Theses and Dissertations

2013

Managing medication regimen : arthritis patients' perception

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The University of Toledo

A Thesis

entitled

Managing Medication Regimen: Arthritis Patients' Perception

by

Gesnita Nugraheni

Submitted to the Graduate Faculty as partial fulfillment of the requirements for the

Master of Science Degree in Pharmaceutical Science

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August 2013

Abstract

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June 2013

Objective: To determine which construct in the Health belief Model is the predictor of

arthritis patients' intention to ask for counseling from pharmacists and to examine the

relationship between self-management ability and the intention to ask for counseling.

Methods: A two-wave mail survey was conducted in a group of 430 patients with

rheumatoid arthritis and osteoarthritis from two clinics. The questionnaire consisted of 15

items related to patients' perception of the benefits, barriers, and self-efficacy regarding

requesting counseling from their pharmacist; and 10 items of self-management ability.

Results: The response rate was 23.5%. The number of patients who had intention to ask

for counseling was equal with those who had no intention. Perceived benefit was the only

significant predictor of patients' intention to ask for counseling ($p < 0.05$), controlling for

other factors. Higher patient's self-management ability significantly correlated with

intention to request counseling from the pharmacist($r=0.347$; $p < 0.01$).

Conclusion: Promotional efforts regarding patient counseling should be on going and

emphasize more on the benefit of counseling.

Keywords: Rheumatoid arthritis, osteoarthritis, counseling, medication management

"I dedicate this thesis to my mom and dad for nursing me with affections and love and dedicated partnership for success in my life."

Acknowledgements

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List of Abbreviations

ACR ....American College of Rheumatology
ADR ....Adverse Drug Reaction
CDC ....Center of Disease Control and Prevention
CMR..........................Comprehensive Medication Review
COPD.........................Chronic Obstructive Pulmonary Disease
DHRP.........................Department for Human Research Protection
DMARD.....................Disease Modifying Anti-Rheumatoid Drug
DRP...........................Drug Related Problem
DTP...........................Drug Therapy Problem
DUR ....Drug Utilization Review
ECHO.........................Economic Clinic and Humanistic Outcomes
FEV ....Forced Expiratory Volume
GP ....General Practitioner
HBM ....Health Belief Model
HUI3 ....Health Utilities Index Mark 3
IRB............................Institutional Review Boards
LEFS ....Lower Extremities Function Scale
MAP..........................Medication Action Plan
MMA..........................Medicare Prescription Drug, Improvement and Modernization Act
MR ....Modified release
MTM..........................Medication Therapy Management
NSAID ....Non-Steroidal Anti-Inflammatory Drug
OA.............................Osteoarthritis
OBRA ....Omnibus Budget Reconciliation Act
OTC...........................Over the Counter
PAT-5D......................Paper Adaptive Test-5D
PCS ....Pharmaceutical Care Service
PMR ....Personal Medication Record
RA.............................Rheumatoid Arthritis
SPSS..........................Statistical Package for the Social Sciences
SR..............................Sustain Release
WOMAC....................Western Ontario and McMaster Universities Osteoarthritis index
UTMC........................University of Toledo Medical Center
US ....United State

Chapter 1

Introduction

Chapter one introduces the reader to the drug related problems faced by patients with osteoarthritis or rheumatoid arthritis. This chapter also explains the shifting role in pharmacy practice where pharmacists provide more clinical and more patient oriented services than before. Arthritis patients' behavior is described, as well as The Health Belief Model. Furthermore, the problem statement, need and significance of this study are included, as well as the research goal, objectives, research questions and hypotheses for the study.

1.1 Drug Related Problems

Johnson and Bootman (1995) estimated that drug related morbidity and mortality in ambulatory settings in the US reached $76.6 billion annually, with the largest component related to medication-related problems[1]. Another study conducted by Ernst and Grizzle, tried to update the component of costs that had been used to estimate drug related morbidity and mortality based on US costs in 2000. There was a 131% increase in

the cost of illness in the year 2000 compared with that in 1995, with the total estimation achieved to be $177.4 billion[2].

Pharmacists have a potential role to reduce morbidity and mortality related to errors in medication use. This role is the kind of responsibility that cannot be substituted with other tasks. Pharmaceutical care concepts emphasize the patient oriented services of pharmacists. It is a key responsibility of the pharmacist to ensure that patients obtain the optimum result from their medication therapy and thus, increase their quality of life. This is a sign of change from the previous era of product-oriented services, when the pharmacists focused on ensuring the purity, authenticity, and proper preparation of medications dispensed. Product oriented services have changed gradually to more clinically oriented services, along with the development of industrial pharmacy that took on the previous manufacturing role of pharmacists, particularly in a community pharmacy setting [3].

The Omnibus Budget Reconciliation Act (OBRA) of 1990 mandated pharmacists to conduct a prospective and retrospective drug utilization review (DUR) and offer patient counseling[4]. The purpose of medication review and counseling is to prevent drug related problems (DRPs) such as receiving the incorrect drug for a medical condition, failure to receive a medication that is needed, taking too low or too high a dose of the correct drug, and others, giving the optimal quality of care to relieve symptoms, cure the disease, or slow disease progression[5].

1.2 Drug Related Problems in Arthritis Patients

Non-steroidal anti-inflammatory drugs (NSAIDs) are the medicines that are mostly used by arthritis patients. The NSAIDs have unique pharmacological mechanisms that potentially cause adverse drug reactions (ADR). Most arthritis patients will be prescribed NSAIDs for long term pain treatment. The ADR of NSAIDs is due to the toxicity in the gastrointestinal tract and kidneys. Cheatum et al. (1999) found that prolonged use of NSAIDs caused 37.1% of patients to have gastro-duodenal lesions, and 24% to have ulcers[6].

A study in patients with osteoarthritis (OA), rheumatoid arthritis (RA), and low back pain (LBP) reported that pharmacist interventions could detect potential DRPs. The DRPs were addressed through one-on-one assessment sessions, resulting in 926 cumulative DRPs identified. The outcome of therapy and the pharmacists' interventions to solve the DRPs were also monitored. This pharmacist-patient interaction successfully helped patients gain improvement of 70.7% of DRPs[7].

Since most arthritis patients have other diseases, such as hypertension, heart disease, and diabetes, it is possible for them to have problems in managing their medication regimens[7,8]. Another potential DRP is related to drug interactions with other medicines being taken by patients in the same time period. NSAIDs such as, ibuprofen (Advil, Motrin), naproxen sodium (Aleve), and aspirin (Ascriptin, Bayer, Ecotrin) can be obtained without a doctor's prescription. Patient counseling and assessment of medications being taken by those patients can be done by the pharmacist to prevent simultaneous duplicate treatments and drug-drug interactions.

The economic status of a patient influences their ability to pay for medications, as well as their medication-taking behavior. Arthritis patients frequently take complementary products such as Glucosamine, in addition to their medications, that could burden them financially. Arthritis patient often self-rationalize their medication use, including omission of analgesics, until they get severe pain that could decrease their quality of life[9].

Optimally, patients should have their health care provider monitor the outcomes of treatment and evaluate drug therapy problems that may occur during the life-long treatment of arthritis. However, non-integrated systems of patient medical records prevent each health care provider from having the same information regarding the medications that have been taken by patients. Collaboration between health care providers should be enhanced in order to optimize patient outcomes. One way of performing health care provider collaboration practices is by conducting Medication Therapy Management.

1.3 The Shifting Role in Pharmacy Practice

Medication therapy management is "a distinct service or group of services that optimize therapeutic outcomes for individual patients"[10]. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 declared that a Part D sponsor must have established a medication therapy management (MTM) program for targeted beneficiaries. However, Part D sponsors are allowed to choose their own targeted beneficiaries with specific chronic diseases. Programs must include at least five of the nine core chronic conditions, including OA and RA[11].

Pharmaceutical care services in the form of MTM have been proven to improve patients' clinical, economic, and humanistic outcomes, and medication adherence in patients with chronic diseases such as hypertension, hyperlipidemia, diabetes mellitus, and asthma[12-17]. MTM has also been proven to successfully identify and resolve drug related issues in community pharmacy[18]. Pharmacists have ample opportunity to become effective health care providers and to assist patients to obtain the goal of therapy and prevent drug therapy problems.

According to studies conducted by Herbert et al. (2006) and Blake et al. (2009), around 20-30% of community pharmacies provide pharmaceutical care services or MTM[19,20]. A survey administered to pharmacists showed that there was encouraging intention to provide MTM[20,21]. However, there are barriers to conducting MTM, such as lack of time, lack of reimbursement, and lack of counseling area. Despite the barriers to providing MTM, pharmacists perceived patients' willingness to participate to be one of the greatest facilitators to conducting MTM[20]. Furthermore, patients were more likely to join a MTM program if they had seen their physician for an unwanted drug reaction[22].

Although MTM has been conducted in different kinds of chronic diseases, there are few, if any, MTM programs focusing on arthritis patients in the US. One study in Canada reported significant improvements from the intervention group compared to the control group, proving that indeed pharmacists have a potential role in helping arthritis patients manage their disease and medication regimens. This study also revealed another problem in society; many people did not realize that they have arthritis, going undiagnosed. The undiagnosed arthritis patients potentially have problems, are confused regarding their condition, and about how to overcome their health problems. Pharmacists

could help screen people with undiagnosed OA so that patients can obtain proper treatment upon referral[23].

MTM encourages the collaboration of healthcare providers by not only doctors and pharmacists, but even physical therapists and dieticians. Beside medication, arthritis patients need non-pharmacological therapy, such as walking, hydrotherapy, and Tai chi to enhance their muscle strength and improve mobility. According to an interview of arthritis patients, most prefer to use medication over doing a non-pharmacology treatment. Lack of time, lack of motivation, or obstacles such as transportation, are barriers for not doing the non-pharmacologic therapy[9]. However, the benefits to participating in these activities are vast. Furthermore, non-pharmacological therapy is considered the first line of treatment in OA. Pharmacists can help bridge these needs by collaborating with other health care providers.

1.4 Arthritis Patient Behavior

Patient noncompliance behavior relates to financial burdens, and the complexity of taking multiple medications[9]. OA patients emphasized the complexity of taking multiple medications. It is common for arthritis patients to use different medications in order to find the best drugs for their symptoms[7]. These patients perceive other chronic diseases that they have, such as diabetes, hypertension, or ischemic heart disease, to have a larger impact on their overall health condition[9].

Often arthritis patients obtain medicines on an as-needed basis, which frequently leads to manipulation of dosage and formulations, as well as self-removal in experimentation of effectiveness. Patients will often take the lowest recommended dose

despite effectiveness. Patients also lack the knowledge to monitor for duplicate ingredients, especially when taking additional over-the-counter (OTC) drugs[9]. Arthritis patients frequently experience medication and dosage changes. Some of them indicated that they kept the medication from previous prescriptions in case they were needed, adding to the complexity of their medication management[9]. A study by Dominick et al. (2004) reported that 44% of patients with OA had at least one non-adherent behavior related to their OA medication[24].

Fontaine et al. conducted a study in 2003 and found fewer than 50% of adults with OA recalled being advised to become more physically active by a health professional[25]. Another study in 2005 found that most of the OA patients surveyed made lifestyle changes such as exercise, use of a healthcare aid, and implementation of pain medications independent of the advice of a healthcare professional[26].

Without any monitoring from health care providers who are able to do a personal medication review, the potential occurrence of ADR or toxicity related to the medication is high. A previous study showed that the occurrence of DRPs was related to a low score in quality of life compared to patients with no DRPs[7]. Therefore, the need for insight from arthritis patients' perspective about their medication regimens, understanding the complexities and problems that they face is vital. Information related to how these patients interact with pharmacists is needed as well.

1.5 Health Belief Model

The Health Belief Model (HBM) is one of the theories that explain intrapersonal factors that influence someone to perform a behavior. A person's decision to follow a

recommended action is influenced by his/her perception. According to this theory, someone will be more likely to perform a recommended action if his perception towards the severity of the disease, or other condition, is high and they feel susceptible to that condition. Other personal perceptions used in this theory include: perceived benefits and perceived barriers about conducting said recommended action. Self-efficacy in performing said recommended action and cues-to-action have been added to the main constructs. People's perception towards their confidence to perform an action will influence them more to conduct that behavior. On the other hand, all things that trigger someone to perform an action can act as an activator or cues to action.

Reviewing the constructs involved, HBM is suitable to be used in the present research. Using the HBM constructs as the underlying theory of behavior in addressing arthritis patients' perception towards their disease, DRPs, and interaction with the pharmacist provides a structural template for the survey instrument and subsequent analysis.

1.6 Problem Statement

The problems related to medication use of arthritis patients could prevent them from achieving the optimum outcomes from their pharmacologic therapy, often enduring adverse drug reactions from their medications. Non-steroidal anti-inflammatory drugs have potential ADRs in long-term use, especially in the gastro-intestinal tract. Rheumatoid Arthritis patients have another complexity in their medications related to the use of disease modifying anti-arthritis drugs (DMARDs). Moreover, OA patients are mostly elderly with more than one chronic disease, thus are potentially taking more than

one medication, and without an integrated system for patient medical records, can potentially lead to DRPs.

Healthcare providers, particularly pharmacists, have a responsibility to ensure the safety and effectiveness of patients' medications. The shifting role of pharmacists to provide more clinical services in the community setting warrants the development of MTM programs in which they can help patients address, prevent, and overcome the DRPs, optimizing therapy outcomes through patient counseling. Patient counseling is involved in pharmaceutical care and MTM programs that have been implemented in many states. However, MTM mostly assists patients with chronic diseases such as hypertension, hyperlipidemia, diabetes mellitus, and asthma. There are few, if any, the MTM programs focusing on arthritis.

One of the key factors related to pharmacist counseling of patients is the patients' willingness to participate in that service. Furthermore, patients are more likely to enroll in a MTM program if they have problems related to their medication. There is no research that has been conducted to address the perception of arthritis patients in the US about their medication regimens. There is a gap in the identification of arthritis patients' perceptions toward their disease and medication regimen. Hence, there is a need to address arthritis patients' perceptions towards patient counseling provided by pharmacists, their intention to ask for patient counseling regarding their medications, and their ability to manage their medication regimens.

By conducting this study, the researcher would be able to identify the need for patient counseling based on patients' perceptions. Pharmacists would have insight into the ability of arthritis patients to manage their medication regimens, their perception and

intention towards patient counseling provided by pharmacists, and other factors that influence arthritis patients' behavior related to asking for patient counseling. The results from this study could be used by pharmacists to improve the quality of services to arthritis patients in helping them manage their medications to optimize therapeutic outcomes.

1.7 Goal and Objectives

The purpose of this study was to investigate arthritis patients' perceptions towards their medication regimens and the pharmacist's role based on their interaction with pharmacists. Three constructs from the Health belief model (HBM) including perceived benefits, perceived barriers, and self-efficacy were used as a basis model to develop questions in the questionnaire.

The objectives of this study were:

1. To identify possible differences in arthritis patients' intention to ask for patient counseling from pharmacists based on their demographic information

2. To examine the extent to which the combination of constructs in the health belief model (perceived benefits, perceived barriers, and self-efficacy) explain arthritis patients' intention to ask for patient counseling from pharmacists

3. To determine which construct in the health belief model (perceived benefits, perceived barriers, and self-efficacy) accounts for the largest proportion of variance when predicting arthritis patients' intention to ask for patient counseling from pharmacists, controlling for other variables

4. To identify arthritis patients' ability to manage their medication regimens

5. To identify the relationship between the arthritis patients' ability to manage their medication regimens and their intention to ask for patient counseling from their pharmacists

1.8 Research Questions and Hypotheses

1.8.1 Research Question 1

a. Is arthritis patients' intention to ask for patient counseling from pharmacists different based on the demographic information (non-continuous variable)?

Ho 1.1: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacists based on severity of the symptoms

Ho 1.2: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacists based on annual income

Ho 1.3: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacists based on race/ethnicity

Ho 1.4: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacists based on gender

Ho 1.5: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacists and their age group

Ho 1.6: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacist and their insurance status

b. Is there a relationship between arthritis patients' demographic information (continuous variable) and their intention to ask for patient counseling from pharmacists?

Ho 1.7: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacists and the number of medication taken

Ho 1.8: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacists and the number of comorbidity

1.8.2 Research Question 2

How much variance does the combination of constructs in the health belief model (perceived benefits, perceived barriers, and self-efficacy) explain related to arthritis patients' intention to ask for patient counseling from pharmacists?

Ho: The variance explained by the HBM will not be statistically significant

1.8.3 Research Question 3

Which construct in the health belief model (perceived benefits, perceived barriers, and self-efficacy) and the demographic information (severity of the symptom, age, gender, socio-economic status, race/ethnicity, the number of medication, and the number of comorbidity) account for the largest proportion of variance when predicting arthritis patients' intention to ask for patient counseling from pharmacists?

Ho: All constructs and demographic information (odd ratios) will not be statistically significant.

1.8.4 Research Question 4

What is arthritis patients' ability to manage their medication regimens? (no hypothesis, descriptive analysis)

1.8.5 Research Question 5

What is the relationship between arthritis patients' ability to manage their medication regimens and their intention to ask for counseling from their pharmacists?

Ho: There is no statistically significant relationship between arthritis patients' ability to manage their medication regimens and their intention to ask for counseling from their pharmacists (Spearman Correlation)

Chapter 2

Review of Literature

The second chapter contains fundamental literature that underlies the idea of this study. A brief explanation about osteoarthritis and rheumatoid arthritis including the prevalence, symptoms, pharmacological and non-pharmacological therapy is provided. The drug related problems and the pharmaceutical care services related to arthritis are described. The pharmacists' role in helping patient through counseling and medication therapy management is addressed. The results of two pharmaceutical care programs focusing on arthritis conducted in Canada and the United Kingdom are provided. This proposed study is primarily based on identifying arthritis patients' perceptions towards their medication regimens using the Health Belief Model as a theoretical framework. Therefore, the constructs of the model are explained. The literature review included:

1. Arthritis—Data and statistics

2. Osteoarthritis

3. Rheumatoid arthritis

4. Drug related problems

5. Pharmacists' counseling services and benefits

6. Medication therapy management

7. Osteoarthritis-focused pharmaceutical care services in Canada

8. Osteoarthritis-focused pharmaceutical care services in the United Kingdom

9. Health belief model

2.1 Arthritis—Data and Statistics

It is estimated that 50 million adults in the United States (US), or 1 out of 5, suffer from arthritis. Arthritis is the most common cause of disability in the US. The prevalence of adults with physical inactivity is higher in people who have been diagnosed with arthritis compared to patients with no arthritis. As many as 1 out of 3 working-age adults (ages 18-65 years) report work limitation caused by arthritis[8].

The lifetime risk of arthritis is high. A study reported that the estimated lifetime risk of developing severe knee osteoarthritis (OA) is 45%. Studies regarding the burden of cost related to arthritis are continuously being conducted. Based on a report by the CDC, in 2003, the total cost of arthritis was $128 billion with the indirect cost reaching almost 50% of the direct cost. There was close to one million hospitalization and over 40 million ambulatory visits related to the disease[8].

Arthritis, which causes a person to be physically inactive, is thought to lead to other chronic conditions, such as heart disease, diabetes, and obesity. There are 47% of US adults who live with arthritis who also have at least one other disease or condition[8]. Within more than 100 types of arthritis, the most common forms are OA and Rheumatoid Arthritis (RA). This study focused on both OA and RA patients.

2.2 Osteoarthritis

OA is the most common form of arthritis and the leading cause of pain and disability in the elderly. It is characterized by degeneration of joints including cartilage and its underlying bone. The pain and joint stiffness is caused by the breakdown of these tissues. The common joints affected by OA are knees, hips, hands, feet, and spine[27,28].

Since 78.2 million baby boomers reached retirement age in 2011, the estimated number of 27 million Americans who live with OA is projected to increase[30]. Unhealthy life style causes many diseases related to obesity, one of the risk factors of hip and knee OA. The increasing rate of obesity will also potentially raise the incidence of OA in future years. Scientists and clinicians are working together to find better treatments for patients. As lifetime span increases, there is an increased likelihood of people living with aging-related ailments such as OA[29].

OA is classified as primary and secondary based on the cause. Primary OA is idiopathic and attacks localized (one to two joints) or generalized joints (affects more than three joints). Secondary OA has an underlying causes, such as congenital or acquired defect of joint structures, trauma, inflammation, and metabolic disorders[27].

OA typically affects joints in fingers and hands first, followed by knees, and then hips and feet. The deterioration of the cartilage will change the bone and joint shape that will hinder OA patients from using them smoothly, as shown in figure 2.1. The fragments of bone and cartilage will lead to irritation, inflammation and pain. Inflammation releases cytokines and enzymes that afterward can damage cartilage. The decrease of hyaluronic acid, one of the components in synovial fluid, will reduce the ability of the joint to absorb shock[30].
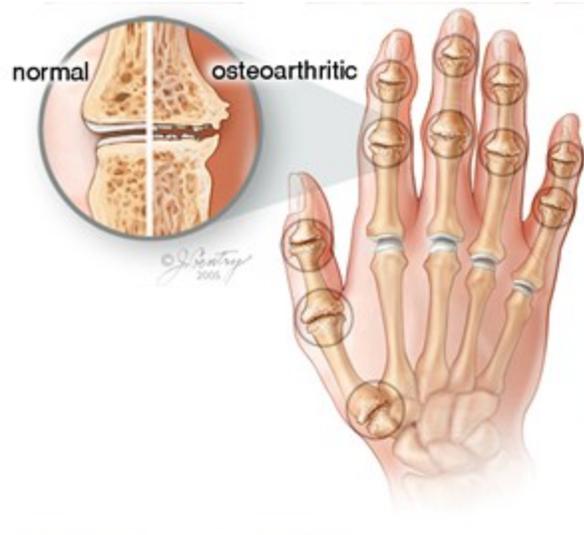
Figure 2-1: Cartilage break down in OA, the affected bones slowly get bigger (copyright ©2013, American College of Rheumatology)[31]

The major goals of the management of OA includes patient, caregiver and family education related to OA, pain and stiffness relief, maintenance or improvement of joint mobility, limitation of functional impairment and maintenance or improvement of quality of life with avoidance of toxic effects of therapy[32,33].

The American College of Rheumatology in 2012 has published the treatment guidelines for OA. It is important for the OA patients to obtain the appropriate non-pharmacological and pharmacological treatments based on their condition. The non-pharmacologic and pharmacologic treatment for patients with OA of the hand, hip, and knee are shown in tables 2.1 to 2.6 below[34].

Table 2.1: Non-pharmacologic recommendations for the management of hand OA[34]

It is conditionally recommended for health care professionals to do things mentioned below: 1. Evaluation of the ability to perform activities of daily living (ADLs)   2. Instruct in join protection techniques   3. Provide assistive devices, as needed, to help patients perform ADLs   4. Instruct in use of thermal modalities   5. Provide splints for patients with trapeziometacarpal joint OA
No strong recommendations were made for the non-pharmacologic management of hand OA. The evidence supporting these interventions demonstrated only a small to moderate effect size.

Table 2.2: Pharmacologic recommendations for the management of hand OA[34]

It is conditionally recommended for health care professionals to use one or more of following: 1. Topical capsaicin   2. Topical NSAIDs*, including trolamin salicylate   3. Oral NSAIDs, including COX-2** selective inhibitors   4. Tramadol   It is conditionally recommended that health professionals should not use the following: 1. Intra-articular therapies   2. Opioid analgesics   It is conditionally recommended that person ≥ 75 years should use topical rather than oral NSAIDs. In persons age <75 years, the TEP*** expressed no preference for using topical rather than oral NSAIDs.
No strong recommendations were made for the pharmacologic management of hand OA. For patients who have an inadequate response to initial pharmacologic management. *NSAIDs = non-steroidal anti-inflammatory drugs; **COX-2 = cyclooxygenase 2; ***TEP = Technical Expert Panel.

Table 2.3: Non-pharmacologic recommendations for the management of knee OA[34]

It is strongly recommended that patients with knee OA should do the following:
1. Participate in cardiovascular (aerobic) and/or resistance land-based exercise
2. Participate in aquatic exercise
3. Lose weight (for persons who are overweight)

It is conditionally recommended that patients with knee OA should do the following:
1. Participate in self-management programs
2. Receive manual therapy in combination with supervised exercise
3. Receive psychosocial interventions
4. Use medially directed patellar taping
5. Wear medially wedged insoles if they have lateral compartment OA
6. Wear laterally wedged subtalar strapped insoles if they have medial compartment OA
7. Be instructed in the use of thermal agents
8. Receive walking aids, as needed
9. Participate in tai chi programs
10. Be treated with traditional Chinese acupuncture*
11. Be instructed in the use of transcutaneous electrical stimulation*

The expert panel have no recommendations regarding the following:
1. Participation in balance exercise, either alone or in combination with strengthening exercises
2. Wearing laterally wedged insoles
3. Receiving manual therapy alone
4. Wearing knee braces
5. Using laterally directed patellar taping

*These modalities are conditionally recommended only when the patient with knee OA has chronic moderate to severe pain and is a candidate for a total knee arthroplasty but either is unwilling to undergo this procedure, has comorbid medical conditions, or is taking concomitant medications that lead to a relative or absolute contraindication to surgery or a decision by the surgeon not to recommend the procedure.

Table 2.4: Pharmacologic recommendations for the management of knee OA[34]

It is conditionally recommended that patients with knee OA should use one of the following:
  1. Acetaminophen
  2. Oral NSAIDs
  3. Topical NSAIDs
  4. Tramadol
  5. Intra-articular corticosteroid injections
 	
It is conditionally recommended that patients with knee OA should use the following:
  1. Chondroitin sulfate
  2. Glucosamine
  3. Topical capsaicin
 	
The expert panel have no recommendation regarding the use of intra-articular hyaluronate, duloxetine, and opioid analgesics

No strong recommendations were made for the initial pharmacologic management of knee OA. For patients who have an inadequate response to initial pharmacologic management.

Table 2.5: Non-pharmacologic recommendation for the management of hip OA[34]

It is strongly recommended that patients with hip OA should do the following:
  1. Participate in cardiovascular and/or resistance land-based exercise
  2. Participate in aquatic exercise
  3. Lose weight (for persons who are overweight)
It is conditionally recommended that patients with hip OA should the following:
  1. Participate in self-management programs
  2. Receive manual therapy in combination with supervised exercise
  3. Receive psychosocial interventions
  4. Be instructed in the use of thermal agents
  5. Receive walking aids, as needed
The expert panel have no recommendations regarding the following:
  1. Participation in balance exercises, either alone or in combination with strengthening exercises
  2. Participation in tai chi
  3. Receiving manual therapy alone

Table 2.6: Pharmacologic recommendations for the management of hip OA[34]

It is conditionally recommended that patients with hip OA should use one of the following: 　1. Acetaminophen 　2. Oral NSAIDs 　3. Tramadol 　4. Intra-articular corticosteroid injections It is conditionally recommended that patients with hip OA should not use the following: 　1. Chondroitin sulfate 　2. Glucosamine The expert panel have no recommendation regarding the use of the following: 　1. Topical NSAIDs 　2. Intra-articular hyaluronic injections 　3. Duloxetine 　4. Opioid analgesics
No strong recommendations were made for the initial pharmacologic management of hip OA.

Pharmacological therapy for OA patients involves pain reliever medicines such as acetaminophen, Non-Steroid Anti Inflammatory Drugs (NSAIDs), and adjuvant medicines such as a muscle relaxant. The use of acetaminophen is the first line of medication, except for OA patients with liver disease or those who are chronic alcohol users. This medication could be substituted for the NSAIDs when the first drug does not give adequate response or if inflammation occurs.

The choice of medication should be considered on the balance of its efficacy, cost-effectiveness, safety, and patient condition. The non-selective and selective NSAIDs have their own risk and benefit as the results of selective inhibition of cyclooxygenase enzyme. The most common adverse drug reaction (ADR) of NSAIDs is gastro-intestinal

complaints such as nausea, dyspepsia, abdominal pain, flatulence, anorexia, and diarrhea that occur in 10-60% of patients[32].

Gastro-intestinal toxicity can arise both directly, because of the acidity of medicines or indirectly through the systemic mechanism. The risk factors of gastro-intestinal related ADR includes increased age, comorbidities including cardiovascular disease, concomitant corticosteroid or anticoagulant therapy, history of peptic ulcer disease or upper gastrointestinal bleeding. If these ADRs occur, patients may need to obtain other treatments. Thus, they might take multiple drugs. Poly-drug uses in OA patients are also high because of the comorbidities of elderly patients such as hypertension, hyperlipidemia, heart failure, diabetes, and so forth. The multiple uses of these drugs, along with the use of NSAIDs, can be harmful. The most serious interactions occur when NSAIDs are taken alongside lithium, warfarin, oral hypoglycemics, high-dose methotrexate, anti-hypertension, angiotensin-converting enzyme inhibitors, B-blockers, and diuretics, which are highly used among elderly patients who have hypertension or heart failure[32].

2.3 Rheumatoid Arthritis

RA is a systemic inflammatory disease involving multiple joints of the body (polyarthritis). It can occur in people at any age, causing pain, swelling, and stiffness even after taking a rest, leading to limited function of the joints. It is believed that the cause of RA is related to a faulty immune system in the body that later leads to the destruction of the synovial membrane, cartilage and bone deformity[35].

According to 2001-2005 US ambulatory healthcare system data, it is estimated that 1.5 million US adults are living with RA. The prevalence among women is higher than men. In 2009, there were 15,600 hospitalizations related to RA, resulting in high medical costs that reached $545 million or $35,000 per person per year on average[35].

Similar to OA, RA attacks the joint(s). However, there may be systemic inflammation occurring in RA patients as a result of a faulty immune system. Instead of protecting the human body from a virus, bacteria, or foreign cells, the immune cell attacks its own tissues, particularly the synovial that is lining the joint[36]. The most frequent joints affected by RA are small joints in hands and feet, but inflammation can also affect organs such as heart, lungs, kidneys, eyes, muscles, and blood vessels[37]. This is a chronic disease, meaning that it cannot be cured, but should be controlled.
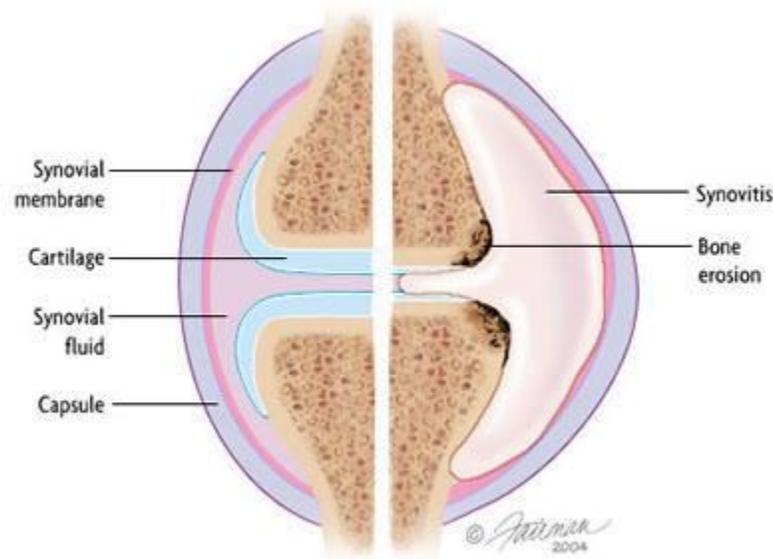
Figure 2-2: Comparing the normal joint structure (left) and joint with RA (right) (copyright ©2013, American College of Rheumatology)[37]

The goals of therapy in RA are relief of symptoms, preservation of function, prevention of structural damage and deformity, and maintenance of patient's normal

lifestyle[38]. The treatments for RA have greatly improved in the past 30 years. The success of treatment is when RA patients achieve remission, or living without symptoms from active disease.
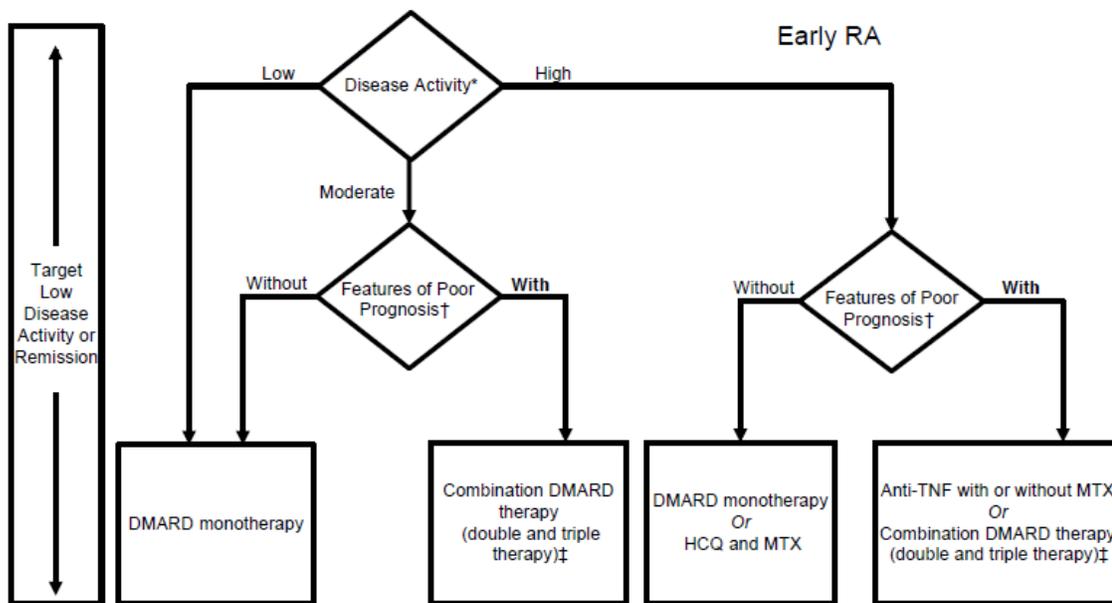
Figure 2-3: ACR recommendation for the treatment of early RA (disease duration less than 6 months) (use with permission of Dr. Jasvinder Singh)[39]

Disease Modifying Anti-Rheumatic Drugs (DMARDs) are usually given with NSAIDs or corticosteroids. They are intended not only to relieve symptoms but also to slow progression of the disease. Non-biological DMARDs include methotrexate (Rheumatrex, Folex), leflunomide (Arava), hydrochloroquin (Plaquenil) and sulfasalazine (Azulfidine). Biological DMARDs are needed in patients with more serious diseases. Examples include abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), rituximab (Rituxan), and tocilizumab (Actemra) (American College of

Rheumatology, 2012a). As with OA, the American College of Rheumatology also released a guideline for RA therapy as shown in figure 2.3[39] (above) and 2.4[39] (below).
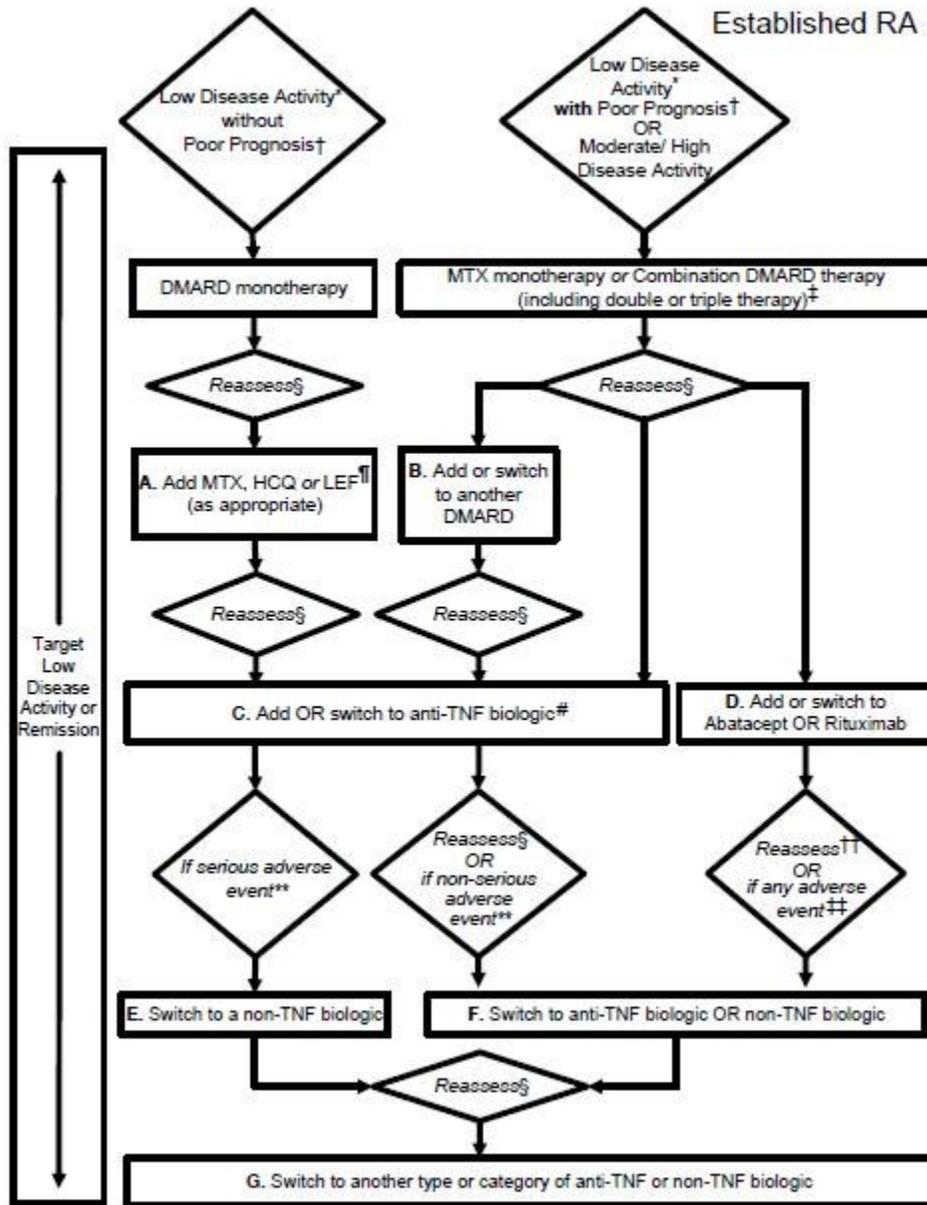
Figure 2-4: ACR recommendation for the treatment of established RA (disease duration 6 months or longer) (use with permission of Dr. Jasvinder Singh)[39]

2.4 Drug Related Problems

According to Cipolle, et al., 2012, pharmaceutical care is a patient-centered practice in which the practitioner assumes responsibility for a patient's drug related needs and is held accountable for this commitment. This healthcare professional practice is designed to meet the patient's drug related needs by identifying, resolving, and preventing drug therapy problems. The pharmaceutical care concept is the underlying concept of pharmaceutical practice. There are seven categories of drug therapy problems such as[40]:

1. The patients require drug therapy for an indication that would benefit from medication but presently is not being treated with medication.

2. The patient does not have a legitimate indication for a medication, which is being taken, and the medication should be discontinued.

3. The patient is taking medication that is not effective for the medical condition being treated.

4. The patient is not taking the medication in a manner that allows it to be therapeutically effective.

5. The patient is experiencing an adverse event as a result of the medication so the medication should be discontinued.

6. The patient is taking too much of the medication and it is causing a toxic effect.

7. The patient is not able and/or willing to take medication as intended.

A study by Ernst, et al., in 2003, was conducted to address the DRPs occurrence in arthritis (OA and RA) and low back pain (LBP) patients. They conducted a 12 month

observation in 12 independent community pharmacies in Iowa. Pharmacists reviewed the follow-up reports and had an interview with patients to identify the DRPs. During the medication assessment, pharmacists collected the information about prescription and non-prescription medications being taken by the patients. Once the DRP had been identified, pharmacists documented the DRPs, the disease state affected and interventions to resolve them. The information about the outcomes of the interventions had also been collected[7].

At the end of their program, as many as 926 DRPs had been reported. The need for additional medicines, ADRs, inappropriate compliance, too low dose, and incorrect drug were the most common DRPs that occurred. After the pharmacists' intervention, 70.7% of the DRPs were reported to be resolved or improved. This research has proven that pharmacists have a significant role in helping arthritis patients manage their disease and medications by identifying and resolving DRPs. Pharmacists conduct therapy monitoring which is a good approach to observe the outcomes from patients' medication therapy. Furthermore, pharmacists, as a healthcare provider, can function as a point person in monitoring therapy and initiating communication or collaboration with physicians to solve the problems related to the medication[7].

DRPs in RA patients frequently occur due to the use of DMARDs. DMARDs are now recommended to patients with RA in the earlier phase. Because of the potential ADRs, the use of DMARDs should have continuous monitoring by healthcare providers. Based on an observation of DMARD use of patients from 1986 to 1999, it was noted that only 50% of patients remain on a given DMARDs. The DMARDs discontinuations were due to ADRs or inefficacy[41].

According to a study performed by Grove, et al., that observed the use of DMARDs, including sulfasalazine, myocrisin, D-penicillamine, methotrexate, auranofin, azathioprine, and cyclophosphamide, the most common ADR was gastro-intestinal disturbance, such as abdominal pain, diarrhea, nausea or vomiting (11.8%). Other ADRs of DMARDs included skin rash, blood dyscrasias, renal impairment, and liver abnormalities, which resulted in discontinuation of these drugs[41].

The success of therapy is determined by the effectiveness of the medications and patient compliance. Tuncay, et al., 2007, conducted a research study that observed RA patients compliance in three time points. At baseline, the proportion of medication compliance among RA patients was 52.3%. This number decreased over the time period. In the last time point of observation, only 30.2% of RA patients were consistently compliant with DMARDs[42].

2.5 Patient Counseling

To reduce drug-related morbidity and mortality, communication between patients and healthcare providers is important. Patient counseling may be beneficial in many ways. For instance, patients may want to make sure that the medication that they are taking is safe and effective. Another case is when patients need additional information about their illness that they did not get from their physician because they felt upset, rushed, or embarrassed to ask[43].

Counseling not only applies to giving advice but also involves a two-way communication such as discussion and exchange of opinions. The Omnibus Budget Reconciliation Act (OBRA) of 1990 has mandated pharmacists to conduct patient

counseling based on the patients' agreement. Pharmacists should explain (but are not limited to) the name and description of medication, route of administration, dose, dosage form, duration of drug therapy, special directions and precautions for preparing the drugs, administration and use by patient, common side effects, interactions, and contraindications (including their avoidance and the action required if experienced). Moreover, pharmacists should counsel patients about techniques for self-monitoring medication therapy, proper storage, refill information, and appropriate action in case of a missed dose[4].

The literature cites many benefits to patient counseling, as mentioned below[44].

1. Reduced errors in using medication

2. Increased patient adherence/compliance

3. Reduced ADRs

4. Reassurance about the safety and effectiveness of a medicine

5. Providing additional information about a patient's illness

6. Assistance about self-care

7. Referral for assistance with non-drug-related situations such as family planning or emotional problems

8. Reduction in health-care cost to the individual, government, and society

There are several sources that influence patients performing their own medication self-regulation; these include health beliefs, communication, and psychological aspects. Factors related to a patients' health beliefs that cause medication self-regulation include: perceived lack of seriousness of the disease and outcomes of non-treatment, perceived

ineffectiveness of the treatment, lack of social support, complex medication regimens, lengthy therapies, and presence of adverse effects[44].

Another aspect of medication self-regulation that should be considered is communication. The communication aspect includes lack of medical supervision, lack of instruction that is explicit, clear, appropriate, adequate in quantity and feedback provision, disposition or interaction with healthcare professional, lack of strategy to modify patients' attitude and beliefs, and low involvement of patient in decisions regarding treatment. Patient psychology also influences their behavior in managing their medication. The psychological aspect includes negative experience with the drugs or desire to test the drug efficacy or to assert control over the doctor-patient relationship[44].

2.6 Medication Therapy Management

There are three important factors in explaining the need for medication management services, including increased medication complexity, and the increased use and increased costs of medications[40]. Medication therapy management (MTM) is a service or group of services that optimize therapeutic outcomes for individual patients[10]. MTM consists of five core elements including:

1. Comprehensive medication review (CMR)

2. Personal medication record (PMR)

3. Medication action plan (MAP),

4. Intervention/referral, and

5. Documentation and follow up.

OBRA 1990 directed the pharmacists to offer counseling regarding medication to the patients, conduct Drug Utilization Review (DUR), and record patients' drug therapy[4]. At this time, the role of pharmacists continues to develop with the implementation of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003, which mandated pharmacists to offer MTM programs to patients who are eligible.

According to the Medicare Part D Prescription Drug Plan of 2006, the patients who are eligible to enroll in MTM programs are those who have multiple chronic diseases, called the seven core chronic diseases. They include hypertension, heart failure, diabetes, dyslipidemia, respiratory disease (such as asthma, COPD, or chronic lung disorders), bone disease-Arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis), and mental health diseases (such as depression, schizophrenia, bipolar disorder, or chronic and disabling disorders). The patients must also be taking multiple ongoing medications[11]. The threshold of a beneficiary's drug cost for MTM eligibility was even decreased from $4000 in 2006 to $3000 in 2010[45].

Pharmacists' efforts to optimize therapeutic outcomes and pursue efficiency in the drug therapy plan made community pharmacists more actively involved in the provision of clinical services. This development supports the advancement of the profession of pharmacy. The pharmacists' role is to help a patient achieve their optimum therapeutic outcome and prevent drug therapy problems (DTPs) including adverse drug events. The impact of MTM programs not only provides efficacious results in clinical but also in humanistic and economic outcomes. Early research in many cities showed similar results, that pharmacists were able to help patients to manage their therapy and improve their quality of life.

In 2006, Medicare Part D insisted on the provision of MTM to enrollees. Today, the lower threshold of beneficiaries' drug costs makes the opportunity to obtain MTM for Part D beneficiaries even greater. Many reports have described the implementation of MTM to patients with chronic diseases such hyperlipidemia, hypertension, diabetes, and asthma. MTM programs in patients with hyperlipidemia and hypertension have shown that it improved patients' lipid profile and blood pressure, and decreased cardiovascular related medical costs[13-15,17]. In a study of patients with diabetes, community pharmacy provision of the Diabetes Care Program successfully decreased the A1C level at every follow-up and lowered the amount paid per patient per year for insurance claims[46]. Furthermore, in a study of asthma patients, MTM programs led to the improvement of Forced Expiratory Volume (FEV1), and a decrease in the number of emergency department visits and hospitalizations[47]. Hence, MTM programs can be beneficial both for patients and payers through the achievement of economic, clinical and humanistic outcomes (ECHO).

A study in 2009 showed that pharmacists perceive that a patient's willingness to participate in MTM is one of the greatest facilitators in conducting these programs (in addition to the pharmacist's educational background)[20]. A survey on diabetes patients found that perceived susceptibility to have a condition predicted the perceived threat reduction, which was found to be one of the predictors of retaining patients as participants in MTM services[48].

To date, there are few, if any, research studies in existence that assess arthritis patients' perception towards pharmacists' roles in their care. Knowing the need and patients' perception towards the pharmacist's role in conducting patient counseling is

essential to improve the quality of care and optimize outcomes for patients with arthritis. The results can trigger the health care provider, especially community pharmacists, to expand their role to help arthritis patients.

2.7 OA-Focused Pharmaceutical Care Service in Canada[23]

A pharmaceutical care program focusing on knee OA was conducted in Canada. This study was conducted to determine whether community pharmacists could fill the gap in OA patient care, such as being undiagnosed and untreated. In the control group, participants received common care in the form of an educational pamphlet on knee OA, while the intervention group participants received one-on-one consultation with a pharmacist. In the intervention group, the pharmacist offered education, medication management, and referral to a physiotherapist. Pharmacists, using a screening tool, tried to determine the likelihood of having knee OA. The pharmacist reported to the patients' physicians as to whether the patients had the likelihood to have knee OA and the outcomes from the counseling activity between the pharmacist and patient[23].

Education involved counseling sessions about the symptoms and other information related to knee OA. Patients were given the opportunity to join the Arthritis Self-Management Program. Meanwhile, in medication management, pharmacists reviewed the patient's medication, both prescription and non-prescription, assessing the concordance with the OA medication guidelines and the rationality based on the patient's condition. Counseling about the benefit, risk, and the appropriate medication use was also provided[23].

Outcomes measures that were recorded included function, quality of life, and pain. Function was measured using Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) and the Lower Extremities Function Scale (LEFS). Measurements of the quality of life were performed using the Paper Adaptive Test-5D (PAT-5D) and the Health Utilities Index Mark 3 (HUI3). The WOMAC pain scale, HUI3, and PAT-5D pain attributes were used to assess pain, which was measured in month three and six of the program[23].

This study showed significant results in many aspects. The quality of care was significantly higher in the intervention group than in the control group in the aspects of pain and functional assessment, exercise, education, weight loss, and knee radiographs. Moreover, different pain scales and function-assessment tools (WOMAC, LEFS, and the PAT-5D) displayed significant improvement in many aspects as shown in table 2.7. Monthly pharmacist follow-ups demonstrated the value of pharmacist assistance to OA patients in managing their disease and medication[23].

2.8 OA-Focused Pharmaceutical Care Services in United Kingdom[49]

A research study that was conducted in the UK in 2006 supports the potential role and opportunity of pharmacists to expand their services in community pharmacist settings, in terms of conducting more clinical activities for patients. The participants in this study were divided into three groups. The control-group participants received an information leaflet about arthritis and self-management and had a rheumatology nurse reinforce the information after seven days from obtaining the leaflet. There were two

intervention groups. The first intervention group received an enhanced pharmacy review while the second intervention group was allocated to community physiotherapy[49].

In the enhanced pharmacy review, participants also received an educational leaflet. Pharmacists reinforced self-help messages contained in the educational leaflet. Furthermore, pharmacists used a pre-defined questionnaire to conduct an initial patient assessment regarding patients' pain control and drugs. Patients' risk to have ADRs from NSAIDs also had been assessed. In this setting, pharmacists had a chance to gain access to the patients' medical records[49].

Table 2.7: Differences in Quality of Life scores measured between the usual care and the intervention group at each time point (baseline, 3 months, and 6 months)[49]

Tool	Significance		
	Estimate of Difference sat Baseline	Estimate of Differences at 3 months	Estimate of differences at 6 months
WOMAC score Global	Not significant	Significant *	Significant*
Pain subscale	Not significant	Significant *	Significant *
Function subscale	Not significant	Significant *	Significant *
Stiffness subscale	Not significant	Not significant	Not significant
LEFS score Total	Not significant	Not significant	Significant
HUI3 score Total	Not significant	Not significant	Not significant
HUI3 pain score	Significant *	Significant *	Significant *
HUI3 ambulation score	Not significant	Not significant	Not significant
PAT-5D score Daily activities domain	Not significant	Significant *	Significant *
Pain domain	Not significant	Not significant	Significant *
*p < 0.05 WOMAC=Western Ontario and McMaster Universities Osteoarthritis; LEFS= Lower Extremities Function Scale; PAT-5D=Paper Adaptive Test-5D; HUI3=Health Utilities Index Mark 3			
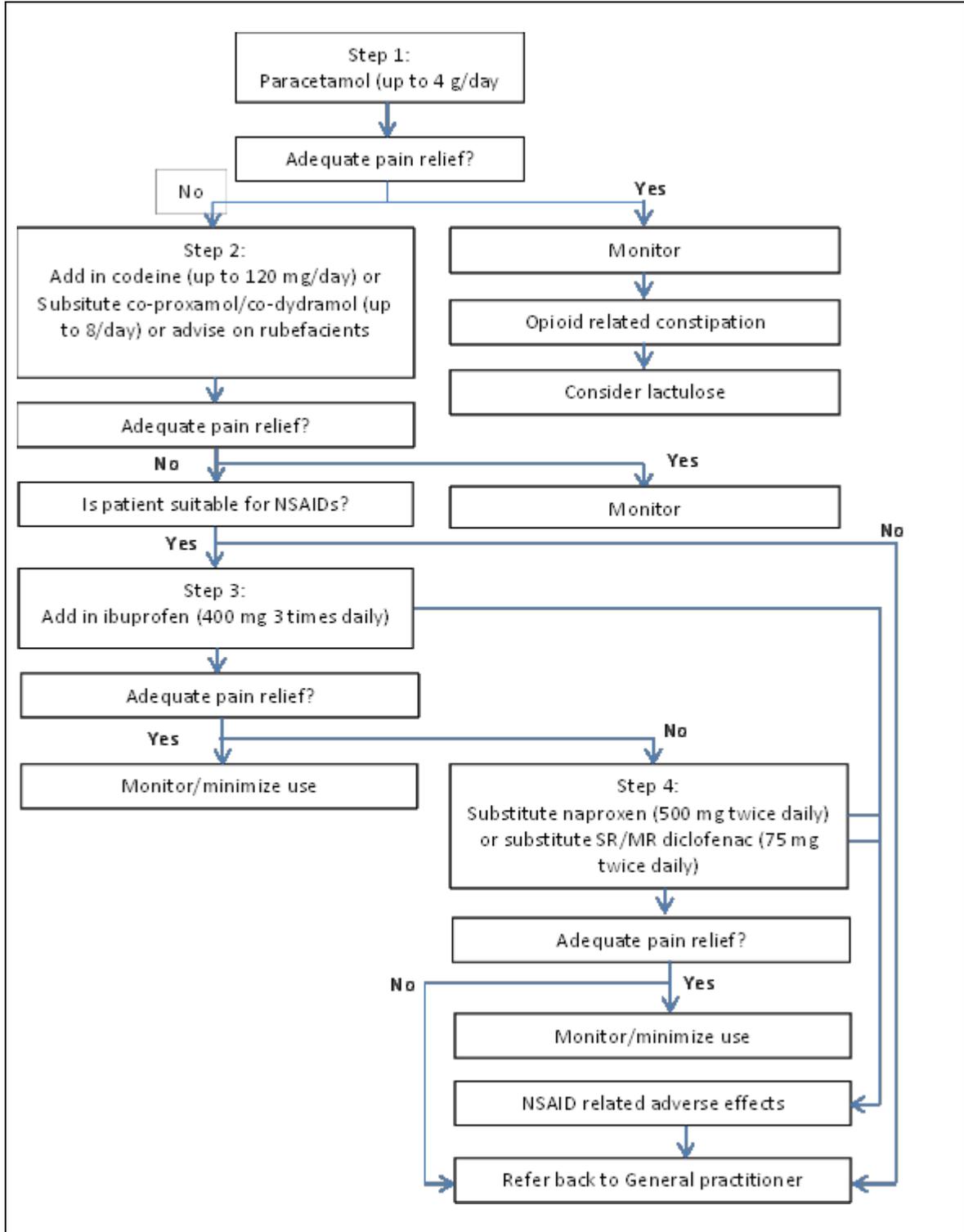
Figure 2-5: The Algorithm of medication regimen for OA
(GP= General Practitioner; NSAIDs=Non-Steroid Anti Inflammatory Drugs;
SR/MR=Sustain Release/Modified Release)[49]

Pharmacists in this study were also eligible to change patients' medications based on the standard algorithm that had been set before (Figure 2.5). Drug changing was evaluated based on patients' preference, adherence and potential drug interactions. A twenty minute-assessment session, three to six times over a 10 week period, was permitted. Furthermore, pharmacists conducted follow-up visits to monitor the effectiveness and acceptability of drugs and recommended necessary changes[49].

The second intervention group utilized collaboration with a physiotherapist. This group's target was to encourage patients to be more active in taking a role to manage their pain through education about safety and importance of exercise and pain relief. They also engaged in an individualized exercise program that involved activities such as general aerobic exercise and specific muscle-strengthening exercise (non-weight bearing and weight bearing). The outcomes measured were pain and physical function, self-efficacy, and psychological distress at three, six, and twelve months. ADRs and self-reports of co-interventions (consultation with physician or other healthcare provider) were collected at each visit[49].

This program resulted in significant improvements in WOMAC pain and function scores in the physiotherapy group and in pain scores in the pharmacy group, compared with control group. The number of NSAIDs used by participants from these two groups was lower than in the control group. This was a positive outcome, considering the potential ADRs of NSAIDs. Moreover, there was a potentially better implication in cost reduction. In conclusion, after three months, there was proven clinical effectiveness with both community physiotherapy and enhanced pharmacy review in the management of pain[49].

2.9 Health Belief Model

The Health Belief Model (HBM), developed by Godfrey Hochbaum and Irwin M. Rosenstock, has been one of the most widely used models in the research related to health behavior[50-55]. This theory consists of six constructs of individual perception (intrapersonal factor) and modifying factors related to a behavior/action[56]. It can be used to find out what factors influence someone's decision to perform an action. This model can be used for people without disease in order to perform a screening test/action to prevent a disease. HBM can also be applied to people who already have a disease, evaluating behavior related to adherence to a treatment or any activity that prevents them from having more severe disease or complications.

Table 2.8: HBM constructs[56], definition[56], and sample statement

Construct	Definition	Sample Statement in Questionnaire
Perceived Susceptibility	One's belief that he has a chance to get a disease/condition	There is no possibility that I could have a bad side effect from my medicines
Perceived Severity	One's belief about the severity/seriousness of the disease might be to his health or other important thing in his life	Arthritis can be a serious disease if you don't control it
Perceived Benefits	One's belief about the benefit/efficacy of the advised action to reduce the risk (of getting that disease/condition) or the seriousness of the impact from that disease/condition	Pharmacist counseling can help me to have a better understanding about my medications
Perceived Barriers	One's belief about the barrier of conducting the action advised, could be tangible or psychological costs	My pharmacist is easily approachable to discuss my medications
Self-Efficacy	Confidence in one's ability to perform the action advised	I am afraid to have pharmacist counseling
Cues to Action	Strategies to activate one's readiness of performing the action advised	My doctor encourages me to ask a pharmacist about my medications

The six constructs involved are perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy and cues to action as explained in table 2.8. Related to arthritis, the actions recommended are related to the arthritis patients' interaction with the pharmacist (i.e. counseling). Perceived susceptibility is related to the progressivity of the disease and drug related problems, such as ADR. Perceived severity in this case is the severity of the arthritis and its implications. For example, this includes perceived major disability, high burden of the cost, possibility of retiring early, and others. Perceived severity and susceptibility form perceived threat.

INDIVIDUAL PERCEPTIONS   MODIFYING FACTORS   LIKELIHOOD OF ACTION

Demographic variables (age, sex, race, ethnicity, etc)
Socio-psychological variables (personality, social class, peer and reference group pressure, etc)
Structural variables (knowledge about the disease, prior contact with the disease, etc)

Perceived benefits of preventive action minus Perceived barriers to preventive action

Perceived Susceptibility to Disease "X"
Perceived Seriousness (Severity) of Disease "X"

Perceived Threat of Disease "X"

Likelihood of taking recommended preventive health action

Cues to Action
Mass media campaign
Advice from others
Reminder postcard from physician or dentist
Illness of family member or friend
Newspaper of magazine article

Figure 2-6: Conceptual model of HBM[57]

Other constructs are patients' perceptions of the benefits and barriers of conducting the recommended action. Self-efficacy is how confident they are in conducting an interaction with pharmacists (e.g., asks pharmacist to give counseling). Meanwhile, cues-to-action are all things that trigger one to ask a pharmacist to give them counseling about their disease and medication. The way someone perceives a behavior could also be influenced by their demographic profile such as knowledge, ethnicity, socio-economic, and others that called modifying factors. The conceptual model of HBM can be seen in figure 2.6 above.

Chapter 3

Methods

This section describes the methods of the study. The methods described in this section include the Selection Process, Instrument, Questionnaire Administration, and Data Analysis. Data analysis will refer to the objectives as mentioned in the first chapter. This is a cross sectional study, exploring the perception of arthritis patients regarding their medication regimens.

3.1 The Selection Process

The population of this survey research was patients with Osteoarthritis (OA) and/or Rheumatoid Arthritis (RA) who got treatments from the University of Toledo Medical Center (UTMC), particularly in the Rheumatology clinic and Pain Management clinic. The Division of Rheumatology at UTMC provides comprehensive diagnostic and therapeutic evaluation for adults and children with acute and chronic rheumatic disease. Emphasizing early diagnosis and intervention, this division has a broad range of interests including chronic arthritis, rheumatoid arthritis, systemic lupus, scleroderma, and others. The Pain Management clinic at UTMC offers inpatient and outpatient care to people of

all ages who suffer from acute, chronic, and cancer-related pain. This clinic provides an individual pain management plan for each patient. Types of pain that are treated include arthritis, arm and leg pain, back and neck pain, pain resulting from cancer and injuries, as well as others. The Pain Management clinic has collaborations with physical therapists, physical medicine, rehabilitation specialists, and psychologists.

The medical chiefs of the Division of Rheumatology and the Pain Management clinic agreed to collaborate in this study. Potential respondents included all patients who attended the Rheumatology clinic or the Pain Management clinic during January-December of 2012 and met the followed inclusion criteria: 1) Patients over 18 years, 2) Have osteoarthritis and/or rheumatoid arthritis, and 3) Willing to participate in this study.

3.2 Instrument

The survey instrument contained questions regarding arthritis patients' perceptions of the role of pharmacists and their ability to manage their medication regimens. Demographic information of the respondents was also collected. To establish validity, this questionnaire had content and face validation from an expert pharmacist, an expert on the Health Belief Model (HBM), and an expert in survey methods. A pilot survey was conducted to ensure the clarity of the sentences and establish the approximate time needed to fill out the questionnaire.

The questionnaire consisted of four sections. The HBM was used in constructing the questions in the first section of the questionnaire. This section consisted of three constructs from the HBM including perceived benefits and perceived barriers of asking

for patient counseling from pharmacists, and self-efficacy in asking for patient counseling from pharmacists with regard to their arthritis medications. These three constructs have been known to have significant influence on a person's health behavior[50-55]. Definitions were set for the three HBM constructs. Perceived benefits in this study are patients' perceived benefits in obtaining patients counseling from the pharmacist. Perceived barriers are patients' perceived barrier from asking for counseling, while self-efficacy is the confidence regarding asking for counseling and participating the counseling. The health beliefs of each participant were addressed using a four-point Likert scale from "strongly disagree" to "strongly agree".

The second section consisted of questions related to the patients' experience in their medication use, which would reflect their ability in managing all of their medications. As with the scales used in the first section, the second section also used the four-point Likert scale from "strongly disagree" to "strongly agree". The third section addressed participants' intention to seek patient counseling from pharmacists. A dichotomous yes/no response was applied in identifying arthritis patients' intention.

The last part of the questionnaire asked respondents about demographic information including the severity of their condition, the number of medications that they are taking, comorbidities, age, race/ethnicity, gender, income, and health coverage. The number of medications was a continuous variable. The remaining variables were categorical.

3.3 Questionnaire Administration

This study was a mail survey using a validated questionnaire. Patients' names and addresses were obtained through the Quality Management Department of UTMC. The survey packages were sent by mail through the clinics. To maintain the confidentiality of respondents, one of the investigators was assigned as a code-book holder. This investigator made a code-book that contains the patients' names, addresses and codes as patients' new identifiers. The data analyst did not have access to the code-book and the code-book holder did not have access to the data collected. Hence, there was no way to back track the data collected which contains the new identifier, to the patients' real names and addresses.

The survey package consisted of a cover letter, a two-page questionnaire, and a prepaid envelope. The cover letter explained the aim of the survey and the informed consent. By completing the questionnaire, patients agreed to be participants in the study and gave their consent to voluntarily participate in this study. The patient's name and address were printed on the envelope, while the potential respondent's code was on the top of the questionnaire sheet. The code-book holder put the questionnaires into the appropriate envelopes based on the code-book and then sealed it. The questionnaires that were completed were collected and the data were analyzed by the researcher. The data collection was conducted in two periods. The first period was from the initial mailing to two weeks after the survey packages had been mailed. A second survey package was mailed to remind the potential subjects who had not given their response. Then, surveys were collected for an additional two weeks. The entire data collection period was four weeks.

Because this study involves human subjects, permission to conduct the study was required. After obtaining the approval from the Department for Human Research Protection (DHRP) and Institutional Review Boards (IRB) of University of Toledo, particularly the Biomedical IRB, the research commenced.

3.4 Data Analysis

The data were entered into Statistical Package for the Social Sciences (SPSS) version 20 and analyzed based on the objectives. The internal consistency of the questionnaire was estimated using Cronbach coefficient alpha. Reliability of the first and second sections was analyzed. Missing values of the first section were replaced using the Series Mean method from SPSS, for the purpose of running logistic analysis only. Details of the statistical analyses performed are explained below.

3.4.1 Research Question 1

a. *Is arthritis patients' intention to ask for patient counseling from pharmacists different based on the demographic information (non-continuous variable)?*

Ho 1.1: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacist based on the severity of the symptoms (Chi square)

Ho 1.2: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacist based on the annual income (Chi square)

Ho 1.3: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacist based on race/ethnicity (Chi square)

Ho 1.4: There is no statistically significant difference in arthritis patients' intention to ask for patient counseling from pharmacist based on gender (Chi square)

Ho 1.5: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacist and their age group (Chi square)

Ho 1.6: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacist and their insurance status (Chi square)

b. *Is there a relationship between arthritis patients' demographic information (continuous variable) and their intention to ask for patient counseling from pharmacists?*

Ho 1.7: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacist and the number of medication taken (logistic regression)

Ho 1.8: There is no statistically significant relationship between arthritis patients' intention to ask for patient counseling from pharmacist and the number of comorbidity (logistic regression)

3.4.2 Research Question 2

How much variance does the combination of constructs in the health belief model (perceived benefits, perceived barriers, and self-efficacy) explain related to arthritis patients' intention to ask for patient counseling from pharmacists?

Ho: The variance explained by the HBM will not be statistically significant (logistic regression)

3.4.3 Research Question 3

Which construct in the health belief model (perceived benefits, perceived barriers, and self-efficacy) and the demographic information (severity of the symptom, age, gender, socio-economic status, race/ethnicity, the number of medication, and the number of comorbidity) account for the largest proportion of variance when predicting arthritis patients' intention to ask for patient counseling from pharmacists?

Ho: All constructs and demographic information (odd ratios) will not be statistically significant (logistic regression)

3.4.4 Research Question 4

What is arthritis patients' ability to manage their medication regimens? (Descriptive)

3.4.5 Research Question 5

What is the relationship between arthritis patients' ability to manage their medication regimens and their intention to ask for counseling from their pharmacists?

Ho: There is no statistically significant relationship between arthritis patients' ability to manage their medication regimens and their intention to ask for counseling from their pharmacists (Spearman Correlation)

Chapter 4

Data Analysis and Result

Chapter four presents the results of data collection and data analyses. The data were collected using a questionnaire as a survey tool and will be presented according to the following order:

- Pilot Study

- Reliability of the Questionnaire

- Sample Size and Response Rate

- Demographic Characteristics of the Respondents

- Non-Response Bias - Comparison of the Early and Late Respondents

- Analysis of the Research Questions

- Comments from Respondents

4.1 Pilot Study

A pilot study was conducted to test the instrument of this survey with regard to the questionnaire content, the clarity of the questions and the instructions, and the overall appearance of the questionnaire sheet. The pilot test was also intended to address the

possible problems that the participants might have while they were completing the questionnaire. Nineteen arthritis patients who were waiting for their doctors' appointments participated in this pilot study. After conducting the pilot study, it was determined that the questionnaire was clear enough to be used as the instrument for this survey research. The average time needed to complete the questionnaire was 11.3 minutes.

4.2 Reliability of the Questionnaire

The reliability of the final questionnaire was determined using Cronbach's Coefficient Alpha. There were four sections in the questionnaire. However, the third section only contained one question asking about participants' intentions to ask for counseling from their pharmacists. This was not included in the reliability measurement. The fourth section was not analyzed in the term of reliability because it consisted of exclusively demographic information.

The first section assessed patients' health beliefs regarding patient counseling provided by pharmacists. This section consisted of three subsections: perceived benefits, perceived barriers, and self-efficacy. The reliability of each subsection was analyzed. The first, second, and third subsections yielded an α of .918, .749, and .845 respectively, making an overall alpha of .874 for the first section. The second section addressed arthritis patients' ability to self-manage their medication regimens and yielded an α of .809.

4.3 Sample Size and Response Rate

From 434 patients as potential respondents, four were excluded because they either did not use any medicine for arthritis, had died, or lived in a nursing home. A power analysis revealed that, given the population size of 430, a margin error of 5%, a confidence level of 95%, and a 50% response distribution, at least 204 participants were needed for this investigation[58]. However, according to Osborn and Costello (2004), at least ten participants were needed for every item measured within a construct[59]. Thus, the minimum number of participants needed was 150, because the total number of items within the Health Belief Model (HBM) analyzed in this study was 15.

A two-phase mail survey was conducted, resulting in a total data collection time of four weeks. The first phase participants were noted as early respondents, and those who participated in the second phase were noted as late respondents. From 430 questionnaires mailed, 97 submitted questionnaires and 18 returned survey packages were received by the study cut-off date. Any additional responses that were received after the cut-off date were not included in the data analysis. Table 4.1 below presented the response rate of this mail survey.

Table 4.1: Survey response rate

Questionnaires Mailed	430
Returned Survey Package	18
Submitted questionnaires	97
Response Rate	23.54 %

4.4 Demographic Characteristics of Respondents

Arthritis patients who participated in this study were dominated by females with 78.4 % completing the survey. Whereas, males represented 21.6 % of the sample population. In this survey, most of the respondents were 61 to 70 years old, followed by 51 to 60 years, contributing 61.2 % of the total participants. The majority of respondents had an annual household income less than $15,000 (23.6 %) followed by $15,000 to 24,999 with 18 %. Another demographic variable addressed respondents' health coverage plans. The most prevalent health coverage plan was Medicare (35.9%). All respondents had health coverage plans. Most participants with Medicare were enrolled in Medicare Part A and B (almost 40 % each), followed by Medicare Part D (17.4 %).

Most respondents perceived that their disease severity was moderate (39.6 %). Almost 60% of respondents had one or two comorbid diseases. Among five chronic diseases as comorbidities, the three most prevalent diseases were high blood pressure (29.5 %), high cholesterol (19.1 %), and diabetes (10.4 %). Few respondents had arthritis as the only illness (8.7 %). On average, respondents took eight to nine medications including prescription, non-prescription, vitamin, and dietary supplements for all their illnesses. Most of them had been taking six to ten medications (41.9 %). The last question in the demographic section asked about enrollment in any program where pharmacists conduct counseling about medications, provide a medication record, monitor the effectiveness of the medications and solve medication-related problems such as side effects. Almost all the respondents answered "No" (92.7 %) for having enrolled in such a program. Demographic and clinical information is shown in table 4.2.

Table 4.2: Demographic and clinical information of respondents

Characteristic	N	%
Gender (N=74)		
Male	16	21.6
Female	58	78.4
Age (N=85)		
18 to 30	4	4.7
30 to 40	3	3.5
41 to 50	13	15.3
51 to 60	23	27.1
61 to 70	29	34.1
71 to 80	8	9.4
Above 80	5	5.9
Annual Household Income (N=89)		
Less than $ 15,000	21	23.6
$ 15,000 to $ 24,999	16	18.0
$ 25,000 to $ 34,999	9	10.1
$ 35,000 to $ 44,999	7	7.9
$ 45,000 to $ 54,999	6	6.7
$ 55,000 to $ 64,999	10	11.1
$ 65,000 to $ 74,999	2	2.2
$ 75,000 to $ 84,999	3	3.4
$ 85,000 to $ 94,999	5	5.6
More than $ 95,000	10	11.2
Race (N=95)		
White, Non-Hispanic	78	82.1
Black/African-American	10	10.5
Hispanic	4	4.2
Asia	0	0
Multi-racial/Others (Native American)	3	3.2
Health Coverage Plan (N=95)		
Medicare	51	53.7
Medicaid	23	24.2
VA	0	0
Insurance through a current or former employer	45	47.4
Insurance purchased directly from an insurance company	15	15.8
Others (student insurance, insurance through spouse)	8	8.4
Do not have any health coverage plans	0	0
Medicare (N=92)		
Part A	36	39.1
Part B	35	38.0

Characteristic	N	%
Part C	5	5.4
Part D	16	17.4
Disease Severity (N=96)		
Mild	19	19.8
Moderate	38	39.6
Bad	26	27.1
Very bad	13	13.5
# Comorbidities (N=94)		
Mean=1.72		
0	15	16
1-2	56	59.6
3-4	19	20.2
More than 4	4	4.3
Comorbidities (N=94)		
None	15	16
Diabetes	18	19.1
High Blood Pressure	51	54.3
Asthma	14	14.9
Gastritis/GERD	15	14.9
High Cholesterol	33	35.1
Others	27	28.7
# Medication (N=93)		
Mean=8.69		
1-5	28	30.1
6-10	39	41.9
11-15	16	17.2
More than 15	10	10.8
PCS (N=95)		
Yes	7	7.4
No	88	92.6

-Other comorbid diseases: depression, anxiety, insulin resistance, schleroderma, pulmonary fibrosis, COPD, osteopenia, heart disease, fibromyalgia, hatchimotos, lymphadema, graves disease.
-PCS: Pharmaceutical Care Services, a kind of program where your pharmacist counsels you about your medication, gives you a medication list/record, monitors the effectiveness of your medication and solves your medication related problem (e.g. side effect).
-N: total respondents answered the question which may be less than 97 because of missing data.
-Total of percentage may be more than 100 due to multiple answers in one question

4.5 Non-Response Bias - Comparison of the Early and Late Respondents

Non-response bias may occur if the group of non-respondents had different

characteristics than respondents. This study did not compare characteristics among

respondents and non-respondents because there was no follow-up survey to access non-respondents. However, demographic information comparisons between early and late respondents are presented in the tables below. The only significant difference was in the number of comorbidities, as shown in table 4.4.

Table 4.3: Response time by demographic information (categorical)

Demographic Information and Clinical Characteristic	Early Respondents N (%)	Late Respondents N (%)	*p*-value
Gender (N1=52; N2=22)			
Male	11 (21.2)	5 (22.7)	1.000
Female	41 (78.8)	17 (77.3)	
Age (N1=59; N2=26)			
18 to 30	4 (6.8)	0 (0)	.741
31 to 40	2 (3.4)	1 (3.8)	
41 to 50	9 (15.3)	4 (15.4)	
51 to 60	16 (27.1)	7 (26.9)	
61 to 70	21 (35.6)	8 (30.8)	
71 to 80	4 (6.8)	4 (15.4)	
Above 80	3 (5.1)	2 (7.7)	
Annual Household Income (N1=61; N2=28)			
Less than $ 15,000	14 (23.0)	7 (25.0)	.382
$ 15,000 to $ 24,999	10 (16.4)	6 (21.4)	
$ 25,000 to $ 34,999	6 (9.8)	3 (10.7)	
$ 35,000 to $ 44,999	7 (11.5)	0 (0)	
$ 45,000 to $ 54,999	2 (3.3)	4 (14.3)	
$ 55,000 to $ 64,999	7 (11.5)	3 (10.7)	
$ 65,000 to $ 74,999	1 (1.6)	1 (3.6)	
$ 75,000 to $ 84,999	2 (3.3)	1 (3.6)	
$ 85,000 to $ 94,999	5 (8.2)	0 (0)	
More than $ 95,000	7 (11.5)	3 (10.7)	
Race (N1=66; N2=29)			
White, Non-Hispanic	54 (81.8)	24 (82.8)	.533
Black/African-American	6 (9.1)	4 (13.8)	
Hispanic	4 (6.1)	0 (0)	
Asia	0 (0)	0 (0)	
Multi-racial/Others (Native American)	2 (3.0)	1 (3.4)	

Demographic Information and Clinical Characteristic	Early Respondents N (%)	Late Respondents N (%)	p-value
Health Coverage Plan (N1=66; N2=29)			
Medicare	35 (53.0)	16 (55.2)	.704
Medicaid	16 (24.2)	7 (24.1)	
VA	0 (0)	0 (0)	
Insurance through a current or former employer	30 (45.4)	15 (51.7)	
Insurance purchased directly from an insurance company	12 (18.2)	3 (10.3)	
Others (student insurance/insurance through spouse)	7 (10.6)	1 (3.4)	
Do not have any health coverage plans	0 (0)	0 (0)	
Disease Severity (N1=66; N2=30)			
Mild	13 (19.7)	6 (20.0)	.714
Moderate	24 (36.4)	14 (46.7)	
Bad	20 (30.3)	6 (20.0)	
Very bad	9 (13.6)	4 (13.3)	
Intention (N1=65; N2=31)			
No	32 (49.2)	16 (51.6)	1.00
Yes	33 (50.8)	15 (48.4)	

-*Variable differences were analyzed using Chi-Square or Fisher test*
-*Total sample might less than 97 due to missing data; total percentage may be more than 100 due to multiple answers in one question*
-**Statistically significant at α=.05*
-*N1=total response from the early respondents; N2: total response from the late respondents*

Table 4.4: Response time by demographic information (continuous)

Demographic Information and Clinical Characteristic	Mean		P-value
	Early	Late	
Number of comorbidities (N1=64; N2=30)	1.42	2.37	.006*
Number of medications (N1=66; N2=27)	8.41	9.37	.677

-*Variable differences were analyzed using Mann Whitney U test because the data were not normally distributed*
-** Statistically significant at α=.05*
-*Total sample might less than 97 due to missing data*
-*N1=total response from the early respondents; N2: total response from the late respondents*

4.6 Analysis of the Research Questions

4.6.1 Intention to Ask for Counseling from Pharmacists

Section 3 queried respondents about their willingness to ask their pharmacists to provide counseling regarding their medications, specifically their arthritis medications. A definition was provided, stating that counseling included medication review and explanations such as common side effects, dose, special directions, techniques for self-monitoring, what each medication is supposed to do, and other relevant information. According to the present study, the number of respondents who had intentions was equal to those who had no intentions to ask for counseling from their pharmacists regarding their medication regimens (table 4.5).

Table 4.5: Intention to ask for counseling from pharmacists regarding medication

Intention (N=96)	N	%
Yes	48	50.0
No	48	50.0

-Total sample might less than 97 due to missing data

4.6.2 Respondents' Health Beliefs

This section addressed respondents' health beliefs towards pharmacists' counseling regarding their medications. From the Health belief Model (HBM), perceived benefits, perceived barriers, and self-efficacy were included in this questionnaire. The scale used was a Likert scale from 1 to 4, where 1 represented "strongly disagree" and 4 represented "strongly agree". The opposite way of scoring worked for negatively phrased items. The results from the three constructs of the HBM theory were explained as followed.

4.6.2.1 Perceived Benefits

Table 4.6 shows respondents' perceptions with regard to the benefit of patient counseling by pharmacists. Among six items reflecting the benefit of pharmacists conducting patient counseling, respondents mostly agreed that asking the pharmacist about the side effects of medication was helpful (mean 3.45±.711). Respondents also perceived that having pharmacist counseling would help motivate them to use medication(s) appropriately to ease their arthritis pain (mean 3.08±.886).

Table 4.6: Perceived benefits of patient counseling provided by pharmacists

N	Item	Disagree – N (%)		Agree – N (%)		Mean ± SD	NA
		SD	D	A	SA		
83	Having my pharmacist counsel me will help motivate me to use medication(s) appropriately to ease my arthritis pain	4 (4.8)	17 (20.5)	30 (36.1)	32 (38.6)	3.08±.886	14
87	Asking the pharmacist about the side effects of my medication is helpful	2 (2.3)	5 (5.7)	32 (36.8)	48 (55.2)	3.45±.711	10
81	I feel more secure in taking my medication(s) after my pharmacist has counseled me	4 (4.9)	10 (12.3)	37 (45.7)	30 (37.0)	3.15±.823	16
81	I feel more relaxed after my pharmacist has counseled me about my medication(s)	3 (3.7)	12 (14.8)	43 (53.1)	23 (28.4)	3.06±.764	16
76	Because my pharmacist monitors me, I better understand how my medication(s) works	4 (5.3)	15 (19.7)	33 (43.4)	24 (31.6)	3.01±.856	21
78	My pharmacist can help me in managing my arthritis	4 (5.1)	20 (25.6)	38 (48.7)	16 (20.5)	2.85±.807	19
	Overall scale mean	3.10					

NA = not applicable was combined with no response/missing

4.6.2.2 Perceived Barriers

There were five items in the subsection of perceived barriers to asking for patient counseling from pharmacist as shown in table 4.7. Respondents perceived that pharmacists are too busy to give proper explanations about medication(s), resulting in the lowest score on this item (mean 2.86±.996). Patients' time was the second most common barrier to asking for counseling from pharmacists (mean 3.23±.690).

Table 4.7: Perceived barriers of patient counseling provided by pharmacists

N	Item	Disagree – N		Agree – N		Mean ±	NA
		SD	D	A	SA	SD	
85	My pharmacist is approachable to discuss my medication(s)	0 (0.0)	13 (15.3)	34 (40.0)	38 (44.7)	3.29±.721	12
88	Pharmacists are too busy to give proper explanations about medication(s)*	25 (28.4)	39 (44.3)	11 (12.5)	13 (14.8)	2.86±.996	9
91	I feel embarrassed to talk about my medication with my pharmacist*	43 (47.3)	42 (46.2)	2 (2.2)	4 (4.4)	3.36±.738	6
88	I have no time to ask my pharmacist about my medication(s)*	31 (35.2)	48 (54.5)	7 (8.0)	2 (2.3)	3.23±.690	9
86	I am worried about the extra cost of being counseled by my pharmacist*	39 (45.3)	36 (41.9)	7 (8.1)	4 (4.7)	3.28±.807	11
	Overall scale mean	3.20					

NA = not applicable was combined with no response/missing
 *Negatively phrased item

4.6.2.3 Self-Efficacy

The last construct from the HBM used in this questionnaire was respondents' self-efficacy to ask for counseling from their pharmacists. Table 4.8 below shows that more than three-quarters of respondents were confident and felt no hesitation to ask their

pharmacists to provide them with counseling. Around 80% also felt confident to ask the

pharmacist whatever questions they had regarding their medication(s).

Table 4.8: Respondents' self-efficacy to ask for patient counseling from their
pharmacists

N	Item	Disagree – N (%)		Agree – N (%)		Mean ± SD	NA
		SD	D	A	SA		
83	I feel confident asking my pharmacist to counsel me about my medication(s)	2 (2.4)	13 (15.7)	43 (51.8)	25 (30.1)	3.10±.743	14
82	I ask the pharmacist whatever questions I need answered regarding my medication(s)	1 (1.2)	8 (9.8)	50 (61.0)	23 (28)	3.16±.638	15
81	I understand the pharmacist's directions concerning my medication(s)	1 (1.2)	1 (1.2)	54 (66.7)	25 (30.9)	3.27±.548	16
80	I feel no hesitation in asking the pharmacist to repeat their instructions.	0 (0.0)	7 (8.8)	47 (58.8)	26 (32.5)	3.24±.601	17
	Overall scale mean	3.19					

NA = *not applicable was combined with no response/missing*

4.6.3 Respondents' self-management ability

This section addressed respondents' ability to perform self-management of their

entire medication regimens, including prescribed medications, non-prescribed

medications, vitamins, and dietary supplements. Questions in this section were related to

medication information and concern about medications. Among all items in this section,

knowing what to do if they were missing a dose had the highest mean score (mean

3.22±.721), followed by the awareness of special precautions to take with their

medications (mean 3.20±.720). Table 4.9 below presents the results for arthritis patients'

ability to manage their medication regimens (research question 4).

Table 4.9: Respondents' ability to manage their medication regimens

N	Item	Disagree – N (%)		Agree – N (%)		Mean ± SD	NA
		SD	D	A	SA		
96	I remember the name of ALL my medication(s)	6 (6.3)	19 (19.8)	42 (43.8)	29 (30.2)	2.98±.870	1
94	I know the purpose of each of my medication(s)	4 (4.3)	9 (9.6)	48 (51.1)	33 (35.1)	3.17±.771	3
94	I always remember to take my medicine(s) on time	2 (2.1)	19 (20.2)	47 (50.0)	26 (27.7)	3.03±.754	3
96	I am aware of special precautions (e.g., taking with food or on empty stomach, etc.) to take with my medication(s)	3 (3.1)	8 (8.3)	52 (54.2)	33 (34.4)	3.20±.720	1
95	I am capable of monitoring myself for any side effects from my medication(s)	3 (3.2)	6 (6.3)	60 (63.2)	26 (27.4)	3.15±.668	2
94	I know what to do if I am experiencing an allergic reaction to my medication(s)	5 (5.3)	11 (11.7)	48 (51.1)	30 (31.9)	3.10±.804	3
94	I know what I should do if I missed a dose (forget to take medication)	3 (3.2)	7 (7.4)	50 (53.2)	34 (36.2)	3.22±.721	3
83	I kept my past arthritis pain medications even if I get a new pain medicine	7 (8.4)	21 (25.3)	34 (41.0)	21 (25.3)	2.83±.908	14
93	I have had a physician, pharmacist, or other health professional look at ALL of my medications in the past 6 months	12 (12.9)	10 (10.8)	31 (33.3)	40 (43.0)	3.06±1.03	4
92	I always carry my medication list with me	12 (13.0)	19 (20.7)	27 (29.3)	34 (37.0)	2.90±1.05	5
	Overall scale mean	3.06					

NA = *not applicable was combined with no response/missing*

4.6.4 Statistical Analysis to Test Hypotheses

All statistical analysis in this study used a priori level of 0.05 to test hypotheses.

Chi square was used to analyze the difference in intention among different categories,

such as severity, annual income, race/ethnicity, gender, age group, and insurance status.

Meanwhile, association between patients' intentions with continuous variables such as number of comorbidities, number of medications, and self-management ability were assessed using correlations.

4.6.4.1 Testing Hypotheses from Research Questions 1.1 to 1.8

Chi-square analyses to test hypotheses 1.1 to 1.5 showed significant differences only in gender (p=.014). Other demographic characteristics did not significantly differ among respondents who had intention compared with those who had no intention to ask for patient counseling from their pharmacists. Research question 1.6, comparing insured and non-insured patients pertaining to their intentions to ask for patient counseling, could not be addressed because all respondents were insured. Hypotheses 1.7 and 1.8 that were analyzed using logistic regression also indicated no significant association either between intention and the number of medications or intention and the number of comorbidities that the patients had.

Because of the small sample size, some variables, including age, annual household income, and severity of the disease were collapsed into fewer categories. The variable age was collapsed into three categories: less than 51, 51 to 70, and above 70. Annual household income was collapsed into 3 categories: less than $ 25,000; $ 25,000 to $64,999; and $ 65,000 or higher. For severity of the disease, mild and moderate were grouped into one category, while bad and very bad were grouped into another category. Race categories were collapsed into 2 groups: White, Non-Hispanic and Others. The overall results are shown in table 4.10 below.

Table 4.10: Demographic information and clinical characteristics of respondents based on their intention to ask for counseling from pharmacists

Demographic Information and Clinical Characteristics	Number of Respondent		P-Value*
	No	Yes	
Gender (N=73)			
Male	12	4	.014*
Female	23	34	
Age (N=85)			
<51	13	7	.396
51-70	25	27	
>70	6	7	
Annual Household Income (N=88)			
Less than $ 24,999	13	23	.063
$ 25,000 to $ 64,999	20	12	
More than $ 65,000	12	8	
Race (n=94)			
White, Non-Hispanic	42	35	.061
Other than White, non-Hispanic	5	12	
Severity of the disease (N=94)			
Mild to Moderate	33	24	.057
Bad to very Bad	14	23	
Insurance status (N=95)			
Medicare	21	29	.054
Medicaid	7	16	
Employer	29	15	
Private	8	7	
Others	4	4	
# Comorbidities (N=93)			
Logistic regression	-------	-------	.520
# Medication (N=92)			
Logistic regression	-------	-------	.983

Significant difference (p< .05), through chi-square analysis

4.6.4.2 Testing Hypotheses from Research Question 2

Items related to the three constructs based on the HBM as a theoretical framework in this study were analyzed. Missing data were approximately14% of total items in the first section and around 4% in the second section. The missing values in the first section

were replaced using the Series Mean method in SPSS. Then, logistic regression was used

to test how much variance the combination of constructs in the HBM (perceived benefits,

perceived barriers, and self-efficacy) explains in arthritis patients' intentions to ask for

counseling from pharmacists (table 4.11). Logistic regression results showed that this

model was significant ($p<.000$). The Hosmer and Lemeshow test indicated that this

model fit the data being analyzed ($p=.178$). The sensitivity of this model, showed by the

number of percentage correct between observed and predicted intention was 72.9%. The

Nigelkerke R^2 indicated that 43.1% of variance in the intention could be explained by

variables included in this model. Among the three constructs, perceived benefits was the

only significant predictor of intention ($p=.001$).

Table 4.11: Logistic regression analysis of patients' perceived benefits, perceived
barriers, and self–efficacy towards intention to ask for patient counseling
from the pharmacist

	B	SE	Wald	df	Sig.	Exp(B)
P. Benefits	.362	.104	12.088	1	.001*	1.436
P. Barriers	.127	.113	1.262	1	.261	1.136
Self-Efficacy	.342	.190	3.263	1	.071	1.408
Constant	-13.114	2.934	19.979	1	.000	.000

Significant difference (p< .05)

4.6.4.3 Testing Hypothesis from Research Question 3

When analyzing predictors of intention, there is a need to control demographic

characteristics that might impact intention. Independent variables involved in Research

Question 3 were the three constructs from the HBM (perceived benefits, perceived

barriers, and self-efficacy) and demographic characteristics, including severity of the

arthritis, age, gender, income, race, number of comorbidities and number of medications.

Logistic regression results showed that this model was significant ($p=.002$). However, the

Hosmer and Lemeshow test, another way to assess the goodness of fit, indicated that the

model did not suit the data well ($p= .043$). Nigelkerke R^2 showed that 53.1% of variance

in intention could be explained by the variables in this model. The sensitivity of this

model was 81.5%. Perceived benefits was again the only significant predictor of intention

($p=.036$).

Table 4.12: Logistic Regression of demographic characteristics, perceived
benefits, perceived barriers, and self-efficacy of the respondents
towards intention to ask for counseling from the pharmacist

	B	SE	Wald	Df	Sig.	Exp(B)
P. Benefits	.327	.156	4.384	1	.036*	1.387
P. Barriers	.166	.186	.792	1	.374	1.180
Self-Efficacy	.242	.272	.793	1	.373	1.274
Gender	1.740	1.144	2.314	1	.128	5.698
Severity	.031	.928	.001	1	.974	1.031
Income	-.700	.599	1.368	1	.242	.496
Age	.159	.638	.062	1	.804	1.172
Race	.927	1.045	.786	1	.375	2.526
Comorbid	-.687	.387	3.160	1	.075	.503
Medication	-.075	.095	.634	1	.426	.927
Constant	-13.467	5.020	7.198	1	.007	.000

Significant difference ($p< .05$)

4.6.4.4 Testing Hypothesis from Research Question 5

The Spearman rank test was used to assess the relationship between patients'

intention and their ability to manage their medication regimens. Table 4.13 below showed

that there was a positive, fair degree, and significant relationship between the ability of

arthritis patients to manage their medication regimens and their intention to ask for

counseling from pharmacists (r=.347, p=.003). The positive coefficient from the logistic

regression equation showed that the higher the patient's ability to manage their

medication, the higher the likelihood of asking for counseling from the pharmacist.

Table 4.13: Spearman's rank analysis of relationship patients' ability to manage their
medication regimens and their intention to ask for patient counseling from
the pharmacist

		Ability to manage medication	Intention
Ability to manage medication	Correlation coefficient	1.000	.347*
	Sig. (2-tailed)	.	.003
	N	74	73
Intention	Correlation coefficient	.347*	1.000
	Sig. (2-tailed)	.003	.
	N	73	96

Significant difference (p< .05)

4.7 Comments from Respondents

Although there was no open ended question in the questionnaire, several

respondents wrote their comments regarding patient counseling and their drug-related

problems. Overall, respondents stated that either they did not know that they could ask

for counseling from a pharmacist if they received their medication through mail order

pharmacy; they did not believe that pharmacists could do patient counseling; or they

simply never saw people ask for counseling from the pharmacist (table 4.14).

Table 4.14: Comments from respondents

Comments related to patient counseling
"No pharmacist available ever"
"I get scripts through mail" [and then choose no for intention to ask patient counseling from pharmacists]
"Mail order" [and then choose no for intention to ask patient counseling from pharmacists]
"[I]would like to be able to [ask patient counseling] but not sure my pharmacist provides this service"
"My Rph [pharmacist] doesn't monitor me or counsel me, it is simply a retail transaction"
"My MD [physician] is the more appropriate person to talk to as they know my entire health rx [prescription]"
"I honestly never have asked my Rph [pharmacist] for advice or info"
"A pharmacist can't reconcile medications without an accurate problems list. This is best done in the ambulatory setting by the PMD. Medication recon [reconciliation] is the biggest problem in healthcare right now – Can you tell I'm a healthcare IT professional☺!"
"Until we have an Health Information Exchange between institutions including the Rph [pharmacist] that includes the problem list, the pharmacist is at a disadvantage in providing advice as they don't have the pts [patients] problem list. How can you truly reconcile meds w/o [without] that info too!"
"I stand in line many times at retail pharmacies and rarely see pts [patients] ask for counseling"
Comments related to drug related problem
"[I] just skip [the medication when I forget to take it]"
"[checked the box stated that she has high blood pressure] no medication as it varies" (and again checked the box stated that she has high cholesterol but wrote that no medication for her condition)
"Synthroid-Meloxicam [drugs taken] not working too well"
"I have taken Aleve and overall medication but it doesn't help. The government changed my medicine from Medco to a drug with one I'm terrible and allergic to. None hence I can take."

Chapter 5

Discussion and Conclusion

Chapter five presents a brief discussion based on findings described in the previous chapter. The discussions follow the outline below.

- Reliability and Validity

- Discussion on the Response Rate

- Discussion on the Descriptive and Statistical Analysis Results

- Study Limitations

- Suggestions for Future Research

- Conclusion of the Study

5.1 Reliability and Validity

This study was preceded by a pilot study to ensure clarity. The internal consistency was measured using Cronbach-alpha, indicating the precision of the measuring instrument. The reliability of the first, second, and third subsections were .918, .749, and .845 respectively, making the overall first section reliability .874. The section I-subsection 2, with the lowest value, contained four negatively phrased items. Negatively

phrased sentences may have confused respondents who were not carefully reading the sentences or those who were in a hurry completing the questionnaire. Section II measuring medication self-management, yielded an alpha of .809. The Cronbach-alpha values showed that the questionnaire used in this survey was highly reliable.

5.2 Discussion on the Response Rate

Many studies using mail survey methods with patients as subjects result in varied response rates. One example, a patient satisfaction mail survey using a single wave mailing with a cover letter and a business reply envelope, generated a 41.1% response rate[60]. A 2001 mail survey targeting patients with multiple sclerosis had a 65% response rate[61]; yet another study targeting patients with psoriatic arthritis was answered by 43% of potential respondents[62].

Spending four weeks on data collection time, the present study yielded a 23.54% response rate, which was relatively lower compared to similar mail surveys mentioned previously. Several strategies that are recommended to increase response rate were used in this study[63,64]. Using a cover letter signed by the patients' physician, using blue colored paper for printing the questionnaire, using envelope and cover letter with the university logo, providing a pre-paid envelope, sending an additional survey package as a reminder, and a chance to receive a gift card through a raffle drawing, were strategies applied to increase the response rate. Furthermore, the survey instrument, according to the pilot study, only took approximately 11 minutes on average to complete. The present study used a two-wave mailing protocol. The second wave of surveys increased the response by 31 respondents, nearly half of those that participated in the first wave.

Based on the result, around half of respondents were above 60 years of age or elderly[65]. According to a previous study, age had significant impact on response rate of a mail questionnaire where the response rate fell more than .5 percentage points for each unit measure of age[66]. Therefore, the higher age of the population could be a reason for the lower response rate obtained in the present study.

Some of the respondents had none to limited experience or knowledge regarding interacting with their pharmacists. This fact made respondents either answer the questions with not applicable (NA) or they did not respond at all, resulting in missing data in the data collection. Because of the small sample size, replacing missing data using the Series Mean method from SPSS was conducted. However, reliability and descriptive analysis were run without replacing missing values. Missing value replacement was conducted for logistic regression only.

5.3 Discussion on the Descriptive and Statistical Analysis Results

5.3.1 Demographic Information of Respondents

The results from this study were compared to RA and OA patients' characteristics, according to the Center for Disease Control and Prevention (CDC). The demographic characteristics of respondents consisted of gender, age, race, comorbidities, number of medications being taken, income, and insurance status.

5.3.2 Gender, Age, Race, Annual Household Income, Comorbidities, and Number of Medications

Respondents of this survey were mostly females (78.4%) and White, non-Hispanic. Almost half (49.4%) of respondents were 61 to above 80 years of age. According to the CDC, the prevalence of rheumatoid arthritis (RA) and osteoarthritis (OA) increases with age. The incidence of RA is typically two to three times higher in women than in men, its incidence peak is among people aged 65 to 74 years. The onset of RA is highest in the sixties in both women and men. For OA, women have higher rates than men, especially after age 50. For both genders, incidence rates increase with age, and level off around age 80 [28,35]. Overall, arthritis patients in the present study are comparable with the arthritis population mentioned in the literature above, except for the females that were slightly over represented in the present study. The race/ethnicity demographics from the present study could not be compared due to the lack of respondents from specific categories.

According to the United States Census Bureau, the per capita income of people in Toledo city, in the past 12 months (2011 dollars), was $18,809 and the median household income in the years of 2007 to 2011 was $34,170[67]. Almost fifty percent of respondents in the present study had annual household incomes of less than $15,000 to $24,999. This is not surprising, since most respondents were elderly and likely living on fixed incomes.

The four most common comorbidities among RA patients are cardiovascular disease, infections such as tuberculosis, mental health conditions including anxiety and depression and malignancies such as leukemia[35,68]. In the present study, the most common comorbid illnesses reported by arthritis patients were high blood pressure followed by high cholesterol, and diabetes. The most common comorbid disease was

similar to that of other studies involving patients with arthritis[7,9]. Also according to Manias et al., (2007), other comorbid illnesses of OA patients included ischemic heart disease, and peptic ulcer disease[9].

In the present study, approximately 15% of arthritis patients had gastritis/GERD while other studies found higher percentages with 25% and 32%[7,9]. A very small number of respondents reported depression and anxiety. It might have been due to the respondents not being aware that depression and anxiety were illnesses if they did not take any medication for those diseases. A majority of arthritis patients in the present study suffered moderate to bad pain, had one to two comorbid illnesses and took eight to nine medications, including prescribed medication, OTC, vitamins, and dietary supplements, on average while a previous study found that most arthritis patients take two to four prescribed medications[7].

5.3.3 Insurance Status

The Omnibus Budget Reconciliation Act of 1990 made pharmacists responsible for providing prospective drug use reviews (ProDUR), patient counseling, and maintaining proper patient records for Medicaid recipients, but after time, it was intended to be applied to all patients. This law has been in effect since January 1, 1993. Prospective drug use review requires pharmacists to evaluate Medicaid beneficiaries' entire medication profile before filling their prescriptions[4]. This service could address drug therapy problems such as therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interaction with OTC drugs), incorrect drug dosage or duration of drug treatment, allergic reactions, and evidence of clinical

abuse/misuse. In the present study, 23 respondents were Medicaid beneficiaries. Among those people, 69.6% intended to ask for patient counseling from pharmacists. Meanwhile, similar intentions were also indicated by 58% of Medicare beneficiaries, 46.7% of people with private insurance, and 34.1% of people with insurance through their current/former employer. Therefore Medicaid beneficiaries' intentions were the highest among all forms of insurance coverage.

All respondents were insured either through Medicare, Medicaid, former or current employer/school, private insurance, and insurance through spouse. Among the 51 respondents who were Medicare beneficiaries, 31.4% had been enrolled in Medicare Part D. This plan covers patients medicines based on the medication list on the formulary. Medicare Part D enrollees are eligible for Medication Therapy Management (MTM) program/services if they have multiple chronic diseases, have been taking multiple medications covered by Medicare Part D and spend at least $ 3,000 on their Part D medications. Among those Part D enrollees with multiple chronic diseases, 27.3% implied that they had been enrolled in a program where a pharmacist counseled medication, provided medication list, monitored medication effectiveness and resolved medication related problems. Those respondents had four comorbid illnesses on average. However, this finding may not be representative of the Medicare Part D beneficiaries as the number of respondents who had Medicare Part D in this survey was very small (16 respondents).

5.3.4 Difference in the Demographic Characteristics towards Intention

Among the demographic information of participants, only gender showed significant differences in patients' intention to ask for counseling from pharmacists. The number of female respondents who had intention towards requesting patient counseling was significantly higher than that of male respondents, according to chi square analysis. However, the logistic regression results showed that gender was not a significant predictor of intention when controlling for other factors. In a related study, Neame and Hammond (2005) showed that there was a significantly slightly higher level of need for information regarding RA in women than in men, although both genders had very high scores[69].

In the present study, severity of arthritis that had been reflected by pain level, was not a significant predictor of intention, controlling for other variables. Yet in another study, arthritis pain was significant predictor of intention toward information-seeking either from pharmacists, physicians, or from the Internet[70]. Respondents from the previous study had seen a medication advertisement as a stimulation to ask for further information. They felt the need for medication to relieve their arthritis symptoms. On the other hand, arthritis patients in the present study had been taking arthritis medications. Those who have severe pain may want to immediately obtain and consume the medication prescribed and thus, skip the counseling, while people with mild pain may not perceive the immediate benefit of receiving counseling from a pharmacist and simply refuse the offer.

5.3.5 Arthritis Patients' Health Beliefs

The Health Belief Model (HBM), a theoretical framework was used in developing Section I of this questionnaire. In the present study, the three constructs from the HBM (perceived benefits, perceived barriers, and self-efficacy) were used to predict intention to request patient counseling from pharmacists pertaining to their medications. The results from the three HBM constructs used in the questionnaire are discussed below.

5.3.5.1 Perceived Benefits

One of the HBM constructs explains people's beliefs regarding the benefit of performing a particular health related action. Almost three-quarters of respondents believed that having patient counseling from the pharmacist would help motivate them to use medications appropriately to ease arthritis pain. They also believed that asking their pharmacists about side effects of their medications would be helpful which gave this item the highest mean score (3.45±.711). Approximately 25% of respondents did not believe that they could better understand how their medications worked. One-third of arthritis patients in the present study disagreed that a pharmacist could help them manage their arthritis. The importance of patient counseling is related to medication adherence. The misunderstanding of prescribing instructions, limited faith in the medication or the provider, and concern about taking drugs (all issues that the patient counseling could overcome), potentially decrease medication adherence[71]. Thus, there are patients that still need to be motivated in order to increase their beliefs regarding the benefit of counseling provided by the pharmacist.

More than three-quarters of arthritis patients in the present study agreed that patient counseling provided by pharmacists could help them feel more relaxed in taking their medications by reducing fears about long-term effects of their medication regimens. According to a study conducted by Neame and Hammond (2005), RA patients believed in the necessity of their medications, but expressed strong concern regarding the potential and actual adverse effects[69]. Furthermore, RA patients tended to stop their medications when experiencing adverse drug events[72]. As concern for medication safety had more impact on medication adherence than medication necessity[69], it was very important to provide brief information about medications that would make patients feel more relaxed and secure in taking them.

Perceived benefit in the present study was significantly related to the intention to ask for counseling, which was similar to findings from previous studies[52,53]. This finding indicated the importance of belief in the benefit of a recommended action. Hence, being female or male, either young or elderly, having higher or lower income, or being whatever race, as long as a person perceives benefits towards patient counseling, his/her intention to ask for counseling from the pharmacist was higher than that of those who did not perceive such benefit. Given the significance of arthritis patients' beliefs about the benefit of a program, a strategy to increase belief regarding the benefit of patient counseling provided by pharmacists should be developed in order to change or increase patients' perceptions.

5.3.5.2 Perceived Barriers

Based on the results of the present study, arthritis patients agreed that pharmacists are approachable (84.7%) but too busy to give proper explanations about medication (27.3%). This result was comparable to a previous study in 2011 in regards to the pharmacist's approachability[73]. Only a few arthritis patients in the present study felt embarrassed to talk about their medication to their pharmacists. Most arthritis patients in the present study disagreed that they have no time to ask the pharmacist about their medication. These findings suggest that the most common barrier to asking for counseling from pharmacists was the perception that pharmacists seemed too busy with their work. This finding is consistent with research from Schommer & Wiederholt (1994) and O'Donell et al., (2006), which found that the most common barrier to performing patient counseling was lack of time to communicate with patients[74,75]. Thus, according to the present study, even though patients felt no embarrassment when talking about their medications, and did not mind spending their time talking with their pharmacists, they might not have wanted to bother the pharmacist with the questions they had. On the other hand, patients' lack of demand also influenced pharmacists' decision to not counsel them[74,75]. This cyclical misunderstanding should be resolved, so that pharmacists can optimize their services to patients.

Instead of focusing on traditional patient counseling, Lounsbery et al., (2009) conducted a survey addressing pharmacists' barriers to performing MTM. This study suggested that pharmacists had done better in overcoming those barriers. For example, almost all pharmacists who were interested in providing MTM agreed that lack of additional staffing was a barrier towards providing MTM while only around half of

pharmacists who had conducted MTM with compensation, agreed with the same statement[76]. This finding indicates that through more systematic counseling services such as MTM whereas pharmacists provide counseling based on patients appointment, pharmacists can overcome the barrier of traditional counseling regarding the time constraint.

In the present study, logistic regression results showed that patients' perceived barriers was not a significant predictor of intention to ask for counseling from the pharmacist. Therefore, perceived barriers are not as impactful as benefits are in predicting intention to ask for counseling. This finding may be due to a unique characteristic of respondents in the present study. Mostly respondents were elderly, white-Non Hispanic, have time, not embarrassed talking with their pharmacists, and were insured. Therefore, they may not perceive the barriers mentioned in the present survey. A population with more diverse age, race, and insurance status may have more variations in perceived barriers.

The last item in Section I-Subsection 2 asked about patient concerns about the extra cost of being counseled by pharmacists. More than three-quarters of respondents were not worried about the cost that might arise. In most cases, there is no charge for being counseled by a pharmacist. However, if we relate this finding to the more comprehensive pharmaceutical care services such as MTM which would involve some kind of payments, there appears to be a positive response from arthritis patients regarding the willingness to pay for pharmaceutical care services if required.

5.3.5.3 Self-Efficacy

Self-efficacy was the third construct from the HBM that was used in this study. A sufficient level of self-efficacy facilitates the likelihood of performing a behavior. The present study revealed that more than three-quarters of respondents felt confident in asking pharmacists for counseling or to ask whatever questions they had. Respondents also implied that they do not have any problems understanding pharmacists' directions concerning their medications and felt no hesitation asking their pharmacists to repeat their instructions. However, self-efficacy was still a problem for some patients.

Less than 20% patients were not confident enough to ask for patient counseling from pharmacists. This result is in line with findings from a previous study which stated that arthritis patients may not take the initiative to ask questions[73]. This finding suggests that there is a lack of initiative to ask for counseling among arthritis patients. On the other hand, pharmacists might perceive that those patients had no questions regarding their medication. If there was no effort from either side to initiate communication, this action could lead to undetected medication-related problems such as using medication inappropriately, unawareness of adverse drug reactions, medication non-adherence, and others.

Although the present study showed that perceived self-efficacy did not significantly predict the intention to ask for counseling, a previous study showed that it was the key for predicting exercise activities among people with OA and RA, along with perceived benefits[52]. Self-efficacy may be more essential for exercise than requesting counseling for medication based on the complexity of the behaviors.

5.3.6 Arthritis Patients' Intention to Ask for Medication Counseling from Pharmacists

In the present study, the number of respondents who had intentions to ask for counseling from their pharmacists was equal to those who had little to no intentions. Previous research has shown that intention to ask for counseling is a significant predictor of the actual behavior[70]. Therefore, it is important to know the predictors of intention. Similarly, according to Schommer & Wiederholt, (1994), patient motivation was also the most frequently cited factor that determined the amount and type (oral/written) of counseling provided[74]. A majority of respondents had two to three chronic diseases. According to a previous study involving elderly who had chronic diseases and received new medication, after a period of time using medications, they had concerns about the medications, and wanted more information about their medications and conditions. Furthermore, they experienced adverse drug reactions and faced difficulties in the practical aspects of taking medication[77]. Given that community pharmacists are relatively more accessible than other health care professionals, it would be beneficial for the patients to initiate communication by asking for counseling regarding their medications and medication-related problems. The present study revealed that perceived benefits was a significant predictor of intention to ask for counseling from the pharmacist and demographic characteristics did not significantly predict that intention. Strategies to improve perceived benefits could increase patients' likelihood of requesting counseling from their pharmacists.

5.3.7 Patient Counseling Campaigns from the Literature

Campaigns for the purpose of increasing patients' awareness to ask questions regarding their medicines have been used in many countries. One example was the "Questions to Ask about Your Medicines (QaM)" campaign from The Regional Office for Europe of the World Health Organization. This campaign, targeted to pharmacy consumers and patients, was intended to emphasize the importance of gathering relevant information before starting to take a medication. This campaign encouraged them to actively ask their physicians or pharmacists some basic questions and volunteer personal information of concern when taking medications. Media such as leaflets, posters, and others suitable to local situations were utilized[78].

In the United States, a similar program is "Script Your Future." It is a campaign of the National Consumers League (NCL), collaborating with health care professionals, patient communities, and other relevant groups/organizations. It is a national campaign to increase the awareness of the importance of medication adherence. This program also encourages patients to ask questions regarding their medications. One of their tools is the "Script Your Future Wallet Card," which contains questions to ask the doctor or pharmacist, including: 1) What's my medicine called and what does it do? 2) How and when should I take it? And for how long? 3) What if I miss a dose? 4) Are there any side effects? 5) Is it safe to take it with other medicines or vitamins? and 6) Can I stop taking it if I feel better? This card comes in pocket size and is color-printed[79].

Encouraging pharmacists to provide patient counseling can also serve to create awareness among patients about the role of pharmacists. A brown bag is a program where patients bring all their medications from home, including prescription or non-prescription

medication, vitamins, and dietary supplements. A pharmacist will review all of them, address and solve the drug-related problems that may be apparent, and make sure patients use them appropriately. A brown bag program is a popular example of a pharmacist service and not only can be beneficial in detecting DRPs but also in promoting patient counseling. This 20 to 25 minute service also has a benefit in terms of promoting patient-pharmacist communications[80]. In fact, pharmacists perceived that conducting patient counseling would be much easier if they knew the patient, according to Schommer and Wiederholt[74].

5.3.8 Suggested Remedies based on Study Results

The results of the present research brought additional insight to improve the design of patient counseling campaigns. As patients' perceived benefits was a significant predictor of intention to request patient counseling, the message on the campaign should emphasize more on the benefits of counseling. Slogans such as *"Worried about the side effects of your medicines? Ask your pharmacist!"* could raise patients' awareness of the benefits of pharmacist counseling and potentially function as a cue to action for requesting this service. Another example is by bringing the benefits of counseling to the patients. Providing a MTM pilot project to arthritis patients may increase their perceived benefits and thus, increase the likelihood of asking for counseling from the pharmacist, especially when they receive new medications or experience ADRs. Media such as the newspaper is one way to spread information regarding the benefit of patient counseling from the pharmacist.

Perceived barriers, even though it did not significantly predict intention to ask for counseling, should still be minimized. Pharmacists seem too busy or unapproachable to

provide counseling. Although providing patient counseling by request is mandatory, patients might perceive that the pharmacist is unapproachable due to the workload. Furthermore, at a minimum, Ohio pharmacists must at least offer counseling to a patient/client. Frequently, this offer is not conducted by directly asking the patients, but appears as an option on the screen along with the billing information, and therefore, may not be taken seriously by the patients. Moreover, the pharmacist might not be distinguishable from other employees in the pharmacy. This issue may be solved by increasing the direct interaction between the pharmacist and patient, for instance by constantly checking the understanding of the patients regarding their medications. This service potentially creates a closer relationship between the pharmacist and patient, and increases patients' trust to their pharmacists.

5.3.9 Arthritis Patients' Medication Self-Management Ability

Among ten items in this section, the biggest problem in medication management faced by arthritis patients was keeping past arthritis pain medications even if they received a new pain medicine (66.3%). Manias et al. (2007) also found that 35.3% of arthritis patients kept previously prescribed medication on hand, in case it was needed, which added to the complexity of managing multiple medications[9]. Nearly one-quarter of patients in the present study did not remember the name of all their medications. Furthermore, around one-third did not always carry their medication list. These medication management problems could potentially bring difficulties in the medication review process by their doctors or pharmacists, especially if they went to different clinics or pharmacies.

In the present study, almost one-quarter of respondents did not have their physicians or pharmacists look at all their medications in the past six months. Multiple medication use and frequent changes of the medications could overwhelm arthritis patients. Medication review by health care providers could help them not only to manage their medication better, but also to address and overcome the actual and potential medication-related problems.

Knowing the purpose of a medication potentially increases medication adherence. There were some arthritis patients in the present study who did not know the purpose of each medication. Regarding medication adherence, some patients stated that they did not always remember to take medications on time, and indicated that they did not know what they should do if they forgot to take their medications. Different medications have different outcomes when they are not taken. Analgesics or NSAIDs probably bring little impact, such as the occurrence of pain, but medication such as DMARDs should be maintained in a certain level in a patient's blood stream in order to prevent flare-ups from RA. Additionally, many arthritis medications have special precautions, such as taking with food to prevent stomach upset. The lack of knowledge regarding special precautions could potentially lower their medication adherence due to the occurrence of preventable adverse drug reactions. Lack of knowledge of side effects and allergic reactions potentially lower medication adherence. The occurrence of these medication-related problems may prevent them from taking their medications or even harm them.

Patient counseling provides information particularly about medications taken by patients, including the name and purpose of each medicine, the outcome expected from taking each medicine, adverse drug reactions that might be happening, self-management

in regards to medication or non-pharmacological therapy, and other relevant information. It is necessary to have an open communication of expectations between patients and their physicians for mutual development of a treatment regimen that would result in an improved patients' effort in managing their therapy. Pharmacists, as a member of the health care team, may also take this role to build good communication with patients by providing patient counseling. MTM has provided further opportunities to pharmacists to collaborate with patients and other health care professionals. Furthermore, in these services, pharmacists can create a medication-related action plan (MAP) based on an agreement with patients.

5.3.10 The Relationship between the Ability to Self-Manage Medications and Intention to Ask for Counseling

It is assumed that the lower the patients' ability to perform self-management of their medications, the greater their intention to ask their healthcare providers for medication counseling. This study revealed the opposite finding. Spearman rank correlation results indicated that arthritis patients' ability to manage their medication regimens had a positive, fair degree, and significant relationship with intention to ask for patient counseling from the pharmacist. This finding suggests that higher patient ability to manage their medications increases the likelihood of asking for counseling from pharmacists.

A higher patients' medication management ability reflected high involvement in managing disease and its treatment, and motivation to achieve a better quality of life. This kind of curiosity could have been a strong motivator of a behavior, including the

willingness of initiating actions to discover information they had not known, and learning about new things regarding their diseases and treatments. Another study revealed that asthma patients who had active health beliefs exemplified by actively sharing the decision of treatment with providers had 4.5 times the likelihood of using their controller medication every day[81]. This finding indicated that patients' ability to manage their medication had a positive relationship with their behavior related to previous interactions with their health care provider. Further study should be conducted to examine the possible predictors of medication management ability based on the quality of interaction between patients and health care providers.

5.3.11 Comments from Respondents

Some of the respondents wrote comments on the questionnaire that mostly talked about their experiences or opinions regarding pharmacists conducting patient counseling. Other respondents expressed their drug-related problems that possibly have not been addressed by their health care providers.

According to the Ohio Administrative Code number 4729-5-22, Pharmacists-Administrative Provisions regarding patient counseling, a pharmacist or the pharmacist's designee shall personally offer to provide the service of counseling to the patient or caregiver whenever any prescription, new or refill, is dispensed. However, a pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel[82]. This regulation seems to not be known by every patient. One patient wrote "Would like to be able to [ask patient counseling] but not sure my pharmacist provides this service," which

implied that there was a lack of knowledge about the role of the pharmacist, particularly in the community pharmacy. Another respondent stated, "No pharmacist available ever." This statement showed that either he was not sure who had served him or had a difficulty approaching the pharmacist in charge. Other respondents chose not to ask for counseling from pharmacists stating they were using the mail order pharmacies to provide their medications. These patients might not have known that they could ask for counseling from pharmacists in every pharmacy, including the mail order pharmacies.

A respondent wrote "My MD [physician] is the more appropriate person to talk to as they know my entire health rx [prescription]". Others stated "My RPh [pharmacist] doesn't monitor me or counsel me, it is simply a retail transaction" and "I honestly never have asked my RPh [pharmacist] for advice or info." This implied that there was a greater trust in asking for counseling from the physician rather than the pharmacist. This was in line with a previous study that revealed "Trust in the physician/do not want to go against physician" and "Questioning the credibility of pharmacist" as two barriers for obtaining counseling from a pharmacist[73].

Another comment was "I stand in line many times at retail pharmacies and rarely see pts [patients] ask for counseling". This comment implied that this person saw what other people normally did with regards to asking for counseling. This action then might have impacted his/her perception about this behavior. This phenomenon could be explained by "behavior acceptance" as a modifying factor of requesting counseling from pharmacists. This finding could also be an indication of "subjective norm" from the Theory of Reasoned Action[83], whereby individuals are influenced by the behaviors and approval of others.

The last interesting finding from respondents' comments related to patient counseling was about the health information exchange between institutions, including the pharmacy. Although medication review could be conducted through different ways, such as asking the patient directly or through a "brown bag" service, it would be faster if there was some kind of system and agreement to exchange patients' health information among health care providers.

5.4 Study Limitations

The results from this mail survey should be interpreted with cautions. First, the cross-sectional method obtained data that only represented one point of time. Thus, it does not reflect changes that might have happened in arthritis patients' perceptions over time. Moreover, this study only involved RA and OA patients from two clinics: the Rheumatology clinic and the Pain Management clinic, in one hospital. Potential respondents were limited to RA and OA patients who had visited Rheumatology and Pain Management clinics at UTMC in 2012. Hence, the generalizability was very limited. Additionally, lower response rate resulting in small sample size, made it difficult to detect small differences among variables being analyzed.

Some potential respondents might have previously seen the questionnaire used in this study if they had visited the Rheumatology clinic in 2012 and were at the clinic at the time when the pilot survey was conducted. Another potential bias regarding social desirability may have occurred. Respondents were asked to answer the questions honestly. Furthermore, participation was strictly voluntary and refusal to participate would not have any impact on the relationship with their clinicians. However, there was

still a possibility from the respondents to answer those questions according to their perceptions of researcher/clinicians' desire.

The research question addressing the difference between insured and uninsured arthritis patients towards the intention to ask for counseling could not be analyzed due to the fact that all respondents in this study were insured. Lastly, the non-respondents of this survey were not followed-up. Non-respondent bias might have occurred if non-respondents had different perceptions from respondents. For Section II of the questionnaire, the ability of arthritis patients to manage their medication regimens was based on self-reported information. There was no evaluation to re-check the accuracy of information that respondents had been provided.

The present study did not compare the demographics of respondents with the study population. It is possible that the variation in the demographic information occurred due to study population characteristics. This study includes two types of arthritis patients but did not analyze the results for OA and RA separately. Given that the medication therapy is different for OA and RA, it is possible that patients have different characteristics in terms of their intention to request counseling from a pharmacist and their medication management ability. The places where patients obtain their medication and the person who picks up the medication were not addressed in this study. Some patients may obtain their medication from pharmacies where they can meet their pharmacist, while others may receive their medication through mail order pharmacies. Although both pharmacies provide patient counseling, the fact that patients do not see the pharmacist in the mail order system possibly results in different patients' perceptions.

The perception of patients who have their caregivers pick up their medication could be different compared to those who pick up their medication by themselves.

5.5 Suggestions for Future Research

This study addressed arthritis patients' perceptions regarding patient counseling provided by pharmacists and their medication management ability. A previous study showed intention to be a strong predictor of information-seeking behavior[70]. Therefore, measuring the actual behavior regarding requesting patient counseling would be beneficial to obtain a more complete picture. Future research could target arthritis patients who were enrolled in a pharmacist-provided program, for instance, conducting a survey addressing patients' health beliefs towards patient counseling by pharmacists before and after a brown bag or the medication therapy management program. A wider sampling area might be beneficial to obtain more diverse patient demographic information and potentially increase the sample size.

The findings from the present study suggested that not all arthritis patients were familiar with the role of the pharmacist regarding patient counseling. Expanding the study to target patients with other chronic diseases would be beneficial as they experience different symptoms. Arthritis patients mostly have clear symptoms such as pain and stiffness. However, chronic diseases such as hypertension, hypercholesterolemia or the early stage of diabetes typically do not give clear symptoms, thus, being called silent diseases. Moreover, patients with chronic diseases, such as asthma, which involve the use of medication tools, might have different health beliefs regarding patient counseling. Hence, depending on the disease, there may be a need for different strategies pertaining to the intervention to improve patient behaviors.

Some states such as California, Alabama, Arizona, and the District of Columbia mandate that pharmacists counsel patients or caregivers regarding new medication. Patients who are more familiar with pharmacist counseling possibly have a closer relationship with their pharmacists, resulting in different perceptions regarding pharmacists and pharmaceutical services.

5.6 Conclusion of the Study

The present study explored arthritis patients' health beliefs regarding patient counseling from the pharmacist. Using three constructs from the Health belief Model: perceived benefits, perceived barriers, and self-efficacy, controlling for demographic characteristics, including gender, age, income, race, the number of medications, the number of comorbidities, and severity of the arthritis pain, the result from the present study revealed that perceived benefits was a significant predictor of intention to ask for patient counseling from the pharmacist. The higher the perceived benefits regarding patient counseling, the greater the likelihood of intention to request counseling from the pharmacist. Given the high potential for occurrence of ADRs, arthritis patients should be made fully aware of the benefits of patient counseling.

As the number of arthritis patients with intention was equal to those who had no intention to ask for counseling from a pharmacist, promotion of patient counseling should be on going and assertive. Promotional efforts regarding patient counseling from pharmacists should place more emphasis on the benefits of counseling to encourage more patients to experience this worthwhile service.

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Appendix A

IRB Approval

THE UNIVERSITY OF TOLEDO
1872

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The University of Toledo
Department for Human Research Protections
Biomedical Institutional Review Board
Center for Creative Education Building – Room 0106
3025 Arlington Avenue, Toledo, Ohio 43614-2570
Phone: 419-383-6796   Fax: 419-383-3248
(FWA00010686)

</div>

TO: **Monica Holiday-Goodman, Ph.D.**
            UT Department of Pharmacy Practice

FROM: Roland Skeel, M.D., Chair
            Deepak Malhotra, M.D., Vice Chair
            Gregory Siegel, R.Ph., J.D., Chair Designee
            UT Biomedical Institutional Review Board

SIGNED: _____   **DATE** 4/17/2013

SUBJECT: **IRB # 108209**
            TITLE: Managing Medication Regimen: Arthritis Patients' Perceptions

On 04/03/2013, the above project was reviewed and approved by the Chair and Chair Designee of the University of Toledo Institutional Review Board as an **expedited review** (category #7). The requirement to obtain a signed consent/authorization for use and disclosure of protected health information form has been waived as this research is determined to be minimal risk and a signed consent/authorization document would be the only record linking the subject to the data. It was determined that this waiver for signed consent/authorization for use and disclosure of protected health information form will not adversely affect the rights or welfare of the participants. The Principal Investigator must provide a copy of the Cover Letter/Information Sheet referenced below to all participants prior to participation. This research is **approved** for a period of up to one year from the date of this review and approval. The full board will review it at its meeting on 04/18/2013.

Items Included for Review:
- IRB Application Requesting Initial Review of Expedited Research
- Protocol/Thesis (version date February, 2013)
- Survey (assigned version date 04/03/2013)
- Cover Letter (assigned version date 04/03/2013)
- Patient Identifier List (assigned version date 04/03/2013)
- Data Collection Tool (assigned version date 04/03/2013)
- Invitation to Participate Letter - Rheumatology Clinic (assigned version date 04/03/2013)
- Invitation to Participate Letter- Pain Management Clinic (assigned version date 04/03/2013)
- Signed Permission Letter – Rheumatology Clinic (dated 02/01/2013)
- Signed Permission Letter – Pain Management Clinic (dated 01/30/2013)
- Request for Waiver of Individual Authorization For Use and Disclosure of Protected Health Information (PHI) for Purposes of Research

This research is **approved** until the expiration date listed below, unless the IRB notifies you otherwise.

Only the most recent IRB approved Cover Letter/Information Sheet listed above may be used when enrolling participants into this research.

You are approved to enroll up to **600** participants in this study.

APPROVAL DATE: 04/03/2013   **EXPIRATION DATE: 04/02/2014**

Please read the following attachment detailing Principal Investigator responsibilities.
IRB Determination Letter   Page 1 of 1   *108209 Holiday-Goodman*

Appendix B

Adult Research Subject Information Form

UT IRB # 108209

ICF Version Date: 04/03/2013

THE UNIVERSITY OF TOLEDO
1872

Department of Pharmacy Practice
Frederic and Mary Wolfe Center, Room 141
Toledo, Ohio 43614
Phone 419.383.1566
Fax: 419.383.1950

ADULT RESEARCH SUBJECT INFORMATION FORM

MANAGING MEDICATION REGIMEN: ARTHRITIS PATIENTS' PERCEPTIONS

Principal Investigator	: Dr. Monica Holiday-Goodman
Other Staff (identified by role)	: Dr. Tavis Glassman (Co-Investigator) Dr. Mary Powers (Co-Investigator) Gesnita Nugraheni (Student-Investigator) Adam McCabe (Student-Investigator)
Contact Phone number(s)	: (567)322-0153 (Gesnita Nugraheni) or (419)383-1968 (Dr. Monica Holiday-Goodman)

Purpose (Why This Research Is Being Done)
You are being asked to take part in a research study of arthritis patients' perceptions towards their ability to manage their medications and their interaction with their pharmacists. The purpose of the study are to address arthritis patients' ability to manage their medications, to identify their perception towards counseling about medications provided by pharmacists, and to find out their willingness to ask questions to their pharmacists regarding their medications.

You were selected as someone who may want to take part in this study because you are listed as an arthritis patient who attended the Rheumatology clinic or the Pain Management clinic at the University of Toledo Medical Center in the period of January to December 2012. The maximum number of subjects in this study is 600.

Description Of The Research Procedures And Duration Of Your Involvement
If you decide to take part in this study, you will be asked to answer all questions on the following 2-page questionnaire as honestly as possible and send back the complete questionnaire using the pre-paid envelope provided before .../.../ 2013. This questionnaire will require approximately 15 minutes to complete.

Risks And Potential Benefits
There are very minimal risks to participation in this study, including loss of confidentiality. To reduce this risk, we will not ask you to sign a copy of this consent form. There might be a possibility of inconvenience while completing the questionnaire.

The only direct benefit to you if you participate in this research may be that you may learn more about pharmacists' role particularly in medication counseling to arthritis patients. Others may benefit by learning about the results of this research.

Confidentiality
The researchers will make every effort to prevent anyone who is not on the research team from knowing that you provided information, or what that information is.

RR050

Page 1 of 2

APPROVED BY
UNIVERSITY OF TOLEDO IRB
This space for IRB Approval Date Stamp

Voluntary Participation

Taking part in this study is <u>voluntary</u>. You may refuse to participate or discontinue participation at any time without penalty or a loss of benefits to which you are otherwise entitled. If you decide not to participate or to discontinue participation, your decision will not affect your future relations with the University of Toledo or The University of Toledo Medical Center.

Offer To Answer Questions

Before you decide to participate, you may ask any questions on any aspect of this study that is unclear to you. You can keep this form with you so that you have important information about the research. If you have questions regarding the research at any time before, during or after the study, you may contact: Gesnita Nugraheni (567-322-0153) or Dr. Monica Holiday-Goodman (419-383-1968).

If you have questions beyond those answered by the research team or about your rights as a research subject or research-related injuries, please feel free to contact the Chairperson of the University of Toledo Biomedical Institutional Review Board at 419-383-6796.

Appendix C

Cover Letter

UT IRB# 108209

THE UNIVERSITY OF
TOLEDO
1872

Dear Mr/Ms._____,

We are inviting you to participate in this research study by completing the attached surveys. This study is examining arthritis patients' perceptions regarding their medications and their interaction with their pharmacists. The participation is strictly voluntary. With completing the questionnaire you will also give your consent to be a participant of this study. Refusal to participate will not affect your relationship with participating clinics or the university. I will not re-use or disclose your private information to any other person for any purpose than that approved by the UT IRB as part of this research.

You have to be 18 years old or above to be eligible as a participant. The following questionnaire will require approximately 15 minutes to complete. In order to ensure that all information will remain confidential, please do not include your name. There is no known risk to participation beyond those encountered in everyday life. If you choose to participate in this project, please answer all questions as honestly as possible and send back the complete questionnaire using the prepaid envelope provided before ..../...**2013**.

Thank you for taking the time in our research study. If you require additional information or have questions, please contact me c/o Gesnita Nugraheni at phone number 567-322-0153 or email at Gesnita.Nugraheni@rockets.utoledo.edu.

P.S.: Your participation is very important to the development of pharmaceutical care, particularly in arthritis.

Warm regards,

Joseph N. Atallah, MD.
Chief of the Pain Management Clinic at UTMC

A $50 gift card will be awarded to two different randomly selected participants each.
Please complete the questionnaire and send it back to us using the prepaid envelope provided.
The winners will receive the gift cards no later than .../.../ 2013.
Again, thank you for participating in this survey!

College of Pharmacy and Pharmaceutical Sciences
Pharmacy Practice • Mail Stop 1013 • 3000 Arlington Ave. • Toledo, OH 43614
Phone: 419.383.1951 • Fax: 419.383.1950 • www.utoledo.edu

APPROVED BY
UNIVERSITY OF TOLEDO IRB

Assigned Version Date: 04/03/2013

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THE UNIVERSITY OF
TOLEDO
1872

Dear Mr/Ms._____,

    We are inviting you to participate in this research study by completing the attached surveys. This study is examining arthritis patients' perceptions regarding their medications and their interaction with their pharmacists. The participation is strictly voluntary. With completing the questionnaire you will also give your consent to be a participant of this study. Refusal to participate will not affect your relationship with participating clinics or the university. I will not re-use or disclose your private information to any other person for any purpose than that approved by the UT IRB as part of this research.

    You have to be 18 years old or above to be eligible as a participant. The following questionnaire will require approximately 15 minutes to complete. In order to ensure that all information will remain confidential, please do not include your name. There is no known risk to participation beyond those encountered in everyday life. If you choose to participate in this project, please answer all questions as honestly as possible and send back the complete questionnaire using the prepaid envelope provided before ..../...**2013**.

    Thank you for taking the time in our research study. If you require additional information or have questions, please contact me c/o Gesnita Nugraheni at phone number 567-322-0153 or email at Gesnita.Nugraheni@rockets.utoledo.edu.

P.S.: *Your participation is very important to the development of pharmaceutical care, particularly in arthritis.*

Warm regards,

Bashar Kahaleh, MD.
Chief of the Rheumatology Division at UTMC

A $50 gift card will be awarded to two different randomly selected participants each.
Please complete the questionnaire and send it back to us using the prepaid envelope provided.
The winners will receive the gift cards no later than .../.../ 2013.
Again, thank you for participating in this survey!

APPROVED BY
UNIVERSITY OF TOLEDO IRB

Assigned Version Date: 04/03/2013

Appendix D

Final Questionnaire

THE UNIVERSITY OF
TOLEDO
1872

Code: _____

Please consider the following definition when answering the survey questions: Patient counseling is a service provided by a pharmacist to a patient when he/she reviews all of your medications, explains your medication (e.g. common side effects, dose, special directions, techniques for self-monitoring medication therapy, what the medicine is supposed to do, etc.)

In regard to your arthritis medications, please circle your response based on your level of agreement to the statements below. Please answer the questions based on your arthritis medications only.

Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4	Not Applicable 5

Subsection 1					
Having my pharmacist counsel me will help motivate me to use medication(s) appropriately to ease my arthritis pain	1	2	3	4	5
Asking the pharmacist about the side effects of my medication is helpful	1	2	3	4	5
I feel more secure in taking my medication(s) after my pharmacist has counseled me	1	2	3	4	5
I feel more relaxed after my pharmacist has counseled me about my medication(s)	1	2	3	4	5
Because my pharmacist monitors me, I better understand how my medication(s) works	1	2	3	4	5
My pharmacist can help me in managing my arthritis	1	2	3	4	5
Subsection 2					
My pharmacist is approachable to discuss my medication(s)	1	2	3	4	5
Pharmacists are too busy to give proper explanations about medication(s)	1	2	3	4	5
I feel embarrassed to talk about my medication with my pharmacist	1	2	3	4	5
I have no time to ask my pharmacist about my medication(s)	1	2	3	4	5
I am worried about the extra cost of being counseled by my pharmacist	1	2	3	4	5
Subsection 3					
I feel confident asking my pharmacist to counsel me about my medication(s)	1	2	3	4	5
I ask the pharmacist whatever questions I need answered regarding my medication(s)	1	2	3	4	5
I understand the pharmacist's directions concerning my medication(s)	1	2	3	4	5
I feel no hesitation in asking the pharmacist to repeat their instructions.	1	2	3	4	5

In regard to ALL of your medications, please circle your response based on your level of agreement to the statements below. Please answer the questions based on ALL your medications.

Version Date: 04/03/2013

Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4	Not Applicable 5				
Understanding the Medication's Information								
I remember the name of ALL my medication(s)				1	2	3	4	5
I know the purpose of each of my medication(s)				1	2	3	4	5
I always remember to take my medicine(s) on time				1	2	3	4	5
I am aware of special precautions (e.g., taking with food or on empty stomach, etc.) to take with my medication(s)				1	2	3	4	5
I am capable of monitoring myself for any side effects from my medication(s)				1	2	3	4	5
I know what to do if I am experiencing an allergic reaction to my medication(s)				1	2	3	4	5
I know what I should do if I missed a dose (forget to take medication)				1	2	3	4	5
Concerns about Medication								
I kept my past arthritis pain medications even if I get a new pain medicine				1	2	3	4	5

Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4	Not Applicable 5				
I have had a physician, pharmacist, or other health professional look at ALL of my medications in the past 6 months				1	2	3	4	5
I always carry my medication list with me				1	2	3	4	5

In this section please indicate how you would respond to the following scenario by placing a check in the appropriate box

If your doctor prescribed a new medicine for your arthritis, will you **ASK** your pharmacist to counsel you on the medication? (Patient counseling is where your pharmacist reviews all of your medications, explains your medication (e.g. common side effects, dose, special directions, techniques for self-monitoring medication therapy, what the medicine is supposed to do, etc.)

No ☐   Yes ☐

Please fill the blank or check on the box provided

1. How much pain are your arthritis symptoms causing you?
   ☐ Very bad   ☐ Bad   ☐ Moderate   ☐ Mild

2. Gender: ☐ Female   ☐ Male

3. What is your annual household income?
   ☐ Less than $ 15,000
   ☐ $ 15,000 to $ 24,999
   ☐ $ 25,000 to $ 34,999
   ☐ $ 35,000 to $ 44,999
   ☐ $ 45,000 to $ 54,999
   ☐ $ 55,000 to $ 64,999
   ☐ $ 65,000 to $ 74,999
   ☐ $ 75,000 to $ 74,999
   ☐ $ 85,000 to $ 74,999
   ☐ > $ 95,000

4. Age:
   ☐ 18 to 30
   ☐ 31 to 40
   ☐ 41 to 50
   ☐ 51 to 60
   ☐ 61 to 70
   ☐ 71 to 80
   ☐ Above 80

5. Please specify your race/ethnicity:
   ☐ White, Non-Hispanic   ☐ Hispanic   ☐ Multi-racial
   ☐ African-American   ☐ Asian   Other (please specify):...

6. Please check if you have any of these conditions:

Version Date: 04/03/2013

☐ Diabetes ☐ High Blood Pressure ☐ Asthma ☐ Gastritis ☐ High Cholesterol ☐ I don't have other disease beside my arthritis Other *(please specify):*..	
7. How many medications (including prescription, non-prescription, vitamin, dietary supplement) are you taking right now?	
8. Please check if you have any of the following types of health coverage plans: ☐ Medicare ☐ Insurance through a current or former employer ☐ Medicaid ☐ Insurance purchased directly from an insurance company ☐ VA ☐ I don't have any health coverage plans Other *(please specify):*..	
9. If you are Medicare beneficiary, what kind of plan do you enroll in? **Part A/B/C/D***(circle your plan)*	
10. Have you enrolled in a kind of program where your pharmacist counsels you about your medication, gives you a medication list/record, monitors the effectiveness of your medication and solves your medication related problem (e.g. side effect)? No ☐ Yes ☐	