EVALUATION OF PHARMACIST'S EDUCATIONAL INTERVENTION IN IMPROVING TREATMENT OUTCOMES OF PATIENTS WITH RHEUMATOID ARTHRITIS

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by

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TABLE OF CONTENTS

APPENDICES

LIST OF PUBLICATIONS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ACR	American College of Rheumatology
ACREU	Arthritis Community Research and Evaluation Unit
ADPB	Additional disease and pill burden
AGFI	Absolute goodness of fit
ARMS	Adherence to Refills and Medications Scale
BMI	Body mass index
BMQ	Brief Medication Questionnaire
CFI	Comparative fit index
CG	Control group
CM	Contextual Model
CRNA	Cost related non-adherence
CSM	Common-Sense Model of Illness Representation
CRP	C-reactive protein
CVI	Content validity index
CVR	Content validity ratio
DALY	Disease adjusted life year
DAS	Disease activity score
DMARDs	Disease modifying antirheumatic drugs
EFA	Exploratory factor analysis
ESR	Erythrocyte sedimentation rate
EULAR	European League Against Rheumatism
GFI	Goodness of fit
GMAS	General medication adherence scale
GRAS	General rehabilitation adherence scale
HBM	Health Belief Model
HCP	Health care professional
HRQoL	Health related quality of life
ICC	Intra-class correlation
IG	Intervention group
IHME	Institute for Health Metrics and Evaluation
ITC	Item-to-total correlation
KMO	Kaiser-Mayer-Olkin
LMIC	Low-to-middle income country
MCQ	Multiple choice question
MDRAW	Modified drug adherence workup
MLA	Maximum likelihood analysis
MMAS	Morisky’s Medication Adherence Scale
MTX	Methotrexate
NCD	Non-communicable disease
NFI	Normed fit index
NSAIDs	Non-steroidal anti-inflammatory drugs

OPD	Out-patient department
PBNA	Patient behavior related non-adherence
PGFI	Parsimony goodness of fit
PCA	Principle component analysis
PCFA	Partial confirmatory factor analysis
Pharm.D	Doctor of Pharmacy
PKQ	Patient Knowledge Questionnaire
PKR	Pakistani Rupee
PSF	Patient satisfaction feedback
PT	Physical therapy
QALYs	Quality adjusted life years
QoL	Quality of life
RA	Rheumatoid arthritis
RAKAS	Rheumatoid arthritis knowledge assessment scale
RAQoL	Rheumatoid Arthritis Quality of Life
RCT	Randomized controlled trial
RMSEA	Root mean square error of approximation
RR	Response rate
SLE	Systemic lupus erythematosus
SMS	Short message service
SPSS	Statistical Package for Social Sciences
SR	Simple randomization
SRMR	Standardized root mean square residual
TBMM	Traditional Biomedical Model of Medicine
TLI	Tucker Lewis index
TTM	The transtheoretical model
TARP	Technical Assistant Research Program
UK	United Kingdom
USA	United States of America
USD	United States Dollar
VAS	Visual analogue scale
WHO	World Health Organization
YLD	Years lived with disability

GLOSSARY

Rheumatoid arthritis	It is an auto-immune disease that mainly affects joints and results in joint deformity, work related disability. The disease affects productivity and quality of life.
Patient education	It is a planned activity to empower patients to adopt such behaviors that are helpful in attaining positive health outcomes.
Health literacy	The extent to which an individual attains, apply and appreciate health information that empowers him/her to make decisions that are helpful in achieving positive health outcomes.
Quality of life	The degree to which an individual feel satisfied in his/her life.
Health related quality of life	A person's perceived quality of life that highlights satisfaction in those aspect of lifestyle that is likely to affect that person's life.
Adherence	The extent to which a patient follows advice regarding medicines, diet, lifestyle changes and any additional therapy prescribed for treatment of a disease.
Disease knowledge	The disease information and awareness that a patient possess.
Self-care	The ability to identify and manage disease symptoms as well as physical and psychological consequences of a disease.
Pharmaceutical care	An individualized patient-oriented care provided by pharmacist aimed at helping patients to achieve desired health outcomes.
Intervention	An external action that affects and modifies a patients' behavior, cognitive and emotional state towards a phenomenon.

LIST OF APPENDICES

PENILAIAN INTERVENSI PENDIDIKAN AHLI FARMASI DALAM MENINGKATKAN HASIL RAWATAN PESAKIT ARTRITIS REUMATOID

ABSTRAK

Secara tradisinya peranan ahli farmasi dalam sistem penjagaan kesihatan Pakistan hanya terhad pada pengagihan ubat-ubatan. Pihak berkepentingan dan penggubal dasar kesihatan telah berulang kali menyeru untuk meningkatkan peranan ahli farmasi dan melibatkan mereka dalam penjagaan pesakit secara langsung. Oleh hal yang demikian, kajian ini bertujuan untuk menilai intervensi pendidikan yang diketuai ahli farmasi dalam usaha meningkatkan hasil rawatan pesakit artritis reumatoid. Satu percubaan terkawal bagi dua kumpulan pesakit yang dibuat secara rawak dirancang. Satu kumpulan dilabelkan sebagai kumpulan 'kawalan' (CG), manakala kumpulan yang lain sebagai kumpulan 'intervensi' (IG). Ahli farmasi melakukan intervensi pendidikan dalam IG dan penjagaan biasa dalam CG. Kajian ini dijalankan di klinik reumatologi di 7 hospital di Karachi, Pakistan. Seramai 714 pesakit yang mendaftar, iaitu, (IG = 354, CG = 360). Data sebelum intervensi mendedahkan bahawa pengetahuan tentang penyakit dalam kedua-dua IG dan CG adalah rendah, iaitu masing-masing, 4.7 [5 – 4] dan 5.1 [5 – 4]. Skor pematuhan ubat ialah 28.9 [29 – 4] dalam IG dan 28.5 [29 – 4] dalam CG. Skor pematuhan terapi fizikal ialah 16.7 [17 – 0] dalam IG dan 16.5 [17 – 0] dalam CG. Skor nilai indeks EQ masing-masing ialah 0.58 [0.59 – 0.1] dan 0.57 [0.59 – 0.1] dalam IG dan CG. Min kos rawatan langsung ialah PKR 37723.76 dalam IG dan PKR 37514.47 dalam CG. Pesakit dipantau selama 3 bulan selepas intervensi dan seramai 6 pesakit hilang untuk pemantauan susulan. Data dikumpul daripada 352 pesakit dalam IG dan daripada 356 pesakit dalam CG. Pengetahuan tentang penyakit meningkat pada pesakit IG dengan skor 9 ± 1.4 [9 – 2]. Pematuhan terhadap pengambilan ubat juga meningkat pada pesakit IG, iaitu 31.1 ± 1.6 [32 – 1]. Skor untuk mematuhi terapi fizikal adalah lebih tinggi pada pesakit IG, iaitu 19.4 ± 1.2 [20 – 0]. Nilai indeks EQ meningkat pada pesakit IG, iaitu, 0.62 ± 0.1 [0.62 – 0.1]. Kos rawatan yang berkurangan dilaporkan dalam pesakit IG iaitu, PKR 36029.76. Perubahan dalam hasil antara kedua-dua kumpulan adalah signifikan secara statistik ($p < 0.05$). Selain itu, perbezaan dalam pengetahuan bagi skor sebelum dan selepas intervensi secara statistik adalah signifikan dalam pesakit IG. Kebanyakan pesakit dalam IG yang menerima intervensi pendidikan ahli farmasi (N = 283, 80.4%) berpuas hati dengan hasilnya. Sebagai kesimpulan, intervensi pendidikan ahli farmasi mempunyai kesan positif terhadap hasil rawatan pesakit RA. Intervensi ini meningkatkan pengetahuan tentang penyakit, meningkatkan pematuhan dan HRQoL serta mengurangkan kos rawatan langsung. Penemuan ini menekankan keperluan untuk menyediakan penjagaan farmaseutikal kepada pesakit sebagai perkhidmatan penjagaan kesihatan rutin kerana usaha ini dapat membantu pesakit mencapai matlamat rawatan mereka. Selain itu, kepuasan pesakit adalah penentu utama yang mendorong pesakit untuk mematuhi objektif rawatan dan dengan itu dapat meningkatkan keberhasilan rawatan.

EVALUATION OF PHARMACIST'S EDUCATIONAL INTERVENTION IN IMPROVING TREATMENT OUTCOMES OF PATIENTS WITH RHEUMATOID ARTHRITIS

ABSTRACT

Pharmacist’s role in Pakistan’s healthcare system has traditionally been limited to dispensing of medications. Healthcare stakeholders and policy makers have repeatedly called for enhancing this role and involving pharmacists in direct patient care. Therefore, this study was aimed to evaluate pharmacist led educational intervention in improving treatment outcomes of patients with rheumatoid arthritis. A two arm-randomized single-blind controlled trial was designed. One arm was labeled as, ‘control’ group (CG), while other was, ‘intervention’ group (IG). The pharmacist provided an educational intervention in IG and usual care in CG. This study was conducted in rheumatology clinics of 7 hospitals in Karachi, Pakistan. A total of 714 patients were randomly enrolled, 354 in the IG and 360 in the CG. Pre-interventional data revealed that disease knowledge in both IG and CG was poor, i.e., 4.7 [5 – 4] and 5.1 [5 – 4] respectively. Medication adherence score was 28.9 [29 – 4] in IG and 28.5 [29 – 4] in CG. Physical therapy adherence score was 16.7 [17 – 0] in IG and 16.5 [17 – 0] in CG. EQ index value score was 0.58 [0.59 – 0.1] and 0.57 [0.59 – 0.1] in IG and CG respectively. The direct cost of treatment was PKR 37723.8 in IG and PKR 37514.5 in CG. Patients were followed up 3 months after intervention and 6 patients were lost to follow-up. Data were collected from 352 patients in IG and from 356 patients in CG. Disease knowledge increased in IG patients with a score of 9 ± 1.4 [9 – 2]. The adherence to medications also increased in IG patients, i.e., 31.1 ± 1.6 [32 – 1]. Score for adherence to physical therapy was higher in IG patients, i.e., 19.4 ± 1.2 [20 – 0].

EQ index value improved in IG patients, i.e., 0.62 ± 0.1 [0.62 – 0.1]. A reduced treatment cost was reported in IG patients i.e., PKR 36029.76. The change in outcomes between two groups was statistically significant ($p<0.05$). Additionally, within-subject difference in pre and post intervention scores was statistically significant in the IG patients (<0.01). Most patients in the IG who received pharmacist's educational intervention (N = 283, 80.4%) were satisfied from it. In conclusion, pharmacist's educational intervention had a positive impact on treatment outcomes of RA patients. It significantly increased disease knowledge, improved adherence and HRQoL as well as, decreased direct treatment cost. These findings highlight the need to provide pharmaceutical care to patients as a routine healthcare service as it helps patients achieve their treatment goals. Besides, patient satisfaction is a key determinant that motivates patients to adhere to treatment objectives thereby increasing likelihood of treatment success.

CHAPTER 1: GENERAL INTRODUCTION

1.1 Research background

Non-communicable diseases (NCDs) have emerged as major cause of disability and death since last century. The advent of vaccines and antibiotics together with rapid urbanization and development, led to increased life expectancy and improved quality of life. People lived longer and had better living standards. However, this resulted in increased burden of non-communicable diseases. (Boutayeb and Boytayeb, 2005). Initially, NCDs were known as the disease of the affluent and mostly affected people in economically developed countries. However, an increasing trend of NCDs related morbidity and mortality was reported from developing countries (Boutayeb, 2006). The recent figures from World Health Organization (WHO) highlight that noncommunicable diseases have surpassed communicable diseases as major cause of deaths globally and were responsible for 38 million deaths, i.e., 68%, of total 56 million deaths worldwide in 2012. Moreover, most deaths due to NCDs, i.e., 28 million which account for almost 82% of total, occurred in developing countries. (Global Status Report on noncommunicable diseases, 2014).

Aside NCDs related morbidity and mortality, the diseases also contribute to economic burden on the society. A lot of money is spent by patients and organizations to manage these diseases. This healthcare spending depends on terms and condition of healthcare service provided to patients. For instance, in developed countries the money is spent by healthcare system and public agencies; however, patients in developing countries mostly pay direct medical costs. Moreover, NCDs may lead to terminal disabilities that further reduce an individual's productivity and income. The WHO estimates that noncommunicable illnesses would cost low-to-middle income countries (LMICs) around USD 21 trillion on treatment and productivity loss (Richards et al., 2016).

In this context, the region of South Asia currently experiences a transition from communicable disease outbreak related deaths to noncommunicable diseases ones. The region contributes to 60% of all deaths and, 47% of deaths to global burden of disease (Ghaffar, Reddy, Singhi, 2004). Pakistan is a low-to-middle income country located in South Asia. Pakistan hosts a large population and shares a huge disease burden of NCDs. The age expectancy has increased in recent years and therefore, the prevalence of NCDs is expected to increase in future (The World Bank, 2016). Literature highlights that NCDs are the leading cause of deaths in Pakistan (Institute for Health Metrics and Evaluation, 2017a). The data from Global Burden of Disease Report (2010) projects that by year 2025, about 3.87 million premature deaths of Pakistanis aged 30-69 years will be from NCDs (Jafar et al., 2013).

Musculoskeletal illnesses are a major contributor to an individual’s decreased productivity, economic burden and mobility. Unlike other noncommunicable diseases, these illnesses may not result in death. However, they are the most common cause of persistent pain and impaired functioning (Woolf & Pfleger, 2003). They significantly decrease a person’s mobility, productivity and quality of life (Woolf & Akesson, 2001; Naqvi et al., 2017). Most common musculoskeletal illnesses are osteoarthritis, rheumatoid arthritis and osteoporosis (Woolf & Pfleger, 2003; Naqvi et al., 2017).

Rheumatoid arthritis (RA) is a chronic inflammatory disease of joints characterized by pain, stiffness, inflammation and decreased mobility. It results in joint deformity, decrease work ability, productivity and subsequently reduces quality of life of an individual (Woolf & Pfleger, 2003; Naqvi, Hassali & Aftab, 2019). Approximately 0.5% - 1% of population is affected by RA globally (Naqvi et al., 2017; Naqvi, Hassali & Aftab, 2019). Data from the Institute of Health Metrics and Evaluation entails that the prevalence of RA in Pakistan is 0.22% (0.22% – 0.25%). However, the figures for years lived with disability (YLDs) were high, i.e., 28.59 years (19.12 – 39.02), and disease adjusted life years (DALYs) were 39.64 years (28.84 – 51.75). These figures further increased to 0.92 (0.52 – 1.69) deaths due to RA, 40.12 (26.73 – 54.81) YLDs and 56.67 (40.22 – 75.92) DALYs in case of female RA patients. All figures were reported out of 100,000 patients (Institute for Health Metrics and Evaluation, 2017b). Considering nature of disease and its prevalence in geriatric population. The disease burden of RA is expected to increase in future as the world deals with an aging population (Lawrence et al., 1998).

The treatment of RA encompasses both pharmacological and non-pharmacological treatments. Notwithstanding role of pharmacological therapy in RA treatment, evidence indicates importance of non-pharmacological treatment such as physical therapy and patient education in managing RA (Forestier et al., 2009). The American College of Rheumatology (ACR) stresses on patient education and physical/occupational therapy alongside use of disease modifying antirheumatic drugs (DMARDs), non-steroidal anti-inflammatory drugs (NSAIDs) and low-dose steroids (American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines, 2002). Pharmacological treatment may be essential in managing the acute flares and episodic pain associated with the disease. Nevertheless, self-care and home-based management of RA is another important area of care which patients incorporate to manage it effectively.

This could be achieved if the patients are aware of the disease and have adequate symptom attribution. This will enable early recognition and prompt treatment. This proactive approach towards recognition and management can help a patient to maintain mobility and a quality of life (Naqvi et al., 2017). For this purpose, patients require rational and up-to-date information about disease and its management. Several information resources are available to patients such as healthcare professionals, friends and peers, internet, printed materials, etc. However, reliable, unbiased and updated information about disease and its management could only be provided by pharmacists (American Society for Health System Pharmacists, 2019). Pharmacist provide pharmaceutical care and counselling services that could increase patient awareness. It could help them identify treatment goals and focus on ways to achieve the targets. Evidence indicates that a pharmacist driven educational interventions have improved adherence to medications, knowledge about disease and health related quality of life in patients with NCDs (Bouvy, Heerdink, Urquhart, Grobbee, Hoes & Leufkens, (2003); Murray et al., 2007; Saleem et al., 2015).

Unfortunately, pharmacists are not employed as disease educators and interventions performed by pharmacists are not seen regularly. The provision of a pharmacist driven pharmaceutical care is not common in Pakistan’s healthcare system. Therefore, physicians are the only source of reliable information to patients. This overburdens the health practitioners and add to their responsibilities that consequently compromise their time, attention and care, to address the health care needs of patients (Khan, 2011).

Therefore, to overcome this debacle, a patient-centered educational intervention by pharmacists is required. A patient centered education may take place in the form of face-to-face consultations, provision of written material, etc., and may augment patients’ disease knowledge and improve adherence to medications as well as physical therapy for the condition. (Mahmud, Comer, Roberts, Berry & Scott, 1995). This may not only improve productivity and quality of life of patients but, may reduce hospital admissions, frequent emergency visits to hospital thereby decreasing the cost of treatment.

1.2 Rationale of the study

Several studies have reported that a patient driven self-care approach in rheumatoid arthritis disease effectively reduces acute flares (Barlow & Wright, 1998; Lagger, Pataky & Golay, 2010). This could be achieved by providing patient education and counselling through pharmacists. Pharmacist provide pharmaceutical care that incorporates these areas of care. Pharmaceutical care is an individualized patient-centric health service delivered by pharmacists that incorporates, but is not limited to, disease education, therapy management, self-care and self-management of disease and therapy, as well as motivational guidance (Bouvy, Heerdink, Urquhart, Grobbee, Hoes & Leufkens, 2003; Murray et al., 2007; Saleem et al., 2015).

Literature highlights several educational strategies and programs to improve patient education for managing rheumatoid arthritis (Bornstein, Craig, Tin, 2014). However, there have been only few studies conducted that have evaluated the impact of pharmacist led pharmaceutical care on treatment outcomes in patients with rheumatoid arthritis. Moreover, these programs were designed and implemented in patients of developed countries. Hence, there is a need to conduct such studies in developing countries where the socioeconomic status of patients, standard of living and culture are different from developed countries.

In Pakistan, there are no published studies to date, that evaluate the impact of pharmacist led pharmaceutical care on treatment outcomes in patients with RA. Since, the disease prevalence has increased in Pakistani population of late, and mainly affects the middle-aged individuals, it is expected that RA would affect their productivity, employability and income. This would worsen their health-related quality of life and adds to economic burden of this disease on the society (Naqvi, Hassali & Aftab, 2019). Hence, development of an educational program for disease awareness and management of RA is needed.

This study reports the outcomes of an education intervention performed by pharmacists in Pakistani patients with RA. The role of pharmacist as an educator and counselor was defined and executed to address the healthcare needs of patients with RA. The objective was to highlight the advantages of inclusion of pharmacist as a member of healthcare team and determine its impact in terms of patient reported outcomes.

1.3 Overview of thesis

The first chapter provides a general background of non-communicable diseases and their clinical and economic burden globally. This is followed by discussion about non-communicable disease in South Asia particularly Pakistan. Following that, the scope of the discussion converges to musculoskeletal diseases and their impact on patients. The discussion further narrows to rheumatoid arthritis (RA) disease and discusses its impact on patients followed by detailed review of figures related to epidemiology of RA in Pakistan. The diagnosis, treatment and management become the focus of discussion after that and importance of pharmaceutical care is touched upon. This is followed by elaborating the current scenario of pharmaceutical care in Pakistan. This chapter also includes the rationale of the study and provides guidance to readers about topics discussed in rest of the thesis.

The second chapter is the literature review that focuses on patient education and related theoretical models. It further discusses the structure of patient education, barriers and role of healthcare professionals in education of patients followed by specifically elaborating the importance of educating patients with rheumatoid arthritis. Furthermore, this chapter also discusses adherence in detail and highlights its relationship with theoretical models followed by factors affecting adherence, methods for measuring adherence and consequences of non-adherence. Moreover, this chapter also reviews literature pertaining to rheumatoid arthritis (RA) disease, its prevalence, diagnosis, management and treatment. This further includes importance of disease awareness, adherence to treatment and economic burden of disease. A detailed account of health-related quality of life (HRQoL) is available at the end of this chapter. An effort is made to discuss HRQoL via linking it with theoretical models, explanation of HRQoL as a measure of health status and different tools that measure this phenomenon are reviewed. It further focuses on relationship of HRQoL and RA. The chapter ends with a brief discussion on interventions that improve treatment outcomes.

Chapter three contains general methodology of the study including trial protocol. It also includes description of intervention, training of pharmacists and materials used in training. It further mentions the research instruments used to measure the treatment outcomes. Chapter four is based on development and validation of disease education literature for patients with rheumatoid arthritis. Chapter five, six, seven and eight entail the tool development and validation process for measuring adherence to medications, physical therapy adherence, disease knowledge and satisfaction from pharmacist intervention respectively. Chapter nine contains the study trial. It describes the pre-interventional findings and evaluates the impact of intervention in post-interventional analyses. Chapter ten provides an overall summary of the thesis and draws the discussion to a conclusion followed by recommendations.

1.4 Study objectives

The objective of the study was to evaluate the effectiveness of a multifactorial educational intervention provided by pharmacists in clinical, economic and humanistic outcomes of patients with rheumatoid arthritis disease. Specific objectives are discussed in detail later in Chapter 3.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Pharmacist role has significantly progressed from compounding and dispensing of medications to disease educators, counselors and healthcare providers. Pharmacy had been traditionally inclined towards manufacturing and compounding of medicines as well as commercial drug sales. However, during the last two decades these functions were greatly reduced and at the same time, the importance of pharmaceutical care was realized in patient care (Tipnis, 2012; Toklu & Hussain, 2013). Thus, the role of pharmacist expanded to patient care provider as a member of allied health professionals. Pharmacist is now recognized as a health care professional (HCP) who could address the healthcare needs of patients by performing interventions and providing pharmaceutical care (Barber, Smith & Anderson, 1994). This care is aimed at improving treatment outcomes of patients who suffer from communicable as well as noncommunicable illnesses.

A plethora of evidence supports inclusion of pharmacists in healthcare system. Several cohort studies and trials have been conducted during the last twenty years that evaluated pharmacists' role in increasing disease awareness and improving adherence to treatment. Several studies reported that pharmacist driven pharmaceutical care increased disease knowledge and improved treatment adherence (Mahmud, Comer, Roberts, Berry & Scott, 1995; Salman, SAlnuaimi, Lateef & Kadhum, 2014; Khalil, Salim, Amjad & Malik, 2017). Moreover, studies have also reported a positive impact of pharmacists on reduction of direct treatment costs and improvement in health-related quality of life (HRQoL) (Onatade, Appiah, Stephens, & Garelick, 2018).

2.2 Patient education

Patient education is an organized and planned information provided by HCPs to patients that could change their perception, behavior and beliefs to achieve a better health status (Ryan, 2007). The World Health Organization (WHO) mentioned in its charter that patients have the right to receive health education that contains factual, comprehensive and appropriate information provided to them in a way that empowers them to decide the fate of therapy (WHO, 1994). It is essential to educate patients regarding their condition and therapy. This education may not be limited to clinical settings alone but also applies to non-clinical settings (Falvo, 2004). This could be categorized as therapeutic or clinical patient education that encompasses information about chronic illnesses and other clinical outcomes as well as, health education, preventive education and health promotion, that may take place in a non-clinical environment (WHO, 1998; Lorig, 2000; Koongstvedt, 2001).

Patient education is aimed to increase disease awareness, improve adherence to therapy and self-management, with an eventual goal of improving health related quality of life of the patient (Sudre, Jacquemet, Uldry, Perneger, 1999; Feudtner, 2001; Lenz, Steckelberg & Muhlhauser, 2008). This education intervention subsequently increases a patient's health literacy that further helps patients in understanding the education given to them. Health literacy is defined in literature as patients' willingness to seek, understand and act on information provided to them (Nutbeam, 2008; Paterick, Patel, Tajik, & Chandrasekaran, 2017). Increased health literacy results in better comprehension and processing of health-related information by patients that empowers them in rational decision-making (Cornett, 2009).

This becomes ever important in today’s world as medical treatment has transcended from a disease-based treatment approach to patient-centered approach. Patient-centered approach aims to empower patients to actively participate in clinical decision-making and care (Reynolds, 2009). The care not only encompasses clinical goals, but also a patient’s mental, social and financial perspectives are also considered. The care process is driven by a patient’s health needs and expected treatment outcomes (NEJM Catalyst, 2017). The latter are not considered essential in disease-based model (Green, Carrillo, & Betancourt, 2002). Patient-centered care focuses on risk prevention strategies. This takes place through patient empowerment regarding disease management and risk factors. However, the extent to which these strategies benefit depends upon the health literacy of patient (Dreeben-Irimia, 2010).

2.2.1 Health Belief Model (HBM)

One of the most commonly used models to understand human behavior towards health services is the Health Belief Model (HBM) (Becker, 1974; Jones et al., 2015). The HBM predicts health behavior of an individual based on;

- Perception of a negative outcome that could be avoided
- Positive perception about a health measure that if taken, could avoid the negative outcome
- Confident in successfully executing the action

For instance, a patient with asthma would take a health-related action (use of inhaler) if he/she;

a) perceives that an asthmatic attack (negative outcome) could be avoided and,

b) believes that the action (use of inhaler) would effectively prevent recurrent asthmatic attacks (negative outcome) as well as,
c) has confidence in executing this action (use of inhaler) appropriately.

HBM assumes that an individual’s health behavior depends on how severe he/she takes that illness and provided he/she has a definite course of action to take in response to the illness. The model has six concepts namely perceived severity, perceived susceptibility, perceived barriers, perceived benefits, cues to action and self-efficacy (Becker, 1974; Jones et al., 2015). Perceived susceptibility denotes that a patient would believe that he/she could suffer from an illness. Perceived severity represents the belief in a patient’s mind that complications resulted from that illness must be avoided. Perceived benefit means that patient believe the health action would help avoid illness resultant complications. Perceived barriers denote that patient could identify factors that would influence the use of health action. Cues to action represent the reminders for the recommended health action and self-efficacy denotes that patients are trained on that health action (Jones et al., 2015).

Moreover, the model notes that a patient would first indulge in a cost-benefit analysis before selecting a health action (Becker, 1974; Jones, et al., 2015). For instance, despite known benefits of exercise and rehabilitation in improving mobility in patients with RA, patients may not undergo such interventions due to various reasons (Crowley & Kennedy, 2009). These may be external as well as internal such as cost of treatment, time, logistic issues, treatment resulted pain, exhaustive attendance, etc. These would influence an overall patient behavior towards exercise in RA.

The success of a treatment education program would depend upon a patient’s understanding of how susceptible he/she feels in contacting the disease, the level of disease severity in his/her mind and how beneficial is the treatment in his/her view. Therefore, it is important to investigate these factors before designing an educational program as failure to achieve success in any of the above-mentioned domains may compromise the effectiveness of intervention.

2.2.2 The Theory of Planned Behavior

The theory of planned behavior explains the relationship between an individual’s attitude towards a behavior and the displayed behavior. The theory is based on several constructs namely the attitude towards behavior, subjective norm and perceived behavioral control (Ajzen, 1991). The attitude towards behavior denotes an individual’s belief about a certain behavior that contributes positively or negatively in his/her life. For instance, a patient’s belief that opting for counselling service offered at a pharmacy for self-management of rheumatoid arthritis makes sense or not. The subjective norm focuses on factors associated with the patient such as social network, cultural norms, etc. For example, a patient’s perception of others in his/her social circle who might judge him/her for selecting counselling service for his condition. Perceived behavioral control denotes the thoughts of a patient to assess how difficult or easy it is to display a certain behavior. In context of counselling service example, a patient might try to experience a session to have an idea if the opinion of others in his/her social circle was right or it is different.

The theory predicts that if a patient had positive attitude towards a certain behavior, favorable social norms and firm perceived behavioral control, may form a behavioral intention to attend counselling and ultimately lead to a displayed behavior. Therefore, considering the example of counselling service, if a patient believes that undergoing counselling for self-management of rheumatoid arthritis is better than not undergoing, and also perceives that others in his/her social circle believe the same and, feels confident in undergoing counselling, will eventually attend a counselling session. Strating and colleagues applied this theory to test effectiveness of partner support towards self-management of disease in patients with rheumatoid arthritis. They found that partner support contributed to increased intention and self-management thereby proving effectiveness of this theory in health practice (Strating, van Schuur & Suurmeijer, 2006).

It is quite difficult to change a patient's perception and cultural beliefs about a certain healthcare service or intervention. Moreover, the likelihood of change becomes arduous if the societal beliefs and cultural norms are against it. Therefore, it is essential to consider these factors while designing an educational program and intervention to address a patients' healthcare needs.

2.2.3 The Common-Sense Model of Illness Representation (CSM)

The common-sense model of illness representation (CSM) explains an individual's response to illness. The theory focuses on an individual's perception of health risk and emotional response associated with the risk (French & Weinman, 2008). The theory links these perceptions and emotional responses of individuals with actions taken to manage the disease and, would affect the outcomes of the treatment (Cameron, Leventhal, & Leventhal, 1993; Hagger & Orbell, 2003; McAndrew et al., 2008). According to Leventhal and colleagues, the perception of illness an individual has, is based on information as well as personal experience that individual has acquired over a period (Cameron & Leventhal, 2012; Diefenbach & Leventhal, 1996). There are six domains this theory focuses on:

- identity

- timeline
- consequences
- cause
- perceived controllability and curability
- emotional perception

The identity of the disease includes name as well as associated sign and symptoms of disease. The timeline of disease connects it to a predictable timeframe i.e., how long disease would last. The consequences of disease, i.e., what could happen, if the disease is not treated or, as a result of treatment. The cause of disease, i.e., how was it caused in the first place. The perceived controllability or curability and, emotional perception about disease (Huston & Houk, 2011).

Mäkeläinen and colleagues reported a varying degree of knowledge about disease and its treatment, among patients with rheumatoid arthritis. The patients seemed aware about disease, symptoms, laboratory tests and exercises. Patients with a long history of disease had better knowledge. (Mäkeläinen, Vehviläinen-Julkunen & Pietilä, 2009). Furthermore, in another study, Khalil and colleagues reported a partial-to-low knowledge among patients with rheumatoid arthritis. The patients seemed to be aware of sign and symptoms of RA, consequences of disease and gender predisposition. Three quarter of patients were aware of the chronic nature, i.e., lifelong duration of illness (Khalil, Salim, Amjad & Malik, 2017). Cordingley et al., evaluated psychological factors on disease activity in patients with rheumatoid arthritis using CSM and found that patient reported score on visual analogue scale (VAS), was associated with cognitive factors and depression, i.e., emotional response (Cordingley, et al., 2014).

2.2.4 Structure of Patient Education

Patient education is important to achieve treatment goals. It is dependent on perception of health service delivered, care as well as awareness regarding disease and treatment. Evidence indicates that patients who are well aware of their disease state may achieve better treatment outcomes compared to their counterparts (Koo, Krass, & Aslani, 2003). For instance, study by Taibanguay and colleagues reported that patients with rheumatoid arthritis who are aware about their disease had better medication adherence compared to patients with low disease awareness (Taibanguay, Chaiamnuay, Asavatanabodee & Narongroeknawin, 2019). Another study in the UK reported significant correlation between knowledge and medication adherence scores (Homer, Nightingale & Jobanputra, 2009).

Educating patients may inculcate a positive perception about health care in patients' mind that may influence empowerment and motivation to actively seek treatment (Aslani, 2013). This in turn, is beneficial for achievement of treatment goals. Similarly, Senara and colleagues reported improvement in pain, disability, health perception and disease activity of patients who were enrolled in a patient education program as compared to those patients who were not (Senara, Wahed & Mabrouk, 2019).

Patient education is a mix of knowledge empowerment, improvement in abilities and conducts, and psychological support. Educational strategies may include providing information only that could take place via verbal communication or written materials, taught lectures, online audio-visual videoclips, etc. It could take place as a cognitive-behavioral therapy such as exercise, yoga, behavioral modification, psychosocial support, motivation counselling, etc. (Cooper, Booth, Fear & Gill, 2001; Khoury, Kourilovitch & Massardo, 2015). A combination of these strategies may be used (Cooper, Booth, Fear & Gill, 2001). Education may be designed as short-term, i.e., one-time contact or long-term, i.e., continuous contact at several follow-up appointments (Cooper, Booth, Fear & Gill, 2001).

The selection of an education strategy may be dependent on treatment goals. For instance, patients with rheumatoid arthritis require an educational program that empowers them to cope up with and adjust disease related disability in life (Ndosi and Adebajo, 2015). Within the context of RA education program, the needs of patient might vary depending upon stage of disease activity. Patient in early RA may require knowledge and awareness regarding disease symptoms and medication therapy while those in advanced stage may require information about self-care and work-based management of disease related complications and disability (Khoury, Kourilovitch & Massardo, 2015; Ndosi and Adebajo, 2015).

2.2.5 Role of Healthcare Professionals in Patient Education

The health care services in present time, have shifted from disease-based care to patient-oriented care. It has transcended from patient education to patient engagement. Patients are now expected to be actively involved in their clinical decision making. In order to achieve a successful patient-oriented care, attention must be paid on provision of knowledge, skills, as well as motivational counselling to help patient take active part in self-management of disease state (Gruman et al., 2010). At the same time, it is equally important for health care professionals to consider providing relevant information in a simple and easy to understand content that corresponds to patients' intellect. Not providing patient education in simplistic manner would complicate patient's understanding about disease management and may prompt him/her to consult other sources such as internet, media, friends and peers. These sources may not be reliable, and patient could suffer from adverse events. Therefore, it is important to educate patients in a way that augments their knowledge and understanding about their disease, enhances their self-management and self-care skills, and empowers them to manage their condition without the need to consult any other source (Maycock, 1991; Kreitzer, Kligler, & Meeker, 2009).

Pharmacists are considered as educators and counselors for helping patients manage their illness state. A pharmacist present at the time of drug refilling, is the last health care professional patients see before leaving the clinic (Awofisayo, Awofisayo, Iferi, & Akpan, 2008). Pharmaceutical care is a term coined for pharmacist driven patient-centered care that focuses on achievable outcomes set by pharmacist in collaboration with patient and patient's health care team. The care focuses on prevention and/or treatment of disease as well as initiation, maintaining, assessment and modification of therapy to achieve better clinical outcome, improve quality of life and reduce health expenditure (American Pharmacist Association, 2019). Pharmacists could help patients achieve treatment goals and targets, counsel them on safe use of medicines and motivate them for active participation in management of their disease (American Society for Health System Pharmacists, 2019). Therefore, it is of paramount importance that pharmacist should be prepared to educate and counsel patients before leaving the clinic as this would ensure better adherence to treatment by patients at home (Raman-Wilms, 2009).

2.2.6 Patient Education in Rheumatoid Arthritis

Rheumatoid arthritis results in pain and inflammation of the joints that significantly reduces joint mobility. It could reduce a patient's capacity to work, cause disability and deteriorate health related quality of life (Khoury, Kourilovitch & Massardo, 2015;

Naqvi et al., 2017; Naqvi, Hassali & Aftab, 2019). Literature mentions that patient with RA are at a higher risk of morbidity and mortality from cardiovascular diseases as compared to general population (Kitas & Erb, 2003; Kitas & Gabriel 2010). Though, pharmacological research has resulted in better medicines being available for treatment however, poor treatment outcomes are still seen in RA patients. Evidence indicates low disease awareness, understanding about treatment and self-management strategies as determinants of treatment success (Georgopoulou, Prothero, Lempp, Galloway, Sturt, 2016). Considering the nature of this illness, it is important to educate patients about its management.

Patient education along with pharmacotherapy forms a cornerstone of treatment. Clinical guidelines for management of RA recommend patient education from beginning of treatment (Khoury, Kourilovitch & Massardo, 2015; Naqvi et al., 2017; Naqvi, Hassali & Aftab, 2019). Recent evidence highlights that treatment of rheumatoid arthritis is patient centric and is based on shared decision making (Khoury, Kourilovitch & Massardo, 2015). Patients need to be informed about the risks posed by RA and benefits of adhering to treatment. Studies have reported a low disease activity in adherent patients (Li et al., 2017). Therefore, educating patients with rheumatoid arthritis is important to achieve positive treatment outcomes as it improves perception about disease, builds a positive approach towards disease and increase motivation to pursue treatment.

2.2.7 Barriers to Patient Education

Several factors exist that may hinder health care providers to educate patients. These barriers may be financial, logistic, social, linguistic as well as health care provider related. Available evidence highlights that low financial resources, low competency of health care provider and scarce human resource, are most common barriers to patient education (Ling, Brereton, Conklin, Newbould, & Roland, 2012; Ngoh, 2009; Penz et al.,2007). The health care providers may lack proper training and expertise regarding patient education that may become a determinant (Raehl et al., 2006; Alkatheri and Albekairy, 2013). Moreover, coordination among health care providers is important to treat, educate and follow-up patients. Lack of harmonization among doctors and pharmacists may act as a barrier to patient education. Apart from these barriers, patients especially in developing countries, may not be well informed of pharmacist's role as an educator (Alkatheri and Albekairy, 2013; Kelly, Young, Phillips & Clark, 2014). At the same time, pharmacists may not be willing to educate a patient due to fear of instigating stigma towards medicines. For example, pharmacist may deliberately avoid educating patients about a medicine's side effects out of fear of decreasing patient adherence (Kessler, 1991). Lastly, language may also act as a barrier to educating patients. It is imperative to address these barriers to ensure an effective patient education program.

2.3 Adherence

According to the World Health Organization, adherence is defined as, 'the extent to which a person's behavior, medication taking, following a diet and/or executing lifestyle changes corresponds with agreed recommendations from a health care provider' (World Health Organization, 2009). Osterberg and Blaschke mentioned that adherence in general highlights that a patient and his/her health care provider agree in clinical decision making (Osterberg & Blaschke, 2005). Other terminologies that are synonymously used with adherence are compliance and concordance. However, the term adherence is preferred over compliance as adherence demonstrates an active participation and follow-up by patients whereas compliance describes that patients follow instructions passively. The term concordance depicts that patient and health care provider are equal partners when it comes to making decisions regarding medication therapy (Osterberg & Blaschke, 2005; World Health Organization, 2009; Naqvi, Hassali, Jahangir, Nadir & Kachela, 2019).

2.3.1 Theoretical explanations for adherence

Several models have been reported in the literature that have explained patient adherence to treatment. These are discussed below:

2.3.1(a) Health Belief Model (HBM) and its relationship with adherence

According to the HBM, a patient's adherence to treatment is based on the perception and beliefs of the patient. A positive perception and belief would result in an inclination of patients towards their treatment. This prompts patients to adhere to treatment recommendations that subsequently results in achieving positive outcomes (Maiman & Becker, 1974). This further reinforces the perceptions and beliefs of patients. However, the success of treatment and patient adherence to treatment is partially dependent upon the initial beliefs and perception patients have regarding their condition. There is a plethora of evidence that proves the effectiveness of interventions designed on HBM that aimed to improve adherence to medication and treatment (Jones, Smith & Llewellyn, 2014).

Behavior change is a subjective process that takes place in three steps. The first step is the willingness to change behavior. The second step is a comparative analysis of advantages and disadvantages of the change while third step is the development of cues that could be either intrinsic or extrinsic that results in a change. A patient would only take the second step if he/she has the necessary knowledge to compare the advantages and disadvantages and be able to justify the change in behavior (Cerkoney & Hart, 1980). This is important in addressing healthcare needs of patients with rheumatoid arthritis.

For instance, RA patients are routinely prescribed physical therapy along with medication therapy as part of treatment. Adherence to physical therapy along with medication therapy is important to achieve positive outcomes. Patients would compare the benefits and drawbacks of physical therapy. A comparative analysis of benefits of physical therapy such as better mobility, joint movement and functional capacity with perceived shortcomings, some of which could be identified as, direct cost, exhaustive attendance, treatment resulted pain, and delayed results. This comparison could affect adherence to treatment. Therefore, any action taken by healthcare professional to improve patient adherence to treatment need to incorporate behavioral intervention to address patients' perception and beliefs about disease and its treatment (Demmelmaier, Åsenlöf & Opava, 2013). In a systematic review by Larking and colleagues, studies that have incorporated behavioral interventions were reported to be successful in promoting physical activity in patients with rheumatoid arthritis (Larkin, Gallagher, Cramp, Brand, Fraser & Kennedy, 2015).

2.3.1(b) Transtheoretical Model and its relationship with adherence

The transtheoretical model (TTM) has been extensively used in researches conducted on health behavior worldwide (Armitage, 2009). It examines the willingness of an individual to change their habits and adapt a new healthier behavior and provides guidance regarding the stages of change. According to TTM, there are six stages of behavior change (Prochaska et al., 1994; Prochaska & Di Clemente, 2005). These are as under:

- Precontemplation