a statement about it then the item was marked as ‘physician initiated medication cost discussion’). Alternately, the initiation of medication cost discussion was coded as ‘patient initiated medication cost discussion’ if the patient brought up a medication cost topic *before* the physician in the medical visit. This means that if a patient asked the physician about obtaining a medication from a prescription drug assistance program or made a statement about the cost of a prescription prior to the physician asking the patient a question about medication costs or making a statement about medication costs then the item was marked ‘patient initiated medication cost discussion’. As has been written previously, multiple discussions of cost may occur in each visit. However, for the purposes of coding this item, we were interested only in who *first* brings up the topic since multiple discussions are likely to flow from first initiation of the topic. Measuring which participant initiates the medication cost discussion permits the assessment of potential differences in the types and number of discussions started by patients or physicians.

Patient-initiated medication regimen change communication: This dichotomous variable was measured from the coding tool that accompanies the audiotape. Presence of discussion of a patient initiated change to the medication regimen will be coded as 'yes' if during the visit the patient or the physician discuss a change to the regimen made by the patient independent of medical advice. Patient-initiated changes to the medication regimen can be considered a facet of medication management. For our purposes, medication management is defined as a patient's ability to manage symptoms through medications and deal with physical and psychosocial consequences of their medication-taking (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002). Effective management involves a continuous feedback loop of monitoring one's condition, taking medications, and managing medication effects. RA patients must make decisions about the amount, timing, and quantity of medication to take based on a number of personal factors, including the cost of their medications. Using this concept of medication management as a base, coders marked this item as 'yes' when patients and physicians discussed patient-initiated changes to the medication regimen that require a behavior change. Patients may choose to take less or more medication than prescribed, split-pills to stretch out the time between prescription fills, alter their dosing schedule to accommodate their lifestyle, add or drop medications from their regimens, or substitute one medication for another. These examples do not make up the entire universe of possible conversations about patient-initiated changes in the regimen but are examples of some of the types of discussions. In the context of this study, we were primarily interested in the discussions between patients and physicians about patients' independent, purposeful actions to manage their medications. Physicians may actively participate in these discussions but the changes to the regimen should be patient initiated and directed.

Discussion of modifying the regimen: This dichotomous variable was measured from the coding tool used in the larger study upon which this analysis is based. In the main

audiotape coding tool coders responded to the item “Was the medication regimen changed at all during this visit?” Presence of discussion of modifying the regimen was coded as ‘yes’ if during the visit the patient and the physician agreed to make a change to the current regimen. Medication regimen change was defined as any single or combination of the five following actions: (1) adding one or more medication(s), (2) stopping or holding one or more medication(s), (3) changing dose of one or more medication(s), (4) changing the schedule or frequency of one or more medication(s), or (5) switching from brand to generic(s). From the main coding tool, this item had an inter-rater correlation of 0.95 among 6 coders, coding 41 (21.2%) tapes. This variable is being included in the study to facilitate sensitivity analysis of the patient-initiated medication regimen change communication variable. The measurement of both discussions of patient-initiated changes to the medication regimen and patient-physician agreed upon changes to the regimen, permits the assessment of the relationship of each to medication cost communication and medication satisfaction. The purpose of incorporating a measure of discussion of modifying the medication regimen is to compare and contrast the results obtained using this variable with those found using patient-initiated medication regimen change communication. Patient-initiated medication regimen change communication should be a distinct construct from discussions of modifying the regimen. Assessing the differences in the predictors of the two variables and should help validate the differences in the constructs and permits examination of the ways in which the sample discussing regimen changes overall differed from the sample disclosing self-initiated regimen changes to physicians.

Patient Characteristics

Gender: Two-category variable measured at baseline indicating male or female.

Age: Continuous variable measured in baseline patient questionnaire indicating patient age in years at the time of the baseline visit.

Education: Six-category variable indicating highest grade completed in school with the following categories: '8th grade or less', 'Some high school', 'High school graduate', 'Some college', 'College graduate', or 'Any post-graduate work'. To assess suspected meaningful differences with this variable in analysis, education was dichotomized into 'High school graduate or less' and 'More than high school education'.

Income: Five-category variable indicating household's total income from all sources with the following categories: 'less than \$20,000', '\$20,000 - \$39,999', '\$40,000 - \$59,999', '\$60,000 - \$79,999', or '\$80,000 or more'. To assess suspected meaningful difference in thresholds of income, in some analyses this variable was dichotomized into '\$39,999 and less' and '\$40,000 and more'.

Race: Five-category variable indicating category that best described patient's racial background. Categories were as follows: 'Black/African American', 'White/Caucasian', 'Asian/Oriental or Pacific Islander', 'American Indian/Alaskan Native', or 'Other'. Based on the population, in some analyses this variable was collapsed into 'White' and 'Non-white'.

Spanish/Hispanic Ethnicity: Dichotomous variable indicating whether patients were of Spanish or Hispanic origin or ancestry.

Marital status: Five-category self-report variable asking participants to choose the category that best describes their current marital status. Categories were as follows: 'Married', 'Widowed', 'Separated', 'Divorced', or 'Never married'. Based on the distribution of the variable for analysis marital status was dichotomized into 'Married' and 'Not married'.

RA severity: Rating of patient RA severity was measured using the American College of Rheumatology (ACR) Classification of Global Functional Status (Hochberg et al., 1992). This four-category rating is completed by the physician at the end of the medical visit and places patients in the following categories based on their RA: (I) no restriction of ability

to perform normal activities, (II) moderate restriction but adequate for normal activities, (III) marked restriction, inability to perform most duties of the patient's usual occupation or self-care, or (IV) incapacitation or confinement to a bed or wheelchair, permitting little or no self-care. This measure has been shown to be able to discriminate between patients with different levels of RA severity (Hochberg et al., 1992).

Self-rated pain: At the interview immediately following the medical visit patients were asked to rate their level of pain in the past 24 hours as measured by a horizontal visual analog scale (VAS) from 0 to 10 where 0 indicated 'no pain' and 10 indicated the 'worst pain ever'. Self-rated pain as measured by VAS is a recommended measure of RA disease activity by the American College of Rheumatology because it has demonstrated criterion, discriminant, and face validity as well as high test-retest reliability (Felson et al., 1993).

Prescription drug coverage: Prescription drug coverage is a three-category variable based on patient health insurance plan type, which comes from patient medical records. The depth and quality of recorded health insurance information was variable. For patients at particular clinics, great detail was recorded about the health insurance carrier, associated prescription drug plan, and medication co-payment amounts. For those same patients there was generally an extensive listing of the initiation and discontinuation dates of health insurance coverage by insurance carrier. Alternately, for patients seen at other clinics, the information was more abbreviated and while health insurance carriers were listed, little to no information was provided about the associated prescription drug plan or medication co-payment amounts. Research assistants abstracting health insurance information from the medical records were instructed to record all information available. When both electronic and paper medical records were available, both were consulted to confirm the recorded health insurance information. Based on the information recorded on the medical record abstraction form, health insurance was then coded as one of six categories. The six categories and their definitions are as follows:

- (1) 'Private or employer sponsored insurance' – these are programs provided by companies such as Blue Cross and Blue Shield of North Carolina, the state employees health plan, Aetna, Cigna, etc. This category contains all the insurance types that are not directly funded and maintained as either a state or federal entitlement program.
- (2) 'Medicare with supplemental insurance' – this category includes patients who have Medicare listed as their primary insurance and then have a secondary private or employer sponsored insurance program listed in the record.
- (3) 'Medicare only' – this category includes patients who only have Medicare listed as their health insurance provider
- (4) 'Medicaid only' – this category includes patients who only have Medicaid listed as their health insurance provider
- (5) 'Medicare + Medicaid' – this category includes patients who have both Medicare and Medicaid listed as health insurance providers.
- (6) 'Self-pay' – this category includes patients who have a note that they are self-pay customers and/or have a note that they have no known health insurance provider.

Based on the health insurance category selected and the written notes on insurance from the medical record abstraction form, categories of prescription drug coverage were created. Categories are as follows: 'no coverage', 'partial coverage' (e.g. Medicare HMO, self-purchased Medicare supplement with drug coverage, or state-sponsored low-income plans), and 'generous drug coverage' (e.g. employer-sponsored coverage or Medicaid drug coverage). Previous researchers conducting medication cost research have employed these categories. Plans classified as partial coverage have been consistently found to offer more limited benefits, including higher cost sharing and lower spending allowances, compared with Medicaid and employer-sponsored plans (Soumerai et al., 2006). Further, employer-sponsored plans and Medicaid have been shown to be fairly similar in their coverage generosity and breadth (Soumerai et al., 2006). An analysis of insurance plans and

generosity using OOP and total medication cost data further supports the generosity category definitions (Artz, Hadsall, & Schondelmeyer, 2002). Further, prescription drug coverage generosity has been shown to predict prescription drug use and expenditures (Artz et al., 2002).

Physician Characteristics

The physician demographic variables: gender, age, race, and ethnicity were measured using the same questions as those administered to patients.

Medication Characteristics

Cost of RA medications: The listing of patient medications, taken from the medical records, was used to derive the continuous cost of RA medications variable. Calculation of RA medication costs was selected because the costs of these medications are the most salient since patients and physicians negotiate the prescribing of RA medications in rheumatology medical visits. To determine the appropriate RA medications to include in cost calculation, the principal investigator again consulted with a clinical pharmacist specializing in medication management for older adults. Jointly, the two researchers reviewed the medical record abstractions. Drawing upon the 2002 ACR “Guidelines for the management of rheumatoid arthritis” and current standards of practice, a listing of RA medications and adjuvant therapies prescribed to balance the effects of RA medications was generated. Table 4 showing the medication costs details the RA medications that appeared in the medical records and were included on the generated RA medication list.

Medication cost figures were derived using Average Wholesale Price (AWP) according to *Red Book: Pharmacy’s Fundamental Reference* (Thomson Corporation., 2004)

from 2004. Since study data were collected from 2003-2005, AWP from 2004 were abstracted to represent the most common medication cost figures for the period under study. To test the sensitivity of medication cost information taken from *Red Book*, price information was also taken from the online medication retailer www.drugstore.com. While prices from Drugstore.com were slightly higher than AWP, the differences were consistent across medications. The presence of similar cost figures reinforced the medication cost trends present in AWP. While there has been considerable controversy over the accuracy and use of AWP in the past, the use of AWP in generating cost estimates still remains an accepted standard (Drummond, 1997). Further, calculation of an accurate, actual OOP medication cost variable or cost-to-patient variable is incredibly difficult. Multi-tier formularies are now standard and they offer discounts for purchases through mail order or in network pharmacies. Deductibles, OOP maximums, and benefit caps also complicate these calculations. This means that the cost of a medication depends not only on its location on the tier system but also the means through which people obtain the medication and how much they have already spent on medications in the benefit year (Goldman, Joyce, Lawless, Crown, & Willey, 2006). For the biologic medication Infliximab (Remicade®), the problem is confounded by the fact that it is usually administered in a clinic by a health care professional and paid for as part of medical services.

Given the restrictions, calculation of RA medication costs using published AWP and use of a measure of total medication cost as opposed to OOP medication cost was chosen. Table 5 contains a listing of the 2004 AWP from *Red Book* for the RA medications used in this study.

Table 5. Average wholesale prices for RA medications from *Red Book: Pharmacy's Fundamental Reference, 2004* (Thompson Corporation).

| Category/Medication (U.S. Brand Name) | Strength (mg) | Quantity | AWP | Per Pill Price/Unit |
|---|------------------|----------|------------|------------------------|
| Non-steroidal anti-inflammatory drugs (NSAIDs) | | | | |
| Valdecoxib (Bextra®) | 10 | 30 | \$94.22 | \$3.14 |
| | 20 | 30 | \$94.22 | \$3.14 |
| Celecoxib (Celebrex®) | 100 | 30 | \$54.25 | \$1.81 |
| | 200 | 30 | \$88.98 | \$2.97 |
| | 400 | 60 | \$269.06 | \$4.48 |
| Ibuprofen | 400 | 30 | \$7.05 | \$0.24 |
| | 600 | 30 | \$8.72 | \$0.29 |
| | 800 | 30 | \$11.22 | \$0.37 |
| Meloxicam (Mobic®) | 7.5 | 30 | \$86.23 | \$2.87 |
| | 15 | 30 | \$111.37 | \$3.71 |
| Rofecoxib (Vioxx®) | 12.5 | 30 | \$90.41 | \$3.01 |
| | 25 | 30 | \$90.41 | \$3.01 |
| | 50 | 30 | \$132.00 | \$4.40 |
| Naprosyn | 500 | 30 | \$52.06 | \$1.74 |
| Naproxen | 250 | 30 | \$23.30 | \$0.78 |
| Naproxen Sodium OTC | 220 | 30 | \$3.34 | \$0.11 |
| Nabumetone (Relafen®) | 500 | 30 | \$50.57 | \$1.69 |
| | 750 | 30 | \$59.71 | \$1.99 |
| Sulindac (Clinoril®) | 200 | 30 | \$36.55 | \$1.22 |
| Diclofenac (Cataflam®; Voltaren®) | 50 | 15 | \$25.01 | \$1.67 |
| | 75 | 180 | \$198.68 | \$1.10 |
| Ketoprofen (Orudis® KT; Oruvail®) | 50 | 30 | \$36.86 | \$1.23 |
| Disease-modifying antirheumatic drugs (DMARDs) | | | | |
| Adalimumab (Humira®) | 40 | 2 | \$1,315.81 | \$657.91 |
| Azathioprine (Imuran®) | 50 | 30 | \$75.84 | \$2.53 |
| Etanercept (Enbrel®) | 25 | 1 | \$164.47 | \$164.47 |
| Infliximab (Remicade®) | 100 | 1 | \$691.61 | \$691.61 |
| Hydroxychloroquine [HCQ – generic] | 200 | 60 | \$70.85 | \$1.18 |
| Plaquenil [HCQ – brand] | 200 | 100 | \$189.20 | \$1.89 |
| Gold Sodium Thiomalate (Myochrysine®) | 100 | 1 | \$76.22 | \$76.22 |
| Myochrysine SOL IM 50mg/ml | 50 | 6 | \$102.42 | \$17.07 |
| Leflunomide (Arava®) | 10 | 30 | \$372.32 | \$12.41 |
| | 20 | 30 | \$372.32 | \$12.41 |
| Methotrexate [MTX] Tablets | 2.5 | 32 | \$114.05 | \$3.56 |
| MTX Solution, Injection 25 mg/ml in 10 ml | 25 | 10 | \$20.49 | \$2.05 |
| Trexall (MTX Sodium) | 5 | 30 | \$225.23 | \$7.51 |
| Sulfasalazine (Azulfidine®) | 500 | 30 | \$7.59 | \$0.25 |
| Glucocorticoids | | | | |
| Prednisone | 5 | 30 | \$2.47 | \$0.08 |
| | 10 | 30 | \$2.42 | \$0.08 |
| | 20 | 30 | \$4.34 | \$0.14 |

| Category/Medication (U.S. Brand Name) | Strength (mg) | Quantity | AWP | Per Pill Price/Unit |
|--|------------------|----------|----------|------------------------|
| Vitamin supplementation for DMARDs | | | | |
| Folic Acid | 1 | 30 | \$2.46 | \$0.08 |
| Leucovorin | 5 | 30 | \$70.81 | \$2.36 |
| Folic Acid OTC | 0.8 | 100 | \$2.48 | \$0.02 |
| Analgesics | | | | |
| <i>Opioid</i> | | | | |
| Methadone | 10 | 60 | \$32.17 | \$0.54 |
| Morphine Sulfate | 15 | 60 | \$26.77 | \$0.45 |
| Oxycodone hydrochloride (OxyContin®) | 10 | 30 | \$52.35 | \$1.75 |
| | 20 | 30 | \$97.90 | \$3.26 |
| | 40 | 30 | \$162.41 | \$5.41 |
| <i>Non-opioid</i> | | | | |
| Acetaminophen(Tylenol® OTC) | 325 | 100 | \$7.15 | \$0.07 |
| Acetaminophen(Tylenol Extra Strength®) | 500 | 50 | \$5.47 | \$0.11 |
| Acetaminophen(Tylenol Arthritis®) | 650 | 50 | \$5.88 | \$0.12 |
| Tramadol (Ultram®) | 50 | 30 | \$37.20 | \$1.24 |
| Lidocaine Patch (Lidoderm®) | 5% | 30 | \$152.90 | \$5.10 |
| Aspirin | 325 | 20 | \$0.48 | \$0.02 |
| Analgesic Combinations | | | | |
| Acetaminophen + codeine (Tylenol® With Codeine) | 300/30 | 100 | \$52.49 | \$0.52 |
| Acetaminophen + hydrocodone [generic] | 500/5 | 100 | \$11.53 | \$0.12 |
| Acetaminophen + hydrocodone (Vicodin®) | 500/5 | 100 | \$69.72 | \$0.70 |
| Acetaminophen + hydrocodone (Lortab®) | 500/10 | 40 | \$41.87 | \$1.05 |
| Acetaminophen + hydrocodone (Lorcet®) | 650/7.5 | 30 | \$36.99 | \$1.23 |
| Acetaminophen + propoxyphene (Darvocet-N®) | 650/100 | 30 | \$35.80 | \$1.19 |
| Acetaminophen + oxycodone (Percocet®) | 325/7.5 | 60 | \$107.35 | \$1.79 |
| Acetaminophen + tramadol (Ultracet™) | 325/37.5 | 30 | \$30.75 | \$1.03 |
| Osteoporosis Prevention | | | | |
| Alendronate Sodium (Fosamax®) | 70 | 4 | \$73.31 | \$18.33 |
| Risedronate (Actonel®) | 35 | 4 | \$70.49 | \$17.62 |
| Raloxifene (Evista®) | 60 | 30 | \$81.52 | \$2.72 |
| Calcitonin (Miacalcin®) nasal spray | 200 iu | 4 | \$90.99 | \$22.75 |
| Caltrate® | 600 | 60 | \$7.82 | \$0.13 |
| Caltrate® 600 + D | 600 | 60 | \$5.78 | \$0.10 |
| Os-Cal® | 500 | 60 | \$6.18 | \$0.10 |
| Os-Cal® 500 + D | 500/125iu | 75 | \$6.88 | \$0.09 |
| Calcium + Vitamin D | 300/100 | 100 | \$3.10 | \$0.03 |

Costing has two elements: measurement of the quantities of the resource and the assignment of unit costs or prices (Drummond, 1997). To calculate the quantities of medication per patient, medication information was taken from the medical record abstraction form. The medication, dose, and frequency of administration information for each RA medication listed in the record were used to calculate the amount of each medication prescribed over the course of 30 days. As an example, a medication of a particular strength to be taken once daily should be 30 pills over 30 days. Estimating the quantity of a medication prescribed over a 30-day period created standardized values so that amounts of medication were directly comparable. The process was repeated for each RA medication on the medical record abstraction form.

Complete information on dose and frequency of administration was available for the majority of RA medications. For any given RA medication less than 2.5% of the dose or frequency information was missing and in no cases were both dose and frequency missing. In cases where dose or frequency was missing, the information was imputed using the usual or standard recommended dose or frequency for a given RA medication as outlined in clinical literature and consistent with recorded dose and frequency in the existing data (Wailoo et al., 2008). For example, in three cases the dosing information on Infliximab was not recorded or incompletely recorded, since the amount administered is dependent on patient weight. In the cases where a milligram per kilogram dose amount was provided for Infliximab, it was possible to calculate the total dose prescribed by using the patient's recorded weight in kilograms (or by converting patient weight in pounds to kilograms) from the medical record abstraction form. In the cases where dose information was not provided for Infliximab, the value was imputed. A study indicated that in 2001 and 2002, years adjacent to the ones under study here, the mean Infliximab dose for a population of 150 RA patients was 3.98 mg/kg (Michaud et al., 2003). Further, this dose was consistent with the mean dose of patients in the study for whom the Infliximab dose was recorded.

Pairing quantity with cost information, the price per pill/unit was multiplied by the 30-day quantity prescribed to generate a cost for the medication (Drummond, 1997). The individual medication costs were summed to create a single per-month medication cost variable for each patient.

Analyses by Aim

Aim 1

To qualitatively examine the content of discussions regarding medication cost and medication management between RA patients and rheumatologists in routine clinic visits.

The purpose of the qualitative analysis of the content of communication between RA patients and rheumatologists was to advance understanding of what actually happens in conversations about medication cost and management. As argued in previous chapters, little is known about the content of communication about medication costs and management and further understanding is important to drive conceptual thinking and theory development in this area. Achievement of this aim required an investigation of the contextual and holistic nature of medical visit communication so a grounded theory approach was chosen.

Specifics of the methods used follows. A brief description of grounded theory is provided, details on audiotape transcription, and details on methods of textual analysis are presented. Details are provided so that readers may understand the methods undertaken and have the opportunity to assess for themselves the truth and quality of the inquiry (Chenail, 1995).

Grounded theory was developed as a way to conceptualize and conduct qualitative analyses. Specifically set apart from quantitative analysis, the use of grounded theory in qualitative analysis is not the quantifying of qualitative data but rather a nonmathematical process of interpretation, undertaken for the purpose of discovering concepts and

relationships in raw data and then organizing these into an explanatory scheme to advance theory development (Strauss & Corbin, 1998). Taking these ideas into practice, grounded theorists propose that researchers analyze qualitative data using joint coding and analysis following systematic guidelines. Codes should be allowed to emerge from the data rather than from predetermined categories. To ensure the rigor of established codes, constant comparison should be employed to ensure consistency within and between codes. Data should be sought to further theory development rather than for purposes of attaining a statistically representative sample. There is a constant interplay between the researcher and the research act. In short, using grounded theory researchers are supposed to remain close to, or “grounded” in, the data throughout the entire analysis process. By staying grounded in the data, researchers can exercise the objectivity necessary to arrive at impartial and accurate assessments of events while also being sensitive to the nuances and meanings in the data that permit the connection between concepts. As this is an exploratory look into medication cost and management communication in rheumatology visits, grounded theory is well suited to facilitate the elucidation of themes and concepts that may serve as building blocks of theory development.

In this study, to complete the qualitative analysis of discussions of medication cost and medication management among rheumatologists and patients with RA, all audiotapes were first reviewed to determine the presence of communication about medication cost and management. The tape review was accomplished through coding the audiotapes using the created coding tool described earlier. As the independent coders reviewed the tapes, those tapes containing communication about medication cost and management were then transcribed. Having transcripts of the physician-patient interactions was necessary for qualitative analysis but it also made coding more reliable. Transcribing rules were used that follow those of previous researchers in the area of physician-patient communication (Mishler, 1984; Waitzkin, 1990). The transcribing rules can be found in Appendix 4. In

general, tapes were transcribed verbatim with the exception of proper names and any other information that could potentially lead to the identification of the participants. Speakers were identified by their role (e.g. physician or patient), a line was started each time there was a new speaker, and interruptions and audible nonverbal behaviors (e.g. laughing or crying) were explicitly transcribed. When the tapes contained portions that were difficult to hear or hard for the transcriptionist to understand they were marked with a time-stamp. The transcripts were stored under the arbitrary patient identification number to further protect the identity of the participants. The principal investigator personally transcribed four of the audiotapes and a professional transcriptionist completed the rest. The transcriptionist went through a training period of rule review, examination of a sample transcript, and transcription of a tape not for use in the analysis to make sure the transcribing rules and procedures were clear. The transcriptionist was blinded to the study purpose.

The principal investigator reviewed the transcripts against the tapes to correct inaccuracies and fill in information that the transcriptionist was not able to hear or understand. Having a better understanding of the context of communication and the regional dialects of participants, the principal investigator was able to complete much of the information that had originally been transcribed with a time-stamp. Common errors corrected included misspellings, incorrect punctuation, and mistaken wording. Review of transcripts and error correction was important to maintain the participants' true voices in the exchanges.

Grounded theory suggests iterative data collection and analysis, so as transcripts were completed they were reviewed to facilitate becoming familiar with the data. Once the transcriptions were completed, they were loaded into ATLAS.ti 5.2 (Atlas.ti Scientific Software Development GmbH, 2008). ATLAS.ti 5.2, a qualitative data analysis program, was used to store the data, create codes, and build a coding scheme. Patient demographics were also loaded into ATLAS.ti to analyze the data by patient characteristics.

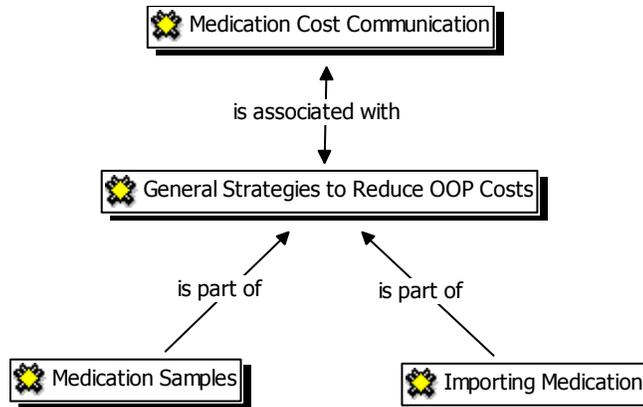
Content analysis of the transcripts was performed using four linked processes: processing the raw data, data reduction, data display, and conclusion drawing/verification (Miles & Huberman, 1994; Morse & Field, 1995). As a general description, this process involved the following: (a) reading and examining the transcripts to identify units of analysis, which are defined as paragraphs, sentences, verb phrases, or single words that conveyed a single meaning, idea, or concept; (b) grouping together and labeling units corresponding to themes; (c) grouping together units that do not correspond to a theme but are deemed significant based on repetition and emphasis throughout the data; and (d) validating themes and data organization.

Codes were generated to describe discovered concepts and the development of these codes loosely followed open coding and axial coding, suggested by Strauss and Corbin (Strauss & Corbin, 1998). Open coding has a descriptive focus and is often a first step since the purpose is to, “open up the text and expose the thoughts, ideas, and meanings contained therein (Strauss & Corbin, 1998).” Open coding uses line-by-line textual analysis to examine the data and break it into discrete parts by comparing similarities and differences. Words, phrases, actions, styles of communication, and subject matter that are found to be similar are grouped into categories and subcategories. In this analysis, categories generally described communication phenomenon and subject matter, such as “physician initiates discussion” and “medication cost”. It is important to note that while codes were allowed to emerge from the data, there was special emphasis on categories of medication cost and management communication. As categories were created a process of constant comparison was employed in assigning new codes, whereby text and subject matter that were considered the same were assigned the same code (Strauss & Corbin, 1998). The process of comparison continued throughout the coding process and as codes began to accumulate that shared similar meanings they were grouped under increasingly abstract category definitions. Grouping data was important because it reduced the number

of concepts into more meaningful units and it added to the explanatory power of the analysis by adding depth. For example, through grouping it became clear that medication cost communication was subtler than discussion of dollars and cents, containing talk about insurance coverage and assistance programs. Effort was made to apply the most concise, representative codes to the text. This meant that there was little to no overlap in the application of subcategory codes but subcategories were sometimes nested within category codes.

Through category refinement the data ceased to be flat and took on a tree-like structure as relationships among them began to appear. The assignment of relationships among codes is characteristic of axial coding. In axial coding the analysis moves from the descriptive to the conceptual looking at how codes crosscut and link. The examination is driven by the basic questions who, what, when, where, why and how with the goal of linking structure with process through code relationships. The basic tasks of axial coding include: (1) laying out the properties of a category, (2) identifying the conditions, interactions, and consequences associated with phenomenon, (3) relating a category to its subcategories through statements denoting how they are related, and (4) looking for cues in the data about the relationships among major categories (Strauss, 1987). As an example of the axial coding employed in this analysis, please see Figure 2 below which shows the major category “Medication Cost Communication”, the associated category “General Strategies to Reduce OOP costs”, and the subcategories “Importing Medications” and “Medication Samples.” Details about the codes and the linkages will be presented in the chapter that follows.

Figure 2. Coding relationships among the major category “Medication Cost Communication”, associated code “General Strategies to Reduce out-of-pocket (OOP) Costs”, and the subcategories “Importing Medications” and “Medication Samples”.



Through cyclical iterations of open coding and axial coding, the definition and conceptualization of the important themes of medication cost and management emerged from the transcripts. The structure of medication cost and management communication became clear in the form of relevant dimensions such as “insurance coverage impacting OOP costs” and “medication assistance programs.” Further, communication processes became clear, such as the differences in patient versus physician initiation of conversation about certain dimensions. The ability to link structure with process as well as the repetition of themes throughout the transcripts indicated that they were grounded in the data and the analysis was reaching a point of saturation (Strauss & Corbin, 1998).

Several sequential data steps were undertaken to improve coding reliability and validate the themes discovered in the analysis. First, as has been mentioned above a process of constant comparison was employed so that each new assignment of a code initiated a brief review of previous uses of the same code to ensure that the content of the code was addressing the same concept. Second, a system of double coding was employed. Double coding involved going through the transcripts and assigning codes to the

text an initial time and then repeating the process. As the transcripts were coded for the second time the codes were compared to the initial coding to make sure that the same sections of text and phrases were consistently coded. Double coding revealed a high degree of consistency between the initial and second coding, although refinements to the coding scheme were made. Third, negative cases were sought out and used to strengthen existing codes. Negative cases are those that do not fit within the existing code structure. For example, in a medical visit where a patient discussed importing medications from Mexico to save money it seemed to fit into the category of general strategies to reduce OOP costs. However, when a second patient discussed importing medication from outside the United States it seemed that this was not best defined as reducing OOP and a new code, “importing medication”, was created. Hence, the coding scheme was revised to better represent the underlying concept. Finally, an experienced qualitative-oriented researcher was consulted about the selection of particular codes and the process of coding to help ensure that codes had clear definition and appropriate application. While none of these actions guarantee valid results, it is believed that, taken together, they indicate a rigorous approach to the conduct of the qualitative analysis and improve the validity of the findings.

Aim 2

To describe relationships among patient characteristics, physician characteristics, and patient-physician communication about medication cost and medication management among RA patients and rheumatologists during routine clinic visits.

H1: Discussions of medication cost and medication management are more likely to occur among physicians who are female and younger.

H2: Discussions of medication cost and medication management are more likely to occur when patients are female, younger, more educated, have higher income, and have more severe RA.

H3: Discussions of medication cost and medication management are more likely to occur when physicians and patients are in race concordant relationships.

H4: Older patients are more likely to ask physicians questions about medication costs than younger patients.

Analysis Overview

All study data were entered into SPSS 15.0 (SPSS Inc., 2007) and converted to STATA 9.2 (StataCorp LP, 2007) for analysis. In addition, codes generated from the qualitative analysis in ATLAS.ti were also converted to STATA 9.2 and all variables were combined into a single analysis dataset. Data analysis was broken into three distinct stages. First, descriptive data analysis was undertaken to describe in detail the characteristics of the sample and the medical visit communication measured in the study. Second, the data were examined to assess the impact of missing data, as well as the influence of the study design with patients nested within physicians. Using information gained from the data examination, methods for addressing missing and nested data were employed in subsequent analyses. The third stage of data analysis focused on hypothesis

testing by assessing bivariate relationships between measured variables and using multiple logistic regression to examine how patient, physician, and medication characteristics influenced whether: (1) medication cost was brought up during the medical visit and (2) patient-initiated medication regimen changes were discussed. Examining communication about medication costs in more depth, bivariate relationships and multiple logistic regression were used to examine the influence of measured variables on whether: (1) physicians asked questions about medication costs, (2) patients asked questions about medication costs, and (3) patients or physicians initiate cost discussions.

Further, to compare and contrast with the predictors of patient-initiated medication regimen change communication, multiple logistic regression was also used to examine how patient, physician, and medication characteristics influenced whether the medication regimen was changed during the medical visit. Assessing predictors of both patient-initiated medication regimen change communication and overall discussion of medication regimen changes in the medical visit provided a more complete picture of medication management communication. Each of these stages of data analysis will be discussed in detail below.

Descriptive Data Analysis

First, descriptive statistics were calculated for all physician, patient, medication, and medical visit communication characteristics. Frequencies and percents were used to describe categorical and dichotomous measures (e.g. medication satisfaction, discussion of medication cost, discussion of modifying regimen, patient initiated changes to the regimen, cost discussion initiator, physician gender, physician race, physician Hispanic, functional class, health insurance, patient gender, patient race, patient Hispanic, patient marital status, patient highest grade completed, and patient income). Means and standard deviations were used to describe continuous and count variables (e.g. patient age, physician age, patient-reported pain, number of RA medications, total RA medication cost, patient cost questions,

and physician cost questions). For all continuous and count variables, the data were plotted to examine the structure and deviation from normal. Variables that were skewed or unevenly distributed were transformed. For example, the question asking about medication cost variables were left-skewed because of numerous zero values so they were transformed into dichotomous variables for any question asking. The total RA medication cost variable had a positive skew with the mean exceeding the median as a number of patients had very high total RA medication costs. Both the Box-Cox transformation and natural logarithm of the total RA medication cost variable were computed to adjust the distribution of the variable for analysis. However, neither correction completely adjusted the distribution of the variable as confirmed the Shapiro-Wilk test where the null hypothesis that the sample was drawn from a normally distributed population was rejected for both transformations. As a result, the original total RA medication cost variable was used in the analyses and non-parametric tests were conducted.

In addition, frequencies, percents, means, and standard deviations of key patient and visit variables were also calculated by physician. Chi-square tests were used to assess differences among physicians regarding categorical variables. Analysis of variance was used to test which continuous variables varied among physicians. Examination of patient and communication variables by study physician allowed for the assessment of differences among physicians in patient case-mix as well as medical visit characteristics.

Data Examination

Intra-Physician Correlations

In this study, physicians were initially recruited and then patients were recruited based on whether they saw a participating study physician. Given this arrangement, patients were nested within physicians and there was a need to account for the potential correlation among patients seeing the same study physician. While it would have been

beneficial to utilize statistical techniques such as generalized estimating equations (GEE), which adjusts the standard errors of the regression coefficients to account for the fact that patients are nested within physicians, the number of physicians in the sample is not large enough to utilize these methods (Burton, Gurrin, & Sly, 1998). Since there were only eight study physicians and all of the patient outcome variables were categorical or dichotomous, the methods for assessing intra-physician correlations were somewhat limited.

Cross-tabulations of the outcome variables by physician were generated along with summary statistics, including means. The presence of diversity within physicians on patients' responses and means in the middle of the range of outcome values indicated low intra-physician correlation on the outcome values. In contrast, if there had been a large number of patients within physicians answering 'yes' or 'no' to a dichotomous outcome variable, essentially responses overwhelmingly clustering on a particular value, with a mean close to 0 or 1 it would have indicated a stronger correlation within physicians. For most, but not all variables, analyses revealed variation in outcomes within physicians likely indicating a low intraclass correlation, meaning physicians communicated independently with patients and did not say the same things for each patient. Previous research supports this finding, indicating that physician interaction style is not highly correlated with clinic site or physician (Sleath, Rubin, Campbell, Gwyther, & Clark, 2001; Sleath et al., 2003). However, given that means of assessing the intra-physician correlation were rudimentary, some variables appeared intracorrelated, and patients were selected into the study by physician, physician was used as a stratification variable in analyses.

Missing Data

The data were next examined for the presence and patterns of missing data. Some respondents had missing data on one or more variables. Table 6 below provides a listing of the variables and the frequency and percent missing.

Table 6. Analysis variables and the frequency and percent missing data (N=200).

| Variable | # Missing (%) |
|---|---------------|
| Satisfaction with Medications | |
| Medication Satisfaction | 1 (0.5) |
| Characteristics of Communication | |
| Presence of discussion about medication cost | 7 (3.5) |
| Number of physician questions about cost | 7 (3.5) |
| Number of patient questions about cost | 7 (3.5) |
| Cost discussion initiator | 7 (3.5) |
| Discussion of modifying regimen | 7 (3.5) |
| Discussion of patient initiated changes to the medication regimen | 7 (3.5) |
| Patient Characteristics | |
| Gender | 0 (0.0) |
| Age | 0 (0.0) |
| Education | 10 (5.0) |
| Income | 18 (9.0) |
| Marital Status | 10 (5.0) |
| Race | 0 (0.0) |
| Hispanic | 7 (3.5) |
| RA severity | 27 (13.5) |
| Self-rated pain | 1 (0.5) |
| Number of Prior Visits with Doctor | 0 (0.0) |
| Prescription drug coverage | 0 (0.0) |
| Physician Characteristics | |
| Gender | 0 (0.0) |
| Race/ethnicity | 0 (0.0) |
| Age | 0 (0.0) |
| Medication Characteristics | |
| Cost of medications | 0 (0.0) |
| Number of RA medications prescribed | 0 (0.0) |

As Table 6 shows, data were missing on both outcome variables (medication satisfaction and characteristics of communication) and predictor variables (patient characteristics). The one patient missing data on medication satisfaction was due to a lost patient interview and the communication data characteristics were missing because the medical visit recordings did not exist, generally due to a recording malfunction. In both cases these data can be conservatively considered missing at random (MAR) since the missing data values were unrelated to why the data were missing.

For the predictor variables, data were missing on education, income, marital status, Hispanic ethnicity, and RA severity. The variable with the most missing data, RA severity,

was derived through physician assessment of patients' functional status and required physicians to complete a form containing the ACR functional classification at the conclusion of the medical visit. Many physicians forgot to complete the forms at the conclusion of the visit or took the form to complete later and never returned it to the research staff. While certain physicians were more likely to not provide the data than others, the level of missing data appeared unrelated to the patients' RA severity. For the missing data on patients' education, income, marital status, and Hispanic ethnicity, the level of missing data can be attributed to at least three causes: (1) the placement of these items at the end of the patient survey, (2) patients' improper following of skip patterns, and (3) patients' willful incompleteness of the items. For these variables, it is possible that the data are not missing at random (NMAR). As an example, patients of a particular income category may be more or less likely to not answer the item. Unfortunately, there was no way to formally evaluate whether the data was missing at random or not, since it would require knowledge of the missing values. However, simulation studies and scholars working on multiple imputation methods have shown that with a rich multivariate data set and multiple imputation methods, missing data can be successfully imputed even if the data are not strictly MAR (Faris et al., 2002; Schafer, 1997; Van Buuren, 2006).

For this study, multiple imputation methods were utilized to address the missing data in the predictor variables. A conservative approach was chosen, and outcome variables were not imputed. This decision was made because a small percentage of data were missing on the outcomes and there is debate over the appropriateness of imputing outcome variables (P. D. Allison, 2002). Listwise deletion of patients' missing data on outcome variables left a sample of 192.

Multiple imputation has several advantages: it can be applied very generally and is not problem specific, it preserves the correct conditional framework when there are incomplete covariates, and it can be used to construct comparatively simple sensitivity

analyses (Kenward & Carpenter, 2007). The two major approaches for imputing multivariate data are joint modeling and fully conditional specification (FCS). To best match the analysis models used in the present study, FCS methods were chosen to impute the missing predictor variables and joint modeling was employed as a sensitivity analysis on the FCS imputation methods.

FCS does not start from an explicit multivariate density, as does joint modeling, but instead assumes that the data have an underlying multivariate distribution that can be used to derive underlying conditional distributions for each covariate (Faris et al., 2002). Imputation under FCS is done by iterating over all conditionally specified imputation models, each iteration consisting of one cycle through all incomplete variables (Van Buuren, 2006).

FCS has practical advantages over joint modeling (Van Buuren, 2006). First, FCS allows for the creation of flexible multivariate models so that each variable with missing data has its own separate, specified imputation regression model. One can easily specify models that are outside of the standard normal multivariate density. For this analysis, this is especially powerful because the majority of variables are dichotomous or categorical, clearly not fitting the multivariate normal used in joint distribution modeling. Second, it is easy to model interactions terms with FCS. Third, generalization to models where the data are not missing at random might be easier.

Of course FCS is not without disadvantages. Disadvantages of FCS include: (1) each conditional density has to be specified separately, so substantial modeling effort can be needed for datasets with many variables, (2) it is often computationally more intensive than joint modeling, and (3) relatively little is known about the quality of the resulting imputations because the implied joint distributions may not exist theoretically (Van Buuren, 2006). However, this theoretical weakness is often difficult to verify in practice and FCS appears robust against incompatibility. To test the robustness and convergence of the

imputations in this analysis, imputation models were run with five and with ten iterations. The results of the logistic regressions did not change with additional iterations.

As a further check on the imputations and the quality of imputed data, a second multiply imputed data set was created using joint modeling in SAS 9.1 (SAS Institute Inc., 2003). Regressions run using this data produced similar results to those generated using FCS although the exact regression techniques could not be replicated to account for stratification on physician. Associations with the imputed predictor variables and the outcome variables were assessed through combining chi-square statistics from analysis of the data sets created by the multiple imputations using methods described by Schafer and employed by Allison (P. Allison, 2000; Schafer, 1997). Results indicated that the imputed variables education, income, marital status, Hispanic ethnicity, and RA severity were not significantly related to any of the outcome variables. These results matched those generated using the complete case dataset.

Logistic regression models testing the stated hypotheses were run using the imputed datasets and a complete case dataset using listwise deletion to eliminate patients from the sample that had missing data on any of the modeled variables. Overall, there were few differences in the coefficients, statistical significance, or confidence intervals of the regressions run using the imputed data and those generated using the complete cases. Results from the complete cases are presented since it was through complete case analysis that models could be appropriately stratified on physician.

Hypothesis Testing

The focus of the hypotheses of aim two centered on describing the relationships among patient-physician communication about medication costs and management and patient, physician, and medication characteristics. The specific communication variables under study included: presence of discussion of medication cost, number of physician

questions about cost, number of patient questions about cost, whether the patient or physician initiated the medication cost discussion, discussion of modifying the medication regimen, and discussion of patient initiated changes to the medication regimen. All were dichotomous except for the questions asked about cost variables. Plots revealed that question asking was highly left skewed with many patients and physicians asking zero questions about medication costs. For analyses the variable was transformed for both patients and physicians into the dichotomous ('yes'/'no') variable 'any questions asked about medication costs.'

For each of the communication outcome variables, bivariate analyses between characteristics of communication and patient, physician, and medication characteristics were conducted. Variables were created to indicate gender concordance and racial concordance, indicating that patients and physicians in the medical visits were of the same gender or were of the same race. Chi-square statistics were calculated to test the association between each of the communication outcome variables and categorical characteristic variables. Two-tailed t-tests were calculated to test the association between communication outcome variables and continuous variables. A correlation matrix was also generated to assess the interrelationships among the other variables used in the analysis.

Since all of the communication outcome variables of interest were dichotomous, logistic regression models were constructed to test the impact of patient, physician, and medication characteristics on the outcomes, after controlling for other characteristics. As an exploratory analysis, the goal was to begin to identify which characteristics together are most strongly associated with the communication variables of interest.

An important factor considered in model building was the size of the categories of the dichotomous outcome variables. Some outcomes had relatively few cases per category so care had to be taken to build the most parsimonious models possible in order to achieve

stable estimates from logistic regression equations. Only predictor variables that were statistically significant in the bivariate analyses were modeled in the multivariable analysis.

As mentioned previously, since patients were nested within physicians all regressions were stratified on physician. To address the unequal patient sample sizes within physicians, low-enrolling physicians were combined into a single stratum. While not ideal, establishing strata this way was another means of improving the efficiency and stability of the regression estimates. Physicians in the combined stratum shared several characteristics: all were white, most were younger, and most had been in practice fewer years. Sensitivity analyses were conducted by running the regression models with different strata and control variables to assess the robustness of the main findings.

Aim 3

To examine how discussions of medication cost and medication management in routine clinic visits between rheumatologists and patients with RA affect patient-reported medication satisfaction.

H5: Patients who discuss medication costs with physicians during clinic visits are more likely to report being satisfied with their medications than patients who do not discuss medication costs.

H6: Patients who discuss medication management with physicians are more likely to report being satisfied with their medications than patients who do not discuss medication management.

To address this aim a single item assessing the degree of patient satisfaction with prescribed medications was asked of patients immediately following the audiotape recorded medical visit. A plot of the five-category variable revealed that the data was skewed with zero patients reporting that they were 'Not at all' satisfied with their medications. For analyses, the variable collapsed into a dichotomous variable with the medication satisfaction categories 'A little or somewhat satisfied' and 'Very or totally satisfied.'

Bivariate analyses between medication satisfaction and patient, physician, medication, and communication characteristics were conducted. Chi-square tests were conducted for high versus low medication satisfaction and categorical characteristic variables. Two-tailed t-tests were calculated for high versus low medication satisfaction and continuous variables. Bivariate associations between discussions of medication cost, discussion of regimen modification, patient initiated regimen changes and high versus low medication satisfaction were calculated using Mantel Haenszel tests, stratified on physician.

The goal had been to use multivariable logistic regressions to separately examine the influence of discussions of medication costs and discussions of patient-initiated medication regimen changes on patient medication satisfaction taking into account patient, physician, and medication characteristic variables. In addition, multiple logistic regression was going to be used to measure the influence of the interaction between medication cost discussion and regimen modification discussion on medication satisfaction while controlling for patient and physician variables. However, the relatively few respondents (n=24) reporting low medication satisfaction presented a challenge to multivariable modeling. This constraint meant that only a couple of predictors could be entered into each logistic regression model if it was expected to produce stable estimates from the regression equations. To address this issue, only predictor variables that were statistically significant in the bivariate analyses were used in the multivariable analysis. However, issues of model building were largely avoided since bivariate analyses revealed few significant relationships between medication satisfaction and patient, physician, medication, and communication characteristics. Limited multiple logistic regression models stratified on physician were conducted to assess the predictors of high versus low satisfaction. Again, sensitivity analyses were conducted by running the regression models with different strata and control variables to test the robustness of the findings.

CHAPTER FIVE: RESULTS

Patient and Physician Characteristics

Patient characteristics for the full sample of 200 patients are presented in Table 7. The mean patient age was 62.3 (SD=9.0), 74% were women, 22.5% Black/African American, and 1% identified as being of Spanish or Hispanic origin. The majority, 112 (59%), of patients were married and the majority, 65 (35.7%), reported a yearly total household of income of less than \$20,000. Sixty patients (31.6%) reported being a high school graduate as their highest grade completed in school. In terms of patient functional status, physicians rated the majority of patients, 90 (52.0%), as having moderate restriction but adequate for normal activities. However, most patients were also experiencing some pain at the time of their visit. The mean patient score on the zero to ten pain scale where zero was “no pain at all” and ten was the “worst pain ever” was 4.35 (SD=2.8). Twenty-six patients (13.5%) had family or friends present for the visit. Of the eight physicians in the study, their mean age was 46.2 years (range 32 – 59), six were White/Caucasian, one was Black/African-American, four were women, two identified as being of Spanish or Hispanic origin, and mean duration at the clinic under study was 9.1 years (range 1-15).

Table 7. Characteristics of RA patients in total sample (N=200).

| Characteristics | Total Sample Number of Patients (%)^a | |
|--|--|--------|
| Age, mean (range) | 62.3 (45.2-88.5) | |
| Women | 148 | (74.0) |
| Race | | |
| Black/African American | 45 | (22.5) |
| White/Caucasian | 143 | (71.5) |
| American Indian/Alaskan Native | 7 | (3.5) |
| Other | 5 | (2.5) |
| Spanish or Hispanic Origin | 2 | (1.0) |
| Marital Status | | |
| Married | 112 | (59.0) |
| Widowed | 33 | (17.3) |
| Separated | 11 | (5.8) |
| Divorced | 28 | (14.7) |
| Never Married | 6 | (3.2) |
| Highest Grade Completed in School | | |
| 8 th Grade or Less | 12 | (6.3) |
| Some High School | 28 | (14.7) |
| High School Graduate | 60 | (31.6) |
| Some College | 46 | (24.2) |
| College Graduate | 27 | (14.2) |
| Any Post-Graduate Work | 17 | (9.0) |
| Income | | |
| Less than \$20,000 | 65 | (35.7) |
| \$20,000 - \$39,999 | 47 | (25.8) |
| \$40,000 - \$59,999 | 28 | (15.4) |
| \$60,000 - \$79,999 | 18 | (9.9) |
| Greater than \$80,000 | 24 | (13.2) |
| American College of Rheumatology (ACR) Classification of Global Functional Status | | |
| (I) No restriction of ability to perform normal activities | 50 | (28.9) |
| (II) Moderate restriction | 90 | (52.0) |
| (III) Marked restriction | 29 | (16.8) |
| (IV) Incapacitation or confinement to a bed or wheelchair | 4 | (2.3) |
| Patient-rated pain, mean (SD) | 4.4 | (2.8) |
| Medical Insurance | | |
| Private or employer purchased | 57 | (28.5) |
| Medicare with supplemental | 83 | (41.5) |
| Medicare without supplemental | 24 | (12.0) |
| Medicaid | 6 | (3.0) |
| Medicare with Medicaid | 15 | (7.5) |
| None | 15 | (7.5) |

a. Totals may be less than 200 due to missing data

Patient Characteristics by Physician

Analysis of the full sample of 200 patients and eight physicians revealed statistically significant differences in patient, medication, and medical visit characteristics by physician. Significant differences in patient characteristics by physician included: patient race, RA severity, prescription drug coverage, and number of prior physician visits. Looking at each of these in more detail, two physicians saw more patients that identified as Black/African American than the other physicians (χ^2 (21, 200)=54.8, $p<0.001$); one physician saw more patients in poor health with more severe RA according to ACR functional classification (χ^2 (21, 173)=33.8, $p=0.04$); two physicians saw more patients lacking prescription drug coverage (χ^2 (7, 200)=17.1, $p=0.02$); and two physicians had seen almost all their patients in the sample five or more times prior to the study medical visit (χ^2 (35, 200)=75.7, $p<0.001$). There were also significant differences in the number of RA medications patients were prescribed by physician ($F=2.69$, $p=0.01$). Patients were prescribed an average of approximately four RA medications, but two physicians averaged nearly five medications per patient. Finally, physicians differed on how much time they spent with patients as measured by medical visit length in minutes. Two of the eight physicians in the study spent more time with patients, on average, than the other physicians ($F= 7.19$, $p<0.001$).

Taken together these can be thought of as case-mix and style differences among the physicians in the sample. Differences in characteristics and outcomes by physician will be considered in more detail in subsequent sections and attempts were made to control for patient differences by physician in analyses.

Medication Characteristics

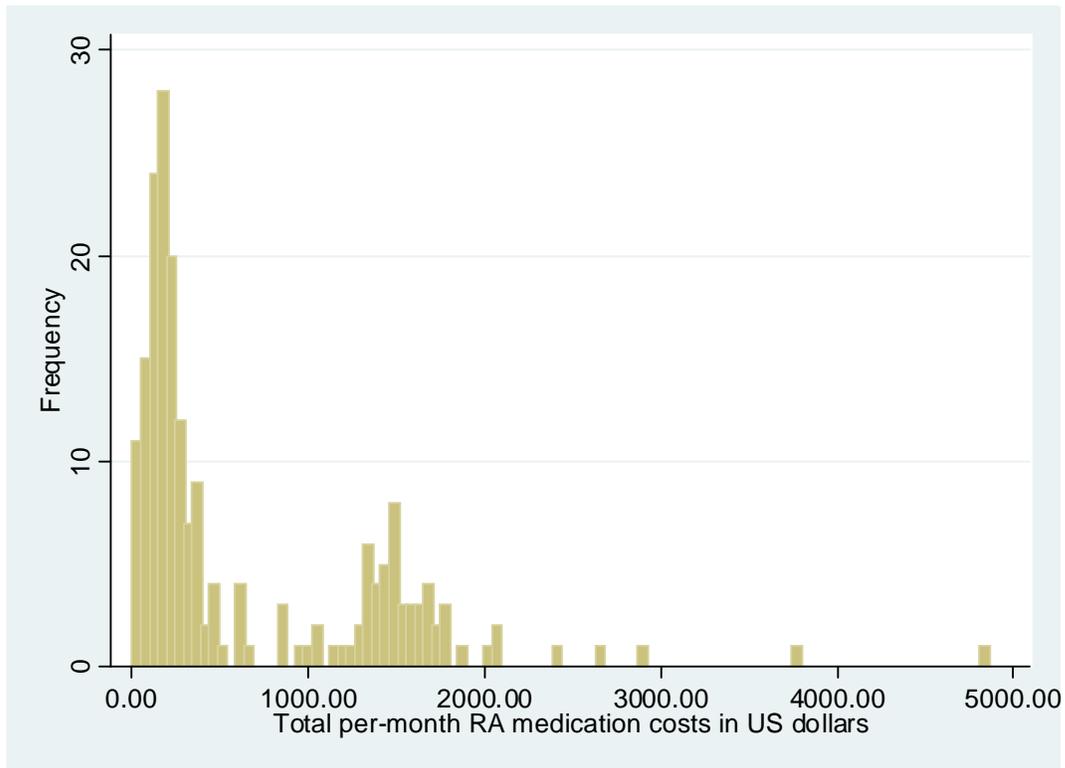
Of the 200 patients enrolled in the study, 199 were prescribed at least one RA medication at the time of their audio recorded medical visit. The mean number of RA medications per patient was 4.3 (SD=1.6) with a range of zero to nine. The overwhelming majority, 183 (91.5%), were prescribed a disease-modifying antirheumatic drug (DMARD), including 62 patients (31%) who were prescribed a tumor necrosis factor(TNF)- α inhibitor. In addition to DMARDs, patients were also prescribed non-steroidal anti-inflammatory drugs (NSAIDs), analgesics, bisphosphonates, and vitamins. Examining these categories, 41 patients (20.5%) were prescribed non-selective NSAIDS and 51 (25.5%) were prescribed COX-2 selective NSAIDs. Forty percent of patients were prescribed opioid analgesics or opioid analgesic combinations. Twenty-nine percent of patients were prescribed bisphosphonates and 51.5% overall were prescribed some form of calcium supplementation for osteoporosis prevention. Table 8 below shows the specific medications patients were taking by category.

Table 8. Medical record indicated RA medications for patients at the time of the audio-recorded medical visit in total sample (N=200).

| Category/Medication (U.S. Brand Name) | Total Sample Number of Patients (%) | |
|---|--|--------|
| Disease-modifying antirheumatic drugs (DMARDs) | | |
| Adalimumab (Humira®) | 12 | (6.0) |
| Etanercept (Enbrel®) | 21 | (10.5) |
| Infliximab (Remicade®) | 29 | (14.5) |
| Leflunomide (Arava®) | 21 | (10.5) |
| Methotrexate (Trexall™) | 119 | (59.5) |
| Hydroxychloroquine (Plaquenil®) | 46 | (23.0) |
| Sulfasalazine (Azulfidine®) | 11 | (5.5) |
| Azathioprine (Imuran®) | 5 | (2.5) |
| Gold Sodium Thiomalate (Myochrysine®) | 2 | (1.0) |
| Vitamin supplementation for DMARD | | |
| Folic Acid | 14 | (57.0) |
| Leucovorin | 2 | (1.0) |
| Glucocorticoids | | |
| Prednisone | 98 | (49.0) |
| Non-steroidal anti-inflammatory drugs (NSAIDs) | | |
| Valdecoxib (Bextra®) | 7 | (3.5) |
| Celecoxib (Celebrex®) | 28 | (14.0) |
| Rofecoxib (Vioxx®) | 16 | (8.0) |
| Meloxicam (Mobic®) | 15 | (7.5) |
| Naproxen (Naprosyn®) | 9 | (4.5) |
| Nabumetone (Relafen®) | 3 | (1.5) |
| Sulindac (Clinoril®) | 1 | (0.5) |
| Diclofenac (Cataflam®; Voltaren®) | 3 | (1.5) |
| Ketoprofen (Orudis® KT; Oruvail®) | 2 | (2.0) |
| Ibuprofen | 8 | (4.0) |
| Analgesics | | |
| Acetaminophen + codeine (Tylenol® With Codeine) | 2 | (1.0) |
| Acetaminophen + hydrocodone (Lorcet®; Lortab®; Norco®; Vicodin®) | 17 | (8.5) |
| Acetaminophen + propoxyphene (Darvocet-N® 100; Darvocet-N® 50) | 39 | (19.5) |
| Acetaminophen + oxycodone (Percocet®; Tylox®) | 17 | (8.5) |
| Acetaminophen + tramadol (Ultracet™) | 6 | (3.0) |
| Methadone | 3 | (1.5) |
| Morphine sulfate | 1 | (0.5) |
| Oxycodone hydrochloride (OxyContin®) | 3 | (1.5) |
| Acetaminophen (Tylenol®) | 19 | (9.5) |
| Tramadol (Ultram®) | 10 | (5.0) |
| Lidocaine Patch (Lidoderm®) | 1 | (0.5) |
| Calcium supplementation and agents for osteoporosis prevention | | |
| Alendronate Sodium (Fosamax®) | 45 | (22.5) |
| Risedronate (Actonel®) | 13 | (6.5) |
| Raloxifene (Evista®) | 5 | (2.5) |
| Calcitonin (Miacalcin®) | 4 | (2.0) |
| Calcium with or without Vitamin D (Caltrate®; Os-Cal® Caltrate® 600+D; Os-Cal® 500) | 103 | (51.5) |

The total per month cost of RA medications prescribed to patients ranged from \$0.00, for the patient not taking any medications, to \$4,860.01. The values were non-normally distributed with a positive skew. Patients at the median had per-month medication costs of \$246.91, while patients at the 25th and 75th percentiles had per-month medication costs of \$145.10 and \$1,314.86, respectively. Patients prescribed TNF- α inhibitors had much higher per-month total medication costs than those who were not prescribed biologic agents. Patients whose regimens included TNF- α inhibitors had median monthly total medication costs of \$1,483.32 with a range of \$843.88 to \$4,860.01. Patients whose RA medication regimens did not include TNF- α inhibitors had median monthly total medication costs of \$177.35 with a range of \$0.00 to \$679.47. Comparing mean per-month total RA medication costs, patients prescribed a TNF- α inhibitor had approximately eight times the medication costs than patients not prescribed such medications. A histogram plot of per-month total RA medication costs (Figure 3) shows the gap in between patients not prescribed TNF- α inhibitors and those that were.

Figure 3. Histogram of patient total per-month RA medication costs (N=200)



Medical Visit Audio Analysis

Descriptive Data about Medication Cost and Management Communication

Out of the total 200 medical visits, 193 were successfully recorded. Reasons for missing audio data included: digital recorder malfunction, failure to start the recorder for the visit, and failure to power on the microphone. Characteristics of the patients and physicians where the tape data were missing were generally similar to the characteristics when the tape data were not missing. The mean age of patients with missing tape data was 60.5 years-old, 85% were women, 43% were married, 71.4% were White/Caucasian, 71.4% had total annual incomes under \$40,000, 14% had a high school education or less, and 57% had generous drug coverage. The mean age of physicians when the audiotape data were missing was 43 years-old and approximately even numbers of data were missing by physician gender and race.

Results of medical visit audio analysis are based on the available sample of 193 audio recordings. The mean visit length was 14.21 minutes (range 3.20 to 33.32 minutes). For most recorded medical visits, 158 (81.9%) the only people in the exam room were the rheumatologist and patient with RA. Another medical professional was present for 11 (5.7%) of the medical visits. The other medical professional present was a medical student or resident for eight of the eleven visits, a nurse was present in the exam room in two visits, and a representative from a pharmaceutical manufacturer was present for one visit. Study participants had family members or friends present for 26 (13.5%) of medical visits. For 24 of those visits, patients were accompanied by an immediate family member or members, generally partners/spouses and adult children. In the other two cases, the identity of the person accompanying the study participant in the medical visit was unknown. For two of the 193 recorded visits both an additional health professional and family member were present.

Sixty-five of the recorded visits (33.7%) included discussions of medication-related cost issues, 47.7% of which were initiated by the patient. The mean length of time spent

discussing medication costs for the 65 visits where cost was discussed was 1 minute 27 seconds with a range of 3 seconds to 6 minutes 11 seconds. During medication cost discussions the majority of patients (51%) did not ask any questions, representing the range minimum, while one patient asked four questions related to cost, representing the range maximum. In contrast, physicians asked a mean of nearly 3 medication cost related questions during each visit where cost was discussed with a range of zero to eleven questions.

Discussion of medication management and modifications to the medication regimen occurred in 99 of the 193 (51.3%) recorded medical visits. In 40 of the recorded medical visits (20.7%), patients and physicians discussed patient-initiated changes to the medication regimen. The mean length of time spent discussing patient-initiated changes to the medication regimen for the 40 visits where such changes were discussed was 38 seconds with a range of 7 seconds to 2 minutes 3 seconds.

Table 8 shows the demographic characteristics of patients who discussed medication costs or patient-initiated changes to their medication regimens during medical visits. Overall, the demographics of patients who discuss medication cost and patient-initiated changes to the medication regimen are similar to each other and the overall population. The sections that follow provide information on the content of communication about patient medication management and medication costs, as well as specific differences in patient demographics within communication content areas.

Table 9. Characteristics of patients discussing medication costs (N=65) or patient-initiated medication regimen changes (N=40) during routine medical visits.

| Characteristics | Discussed Medication Costs Number of Patients (%) ^a | Discussed patient-initiated regimen changes Number of Patients (%) ^b |
|--|---|---|
| Age, mean (range) | 61.5 (45.3-84.2) | 61.1 (45.2-79.8) |
| Women | 45 (69.2) | 31 (77.5) |
| Race | | |
| Black/African American | 9 (13.9) | 5 (12.5) |
| White/Caucasian | 53 (81.5) | 32 (80.0) |
| American Indian/Alaskan | 0 (0.0) | 0 (0.0) |
| Native | | |
| Other | 3 (4.6) | 3 (7.5) |
| Spanish or Hispanic Origin | 1 (1.6) | 1 (2.7) |
| Marital Status | | |
| Married | 34 (57.6) | 21 (56.8) |
| Widowed | 10 (17.0) | 5 (13.5) |
| Separated | 1 (1.7) | 1 (2.7) |
| Divorced | 11 (18.6) | 8 (21.6) |
| Never Married | 3 (5.1) | 2 (5.4) |
| Highest Grade Completed | | |
| 8 th Grade or Less | 3 (5.1) | 0 (0.00) |
| Some High School | 9 (15.2) | 10 (27.03) |
| High School Graduate | 20 (33.9) | 7 (18.92) |
| Some College | 18 (30.5) | 10 (27.03) |
| College Graduate | 4 (6.8) | 7 (18.92) |
| Any Post-Graduate Work | 5 (8.5) | 3 (8.11) |
| Income | | |
| Less than \$20,000 | 19 (33.3) | 12 (33.33) |
| \$20,000 - \$39,999 | 17 (29.8) | 9 (25.00) |
| \$40,000 - \$59,999 | 11 (19.3) | 8 (22.22) |
| \$60,000 - \$79,999 | 6 (10.5) | 4 (11.11) |
| Greater than \$80,000 | 4 (7.1) | 3 (8.33) |
| ACR Classification of Global Functional Status | | |
| (I) No restriction of ability to perform normal activities | 12 (21.4) | 10 (28.6) |
| (II) Moderate restriction | 33 (58.9) | 20 (57.1) |
| (III) Marked restriction | 9 (16.1) | 4 (11.4) |
| (IV) Incapacitation or confinement to a bed or wheelchair | 2 (3.6) | 1 (2.9) |
| Patient-rated pain, mean (SD) | 4.6 (2.8) | 4.8 (2.7) |
| Medical Insurance | | |
| Private or employer purchased | 20 (30.8) | 12 (30.0) |
| Medicare with supplemental | 21 (32.3) | 18 (45.0) |
| Medicare without supplemental | 12 (18.4) | 4 (10.0) |
| Medicaid | 2 (3.1) | 2 (5.0) |
| Medicare with Medicaid | 3 (4.6) | 0 (0.0) |
| None | 7 (10.8) | 4 (10.0) |

a. Totals may be less than 65 due to missing data.

b. Totals may be less than 40 due to missing data.

Results of Aim 1 – Qualitative Examination of Medication Cost and Management

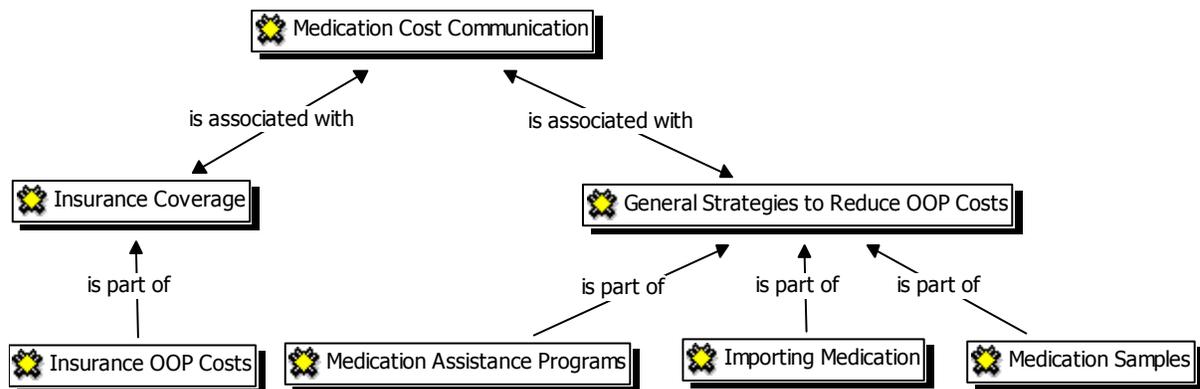
Communication

Medication Cost Discussion Content

This section describes the results of the analysis of the content of communication about medication costs in the 65 medical visits where cost was discussed. Under the major category medication cost, two themes emerged from the content analysis of the medical visit communication. The first theme was insurance coverage and the impact that coverage had on prescription decision-making. The second theme was strategies to reduce patients' OOP medication costs. Under the insurance coverage category was the subcategory insurance coverage affecting OOP costs, which was conceptualized as part of communication about insurance coverage but represented a distinct area of insurance coverage communication. Under the theme of general strategies to reduce OOP medication costs, there were three subcategories that were conceptualized as being part of strategies to reduce OOP medication cost since that was their intention but they were specific strategies to reduce OOP costs. The subcategories were special programs offered by pharmaceutical companies to defray medication costs, importing medications from outside the United States, and receiving medication samples. Attempts were made to apply the most representative code to the corresponding text resulting in little to no overlap in the subcategory codes. However, subcategory codes were sometimes nested within category codes. Figure 4 contains a graphical representation of the categories of medication cost and relationships among categories. The sections below describe the categories in detail and provide illustrative excerpts from the transcripts. Actual transcript data and direct participant quotes are used as much as possible in an attempt to let the data speak for itself (Strauss & Corbin, 1998). To preserve confidentiality, all direct quotations from the

transcripts are presented without identifying the speaker other than noting whether it is a patient, physician, or accompanying family member speaking. Further, all proper names of people and places are omitted. The generic “Dr. X” was used to replace any mention of a specific doctor’s name. Ellipses indicate other omissions and square brackets replace other identifying features or provide clarifying information.

Figure 4. The categories and subcategories of communication related to medication cost in medical visits.



Insurance Coverage

In the context of medication cost communication, discussion of patients’ health insurance coverage particularly prescription drug coverage was a significant, repeated theme. Participants discussed insurance coverage in the context of medication cost communication in 48 medical visits. Specifically, conversations about insurance coverage related either to insurance coverage as a barrier or facilitator to medication access or the influence of insurance coverage on prescription decision-making. The impact of insurance coverage on access to medicine was the most frequently discussed of the two topics occurring in 28 medical visits. In 13 (46%) of those conversations, patients and physicians were discussing insurance coverage as a barrier to accessing prescribed medications.

Patients were actively denied medications prescribed by their rheumatologist for their RA or were struggling to receive enough medication to remain adherent to their prescribed regimens. Patients and physicians both initiated these conversations and physicians asking about access and patients disclosing insurance barriers to accessing medications often occurred in the context of communication about adherence. The following exchange is illustrative of communication about insurance coverage as a barrier to accessing prescribed medications:

Physician: Are you taking the Arava regularly?

Patient: Not regularly, uh, uh.

Physician: And I saw a note from Dr. X that your insurance company was not covering the Arava?

Patient: Ah, they, I have a problem with the insurance company.

Physician: Tell me what's going on because the last time we talked everything was a-okay. Has something happened since then?

Patient: No, not at all they just, they sent a letter to me I don't know why but –

Physician: They sent a letter to you and what did the letter say?

Patient: I can't remember ((mumbles)) anyway it was something about they had refused.

Physician: Usually what, now you had been on the Remicade and they had refused that.

Patient: Yeah, they refused that one.

Physician: But they also sent you a letter about the Arava too?

Patient: Uh, huh.

Insurance coverage was discussed in the context of prescription decision-making in 18 medical visits. These conversations generally occurred as patients and physicians were trying to make decisions about adding new medications to patients' regimens. Generally, physicians initiated these discussions by asking patients about their insurance coverage or

talking about which medications were known to be covered by particular health plans.

Patients and physicians would then engage in communication about what medications were likely to be covered by a patients' insurance before settling on a treatment course of action.

The following excerpt is typical of the communication about the impact of insurance coverage on prescription decision-making:

Physician: Okay, now in terms of looking at the TNF-alpha inhibitors um, one of the other concerns also becomes um, how you know getting coverage because they are

Patient: ((Interrupting)) Oh.

Physician: Extremely expensive.

...

Physician: But um, a self-administered, a self injected drug is not covered by Medicare. They do cover um, Infliximab, which is the TNF-alpha inhibitor that is administered as an IV. In fact um, the other folks in the clinic today are predominantly getting that treatment. Um, either because they have a GI disease um, inflammatory bowel disease or because they have um, rheumatoid um, and that usually has folks coming in for um, about two to three hours, actually more like three to four hours. Two-hour infusion –

Patient: Whoa.

Physician: Um, and coming initially um, ah, starting at baseline -- two weeks, one month and then every two months. Um, so it means sort of coming into the infusion clinic area every two months um, to get that.

Patient: For like all afternoon.

Physician: Yeah.

...

Physician: So um, so it certainly um, then that certainly is covered. We know that um, many of the private insurances cover both the um, Infliximab and also many of them will also cover the self-administered.

Spouse: Well [patient name] is covered by the state, which is really [name of insurance plan].

Patient: It's a good plan.

Physician: Yeah, and they should definitely cover the TNF-alpha inhibitors.

Spouse: Right.

Physician: So if that looks like the way to go um, with the rheumatoid they'll cover it so that shouldn't be a problem for you.

Not surprisingly, the majority of conversations about the impact of insurance coverage on prescribing centered on discussion of brand-name medications. These medications have higher retail prices, often making them more difficult for patients to obtain without the assistance of prescription drug coverage.

Insurance Coverage and OOP Medication Costs

Even for patients with prescription drug coverage for a particular medication, many health insurance plans pass portions of the medication cost onto patients. This cost sharing is the direct charge to a patient at the time a prescription is filled and represents the price of the prescription medication to the insured patient, while insurance covers the remainder of the cost (Gibson, Ozminkowski, & Goetzel, 2005). Typically, medication cost sharing takes the form of co-payments, a flat fee per prescription (e.g. \$10), or coinsurance, a fixed fraction of each dollar of cost (e.g. 20%). The coinsurance or co-payment amount a patient pays for his or her medication is their OOP medication cost.

Insurance coverage determines patient OOP costs for a particular medication and, therefore, can be thought of as a part of insurance coverage communication. Yet, communication about insurance coverage affecting OOP medication costs is more specific. Beyond the access to the medication granted by having insurance coverage there is the *financial ability* to access the medication based on the affordability of the co-payment or coinsurance. In this way insurance coverage affecting OOP costs can be conceptualized as a second tier of communication about accessing medications or making decisions about new prescriptions. Patients and physicians who conclude that a particular medication may be appropriate because it is covered on patients' insurance plans often still have to grapple

with the impact of the costs to the patient. There were 18 discussions of insurance coverage impacting patients' OOP medication costs in 13 medical visits. All of these conversations took place among patients who identified as White/Caucasian. The transcript excerpt below illustrates communication about the impact of insurance coverage on OOP costs incurred by patients:

Physician: Ah, that's actually the shot that you give.

Patient: ((Interrupting)) Oh, the shot.

Physician: Give, you know give yourself or get as an IV. And then the other thing though becomes is that um, often times the state um, coverage is for eighty percent of the cost of the drug.

Patient: Oh, right. So it could still be –

Spouse: ((Interrupting)) So is the twenty percent outrageous, it's still outrageous?

Physician: Well, it's about a thousand dollars a month.

Spouse: Oh.

Patient: Wow.

Physician: So the twenty percent of that actually -

Spouse: Two hundred dollars a month.

Physician: Yeah, um, becomes, so I think in terms of making the choice between the two you know I would clearly go for the TNF-alpha inhibitors if we didn't have the setting of [infection] and that to my mind is a concern.

Patient: Yes, ah -

Physician: So um, I would, I would be much more comfortable to go forward with the Arava but you also have another... this sort of cost barrier which I think is important to also recognize.

...

Spouse: Yeah, because our income is not great anymore. Um, but I mean is this something that's gonna be a lifetime thing or just until it comes under control?

Physician: Well, and that's one of the difficulties too in that this is a newer therapy. Um, it looks like the folks who respond do need to keep dosing and at this point three to five years is what people have been followed and it looks like folks do need to

continue at least through that time.

...

Patient: Right.

Spouse: What, I don't see that we have too many choices anyway.

Physician: Uh, huh.

Spouse: Um, we'll just go along with this Arava ... because you have a stop-loss. I mean eventually you max out on your per annual -

Patient: ((Interrupting)) Right.

Spouse: Payment anyway.

General Strategies to Reduce OOP Medication Costs

There were eleven conversations about general strategies to reduce OOP medication costs in nine medical visits. Conversations qualifying as general strategies to reduce OOP medication costs were those led by patients or physicians about medication use or prescribing, without reference to a specific strategy, which would lessen patients' OOP medication cost burden. Two visits contained more than one conversation about reducing OOP medication costs. Patients initiated these conversations in 4 of the visits. There were no clearly dominant characteristics among patients talking with physicians about reducing their OOP costs. Of the nine patients talking about reducing costs, seven were married, six had no or only partial prescription drug coverage, five were under age 65, four had annual incomes of less than \$40,000, and one was non-White.

Conversations about reducing OOP medication expenses took two forms. One focus was physicians discussing prescribing or medication use that would reduce patients' OOP costs. The following exchange is an example:

Physician: Um, does your insurance help you with your medications?

Patient: Yeah.

Physician: Um, because I could give you a prescription for Aleve ah, in a little more potent form and then that way your insurance would help you ah, cover it if you'd like and, and you could take, I could give it to you in a three hundred and seventy five milligram tablet and you could take one at breakfast and then you could kind of use a second one during the day if you needed it. You know if you didn't feel like you needed it you don't have to take it.

Patient: That would help a little more than the Aleve I'm taking now?

Physician: Yeah, it's a little more potent than the one you're on now.

Patient: Okay.

Physician: You want to do that?

Patient: Yeah.

Physician: Because that would, now that would save you some money.

Patient: Right. Hopefully ah, alright.

The other form conversations took was patient expression of trying to reduce OOP medication expenses by discussing the possibility of eliminating medicine or being prescribed alternate, less expensive medications. Initiating a conversation about cost, one patient stated:

This Arava is so expensive, is there anything else? It has gone up twice since I started taking it. It is now \$279 for 30 pills. See I only have with my Medicare, I only have a supplement which pays an amount on my medicines. Plus, I'm taking Fosamax and the other things and our income has kind of taken a hit with things that have been going on with the economy.

In response to patient questions about being prescribed alternate medications to reduce OOP costs, the physicians always engaged in the cost discussion with the patient by either bringing up alternate medications or dosing schedules to accommodate these patient concerns. In response to the patient above, the physician responded with an alternate dosing schedule and a warning about the possibility a change would exacerbate the patient's disease state:

Physician: I mean one of the things we can try if cost is an issue and I've done this with one patient is to cut the Arava back and take it every other day and see what happens.

Patient: Uh, huh.

Physician: I mean you run the risk of this thing getting out of control and when that happens it really hard to get back in control. So that really worries me a little bit. But if you want to try that I've gotten away with that in some people and -

Patient: Okay.

Physician: You know certainly.

Patient: Well, that would certainly help me ...

Medication Assistance Programs

As indicated in Figure 4, medication assistance programs are conceptualized as being part of strategies to reduce OOP medication expenses for patients since the intention of such programs is to reduce the financial burden medication costs place on patients. There was also a direct link between patient desire to reduce OOP costs and mention of medication assistance programs. Continuing with the patient and physician exchange provided above, after discussing the possibility of the patient altering the Arava dosing, the physician mentions trying to find a medication assistance program for the patient:

Physician: So I wish I could say there was something in my pocket that was going to do just as well for you but it took us so long to get you under control that I'd be really wary to rock the boat I will however say that there are companies and I'm not sure what Aventis, the company that makes Arava is doing right now in terms of helping people like you who are on a limited income, you may not even qualify...

Patient: I probably don't qualify but...

Physician: ...for any of these programs.

Patient: The only thing is I'm soon going to qualify if I've got to use everything I've got to...

Physician: I understand but I can look into that for you...

As this quote also demonstrates, a patient's eligibility for an assistance program was often brought up in tandem with notification about the assistance program. Eligibility for a program was a concern for patients and physicians. For one patient, frustration over

eligibility for assistance programs was part of a larger frustration about medication costs, as can be seen in the following exchange:

Physician: I'm going to find out if there is any kind of program we can get you hooked up with and I will let you know, okay.

Patient: These drugs are great but when they're so expensive... it's the middle income people that lose out.

Physician: Right, because if you were really poor...

Patient: ((Interrupting)) really poor you're going to get it all and if you've got oodles of money you can pay for it yourself. There is no need to keep on researching if they're going to have them [medications] priced to where people can't use them. That's what they say and they talk so much. I've seen on television they are advertising Arava and Remicade on television ads that cost a fortune

Discussions of prescription drug assistance programs to defray personal medication costs occurred in 14 of the 65 visits (21.5%) that contained cost discussions. Patients initiated six of these conversations about prescription drug assistance programs. All communication about medication assistance programs occurred with patients who had no or only partial prescription drug coverage and all but one reported annual income of less than \$40,000. Separate Pearson chi-square tests assessing the association between lacking prescription drug coverage ($\chi^2 (1, 192)=16.8, p < 0.001$) and low income ($\chi^2 (1, 175)=8.39, p < 0.01$) with discussing medication assistance programs confirmed the communication differences were statistically significant.

There were three types of prescription drug assistance programs discussed. The first and most common were prescription drug assistance programs run by pharmaceutical manufacturers to provide the medications they produce to patients experiencing financial difficulties. Eligible patients generally have no healthcare coverage for the requested product and do not have access to alternative sources of coverage or funding. Patients who are determined to be eligible will receive medications for little to no cost (Partnership for Prescription Assistance, 2008).

The second type of assistance program discussed was the publicly funded Medicare Replacement Drug Demonstration (Centers for Medicare & Medicaid Services, 2004). The demonstration program, established by the Centers for Medicare and Medicaid services, ran from September 2004 to December 31, 2005 and provided select medications with the same beneficiary cost-sharing as would apply under standard Medicare Part D coverage. Under the demonstration, Medicare Part B would pay for prescription or biological medications that were prescribed as replacements for medications already covered under Part B. For patients with RA this meant that Medicare beneficiaries with Part B and no other prescription drug coverage could receive Adalimumab (Humira®) or Etanercept (Enbrel®) as a replacement for the already covered Infliximab (Remicade®). Prior to the demonstration Medicare Part B would only pay for treatments administered in a physician's office, hence its coverage of the infused medication Infliximab (Remicade®). During the demonstration, choice of treatment would not be limited by route of administration and eligible patients could receive and have covered the self-injectable medications Adalimumab (Humira®) or Etanercept (Enbrel®).

The third type of assistance program discussed in the medical visits was one administered by the hospital system affiliated with some participating rheumatology clinics. Like the other programs, the purpose is to relieve the financial burden of patients in need through the provision of subsidized medications and services. Also similar to other programs patients had to apply for the program and eligibility was determined by lack of other prescription medication coverage and ability to pay for medications.

Regardless of the type of medication assistance program being discussed the conversations about the programs took on similar forms. The conversations tended to focus on filling out paperwork or completing required processes to qualify for the programs, selecting a medication over another because it was likely to be covered by a program, or following up on patient eligibility and access to medication through a program. The following

medical visit exchange highlights conversation about completing paperwork and selecting a medication based on the likelihood it would be covered by a program:

Physician: Yeah, but we were going to apply for the indigent program to see if -

Patient: ((Interrupting)) Oh, yeah.

Physician: They would donate it.

Patient: To see if I could get it, yeah.

...

Nurse: Ah, I talked to a drug rep yesterday and she says no, Medicare is not covering but she said that if we would go ahead and send it in and I told her who you were and I just talked to her yesterday. She said she would work real hard on getting it covered.

Patient: Oh, okay.

Nurse: So see I've sent it in.

Physician: So for Humira -

Nurse: Uh, huh.

Physician: So she says to give her the prescription?

Nurse: No, she said just, just send it in and she'll remember who she is and she'll work it getting it covered.

Physician: Send it in to her?

Nurse: Uh, huh.

Physician: Okay, but they haven't answered you from the last time?

Nurse: No, no they haven't.

Physician: And Enbrel?

Nurse: Yeah, we've sent it in, now Enbrel I haven't heard anything from Enbrel. I can follow up on that one too.

Physician: Yeah.

Nurse: But it sounded, talking to her yesterday ... Humira sounded like it would be, it would be the one that would approve it. She sounded like that it was a pretty sure thing so.

Patient: Uh, huh.

Nurse: I thought I'd just continue going through her since she gave me a pretty good promise on it yesterday.

...

Physician: Well we'll see if we can get you the Humira.

Patient: Yeah.

Nurse: I'll work real hard on it. She's a new drug rep. She said give her a week and then send the paperwork in.

Physicians responded affirmatively to all patient requests to complete paperwork for assistance programs and followed up with other clinic staff on issues of eligibility. Out of the 14 visits where medication assistance programs were discussed, patients and physicians were talking about trying to get the patient on a program in four, talking about patients receiving medications from a program in three, and talking about a patient being denied program eligibility in one.

Medication assistance programs were just one of the specific avenues discussed for reducing OOP costs. The other two subcategories of strategies for reducing OOP costs were medications purchased outside the United States to reduce OOP medication costs and medication samples provided to patients to reduce medication costs. Like medication assistance programs, they are viewed as specific components of communication about reducing OOP medication costs because they were conversations that occurred within the context of reducing costs but involved very specific strategies to decrease costs. Each of these subcategories is discussed in detail below.

Medications Purchased Outside the United States to Reduce Medication Costs

There were two conversations in two medical visits about patients actively purchasing medications outside the United States to reduce their medication expenses. The two patients were different on almost all demographic characteristics, sharing only two

commonalities: they were both female and had a high school education or less. Both of the conversations about importing medication involved patients bringing to the medical visit or talking about bringing to the visit the medication they had purchased abroad. As the exchange shows the patient brings the medication to the medical visit for the physician to examine:

Patient: Look at the medicine and make sure that um...

Physician: Look at the new shape!

Patient: It's exactly right?

Physician: How much did you pay for it?

Patient: \$91

Physician: Well that's one-third of the price...

Patient: I did want you to look at it.

Physician: I'm glad to know this but I'm sure it's the exact same thing. You have to know Spanish to know how to take it, but you know how to take it, right? And you didn't need a prescription to get this?

Patient: No

Physician: Unbelievable. And you think it's working just as well?

Patient: Yes.

Physician: You haven't noticed any difference?

Patient: I was particularly interested in that to make sure it wasn't cut in any way.

Physician: Right. That it wasn't somehow less potent. In terms of your arthritis do you think you're doing as well as you were on the other one?

Patient: Yes

Medication Samples

Samples are medications provided to physicians' offices by pharmaceutical manufacturers. A medication sample has been defined within the pharmaceutical industry as, "... a package containing a limited quantity of a pharmaceutical product sufficient to

evaluate clinical response, distributed to authorized health care practitioners free of charge, for patient treatment (Groves, Sketris, & Tett, 2003).” The provision of medication samples allows patients to try out a medication before paying for a prescription or acts as a supplement to whatever supply of medication patients already possess. Either way, through the provision of free medication, samples offset patient costs incurred when prescriptions are filled. The intention of providing samples for patients to try a medication is clearly different than providing patients with samples because they cannot access the medicine through other channels or because it would provide them a stock of medication that would offset their prescription medication costs. In this study, communication about samples had to be clearly related to cost communication and the samples had to be provided to relieve a financial burden or permit access to a medication that was financially out of reach for patients.

Medication samples were discussed in 16 instances in 11 medical visits. In eight of the visits the physician was offering or providing the patient with samples, in two visits the patient asks whether the physician has any samples of a particular medication, and in one the patient was informing the physician that she had received some samples of a medication from another physician. The following visit excerpt is a typical example of a physician offering a patient samples:

Physician: Let’s see, we’ve got Fosamax, do you ah, I’ve got some in the cupboard you need some?

Patient: What?

Physician: Fosamax.

Patient: Yeah, sure.

Physician: Yeah, I’ve got some in the cupboard. And, and we have Enbrel.

Patient: I told [nurse name] that I always feel bad doing that...

Physician: No, no, no, you kidding oh, yes, oh, please.

Patient: Because other people probably need it more than I do.

Physician: Oh. [Whispering and can't hear what is being said].

Patient: The way of the world...oh, yeah, yeah, oh, yeah.

When patients asked for samples, in both cases the physicians agreed to follow-up. As the following example shows:

Patient: However, I have ran out of Mobic but I knew I was coming in today so -

Physician: Yeah.

Patient: Do you have any?

Physician: Let me go look and see if I've got some samples. I'll give you some to hold you over until they can -

Patient: ((Interrupting)) Okay.

Physician: Re-supply you. Okay?

Patient: Alright, uh, huh.

There was diversity in patients' characteristics among those that had medication sample discussions with physicians, although the majority of patients discussing medication samples had no or only partial prescription drug coverage and annual incomes of less than \$40,000. There was, however, a clear physician effect among those discussing medication samples. One physician generated the majority of discussion about providing patients with medication samples. While it is unclear whether the effect was due to the physician or the clinic in which the physician practiced, this particular physician offered more samples as part of medication cost communication when compared to the other physicians in the study.

Summary

The results of the qualitative examination of medication cost communication reveal that medication cost communication is not monolithic. Communication about medication costs takes several different forms with the different types of discussions more likely to

happen among different patient populations. Medication cost communication is comprised of the categories insurance coverage and strategies to reduce patient OOP medication expenses. Associated with the category insurance coverage is the subcategory insurance coverage affecting patient OOP costs. Associated with the category reducing patient OOP costs are the subcategories medication assistance programs, importing medication, and medication samples. The constructs that emerged from the data and their associations with one another provide an initial foundation for theory development about medication cost communication. The summary table (Table 10) below lists each code, the number of mentions, the number of medical visits where the code was discussed, and an exemplary quote highlighting the concept.

Table 10. Highlights of the codes and concepts of medication cost communication.

| Total Patient/Physician Statements | | 16,748 | |
|--|------------|------------------|---|
| Total Medical Visits | | 65 | |
| Count of text-units by code | | | |
| Code | # Mentions | # Medical Visits | Exemplary quote |
| Insurance Coverage | 71 | 28 | Physician: Once you know who your new insurance provider is going to be I think it would be a good idea to just let me know and then we can find out what their policy is about some of these medicines and that may make a huge difference for you and hopefully they'll, they'll go for this... |
| Insurance OOP Costs | 18 | 13 | Physician: So you're not paying out of pocket? Patient: No, uh, uh, I've been paying a portion of it but still. Physician: And can you afford that? Patient: Yeah, right now I'm fine. Yeah. |
| General Strategies to Reduce OOP Costs | 11 | 9 | Patient: I mean the pills are okay it's just I'm trying figure out how to decrease cost ((Laughing)). Physician: And, and Fosamax is an expensive one. |
| Medication Assistance Programs | 26 | 14 | Physician: There's a program that we may be able to get it for you because you don't have ah, prescription coverage ... So they may, may qualify you for a program that'll be able to get it for you which would be great. |
| Importing Medication | 2 | 2 | Patient: I'm going to bring it in to you because I get my [medication] from Canada ...because it's a whole lot cheaper. |
| Medication Samples | 16 | 11 | Physician: We can ... keep you stocked with samples because you're here and around. |

Patient Disclosure of Self-Initiated Medication Regimen Changes

This section describes the results of the analysis of the content of communication about patient initiated changes to the medication regimen in the 40 medical visits where such changes were discussed. Special emphasis is placed on the intersection of communication about medication costs and communication about patient medication management. As mentioned in the previous chapter, in this study we were particularly interested in patient actions to manage their RA medications. To qualify as communication about a patient initiated change to the regimen, it had to require a behavior change on the part of the patient (e.g. taking more or less medication than prescribed) and the change had to be patient initiated and directed. The focus on patients' purposeful, independent actions to manage their medications was chosen to be able to examine disclosure of patient regimen changes in the setting of medication cost communication. Looking both at disclosure of changes in medical visits overall and within visits where medication costs were discussed provided insight into patient medication behaviors both in the presence and absence of likely cost pressures.

Examining the 40 medical visit transcripts where patient initiated regimen changes were disclosed, the regimen changes fell roughly into three categories. The first category was patient communication about taking more medication than prescribed or adding an additional medication to their regimen. Eighteen patients (45%) took more medication than had been prescribed or added an additional medication to their RA regimen. Almost unanimously patients who took more medication than prescribed or added a medication to the regimen were doing it to relieve pain. As the following exchange illustrates:

Patient: You was giving me Lorcet 10 but you dropped me down to Vicodin seven and a half's last time.

Physician: Okay.

Patient: So and if it's, if it's any way possible I wish you could give me a few more

because them ninety don't last me three months. That ain't but one a day.

Physician: Okay.

Patient: Some days doc, I have to take a couple -- two or three.

Physician: Okay.

Patient: I mean I've tried to make them last but I mean ...

The second category was discussion of patient substitution of one medication for another. Five patients (12.5%) substituted one medication for another. In three of these cases patients discontinued a prescription NSAID or analgesic for an OTC NSAID or analgesic and in two of these cases patients substituted prescription bisphosphonates with OTC calcium preparations. The following is an exchange where a patient disclosed discontinuing a prescription analgesic for an OTC NSAID:

Patient: So I didn't, I have been taking some -

Physician: ((Interrupting)) Yeah.

Patient: Darvocet. It helped but I wanted to get off of it so I took the [unclear medication name]. That helped but still it wasn't quite like I wanted so I went to Aleve -

Physician: Uh, huh.

The third regimen change category discussed was patient disclosure of taking less medication than prescribed, discontinuing a medication, or never starting a prescribed medication. Seventeen (42.5%) medical visits contained disclosure of patients taking less medication than prescribed, discontinuing, or never starting a medication. There were no clear dominant medications or reasons for taking less medication than prescribed provided by patients. Some patients stopped medications because of actual or perceived side-effects, some the reasons are not stated or are not clear, and in some cases because of cost or life constraints. In the following exchange the patient discloses having never started the medication that was prescribed at the last visit:

Patient: I haven't done what you told me.

Physician: ((Laughing)) So you're gonna confess, huh?

Patient: Yes.

Physician: Oh, let's see now last time ... we were gonna go back on Methotrexate but you didn't do that?

Patient: And I didn't do that.

Physician: Okay.

Patient: It's all because of work. It's like I told [the nurse], if I, I'm the only one there.

Physician: Yeah.

Patient: If I could do it by eight or eight fifteen in the morning I can do that but I can't leave work because I have nobody to cover for me.

Physician: Okay, you mean to come here and get your shots?

Patient: Yes, yeah.

Physician: Okay.

Patient: But you know if I could do that I've got to have some help helping me.

Physician: Yeah.

Patient: Because I don't want to give my job up.

Physician: Yeah, I understand that.

Patient: So that's the reason for that.

As a group, these regimen changes represent a threat to patients' adherence with their medication regimen. Adherence has generally been defined as, "the extent to which patients take medications as prescribed by their health care providers. (Osterberg & Blaschke, 2005)." Through altering their regimens patients are deviating from taking medications as prescribed and exhibiting poor medication adherence to varying degrees.

Of the 40 patients disclosing self-initiated changes to their medication regimens, 23 (57.5%) also discussed medication cost-related issues during their medical visits. Fifteen

(65%) of the 23 patients discussing medication cost issues and self-initiated changes to their medication regimens had no or only partial prescription drug coverage and twelve had annual incomes of \$40,000 or less. There was a strong physician effect in disclosures of patient-initiated medication regimen changes both overall and among patients also talking about medication costs. Overall disclosure of patient-initiated regimen changes occurred in 17 of 40 medical visits with patients seeing the same physician and in 10 of 23 visits where medication costs were also discussed.

For patients and physicians in the 23 medical visits communicating about medication cost issues and patient-initiated regimen changes, 14 patients disclosed taking less medication than prescribed, 7 took more medication than prescribed, and 2 substituted prescription for OTC medications. These findings contrast with the 17 medical visits where patient-initiated regimen changes were discussed but medication cost issues were not. In those cases, 11 patients disclosed taking more medication than prescribed, while only 3 took less medication than prescribed, and 3 substituted prescription for OTC medications. Not only were patients who discussed medication costs more likely to disclose taking less medication than prescribed by physicians, they also explicitly linked their medication restriction with cost pressures. The following exchange is perhaps the best example of this communication:

Patient: Um, well, you know I had been on the hospital plan -

Physician: Uh, huh.

Patient: That paid for my medications well they refused to pay for it anymore.

Physician: Oh, really. So you quit?

...

Patient: So there was no, in my eyes there was no point in coming because I couldn't get any medicine in -

...

Patient: And see since they cut my medicine I haven't had medicine since June. I -

Physician: Oh, you couldn't get any...?

Patient: I have been off of Flexeril. I've come off the estrogen, you name it I mean I have not had ah, the only thing I'm taking, thank God -

Physician: Uh, huh.

Patient: You had written me a prescription for the Prednisone.

Physician: Uh, huh.

Patient: That is so inexpensive -

Physician: Yeah, ah -

Patient: I could get that.

Physician: That's cheap, yeah, oh, yeah.

Patient: So I kept getting the Prednisone. I took my last one this morning. Ah, I take my calcium and my vitamin D -

Physician: Uh, huh.

Patient: And that's it.

Looking closer at the patient-initiated regimen changes among patients who discussed medication cost issues, eight actively decreased the dose of a medication, five stopped a medication altogether, and the one patient mentioned above never started the prescribed medication. In many, but not all, of these cases the decreased or discontinued medications were more expensive brand name medications. For the 7 patients who discussed taking more medication than prescribed and also discussed medication cost issues in their visits, even though they were taking more medication, they were generally increasing use of medications that were fairly inexpensive. Three of these patients were supplementing their pain medications with OTC analgesics; one was taking additional generic prescription analgesic; and three had increased the dose of their prednisone. Further, the two patients disclosing medication substitutions and discussing medication

costs were disclosing changes from brand-name prescription medications to OTC medications. In all cases where patients disclosed to physicians that they made changes to their medication regimens and they had also communicated with their physicians about medication cost issues, patients were likely to have their overall medication costs stay the same or decrease.

Table 11 provides a summary of the medical visit communication about patient-initiated changes to their medication regimens. The table highlights the categories of patient-initiated medication regimen change communication, the number of medical visits where it was discussed, the number of medical visits where medication cost was also discussed, and an exemplary quote from the category.

Table 11. Highlights of the categories of communication about patient-initiated changes to the medication regimen.

| | | | |
|---|--|--|--------|
| Total Patient/Physician Statements | | | 10,865 |
| Total Medical Visits | | | 40 |
| Medical Visits where Medication Costs and Patient-Initiated Regimen Changes Discussed | | | 23 |

| Count of visits by category | | | |
|---|------------------|--|--|
| Category | # Medical Visits | # Visits Where Medication Costs also Discussed | Exemplary quote |
| Taking more medication than prescribed | 18 | 7 | Physician: You are taking for pain Percocet? And you stopped the Tylenol? Patient: No, I'm taking both of them. It seemed like I wasn't getting enough relief at night. |
| Substitution of one medication for another | 5 | 2 | Physician: Could you take ... Actonel once a week? Patient: I didn't, I didn't take it. I'm taking ah, calcium. |
| Taking less medication than prescribed | 17 | 14 | Physician: And so are you getting your Arava at all? Patient: I'm getting it. Physician: You're paying for it out-of-pocket? And how many days a week are you, are you taking it? Patient: I take it three days a week. |

It is important to note that patients' communication about their medication management was measured and, therefore, only represents the vocal fraction of patients who actively make decisions about their medications and alter their regimens. However, looking at patients who talk about medication costs, it appears they are more likely to disclose restricting their medication use than any other type of regimen change. This may be a form of mutual disclosure where patients who are comfortable talking about medication cost issues are also more comfortable revealing to physicians their medication adherence issues.

Summary – Medication Cost and Management Communication Content

These sections provided descriptive details on the content of communication about medication cost, patient medication management, and the intersection between the two. The medical visit transcripts revealed that communication about medication costs was multifaceted and variable based on patient and physician characteristics. The transcripts further revealed patients' active disclosure of their alterations to their medication regimens. Patients appeared to actively manage their medication regimens and the types of regimen alterations disclosed varied by whether medication costs were also discussed. Patients discussing medication cost issues with physicians more often restricted their medication use than patients not discussing medication cost issues. Assessment of the content of communication about medication cost and management provides important context for understanding the two constructs and their relationship to each other. Further, it serves as the building blocks for examination of the patient, physician, and medication characteristics associated with medication cost and patient medication management communication.

Results of Aim 2 – Examination of relationships among patient characteristics, physician characteristics, and patient-physician communication about medication cost and management.

This section describes the results of the examination of the patient, physician, and medication characteristics that are associated with communication about medication costs, patient-initiated medication regimen changes, and whether the medication regimen was changed during the visit. Results in this section are based upon the sample of 192 patients for which complete data were available on the outcome variables. The results build upon each other and are presented in the following sections. First, the results of the bivariate associations between patient, physician, and medication characteristics and the communication variables are presented. Second, the correlations among the independent analysis variables are presented. Third, the results of the logistic regression models predicting medical visit communication about medication costs, patient-initiated regimen changes, and overall medication regimen changes are presented.

Bivariate Results

Communication about medication costs by patient, physician, medication, and other communication characteristics

Table 12 shows the differences in patient, physician, medication, and other communication characteristics when medication costs are and are not discussed. Chi-square statistics were calculated for the cross-tabulation of communication about medication costs by categorical variables. T-tests were conducted to compare the mean values for continuous variables between visits with the presence and visits with the absence of communication about medication costs. For total monthly RA medication costs, the non-

parametric Wilcoxon rank-sum test was used to assess the relationship between this variable and the dependent communication variables of interest.

Looking at communication variables, more patients who had their medication regimens changed during their medical visits communicated about medication costs (40%) than patients who did not have their regimen changed but talked about medication costs (27%). While chi-square test revealed that there were not statistically significant differences in the groups using an alpha of 0.05, the results highlighted the difference with the p-value approaching 0.05. Supporting the findings from the qualitative analysis, patients who discussed medication costs during the visit were significantly more likely to also discuss self-initiated changes to their medication regimens ($p < 0.001$). Nearly sixty percent of patients who disclosed self-initiated medication regimen changes also discussed medication costs.

Examining patient characteristics, there were few differences between those who did and did not discuss medication costs. The groups were similar with respect to gender, age, education, income, marital status, ethnicity, RA severity, pain, and the number of prior visits with the study physician. The two notable differences were in patient race and prescription drug coverage. Among White/Caucasian patients 38% discussed medication costs in their visits while among non-White patients only 22% discussed medication costs ($p = 0.03$). Also, 50% of patients lacking prescription drug coverage discussed medication costs in their medical visits while only 30% of patients who had partial or generous prescription drug coverage discussed medication costs ($p = 0.02$).

There were no significant differences in physician or medication characteristics between the presence or absence of visit communication about medication costs. Communication about medication costs occurred in relatively equal proportions with physicians of both genders and those who were White/Caucasian versus those identified as non-White/Caucasian. Approximately 31% of patients seeing female physicians discussed medication costs and 35% of patients seeing male physicians discussed medication costs.

While more patients seeing White physicians discussed medication costs (38%) than patients seeing non-White physicians (27%), the difference was not statistically significant. For both patients talking and not talking about medication costs in the visit, the mean physician age was 46.3 years.

While there were no statistically significant differences in the number of RA medications patients were prescribed or the total RA medication costs between those who did and did not discuss medication costs, it is notable that the median total monthly RA medication costs were slightly higher for patients who discussed medication costs. In both groups patients were prescribed an average of 4 medications but the median total RA medication cost was \$294.66 for patients talking about medication costs compared to \$241.32 for patients not talking about costs. Despite the expense of TNF- α inhibitors, patients prescribed those medications were no more likely to discuss medication costs than patients not prescribed those medications ($\chi^2 (1, 192) = 0.01, p = 0.91$).

Bivariate associations were also calculated for patient/physician gender and race concordance and medication cost communication. Patients and physicians were in gender concordant relationships when both were female or male and were in race concordant relationships when both identified as being members of the same racial group. Of the 192 patients in the analysis sample, 103 (54%) were in gender concordant relationships with their physician and 121 (63%) were in race concordant relationships with their physician. Bivariate results indicated that neither gender nor race concordance had a statistically significant relationship with medication cost communication (results not shown). This finding does not support hypothesis three of aim two which stipulated that conversations about medication costs were more likely to occur when patients and physicians were in race concordant relationships. It is interesting that a significant bivariate relationship between patients identifying as White/Caucasian and discussing medication costs exists but there is no relationship between racial concordance in the medical visit and communicating about

medication costs. This finding suggests that patient characteristics may matter more in communication about medication costs than characteristics of patients and physicians together.

Table 12. Medical visit communication about medication costs by other characteristics of communication, patient, physician, and medication characteristics (N=192).

| Variable ^b | Medication Cost Communication ^a | |
|---|--|-----------------------------|
| | Yes (n=64) Frequency (%) | No (n=128) Frequency (%) |
| Characteristics of Communication | | |
| Discussion of modifying medication regimen | | |
| Yes | 39 (39.8) | 59 (60.2) |
| No | 25 (26.6) | 69 (73.4) |
| Discussion of patient initiated changes to the medication regimen | | |
| Yes | 23 (57.5) | 17 (42.5) |
| No | 41 (27.0) | 111 (73.0) *** |
| Patient Characteristics | | |
| Gender | | |
| Female | 45 (31.7) | 97 (68.3) |
| Male | 19 (38.0) | 31 (62.0) |
| Age, mean (std dev) | 61.7 (9.4) | 62.9 (9.0) |
| Education | | |
| High school or less | 31 (32.6) | 64 (67.4) |
| More than high school | 27 (30.7) | 61 (69.3) |
| Income | | |
| Less than \$40,000 | 35 (33.0) | 71 (67.0) |
| \$40,000 or more | 21 (30.4) | 48 (69.6) |
| Marital status | | |
| Married | 33 (30.6) | 75 (69.4) |
| Not married | 25 (33.3) | 50 (66.7) |
| Race | | |
| White | 52 (38.0) | 85 (62.0) |
| Non-White | 12 (21.8) | 43 (78.2) * |
| Ethnicity | | |
| Hispanic | 1 (50.0) | 1 (50.0) |
| Non-Hispanic | 61 (66.7) | 122 (33.3) |
| ACR Classification of Global Functional Status | | |
| (I) No restriction of ability to perform normal activities | 12 (24.5) | 37 (75.5) |
| (II) Moderate restriction | 32 (36.8) | 55 (63.2) |
| (III) Marked restriction | 9 (34.6) | 17 (65.4) |
| (IV) Incapacitation or confinement to a bed or wheelchair | 2 (50.0) | 2 (50.0) |

| Variable ^b | Medication Cost Communication ^a | |
|---|--|-----------------------------|
| | Yes (n=64) Frequency (%) | No (n=128) Frequency (%) |
| Self-rated pain, mean (std dev) | 4.6 (2.8) | 4.2 (2.9) |
| Prior visits with physician | | |
| Fewer than five | 12 (30.8) | 27 (69.2) |
| Five or more | 52 (34.0) | 101 (66.0) |
| Prescription drug coverage | | |
| No coverage | 18 (50.0) | 18 (50.0) |
| Partial or generous coverage | 46 (29.5) | 110 (70.5) * |
| Physician Characteristics | | |
| Gender | | |
| Female | 29 (31.2) | 64 (68.8) |
| Male | 35 (35.3) | 64 (64.7) |
| Race | | |
| White | 41 (38.0) | 67 (62.0) |
| Non-White | 23 (27.4) | 61 (72.6) |
| Age, mean (std dev) | 46.3 (8.8) | 46.3 (7.9) |
| Medication Characteristics | | |
| Cost of medications, median (range) | 294.66(5.52-4860.01) | 241.32(0-5087.57) |
| Number of RA medications prescribed, mean (std dev) | 4.3 (1.7) | 4.2 (1.6) |

^a Significance level of the chi-square statistic for categorical variables, two-tailed t-test for continuous variables, and Wilcoxon rank-sum for non-normally distributed continuous variables: * p < 0.05, ** p < 0.01, *** p < 0.001

^b Totals for individual variables may be less than 192 due to missing data.

In addition to examining communication about medication costs, bivariate associations of specific characteristics of medication cost communication were also calculated. Associations among patient, physician, and medication characteristics and whether the patient or physician initiated the medication cost conversation were calculated. Chi-square statistics were calculated for discussion initiator and categorical variables and t-tests were run for continuous variables. Results revealed only two significant differences in whether patients or physicians initiated the medication cost conversation. Patients were more likely to initiate medication cost conversations if they rated their pain lower on average (mean = 3.8, sd = 2.7), than if physicians initiated those conversations (mean = 5.3, sd = 2.6). The difference was statistically significant (t = 2.27, p = 0.03). The only other

difference in whether patients or physicians initiated the medication cost communication in the medical visit was physician age. Patients were more likely to initiate the medication cost conversation if the physician was younger on average. When patients initiated the cost discussion, the physicians they saw had an average age of 43.9 years (sd = 8.2). In contrast, when physicians initiated the cost discussion they had an average age of 48.5 years (sd = 8.8), a difference that was statistically significant ($t = 2.17$, $p = 0.03$). This finding is interesting and may have a couple of explanations. It could be that older physicians are more likely to initiate medication cost communication or that patients feel more comfortable bringing up the topic of medication costs with younger physicians. A logistic regression equation regressing pain and physician age on patient initiation of the medication cost discussion reinforced the results found in the bivariate analyses. Both variables were significant predictors of patient initiation of the medication cost communication and the relationships remained in the same direction. Patients were more likely to initiate cost conversations if they reported lower pain levels (OR = 0.80, 95% CI = 0.70 -0.92) and patients were more likely to initiate cost conversations with younger physicians (OR = 0.94, 95% CI = 0.93-0.95).

The other characteristic of medication cost communication examined was patient and physician question asking about medication costs. The count variables for number of questions about medication costs that patients and physicians asked were collapsed into dichotomous variables for any patient questions about cost and any physician questions about cost. Chi-square statistics and t-tests were used to assess the differences in patient, physician, and medication characteristics between patients and physicians that asked no questions in medication cost communication and those that asked at least one question. Looking at patient question asking about medication costs, results revealed no statistically significant differences in any of the variables examined and whether patients asked any questions. Thus, there was no evidence to support hypothesis four of aim two that older

patients would be more likely to ask questions than younger patients. These findings are not surprising given that patients asked questions in fewer than half the visits where medication costs were discussed, limiting the power to detect differences in characteristics.

Analysis of patient, physician, and medication characteristics with any physician questions asked about medication costs revealed only one significant association. Physicians were more likely to ask medication cost questions to patients with better functional status and less severe RA than they were of patients with more severe RA. In visits where medication costs were discussed and physicians asked patients cost-related questions, physicians asked questions of 38 patients (88.4%) who had no or moderate functional restriction and only asked questions with 5 patients (11.6%) who had marked or severe functional restrictions (χ^2 (3, 55)=8.75, Fisher's exact = 0.023).

Communication about patient-initiated medication regimen changes by patient, physician, medication, and other communication characteristics

Table 13 shows the differences between the presence and absence of communication about patient-initiated changes to the medication regimen and other communication, patient, physician, and medication characteristics. Supporting the qualitative analysis finding of a possible relationship between communication about medication costs and patient-initiated regimen changes, the bivariate analysis revealed a significant association between the variables. Approximately 36% of patients discussing medication costs in their visits also disclosed self-initiated changes to their medication regimens, more than the 13% discussing patient-initiated changes alone ($p < 0.001$). Perhaps not surprisingly, 26.5% of patients had their medication regimens changed during the visit when they disclosed to physicians self-initiated regimen changes, a significant difference from the 15% of patients who did not have their regimens changed and disclosed self-initiated medication regimen changes ($p < 0.05$).

Examination of the associations among patient characteristics and communication about patient-initiated regimen changes, revealed almost no significant relationships. The only distinguishing patient characteristic between patients who did and did not disclose self-initiated regimen changes was age over or under 55 years. Younger patients (under 55 years-old) were more likely to disclose changes to their regimen to physicians than older patients ($p = 0.02$). While this provides some support for the hypothesis that younger patients are more likely to discuss medication management, it is notable that significant differences in disclosure of patient-initiated regimen changes did not exist when comparing mean patient ages between those who did (mean age = 61.1) and did not (mean age = 62.8) discuss patient-initiated regimen changes.

There were significant differences in patient disclosure of medication regimen changes by physician characteristics. Patients were more likely to disclose medication

regimen changes to male physicians (28%) than female physicians (13%) in the medical visit ($p = 0.009$). Patients were also more likely to disclose self-initiated regimen changes to physicians who were, on average, older ($p = 0.01$). The finding that patients were more likely to disclose self-initiated changes to their medication regimens to physicians who were male and older runs directly counter to the hypothesis that communication about medication management would be more likely to occur when physicians were female and younger. However, as discussed in a previous section, qualitative analysis of the communication about patient-initiated regimen changes revealed that the patients of one particular physician were far more likely to disclose regimen changes. The significant differences in patient disclosure are likely due to this particular older, male physician. A comparison of communication about patient-initiated regimen changes with this older, male physician and another older, male physician in the sample who had seen a similar number of patients revealed statistically significant differences in communication ($\chi^2 (1, 86)=5.2, p=0.02$). It may be that the physician differences are due not to the age and gender of the physicians, but instead to something about the particular physician with whom more patients disclosed self-initiated regimen changes. With only eight physicians in the sample, results regarding significant differences among patients seeing physicians with particular characteristics must be interpreted with caution.

While there appeared to be significant communication differences by physician characteristics, the relationship did not extend to matching patient and physician characteristics. Bivariate assessment of patient/physician gender and race concordance with communication about patient-initiated regimen changes revealed no significant relationships (results not shown). Again, this finding counters hypothesis three of aim two which suggested that patients would be more likely to discuss their medication management when they were in race concordant relationships. It is interesting that when examining patient disclosure of medication regimen changes, physician gender had such a significant

impact but not concordance. Again, it may be the influence of the particular physician with whom the majority of patients disclosed their self-initiated regimen changes.

Patients communicating with physicians about self-initiated changes to their medication regimens were prescribed an average of four medications and had median total monthly RA medication costs of \$209.58 while patients not talking about their regimen changes were prescribed the same average number of medications and had median costs of \$253.29. In summary, the differences in medication costs between patients disclosing and not disclosing regimen changes were small and there were no differences in the average number of medications prescribed.

Table 13. Medical visit communication about patient-initiated medication regimen changes by other characteristics of communication, patient, physician, and medication characteristics (N=192).

| Variable ^b | Communication about Patient-Initiated Medication Regimen Changes ^a | |
|--|---|-----------------------------|
| | Yes (n=40) Frequency (%) | No (n=152) Frequency (%) |
| Characteristics of Communication | | |
| Discussion of medication costs | | |
| Yes | 23 (35.9) | 41 (64.1) |
| No | 17 (13.3) | 111 (86.7) *** |
| Discussion of modifying medication regimen | | |
| Yes | 26 (26.5) | 72 (73.5) |
| No | 14 (14.9) | 80 (85.1) * |
| Patient Characteristics | | |
| Gender | | |
| Female | 31 (21.8) | 111 (78.2) |
| Male | 9 (18.0) | 41 (82.0) |
| Age, mean (std dev) | 61.1(10.6) | 62.8(8.7) |
| Over 55 years of age | 27 (17.5) | 127 (82.5) |
| Under 55 years of age | 13 (34.2) | 25 (65.8) * |
| Education | | |
| High school or less | 17 (17.9) | 78 (82.1) |
| More than high school | 20 (22.7) | 68 (77.3) |
| Income | | |
| Less than \$40,000 | 21 (19.8) | 85 (80.2) |
| \$40,000 or more | 15 (21.7) | 54 (78.3) |
| Marital status | | |
| Married | 21 (19.4) | 87 (80.6) |
| Not married | 16 (21.3) | 59 (78.7) |
| Race | | |
| White | 32 (23.4) | 105 (76.6) |
| Non-White | 8 (14.5) | 47 (85.5) |
| Ethnicity | | |
| Hispanic | 1 (50.0) | 1 (50.0) |
| Non-Hispanic | 36 (19.7) | 147 (80.3) |
| ACR Classification of Global Functional Status | | |
| (I) No restriction of ability to perform normal activities | 10 (20.4) | 39 (79.6) |
| (II) Moderate restriction | 20 (23.0) | 67 (77.0) |
| (III) Marked restriction | 4 (15.4) | 22 (84.6) |
| (IV) Incapacitation or confinement to a bed or wheelchair | 1 (25.0) | 3 (75.0) |
| Self-rated pain, mean (std dev) | 4.8 (2.7) | 4.2 (2.9) |
| Prior visits with physician | | |
| Fewer than five | 7 (17.9) | 32 (82.1) |
| Five or more | 33 (21.6) | 120 (78.4) |

| Variable ^b | Communication about Patient-Initiated Medication Regimen Changes ^a | |
|---|---|-----------------------------|
| | Yes (n=40) Frequency (%) | No (n=152) Frequency (%) |
| Prescription drug coverage | | |
| No coverage | 8 (22.2) | 28 (77.8) |
| Partial or generous coverage | 32 (20.5) | 124 (79.5) |
| Physician Characteristics | | |
| Gender | | |
| Female | 12 (12.9) | 81 (87.1) |
| Male | 28 (28.3) | 71 (71.7) ** |
| Race | | |
| White | 27 (25.0) | 81 (75.0) |
| Non-White | 13 (15.5) | 71 (84.5) |
| Age, mean (std dev) | 49.1 (9.5) | 45.6 (7.7) * |
| Medication Characteristics | | |
| Cost of medications, median (range) | 209.58 (0-4606.63) | 253.29(3.1-5087.57) |
| Number of RA medications prescribed, mean (std dev) | 4.1 (1.8) | 4.3 (1.6) |

^a Significance level of the chi-square statistic for categorical variables, two-tailed t-test for continuous variables, and Wilcoxon rank-sum for non-normally distributed continuous variables: * p < 0.05, ** p < 0.01, *** p < 0.001

^b Totals for individual variables may be less than 192 due to missing data.

Communication about medication regimen changes by patient, physician, medication, and other communication characteristics

Table 14 shows the differences in patient, physician, medication, and other communication characteristics by whether or not the medication regimen was changed during the visit. The purpose of assessing the relationships among these variables and whether or not the medication regimen was changed during the visit was to compare and contrast the results obtained when examining patient-initiated regimen change communication. As mentioned in the methods chapter, medication regimen changes were those discussed by patients and physicians that resulted in a change to the medication regimen that represented a distinct departure from the previously prescribed regimen. These sensitivity analyses were conducted to help confirm that the two variables were measuring different latent constructs of medication management.

The association between communication about overall regimen changes during the visit and categorical variables were tested with a chi-square test. T-tests were conducted for the association between regimen changes and the continuous variables. Given the positive skew of the total monthly RA medication cost variable, a Wilcoxon rank-sum test was used to assess the relationship between medication costs and whether the regimen was changed during the visit.

As mentioned in the two previous sections, there were differences in whether patients who talked about medication costs or self-initiated regimen changes had their medications changed during the visit. Patients discussing medication costs or self-initiated changes to their regimens tended to have their regimens modified during the visit.

Several patient characteristics were associated with visit medication regimen changes. Patients under 55 years old were more likely to have their medication regimens changed during the visit than older patients ($p = 0.02$). Fifty-six percent ($n = 77$) of patients who identified as White/Caucasian had their regimens changed during the visit, while 38%

(N = 21) of patients identifying as other than White/Caucasian had their regimens changed ($p = 0.02$). Not unexpectedly, patients who had their medication regimens changed had higher mean pain levels (4.7) than patients who did not have their regimens changed (3.9) in the sample ($p = 0.04$). Patients who had seen the study physician five or fewer prior times were more likely to have their regimen changed in the visit than patients who had seen the study physician more than five times ($p < 0.001$). Patients were also more likely to have their medication regimens changed at the visit if they lacked prescription drug coverage compared with patients who had partial or generous prescription drug coverage ($p = 0.04$).

There were also differences in patient medication regimen changes by physician characteristics. Patients seeing male physicians were more likely to have their medication regimen changed. Sixty percent of patients seeing male physicians had their regimens changed while 42% of patients seeing female physicians had their regimens changed ($p = 0.01$). Physician age was also a significant factor. Patients seeing younger physicians (mean = 45 years-old) were more likely to have their regimen changed than patients seeing older physicians (mean = 48 years-old) in the sample ($p = 0.01$).

There were no significant differences in total monthly medication costs or number of RA medications by whether or not the regimen was changed. Both patients who had and patients who didn't have their medication regimens changed at the visit were taking an average of four medications. The median total monthly RA medication cost for patients who had their medication regimens changed at the visit was \$217.38 while patients who did not have their regimens changed had median totally monthly RA medication costs of \$296.41, a difference that was not statistically significant. It is possible that patients not having their regimens changed at the visit may have already been switched over to medications that were potentially more effective, but expensive.

Table 14. Medication regimen changed during medical visit by other characteristics of communication, patient, physician, and medication characteristics (N=192).

| Variable ^b | Medication Regimen Changed During Visit ^a | |
|---|--|----------------------------|
| | Yes (n=98) Frequency (%) | No (n=94) Frequency (%) |
| Characteristics of Communication | | |
| Discussion of medication costs | | |
| Yes | 39 (60.9) | 25 (39.1) |
| No | 59 (46.1) | 69 (53.9) |
| Discussion of patient initiated changes to the medication regimen | | |
| Yes | 26 (65.0) | 14 (35.0) |
| No | 72 (47.4) | 80 (52.6)* |
| Patient Characteristics | | |
| Gender | | |
| Female | 71 (50.0) | 71 (50.0) |
| Male | 27 (54.0) | 23 (46.0) |
| Age, mean (std dev) | 62.4(10.1) | 62.6(8.1) |
| Over 55 years of age | 72 (46.8) | 82 (53.2) |
| Under 55 years of age | 26 (68.4) | 12 (31.6) * |
| Education | | |
| High school or less | 46 (48.4) | 49 (51.6) |
| More than high school | 47 (53.4) | 41 (46.6) |
| Income | | |
| Less than \$40,000 | 54 (50.9) | 52 (49.1) |
| \$40,000 or more | 38 (55.1) | 31 (44.9) |
| Marital status | | |
| Married | 55 (50.9) | 53 (49.1) |
| Not married | 38 (50.7) | 37 (49.3) |
| Race | | |
| White | 77 (56.2) | 60 (43.8) |
| Non-White | 21 (38.2) | 34 (61.8) * |
| Ethnicity | | |
| Hispanic | 0 (0.0) | 2(100.0) |
| Non-Hispanic | 93 (50.8) | 90 (49.2) |
| ACR Classification of Global Functional Status | | |
| (I) No restriction of ability to perform normal activities | 22 (44.9) | 27 (55.1) |
| (II) Moderate restriction | 46 (52.9) | 41 (47.1) |
| (III) Marked restriction | 13 (50.0) | 13 (50.0) |
| (IV) Incapacitation or confinement to a bed or wheelchair | 4(100.0) | 0 (0.0) |
| Self-rated pain, mean (std dev) | 4.7(2.8) | 3.9(2.8) * |
| Prior visits with physician | | |
| Fewer than five | 30 (76.9) | 9 (23.1) |
| Five or more | 68 (44.4) | 85 (55.6) *** |

| Variable ^b | Medication Regimen Changed During Visit ^a | |
|---|--|----------------------------|
| | Yes (n=98) Frequency (%) | No (n=94) Frequency (%) |
| Prescription drug coverage | | |
| No coverage | 24 (66.7) | 12 (33.3) |
| Partial or generous coverage | 74 (47.4) | 82 (52.6) * |
| Physician Characteristics | | |
| Gender | | |
| Female | 39 (41.9) | 54 (58.1) |
| Male | 59 (59.6) | 40 (40.4) * |
| Race | | |
| White | 49 (45.4) | 59 (54.6) |
| Non-White | 49 (58.3) | 35 (41.7) |
| Age, mean (std dev) | 44.8 (8.1) | 47.8 (8.1) * |
| Medication Characteristics | | |
| Cost of medications, median (range) | 217.38(0-4860.01) | 296.41(3.1-5087.57) |
| Number of RA medications prescribed, mean (std dev) | 4.2 (1.7) | 4.2 (1.5) |

^a Significance level of the chi-square statistic for categorical variables, two-tailed t-test for continuous variables, and Wilcoxon rank-sum for non-normally distributed continuous variables: * p < 0.05, ** p < 0.01, *** p < 0.001

^b Totals for individual variables may be less than 192 due to missing data.

A comparison of the bivariate results of patient, physician, and medication characteristics with patient-initiated regimen change communication and having the medication regimen changed in the medical visit shows several differences. There were several variables that had statistically significant bivariate relationships with having the medication regimen changed during the visit that did not demonstrate statistically significant relationships with patient-initiated regimen change communication. Patient race, prior visits with study physician, and prescription drug coverage were all variables that had a statistically significant relationship with medication regimen communication overall but not patient-initiated regimen change communication. Further, the statistically significant relationship between physician age and having the medication regimen changed during the visit was opposite of the significant relationship between physician age and patient-initiated regimen change communication. Patients seeing younger physicians were more likely to have their regimens changed while patients seeing older physicians were more likely to

communicate about patient-initiated medication regimen changes. The differences in the significant bivariate relationships and the different directions of the relationships with physician age underscore the likely difference in the two constructs. While assessment of the differences in bivariates cannot conclusively demonstrate that the two variables are measuring different latent constructs, this evidence suggests that purposeful patient-initiated changes to the medication regimen disclosed to physicians are separate from general communication about medication regimen changes.

Correlation matrix of patient and medication variables used in analyses

Table 15 presents the Pearson correlation coefficients and statistical significance of the other variables used in the analyses. Thus far the bivariate relationships between predictor variables and communication about medication costs, patient-initiated regimen changes, and changes to the medication regimen as well as differences by physician have already been discussed. Since those relationships have been described, this section focuses on the statistically significant interrelationships among the patient and medication variables used in the analyses. The purpose of assessing these interrelationships is not to draw meaningful conclusions from the results themselves but to look at the potential impact the interrelationships among the variables could have on the multivariable logistic regression models. Put another way, this information is provided as a quick look at the relationships to demonstrate there are no issues of multicollinearity and with this purpose in mind only correlations greater than 0.30 will be focused on in the subsequent text.

Low income patients were more likely to have a high school education or less ($r = 0.44, p < 0.001$) and were less likely to be married ($r = -0.47, p < 0.001$). Patients reporting higher levels of pain were more likely to have more severe RA ($r = 0.33, p < 0.001$). Total monthly RA medication costs were related to the number of RA medications prescribed ($r = 0.39, p < 0.001$) and were negatively related to lacking drug coverage ($r = -0.20, p < 0.01$). This finding makes common sense, the more RA medications a patient is prescribed the greater the total monthly RA medication costs will be. Patients who lack prescription drug coverage will have lower total medication costs because they are less likely to be prescribed expensive medications for which they will have to pay the total cost.

Table 15. Correlation matrix assessing relationships among independent variables predicting communication about medication costs, medication management, and patient-reported medication satisfaction. ^a

| | Female | Age | HS or less education | Low income | Married | White | Hispanic | RA severity | Pain | Prior visits | No drug coverage | Number RA drugs | Total drug costs |
|----------------------|-----------|---------|----------------------|------------|---------|----------|----------|-------------|--------|--------------|------------------|-----------------|------------------|
| Female | 1.000 | | | | | | | | | | | | |
| Age | 0.011 | 1.000 | | | | | | | | | | | |
| HS or less education | 0.009 | 0.109 | 1.000 | | | | | | | | | | |
| Low income | 0.103 | 0.214** | 0.443*** | 1.000 | | | | | | | | | |
| Married | -0.269*** | -0.059 | -0.157* | -0.470*** | 1.000 | | | | | | | | |
| White | -0.087 | 0.099 | -0.159* | -0.286*** | 0.201** | 1.000 | | | | | | | |
| Hispanic | 0.060 | 0.065 | 0.102 | 0.087 | -0.021 | -0.054 | 1.000 | | | | | | |
| RA severity | 0.112 | 0.071 | 0.094 | 0.179* | -0.139 | -0.027 | 0.089 | 1.000 | | | | | |
| Pain | 0.220** | -0.133 | 0.220** | 0.163* | -0.088 | -0.196** | -0.047 | 0.327*** | 1.000 | | | | |
| Prior visits | -0.084 | -0.103 | -0.060 | -0.059 | 0.038 | -0.024 | -0.051 | 0.025 | 0.010 | 1.000 | | | |
| No drug coverage | -0.171* | -0.143* | 0.122 | 0.252*** | -0.059 | -0.109 | -0.049 | 0.059 | 0.020 | 0.156* | 1.000 | | |
| Number RA drugs | 0.172* | 0.094 | 0.035 | -0.092 | 0.021 | 0.090 | 0.080 | 0.222** | 0.143* | -0.232** | -0.159* | 1.000 | |
| Total drug costs | 0.019 | 0.070 | -0.002 | -0.132 | 0.062 | 0.014 | 0.009 | 0.084 | 0.096 | -0.128 | -0.197** | 0.393*** | 1.000 |

^a Based on two-tailed tests: * p < 0.05, ** p < 0.01, *** p < 0.001

Logistic Regression Results

In the next step of the analysis, logistic regression was used to assess predictors of medical visit communication about medication costs, patient-initiated regimen changes, and overall medication regimen changes. As discussed in the methods chapter, the group sizes of the dependent communication variables limited the number of predictors that could be entered into the models and still produce reliable test statistics. For the main models only significant patient, physician, and medication bivariate predictors were entered into the regression equations. To test the robustness of the main models separate regressions were run including all significant bivariate predictors, as well as physician characteristics and patient and medication variables that were significantly different by physician. The purpose of these multivariable logistic regression models was to test the impact of other significant variables on the main predictors of interest and they should be considered sensitivity analyses for the main regression models. The results of these models should be interpreted with caution. They are tempered by the inclusion of increasing numbers of variables, reducing the stability of the estimates, and will not be interpreted directly but only assessed for their impact on the magnitude and variability of the beta-coefficients of the significant variables from the main models.

For each of the dependent communication variables of interest, the main multivariable logistic regression models are based on significant bivariate patient, physician, and medication predictors of communication and are always Regression 1. For each of the models, Regression 1 is always based on the complete case sample of 192. The additional regression models run as sensitivity analyses are Regressions 2-4. Regression 2 presents the predictors of the communication variables of interest based on all statistically significant bivariate predictors. All Regression 2 models are also based on a complete case sample of 192. Regression 3 presents the predictors of the communication variables of interest based

on all the significant bivariate predictors in combination with the variables that differed by physician. Regression 4 builds on Regression 3 by including physician variables when they were not already significant bivariate predictors of the communication variable of interest. Only for the medication cost communication outcome variable were there no significant bivariate associations with physicians characteristics so Regression 4 data including physician variables is only presented for medication cost communication. Regressions 3 and 4 are based on a complete case sample of 166. The study samples did not differ substantially by patient, physician, or medication characteristics. Also, as discussed in the section on missing data, the results of regression models run using the imputed dataset had few differences from those run using the complete cases. Each regression equation was stratified on physician to account for the enrollment of patients within physician. For each of the equations, there were five physician strata. Further, for each model robust standard errors were calculated to account for unknown forms of heteroskedasticity in the models.

Predictors of medication cost communication

Table 16 presents the logistic regression results obtained when testing the predictors of medication cost communication. Examining the results of Regression 1, including significant patient, physician, and medication bivariate predictors of medication cost communication, revealed that patients who identified as White/Caucasian and those with no prescription drug coverage had significantly greater probability of communicating about medication costs in the medical visit. Results indicated that for White patients the odds of communicating about medication costs are 2.5 times the odds of other patients ($p < 0.05$). This finding indicates that White patients were more likely to discuss medication costs and physicians were more likely to engage patients in medication cost discussions if they were White.

Perhaps as expected, results indicated that lacking prescription drug coverage was significantly related to communicating about medication costs ($p < 0.05$). Patients lacking prescription drug coverage had over two and a half times the odds of discussing medication costs in the medical visits as patients who had partial or generous prescription drug coverage (OR 2.8, 95% CI 1.2 – 6.5).

Regression 2, examining all the significant bivariate predictors of medication cost communication, revealed that all variables remained significant predictors of the probability of communicating about medication costs in the medical visit. Patients who identified as White/Caucasian and those with no prescription drug coverage still had significantly greater odds of communicating about medication costs than patients who did not identify as White or who had partial or generous prescription drug coverage. For patients who discussed self-initiated regimen changes in their medical visit, their odds of communicating about medication costs were 3.3 times the odds of patients who did not discuss self-initiated regimen changes ($p < 0.001$). The strength and statistical significance of this relationship is interesting and adds further evidence to support the idea that some form of mutual disclosure may be involved with talking about medication costs and disclosing patient-initiated changes to the medication regimen.

Looking at Regression 3, with the inclusion of variables that differed significantly by physician, and Regression 4, with the inclusion of physician characteristics, results revealed that all three variables that were significant predictors of medication cost communication in Regression 2 remained significant. In fact, in models 3 and 4 the strength of the significance of the relationship between patient-initiated regimen change discussions, White/Caucasian race, having no drug coverage, and communication about medication costs increases. This finding means that even when controlling for the effect of additional variables in the regression models these variables are still significant predictors of communicating about medication costs in the medical visit. Results indicate there is no

support for hypothesis two of aim two that discussions of medication cost would be more likely to occur when patients were female, younger, more educated, had higher income, and more severe RA. In fact, there is no support that any of these variables are significantly related to communication about medication costs.

While it is interesting that the results in Regression 4 indicate that communication about medication costs is significantly more likely to occur with White/Caucasian physicians and younger physicians, these results must be interpreted with caution because of the inclusion of nine predictor variables in the model. The results provide some support for hypothesis one of aim two, that discussions of medication cost would be more likely to occur among physicians who are younger. However, this finding must be interpreted with caution. It may be that some characteristics of physicians do matter in communication about medication costs and these variables are picking up the effect but in the interest of not making inferences beyond what the data will support, the finding is briefly noted here.

Predictors of patient-initiated regimen change communication

Table 17 shows the results when testing the predictors of communication about patient-initiated medication regimen changes. Regression 1 shows the results of the model that included the patient, physician, and medication variables that were significant bivariate predictors of patient-initiated regimen change communication. Results revealed that only the physician variables were significant predictors of communicating about patient-initiated medication regimen changes in the medical visit. The physician variables female (OR 0.43, 95% CI 0.24 – 0.79) and age (OR 1.04, 95% CI 1.02 – 1.10) were significant in Regression 1, indicating that male and older physicians were more likely to communicate about patient-initiated regimen changes than younger or female physicians.

Regression 2 shows the results of the regression model that included all of the significant bivariate predictors of patient-initiated medication regimen change

communication. In Regression 2, medication cost communication, physician gender, and physician age all significantly predicted disclosure of patient-initiated medication regimen changes in the medical visit. Although discussion of overall medication regimen changes and patient age were significant bivariate predictors of patient-initiated regimen change communication, they were not significant in the multivariable model.

Communicating about medication costs in the medical visit was associated with a 3.5 times greater odds of also communicating about patient-initiated medication regimen changes in the visit ($p < 0.001$). The finding indicates approximately the same increase in communication likelihood as found in the previous regression on communication about medication costs. The relationship indicates that communication about medication costs or patient-initiated regimen changes increases the chance of communicating about the other topic by an approximately similar magnitude. Communication about medication costs remained a significant predictor of communication about patient-initiated regimen changes after the addition of variables that differed significantly by physician in Regression 3 ($p < 0.001$).

The physician variables female (OR 0.5, 95% CI 0.27 – 0.87) and age (OR 1.1, 95% CI 1.02 – 1.10), which were significant in Regression 1, remained statistically significant predictors of patient-initiated regimen change communication in Regression 2. The inclusion of variables that differed significantly by physician in Regression 3 strengthened the significance of the findings on the physician variables and indicated that physician race was also a significant predictor of communication about patient-initiated regimen changes. White/Caucasian physicians were more likely to communicate about such regimen changes than physicians who did not identify as White/Caucasian ($p < 0.01$). These findings run counter to hypothesis one of aim two which hypothesized that medication management communication would be more likely to occur with physicians who are female and younger. The finding here that older, male, White physicians are more likely to communicate about

patient-initiated regimen changes is not surprising since the physician who most patients disclosed their self-initiated regimen changes to was an older, White male. As mentioned earlier, this physician was significantly different on this variable even when compared to another older, White male physician so it is entirely possible that this physician represents an outlier and he and his behavior matter more than any of his demographic characteristics. Examination of the medical visit transcripts revealed that this physician engaged in more social talk and had longer visits than most other physicians in the study.

Predictors of having medication regimen changed during the medical visit

Table 18 presents the multivariable logistic regression equations predicting medication regimen changes. As before, Regression 1 contains the patient, physician, and medication variables that were significant bivariate predictors of having the medication regimen changed, Regression 2 contains all variables that were significant bivariate predictors of having the medication regimen changed, and Regression 3 contains those variables plus ones that differed significantly by physician. Results indicate that patient age, pain, and having no drug coverage were the most consistent predictors of having the medication regimen changed at the visit. Patients under 55 years old had approximately two times the odds of having their regimen changed as patients 55 years old and older (OR 2.04, 95% CI 1.22 – 3.43). Patients reporting greater pain also had greater odds of having their medications changed than patients reporting less pain (OR 1.16, 95% CI 1.06 – 1.27). Patients lacking prescription drug coverage were 1.6 times more likely to have their regimen changed than patients with partial or generous prescription drug coverage ($p < 0.01$).

In Regression 1, physician gender was marginally significant ($p = 0.05$), indicating male physicians had greater odds of making regimen changes than female physicians. When additional variables were included in Regressions 2 and 3 this variable was no longer a significant predictor of regimen change communication. Similarly, in Regression 2 model

results indicated that patients who had seen the study physician fewer than five prior times were more likely to have their regimens changed than patients who had seen the study physician five or more times ($p = 0.05$). This finding was only marginally significant and when controlling for fewer variables in Regression 1 and additional variables in Regression 3, the number of prior physician visits was no longer a significant predictor of having the medication regimen changed. The other three predictors (patient age, pain, and lacking drug coverage) all remained significant predictors of having the medication regimen changed in Regression 3 when control variables that differed by physician were added to the model.

It is interesting that neither communicating about medication costs nor discussing patient-initiated regimen changes are significant predictors of having the medication regimen changed. This finding indicates that although changes are disclosed and discussions of cost issues are addressed, patients may not have subsequent changes made to their medication regimens. The finding that talking about medication costs does not predict medication regimen changes is especially interesting given that lacking prescription drug coverage is a significant predictor of having the regimen changed. The finding could indicate several possible scenarios: physicians may be aware of patient insurance status and make changes to the regimen without needing to talk about costs; conversations about cost may prohibit a regimen change if the discussion reveals patients cannot afford a medicine; or not having drug coverage means that patients and physicians must cycle through several sub-optimal therapies to select the one that works best for the price.

These regression results also support the distinction between medication regimen change communication generally and patient-initiated medication regimen change communication. The two communication variables had very little overlap in predictors. For medication regimen changes overall, patient age, pain, and insurance coverage all impacted whether the regimen was changed during the visit. In contrast, physician characteristics

were the biggest predictors of whether patient-initiated regimen changes were discussed in the medical visit. Further communication about patient-initiated regimen changes did not predict having the medication regimen changed. Based on the results, these two variables appear to address different areas of medication management. It is interesting that patient-initiated regimen change communication is strongly related to medication cost communication but neither variable is related to having the medication regimen changed. The variable nature of the relationship of medication cost communication with medication regimen change communication and patient-initiated regimen change communication may highlight important differences in the relationship between medication cost communication and medication management.

Table 16. Multivariable logistic regression results for predictors of medication cost communication including: significant patient, physician, and medication bivariate predictors (Regression 1, N = 192), all significant bivariate predictors (Regression 2, N=192), significant bivariate predictors and characteristics that differed by physician (Regression 3, N = 166), and significant bivariate predictors, characteristics that differed by physician, and physician characteristics (Regression 4, N = 166).

| Medication Cost Communication ^a | | | | | | | | | | | | | | | | |
|--|--------------|------|-------------|-------------|--------------|------|-------------|------------------|--------------|------|-------------|------------------|--------------|-------|-------------|------------------|
| Variable | Regression 1 | | | | Regression 2 | | | | Regression 3 | | | | Regression 4 | | | |
| | Odds Ratio | SE | 95% CI | p | Odds Ratio | SE | 95% CI | p | Odds Ratio | SE | 95% CI | p | Odds Ratio | SE | 95% CI | p |
| White | 2.52 | 1.01 | 1.15 – 5.54 | 0.02 | 2.51 | 0.98 | 1.17 – 5.39 | 0.02 | 2.51 | 0.82 | 1.32 – 4.78 | 0.01 | 2.37 | 0.77 | 1.25 – 4.48 | 0.01 |
| No drug coverage | 2.78 | 1.19 | 1.20 – 6.45 | 0.02 | 3.09 | 1.03 | 1.62 – 5.92 | 0.001 | 3.15 | 0.95 | 1.75 – 5.70 | <0.001 | 3.1 | 1.19 | 1.46 – 6.57 | <0.001 |
| Patient-initiated regimen change discussed | | | | | 3.32 | 0.49 | 2.49 – 4.43 | <0.001 | 3.37 | 0.45 | 2.59 – 4.38 | <0.001 | 3.57 | 0.66 | 2.48 – 5.13 | <0.001 |
| RA severity | | | | | | | | | 1.38 | 0.49 | 0.69 – 2.76 | 0.36 | 1.41 | 0.53 | 0.68 – 2.93 | 0.35 |
| Number RA medications | | | | | | | | | 1.01 | 0.11 | 0.82 – 1.25 | 0.91 | 1.04 | 0.11 | 0.84 – 1.28 | 0.75 |
| Fewer than 5 prior visits | | | | | | | | | 0.85 | 0.26 | 0.47 – 1.53 | 0.58 | 0.78 | 0.23 | 0.43 – 1.40 | 0.40 |
| MD female | | | | | | | | | | | | | 1.3 | 0.4 | 0.71 – 2.37 | 0.39 |
| MD White | | | | | | | | | | | | | 1.48 | 0.26 | 1.04 – 2.09 | 0.03 |
| MD age | | | | | | | | | | | | | 0.98 | 0.003 | 0.98 – 0.99 | <0.001 |

^a Standard errors adjusted for 5 physician strata.

Table 17. Multivariable logistic regression results regressing communication about patient-initiated medication regimen changes on significant patient, physician, and medication bivariate predictors (Regression 1, N = 192), all significant bivariate predictors (Regression 2, N=192), and significant bivariate predictors plus characteristics that differed by physician (Regression 3, N = 166).

| Variable | Communication about patient-initiated regimen changes ^a | | | | | | | | | | | |
|--|--|-----------|-------------|-----------------|--------------|-----------|-------------|------------------|--------------|-----------|-------------|------------------|
| | Regression 1 | | | | Regression 2 | | | | Regression 3 | | | |
| | Odds Ratio | Robust SE | 95% CI | p | Odds Ratio | Robust SE | 95% CI | p | Odds Ratio | Robust SE | 95% CI | p |
| Age – Under 55 | 2.24 | 0.98 | 0.96 – 5.26 | 0.06 | 1.94 | 0.94 | 0.75 – 5.04 | 0.17 | 1.66 | 1.03 | 0.49 – 5.59 | 0.42 |
| MD female | 0.43 | 0.13 | 0.24 – 0.79 | <0.01 | 0.48 | 0.15 | 0.27 – 0.87 | 0.02 | 0.39 | 0.12 | 0.22 – 0.70 | <0.01 |
| MD age | 1.04 | 0.01 | 1.01 – 1.07 | <0.01 | 1.06 | 0.02 | 1.02 – 1.10 | 0.01 | 1.03 | 0.11 | 1.01 – 1.05 | <0.01 |
| Medication Cost | | | | | | | | | | | | |
| Communication Medication Regimen Changed | | | | | 3.52 | 0.45 | 2.74 – 4.53 | <0.001 | 3.22 | 0.63 | 2.19 – 4.72 | <0.001 |
| | | | | | 1.89 | 0.86 | 0.78 – 4.59 | 0.16 | 2.33 | 1.06 | 0.96 – 5.69 | 0.06 |
| MD White | | | | | | | | | 1.82 | 0.32 | 1.29 – 2.57 | <0.01 |
| White | | | | | | | | | 0.76 | 0.31 | 0.34 – 1.71 | 0.51 |
| RA severity | | | | | | | | | 0.77 | 0.24 | 0.42 – 1.41 | 0.40 |
| No drug coverage | | | | | | | | | 0.47 | 0.39 | 0.09 – 2.36 | 0.36 |
| Fewer than 5 prior visits | | | | | | | | | 0.50 | 0.38 | 0.11 – 2.21 | 0.36 |
| Number RA medications | | | | | | | | | 0.87 | 0.16 | 0.61 – 1.24 | 0.44 |

^a Standard errors adjusted for 5 physician strata.

Table 18. Multivariable logistic regression results regressing medication regimen changes on significant patient, physician, and medication bivariate predictors (Regression 1, N = 192), all significant bivariate predictors (Regression 2, N = 192), and significant bivariate predictors plus characteristics that differed by physician (Regression 3, N = 166).

| Variable | Medication regimen changed during medical visit ^a | | | | | | | | | | | |
|---|--|-----------|--------------|-----------------|--------------|-----------|--------------|-----------------|--------------|-----------|--------------|------------------|
| | Regression 1 | | | | Regression 2 | | | | Regression 3 | | | |
| | Odds Ratio | Robust SE | 95% CI | p | Odds Ratio | Robust SE | 95% CI | p | Odds Ratio | Robust SE | 95% CI | p |
| Age – Under 55 | 2.04 | 0.54 | 1.22 – 3.43 | <0.01 | 1.88 | 0.46 | 1.17 – 3.03 | 0.01 | 2.20 | 0.47 | 1.45 – 3.33 | <0.001 |
| White | 3.02 | 2.08 | 0.79 – 11.66 | 0.11 | 2.91 | 1.98 | 0.76 – 11.04 | 0.12 | 3.09 | 2.16 | 0.78 – 12.18 | 0.11 |
| Pain Fewer than 5 prior visits | 1.16 | 0.06 | 1.06 – 1.27 | <0.01 | 1.15 | 0.06 | 1.04 – 1.27 | <0.01 | 1.13 | 0.04 | 1.04 – 1.21 | <0.01 |
| No drug coverage | 2.92 | 1.74 | 0.91 – 9.38 | 0.07 | 2.93 | 1.60 | 1.01 – 8.52 | 0.05 | 2.88 | 2.15 | 0.67 – 12.44 | 0.16 |
| MD female | 1.60 | 0.26 | 1.17 – 2.19 | <0.01 | 1.62 | 0.27 | 1.16 – 2.25 | <0.01 | 1.63 | 0.41 | 1.00 – 2.67 | 0.05 |
| MD age | 0.52 | 0.17 | 0.27 – 0.99 | 0.05 | 0.56 | 0.21 | 0.27 – 1.16 | 0.12 | 0.63 | 0.31 | 0.24 – 1.65 | 0.35 |
| Patient-initiated regimen changes discussed | 0.96 | 0.02 | 0.92 – 1.01 | 0.08 | 0.95 | 0.03 | 0.90 – 1.01 | 0.11 | 0.95 | 0.04 | 0.88 – 1.02 | 0.17 |
| RA severity | | | | | 1.89 | 0.91 | 0.73 – 4.87 | 0.19 | 1.96 | 0.86 | 0.84 – 4.61 | 0.12 |
| Number RA medications | | | | | | | | | 1.12 | 0.21 | 0.78 – 1.61 | 0.55 |
| | | | | | | | | | 1.14 | 0.09 | 0.97 – 1.33 | 0.12 |

^a Standard errors adjusted for 5 physician strata.

Results of Aim 3 – Examination of the impact of discussions of medication cost, patient-initiated regimen changes, and overall regimen changes on patient-reported medication satisfaction.

The purpose of this aim was to examine how discussions of medication cost and medication management in routine clinic visits between rheumatologists and patients with RA affect patient-reported medication satisfaction. Results in this section are based upon the sample of 192 patients for which complete data were available on the outcome variables. First, descriptive information on patient-reported medication satisfaction is presented. Second, bivariate associations among communication, patient, physician, and medication characteristics and high versus low medication satisfaction are presented. Bivariate associations between discussions of medication cost, discussion of regimen modification, patient initiated regimen changes and high versus low medication satisfaction using a Mantel Haenszel test, stratified on physician, are also presented. Third, multiple logistic regression results examining the influence of discussions of medication costs and patient-initiated regimen changes on patient medication satisfaction are presented.

Descriptive Data

Patient-reported Medication Satisfaction

As shown in Table 19, there were no patients who reported being not at all satisfied with the medications they were supposed to take until their next medical visit. Overall, patients in the sample were satisfied with their medications and responses were right-skewed toward the more positive response categories. For the purposes of analysis, this variable was transformed into a dichotomous low versus high satisfaction variable. Low satisfaction was comprised of the 24 patients (12.5%) reporting they were ‘a little’ or ‘somewhat’ satisfied with their medications and high satisfaction was comprised of the 166

patients (87.5%) reporting they were ‘very’ or ‘totally’ satisfied with the medications they were supposed to take until their next visit.

Table 19. Categories of patient-reported medication satisfaction (N = 192).

| Patient-reported medication satisfaction | Number of Patients (%) | |
|--|-------------------------------|---------|
| Not at all satisfied with medications prescribed | 0 | (0.0) |
| A little satisfied with medications prescribed | 2 | (1.04) |
| Somewhat satisfied with medications prescribed | 22 | (11.46) |
| Very satisfied with medications prescribed | 52 | (27.08) |
| Totally satisfied with medications prescribed | 116 | (60.42) |

Bivariate Results

Patient-reported medication satisfaction by communication, patient, physician, and medication, characteristics

Table 20 shows the differences in communication, patient, physician, and medication characteristics by low and high patient medication satisfaction. Chi-square statistics were calculated for the cross-tabulation of low versus high medication satisfaction and categorical variables. T-tests were conducted to test the association between low versus high medication satisfaction and the continuous variables. To take into account the positive skew in the total monthly RA medication cost variable, the non-parametric Wilcoxon rank-sum test was used to assess the relationship between this variable and patient-reported medication satisfaction.

Of all the communication, patient, physician, and medication characteristics, only one had a statistically significant association with medication satisfaction. Patients who talked about medication costs in the medical visit were more likely to report low satisfaction with their medications ($p = 0.02$). Twenty percent of patients talking about medication costs in

their medical visit reported low medication satisfaction while only 9% of patients who did not talk about medication costs reported low satisfaction. This finding runs counter to hypothesis five that patients who discuss medication costs would be more likely to report being satisfied with their medications. There may be several potential reasons for the difference and it is notable that the presence of an association is not indicative of causality. It is possible that patients experiencing cost pressures discussed them in their visits but no solutions were found so patients were left feeling less satisfied with their medications. It is also possible that patients' assessment of satisfaction included medication costs and discussion of medication costs was a marker of low medication satisfaction.

There were no significant relationships between discussion of patient initiated regimen changes or discussion of modifying the regimen and patient-reported medication satisfaction. In fact, 12.5% of patients disclosing medication regimen changes reported low medication satisfaction and 12.5% reported high medication satisfaction, an even proportion. The finding of no difference in satisfaction based on talking or not talking about patient-initiated regimen changes runs counter to the hypothesized relationship postulated in hypothesis six of aim three. That hypothesis stated that patients discussing medication management in their medical visits would be more likely to report being satisfied with their medications. Similarly, there were no differences in patient reported medication satisfaction based on whether the medication regimen was changed at the visit. Fourteen percent of patients who had their medication regimens changed at the visit reported low satisfaction and 11% of patients who did not have their regimens changed at the visit reported low satisfaction.

Similar proportions of patients reporting low satisfaction compared to high satisfaction were female, married, white, non-Hispanic, and lacked prescription drug coverage. As may be expected, patients reporting low medication satisfaction reported higher mean levels of pain than patients reporting high medication satisfaction (5.2 versus

4.2). While the differences were not significant, patients with a high school education or less were more likely to report high satisfaction (90.5%) than patients with more than a high school education (84%) and patients with annual incomes under \$40,000 were more likely to report low medication satisfaction (15%) than patients with annual incomes of \$40,000 or more (9%).

There were no significant differences in the percent of patients reporting low medication satisfaction by physician characteristics. However, more patients reporting low medication satisfaction saw female physicians than male physicians and younger physicians than older physicians.

There were also no significant differences in medication characteristics among patients reporting low versus high medication satisfaction. However, it was interesting that patients reporting low medication satisfaction had higher median total monthly medication costs (\$366.81) than patients reporting high medication satisfaction (\$240.65). Patients reporting low medication satisfaction also were taking more medications on average than patients reporting high medication satisfaction (4.5 versus 4.2 medications).

Table 20. Patient-reported medication satisfaction by communication, patient, physician, and medication characteristics (N=192).

| Variable ^b | Patient-Reported Medication Satisfaction ^a | |
|---|---|-------------------------------|
| | Low (n=24) Frequency (%) | High (n=168) Frequency (%) |
| Characteristics of Communication | | |
| Discussion of medication costs | | |
| Yes | 13 (20.3) | 51 (79.7) |
| No | 11 (8.6) | 117 (91.4) * |
| Discussion of patient initiated changes to the medication regimen | | |
| Yes | 5 (12.5) | 35 (87.5) |
| No | 19 (12.5) | 133 (87.5) |
| Discussion of modifying medication regimen | | |
| Yes | 14 (14.3) | 84 (85.7) |
| No | 10 (10.6) | 84 (89.4) |
| Patient Characteristics | | |
| Gender | | |
| Female | 18 (12.7) | 124 (87.3) |
| Male | 6 (12.0) | 44 (88.0) |
| Age, mean (std dev) | 63.7 (9.8) | 62.3 (9.1) |
| Education | | |
| High school or less | 9 (9.5) | 86 (90.5) |
| More than high school | 14 (15.9) | 74 (84.1) |
| Income | | |
| Less than \$40,000 | 16 (15.1) | 90 (84.9) |
| \$40,000 or more | 6 (8.7) | 63 (91.3) |
| Marital status | | |
| Married | 12 (11.1) | 96 (88.9) |
| Not married | 11 (14.7) | 64 (85.3) |
| Race | | |
| White | 17 (12.4) | 120 (87.6) |
| Non-White | 7 (12.7) | 48 (87.3) |
| Ethnicity | | |
| Hispanic | 0 (0.0) | 2 (100.0) |
| Non-Hispanic | 23 (12.6) | 160 (87.4) |
| ACR Classification of Global Functional Status | | |
| (I) No restriction of ability to perform normal activities | 4 (8.2) | 45 (91.8) |
| (II) Moderate restriction | 10 (11.5) | 77 (88.5) |
| (III) Marked restriction | 6 (23.1) | 20 (76.9) |
| (IV) Incapacitation or confinement to a bed or wheelchair | 1 (25.0) | 3 (75.0) |
| Self-rated pain, mean (std dev) | 5.2 (2.6) | 4.2 (2.8) |

| Variable ^b | Patient-Reported Medication Satisfaction ^a | |
|---|---|-------------------------------|
| | Low (n=24) Frequency (%) | High (n=168) Frequency (%) |
| Prior visits with physician | | |
| Fewer than five | 7 (17.9) | 32 (82.1) |
| Five or more | 17 (11.1) | 136 (88.9) |
| Prescription drug coverage | | |
| No coverage | 5 (13.9) | 31 (86.1) |
| Partial or generous coverage | 19 (12.2) | 137 (87.8) |
| Physician Characteristics | | |
| Gender | | |
| Female | 14 (15.1) | 79 (84.9) |
| Male | 10 (10.1) | 89 (89.9) |
| Race | | |
| White | 13 (12.0) | 95 (88.0) |
| Non-White | 11 (13.1) | 73 (86.9) |
| Age, mean (std dev) | 44.2 (6.8) | 46.6 (8.3) |
| Medication Characteristics | | |
| Cost of medications, median (range) | 366.81(61.84-5087.57) | 240.65(0-4860.01) |
| Number of RA medications prescribed, mean (std dev) | 4.5 (1.4) | 4.2 (1.6) |

^a Significance level of the chi-square statistic for categorical variables, two-tailed t-test for continuous variables, and Wilcoxon rank-sum for non-normally distributed continuous variables: * p < 0.05, ** p < 0.01, *** p < 0.001

^b Totals for individual variables may be less than 192 due to missing data.

Looking further at the relationships between medication satisfaction and communication about medication costs, patient-initiated regimen changes, and visit changes to the medication regimen, the communication variables were stratified on physician and their relationship to high versus low medication satisfaction was calculated using the Mantel-Haenszel chi-square statistic. The null hypothesis of the test is that the odds ratios for the variables within physician are equal to one. The odds ratios are equal to one when the proportions within physicians are the same, indicating no differences in variables when controlling for physician. Looking at the relationship between medication satisfaction and communication about medication costs, stratifying on physician, the Mantel-Haenszel chi-square statistic is 4.26 with an accompanying p-value of 0.04. These results indicate that the null hypothesis can be rejected; the differences in medication satisfaction among those

who communicate about medication costs remain after controlling for physician. As with the bivariate analyses, there were no significant differences in satisfaction by patient-initiated regimen change communication or medication regimen changes using the Mantel-Haenszel and stratifying on physician. However, the results of the Mantel-Haenszel tests must be interpreted with caution due to the small number of patients reporting low medication satisfaction; these findings may or may not be suggestive of actual relationships.

Logistic Regression Results

As mentioned in the methods section, the goal had been to use multivariable logistic regression to separately examine the influence of discussions of medication cost and discussion of regimen modification on patient medication satisfaction after taking into account patient, physician, and medication characteristic variables. In addition, multiple logistic regression was going to be used to measure the influence of the interaction between medication cost discussion and regimen modification discussion on medication satisfaction while controlling for patient and physician variables. However, the relatively few respondents (n=24) reporting low medication satisfaction presented a challenge to multivariable modeling. This constraint meant that only a couple of predictors could be entered into logistic regression models and be expected to produce stable estimates from the regression equations. To address this issue, only predictor variables that were statistically significant in the bivariate analyses were modeled in the multivariable analysis. However, issues of model building were largely avoided since bivariate analyses revealed few significant relationships between high versus low medication satisfaction and patient, physician, medication, and communication characteristics. In fact, the only significant bivariate predictor of patient-reported medication satisfaction was medical visit communication about medication costs.

As an exploratory analysis, three multivariable logistic regression models were run looking at predictors of low patient-reported medication satisfaction. Table 20 shows the results of these regressions. Regression 1, based on the complete case sample of 192, shows the regression of medication cost communication on low medication satisfaction. Regression 2 based on a sample of 166 contains the predictor medication cost communication and the variables that differed significantly by physician. Regression 3 builds on Regression 2 with the addition of physician characteristics. The smaller complete case sample in Regressions 2 and 3 did not constitute a dramatically different sample based on comparisons of patient, physician, and medication characteristics. Additionally, when the regression models were run using a multiply imputed dataset the model results did not change substantially from those generated with the complete case dataset. Each regression equation was stratified on physician to account for the enrollment of patients within physician. For each of the equations, there were five physician strata. Further, for each model, robust standard errors were calculated to account for unknown forms of heteroskedasticity in the models.

Looking at the regression results, medication cost communication was not a significant predictor of medication satisfaction. In fact, none of the variables were significant in Regression 1 or 2. In Regression 3, being a female physician and younger physician age appeared to be significant predictors of low medication satisfaction but with so many variables in the model and so few patients reporting low satisfaction the stability of the estimates are in question. In sum, none of the measured variables can be determined to be reliable predictors of patient-reported medication satisfaction in the sample. With so few patients reporting low medication satisfaction, it is unclear whether any of the findings are detecting an actual relationship between variables or are simply an artifact of having so little diversity in patient-reported medication satisfaction.

Table 21. Multivariable logistic regression results for regressing low medication satisfaction on significant bivariate predictors (Regression 1, N = 192), significant bivariate predictors and significant characteristics by physician (Regression 2, N = 166), and significant bivariate predictors, significant characteristics by physician, and physician characteristics (Regression 3, N = 166)

| Low Medication Satisfaction ^a | | | | | | | | | | | | | |
|--|--------------|-----------------------|-------------------------|------|--------------|-----------------------|-------------------------|------|--------------|-----------------------|-------------------------|------------------|--|
| Variable | Regression 1 | | | | Regression 2 | | | | Regression 3 | | | | |
| | Odds Ratio | Robust Standard Error | 95% Confidence Interval | p | Odds Ratio | Robust Standard Error | 95% Confidence Interval | p | Odds Ratio | Robust Standard Error | 95% Confidence Interval | p | |
| Medication cost communication | 2.71 | 1.47 | 0.94 – 7.86 | 0.07 | 2.48 | 1.53 | 0.74 – 8.31 | 0.14 | 2.54 | 1.69 | 0.69 – 9.34 | 0.16 | |
| White | | | | | 0.73 | 0.25 | 0.37 – 1.44 | 0.36 | 0.81 | 0.25 | 0.44 – 1.49 | 0.50 | |
| RA severity | | | | | 1.61 | 0.80 | 0.61 – 4.29 | 0.34 | 1.58 | 0.78 | 0.60 – 4.17 | 0.35 | |
| No drug coverage | | | | | 1.03 | 0.58 | 0.35 – 3.08 | 0.95 | 0.88 | 0.52 | 0.28 – 2.80 | 0.84 | |
| Fewer than 5 prior visits | | | | | 1.62 | 0.46 | 0.93 – 2.82 | 0.09 | 1.20 | 0.17 | 0.90 – 1.59 | 0.21 | |
| Number RA medications | | | | | 1.07 | 0.18 | 0.78 – 1.48 | 0.67 | 1.12 | 0.20 | 0.79 – 1.60 | 0.51 | |
| MD female | | | | | | | | | 1.48 | 0.11 | 1.29 – 1.71 | <0.001 | |
| MD White | | | | | | | | | 0.92 | 0.16 | 0.66 – 1.28 | 0.62 | |
| MD age | | | | | | | | | 0.94 | 0.01 | 0.93 – 0.95 | <0.001 | |

^a Standard errors adjusted for 5 physician strata.

CHAPTER SIX: DISCUSSION

The purpose of this dissertation was to better understand communication about medication cost and medication management between patients with RA and rheumatologists and its effect on patient-reported medication satisfaction. This study helps address gaps in the literature regarding communication between physicians and patients about medication cost and medication management. While the healthcare literature has stressed the importance of patient-physician communication about medication costs, this was one of the first studies to examine the content and predictors of actual discussions of medication cost in the context of medication management (Alexander et al., 2003; Alexander et al., 2004). Both qualitative and quantitative methods were used to examine communication about medication costs, communication about patient medication management, and the impact that such communication has on patient medication satisfaction. The following sections summarize the findings and discuss the implications of the qualitative and quantitative results, discuss the major limitations and strengths of the study, and present potential directions for future research.

Summary of findings

Medication cost communication

Looking at the descriptive data, results indicated that patients in the sample had total monthly medication costs ranging from \$3.10 to \$4,860.01 for patients taking one or more RA medications. Within the range of total medication costs, there was a gap in total costs

between patients prescribed biologic therapies and those not prescribed biologic therapies. Patients prescribed TNF- α inhibitors had median total monthly medication costs that were over eight times more than the median total monthly medication cost of a patient not prescribed a biologic therapy. The finding of great differences in medication costs between patients prescribed and not prescribed biologic therapies is consistent with the work of other researchers looking both at total costs and patient OOP medication costs (Goldman et al., 2006; Michaud et al., 2003). This provides some support that use of a total RA medication cost variable derived from published average wholesale prices likely has the same trends as actual cost values. Further, the similarity between the medication cost values derived in this study and actual total and OOP costs found by others lends credence to the idea that the values in this study likely performed in a similar manner in the analysis to actual costs or OOP costs, had they been available.

Audiotape analysis results revealed that 34% of visits contained discussions of medication cost, a higher rate than has been reported in previous studies of patient-physician communication about medication costs. A recent examination of actual visit communication between patients and physicians about the cost of newly prescribed medicines found that among a sample of family physicians, internists, and cardiologists medication costs were only discussed for 12% of newly prescribed medications (Tarn et al., 2006). A number of factors could account for this discrepancy. First, this analysis was not limited to medical visits in which new prescriptions occurred as in the prior study (Tarn et al., 2006). The approach undertaken in this study may more accurately reflect the prevalence of medication cost discussions since it takes into account communication about both new and continued medications. Second, our sample was drawn from adults under the care of a specialist for a chronic condition which generally requires ongoing medication use. The patient sample in Tarn et al. (2006) was slightly younger (mean age 55) without a specific chronic illness seeing family physicians, internists, or cardiologists. Finally, participants in

our study all had a diagnosis of RA and new breakthroughs have led to the development of potentially more effective but more expensive RA medications (DeWitt et al., 2006).

A recent study by Wilson and colleagues (2007) lends further support that communication about medication costs may be more likely in older patient populations with chronic conditions. They conducted a survey of over 17,000 community dwelling Medicare beneficiaries 65 years and older living in low-income neighborhoods in all 50 states and found that 30.9% reported talking with their doctor about medication costs and 41.3% with three or more chronic conditions reported talking with their doctor about medication costs (Wilson et al., 2007). Given that the population in the study reported here was older and had at least one chronic condition for which they were seeking care from a specialist it is perhaps not surprising that the prevalence of medication cost communication falls between the rates found by Wilson et al (2007).

Interestingly there were no differences in whether patients or physicians discussed medications costs based on whether patients were prescribed biologic RA medications. The finding is interesting because of the high total and out-of-pocket costs associated with these medications. The finding could indicate that total medication cost burden or cost burden relative to income matters more than the cost of any singular medication. It is also possible that there were not differences by biologic medication prescription because physicians simply did not offer and did not discuss those medications with patients they felt could not afford such medications. More information is needed on the impact of patient and physician perceptions of cost burden to better understand the impact on communication about specific medications.

It is also worth noting that cost pressures may still burden the 66% of patients not discussing medication costs. This study measured communication about medication costs and not patient perception of medication cost burden; it is possible and even likely that a portion of the patients not discussing medication costs were burdened by them. While it is

encouraging that one-third of the sample discussed medication costs, it is important to remember that among the two-thirds of patients not discussing medication costs some may be significantly impacted by their RA medication costs and not addressing these issues with their rheumatologists.

Study results indicated that the majority of patients did not ask questions during medication cost discussions. Previous research has found that patients are reluctant to ask questions about medications during medical visits, a finding which appears to extend to medication costs as well (Sleath et al., 2003). However, physicians did ask medication cost questions, often initiating medication cost communication with patients. The presence of physician-question asking, especially at the outset of medication cost discussions is indicative of the beginning of a participatory dialogue as it requires active patient engagement in the conversation. Further, physician question asking is important because it allows the physician to assess the patient point of view (Sleath et al., 2003). These results provide some evidence that physicians are trying to engage patients in communication when medication costs are discussed in the medical visit. The discovery that physicians were relatively active questioners in medication cost discussions was possible because of the analysis focus on the content of medical visit communication.

In past research, communication about medication costs has been measured in large surveys often using a single question or couple of questions to assess whether patients can recall communicating with physicians about medication costs (Piette et al., 2004b; Wilson et al., 2007). Such measures are subject to patient recall bias and, through limited questions, address medication cost communication as a single concept. In this study, audiotape analysis permitted examination of actual communication about cost, avoiding the pitfalls of recall bias, thereby allowing a deeper examination of communication about medication costs. Examining the specific content of medication cost communication permitted a comprehensive understanding of the cost topics that patients and physicians were covering

and the role that the each participant played in the communication. Developing a deeper understanding of medication cost communication will help move toward more fully developed conceptions and theories of such communication and the impact it has on patient outcomes like medication adherence. Prior scholarship examining conceptual models of patient responses to medication cost pressures have conceptualized communication about medication costs as solely in the purview of physicians (Piette, Heisler, Horne et al., 2006). However, the results of this study indicate that patients actively initiate medication cost discussions and that medication cost communication is not a monolithic concept but is comprised of several components.

In this study, medication cost communication was comprised of the categories insurance coverage and strategies to reduce patient OOP medication expenses. Associated with the category insurance coverage was the subcategory insurance coverage affecting patient OOP costs. Associated with the category strategies to reduce patient OOP costs are the subcategories medication assistance programs, importing medications, and medication samples.

By engaging patients in conversations about insurance coverage, physicians are increasing their own awareness of patients' medication cost burdens (Alexander et al., 2003). Through discussion of insurance coverage and the impact on patients' OOP costs, physicians have more information available for the prescription decision-making process. In this study, when such discussions happened, physicians overwhelmingly selected medications for patients that were covered by their insurance.

In the second major category, general strategies to reduce patient OOP medication costs the conversations generally took one of two forms. The first was physicians discussing prescribing or medication use that would reduce OOP costs and the second was patients discussing their desire to reduce medication costs by being prescribed less expensive medicines or eliminating medicines from their regimens. Patient discussion of

their desire to reduce OOP medication expenses is somewhat surprising given past literature indicating that patients rarely, if ever, disclose to physicians that they want to reduce or eliminate medications to lower costs (Donovan & Blake, 1992; Piette et al., 2004b). However, these discussions are critically important because they provide physicians with an opportunity to help patients differentiate between necessary and discretionary medications and doses when faced with cost pressures (Benedetti et al., 2008).

Under the major category of strategies to reduce patients' OOP medication costs, three distinct subcategories of communication were discovered. With the first, medication assistance programs, patients and physicians discussed several types of programs. Not surprisingly, all communication about medication assistance programs happened with patients who had no or partial prescription drug coverage and all but one had an annual income below \$40,000. All conversations were aimed at providing patients access to medications they would not otherwise be able to afford or receive. It is encouraging that communication about medication assistance programs is happening with the patients these programs are designed to help. The literature on prescription drug assistance programs recommends that physicians and other health practitioners become aware of such programs and direct patients toward programs for which they are eligible (Chisholm & DiPiro, 2002). In this rheumatology setting, both patients and physicians had an awareness of medication assistance programs and results support that in many cases physicians were directing patients towards programs for which they were eligible. Even with Medicare Part D, research indicates that pharmaceutical assistance programs represent an important cost savings avenue for low-income persons (Havrda, Omundsen, Bender, & Kirkpatrick, 2005).

The second subcategory, importing medicines, was geographically interesting because the sample was drawn from North Carolina, a non-border state. Further, while there were only two conversations about medication purchased outside the United States to

reduce medication costs, it represents an interesting and important policy issue. Data from a 2003 large, nationwide survey of Medicare beneficiaries age sixty-five and older found that five percent of seniors said that they had purchased some of their prescription medications from Canada or Mexico (Safran et al., 2005). Additional data indicated that the incidence of medications purchased outside the United States had been steadily increasing prior to 2003 (Saatsoglou, 2004). While the communication captured in this analysis was limited, it may be an indication of the increasing trend of purchasing medications abroad and demonstrates that at least some seniors are discussing their foreign-purchased medications with physicians. Prescription drug counterfeiting and the potential for tampering are just some of the risks associated with foreign-purchased prescription drugs (Saatsoglou, 2004). Patient-physician communication about such purchases may place physicians in a difficult position because, while they want patients to be able to obtain the medications they prescribe, without chemical tests they have no way of validating that foreign-purchased medications are indeed the ones prescribed.

The third subcategory discussed under strategies to reduce OOP medication costs was medication samples. In eleven medical visits the provision of medication samples was discussed. There was diversity in patient characteristics in discussions of medication samples but a clear physician effect because one physician talked the most about sample provision. The physician effect is perhaps not surprising. One physician in the sample appeared to have greater access to and supplies of medication samples than the other physicians in the study. The lack of difference in characteristics among patients receiving samples is counter to recent literature on the topic. An analysis of medication sample receipt using data from the 2002 Medical Expenditure Panel Survey found that sample recipients were more likely to be White and female (Alexander, Zhang, & Basu, 2008). While the provision of medication samples has been suggested as one strategy to assist patients burdened by medication costs, the use of samples in the office setting has been

contested (Alexander & Tseng, 2004; Alexander et al., 2008). Some argue that the provision of samples provides patients access to medications and helps physicians become familiar with new medications, while others argue that sample use encourages use of newer more expensive medications over older but as effective medicines. Further, opponents of sample provision argue that the strategy is unsustainable and ultimately increases patient prescription costs (Alexander et al., 2008). In this study, patients generally received samples of medicines for which there were no equivalent generic medications. However, the issue of sustainability still remains since it was unclear whether patients could stay reliably stocked with samples.

The results of the qualitative analysis provided some clues about the relationships that were discovered in the quantitative analysis. Qualitative examination of communication about medication costs revealed that all conversations about the impact of insurance coverage on OOP costs happened with patients who identified as White/Caucasian. Qualitative analysis also revealed that communication about medication assistance programs and general strategies to reduce OOP costs occurred more often with patients who had no or only partial prescription drug coverage. Building on these findings, multivariable logistic regression results found lacking prescription drug coverage and White/Caucasian patient race to be significant predictors of medication cost communication.

Patients lacking prescription drug coverage had nearly three times the odds of communicating about medication costs as patients who had partial or generous prescription drug coverage. This finding is slightly higher than an earlier study of coverage and communication about costs. A 2003 telephone survey of primary care patients in Los Angeles found that the variable that most powerfully predicted the likelihood patients and physicians would discuss OOP costs was patients' pharmacy benefit design (Shrank et al., 2006). Patients without prescription drug coverage were 2.3 times more likely to discuss OOP costs with their physicians than patients paying no co-payments ($p < 0.001$). In the

present study, my focus on patients with RA and the use of observational, as opposed to survey, methods may partially account for the increase in the magnitude of the relationship between lacking drug coverage and communication about medication costs.

A surprising finding was that patients identifying as White/Caucasian were approximately 2.5 times more likely to communicate about medication costs in their medical visits than patients not identifying as White/Caucasian. The racial differences in communication about medication costs may be due to several factors. Recent research on RA medication costs found that drug costs for non-Hispanic, White patients were \$443 greater for a 6-month period than for non-White patients (Michaud et al., 2003).

Put in the context of other research on racial differences in medical visit communication, this finding makes sense. Cooper-Patrick and colleagues found that African-American patients had significantly less participatory medical visits with their physicians than White/Caucasian patients (Cooper-Patrick et al., 1999). Perhaps due to non-White patients' feelings of differential participatory engagement in the medical visit, they were less likely to bring up medication cost topics and physicians were less likely to address the issue as well. The research literature has demonstrated that non-White patients often have less active communication behaviors in medical visits and physicians are less participatory and are less likely to engage non-White patients in communication (Gordon, Street, Kelly, Soucek, & Wray, 2005; R. L. Johnson, Roter, Powe, & Cooper, 2004). In a counter finding, Heisler and colleagues discovered in their survey study of over 4000 patients that physicians were more likely to ask non-White patients about medication cost issues (Heisler, Wagner, & Piette, 2004). Regardless of the mechanism through which the difference in cost communication is operating, the finding that medication cost conversations were more likely to occur with White/Caucasian patients is troubling. Several research studies have indicated that non-White patients may be more likely to be burdened by their medication costs and are more likely to restrict their medication use for cost-related reasons

(Piette, Heisler, Horne et al., 2006; Soumerai et al., 2006; Steinman, Sands, & Covinsky, 2001). In fact, Steinman and colleagues found that non-White Americans were almost three times as likely to report cutting back on medication use due to cost problems as Whites/Caucasians, even when controlling for OOP costs, overall health and drug coverage, income, and health status indicators (Steinman et al., 2001).

If non-White patients are less likely to discuss medication costs but more likely to alter their medication taking because of cost reasons, then this is an important area to address in medical visit communication. Pre-visit questionnaires can ask patients about medication cost issues but perhaps more importantly communication skills can be taught to both patients and physicians. Patients can be coached on active participation and question asking in medical visits. A prior randomized controlled trial showed that patients who were coached to ask questions and negotiate medical decisions were more active participants in medical visits than patients in the control condition who did not receive such training (Greenfield, Kaplan, & Ware, 1985). Further, training physicians about racial disparities in medical visit communication may improve communication with patients from different cultural backgrounds (Carrillo, Green, & Betancourt, 1999; Culhane-Pera, Reif, Egli, Baker, & Kassekert, 1997).

Communication about medication costs was significantly related to communicating about patient-initiated regimen changes. Logistic regression results revealed that patients talking about one had at least 2.5 times the odds of talking about the other. As has already been mentioned, these findings indicate mutual disclosure in this population, where discussion of one topic was more likely to generate discussion of the other. The reasons for this may have something to do with the nature of disclosure in the medical visit and patients feeling comfortable sharing information with their physician. Physicians using patient-centered communication behaviors have been shown to be positively associated with

patient participation and expression of concern in the medical visit, regardless of the specific subject matter (Zandbelt, Smets, Oort, Godfried, & de Haes, 2007).

Communication about patient-initiated changes to the medication regimen

Looking at patient disclosure of self-initiated medication regimen changes, in 21% of the recorded medical visits patients and physicians discussed patient-initiated changes to the medication regimen. Patient-initiated changes to the medication regimen were those that required a behavior change on the part of the patient and were entirely patient initiated and directed. Just as examination of medication cost communication revealed multiple categories, examination of patients' actions to manage their RA medications revealed several communication categories. Communication about patient-initiated medication regimen changes, revealed three primary categories. Of the 40 patients disclosing self-initiated regimen changes in the medical visit, 18 discussed taking more medication than had been prescribed, five substituted one medication for another, and 17 discussed taking less medication or discontinuing prescribed medication. A 1992 interview and medical visit observation study of patients with RA found patients engaged in similar medication modification behaviors (Donovan & Blake, 1992). Out of their sample of 54 patients, interviews revealed 25 to be what they considered 'non-compliers', 10 no longer took their medications, 13 took fewer pills than prescribed, and two took more medication than prescribed (Donovan & Blake, 1992). These results reveal that patients in both this sample and the prior RA sample were active managers of their medications, choosing to take more or less medication. However, in this study patients were revealing these behaviors to physicians: something that Donovan and Blake did not discover in their patient sample. In that study, none of the patients that altered their DMARD regimens disclosed that to physicians in the recorded medical visits (Donovan & Blake, 1992). The discovery that

nearly a quarter of patients in this sample disclosed regimen changes is encouraging and important. Patient revelations to physicians about self-initiated changes to the regimen are important because they offer a powerful opportunity for patients and physicians to reassess the medication regimen and explore other regimen issues, such as costs and medication administration. Almost unanimously, the patient changes to the regimen discussed in the sample reduced the patients' total RA medication cost burden.

Logistic regression results revealed that physician age and gender were significant predictors of communication about patient-initiated medication regimen changes. However, as was mentioned in the results chapter, patients overwhelmingly disclosed self-initiated regimen changes with a particular physician in the sample. Even when comparing this physician to another with similar demographic characteristics, there remained significant differences in patient disclosure of medication regimen changes. Of special note, the physician that elicited more patient disclosure of self-initiated regimen changes had longer visits on average than most other physicians and engaged patients in more social talk than all other physicians. Further, the same physician had seen all patients in the sample more than five times, some for many years. The combined effect of longer ongoing relationships, longer visit times, and more social talk in the visit may have made it easier for patients to disclose their regimen changes.

Regardless of the mechanism supporting the disclosure, the revelations provided valuable information. Patients disclosed changes that represented potential drug safety issues as well as issues of effectiveness. Some patients were adding medications to the regimen that could potentially result in overdose and some patients were substituting medications that were known to be less effective. The disclosures provided an opportunity to reassess the regimen and discuss the appropriateness of the medicines patients were actually taking, as opposed to the ones they were supposed to be taking. A recent survey of 420 patients who were prescribed DMARDs found that 34% of patients actively altered their

medications (Lim, Ellis, Brooksby, & Gaffney, 2007). It is likely that the patients who revealed medication modifications were a fraction of the total number modifying their regimens. Patients are active agents in medication taking whether they disclose their management issues to physicians or not. Physicians may be well served to recognize the primacy of patients in medication taking and ask patients open-ended questions about how they are using their medications.

Medication regimen changes

Interestingly, analysis results revealed that neither talking about medication costs nor patient-initiated regimen change communication was predictive of having the medication regimen changed during the medical visit. Overall medication regimen change communication resulting in a regimen change was distinct from patient-initiated regimen change communication. The measure of medication regimen change was whether the physician actually made a change to the regimen during the visit, while patient-initiated regimen changes were patient focused and directed. The results indicated there was no significant relationship between medication regimen change communication overall and patient-initiated regimen change communication. This reinforces that the two variables are addressing different aspects of medication management. Overall discussion of medication regimen changes in a medical visit may represent a shared decision-making opportunity or physician-directed process depending on the communication. Patient-initiated regimen changes and disclosure of such changes are manifestations of patient autonomy and may represent intentional patient dissent (Elwyn et al., 2003). On the communication and decision-making spectrum, these two concepts represent different ends. Medication regimen changes are largely within the purview of physicians, while patient disclosures of self-initiated changes are largely in the patients' domain, thus representing different areas of medication management communication.

The lack of clear association between medication regimen changes and communication about medication costs or patient-initiated regimen changes is neither positive nor negative. Discussion of costs and patient regimen changes may provide physicians with information or assuage patient feelings and be useful without resulting in a regimen change.

Looking at the multivariable logistic regression results, four factors significantly predicted having the regimen changed during the visit. The variables patient age under 55 years-old and fewer than five prior visits with the study physician were predictive of having the regimen changed, but not strongly so. These could be patients with more recent RA diagnoses for whom an effective RA medication regimen had yet to be found. The strongest predictors of having the RA medication regimen changed were patient pain rating and lacking prescription drug coverage. Patient pain may be a sign of uncontrolled RA; therefore, medication regimen changes to better control the disease make intuitive sense. The increased odds of a medication regimen change due to lack of prescription drug coverage is an interesting finding. For patients lacking prescription drug coverage, expensive, but effective biologic medications may not be an option and they may have to cycle through other, less-expensive medications to address their RA.

Patient medication satisfaction

In bivariate assessments, patients talking about medication costs appeared to be more likely to report low medication satisfaction. However, the relationship did not remain when using logistic regression where no variables clearly predicted low medication satisfaction. Assessments of factors significantly related to and predictive of medication satisfaction were limited in this study by the small variation in patient-reported medication satisfaction. Just over 60% of the sample said they were totally satisfied with the

medications they were supposed to take until their next visit, the highest rating possible. Patients were asked the item on medication satisfaction by a research interviewer, which may have encouraged patients to respond more positively than had they responded to the item in a survey. Alternately, it is possible that patients in the sample were genuinely very satisfied with their medications. To better assess medication satisfaction, the study would have benefited from using multiple items to assess satisfaction. Had multiple items been available all assessing the latent medication satisfaction construct, it is possible and perhaps likely that there would be greater variation in patient medication satisfaction. Current recommendations in the research literature suggest using multiple items to assess medication satisfaction (Shikiar & Rentz, 2004).

Prior research with patients with RA found that patient perception of a high-level of involvement in medical decisions was significantly associated with satisfaction (Kjeken et al., 2006). Other research indicates that physician communication is related to medication satisfaction and adherence (Bultman & Svarstad, 2000). Bultman and Svarstad argue that a collaborative physician approach where physicians respond to patients by acknowledging, reassuring, clarifying, recommending steps for coping, and/or changing medications can have a powerful effect on medication satisfaction and use (Bultman & Svarstad, 2000). These studies relied on patient perception of communication and satisfaction, whereas this study relied on observational assessment of communication and the impact on satisfaction. The differences between their significant findings and the lack thereof in this study may be partially due to the measurement differences. Research has shown greater correlation between perception measures of behavior and satisfaction than observation measures (Street, 1992). However, patients' perceptions of physician behavior or medical visit activities are components of their perception of satisfaction so it makes sense that these two are highly correlated (Arora, 2003). This measurement issue may contribute to the finding of significant associations between perceptions of communication and satisfaction and limits

the ability to draw meaningful conclusions from the data. While such measurement issues were not present in this study because of the use of observed communication measures, the results demonstrated no clear relationships between communication characteristics and medication satisfaction, inviting further research.

It is also important to note that, while this study asked patients to rate their medication satisfaction, it is possible and perhaps even likely patients' feelings about overall treatment or healthcare delivery system satisfaction influenced their medication satisfaction ratings (Shikiar & Rentz, 2004). Medication cost communication and communication about patient-initiated medication regimen changes may have only had minor influence on patient satisfaction ratings. If patients' satisfaction ratings were influenced by factors beyond medications and their medication communication was a minor influence on their ratings, this would further explain the lack of clear relationship between the communication variables of interest and patient-rated medication satisfaction.

Implications

Communication about medication costs and medication management are features of medical visits between patients with RA and rheumatologists. Medication cost communication and patient disclosure about self-initiated regimen changes are multifaceted concepts with implications for patient care.

Active discussion about medication costs during the prescription decision-making process may have several benefits. First, it may increase the likelihood that physicians and patients will agree on a course of treatment. Second, engaging patients in medication cost discussions may facilitate patient participation in the larger clinical decision-making process. Third, studies have shown that for older patients, both with and without prescription drug coverage, levels of OOP medication costs seem to influence drug utilization (R. E. Johnson,

Goodman, Hornbrook, & Eldredge, 1997; Steinman et al., 2001). Thus, initiating conversations about medication use in relation to cost gives physicians opportunities to assess and negotiate treatment options until both parties are comfortable with a particular plan. Fourth, prescription drug coverage clearly matters in facilitating or hampering access to medications for RA patients. In the absence of universal prescription medication coverage, physicians can inquire about patient drug coverage and dialogue about medication costs to help their patients make difficult choices among medically beneficial medicines (Piette, Heisler, & Wagner, 2006). Without such consultation, patients are making these decisions without physician input and advice.

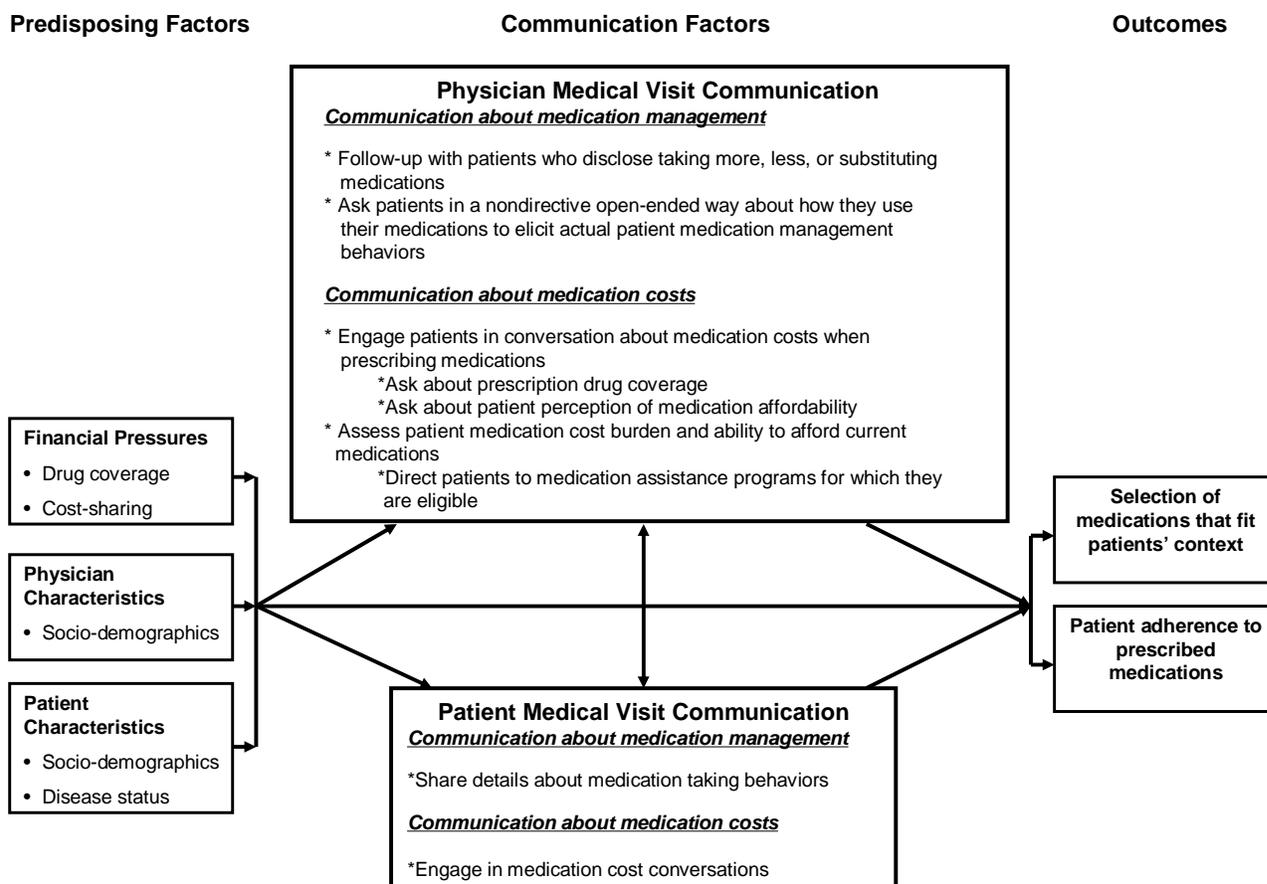
Patients' disclosures of self-initiated regimen changes are admissions of non-adherence since they fundamentally represent a departure from the prescribed medication regimen. Labeling patients as non-adherent is negative and labeling communication about such disclosures this way certainly cannot be expected to facilitate patient admissions of regimen changes. Further, use of adherence as a standard of behavior presupposes that patients are better off taking all their medications as prescribed, a finding that may not always be true. Research examining the use of NSAIDs found that patients who adapted their medication intake and varied their dose according to their symptoms were less likely to be hospitalized for upper gastrointestinal bleeding than patients who rigidly adhered to prescribed doses (Herxheimer, 1998; Wynne & Long, 1996).

A more flexible approach on the part of physicians and health services researchers to medication taking behaviors and communication in the medical visit may be in order. The results of this study demonstrated that patients disclosing regimen changes were active managers of their medications and disclosure about their behaviors in the visit was an important gateway to medication communication. Further, the strong relationship between communication about medication costs and patient-initiated regimen changes may indicate the presence of a disclosure effect in the medical visit where communication about

medication costs may lead to communication about patient-initiated medication regimen changes and visa versa. Encouraging medical visit communication that facilitates patient-involvement and disclosure may be more likely to elicit greater information from patients. Reducing the emphasis on medication adherence and compliance and encouraging greater patient participation in medication communication and decision-making are core concepts of medication concordance. Concordance advocates the sharing of power in the patient-physician relationship and is used specifically to describe communication about medications. The aim of concordance is to, “involve patients in making decisions about their medicines, to ensure that they have enough information for doing this, and to support them with any problems they might have (Pound et al., 2005).” Issues of medication cost and management are not uncommon for patients with chronic illness and recognition and explicit support of these issues in medical visits is likely to benefit both patients and physicians.

The lack of clear association between communication about medication costs or medication management and patient-reported medication satisfaction, as well as the other study findings encourage revision of the conceptual framework that guided this study. Figure 5 presents a revised conceptual framework that builds on the results of this study and was developed to understand factors that influence medical visit communication and the factors that impact medication selection and use. The framework draws upon the results of this study and emphasizes areas of potential impact and intervention. To increase the applicability of the framework, it emphasizes potential alterable medical visit communication factors rather than insurance and financial system factors which are highly variable and more challenging to change.

Figure 5. Revised conceptual framework for understanding medical visit communication about medication costs and medication management and the impact on medication selection and use.



This framework emphasizes the significant predictors of patient and physician medical visit communication and subsequent medication selection and use, while placing heavy emphasis on potential areas of intervention. Moving from left to right, the following paragraphs describe each of the model elements.

The quantitative results emphasized the influence of financial pressures on medical visit communication about medication costs. Results revealed that patients lacking prescription drug coverage were more likely to discuss medication costs in their medical visits than patients who had partial or generous drug coverage. In addition, the qualitative

results revealed that insurance coverage was a major theme of medication cost communication in the studied medical visits. Qualitative results revealed the impact of insurance coverage on OOP costs to be a subcategory of insurance coverage, with communication largely focusing on co-payments or coinsurance amounts that would be incurred through the prescription of particular medications. Based on these results, both drug coverage and cost sharing are thought to be important financial pressures that can precipitate communication about medication costs. Physicians who believe their patients are more likely to be burdened by medication costs may be more likely to discuss costs in the medical visit and patients who are more burdened by medication costs may have more incentive to discuss medication costs and medication management in the medical visit.

Lacking drug coverage and high medication cost-sharing arrangements have been shown to influence cost-related medication non-adherence (Briesacher, Gurwitz, & Soumerai, 2007). Patients are more likely to modify their regimens by taking less medication or substituting less expensive medications in their regimens if they lack prescription drug coverage or have unfavorable cost-sharing arrangements. When physicians are aware that cost is an issue, they are more likely to prescribe medications for patients they can afford (Lundin, 2000). Therefore, financial pressures can be expected to directly influence the medications selected for patients and patients' subsequent adherence to those medications.

In the revised conceptual model, physician characteristics are the second proposed influence on patient and physician medical visit communication and subsequent medication selection and use. The results of this study indicated that physician demographic characteristics were significantly associated with communication about patient-initiated medication regimen changes, as well as medication regimen changes overall. While the small number of physicians in the study tempers the results, findings in the research literature show differences in patient and physician communication by physician

characteristics. The literature documents that older physicians generally use less participatory decision-making than younger physicians (Epstein et al., 2004). Female physicians have been shown to engage in more patient centered communication than males (D. L. Roter & Hall, 2004). Further, physician race has been shown to influence perceptions of participatory decision-making when patients are in racially concordant relationships (Cooper-Patrick et al., 1999) Therefore, physician characteristics are likely to influence physician communication in the medical visit.

Physician characteristics also have the potential to impact patient communication in the medical visit. Patients in this study were more likely to initiate medication cost conversations in medical visits if physicians were younger. This finding is consistent with other medical visit communication research, which found that patients were more likely to ask questions of younger physicians (Sleath et al., 1999).It could be that patients feel more comfortable raising issues or asking questions of younger physicians or it could be that younger physicians are less proactive about raising certain issues or provide less information than older physicians. Other communication research has also demonstrated the potential impact of physician characteristics on patient communication. A study by Cooper and colleagues (2003) examining recorded medical visits found that patients display more positive affect in medical visits with physicians of the same race than when patient and physician were of different self-identified race. In the study, positive affect was a summation of patient engagement, interest, friendliness, and responsiveness in the medical visit (Cooper et al., 2003). Based on the results of my study and the findings in the research literature physician demographics can be expected to influence patient communication in the medical visit.

Finally, physician characteristics can be expected to directly influence the medicines selected in the medical visit. For patients with chronic illnesses like RA physicians can choose from a number of therapies from inexpensive generics to expensive branded drugs

(Fischer & Avorn, 2004). While there are guidelines for the selection of medications in rheumatoid arthritis, there are over 170 possible DMARD combinations from among the non-biologic DMARDs alone (Saag et al., 2008). Physicians are able to exercise a good deal of discretion in selection medications for the treatment of rheumatoid arthritis. Further, physician demographics have been shown to influence medication selection (Davidson, Molloy, & Bedard, 1995; Schnitzer et al., 2003). With physician latitude in physician prescribing and differences in prescribing by physician demographics, physician characteristics can be expected to directly influence medication selection.

In the third box down on the left side of the revised conceptual model, patient characteristics are expected to influence physician communication, patient communication, and medication selection and use. Most communication about insurance coverage and all communication about the impact of insurance coverage on OOP costs happened with patients who identified as White/Caucasian. Quantitative results supported these findings indicating that patients who identified as White/Caucasian were more likely to have medication costs discussed in their medical visits than patients who identified as African American or other race/ethnicity. This finding points both to patient and physician communication because it indicates that physicians were less likely to address medication costs with patients who were non-White and non-White patients were less likely to bring up medication costs. Other research looking at the impact of patient race on physician communication found opposite results to those reported here but nonetheless the results underscored the influence of patient race on physician communication. Heisler and colleagues (2004) found that, independent of whether they reported experiencing burdens related to medication costs, patients who were African American or of other minority race/ethnicity had higher odds of being asked by physicians about medication cost problems than white patients.

Patient gender is another factor that affects both physician and patient medical visit communication. Female patients receive more information, ask more questions, and have more collaborative relationships with physicians than male patients (Cooper-Patrick et al., 1999; Sleath & Rubin, 2002). By virtue of asking more questions and being more actively involved in medical visit communication, female patients not only communicate differently than their male counterparts they also receive different responses and reactions from physicians. Thus, female patient gender influences patient communication and also physician communication since physicians tend to build more collaborative medical visit relationships with female patients than male patients. More educated patients have also been shown to want to participate more actively in medical visit communication than less educated patients (Sleath & Rubin, 2002). Similarly, younger patients often prefer to be more involved in medical decision-making than older patients (Chewning & Sleath, 1996). Active participation on the part of patients may mean that they are more likely to provide information to physicians about their medication management and cost issues or their active participation may trigger physicians to ask more about medication cost and use. As an example, in this study younger patient age had a bivariate association with disclosure of patient-initiated regimen changes. This means that younger patients were more likely to disclose their regimen changes and physicians were more likely to elicit information on patient-initiated regimen changes from younger as opposed to older patients.

Beyond patient demographics, patient pain and disease severity may influence patient desire to address medication management and cost issues. In this study, patients were more likely to initiate medication cost conversations if they rated their pain lower than patients who did not initiate medication cost conversations. Patients with lower pain levels may have felt more flexibility discussing medication costs than patients with highly symptomatic RA. Based on these results, patient disease severity can be expected to influence patient medical visit communication. From the physician point of view, research

has shown that physicians may be more likely to ask patients taking more medications about medication costs than patients taking fewer medications (Heisler, Wagner et al., 2004). Patients with more active disease are more likely to take more medications; in this way patient disease and treatment status can be expected to impact physician visit communication about medication costs. In sum, both patient characteristics like disease severity and demographics can be expected to influence patient and physician medical visit communication.

Characteristics of the patient can also be expected to directly impact medication adherence generally and cost-related medication non-adherence more specifically. Non-white Americans have been shown to be more likely than Caucasians to report cutting back on medication use due to cost reasons, even when controlling for OOP costs, overall health, drug coverage, income and health status indicators (Steinman et al., 2001). Older patients are less likely to forego medications when facing cost pressures than younger patients (Piette et al., 2004a; Steinman et al., 2001).

Moving from the predictors of communication to the communication itself in Figure 5, physician communication can be expected to have a major impact on patient communication and subsequent medication selection and use. Qualitative analysis in this study revealed the importance of communication about medication costs and medication management in the medical visit and specific communication in each of these areas are targeted as a guide for future intervention and research. The following paragraphs discuss physician medication cost and management communication and the recommended interventions in each area.

Looking first at physician communication about medication management, study results revealed that approximately one out of five patients disclosed independently making changes to their regimens. Conversations revealed many of these patients were taking more or less medication than prescribed with a few substituting a medication for one they had been prescribed. To find out how patients actually use their medications and to

discover all the medications patients take, physicians should ask nondirective, open-ended questions about medication use. Patients generally want to please their physicians and sometimes will respond to physicians with the answers they believe physicians want to hear. By acknowledging the difficulties of continual medication use and asking in a nonjudgmental way about medication use, physicians can make patients more comfortable and facilitate candid disclosure of their medication taking behaviors (Osterberg & Blaschke, 2005). Physicians can be taught skills that encourage nondirective communication and asking open-ended questions. Physician education sessions using small groups that are learner centered and incorporate cognitive, experiential, and behavioral components have been shown to improve physician question-asking in the medical visit (Fallowfield et al., 2002; Jenkins & Fallowfield, 2002; D. L. Roter, Cole, Kern, Barker, & Grayson, 1990). These sessions can be tailored to focus on physician communication about patient medication use to encourage open-ended questions and open communication. Similarly, small group skills training using presentations, discussions, simulated patients, and feedback to participating physicians has been successfully used to engender shared decision-making in medical visits (Edwards et al., 2004). Principles of shared decision-making encourage patient involvement in the medical visit and nondirective communication. The evidence demonstrating the success of small group skills training for physicians suggests that small group education sessions that focus on nondirective communication and open-ended question asking and then give physicians an opportunity to practice these skills and receive feedback may be highly effective in changing physician communication behavior.

Once patients reveal to physicians that they are taking more, less, or substituting one medication for another, it is important that physicians follow-up with patients about these behaviors. Study results indicated that some patients were taking potentially dangerous combinations of medications and some were substituting medications that were known to be less effective. Physician skills training should focus on communication follow-up to find out

why patients have altered their medication regimens. Patients may alter their regimens because of side effects, issues with medication administration, dose timing, or cost. Differentiating among the causes of patient-initiated regimen changes is critical for addressing the root causes of the regimen changes. For example, a physician that asks a patient in a nondirective way about a medication regimen change and discovers the patient has made the change because of the OOP costs of the medication can work to address the cost issue by directing the patient to assistance programs or selecting an alternative, more affordable medication.

To make a difference in the area of physician communication about medication management, an intervention study could be designed that focuses on using small group educational techniques to build physician communication skills to elicit patient disclosure of medication regimen changes and then to follow-up on those disclosures. The intervention should capitalize on the experience gained from previous studies and use cognitive, behavioral, and experiential components with repeated sessions to improve physician uptake. The effect of the intervention should be tested through a randomized trial comparing physicians who have had the training to physicians using usual practices to see if physicians who have had the skills training elicit greater patient disclosure of regimen changes and to see if there is a difference in medication selection and use between the groups.

As mentioned throughout this study, medication cost and medication management communication appear to have a relationship with each other and physician communication about medication costs is just as important as communication about medication management. Study results indicated that communication about medication costs occurred in approximately one-third of recorded medical visits and slightly more than half of those conversations were initiated by physicians. Medication cost conversations provided physicians with information on patient insurance coverage as it would affect prescribing,

patients who had purchased medication from abroad, and patients who needed assistance paying for their medications.

Because of the potentially significant impact of medication costs on medication use and the helpful information elicited in conversations about medication costs, physicians should routinely engage in conversations about medication costs when prescribing medications. Physicians should be prompted to routinely ask about patients' prescription drug coverage. With the diversity of drug plans and changing tier copayment levels within plans, asking about prescription drug coverage can initiate communication about medication costs. Physician prompts to discuss insurance coverage could come from patient pre-visit questionnaires, prompt screens in electronic medical records, or flags included in patient charts.

Beyond asking about insurance coverage alone, physicians should probe patients about their perceptions of the affordability of the medications they are considering prescribing. Different patients will perceive the same out-of-pocket medication costs differently. The results of this study showed that medication cost conversations were not limited to only the very expensive biologic medications. For patients who face other barriers to adherence, even relatively minor out-of-pocket costs may lead to medication underuse (Piette, Heisler, Horne et al., 2006). To sensitize physicians to out-of-pocket medication costs and prompt communication about those costs simple tools can be given to physicians that list the relative out-of-pocket costs for commonly prescribed medications. A previous study that provided physicians with pocket guides with the average wholesale prices of commonly prescribed drugs listed found the guides had a modest effect on physicians' awareness of medication costs and willingness to consider those costs when prescribing (Korn, Reichert, Simon, & Halm, 2003). However, it may not be the costs of individual medications that impact patients the most. To really understand the impact of out-of-pocket medication expenses, physicians need to understand patients total medication cost burden.

As was revealed in the exchanges in this study, many times it is not the out-of-pocket expense of a particular medication but the total monthly expenditure for all medications taken that was problematic for patients. To address this issue, patients' medication lists could be updated to include out-of-pocket expense amounts. This information could be gathered by nurses and/or other allied health professionals that routinely collect pre-visit information from patients. By tracking this information physicians would be aware of patients' overall medication burdens when prescribing medications.

By having documentation of patients' overall medication cost burden, physicians could also initiate conversations about patients' ability to afford their medications and direct patients to medication assistance programs for which they are eligible. In this study, medication assistance programs discussed were operated by the pharmaceutical companies manufacturing the medications, a local hospital system, and the federal government. With a limited number of assistance programs available for any given medication, assistance programs available for medications could be listed in a pocket guide, just as out-of-pocket costs could be listed. In fact, it would be possible to create rheumatoid arthritis-specific cost-conscious prescribing guides. This pocket reference could easily list commonly prescribed RA medications, their relative out-of-pocket costs by typical health plan or based on average wholesale prices and medication assistance programs by medication.

Through communication about medication costs and medication management physicians become more aware of the personal context for patients' medication taking. Through such communication physicians are better able to select medications that fit within patients' contexts by prescribing medications that patients can afford to use and fit within their life circumstances. Also, by communicating about medication management and cost issues physicians can impact patients' subsequent medication adherence. Prior research has demonstrated that patients' medication adherence is better when physicians actively

assess potential barriers to adherence and provide clear messages about medication use (DiMatteo, 1995).

In the conceptual model presented in Figure 5, physician and patient communication have a reciprocal relationship where communication from one impacts the communication of the other. In addition to targeting physicians for communication interventions, it is important to also intervene with patients to improve their participation in medical visit communication. Efforts can be targeted toward patient activation to encourage their participation in the medical visit.

In order for physicians to understand how patients are using their medications, patients must share this information. To that end, it is important that patients be activated to share the details of their medication taking behaviors. Written intervention materials in the form of patient workbooks could be provided to patients in the waiting room that focus on models of desirable communication and prompts for recording and discussing their medication information. The written materials would prompt patients to think about medical visit communication and specific areas to discuss in advance of the visit. Cegala and colleagues (2000) were able to demonstrate that provision of a workbook to patients prior to their scheduled medical visit increased the amount and quality of information these patients provided to their physicians (Cegala, McClure, Marinelli, & Post, 2000). For patients that are routinely accompanied to the medical visit by a family member or friend, communication training efforts could be targeted at both the patient and family. Intervention techniques using models of social support could be utilized to encourage support of patient communication about medications in the medical visit and active responses to physician inquiries. Specifically, interventions could be aimed at both the patient and family member/friends to coach them on model communication behaviors and then provide them both an opportunity to practice those communication skills with each other.

Further, patients should be encouraged to engage in medication cost conversations. In this study some patient responses to physician inquiries about prescription drug coverage or out-of-pocket medication costs led to conversations that impacted the selection of medications. Patients need to be encouraged to engage in medication cost conversations and provide enough detail to facilitate prescription decision-making. To prompt patients to engage in medication cost communication, they must understand that the issue is of importance to the physician. To demonstrate that the issue is of importance and to gather information for physicians, as mentioned above, nurses or other allied health professionals could routinely ask patients about out-of-pocket medication expenses as part of the pre-visit routine. The nurse or allied health professional collecting the medication cost information could also ask patients the degree to which they feel burdened by their out-of-pocket costs and prompt patients to discuss the issue with physicians, if they indicate that they feel burdened by the costs. The pre-visit exchange would also offer an opportunity for patients to practice communicating about medication costs and the nurse could provide encouragement and prompts to pursue particular topics with the physician in the medical visit.

Patients who have been exposed to communication training interventions have been shown to provide physicians with more information and elaborate more in response to physician questions (Cegala et al., 2000). The more information that patients can provide to physicians about their use of medications and medication costs, the more likely that medication prescribed in the medical visit will fit within the context of patients' current medication use and financial constraints. The more that prescribed medications fit within patients' lives, the more likely it is that patients will use those medications. In this way, patient communication can directly impact the selection of medications and subsequent medication adherence.

The revised conceptual framework draws both upon the study findings and the research literature and heavily emphasizes interventions to improve communication. Patient-physician communication has shown to be a relatively consistent predictor of patients' subsequent medication use (Osterberg & Blaschke, 2005). Therefore, directing interventions toward altering patient and physician communication has the potential to impact and improve patients' medication use. Directing communication interventions at both patients and physicians is incredibly important because of the interdependent nature of medical visit communication. Teaching patients and physicians communication skills to improve discussions about medication costs and medication management is sort of like teaching dance steps to two partners where the skills learned in each step come together to form a single flowing movement. Through mutual interactions and genuine information exchanges, medications are more likely to be selected that are appropriate for the condition needing treatment and fit within the context of patients' lives. When medications are selected that fit the patients' needs both medically and personally, patients are more likely to use those medications and to derive optimal therapeutic benefit.

Limitations

This study has several limitations. First, we examined only patients with RA and rheumatologists. The results, therefore, may not generalize to other physician specialties or patient populations. However, RA is an excellent model to study medication costs and management because it is a symptomatic disease that requires medications, many of which are very expensive. Second, both patient and physician samples were convenience samples; self-selection biases are possible.

Third, there was uneven recruitment by physician. In the original study, it was difficult to recruit an even number of RA patients for each physician. Physicians tended to specialize in seeing patients with different types of rheumatic conditions, resulting in

different patient pools for recruitment. The uneven recruitment by physician necessitated grouping low-enrolling physicians together for regression analyses. The fourth limitation, and an analysis issue, was the use of multiple testing. Numerous statistical tests were performed, increasing the chances of Type I error.

Fifth, some categories of the outcome variables of interest were small. A larger sample size would have been beneficial to detect meaningful differences in the outcome variables of interest. Future studies with larger sample sizes should provide more information.

Sixth, the cross-sectional study design does not permit determinations of causal relationships among the variables. The design is appropriate given that there is little other examination of actual medication cost communication, especially in an RA population and a deeper understanding of the communication itself was sought. The study results should be considered exploratory in nature. Given that this was an initial exploration, measurement of particular constructs was limited and the full set of factors affecting communication and medication satisfaction may not have been examined. There was limited information on patients' health insurance and there was no information available on patients' particular prescription drug plans when constructing the plan generosity variable. Therefore, the generosity of coverage had to be constructed from indirect information and may not reflect true plan generosity. Further, there was no information on formularies of various plans, which would itself restrict drug choice and possibly medication communication. There may be mediating variables that affect the relationship between patient-physician communication and medication satisfaction. The extent to which patients were burdened by OOP costs was not measured so there was no way to assess how many people needed help with medication costs but did not discuss it. Nor was there information on whether patients restricted their medication use for cost reasons. In fact, there were no measures of patient

medication taking behavior at the time of the medical visit so it is unclear how regularly patients were taking their medications that did not talk about cost or regimen changes.

Finally, the presence of a tape recorder may have altered physician and patient behavior in the medical visit. Although this seems unlikely to meaningfully affect conclusions since the data were collected for another purpose. Patients and physicians were blind to research hypotheses, reducing the likelihood that they would have specifically altered their behavior in the areas of medication cost communication or disclosure about regimen changes.

Strengths

Despite the limitations, this study has several strengths and makes an important contribution to the knowledge base about medication cost and management communication in RA medical visits. First, this study is one of the first to examine communication about medication costs in a population of patients with RA. Second, this study is one of the first to look simultaneously at medication cost communication and patient disclosure of medication regimen changes. Third, the study looked at actual medical visit communication about medication costs and management, providing a deeper understanding of the content of such communication than has previously been reported. The findings of specific categories and subcategories of medication cost and management communication add to our understanding of the taxonomy of these concepts. Fourth, the use of both qualitative and quantitative methods permitted examination of both the content of medical visit communication and predictors of communication and outcomes. Finally, the study provides practical guidance for clinical practice by identifying a strong relationship between disclosure of patient regimen changes and medication cost communications. Medical visit disclosure of patient-initiated regimen changes may reveal cost issues and visa versa. Through open communication and elicitation of patient thoughts and concerns both issues can be

addressed in the medical visit. The revised conceptual model provides direct guidance on how open communication might be facilitated in the medical visit and may serve as a starting point for future efforts.

Directions for Future Research

Both the implications and limitations discussed above suggest a number of future directions for research on medical visit communication about medication costs and management in RA and more generally. First, the revised conceptual framework has interesting potential for further exploring and advancing communication about medications and warrants additional research. Future studies should utilize intervention components mentioned in the revised conceptual framework to begin to systematically test the impact of these interventions on medical visit communication, as well as medication selection and use. In the absence of comprehensive policies to address medication cost issues, directing efforts to improve communication about cost and management could potentially have immediate impacts on medical visits and treatment selections.

Second, the types of communication about medication costs and management may serve as a useful starting point for designing studies looking at the different constructs of cost and management. The findings from the qualitative study are limited to the particular sample in which they were discovered. Future studies examining the content of communication about medication costs and management in a different population of patients with RA would provide insight into whether the concepts are consistent across populations. Also, future studies should examine the order in which medication cost and management topics are discussed because there may be meaningful patterns based on the order topics are discussed within the visit. It is possible that certain cost or management topics reliably lead to discussion of other cost or management topics. Discerning these communication

patterns may provide guidance on how to maximize the benefit of communication focused educational interventions for patients and physicians.

Third, there is a need to look at medical visit communication about cost and management in a larger patient-physician population. With only eight physicians it was difficult to tell whether physician differences were true differences or merely a function of the small sample. Also, given the patient bias toward reporting high medication satisfaction, a greater patient sample and use of confidential satisfaction reporting would perhaps reveal greater variation in satisfaction and permit the detection of meaningful differences in communication and predictors of satisfaction.

Fourth, the use of a cross-sectional study design in the present study provided only a snapshot of the patient-provider relationships. Using a longitudinal study design would permit the assessment of changing communication over time and improve the ability to make causal inferences among communication characteristics and measured outcome variables. Further, in the context of longitudinal study designs, future research should attempt to identify important mediators and moderators of communication about cost and management and the impact of these variables on outcomes. Patients' trust in physicians, socio-cultural differences between patients and physicians, and patients' assessments of their willingness to pay for medications are just some of the factors that may mediate or moderate the relationship between communication and patient outcomes. Further research on medication cost discussions and health outcomes is especially important with the advent of Medicare Part D given the number of specific plans and the variable impact that different plan types may have on individuals' OOP medication expenses (Safran et al., 2005).

Fifth, future studies should include both observational and perception measures of communication. Direct observation of communication permits reliable assessment of time spent discussing certain topics and the content of communication but it fails to capture

whether patients understood the information provided. In assessing the revised conceptual framework, for example, it would be important to not only assess the content of the communication about pharmacologic treatments but also patients' understanding and opinions about their involvement in medical visit communication and decision-making.

Finally, no organizational or social factors were measured and may have influenced the individual level results obtained in the study. It is entirely possible that the clinics in which patients were seen or the geographic differences in populations may have influenced patient-physician relationships and communication. To address this complexity, future studies need to take into account the influence of organizational and structural factors on communication and outcomes. Multilevel study designs should be employed to assess the impact of higher-level determinants.

Conclusion

This study helps address gaps in the literature regarding communication between physicians and patients about medication costs and medication management. While the healthcare literature has stressed the importance of patient-physician communication about medication costs, this was one of the first studies to examine the content and predictors of actual discussions of medication cost in the context of medication management (Alexander et al., 2003; Alexander & Tseng, 2004). Study results indicate that both medication cost and management communication are complex concepts, which take several forms in routine medical visits. This information, combined with the significant predictors of communication about medication costs and management, facilitated the development of a new framework to conceptualize communication about medications. The study results along with the revised framework may facilitate the development of interventions that focus on patient and physician communication to activate discussion of medication costs and medication management issues in rheumatology. Even with significant policy changes affecting the

price and availability of medications, communication about medication in medical visits is likely to remain a salient issue. Interventions utilizing technologies to bring cost and prescribing information to the point of care and those using allied health professionals to activate discussion of critical medication topics may go a long way to improving communication in medical visits where the number topics to cover far exceeds the time allotted.

MEDICAL RECORD INFORMATION ~ Older Adults and Drug Decisions Study

Patient ID _____ **Medical Record #** _____ **Baseline Visit Date:** _____ **Med Rec Collected Date:** _____

Directions

Please review the patient medical record and mark the following:

1. Number of prior visits – look through the records mark the number of prior visits the patient has had with the physician that saw them on their baseline visit date. The baseline visit is the visit in which the patient and physician had their interaction audiotape recorded. The patient may have seen other doctors at the clinic so be certain to record only the number of visits the patient has had with the doctor seen for the baseline visit.
2. Weight – please record the medical chart noted patient weight from the baseline visit. The weight may be recorded in pounds (lbs.) or kilograms (kg). It is incredibly important that weights be recorded for patients receiving Infliximab (Remicade®) infusions.
3. Medications – please mark all the recorded rheumatoid arthritis medications noted in the medical record on the date of the baseline visit. This means medications that the patient is supposed to be taking before seeing the physician for the baseline visit. Check the box next to the medication name, circle or record the dosage (if known), and indicate the date the medication was started. If the dose or medication start dates are unknown indicate that on the sheet. For the medication notes please review physician notes from the baseline visit and follow-up visits through 12 months and follow these guidelines:
 - a. Adherence – record any notes in the medical record that refer to patient adherence/non-adherence on the date of the baseline visit. For example, if the physician records a note that the patient has only been taking been taking prednisone and no other medications – record verbatim the physician’s notes in the adherence box.
 - b. Cost – record any notes in the medical record that refer to medication cost or issues with insurance, etc. that affect cost. For example, if the record contains a note about a patient applying for a prescription drug assistance program, Medicaid, etc. write verbatim the physician’s note in the cost box.
 - c. Regimen Changes – record any physician notes about regimen changes or proposed regimen changes. Record notes on regimen changes made at the baseline visit up through one year of follow-up visits. Next to each regimen change notes write the date of the visit in which the change occurred. For example, if the record contains a note about starting a patient on a TNF-alpha inhibitor based on insurance authorization, write verbatim the physician’s note in the cost box and 11/20/03. Alternately, if the physician recommends a prednisone taper record that kind of note as well along with the date.

4. Other medications – in this section record notes about medications in the medical record that are not mentioned in #2 above. These medications may or may not be medications for treating rheumatoid arthritis. Be sure to record all details contained in the record including: medication name, dose, route of administration, frequency of administration, start and/or stop date, and reason for stopping (if noted).
5. Health insurance – please circle the type of health insurance noted in the medical record. If category is not immediately clear, record verbatim what is in the record. In addition, to the health insurance category please note any information provided in the record about the patient’s prescription drug plan or prescription drug assistance programs if included in the record. Definition of the categories are as follows:
 - a. Private or employer sponsored insurance – these are programs provided by companies such as Blue Cross and Blue Shield of North Carolina, the state employees health plan, Aetna, Cigna, etc. This category contains all the insurance types that are not directly funded and maintained as either a state or federal entitlement program.
 - b. Medicare with supplemental insurance – this category includes people who have Medicare listed as their primary insurance and then have a secondary private or employer sponsored insurance program listed in the record.
 - c. Medicare only – this category includes people who only have Medicare listed as their health insurance provider
 - d. Medicaid only – this category includes people who only have Medicaid listed as their health insurance provider
 - e. Medicare + Medicaid – this category includes people who have both Medicare and Medicaid listed as health insurance providers.
 - f. Self-pay – this category includes people who have a note that they are self-pay customers and/or have a note that they have no known health insurance provider.
6. Other notes – record any notes in this section that seem relevant to the patient’s medications or medication taking that are not contained in any other area.

APPENDIX 3: MEDICAL VISIT AUDIOTAPE CODING RULES

Cost as a Feature of Medication Management Communication in Medical Visits

Audiotape Coding Rules

Preparations for Coding:

For this analysis all the audiotapes should be from the baseline or initial recorded visit. All baseline audiotapes should end with an “a”.

A warm-up time of approximately 2-3 minutes is recommended for each tape. Use the warm-up time to listen to the tape and get used to the voices and dialects of the physician and the patient. During the warm-up, the coder may also complete some of the information about the tape on the coding sheet.

When Coding:

1. Use a dark-lead pencil to code the information on the coding tool.
2. Listen to each file at least 2 or more times in order to correctly code the visit.
 - a) Use the first time to code information on the issues outlined on the following pages. There is a great chance that you will not be able to capture all information.
 - b) Use the second time to capture the information that you have missed during the first time, and to verify that you have followed the rules for coding.
3. Make sure that **each item** and category is coded (circled) appropriately. We recommend double-checking your work.
4. Code legibly and complete all relevant details requested.
5. In order to make accurate assessments pay special attention to the **Notes** and **Examples** throughout the rulebook to clarify anything that you may be confused about.
6. In general, more information is always preferred. If you are unsure of how to code an interaction, record as much detail about the encounter and record any notes or questions that may be helpful in determining why a particular coding decision was made.
7. Whenever you feel that a tape is incomplete (i.e. part of the tape was cut off, etc.), complete the coding tools to the best of your ability. Then, for the parts of the coding tools that you are unsure about, indicate this with a marker and write the reason you think the tape was incomplete.

To Code:

Header: Tape Identification and General Information

- **Tape ID#:** Be sure to put the patient’s 4-digit, single-letter identification number. It should be in the following format:
Example: 2303a
 - 2303 is the patient ID number for the project. The first two digits identify the physician and the second two identify the patient. In this case, physician 23 is seeing patient 03.
 - “a” indicates that the tape is from the baseline/initial medical visit
- **Coder Initials:** Put your initials here.

- **Date Coded:** Record the current date on which you are coding the tape.
- **Date of Medical Visit:** Write down the date that the medical visit was audiotape recorded. For the date of the medical visit, record the date listed as the second half of the patient ID. As an example, if the ID is 2303a_051505, the date of the medical visit is May 15, 2005.

Note:

 1. The physician or research assistant may mention the date on the actual tape recording but do NOT record this as the medical visit date.
- **Length of Physician Visit:** Write in the time (duration/length) of physician visit in minutes. **Only record the time that the physician and patient are interacting.** The final time should be recorded once the physician or patient has left the room for good, or there is no dialogue between the two signaling that the interview has ended. The duration of the exam can be seen on the digital apparatus you are using to listen to the interview, whether you are using a computer, CD player, etc. Also, keep track of how long the patient is alone or with a clinician other than the primary physician and subtract it from the total length of the tape.

Note:

 1. Do not include the time when the patient interacts with a nurse (or another clinician) after the physician has completed the exam, nor when the patient is alone in the exam room.
 2. The coder should stop coding when the interaction with the physician has ceased. This time may be shorter than the total length of time displayed for the digital recording.
- **Other Professionals Present:** Circle Yes/No if another healthcare provider or social worker, etc. is present in the room during the interview. If it is clear, also write the title of person present.

Examples of others present:

 - nurse
 - training physician
 - social worker
 - translator

Note: Please write “Clinician” if the identity of the healthcare provider is unclear

Initial Page Content: Friends/Family Present for Medical Visit Exam

- **Friend and/or family present:**
 - Circle **Yes** if a friend/family member is present in the exam room during the taping of the interview.
 - Circle **No** if there is not a friend/family member in the room during the taping of the interview.

Example of friends/family:

 - Spouse (husband/wife)
 - Mother, father, sister, brother, daughter, son
 - Other family member (aunt, uncle, etc.)
 - Pastor and/or other church members
 - Neighbor or friend

Note:

 1. Please write “Unknown” if the identity of the caregiver is unclear.
 2. During the exam interview, if the caregiver at anytime asks a question, or initiates a discussion about medication costs or medication management – the occurrence of these events should be coded on the coding form but it should be noted that it was the caregiver and NOT patient bringing up the question/conversation. For example, (Caregiver) can be written after coding for a conversation item initiated by the caregiver to separate it out from conversation initiated by the patient.

Table: Medication Costs and Medication Self-Management

Notes about Medications

- For the purposes of this study, we are interested in medications used to treat arthritis and medications commonly prescribed to persons with rheumatoid arthritis. See **Appendix A** for a list of medications that might be discussed during the medical visit.
- Medication conversations of interest should involve medications the patient is taking, has taken, or may take. Do NOT code medication conversations that center around medications that the patient’s family, friends, etc. are taking.
- This includes medications that the patient should have been taking since the last visit, medications the patient has stopped taking or calibrated since last visit, new medications that are being prescribed during this visit, medications that are to be started contingent on something or are just being considered, medications that are just mentioned, and/or medications that are administered in the clinic.
- This also includes medications that the patient is taking regardless of whether or not they were prescribed by the medical visit physician.

Medication Costs

Medication cost conversation includes both indirect and direct communication about medication costs. Direct communication involves explicit communication about the prices patients pay for medications, the total sum a patient has to pay for medications, or the retail price of a medication. As a general rule, direct communication can be thought of as discussion about the dollars and cents of medication costs. Indirect communication, on the other hand, is likely to not involve expression of cost numbers. Such communication may center on physician provision of samples to offset medication costs, prescription drug assistance programs run by pharmaceutical companies and foundations to provide medications at little or no charge, or the influence of patients’ prescription drug insurance coverage.

| | | |
|--|-----------------------------------|--|
| Did the patient or physician discuss issues related to medication costs ? Record discussion of direct medication costs (e.g. out-of-pocket costs incurred by patients) or indirect medication costs (e.g. prescription drug assistance programs or prescription drug insurance coverage) | Yes No | If Yes, ___ Patient initiated medication cost discussion ___ Physician initiated medication cost discussion |
| | Time of Discussion (1) : _____ | |
| | Time of Discussion (2) : _____ | |
| | Time of Discussion (3) : _____ | |
| | Time of Discussion (4) : _____ | |
| Time of Discussion (5) : _____ | | |

➤ **Did the patient or physician discuss issues related to medication costs?**

The coder must circle Yes or No. While multiple discussions of medication cost may occur within a single visit, one conversation about medication costs is sufficient to circle Yes.

When do we circle Yes?

Code Yes whenever:

1. The patient and/or physician discuss direct medication costs (i.e. the dollars and cents of medications).
Example:

Physician – So it would be nice ... we talked about the new medicines the biologic agents: Enbrel, Remicade, Humira. Those are alternatives.

Patient – I'd rather hold off on Enbrel. Remicade the insurance probably won't pay for it. Someone told me it's like \$3000/month.

Physician – It should be around \$1200 a month.

2. The patient and/or physician discuss the provision of medication samples.

Example:

Physician – You are still taking that Evista, right?

Patient – Yes

Physician – I think I have some samples in my cupboard that I can give you, I know it can be expensive.

3. The patient and/or physician discuss pharmaceutical assistance programs.

Example:

Patient – Someone told me that if you completed this form I could get the company to pay for my medication.

Physician – I'd be happy to complete the form. Do you need us to fax it for you?

4. The patient and/or physician discuss patient's insurance coverage and how that might influence prescribing. Discussions about Medicare Part D and the influence of Part D on patients' medication costs are also relevant insurance coverage communication.

Example:

Physician – What kind of insurance do you have for your prescription drugs?

Patient – I only have my Medicare and a small supplement to pay for my medications.

Physician – It pays for a percentage of the cost of your medicines?

Patient – Yes

Physician – Okay, in terms of making medication decisions I think we need to recognize the potential cost barrier.

When do we circle No?

We circle No whenever:

1. The patient and/or physician are discussing cost issues beyond medications. Conversations about procedure costs or the cost of medical visits and services are separate and should not be coded affirmatively.
2. The patient and/or physician discuss medication costs for someone other than the patient.
3. The patient and/or physician discuss abstract medication costs not related to the patient or medication decision-making for the patient (e.g. the influence of direct-to-consumer medication advertising on medication prices broadly speaking).
4. The patient and/or physician discuss follow-up tests, procedures, etc. that would be required in the future by taking a medication (e.g. regular blood testing for patients taking methotrexate). While further tests and procedures will mean future costs, such costs are not guaranteed and are variable. For the purposes of coding consistency and reliability, do not code for adjuvant medication costs unless there is specific and direct cost discussion related to medication-related tests and procedures.

➤ Time of Discussion

For each conversation about medications costs in the medical visit record the start and end time of the conversation as is listed on the digital audio player. The start and end time of conversation about medication costs should be recorded for each conversation about cost occurring in the visit. As an example, for a conversation beginning at 04.05 and ending at 10.20, the coder should record both the start and end time on the Time of Discussion line. There may be multiple conversations about cost as

patients and physicians begin a conversation go on to something else and then return to the cost conversation. This should be repeated for each cost conversation. Five “Time of Discussion” lines are provided but please record all instances of discussion even if this goes beyond five.

(If Yes) Coding Specific Elements of Communication about Medication Costs

➤ **Patient initiated medication cost discussion**

Patient initiated medication cost discussion should receive a mark if the patient brought up a medication cost topic, either direct or indirect, *before* the physician in the medical visit. This means that if a patient asks the physician about obtaining a medication from a prescription drug assistance program or makes a statement about the cost of a prescription prior to the physician asking the patient a question about medication costs or making a statement about medication costs then the coder should mark that the patient initiated medication cost discussion. As has been written previously, multiple discussions of cost may occur in the visit. However, for the purposes of coding this item, we are interested only in who *first* brings up the topic within the medical visit since multiple discussions are likely to flow from first initiation of the topic.

➤ **Physician initiated medication cost discussion**

Physician initiation of medication cost discussion should be coded in the manner described above except the physician must bring up a medication cost topic in the visit, either direct or indirect, *before* the patient. Again, it means that if the physician asks a question about prescription drug insurance coverage or details a medication cost before the patient asks a question or makes a statement about it then the coder should mark that the physician initiated medication cost discussion.

➤ **Number of questions that patient asked about medication cost-related issues**

Throughout all the medication cost discussions keep a tally of the number of questions that patients ask. These questions may be open or closed-ended but should be related to the medication cost discussion. Below are some examples of patient questions:

Patient – How much does this Arava usually cost?

Patient – Do you think I might qualify for the patient assistance program?

Patient – Do you know if there is a way I can receive my medications at a lower price?

Coders should also count questions that may be framed as statements or semi-questions where it is still clear that the patient is inquiring about medication costs.

Patient – I assume it is okay for me to buy generic Naprosyn to save money.

Patient – Methotrexate is cheaper than Arava, right?

➤ **Number of questions that physician asked about medication cost-related issues**

Again this should be coded in the same manner as questions patient asked. A tally should be kept of all types of medication-related questions asked during medication cost conversations. Below are some examples of physician questions:

Physician – What kind of prescription drug insurance do you have?

Physician – How much do you generally pay a month for your medicines?

Physician – Would you like me to put you in touch with our payment specialist to see if we can help you get those medicines?

Coders should also count questions that may be framed as statements or semi-questions where it is still clear that the physician is inquiring about medication costs.

Physician – You’re on disability (?)

Physician – You’re not paying for Humira, right?

Patient-Initiated Changes to the Medication Regimen

Patient-initiated changes to the medication regimen can be considered a facet of medication self-management and are of interest in this study because their relationship to medication cost. For our purposes, medication self-management is defined as a patient’s ability to manage symptoms through medications and deal with physical and psychosocial consequences of their medication-taking. Effective management involves a continuous feedback loop of monitoring one’s condition, taking medications, and managing medication effects. Rheumatoid arthritis patients must make decisions about the amount, timing, and quantity of medication to take based on a number of personal factors, including the cost of their medications. Using this concept of self-management as a base, we are interested in examining patient initiated changes to the medication regimen that require a behavior change. Patients may choose to take less or more medication than prescribed, split-pills to stretch out the time between prescription fills, alter their dosing schedule to accommodate their lifestyle, add or drop medications from their regimens, or substitute one medication for another. These examples do not make up the entire universe of possible conversations about patient-initiated changes in the regimen but should provide some guide for the types of discussions likely to occur. In the context of this study, we are primarily interested in the discussions between patients and physicians about patients’ independent, purposeful actions to manage their medications. Physicians may actively participate in these discussions but the changes to the regimen should be patient initiated and directed.

| | | | |
|---|--------------------------|----|--|
| <p>Did the medical visit include discussion of patient-initiated changes to the medication regimen?</p> <p>Patient-initiated changes to the medication regimen are a facet of medication self-management. These are independent, purposeful patient changes in the drug regimen requiring a behavior change. Discussions include but are not limited to: patients taking less medication than originally prescribed, altering times of medication administration, pill-splitting, adding a medication, or substituting one medication for another.</p> | Yes | No | <p>If Yes,</p> <p>Brief Description of Topic(s) Discussed:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> |
| | Time of Discussion (1) : | | |
| | _____ | | |
| | Time of Discussion (2) : | | |
| | _____ | | |
| | Time of Discussion (3) : | | |
| _____ | | | |
| Time of Discussion (4) : | | | |
| _____ | | | |
| Time of Discussion (5) : | | | |
| _____ | | | |

➤ **Did the medical visit include discussion of patient-initiated changes to the medication regimen?**

The coder must circle Yes or No. While multiple discussions of patient’s changes to the medication regimen may occur within a single visit, one conversation about a patient-initiated change to the regimen is sufficient to circle Yes.

When do we circle Yes?

Code Yes whenever:

1. The patient and/or physician discuss how the patient is purposefully taking less medication than prescribed. This may involve patients splitting pills or taking fewer doses per day.

Example:

Patient – I’ve felt pretty well and didn’t want to take all that prednisone. I’ve only been taking one pill every other day.

Physician – Okay, so you’re only taking 5mg every other day instead of every day?

2. The patient and/or physician discuss the patient purposefully taking more medication than prescribed.

Example:

Physician – You’re taking 5mg of prednisone daily?

Patient – No, I’m taking 10mg a day. I was feeling so achy and stiff that I started taking 10mg a day instead 5mg.

Physician – Hmm... all right. How long are you stiff in the morning?

3. The patient and/or physician discuss the patient taking over-the-counter medicines or medicines that were not prescribed by the medical visit physician for the patient’s arthritis.

Example:

Patient – When it got cold outside I started to feel more aches and pains so I got some Aleve at the pharmacy and have been taking that.

Physician – How many do you take a day?

Patient – I usually take two.

4. The patient and/or physician discuss the patient substituting one medication for another.

Example:

Patient – I just didn’t like Bextra. I didn’t think it was doing anything for me so I’ve been taking Naprosyn instead?

Physician – I don’t think I have a problem with that. How many milligrams are you taking?

When do we circle No?

We circle No whenever:

1. The physician is prescribing medications for the patient and making the prescribing decisions. To count as patient initiated changes to the regimen there must be some initiation/discretion on the part of the patient about managing the medication regimen. The change has to be independently and purposefully chosen on the patient’s part so code No if the patient accidentally takes more or less medication or if the change is initiated by another physician.
2. The patient and/or physician are discussing medication-taking broadly. If the patient and physician are discussing **general** patient medication management strategies, then code No for this item. An example, would be discussing what people in general do to manage their medicines like pill splitting. In order to code Yes, it needs to be clear that the discussion is centering on changes to the patient’s regimen that he/she has initiated.

➤ Time of Discussion

For each conversation about patient-initiated changes to the regimen in the medical visit record the start and end time of the conversation as is listed on the digital audio player. The start and end time of conversation should be recorded for each conversation about management occurring in the visit. As an example, for a conversation beginning at 04.05 and ending at 10.20 the coder should record the start time and end time on the Time of Discussion line. There may be multiple conversations so this should be repeated for each patient-initiated change to the regimen conversation. Five “Time of Discussion” lines are provided but please record all instances of discussion even if this goes beyond five.

(If Yes) Brief Description of the Topics Discussed

In this space please record the topic areas discussed during the patient-initiated changes to the medication regimen discussions. As described above, topics may include alternate dosing schedules, pill splitting, taking more medication than prescribed, or substituting one or more medications for another. However, these are just sample topics so to help better understand the universe of topics discussed as part of this aspect of patient medication self-management coders are requested to write the topics in this section. If you are unsure whether the topic constitutes a patient-initiated change in the medication regimen please record the topic and a note indicating the ambiguity. Differences or questions among coders will be resolved by consensus.

- **Record any helpful notes about the visit below the coding table.**

If the tape is difficult to hear, the dialects are hard to understand, or there appear to be important gaps in the medication conversations, please record them below the coding table. Coders are encouraged to please record any information that you believe will be helpful for understanding your coding decisions and/or the content of the audiotape.

Appendix A

RHEUMATOID ARTHRITIS MEDICATIONS

Antimetabolites

1. Methotrexate (Rheumatrex)

Antirheumatic agents

1. Sulfasalazine (Azulfidine)
2. Leflunomide (Arava)
3. Hydroxychloroquine (Plaquenil)

Immunomodulators

1. Entanercept (Enbrel)

Immunosuppressive

1. Azathioprine (Imuran)
2. Mycophenolate mofetil (Cellcept)

Monoclonal antibodies

1. Infliximab (Remicade)
2. Adalimumab (Humira)

Corticosteroids

1. Prednisone (Deltasone, Sterapred)
2. Dexamethasone (Decadron)
3. Methylprednisolone (Medrol)
4. Triamcinolone (Aristocort)
5. Hydrocortisone (Aristocort)
6. Prednisolone (Orapred)

PAIN MEDICATIONS

Opioid Agonists

1. Codeine (Methylmorphine)
2. Fentanyl (Sublimaze, Actiq, Duragesic)
3. Hydromorphone (Dilaudid)
4. Levorphanol (Levo-Dromoran)
5. Meperidine (Demerol)
6. Methadone (Dolophine, Methadose)
7. Morphine Sulfate (Avinza, MS Contin, Kadian, Roxanol, Oramorph SR, MSIR)
8. Oxycodone (Roxicodone, OxyContin, Percolone, OxyFAST, OxyIR)
9. Oxymorphone (Numorphan)
10. Propoxyphene (Darvon-N, Darvon Pulvules)
11. Methyldihydromorphinone (Metopon)
12. Hydrocodone (Vicodin-Zygon)

Opioid Antagonists

1. Nalmefene (Revex)
2. Naloxone (Narcan)

Opioid Agonist-Antagonists

1. Buprenorphine (Buprenex)
2. Butorphanol (Stadol, Stadol NS)
3. Nalbuphine (Nubain)
4. Pentazocine (Talwin)

Other Analgesics

1. Acetaminophen (Tylenol)
2. Tramadol (Ultram)
3. Lidocaine Patch (Lidoderm)

Non-selective NSAIDs

1. Aspirin* (Bayer, Bufferin, Ecotrin, etc)
2. Diclofenac (Voltaren, Cataflam)
3. Diflunisal (Dolobid)
4. Etodolac (Lodine, Lodine XL)
5. Fenoprofen (Nalfon)
6. Fluriprofen (Ansaid)
7. Ibuprofen (Motrin, Advil, Nuprin, Rufen)
8. Indomethacin (Indocin)
9. Ketoprofen (Orudis, Acton, Oruvail, Orafen)
10. Ketorolac (Toradol)
11. Meclofenamate (Meclomen)
12. Meloxicam (Mobic)
13. Nabumetone (Relafen)
14. Naproxen (Naprosyn, Aleve, Anaprox, Naprelan)
15. Oxaprozin (DayPro)
16. Piroxicam (Feldene)
17. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
18. Sulindac (Clinoril)
19. Tolmetin (Tolectin)

* At least 325 mg of aspirin should be taken every 4 hours to adequately treat pain. Baby aspirin or 81 mg every day is used for coronary artery disease prevention and not for pain treatment.

Selective COX-2 NSAIDs

1. Celecoxib (Celebrex)
2. Rofecoxib (Vioxx)
3. Valdecoxib (Bextra)

Opioid Analgesic Combinations

1. Acetaminophen + codeine (Tylenol #2,#3,#4, Capital with Codeine suspension)
2. Acetaminophen + hydrocodone (Anexsia, Arexxia, Lorcet, Lortab, Maxidone, Vicodin, Zydone)
3. Acetaminophen + propoxyphene (Darvocet, Wygesic)

- | | |
|--|-------------------------|
| 4. Hydrocodone + ibuprofen | (Vicoprofen) |
| 5. Oxycodone + Acetaminophen | (Percocet, Tylox) |
| 6. Oxycodone + Aspirin | (Percodan) |
| 7. Acetaminophen+butalbital+caffeine+codeine | (Fioricet with Codeine) |
| 8. ASA+butalbital+caffeine+codeine | (Fiorinal with Codeine) |

Non-Opioid Analgesic Combinations

- | | |
|--------------------------------------|--|
| 1. Aspirin+Acetaminophen+caffeine | (Excedrin, Goody's Headache Powder, BC Powder) |
| 2. Acetaminophen+Butalbital+caffeine | (Fiorcet, Esgic) |
| 3. Aspirin+butalbital+caffeine | (Fiorinal) |
| 4. Acetaminophen+tramadol | (Ultracet) |
| 5. ASA+MgAl+Ca Carbonate | (Ascriptin) |
| 6. Carisprodol+ASA | (Soma Compound) |
| 7. Orphenadrine+ASA+caffeine | (Norgesic) |

Muscle Relaxants

- | | |
|----------------------------|--|
| 1. Baclofen | (Lioresal) |
| 2. Carisoprodol | (Soma) |
| 3. Chlorzoxazone | (Paraflex, Parafon Forte DSC, Remular-S) |
| 4. Cyclobenzapine | (Flexeril) |
| 5. Dantrolene | (Dantrium) |
| 6. Diazepam | (Valium, Diastat) |
| 7. Diclofenac+mistoprostol | (Arthrotec) |
| 8. Metaxalone | (Skelaxin) |
| 9. Methocarbamol | (Robaxin, Robaxin-750) |
| 10. Orphenadrine | (Norflex) |
| 11. Quinine sulfate | |
| 12. Tizanidine | (Zanaflex) |

Adjuvant Pain Medications

- | | |
|------------------|------------|
| 1. Amitriptyline | (Elavil) |
| 2. Carbamazepine | (Tegretol) |
| 3. Gabapentin | (Neurotin) |
| 4. Nortriptyline | (Pamelor) |

Herbal or Nutritional Supplements

- | | |
|----------------------------|-------------------------|
| 1. Glucosamine | |
| 2. Glucosamine chondroitin | (Osteo Bi-Flex, etc) |
| 3. MSM | (Methylsulfonylmethane) |
| 4. SAmE | |

Topical Analgesics

1. Arthritis Hot
2. Aspercreme
3. Ben-Gay Cream
4. Capsaicin
5. Deep Heating
6. Icy Hot
7. Mineral Ice
8. Thera-gesic Cream

Common Drug Information Fact Sheet

| Drug Name: Brand/(Generic) | Drug Class | What is it used for? | Dosage form(s) | Common Side effects | Precautions/ Monitoring |
|---|--|--|---|---|---|
| Rheumatrex, Tresall/ (Methotrexate) (MTX) | Antimetabolite, antineoplastic: decreases the number of red blood cells in the bone marrow, and helps control symptoms | Severe rheumatoid arthritis (RA), cancer, severe skin rash, lymphomas, and leukemia | Tablet, Injection: (IM/IV/IT) | Stomach ulcer, thinning hair, pain at injection site, nausea, bruising, general body discomfort, unusual tiredness, chills/fevers, dizziness, vomiting, increased risk of bleeding, loss weight, | Monitor: liver function tests, chest x-rays, kidney tests, WBC, CBC and platelets, immunosuppressive agent so will be more prone to infection |
| Folic Acid | Nutritional supplement: Vitamin B 9 needed by the body to produce RBC, platelets, WBC | Cofactor often administered in combination with MTX to minimize SE, anemia | Tablet Injection (IM/IV) | (rare): Skin rash, itching, redness, difficulty breathing | Not common |
| Azulfidine/ (Sulfasalazine) | Antirheumatic agent, anti-inflammatory | RA, diarrhea, rectal bleeding, or ulcerative colitis | Tablet, enteric coated | diarrhea, headache (HA), loss of appetite, upset stomach, vomiting, stomach pain | May cause folate deficiency, contraindicated if have a sulfa allergy |
| Arava/ (Leflunomide) | Antirheumatic Agent: decreases sx. of RA, slows damage to the joints caused by the disease | Treatment of active RA | Tablet | Diarrhea, infection, hair loss, HA, dizziness, nausea/ vomiting (n/v), stomach pain, loss appetite, mouth sores., flu-like symptoms | Monitor liver function (LFT's), hematological function (CBC), and if infection occurs may hold therapy (immunosuppressive agent) |
| Plaquenil/ (Hydroxychloroqui ne) | Antirheumatic Agent, antimalarial ne) | RA, systemic lupus erythematosus (SLE), acute attacks of malaria | Tablet | Headache, dizziness, loss of appetite, n/v, diarrhea, stomach pain, skin rash, ocular changes, skin discoloration | Monitor: eye exam, CBC, and test for muscle weakness, |
| Enbrel/(Entanercept) | Antirheumatic Agent, tumor necrosis factor (TNF) inhibitor | RA, juvenile RA, and psoriatic arthritis, ankylosing spondylitis (AS) | Injection: (subcut.) | Irritation/bruising at injection site, runny nose, sneezing, HA, n/v, weakness, cough, dizziness, rash | May affect defenses against infections, may discontinue if a serious infection develops |
| Humira/(Adalimum ab) | Antirheumatic Agent, monoclonal antibody, (TNF) inhibitor | Used alone or in combo. with MTX to tx. symptoms of RA | Injection: (subcut.) | Irritation/bruising/swellin g at injection site, stomach pain, upset stomach, sinusitis, flu- like syndrome | May increase chance of a serious infection, may discontinue if a serious infection develops |
| Remicade/(Inflixim ab) | Antirheumatic Agent, monoclonal antibody: TNF inhibitor | Used with MTX to tx. symptoms of RA when MTX alone did not work, Crohn's disease, AS | Injection (IV) | Infusion reactions, upset stomach, depression, heartburn, HA, runny nose, back pain, cough, sinusitis | May affect defenses against infections and increase risk, may discontinue if a serious infection develops |
| Deltasone, Sterapred/ (Prednisone) (Prednisolone): injection form | Corticosteroid: similar to natural hormone produced by your adrenal glands | Relieves swelling, inflammation, redness, and pain; used to tx. variety of diseases such as arthritis | Tablet, solution, syrup, concentrate | Easy bruising, increased hair growth, weakens bones, acne, HA, insomnia, anxiety, irritate stomach, vomiting, hyperglycemia | Discontinuation of long-term therapy requires gradual withdrawal by tapering dose . more susceptible to infection |
| Celebrex/(Celecoxib) Vioxx/(Rofecoxib) Bextra/(Valdecoxib) | COX 2 inhibitor: Nonsteroidal Anti- inflammatory (NSAID) | Relieves pain, tenderness, inflammation, and stiffness of arthritis | Capsule, tablet, suspension | Upset stomach, stomach pain, diarrhea, gas or bloating, sore throat , weakness, heartburn, HA | Monitor LFT's, and any signs of GI bleed; must evaluate cardiovascular profile |

APPENDIX 4: AUDIOTAPE TRANSCRIPTION RULES

Cost as a Feature of Medication Management Communication in Medical Visits Audiotape Transcribing Rules

For this analysis all the audiotapes should be from the baseline or initial recorded visit. All baseline audiotapes should end with an “a”.

See sample transcript

1. Name the word file the tape’s number – the tape should be numbered with a 4 initial digits indicating tape ID number, the letter “a”, an underscore, and then six digits indicating the date of the recording (e.g. 2099a_020203).
2. At the top of each file put the tape ID number, the total time of the visit according to the digital player, the transcriber’s initials, the date of the transcription, and a key indicating the shorthand used for the people in the visit (e.g. D – Doctor, P-Patient, S-Spouse, U – Unknown). If there is more than one physician, etc. in the exam room number use letters and numbers (e.g. P1 – Main physician, P2 – Resident physician).
3. Insert line numbers and page numbers using the word functions
4. A new line should be started each time a new person speaks. The new line should begin with the key initial of the person speaking (e.g. D – Doctor).
5. If an interruption occurs (e.g. phone call, knock at door)-type interruption in capital letters on a new line. If the interruption is a person walking in the room please transcribe what is said and put what the person says who enters the room in brackets. For example:
Interruption: [nurse:]
If the interruption is a phone call type Interruption: Phone Call
6. Put a “.” For every second of silence.
Example:
..... (These dots would indicate 6 seconds of silence)
7. If you are unclear of what they are saying put it in parentheses.
Examples: (foot) (words)
8. Use question marks and periods
9. If a speaker breaks off in the middle of a word or phrase, this is marked by a hyphen as in “haven’t felt like-“
10. Double parentheses enclose descriptions
Examples:
((cries))
((laughs))
((annoyed))
11. To protect confidentiality, blank lines substitute for proper names. Do not transcribe any patient, caregiver, clinic, town, or provider first or last names. Do not transcribe phone numbers. However, do put doctor before reference to another doctor (e.g. Dr. ____). Also if the relationship of the person named is known, please include in parentheses the relationship (e.g. patient’s cousin, patient’s cardiologist).
Examples:
_____ (patient’s cousin)
Dr. _____

For the purposes of this study, we are interested in medications used treat arthritis and medications commonly prescribed to persons with rheumatoid arthritis. See below for a list of medications that might be discussed during the medical visit.

RHEUMATOID ARTHRITIS MEDICATIONS

Antimetabolites **DRUG CLASS**

Methotrexate **GENERIC NAME** (Rheumatrex) **BRAND NAME**

Antirheumatic agents

Sulfasalazine (Azulfidine)
Leflunomide (Arava)
Hydroxychloroquine (Plaquenil)

Immunomodulators

Entanercept* (Enbrel)

Immunosuppressive

Azathioprine (Imuran)
Mycophenolate mofetil (Cellcept)

Monoclonal antibodies

Infliximab* (Remicade)
Adalimumab* (Humira)

* These medications are also collectively called TNF-alpha inhibitors

Corticosteroids

Prednisone (Deltasone, Sterapred)
Dexamethasone (Decadron)
Methylprednisolone (Medrol)
Triamcinolone (Aristocort)
Hydrocortisone (Aristocort)
Prednisolone (Orapred)

PAIN MEDICATIONS

Opioid Agonists

Codeine (Methylmorphine)
Fentanyl (Sublimaze, Actiq, Duragesic)
Hydromorphone (Dilaudid)
Levorphanol (Levo-Dromoran)
Meperidine (Demerol)
Methadone (Dolophine, Methadose)
Morphine Sulfate (Avinza, MS Contin, Kadian, Roxanol, Oramorph SR, MSIR)
Oxycodone (Roxicodone, OxyContin, Percolone, OxyFAST, OxyIR)
Oxymorphone (Numorphan)
Propoxyphene (Darvon-N, Darvon Pulvules)

Methyldihydromorphinone
Hydrocodone

(Metopon)
(Vicodin-Zygon)

Opioid Antagonists

Nalmefene
Naloxone

(Revex)
(Narcan)

Opioid Agonist-Antagonists

Buprenorphine
Butorphanol
Nalbuphine
Pentazocine

(Buprenex)
(Stadol, Stadol NS)
(Nubain)
(Talwin)

Other Analgesics

Acetaminophen
Tramadol
Lidocaine Patch

(Tylenol)
(Ultram)
(Lidoderm)

Non-selective NSAIDs

Aspirin
Diclofenac
Diflunisal
Etodolac
Fenoprofen
Fluriprofen
Ibuprofen
Indomethacin
Ketoprofen
Ketorolac
Meclofenamate
Meloxicam
Nabumetone
Naproxen
Oxaprozin
Piroxicam
Sulfasalazine
Sulindac
Tolmetin

(Bayer, Bufferin, Ecotrin, etc)
(Voltaren, Cataflam)
(Dolobid)
(Lodine, Lodine XL)
(Nalfon)
(Ansaid)
(Motrin, Advil, Nuprin, Rufen)
(Indocin)
(Orudis, Acton, Oruvail, Orafen)
(Toradol)
(Meclomen)
(Mobic)
(Relafen)
(Naprosyn, Aleve, Anaprox, Naprelan)
(DayPro)
(Feldene)
(Azulfidine, Azulfidine EN-tabs)
(Clinoril)
(Tolectin)

Selective COX-2 NSAIDs

Celecoxib
Rofecoxib
Valdecoxib

(Celebrex)
(Vioxx)
(Bextra)

Opioid Analgesic Combinations

Acetaminophen + codeine

Acetaminophen + hydrocodone

Acetaminophen + propoxyphene
Hydrocodone + ibuprofen

(Tylenol #2,#3,#4, Capital with Codeine suspension)
(Anexsia, Arexxia, Lorcet, Lortab, Maxidone, Vicodin, Zydone)
(Darvocet, Wygesic)
(Vicoprofen)

| | |
|---|-------------------------|
| Oxycodone + Acetaminophen | (Percocet, Tylox) |
| Oxycodone + Aspirin | (Percodan) |
| Acetaminophen+butalbital+caffeine+codeine | (Fioricet with Codeine) |
| ASA+butalbital+caffeine+codeine | (Fiorinal with Codeine) |

Non-Opioid Analgesic Combinations

| | |
|-----------------------------------|--|
| Aspirin+Acetaminophen+caffeine | (Excedrin, Goody's Headache Powder, BC Powder) |
| Acetaminophen+Butalbital+caffeine | (Fiorcet, Esgic) |
| Aspirin+butalbital+caffeine | (Fiorinal) |
| Acetaminophen+tramadol | (Ultracet) |
| ASA+MgAl+Ca Carbonate | (Ascriptin) |
| Carisprodol+ASA | (Soma Compound) |
| Orphenadrine+ASA+caffeine | (Norgesic) |

Muscle Relaxants

| | |
|-------------------------|--|
| Baclofen | (Lioresal) |
| Carisoprodol | (Soma) |
| Chlorzoxazone | (Paraflex, Parafon Forte DSC, Remular-S) |
| Cyclobenzapine | (Flexeril) |
| Dantrolene | (Dantrium) |
| Diazepam | (Valium, Diastat) |
| Diclofenac+mistoprostol | (Arthrotec) |
| Metaxalone | (Skelaxin) |
| Methocarbamol | (Robaxin, Robaxin-750) |
| Orphenadrine | (Norflex) |
| Quinine sulfate | |
| Tizanidine | (Zanaflex) |

Adjuvant Pain Medications

| | |
|---------------|------------|
| Amitriptyline | (Elavil) |
| Carbamazepine | (Tegretol) |
| Gabapentin | (Neurotin) |
| Nortriptyline | (Pamelor) |

Herbal or Nutritional Supplements

| | |
|-------------------------|-------------------------|
| Glucosamine | |
| Glucosamine chondroitin | (Osteo Bi-Flex, etc) |
| MSM | (Methylsulfonylmethane) |
| SAMe | |

Topical Analgesics

Arthritis Hot
 Aspercreme
 Ben-Gay Cream
 Capsaicin
 Deep Heating
 Icy Hot
 Mineral Ice
 Thera-gesic Cream

REFERENCES

- Alexander, G. C., Casalino, L. P., & Meltzer, D. O. (2003). Patient-physician communication about out-of-pocket costs. *Jama*, *290*(7), 953-958.
- Alexander, G. C., Casalino, L. P., & Meltzer, D. O. (2005). Physician strategies to reduce patients' out-of-pocket prescription costs. *Arch Intern Med*, *165*(6), 633-636.
- Alexander, G. C., Casalino, L. P., Tseng, C. W., McFadden, D., & Meltzer, D. O. (2004). Barriers to patient-physician communication about out-of-pocket costs. *J Gen Intern Med*, *19*(8), 856-860.
- Alexander, G. C., & Tseng, C. W. (2004). Six strategies to identify and assist patients burdened by out-of-pocket prescription costs. *Cleve Clin J Med*, *71*(5), 433-437.
- Alexander, G. C., Zhang, J., & Basu, A. (2008). Characteristics of patients receiving pharmaceutical samples and association between sample receipt and out-of-pocket prescription costs. *Med Care*, *46*(4), 394-402.
- Allison, P. (2000). Paul Allison's Home Page. Retrieved June 4, 2008, from <http://www.ssc.upenn.edu/~allison/>
- Allison, P. D. (2002). *Missing data*. Thousand Oaks, Calif.: Sage Publications.
- American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. (2002). Guidelines for the management of rheumatoid arthritis: 2002 Update. *Arthritis Rheum*, *46*(2), 328-346.
- Arora, N. K. (2003). Interacting with cancer patients: the significance of physicians' communication behavior. *Soc Sci Med*, *57*(5), 791-806.
- Artz, M. B., Hadsall, R. S., & Schondelmeyer, S. W. (2002). Impact of generosity level of outpatient prescription drug coverage on prescription drug events and expenditure among older persons. *Am J Public Health*, *92*(8), 1257-1263.
- Atella, V., Schafheutle, E., Noyce, P., & Hassell, K. (2005). Affordability of medicines and patients' cost-reducing behaviour: empirical evidence based on SUR estimates from Italy and the UK. *Appl Health Econ Health Policy*, *4*(1), 23-35.
- Atlas.ti Scientific Software Development GmbH. (2008). ATLAS.ti (Version 5.2.0). Berlin.
- Barlow, J., Wright, C., Sheasby, J., Turner, A., & Hainsworth, J. (2002). Self-management approaches for people with chronic conditions: a review. *Patient Educ Couns*, *48*(2), 177-187.
- Benedetti, N. J., Fung, V., Reed, M., Price, M., Brand, R., Newhouse, J. P., et al. (2008). Office Visit Copayments: Patient Knowledge, Response, and Communication With Providers. *Med Care*, *46*(4), 403-409.

- Briesacher, B. A., Gurwitz, J. H., & Soumerai, S. B. (2007). Patients at-risk for cost-related medication nonadherence: a review of the literature. *J Gen Intern Med*, 22(6), 864-871.
- Brus, H., van de Laar, M., Taal, E., Rasker, J., & Wiegman, O. (1999). Determinants of compliance with medication in patients with rheumatoid arthritis: the importance of self-efficacy expectations. *Patient Educ Couns*, 36(1), 57-64.
- Bultman, D. C., & Svarstad, B. L. (2000). Effects of physician communication style on client medication beliefs and adherence with antidepressant treatment. *Patient Educ Couns*, 40(2), 173-185.
- Burton, P., Gurrin, L., & Sly, P. (1998). Extending the simple linear regression model to account for correlated responses: an introduction to generalized estimating equations and multi-level mixed modelling. *Stat Med*, 17(11), 1261-1291.
- Carrillo, J. E., Green, A. R., & Betancourt, J. R. (1999). Cross-cultural primary care: a patient-based approach. *Ann Intern Med*, 130(10), 829-834.
- Cegala, D. J., McClure, L., Marinelli, T. M., & Post, D. M. (2000). The effects of communication skills training on patients' participation during medical interviews. *Patient Educ Couns*, 41(2), 209-222.
- Centers for Medicare & Medicaid Services. (2004). *The Medicare Replacement Drug Demonstration*. Retrieved from http://www.cms.hhs.gov/DemoProjectsEvalRpts/01_Overview.asp#TopOfPage.
- Chenail, R. J. (1995). Presenting Qualitative Data. *The Qualitative Report*, 2(3).
- Chewning, B., & Sleath, B. (1996). Medication decision-making and management: a client-centered model. *Soc Sci Med*, 42(3), 389-398.
- Chewning, B., Wiederholt, J., Bell, C., Boh, D., Boh, L., Douglas, J., et al. (2001). Does the Concordance Framework Serve Medicine Management? *International Journal of Pharmacy Practice*, 9, 71-79.
- Chisholm, M. A., & DiPiro, J. T. (2002). Pharmaceutical manufacturer assistance programs. *Arch Intern Med*, 162(7), 780-784.
- Cleary, P. D., & McNeil, B. J. (1988). Patient satisfaction as an indicator of quality care. *Inquiry*, 25(1), 25-36.
- Cooper-Patrick, L., Gallo, J. J., Gonzales, J. J., Vu, H. T., Powe, N. R., Nelson, C., et al. (1999). Race, gender, and partnership in the patient-physician relationship. *Jama*, 282(6), 583-589.
- Cooper, L. A., Roter, D. L., Johnson, R. L., Ford, D. E., Steinwachs, D. M., & Powe, N. R. (2003). Patient-centered communication, ratings of care, and concordance of patient and physician race. *Ann Intern Med*, 139(11), 907-915.

- Culhane-Pera, K. A., Reif, C., Egli, E., Baker, N. J., & Kassekert, R. (1997). A curriculum for multicultural education in family medicine. *Fam Med*, 29(10), 719-723.
- Davidson, W., Molloy, D. W., & Bedard, M. (1995). Physician characteristics and prescribing for elderly people in New Brunswick: relation to patient outcomes. *CMAJ*, 152(8), 1227-1234.
- DeVellis, R. F. (2005). Inter-Rater Reliability. In K. Kempf Leonard (Ed.), *Encyclopedia of social measurement* (1st ed., pp. 317-322). San Diego, Calif. ; London: Academic.
- DeWitt, E. M., Glick, H. A., Albert, D. A., Joffe, M. M., & Wolfe, F. (2006). Medicare coverage of tumor necrosis factor alpha inhibitors as an influence on physicians' prescribing behavior. *Arch Intern Med*, 166(1), 57-63.
- DiMatteo, M. R. (1995). Patient adherence to pharmacotherapy: the importance of effective communication. *Formulary*, 30(10), 596-598, 601-592, 605.
- Donovan, J. L., & Blake, D. R. (1992). Patient non-compliance: deviance or reasoned decision-making? *Soc Sci Med*, 34(5), 507-513.
- Drummond, M. F. (1997). *Methods for the economic evaluation of health care programmes* (2nd ed.). Oxford ; New York: Oxford University Press.
- Edwards, A., Elwyn, G., Hood, K., Atwell, C., Robling, M., Houston, H., et al. (2004). Patient-based outcome results from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. *Fam Pract*, 21(4), 347-354.
- Elwyn, G., Edwards, A., & Britten, N. (2003). "Doing prescribing": how might clinicians work differently for better, safer care. *Qual Saf Health Care*, 12 Suppl 1, i33-36.
- Epstein, R. M., Alper, B. S., & Quill, T. E. (2004). Communicating evidence for participatory decision making. *Jama*, 291(19), 2359-2366.
- Ess, S. M., Schneeweiss, S., & Szucs, T. D. (2003). European healthcare policies for controlling drug expenditure. *Pharmacoeconomics*, 21(2), 89-103.
- Fallowfield, L., Jenkins, V., Farewell, V., Saul, J., Duffy, A., & Eves, R. (2002). Efficacy of a Cancer Research UK communication skills training model for oncologists: a randomised controlled trial. *Lancet*, 359(9307), 650-656.
- Faris, P. D., Ghali, W. A., Brant, R., Norris, C. M., Galbraith, P. D., & Knudtson, M. L. (2002). Multiple imputation versus data enhancement for dealing with missing data in observational health care outcome analyses. *J Clin Epidemiol*, 55(2), 184-191.
- Felson, D. T., Anderson, J. J., Boers, M., Bombardier, C., Chernoff, M., Fried, B., et al. (1993). The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. The Committee on Outcome Measures in Rheumatoid Arthritis Clinical Trials. *Arthritis Rheum*, 36(6), 729-740.

- Fillenbaum, G., Heyman, A., Williams, K., Prosnitz, B., & Burchett, B. (1990). Sensitivity and specificity of standardized screens of cognitive impairment and dementia among elderly black and white community residents. *J Clin Epidemiol*, *43*(7), 651-660.
- Fischer, M. A., & Avorn, J. (2004). Economic implications of evidence-based prescribing for hypertension: can better care cost less? *JAMA*, *291*(15), 1850-1856.
- Gibson, T. B., Ozminkowski, R. J., & Goetzel, R. Z. (2005). The effects of prescription drug cost sharing: a review of the evidence. *Am J Manag Care*, *11*(11), 730-740.
- Goldman, D. P., Joyce, G. F., Lawless, G., Crown, W. H., & Willey, V. (2006). Benefit design and specialty drug use. *Health Aff (Millwood)*, *25*(5), 1319-1331.
- Gordon, H. S., Street, R. L., Jr., Kelly, P. A., Soucek, J., & Wray, N. P. (2005). Physician-patient communication following invasive procedures: an analysis of post-angiogram consultations. *Soc Sci Med*, *61*(5), 1015-1025.
- Greenfield, S., Kaplan, S., & Ware, J. E., Jr. (1985). Expanding patient involvement in care. Effects on patient outcomes. *Ann Intern Med*, *102*(4), 520-528.
- Groves, K. E., Sketris, I., & Tett, S. E. (2003). Prescription drug samples--does this marketing strategy counteract policies for quality use of medicines? *J Clin Pharm Ther*, *28*(4), 259-271.
- Hall, J. A., Roter, D. L., & Katz, N. R. (1988). Meta-analysis of correlates of provider behavior in medical encounters. *Med Care*, *26*(7), 657-675.
- Havrda, D. E., Omundsen, B. A., Bender, W., & Kirkpatrick, M. A. (2005). Impact of the Medicare modernization act on low-income persons. *Ann Intern Med*, *143*(8), 600-608.
- Heisler, M., Langa, K. M., Eby, E. L., Fendrick, A. M., Kabeto, M. U., & Piette, J. D. (2004). The health effects of restricting prescription medication use because of cost. *Med Care*, *42*(7), 626-634.
- Heisler, M., Wagner, T. H., & Piette, J. D. (2004). Clinician identification of chronically ill patients who have problems paying for prescription medications. *Am J Med*, *116*(11), 753-758.
- Herxheimer, A. (1998). Many NSAID users who bleed don't know when to stop. *BMJ*, *316*(7130), 492.
- Hochberg, M. C., Chang, R. W., Dwosh, I., Lindsey, S., Pincus, T., & Wolfe, F. (1992). The American College of Rheumatology 1991 revised criteria for the classification of global functional status in rheumatoid arthritis. *Arthritis Rheum*, *35*(5), 498-502.
- Jackson, J. L., Chamberlin, J., & Kroenke, K. (2001). Predictors of patient satisfaction. *Soc Sci Med*, *52*(4), 609-620.
- Jenkins, V., & Fallowfield, L. (2002). Can communication skills training alter physicians' beliefs and behavior in clinics? *J Clin Oncol*, *20*(3), 765-769.

- Johnson, R. E., Goodman, M. J., Hornbrook, M. C., & Eldredge, M. B. (1997). The effect of increased prescription drug cost-sharing on medical care utilization and expenses of elderly health maintenance organization members. *Med Care*, 35(11), 1119-1131.
- Johnson, R. L., Roter, D., Powe, N. R., & Cooper, L. A. (2004). Patient race/ethnicity and quality of patient-physician communication during medical visits. *Am J Public Health*, 94(12), 2084-2090.
- Kane, R. L., Maciejewski, M., & Finch, M. (1997). The relationship of patient satisfaction with care and clinical outcomes. *Med Care*, 35(7), 714-730.
- Kenward, M. G., & Carpenter, J. (2007). Multiple imputation: current perspectives. *Stat Methods Med Res*, 16(3), 199-218.
- Kjeken, I., Dagfinrud, H., Mowinckel, P., Uhlig, T., Kvien, T. K., & Finset, A. (2006). Rheumatology care: Involvement in medical decisions, received information, satisfaction with care, and unmet health care needs in patients with rheumatoid arthritis and ankylosing spondylitis. *Arthritis Rheum*, 55(3), 394-401.
- Korn, L. M., Reichert, S., Simon, T., & Halm, E. A. (2003). Improving physicians' knowledge of the costs of common medications and willingness to consider costs when prescribing. *J Gen Intern Med*, 18(1), 31-37.
- Krobot, K. J., Miller, W. C., Kaufman, J. S., Christensen, D. B., Preisser, J. S., & Ibrahim, M. A. (2004). The disparity in access to new medication by type of health insurance: lessons from Germany. *Med Care*, 42(5), 487-491.
- Lapsley, H. M., March, L. M., Tribe, K. L., Cross, M. J., Courtenay, B. G., & Brooks, P. M. (2002). Living with rheumatoid arthritis: expenditures, health status, and social impact on patients. *Ann Rheum Dis*, 61(9), 818-821.
- Lewin, K. (1935). *A dynamic theory of personality; selected papers* (D. K. Adams & K. E. Zener, Trans. 1st ed.). New York, London,: McGraw-Hill Book Company, inc.
- Lewis, M. A., DeVellis, B. M., & Sleath, B. (2002). Social influence and interpersonal communication in health behavior In K. Glanz, B. K. Rimer & F. M. Lewis (Eds.), *Health Behavior and Health Education: Theory, Research, and Practice* (pp. 240-264). San Francisco: Jossey-Bass Publishers.
- Lim, A. Y., Ellis, C., Brooksby, A., & Gaffney, K. (2007). Patient satisfaction with rheumatology practitioner clinics: can we achieve concordance by meeting patients' information needs and encouraging participatory decision making? *Ann Acad Med Singapore*, 36(2), 110-114.
- Lundin, D. (2000). Moral hazard in physician prescription behavior. *J Health Econ*, 19(5), 639-662.
- Maradit-Kremers, H., Nicola, P. J., Crowson, C. S., O'Fallon, W. M., & Gabriel, S. E. (2006). Patient, disease, and therapy-related factors that influence discontinuation of disease-modifying antirheumatic drugs: a population-based incidence cohort of patients with rheumatoid arthritis. *J Rheumatol*, 33(2), 248-255.

- Michaud, K., Messer, J., Choi, H. K., & Wolfe, F. (2003). Direct medical costs and their predictors in patients with rheumatoid arthritis: a three-year study of 7,527 patients. *Arthritis Rheum*, *48*(10), 2750-2762.
- Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: An expanded sourcebook*. Thousand Oaks: Sage Publishing.
- Mishler, E. G. (1984). *The Discourse of Medicine: Dialectics of Medical Interviews* Ablex Publishing.
- Morse, J., & Field, L. (1995). *Qualitative research methods for health professionals*. . Newbury Park: Sage Publishing.
- Neame, R., & Hammond, A. (2005). Beliefs about medications: a questionnaire survey of people with rheumatoid arthritis. *Rheumatology (Oxford)*, *44*(6), 762-767.
- Noyce, P. R., Huttin, C., Atella, V., Brenner, G., Haaijer-Ruskamp, F. M., Hedvall, M., et al. (2000). The cost of prescription medicines to patients. *Health Policy*, *52*(2), 129-145.
- Osterberg, L., & Blaschke, T. (2005). Adherence to medication. *N Engl J Med*, *353*(5), 487-497.
- Parsons, T. (1951). *The social system*. Glencoe, Ill.,: Free Press.
- Partnership for Prescription Assistance. (2008). What is the Partnership for Prescription Assistance? Retrieved May 19, 2008, from <https://www.pparx.org/Intro.php>
- Piette, J. D., Heisler, M., Horne, R., & Caleb Alexander, G. (2006). A conceptually based approach to understanding chronically ill patients' responses to medication cost pressures. *Soc Sci Med*, *62*(4), 846-857.
- Piette, J. D., Heisler, M., & Wagner, T. H. (2004a). Cost-related medication underuse among chronically ill adults: the treatments people forgo, how often, and who is at risk. *Am J Public Health*, *94*(10), 1782-1787.
- Piette, J. D., Heisler, M., & Wagner, T. H. (2004b). Cost-related medication underuse: do patients with chronic illnesses tell their doctors? *Arch Intern Med*, *164*(16), 1749-1755.
- Piette, J. D., Heisler, M., & Wagner, T. H. (2006). Medication characteristics beyond cost alone influence decisions to underuse pharmacotherapy in response to financial pressures. *J Clin Epidemiol*, *59*(7), 739-746.
- Pound, P., Britten, N., Morgan, M., Yardley, L., Pope, C., Daker-White, G., et al. (2005). Resisting medicines: a synthesis of qualitative studies of medicine taking. *Soc Sci Med*, *61*(1), 133-155.
- Rasch, E. K., Hirsch, R., Paulose-Ram, R., & Hochberg, M. C. (2003). Prevalence of rheumatoid arthritis in persons 60 years of age and older in the United States: effect of different methods of case classification. *Arthritis Rheum*, *48*(4), 917-926.

- Richard, C., & Lussier, M. T. (2006). Measuring patient and physician participation in exchanges on medications: Dialogue Ratio, Preponderance of Initiative, and Dialogical Roles. *Patient Educ Couns*.
- Roter, D., & Hall, J. A. (1992). *Doctors talking with patients/patients talking with doctors : improving communication in medical visits*. Westport, Conn.: Auburn House.
- Roter, D., & Hall, J. A. (2006). *Doctors talking with patients/patients talking with doctors : improving communication in medical visits* (2nd ed.). Westport, Conn.: Praeger.
- Roter, D. L. (2003). Observations on methodological and measurement challenges in the assessment of communication during medical exchanges. *Patient Educ Couns*, 50(1), 17-21.
- Roter, D. L., Cole, K. A., Kern, D. E., Barker, L. R., & Grayson, M. (1990). An evaluation of residency training in interviewing skills and the psychosocial domain of medical practice. *J Gen Intern Med*, 5(4), 347-354.
- Roter, D. L., & Hall, J. A. (2004). Physician gender and patient-centered communication: a critical review of empirical research. *Annu Rev Public Health*, 25, 497-519.
- Royal Pharmaceutical Society of Great Britain. (1997). *From compliance to concordance. Achieving shared goals in medicine taking*. London: Royal Pharmaceutical Society of Great Britain and Merck Sharp & Dohme.
- Saag, K. G., Teng, G. G., Patkar, N. M., Anuntiyo, J., Finney, C., Curtis, J. R., et al. (2008). American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*, 59(6), 762-784.
- Saatsoglou, P. (2004). Pharmaceutical reimportation: magnitude, trends, and consumers. *Manag Care*, 13(3 Suppl), 7-9.
- Safran, D. G., Neuman, P., Schoen, C., Kitchman, M. S., Wilson, I. B., Cooper, B., et al. (2005). Prescription drug coverage and seniors: findings from a 2003 national survey. *Health Aff (Millwood)*, Suppl Web Exclusives, W5-152-W155-166.
- Saha, S., Komaromy, M., Koepsell, T. D., & Bindman, A. B. (1999). Patient-physician racial concordance and the perceived quality and use of health care. *Arch Intern Med*, 159(9), 997-1004.
- SAS Institute Inc. (2003). SAS for Windows (Version 9.1.3). Cary, NC.
- Schafer, J. L. (1997). *Analysis of incomplete multivariate data* (1st ed.). London ; New York: Chapman & Hall.
- Schafheutle, E. I., Hassell, K., Noyce, P. R., & Weiss, M. C. (2002). Access to medicines: cost as an influence on the views and behaviour of patients. *Health Soc Care Community*, 10(3), 187-195.

- Schnitzer, T. J., Kong, S. X., Mitchell, J. H., Mavros, P., Watson, D. J., Pellissier, J. M., et al. (2003). An observational, retrospective, cohort study of dosing patterns for rofecoxib and celecoxib in the treatment of arthritis. *Clin Ther*, 25(12), 3162-3172.
- Selye, H. (1956). *The stress of life*. New York,: McGraw-Hill.
- Shikiar, R., & Rentz, A. M. (2004). Satisfaction with medication: an overview of conceptual, methodologic, and regulatory issues. *Value Health*, 7(2), 204-215.
- Shrank, W. H., Fox, S. A., Kirk, A., Ettner, S. L., Cantrell, C. H., Glassman, P., et al. (2006). The effect of pharmacy benefit design on patient-physician communication about costs. *J Gen Intern Med*, 21(4), 334-339.
- Sleath, B., Chewing, B., de Vellis, B. M., Weinberger, M., de Vellis, R. F., Tudor, G., et al. (2008). Communication about depression during rheumatoid arthritis patient visits. *Arthritis Rheum*, 59(2), 186-191.
- Sleath, B., Roter, D., Chewing, B., & Svarstad, B. (1999). Asking questions about medication: analysis of physician-patient interactions and physician perceptions. *Med Care*, 37(11), 1169-1173.
- Sleath, B., & Rubin, R. H. (2002). Gender, ethnicity, and physician-patient communication about depression and anxiety in primary care. *Patient Educ Couns*, 48(3), 243-252.
- Sleath, B., Rubin, R. H., Campbell, W., Gwyther, L., & Clark, T. (2001). Physician-patient communication about over-the-counter medications. *Soc Sci Med*, 53(3), 357-369.
- Sleath, B., Rubin, R. H., & Huston, S. A. (2003). Hispanic ethnicity, physician-patient communication, and antidepressant adherence. *Compr Psychiatry*, 44(3), 198-204.
- Sleath, B., Svarstad, B., & Roter, D. (1998). Patient race and psychotropic prescribing during medical encounters. *Patient Educ Couns*, 34(3), 227-238.
- Soumerai, S. B., Pierre-Jacques, M., Zhang, F., Ross-Degnan, D., Adams, A. S., Gurwitz, J., et al. (2006). Cost-related medication nonadherence among elderly and disabled medicare beneficiaries: a national survey 1 year before the medicare drug benefit. *Arch Intern Med*, 166(17), 1829-1835.
- SPSS Inc. (2007). SPSS 15.0 Windows (Version 15.0.1). Chicago, IL: SPSS Incorporated.
- StataCorp LP. (2007). Intercooled Stata 9.2 for Windows (Version 9.2). College Station, TX: StataCorp LP.
- Steinman, M. A., Sands, L. P., & Covinsky, K. E. (2001). Self-restriction of medications due to cost in seniors without prescription coverage. *J Gen Intern Med*, 16(12), 793-799.
- Strauss, A. L. (1987). *Qualitative analysis for social scientists*. Cambridge [Cambridgeshire] ; New York: Cambridge University Press.

- Strauss, A. L., & Corbin, J. M. (1998). *Basics of qualitative research : techniques and procedures for developing grounded theory* (2nd ed.). Thousand Oaks, Calif.: Sage Publications.
- Street, R. L., Jr. (1992). Analyzing communication in medical consultations. Do behavioral measures correspond to patients' perceptions? *Med Care*, 30(11), 976-988.
- Tarn, D. M., Paterniti, D. A., Heritage, J., Hays, R. D., Kravitz, R. L., & Wenger, N. S. (2006). Physician communication about the cost and acquisition of newly prescribed medications. *Am J Manag Care*, 12(11), 657-664.
- Thomson Corporation. (2004). Red book: pharmacy's fundamental reference (pp. v.). Montvale, NJ: Thomson PDR.
- Van Buuren, S., Brand, J.P.L., Groothuis-Oudshoorn, C.G.M., Rubin, D.B. (2006). Fully conditional specification in multivariate imputation. *Journal of Statistical Computation and Simulation*, 76(12), 1049-1064.
- Wailoo, A. J., Bansback, N., Brennan, A., Michaud, K., Nixon, R. M., & Wolfe, F. (2008). Biologic drugs for rheumatoid arthritis in the medicare program: a cost-effectiveness analysis. *Arthritis Rheum*, 58(4), 939-946.
- Waitzkin, H. (1990). On studying the discourse of medical encounters. A critique of quantitative and qualitative methods and a proposal for reasonable compromise. *Med Care*, 28(6), 473-488.
- Wilson, I. B., Schoen, C., Neuman, P., Stollo, M. K., Rogers, W. H., Chang, H., et al. (2007). Physician-patient communication about prescription medication nonadherence: a 50-state study of America's seniors. *J Gen Intern Med*, 22(1), 6-12.
- Wynne, H. A., & Long, A. (1996). Patient awareness of the adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs). *Br J Clin Pharmacol*, 42(2), 253-256.
- Zandbelt, L. C., Smets, E. M., Oort, F. J., Godfried, M. H., & de Haes, H. C. (2007). Patient participation in the medical specialist encounter: does physicians' patient-centred communication matter? *Patient Educ Couns*, 65(3), 396-406.