

## DESIGN AND EVALUATION OF MONITORING PROGRAMME FOR METHOTREXATE USERS IN THE ARTHRITIC POPULATION - A STUDY AT THE PRIMARY AND THE SECONDARY CARE INTERFACE

Aygin BAYRAKTAR EKİNCİOĞLU<sup>1,2\*</sup>, Steve HUDSON<sup>2</sup>

<sup>1</sup> Hacettepe University, Faculty of Pharmacy, Ankara, TURKEY

<sup>2</sup> University of Strathclyde, Strathclyde Institute for Biomedical Sciences (SIBS), Glasgow / Scotland- UK

### Abstract

*The objective of the study is to design, implement and evaluate a patient monitoring process by involving community pharmacists in order to maintain continuity of care in patients with rheumatoid arthritis. The study was undertaken in Glasgow between December 2001- November 2002, as a short-term randomised controlled trial. Community pharmacists were randomly assigned to the study and the control group. The study group were intended to receive a methotrexate care plan issued by the rheumatology specialists and by the pharmacist at the hospital which is designed to enable the pharmacist to support the general practitioner in the patient monitoring role. The control group patients only received a methotrexate monitoring card in addition to their routine health care that they used to receive. During the recruitment period, 30 community pharmacists (17 in the control; 13 in the study group) and 59 patients (31 in the control; 28 in the study group) were involved. For the total patient population, 76% were female, 85% were diagnosed with rheumatoid arthritis, 13.3% with psoriatic arthritis and 1.7% with polyarthritis. The comparison between the frequency of the identified drug therapy problems in the hospital and in the community settings showed no statistically significant difference regarding the medication needs and safety problems (Chi-square test,  $p > 0.05$ ). There were significantly more drug therapy problems identified in the hospital clinics for the effectiveness and compliance problems (Chi-square test,  $p < 0.05$ ).*

*In conclusion, pharmacists are in a distinct position to support patient care through identifying drug therapy problems, guidance on patient self-management and monitoring of the patients who potentially need extra vigilance in the community settings.*

**Key words:** *Pharmaceutical care, Clinical pharmacy, Drug therapy problems, Arthritis, Pharmacist*

### **Metotreksat Kullanan Artritli Hasta Grubunda Tedavi İzlem Programının Geliştirilmesi ve Değerlendirilmesi - Birinci ve İkinci Basamak Sağlık Bakım Hizmetleri Arasındaki Bir Çalışma**

*Bu çalışmanın amacı, romatoid artritli hastaların bakımındaki sürekliliği sağlamak için serbest eczacının katılımını sağlayan bir hasta izlem süreci geliştirilmesi, uygulanması ve değerlendirilmesidir. Aralık 2001- Kasım 2002 tarihleri arasında Glasgow'da, kısa süreli randomize kontrollü bir çalışma olarak gerçekleştirilmiştir. Serbest eczacılar, çalışma ve kontrol gruplarına randomize edilmiştir. Çalışma grubundaki eczacıların, hastanede romatoloji uzmanı ve eczacı tarafından hazırlanan ve eczacının aile hekiminin hasta izlemindeki rolünü desteklemesine yardımcı olan metotreksat bakım planını alması planlanmıştır. Kontrol grubu hastalarına ise sadece metotreksat izlem kartı verilmiştir ve almakta oldukları rutin sağlık hizmetini almaya devam etmişlerdir. Hasta seçimi süresince, 30 serbest eczacı (17'si kontrol; 13'ü çalışma grubu) ve 59 hasta (31'i kontrol grubu; 28'i çalışma grubu) çalışmaya katılmıştır. Total hasta popülasyonunun %76'sı kadın olup, hastaların %85'i romatoid artrit, %13.3'ü psöriyatik artrit ve %1.7'si poliartrit tanısı almıştır. Hastane ve serbest eczanelerde belirlenen*

*ilaç tedavisi ile ilgili problemlerin sıklığı açısından ilaç tedavisine ihtiyaç ve güvenlik problemleri yönünden istatistiksel olarak anlamlı bir fark bulunamamıştır ( $X^2$  test,  $p>0.05$ ). Hastanede etkinlik ve uyum problemleri açısından istatistiksel olarak anlamlı derecede daha fazla ilaç tedavisine dair problemler saptanmıştır ( $X^2$  test,  $p<0.05$ ).*

*Sonuç olarak, eczacılar, hastanın kendi kendine bakımı konusunda yardımcı olarak ve özellikle toplumda ekstra dikkat edilmeye gereksinim duyan hastalarda izlem yaparak, hasta bakımını destekleyebilecek belirgin bir pozisyona sahiptirler.*

**Anahtar kelimeler:** *Farmasötik bakım, Klinik eczacılık, İlaç tedavisi problemleri, Artrit, Eczacı*

\*Correspondence: E-mail: aygin@hacettepe.edu.tr, Tel: +90 312 3052043,

## INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune, chronic debilitating disease affecting 0.5-1% of the population and the disease has potential effects on a patient's quality of life. Although consultation rates in primary care for RA in the United Kingdom (UK) are declining, RA still constitutes just over half of the rheumatology workload in secondary care and is responsible for about 54 general practitioners (GPs) consultation per year in the average general practice (1). The results showed that between the year 1999-2000 there were 66,931 rheumatology outpatient attendances at the 34 clinic sites in Scotland and 20% of those were new referrals and 2,760 discharges from the 13 in-patient units (2). The survey also indicated that distribution of rheumatology specialists does not adequately match distribution of health care needs of patients in the UK and this has been a particular disadvantage for the socially deprived population (3).

It has been shown that GPs are less confident to manage early RA with their own skills and knowledge or with an advice from a consultant which emphasised a need for a multidisciplinary approach (4). Moreover, the studies showed that pharmacists at community are able to detect undiagnosed knee osteoarthritis as well as RA in patients suffer from chronic pain by partnering with GPs and patients in order to improve health outcomes (5) and are in a position to help managing complex drug regimens (6).

The management of RA with oral methotrexate (MTX) therapy is currently undertaken by a shared care arrangement between rheumatology specialists in the hospitals and GPs in the community. The involvement of the nurses is maintained through provision of education and counselling and follow-up for blood monitoring in the hospital (by a nurse specialist) and in the community (by a practice nurse based in the surgery). Pharmacists are engaged with medication review activities in patients who are admitted to the hospital and also in the dispensing of methotrexate prescriptions in the community. Although MTX is a preferred drug; medication errors with oral methotrexate were reported and errors mainly occurred because of availability of two tablet strengths (2.5mg and 10mg), 'weekly' dosage regimen and unfamiliarity of primary care health providers about the overall treatment processes (7-13). It has been recognised that there is a need for more attention by health care providers on potential problems with methotrexate therapy at the hospital and in the community among arthritic population.

A study by Viktil et al (14) indicated that MTX is the most common drug among disease modifying anti-rheumatic drugs (DMARDs) in hospitals, and 30% of patients with rheumatic diseases used 'MTX and folic acid'; 20% of patients used 'MTX and non-steroidal anti-inflammatory drugs (NSAIDs)' and 18% used 'MTX and corticosteroids' combinations. Although a weekly dosage regimen of MTX therapy in RA is well established, there are still unknown factors about the treatment, mainly in the community (15).

It was shown that assessment of patient's health outcomes can also be undertaken in community pharmacy (16, 17) and pharmacists are indispensable in identifying drug therapy problems in patients by provision of pharmaceutical care services (18). However, the role of

community pharmacists at primary/secondary care interface in the management of RA has not been fully defined or exploited (19).

Therefore, aim of this study is to implement and evaluate patient monitoring processes within community in order to ensure continuity of care by involving community pharmacists in patients diagnosed with arthritic conditions who receive oral MTX therapy. And any influences of social deprivation were investigated.

## EXPERIMENTAL

The study was a short-term randomised controlled trial. The study population was selected within four Local Health Care Co-operatives (LHCCs), of those served by two rheumatology clinics in Glasgow, Scotland. These environments were characterised in terms of Carstairs deprivation category (20) based on postcodes, practice population, number of GPs and community pharmacies located within their boundaries.

The patients were recruited both in the community pharmacies and at the hospital outpatient clinics during the period of December 2001-May 2002. They were considered "eligible" if they; aged over 16 years, able to read and understand the English language, diagnosed with RA or psoriatic arthritis, currently receiving oral methotrexate therapy, residing in the identified LHCC environments. During the recruitment, the patients were given sufficient time to read the study information leaflets and their informed consent was sought only if their nominated pharmacist had already agreed to participate. The patients were allocated in the control or the study group according to the results of the randomisation of their community pharmacy that they had nominated. They were also asked to attend the same community pharmacy during the study period.

The unit of randomisation was the community pharmacists nominated by the patients who agreed to participate. Sampling was stratified to ensure similar numbers of community pharmacies in postcode sectors identified as 'deprived' (Carstairs Category 4,5,6 and 7) compared with sectors identified as 'non-deprived' (Carstairs Category 1,2 and 3). The community pharmacies were considered eligible if they were nominated by a patient who agreed to take part in the study. They were asked to sign a written agreement to participate and enter into the randomisation. Community pharmacists in participating LHCCs were randomly assigned to the study group. The education and training on methotrexate therapy and management of RA was conducted by the members of the project team before the study was initiated and this was accredited by the Scottish Centre for Post Qualification Pharmaceutical Education (SCPPE). The study group pharmacies were intended to receive an MTX care plan issued by the rheumatology specialist, which is designed to enable the pharmacist to support the GP in the patient monitoring role. The participated community pharmacists were introduced to newly designed rheumatology care plan, shared care monitoring protocol and MTX monitoring card.

The community pharmacists were also asked to provide information about themselves and their dispensed MTX prescriptions (dose, tablet strength, approximate time spent with patient). Those data were collected and manipulated in an anonymised form. The participating community pharmacists received an *ex gratia* payment for their involvement in the study by the Primary Care NHS Trust.

The intervention involved the study group pharmacists were being issued a copy of the care plan for MTX monitoring which were designed by the researcher and academic collaborators, and were based on studies that have previously been undertaken. The care plan includes contact details of the nominated pharmacists, information regarding patient's relevant medical history (rheumatological or other co-morbidities), previous DMARDs therapy and reason for discontinuation, routine laboratory results, prescribed medications (date for start and discontinuation of therapy) and complementary therapies, identified care issues on 'pain and symptom control', 'checking signs & symptoms of unwanted effects' and 'patient

comprehension and treatment continuity' and other relevant care issues that the pharmacist identified. Patient-specific monitoring requirements were initiated by the rheumatology specialist and conveyed to each patient's GP in the routine by letter from the hospital clinic. The care plan was drawn up by the researcher and checked by a clinical pharmacist, expanded if required, augmented and approved by the rheumatologist during consultation with the patient at the clinic. The care plans were issued to the community pharmacists, the GPs and patients themselves and were updated on the next hospital visit. When the patient might have new care issues which were added; the new care plan replaced the old one, therefore while patients on primary care settings until the next visit to the specialist, patient's potential drug-therapy problems regarding MTX therapy are examined by pharmacist in advanced and potential unwanted effects are prevented where appropriate.

All patients received a new MTX monitoring card and the patients' GPs received a letter from the specialists explaining the study and they were also provided with a copy of the shared care monitoring protocol and the care plans where appropriate during the study.

The study was approved by each related primary and secondary care Ethics Committees in 2001. All data were collected by the research pharmacist, anonymised and stored in computer, then analysed by using SPSS for Windows version-9 and Access version 97. The results were evaluated between data collected at baseline and the 6 months after.

This study was a part of a research which aimed to explore 'the patient's desire for information and their beliefs and attitudes towards MTX therapy' and part the results were previously reported elsewhere (21). Therefore, a sample size calculation for the total project was based on the questionnaire results that have been previously reported by the original authors of two previously validated questionnaire instruments for discriminating differences in patients' attitudes to their medicines (22, 23). A total sample size of 88-112 was calculated as the total number of patients required, demonstrating, with 80% power, the following changes in the outcome measures;

- *Intrinsic Desire for Information (IDI)*: 50% of patients recording  $\leq 30$  on the IDI scale (anticipated in the pre test) reducing to 25% (at the post test). (n=112)
- *Beliefs About Medicines - NECESSITY*: 34% of patients recording  $\leq 18$  on the specific 'NECESSITY' scale (anticipated in the pre test) reducing to 10% (at the post test). (n=88)
- *Beliefs About Medicines - CONCERNS*: 33% of patients recording  $> 16$  on the specific 'CONCERNS' scale (anticipated in the pre test) reducing to 10% (at the post test). (n=94)

## RESULTS

Thirty pharmacies were nominated by the patients during the recruitment process, of those 13 were allocated in the 'study' and 17 in the 'control' group. However, only 23 out of 30 (76.6%) pharmacies provided information about themselves and their demographics were summarised in Table 1.

**Table 1.** Characteristics of respondents to the questionnaire for 23 out of 30 participating pharmacies in the study

	<b>Study (n=12)</b>	<b>Control (n=11)</b>
Located in 'non-deprived' LHCC	4	5
Located in 'deprived' LHCC	8	6
Number of MTX patients on PMR;		
<i>≤ 2 patients</i>	7	5
<i>3 or 4 patients</i>	4	3
<i>5 or 6 patients</i>	1	3
Number of part-time pharmacists working >2days/week in the pharmacy;		
<i>One pharmacist</i>	9	10
<i>Two pharmacists</i>	3	1
Type of pharmacy:		
<i>Independent</i>	3	4
<i>Small chain</i>	5	3
<i>Large chain</i>	4	4
Location of pharmacy:		
<i>In health centre</i>	0	0
<i>Close to GP surgery</i>	8	7
<i>In shopping centre</i>	2	1
<i>High street shop</i>	1	3
Total number of pharmacists per pharmacy		
<i>One pharmacist</i>	12	10
<i>Two pharmacists</i>	0	1
Number of pharmacies with a pre-reg pharmacist;		
<i>No pre-reg pharmacist</i>	12	7
<i>One pre-reg pharmacist</i>	0	4
Number of other non-pharmacist staff;		
<i>≤3 staff</i>	7	5
<i>4-7 staff</i>	3	5
<i>&gt;7 staff</i>	-	1
Number of prescription items dispensed/week:		
<i>&lt;500</i>	0	0
<i>500-1000</i>	2	5
<i>1000-2000</i>	9	4
<i>&gt;2000</i>	1	2
<b>25 participating pharmacists in the study (in 23 pharmacies)</b>	<b>Study (n=14)</b>	<b>Control (n=11)</b>
<i>Mean age, years (SD)</i>	39.7 (11.4)	39.0 (9.4)
<i>Female (%)</i>	71.0	36.0
<i>Mean number of years on register (SD)</i>	15.8 (11.6)	14.8 (8.3)
<i>Mean number of recorded CPD hours (SD)</i>	22.3 (10.8)	22.5 (20.1)
<i>Mean number of recorded SCPPE hours (SD)</i>	8.8 (9.4)	10.2 (13.6)

LHCC: Local Health Care Co-operatives; PMR: Patient Medication Record; MTX: methotrexate; GP: General Practitioner; CPD: Continuing Professional Development; SCPPE: The Scottish Centre for Post Qualification Pharmaceutical Education

During the recruitment process, 59 patients responded to the questionnaire, of those 76% were female, 85% were diagnosed with RA, 13.3% with psoriatic arthritis and 1.7% with polyarthritis. Following the randomisation, 31 patients were in the control group and 28 patients were in the study group (Table 2). No statistically significant difference was found between the study and the control group patients in terms of diagnoses of other conditions (Chi-square tests,  $p>0.05$ ).

**Table 2.** Demographics of patients participating in the study (n=59).

	Study (n=28)	Control (n=31)	Total (n=59)
Mean age in years (SD)	60.7 (11.2)	59.5 (10.8)	60.1 (10.9)
Gender (female %)	75	77	76
Carstairs category;			
1, 2 and 3 ('non-deprived')	11	11	22
4, 5, 6 and 7 ('deprived')	17	20	37
Number of previous DMARD courses (number of patients);*			
<i>Sulphasalazine</i>	25 (22)	28 (27)	53 (49)
<i>Penicillamine</i>	12 (12)	11 (11)	23 (23)
<i>Gold</i>	17 (17)	19 (19)	36 (36)
<i>Azathioprine</i>	3 (3)	3 (3)	6 (6)
<i>Hydroxychloroquine</i>	9 (9)	9 (8)	18 (17)
<i>Chloroquine</i>	3 (3)	2 (2)	5 (5)
<i>Cyclosporin</i>	1 (1)	-	1 (1)
<i>Methotrexate</i>	1 (1)	2 (2)	3 (3)
<i>Prednisolone</i>	2 (2)	1 (1)	3 (3)

\*DMARD: Disease Modifying Anti-Rheumatic Drug

During the period of December 2001-December 2002, fifty two rheumatology care plans were issued by the hospital clinics for 28 'study' group patients where 500 care issues were identified. The identified care issues were categorised according to the classification of drug therapy problems (DTPs) proposed by Strand et al (24) and adapted by McAnaw (25) (Table 3 and Table 4).

**Table 3.** The distribution (%) of drug therapy problems (DTPs) and monitoring inquiries identified at the hospital clinics for the all patients.

Drug therapy problems	Potential	Actual
Medication needs	168 (33.9%)	4
Effectiveness	15 (3.0%)	-
Safety	142 (28.6%)	-
Compliance	171 (34.5%)	-
Total	496 (100%)	4

**Table 4.** The distribution of drug therapy problems (DTPs) identified at the hospital clinics for the 'non-deprived' (n=11) and the 'deprived' (n=17) patient population.

Category	Drug therapy problems (per patient)			p value*
	Non-deprived (n=11)	Deprived (n=17)	Total (n=28)	
Medication needs	85 (7.7)	87 (5.1)	172 (6.1)	0.089
Effectiveness	9 (0.8)	6 (0.4)	15 (0.5)	0.210
Safety	55 (5.0)	87 (5.1)	142 (5.1)	0.121
Compliance	72 (6.5)	99 (5.8)	171 (6.1)	0.496
Total	221	279	500	

\* Chi-square tests

The mean (SD; Median) number of issued care plans was 1.9 (0.65; 2.0) and the mean (SD; Median) number of care issues identified per patient was 17.8 (9.3; 17). One patient (the study group) dropped out of the study after having been issued one rheumatology care plan. There were no statistically significant differences found between non-deprived and deprived patient population in terms of drug therapy problems for medication needs, safety and compliance inquiries (Chi-square test,  $p > 0.05$ ); however, a statistically significant difference was found in terms of the monitoring of specific laboratory markers for the medication needs (Chi-square test,  $p = 0.003$ ) (Table 5).

**Table 5.** The distribution of monitoring inquiries identified at the hospital clinics for the 'non-deprived' (n=11) and the 'deprived' (n=17) population.

Monitoring inquiries	Drug therapy problems (%)		
	Non-deprived (n=11)	Deprived (n=17)	Total (n=28)
Medication needs	85 (38.5)	83 (30.2)	168 (33.9)
<i>Clinical</i>	65 (29.4)	77 (28.0)	142 (28.6)
<i>Laboratory*</i>	20 (9.0)	6 (2.2)	26 (5.3)
Effectiveness	9 (4.1)	6 (2.2)	15 (3.0)
<i>Clinical</i>	3 (1.4)	-	3 (0.6)
<i>Laboratory</i>	6 (2.7)	6 (2.2)	12 (2.4)
Safety	55 (24.9)	87 (31.6)	142 (28.6)
<i>Clinical</i>	26 (11.7)	34 (12.3)	60 (12.1)
<i>Laboratory</i>	29 (13.1)	53 (19.3)	82 (16.5)
Compliance	72 (32.6)	99 (36.0)	171 (34.5)
<i>Clinical</i>	30 (13.6)	40 (14.5)	70 (14.1)
<i>Laboratory</i>	42 (19.0)	59 (21.5)	101 (20.4)
<b>Total</b>	<b>221 (44.6%)</b>	<b>275 (55.4%)</b>	<b>496 (100%)</b>

\* Statistically significance difference at  $p < 0,05$  (Chi-square test,  $p = 0,003$ )

Thirty seven out of 59 (63%) patient data collection forms were returned by the pharmacists. The community pharmacists initiated one hundred and two queries for 10 'study' group patients and 15 'control' group patients, regarding their disease status and drug therapies. Ninety out of 102 (88%) queries were specified on the data collection forms; however, the remaining 12 (12%) queries were not specified, because the pharmacist did not see the patient at the time the prescription was presented. Among the indicated treatment issues/queries, 30 (33%)

were to verify that the patient does not have any problems or confirmed the patient was feeling well at the time of the visit. Of those, 18 (60%) and 12 (40%) were for the 'study' group and the 'control' group patients respectively (Table 6).

**Table 6.** Distribution of drug therapy problems (DTPs) identified as monitoring inquiries at the community pharmacy settings.

<b>Drug therapy problems</b>	<b>Study</b>	<b>Control</b>	<b>Total</b>
<i>Monitoring inquiries</i>	<b>(n=10 patients)</b>	<b>(n=15 patients)</b>	<b>(n=25 patients)</b>
Medication needs	7 (32%)	11 (28%)	18 (30%)
<i>Clinical</i>	3	8	11
<i>Laboratory</i>	4	3	7
Effectiveness	4 (18%)	3 (8)	7 (11%)
<i>Clinical</i>	1	2	3
<i>Laboratory</i>	3	1	4
Safety	8 (36%)	15 (38%)	23 (38%)
<i>Clinical</i>	6	8	14
<i>Laboratory</i>	2	7	9
Compliance	3 (14%)	10 (26%)	13 (21%)
<i>Clinical</i>	2	4	6
<i>Laboratory</i>	1	6	7
<b>Total*</b>	<b>22 (36%)</b>	<b>39 (64%)</b>	<b>61 (100%)</b>

\*Chi-square test,  $p=0.024$

The comparison between the frequency of the identified drug therapy problems in the hospital and in the community settings showed that no statistically significant difference was found regarding the medication needs and safety problems (Chi-square test,  $p>0.05$ ). However, there were significantly more drug therapy problems identified in the hospital clinics for the effectiveness and compliance problems (Chi-square test,  $p<0.05$ ). Therefore, regardless of a practice location of the pharmacists, they were able to identify drug therapy problems and to inform relevant health care providers when necessary.

Total of 247 methotrexate prescriptions were presented by 37 patients (15 patients from the study group and 22 from the control group). No statistically significant difference was found between the 'control and the 'study' group in terms of the number of prescriptions presented for methotrexate and for other medication (Chi-square test,  $p>0.05$ ). The results indicated that patients from the 'deprived' environment did not present more prescriptions than those from the 'non-deprived' environment (observed findings in the 'deprived' is 63% (expected 60%; Chi-square test,  $p>0.05$ ). However, in regards to the indicated dose of methotrexate, the proportion of prescriptions presented by patients for methotrexate at the dose of  $\geq 15\text{mg/week}$  was 18% in the 'deprived' group compared to 47.5% in the 'non-deprived' (Chi-square test,  $p<0.05$ ) population.

Among 247 visits to pharmacy, number of visit (per person) were 98 (5.8) in the study group and 149 (7.5) in the control group. The pharmacists indicated in one hundred and twenty six visits that the mean (SD; Median) time that they spent with patients on each was 2.6 (2.3; 2) minutes in order to dispense the prescription presented and/or to discuss any problems that the patient may have at the time of the visit to the pharmacy.

The community pharmacists also highlighted the potential medication errors on six occasions;

- the dose of methotrexate had been changed by the hospital but was not changed on the prescription by the GP (2 occasions).



- the dose of methotrexate on the GP prescription was twice as high as it was supposed to be (1 occasion)
- the dose of methotrexate indicated 'as directed' on the prescription (1 occasion)
- the dose of methotrexate 10mg was not specified on the prescription (1 occasion)
- diclofenac was ordered instead of celecoxib which the patient was taking for a while (1 occasion)

## DISCUSSION

The purpose of reporting pharmaceutical care activities by the categorisation system was to reduce ambiguity and to produce more specific and focused themes for care issues. The care issues can be described as the 'drug therapy problems' or as the 'activities that must be performed'. It has been suggested that reducing the *actual* drug therapy problems may indicate better provision of pharmaceutical care, therefore allows increased quality of care. Moreover, reporting the 'actual drug therapy problems' per patient will help to identify the exact prevalence of drug therapy problems (25).

The drug therapy problems identified in the hospitals were mostly 'potential' problems where the patient may experience reduced quality of care if preventative action is not taken in near future. The most common problems identified in the hospitals were patient compliance, which was followed by the 'medication needs', 'safety' and 'effectiveness' drug therapy problems. The patients from the different socio-economic environments did present similar patterns for the drug therapy problems however, there were slightly more drug therapy problems identified for the patients in the 'deprived' environment (279 for the 'deprived' 16.4 per patient vs 221 for the 'non-deprived' 20.1 per patient) which may indicate the special group of patients who need additional contributions from the health care professionals.

On the other hand, the drug therapy problems that were identified in the community indicated that the most common problem are the 'safety', followed by the 'medication needs', 'compliance' and the 'effectiveness' categories of drug therapy problems. It was clear that the community pharmacists were apprehensive about the safety of drug therapy of their patients, which also emphasised a potential role of the pharmacists in the monitoring process. In comparison to the study results of Rao et al (18), the main drug therapy problems for the arthritic population were identified as 'needs of additional therapy' and 'dosage too low' which might reflect the results of 'medication needs' and treatment 'effectiveness' in this study. Similar to the results of Ernst et al. (26), 'needs of additional drug therapy' was the most common problem among patients at the community settings which was followed by 'adverse drug reactions', 'inappropriate compliance' and 'dose too low' which also corresponds with the results of this study.

The community pharmacists managed to identify a possibility of medication errors with methotrexate therapy and they took an action before those errors resulted in serious consequences. Therefore, pharmacists highlighted their impact on the maintenance of the safety of drug therapy for the patients.

The results indicated that the patients in the control group presented more prescriptions compared to the patients in the study group (60% vs 40%, respectively), which might reflect a demand of a patient support from health care providers; but the patterns of methotrexate prescriptions presented at the pharmacy were similar in the two groups. The proportion of patients who received methotrexate at the dose of  $\geq 15$ mg/week was 43% in the study group whereas it was 21% in the control group. Even though the patients in the study group are receiving a higher dose regimen for the methotrexate treatment, the proportion of identified drug therapy problems was similar for both groups, which might indicate the potential contributions of the proposed model of care in this study.

Although it appeared that the patients from the 'deprived' group presented more prescriptions compared to the patients in the 'non-deprived' group, the patterns of methotrexate prescriptions presented at the pharmacy was similar in the two groups of patients. However, the interesting finding was that the proportion of patients who received methotrexate at the dose of  $\geq 15\text{mg/week}$  was higher in the 'non-deprived' group (47.5%) compared to the 'deprived' group (18%). This figure has raised the question of why patients in the relatively deprived areas were less likely to be put on the higher dose methotrexate regimens. Therefore it might be considered that there is a potential effect of socio-economic environment on the treatment process. This question deserves further study.

There might be a lack of beliefs existed among the rheumatology specialists in pharmacists' contribution in monitoring process of the patients with RA. The results from the study highlighted the potential opportunities for community pharmacists to be involved in the provision and process of a seamless care for the patients. Therefore, further investigation of the role of the community pharmacists in disease management which is undertaken among community pharmacist would or might demonstrate the benefits of the new model of shared care.

The participating pharmacists also acknowledged the advantages of receiving information about their patients' disease status and medications. They ascertained that they could extend their roles beyond the dispensary by the provision of supportive information and knowledge about the chronic disease management and through reciprocal collaboration with other health care providers. It has been confirmed through the patient data collection forms that were gathered from community pharmacy that the pharmacists are able to identify the patients' needs about their medicines and their problems regarding methotrexate therapy in the assistance of the shared care protocol provided. They are also in a position to discuss any problems about the prescriptions with the GPs or any other health care providers.

The study also has limitations. Randomisation was based on the pharmacies; otherwise patients in a study and control group would be attending the same community pharmacy, thus pharmacist would have faced unethical circumstances on whether providing monitoring plan for a patient or not. In order to overcome this bias, initially pharmacies were identified from the LHCCs' list and their consents were gathered, then the patients were asked to participate and nominate a pharmacy that they willing to attend.

Outcome variables were considered as the scores of the questionnaire and the frequency and the characteristics of drug-therapy problems that were identified by the pharmacist either in the community or hospitals. A sample size calculation indicated that a total of 88-112 patients should be included in order to detect differences between the groups. Even though one month recruitment period was initially planned, recruitment of 58 eligible patients took longer than an expected (approximately 6 months). The study aimed to allow for a 6 months follow up period for each patient, therefore the study was expanded until the last patient was followed up for 6 months which resulted in a small sample size and relatively shorter period of time for intervention and assessment. There was also a lack of control over the patients as well as contributions from the GPs. It was assumed that those drawbacks can be overcome for similar projects in the future by modification of certain parameters.

## **CONCLUSION**

In conclusion, the pharmacists are in a position to support patient care through counselling on medications and potential side effects, giving advice on self-management activities and monitoring of the patient groups who potentially need extra vigilance in the community settings. Improved outcomes in the management of rheumatoid arthritis can be achieved by close-control and monitoring of the patients. An engagement of patients with self-management activities would create opportunities for different level of involvement. There is a need for a

multidisciplinary team with a structured pro-active approach to disease management in rheumatoid arthritis.

The proposed pharmaceutical care model is shown to be feasible to meet the health care professionals' as well as the patients' needs which builds a link between the secondary and the primary care, particularly with community pharmacies.

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Received: 26.12.2012  
Accepted: 21.03.2013