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# Evaluation of the Impact of A Pharmaceutical Care Service Offered to Rheumatoid Arthritis Patients Within an Ambulatory Setting

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## ABSTRACT

The objectives of the study were to evaluate the impact of a newly developed pharmaceutical care services directed to rheumatoid arthritis patients attending an out-patient setting. A total of 88 patients participated in the study and were randomly divided into two equal groups, Group A and Group B. The study was carried out over three phases. In phase 1 (time 0), Group A patients were assessed and offered a pharmaceutical care session. Group B patients were assessed but no pharmaceutical care session was delivered. At phase 2 (4-6 months), group A patients were re-assessed (first assessment post pharmaceutical care plan). Group B patients were re-assessed a second time (second baseline assessment) and a pharmaceutical care session was offered to Group B patients. At phase 3 (time 10-11 months) both groups were re-assessed a third time. The Health Assessment Questionnaire and the Short Form-36 were used as outcome measures during each assessment. There were statistically significant differences ($p<0.05$) in all the 8 domains of the SF-36 between Phase 1 and 3 for both groups. For the Health Assessment Questionnaire, a statistical improvement in the daily activities was identified after the pharmaceutical care intervention for both groups (Phase 2 for Group A and phase 3 for Group B). The newly developed individualised pharmaceutical care service provided by the pharmacist led to an improved quality of life as measured by the health related quality of life questionnaires.

**Keywords:** pharmaceutical care, quality of life, rheumatoid arthritis, drug therapy problems, pharmacist contribution

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## INTRODUCTION

Rheumatoid arthritis affects approximately 0.3-1% of the population in developing countries[1-2]. It is a chronic autoimmune systemic inflammatory disorder of the joints characterized by potentially deforming symmetrical polyarthritis and accompanied by extra-articular features associated with direct and indirect cost related to work disability and loss of function[3]. Management of rheumatoid arthritis has over the years moved away from the typical pyramidal approach of using simple analgesia as first line pharmacological therapy stepping up therapy with disease modifying anti-rheumatic drugs at a later stage. Radiological evidence that erosions occur within the first two years of the condition led to physicians aiming for early treatment and treatment to target[4-5].

The pharmaceutical research and development of biological agents, such as tumour necrosis factor inhibitors, monoclonal antibodies and interleukin inhibitors, has led to the inversion of the pyramidal approach. The current management of rheumatoid arthritis therefore focuses on early aggressive treatment using disease modifying agents and biological agents early on to slow the disease progression if not to stop disease progression and afford remission[6]. Patient safety is a major feature in management decisions. The increasing effectiveness of drug therapy in current disease management is brought about by new classes of agents acting at a fundamental inflammatory level ('biologicals') and by earlier more aggressive treatment to markedly reduce the rate of progression if not stop disease progression in certain instances. Treatment must be individualised and patients helped to be actively involved in their own management and monitoring for effectiveness and safety. This could be achieved through a pharmaceutical care service. The context above raises questions about how to achieve optimal care within a multidisciplinary setting in which specialist pharmacists are providing new services requiring networking arrangements to underpin the quality of care as the patient moves between clinical settings, home, hospital, and clinic.

In Malta the chronic disease management of patients with rheumatoid arthritis is delivered via a specialist physician multidisciplinary team that has included a pharmacist since 2003. Newly diagnosed patients are referred to the consultants' rheumatology clinic via general practitioners or hospital specialists in other disciplines. The multidisciplinary rheumatology team also includes specialist nurse, occupational therapist, physiotherapist and podologist. The pharmacist input has been developing over the past seven years via inpatient services. The aim of this study

was to evaluate the impact of a newly developed pharmaceutical care service within a multidiscplinary rheumatology outpatients service.

## MATERIALS AND METHODS

### Patient recruitment

The study was approved by the Research Ethics Committee. Rheumatoid arthritis adult patients who were on methotrexate regularly attending the Rheumatology Out-Patient Clinic were eligible to participate in the study. patients were excluded if they were unable to read or understand English or Maltese, suffered from a mental health problem, or refused to give their written informed consent.

A total of 96 patients were randomly assigned to two equal groups (A and B) and followed up in parallel for 11 months. The patients completed health related quality of life questionnaires at baseline and at each clinical assessment visit. Pharmaceutical clinical assessments were carried out at outpatient appointments fixed twice between 4-8 months and between 10-11 months during the 11 month study. Pharmaceutical care assessment involving the establishment of a care plan was conducted at baseline entry to the study (time zero; Group A) or at the 4-8 month visit (Group B). Study group A therefore provided a pre-test baseline health related quality of life measurement followed by two post-test measurements. Study group B received a pharmaceutical care assessment and care plan after two pre-test health related quality of life measurements at zero and 4-8 months and the group provided a post-test measurement at 2-7 months (at the 10-11 month point in the 11 month study). The study design allowed for each of the group to act as control within itself as well as to provide a comparison of parallel active and control phases.

Prior to patient contact the pharmacist-researcher developed an information leaflet on methotrexate therapy in English and Maltese. The compiled leaflet which was validated by an expert panel consisting of the rheumatology clinic medical team was designed to be easily understood by patients and their careers.

### The pharmaceutical care consultation

A pharmaceutical care consultation led to the identification of pharmaceutical care issues. The session focused on determining whether all patient's drug therapy was the most appropriate, safe, effective and conveniently available for the patient During the pharmaceutical care consultation, the clinical pharmacist identified pharmaceutical care issues. These were then classified as drug therapy problems according to the Strand et al classification[7] and further subdivided into actual and potential drug therapy problems according to a categorization system developed by

colleagues[8-9] at the Strathclyde Institute of Pharmacy and Biomedical Sciences, at the University of Strathclyde . Actual drug therapy problems are problems which are present and hence need to be resolved immediately whereas potential drug therapy problems are problems which are not yet present but which might arise in future and which could be avoided if the correct action is taken[10] The category non-drug therapy problems was added to the list to accommodate pharmaceutical care issues which were not directly related to drug therapy but relied on patient's perception, information on treatment or the need of other help from other health care professionals. Actions (checks or changes) needed to resolve each care issue problem were documented in the care plan within the patient's medical file.

All patients were counseled on methotrexate therapy and given a copy of the developed leaflet. The pharmaceutical care session was documented on a pharmaceutical care form developed for the purpose of the study. A referral form was also designed for the purpose of the study. The referral form documented in point form the type of drug therapy problem identified during the session and action taken or suggested to resolve the problem. The referral form was used as an easy way of documenting and retrieving information for use by the medical prescriber.

**Statistical analysis**

The evaluation of the pharmaceutical care session was studied using the Health Assessment questionnaire and the SF36 questionnaire. Data was analyzed using SPSS version 7 and the Wilcoxon test was undertaken.

## RESULTS AND DISCUSSION

A total of 88 patients were recruited in the study since eight patients failed to attend for their first appointment. The mean (SD) age of the patients was 60.8 (11.6) years. The mean number of years on methotrexate was 10 years. Both groups were found to be statistically similar. Approximately 84% (n=74) of the patients stated that the information leaflet was found to be useful and 89% (n=78) stated that the leaflet was self-explanatory. Comments were received from 74% (n=65) of the patients, 85% (n=55) of whom stated that the leaflet was a good initiative and 15% (n=10) of whom stated that they would appreciate similar leaflets on other drugs, the role of physiotherapy and the role of occupational therapy in rheumatoid arthritis (Figure 1).

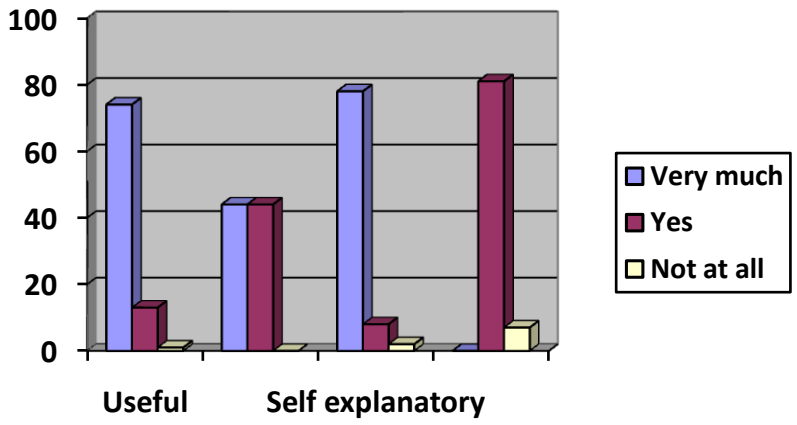


**Figure 1. Evaluation of the information leaflet**

A total of 106 pharmaceutical care issues were identified for the 88 patients giving a mean of 1.2 per patient where 72% (n=76) were actual drug therapy problems requiring alteration of the therapeutic plan and 28% (n=30) were potential drug therapy problems requiring resolution by reference back to the therapeutic plan. This data contrasts to similar studies carried out in cancer care patients[11] and in rheumatoid arthritis patients[10] in the United Kingdom where the majority of pharmaceutical care issues were classified as checks This difference could be explained because in this study the pharmacist researcher was easily accessible being present at the clinic with the medical team hence being directly involved in discussions regarding drug therapy to be prescribed. Such discussions resulted in a higher number of changes rather than checks. Another reason for the low number of checks could be well due to the role of the specialist nurse at the clinic who carried out monitoring of the patients including checking of routine laboratory tests to identify potential problems, as well as assessed the general well being of the patients as influenced by rheumatoid arthritis.

The results of the health assessment questionnaire showed an improvement in the daily activities associated with an intervention compared with baseline with overall score improvements (Table 1). The results of the SF 36 showed that overall there was significant improvement in all the 8 domains of the SF36 after the intervention (Table 2). For Group A patients there was a statistically significant improvement at time 4 months (Phase 2) following the pharmaceutical session for six of the eight domains of quality of life namely role physical, bodily pain, social function, vitality, general health and mental health. This improvement in the quality of life effected by these six domains further improved over time at Phase 3. In contrast the domain physical function and role emotion showed a statistically significant improvement at Phase 3

indicating a longer term. Group B patients showed no difference and no improvement in all the eight domains of the SF36 between Phase 1 and Phase 2 prior to any pharmaceutical sessions. There was a statistically significant improvement in all the eight domains of the SF36 between Phase 2 and Phase 3 following a pharmaceutical contribution by the pharmacist.

**Table 1. Statistical analysis for Health Assessment Questionnaire**

| **Positive and negative mean rank score (p value)** | | | |
|---|---|---|---|
| Group A | Phase 1 – Phase 2 | Phase 2- Phase 3 | Phase 1- Phase 3 |
| | 8.8-10.2 (0.767) | 11.3-11.0 (0.001)* | 9.3-11.2 (0.001)* |
| Group B | Phase 1 – Phase 2 | Phase 2- Phase 3 | |
| | 1.0-3.0 (0.141) | 8.5-11.6 (<0.001)* | |

**p value from Wilcoxon signed rank test (p>0.05)

**Table 2 Statistical analysis for the SF36, p value**

| **Group A** | **Phase 1 – Phase 2** | **Phase 2- Phase 3** | **Phase 1- Phase 3** |
|---|---|---|---|
| *Domain* | | | |
| Physical Function | 0.301 | <0.001 | <0.001 |
| Role Physical | 0.03 | 0.00 | 0.001 |
| Role Emotion | 0.07 | 0.157 | 0.019 |
| Bodily Pain | <0.001 | <0.001 | <0.001 |
| Social Function | 0.004 | 0.001 | <0.001 |
| Vitality | 0.007 | <0.001 | <0.001 |
| General Health | <0.001 | <0.001 | <0.001 |
| Mental Health | <0.001 | <0.001 | <0.001 |

***p value from Wilcoxon signed rank test (p>0.05)**

This study attempted to evaluate the impact of the provision of professional pharmacy services within a pharmaceutical care model in an out-patient setting. Two health related questionnaires were chosen as a measuring tool to assess the impact of the pharmacist's contribution on the quality of life of rheumatoid arthritis patients. The decision to adopt the Health Assessment Questionnaire and the SF36 was based on literature review which demonstrated the tools' validity and reliability.[10,12-17] The tools also proved practical and applicable within the local set up making it feasible to incorporate the use of these tools within a framework of service provision.

For group A patients the results indicate that there was an improvement in the quality of life of the patients reflected by a decrease in the health assessment questionnaire score which occurred following the pharmacist's intervention during the pharmaceutical intervention at Phase 1. This improvement in the quality of life of the patients increased over time (Phase 3) meaning that the impact of the pharmacist's intervention through individualized pharmaceutical care showed a further improvement in the quality of life of patients on a longer term.

Group B patients registered a statistically significant improvement in their health assessment questionnaire score following a pharmaceutical care session which mirrors the fact that pharmacist intervention improves quality of life.

From the results of the Short Form 36 analysis, the impact of the pharmacist's contribution after 11 months resulted in an improvement of quality of life. However for some domains namely physical function and role emotion this impact may take longer to result in an improvement. The results from Group B patients mirrored those of Group A.

## CONCLUSION

Pharmaceutical care services offered within a rheumatology out-patient clinic multidisciplinary team can help to improve the patients' quality of life. This study has confirmed the positive impact of the pharmacist intervention within this multidisciplinary team on the patients' quality attending the rheumatology out-patient clinic. This has been confirmed in other studies in other areas such as in the management of cardiovascular patients and diabetes patients[18-23]. Processes to identify patients who would require pharmaceutical care services within the setting may need to be identified in the scenario that the pharmaceutical care services are offered to all patients attending the clinic. Research to standardize the pharmaceutical care services is now being undertaken to ensure a harmonized evidence based quality service.

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