Medication management and education of osteoarthritis patients: evaluation of a role for community pharmacists

2003-013

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The University of Sydney
May 2006
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Acknowledgements
This work was funded by the Commonwealth Department of Health and Ageing as part of the Third Community Pharmacy Agreement.

We gratefully acknowledge the contributions of pharmacist participants.

We have consulted the following persons and acknowledge their advice and support:
Mr Philip Hopkin Chief Executive Officer of Arthritis Foundation in NSW;
Ms Lily Chong, formerly HMR Manager from the PSA (NSW Branch);
Ms Carlene Smith, MMR facilitator from the Pharmacy Guild (NSW);
Professor Nicholas Bellamy, Director of Centre of National Research on Disability and Rehabilitation Medicine (CONROD), The University of Queensland;
Division of General Practice MMR facilitators in Central Sydney, Western Sydney and Bankstown.

Special thanks go to Professor Bellamy for allowing us to use the WOMAC™ and AUSCAN™ Indices in this research.

\textsuperscript{1} We wish to thank Dr Abilio de Almeida Neto for his assistance in preparing this report.
Executive Summary and Recommendations

Introduction

Traditionally, the role of the pharmacist has been restricted to the supply of medicines with the training of pharmacists focusing on a product-oriented role with little clinical responsibility. The reliable measurement of osteoarthritis status followed by appropriate counseling provides the pharmacy profession with the opportunity to introduce a new professional service that will be valued by the community, government and the pharmacy profession.

The dramatic increase of life expectancy in Australia coupled with a decrease in fertility rates indicate that the proportion of younger people will decrease, while the proportion of older people will continue to rise (1). As the prevalence of all major forms of arthritis increases with age, the disease burden caused by osteoarthritis will become more prominent in Australian society especially because osteoarthritis typically cause disability for long periods of time (1).

This change in osteoarthritis (OA) prevalence due to changes in population demographics has clear implications for the pharmacy profession. The number of people with osteoarthritis will increase leading to greater demand for community-based health services. The current study attempted to be proactive in filling predicted health gaps in the management of osteoarthritis by developing, implementing and evaluating practical methods for the delivery of a specialised pharmacy service for people living with osteoarthritis.

Aims of the Study

The overall aim of this study was to develop, implement and evaluate a practical method for the delivery of a specialised pharmacy service for patients with osteoarthritis (OA). The study also aimed to profile patients who frequent community pharmacy using a variety of self-report questionnaires (e.g. WOMAC Index™, AUSCAN Osteoarthritis
Hand Index™, Dartmouth COOP Chart System) and to assess the feasibility of pharmacists using these questionnaires to monitor OA patients.

**The specific objectives were to:**
1. improve clinical (eg physical functioning, reduction of perceived pain) and humanistic outcomes (eg quality of life) for patients with OA.
2. demonstrate a role for the pharmacist in optimising the management of OA through evidence-based and quality use of medicines.
3. establish pharmacists as integral members of the primary health care team (including GPs, specialists and physiotherapists) in the seamless management of patients with OA.
4. establish a cost-effective and transportable model for the multidisciplinary management of OA in the primary care setting.

Participating pharmacists were required to monitor osteoarthritis patients by carrying out assessments of osteoarthritis status, including pain, stiffness and function using the WOMAC™ and AUSCAN Osteoarthritis Hand Index™ instruments, and also assessments of quality of life, using the COOP instrument. Participants were also required to assess satisfaction with OA services using an instrument developed by the researchers. This procedure would provide pharmacists with the opportunity to counsel patients on the management of OA, in addition to collecting reliable and valid clinical measurement of OA status. In addition, greater understanding of the patient’s OA status would place the pharmacist in a better position to liaise more closely with other healthcare professionals and to better manage the patient’s pharmacotherapy for OA.

**Study Design**
A pre-test/post-test purposive sampling design was adopted. Seventy-two OA patients were recruited from purposefully selected pharmacies which were assigned to either intervention or control group.
**Intervention Group:** Patients in the intervention group received pain and quality of life assessment using standardised and validated measures such as the WOMAC™ or AUSCAN Osteoarthritis Hand Index™ (disease specific instruments for osteoarthritis)\(^3\), and the COOP instruments (general measures of quality of life (QOL). Pain and QOL assessments were conducted by the community pharmacist every two months for 10 months, along with counselling on the use of OA medications and the provision of information on non-pharmacological approaches to OA. At the final visit (10 months after study inception), the Patient Satisfaction Questionnaire was administered to all subjects in this group.

**Control Group:** this was a control group comprised of patients who did not receive regular pain and quality of life assessment throughout the study period. Usual care was provided by the pharmacist over the study period (10-month period). Pain (WOMAC™ and/or AUSCAN Osteoarthritis Hand Index), plus the COOP were only measured at baseline and at the final visit (10 months after study inception). The Patient Satisfaction Questionnaire was administered at the final visit.

**Results**
A total of 23 pharmacists from 16 pharmacies were trained to provide the intervention. One of the pharmacies declined to participate in the study following training since the pharmacists had too many other commitments. A further 6 pharmacies whose pharmacists received training formally withdrew from the study alleging time constraints leaving a total of 9 pharmacies in the study. Pharmacists enrolled in the study were paid a professional fee for each patient recruited to the study and were supported by researchers throughout the study period. Pharmacists found it challenging to recruit patients to this study. Pharmacist participants were asked about the lower than expected recruitment rate with time constraints being mentioned as a barrier. In addition the proportion of patients who completed the study in the Intervention Group was very low. This smaller than expected sample size is likely to have rendered the study underpowered to test the above hypotheses in a conclusive way.
Overall, significant results were not found for most comparisons between Baseline and Post-Intervention visits and across time. However a few comparisons reached statistical significance:

- Patients in the Control Group reported significant deterioration in mobility from Baseline to Post-Intervention whereas patients in the Intervention Group did not as measured by the Physical Function Subscale of the AUSCAN Osteoarthritis Hand Index™.

- Patients in the Control Group reported significant deterioration in physical activity from Baseline to Post-Intervention as measured by the Physical Fitness Subscale of the Dartmouth Functional Assessment Charts whereas patients in the Intervention Group did not.

- Intervention Group patients’ measurements of stiffness significantly improved over the course of the study as measured by the WOMAC™ Stiffness Subscale.

- Patients in the Intervention group reported greater change (improvement) in COOP Functional Chart pain scores and greater change (improvement) in COOP Functional Chart social support from Baseline to Post-Intervention compared to Control Group patients.

- Intervention Group patients rated that the pharmacist’s hours were good for them and that they could speak to the pharmacist whenever it is convenient for them at a higher rate than did patients in the Control Group.

Satisfaction measurements demonstrate that patients in the study responded favourably to the monitoring of osteoarthritis by pharmacists providing some support for the feasibility of using assessment instruments in the provision of pharmacy-based OA services.
Discussion

The current study represented the first attempt in Australia, and perhaps globally, to develop, implement and evaluate a method for the delivery of specialized pharmacy service for patients living with osteoarthritis. Although time constraints, from a pharmacists’ perspective, proved to be a barrier to the implementation of the OA service and a smaller than expected sample size limited researchers’ ability to evaluate the service, our results are useful in guiding future pharmacy practice research in the OA area.

The fact that recruitment was a challenge and that many pharmacists in the Intervention Group either withdrew from the study alleging time constraints or failed to complete the study, could have indicated that the OA service in its current format, may not have been entirely suitable for current practice environment. Pharmacists perceived the service as being too time consuming and were not able to integrate it to their daily professional activities. This assumption is backed by anecdotal accounts from pharmacists who completed the study that they had made their graduate pharmacist in charge of collecting the data. That is, the service was not conducted as part of their routine daily activities, but as an extra professional duty. The successful implementation of sustainable cognitive services in community pharmacy requires that pharmacists develop mechanisms to allow them to integrate new professional services into their routine professional practice.

Future study may need to place greater emphasis on inherent time-constraints of community pharmacies in the current practice environment, adapting the current service to be less time-consuming. Reduction in the length and number of questionnaires could enhance pharmacists’ motivation to deliver OA services. However, this potentially would comprise the utility of having more routine evaluations.

The fact that pharmacists were not required to assess or to interpret the results from the questionnaires, i.e. questionnaires were delivered to patients in a mechanistic manner
for research purpose only, may have had a negative impact on their motivation to incorporate it into their daily professional practice. On the other hand, assessment and interpretation of results may have added to the time spent with the patients rendering the service even less suitable for current community pharmacy practice environment.

It is noted that the significant results observed in this study were all consistent with the assumption that community pharmacists are able to impact on clinical outcomes for patients with OA by conducting pain assessment and counseling on regular basis. However, some statistically significant results were likely to be observed simply due to the sheer number of comparisons made with experimental demand characteristics likely to have influenced results in the expected direction. Also, these results were derived from a relatively low number of patients, making it difficult to interpret their significance.

Conclusion
The vast majority of participants reported to highly value the pharmacist’s advice on how to take their OA medicines and believed that the pharmacist treated them with genuine interest. This acceptance of OA services, places community pharmacists at a prime position for optimising the management of OA through evidence-based and quality use of medicines. However, barriers associated with the integration of the OA service into routine professional practice of community pharmacists may need to be addressed before such services can be successfully implemented in community pharmacy.

Recommendations

1. It is recommended that further feasibility studies of the role of the pharmacist in on-going OA management be conducted, in which the use of the standardized instruments are incorporated into routine professional pharmacy services. Such studies will be required before developing a model suitable for dissemination to the broader community pharmacy profession.

2. Osteoarthritis services developed for community pharmacists should place greater emphasis on inherent time-constraints of community pharmacies in the current practice environment, and focus on the integration of professional
activities into routine pharmacy practice.

3. In light of the positive satisfaction responses to the OA service from patients who completed the study, it is recommended that the development of an OA service that can be more easily incorporated into the professional services provided by pharmacists, be pursued in the future.

4. Unlike the current study which assessed satisfaction from a patient’s perspective only, satisfaction with OA service also should be assessed from a pharmacist’s perspective in future attempts to develop and implement an OA service.

5. Based on patients’ response about willingness to pay for OA services, once the methodology presented in the current study is refined to better suit the current community pharmacy environment, pharmacists should be encouraged to introduce a fee-for-service for OA services.
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INTRODUCTION
INTRODUCTION

Background
Arthritis is a major cause chronic pain in Australia (2) being the third most common cause of disability and costing the community $9 billion per annum (2).

In 2000, 3.1 million Australians were affected by arthritis (2). Evidence suggests that there are a large number suffering from arthritis that is undiagnosed and untreated (2). Over 80,000 years of healthy life are lost to arthritis each year, which places it ahead of both diabetes and asthma in terms of disease burden (2). Forty per cent of arthritis sufferers are over 65 years of age and as the Australian population ages the burden of arthritis will grow (2). Australia has followed other countries leads by listing arthritis as a National Health Priority in 2002.

Osteoarthritis (OA) is the most common form of arthritis. Sixty per cent of those suffering from osteoarthritis are female and the majority are of working age (15-64 years) (2).

OA is a disorder of the synovial joints. It is characterised by progressive abnormalities in the articular cartilage, often caused by joint trauma, aging or failure of repair mechanisms of the joints (3, 4). The causes of OA is unknown but a number of risk factors have been identified including obesity, age, low socio-economic status, hereditary factors, nutritional factors (low dietary intake of vitamins C, D and E) and chronic stress on joints or joint trauma (4). The symptoms of OA include pain, stiffness, tenderness in the joints and surrounding muscles and ligaments. These symptoms can also lead to anxiety, a decrease in motor skills and deformities (5). OA most commonly affects the synovial joints of the hands, knees, hips and spine (6).

Pain is the principal symptom of OA and is the major reason why patients seek medical attention (3, 7). Pain is also a major determinant of loss of function and disability associated with OA (3). In clinical practice pain is not always assessed and this may lead to poor health outcomes (7). In chronic diseases such as OA, quantitative data on
functional status and/or pain is essential in the recording of patient outcomes and for patient care (7). A number of studies have shown that there is a low association between a patient’s perception of pain and the physician’s assessment of pain (8, 9). This can lead to poor management of the patients’ condition and possibly undesirable adverse effects.

Standardised information on health status, pain and function can be obtained easily from self-reported questionnaires (7). Without patient questionnaire information, physicians may not identify or underestimate osteoarthritis, functional losses, pain and fatigue associated with the patients’ condition (7). Self-report questionnaires rely on the patient’s perception of pain and this may be influenced by a number of other factors (10) (11) (4). Studies have found that self-reported variables outperform the ‘usual’ clinical variables used in practice (11, 12). This is reinforced by the fact that these ‘usual’ clinical variables, such as laboratory results and a physical examination are not regularly collected (7). Patient questionnaires appear to be of value in all rheumatic diseases (7). They provide a better understanding of the patients’ health status and enable better monitoring of patient care than laboratory tests and other traditional medical sources (13) (5). Self-report questionnaires may be useful to screen for functional problems, monitor disease progression or therapeutic response, improve health professional-patient relationships, assess quality of care, and to compare outcomes between groups (5). A number of self-report questionnaires have been developed and successfully used in the area of osteoarthritis. Some of these questionnaires are discussed below.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC™)
The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC™) is a tri-dimensional, OA specific, self-administered health status measure (Appendix 1). It assesses patient relevant symptoms in the three areas of pain, stiffness and physical function of patients with OA of the hip or knee. It is relatively short in length, containing only 24 questions. The WOMAC™ gives additional detail on restriction of specific tasks and the ‘real life’ impact of OA pain and disability (14). In a recent review of the WOMAC™ Index, the reliability, validity and responsiveness of the instrument were demonstrated in a wide range of patient groups and interventions (15). The WOMAC™
Index is now a widely used condition specific instrument for the assessment of hip and knee osteoarthritis.

The development of the WOMAC™ Osteoarthritis Index was propelled by the need for international standards of clinical measurement in osteoarthritis. Before the development of the WOMAC™ Index, a variety of scales was used to assess severity of osteoarthritis of the hip and knee (6). Not only did the variables differ, but there was considerable variability in the scales and instruments used. In addition, most of the measures used in osteoarthritis research were observer-dependent, i.e., required a physician or allied health professional to make a judgement based on observed performance or clinical examination (6). The WOMAC™ Osteoarthritis Index focuses on three observer-independent, patient-relevant measures, i.e., pain, stiffness, and physical function.

The WOMAC™ Osteoarthritis Index is considered the gold standard for evaluating OA of the hip and knee. The WOMAC™ Index has now been translated into several different languages and has been requested for use by more than 300 researchers in more than 50 countries including Australia (6).

Previous study conducted by at the Faculty of Pharmacy, The University of Sydney, on the feasibility of pharmacists using the WOMAC™ Index to provide a service to monitor OA patients provided encouraging results. This study demonstrated that the WOMAC™ Index was easy for the pharmacists and patients to use and was not too time consuming and concluded that the WOMAC™ Index could be a valuable tool for use in community pharmacy (16).

**AUSCAN Osteoarthritis Hand Index™**

The AUSCAN Osteoarthritis Hand Index™ is a disease-specific health status measure for hand OA. Like the WOMAC™ Index, the development of the AUSCAN Osteoarthritis Hand Index™ arose from the lack of standardisation of clinical measurements of osteoarthritis of the hand joints. Prior to the development of the AUSCAN Osteoarthritis Hand Index™ not only did the variables used to assess OA of the hand joints differ, but
also there was considerable variability in the scales and instruments employed (17). The AUSCAN Osteoarthritis Hand Index™ also focuses on observer-independent, patient relevant measures, i.e., pain, stiffness, and physical function.

The items inventory of the AUSCAN Osteoarthritis Hand Index™ has been designed to capture the essential elements of pain, stiffness and physical disability in patients with osteoarthritis of the hand joints (17). The Index consists of 15 items, five items measure pain, 1 item measures stiffness and 9 items measure difficulties with daily activities. It exists as a Numerical Rating Scale (NRS) and a visual analogue scale (VAS) (10 cm horizontal). The NRS version gives the patient a choice of eleven responses on a Likert scale (from 0 to 10) within each of the 15 items. The pain dimension assesses the amount of hand pain at rest, when gripping, lifting, turning or squeezing objects. The stiffness dimension asks for stiffness after waking, during the last 48 hours. The physical dimension measures difficulties associated with common daily activities such as turning taps and a round doorknob or handle, doing up buttons, fastening jewellery, opening a new jar, carrying a full pot with one hand, peeling vegetables/fruit, picking up large, heavy objects and wringing out washcloths.

Two major validation studies of the AUSCAN Osteoarthritis Hand Index™ have been completed (12) and it has now been translated into over twenty different languages.

**Dartmouth COOP Functional Assessment Charts**

Functional health status is a measure of a patient’s overall biological, physical, emotional and social well-being and quality of life. Quality-of-life measurement tools can provide useful insight into quality of life in patients (18). They may be used to identify clinical issues and problems of importance to patients and to aid healthcare professionals in identifying individuals with special needs (18). Recognising the need for reliable and valid ways of assessing patient’s functional status in the clinical setting, the Dartmouth COOP Functional Assessment Charts were developed (Appendix 2).

The development of the COOP Chart System arose from the need for a practical measure of health status suitable for office practice. Although there are many validated
measures of health status which have been used in a research context, often they are
time consuming to administer and scoring is complex rendering them unsuitable for use
in the practice setting (19). The Dartmouth COOP Functional Assessment Charts are
quick and easy to administer. They utilise visual images to assess multiple domains.
The charts provides a brief, practical and valid method to assess the functional status of
adults and adolescents. Each chart consists of a title, a question referring to the status
of the patient over the past two to four weeks, and five response choices. Each
response is illustrated by a drawing that depicts a level of functioning or well-being along
a five point ordinal scale. In accordance with clinical convention, high scores (i.e.,
patient rating of 4 or 5) represent unfavourable levels of health (eg quality of life or social
support) on each respective chart. For example, Physical Chart responses range from 1
to 5 with a score of 5 representing major limitations. The COOP Chart System has been
extensively tested to evaluate its validity, reliability, and acceptability (20).

The COOP Chart System has also been successfully used in the pharmacy setting (21).
In a project aimed at establishing an appropriate mechanism for delivery of domiciliary
based medication review services for domiciliary patients the COOP Chart System was
used for measuring quality of life (21).

**Patient Satisfaction Questionnaire**
Patient satisfaction is considered a valuable measure of outcome of healthcare
processes (22). Satisfaction may have an important influence on various aspects of
patient’s behaviour, such as global consumption of healthcare resources, compliance
with treatment or steadiness of relationships with healthcare providers (22). Patient
satisfaction with the OA intervention service could be measured by using simple self-
completion questionnaires. Usually such questionnaires consist of items on various
themes related to satisfaction with the service being evaluated. They may contain Likert
type items that measure attitudes toward the more salient characteristics of healthcare
professionals and medical care services (eg technical and interpersonal skills of
providers, waiting time to see the healthcare professional, costs of care, and other
resources) and satisfaction with care in general. Empirical tests of validity of patient
satisfaction questionnaires have also produced generally favourable results (22-24).
Information on OA health status and pharmacy
Although osteoarthritis is the most common form of arthritis, patients frequently do not receive adequate pain relief primarily because self-reported questionnaires are not used and patients’ pain is not properly assessed with pharmacological therapy not always complying with evidenced-based practice. The accessibility of the community pharmacist enables them to assist osteoarthritic patients by conducting pain assessments and counselling on a regular basis, in collaboration with other health-care professionals.

In a recent review on the value of professional pharmacy services in the community over 70 randomised control trials were evaluated (25). There is comprehensive evidence for the effectiveness of pharmaceutical care services, continuity of care services as well as patient and pharmacist education services which lead to improved patient outcomes or medication use (25). Pharmaceutical care services have shown a reduction in adverse drug events, more appropriate use of medications, a reduction in medication related problems, improvements in symptoms for asthma patients and improvements in surrogate endpoints including blood pressure, glycosylated haemoglobin and cholesterol levels (25).

Community pharmacy is the primary access point for obtaining analgesic medications both prescribed and pharmacist and pharmacy only medicines (Schedule 3 and Schedule 2). NSAIDs are the most commonly prescribed analgesic medicines (26). NSAIDs are responsible for a large proportion of drug-related problems and patient’s knowledge of NSAIDs has shown to be poor (26). Furthermore, patients often self-medicate with over-the-counter (OTC) and complementary medicines, which may be in addition to their prescribed medications for the same condition. As pharmacists have regular and frequent contact with patients and because patients often seek advice from pharmacists, they are well positioned to play an important role in monitoring and assessing chronic conditions such as OA.
However, little is known about the impact that pharmacists may have when specific interventions for patients with chronic pain are implemented. The accessibility and expert medication knowledge of community pharmacists’ means they are ideally placed to play an important role in the assessment and medication management of patients with OA.
AIMS AND OBJECTIVES
Aims of the study
The overall aim of this study was to develop, implement and evaluate a practical method for the delivery of a specialised pharmacy service for patients with osteoarthritis (OA). The study also aimed to profile patients who frequent community pharmacy using a variety of self-report questionnaires (e.g. WOMAC Index™, AUSCAN Osteoarthritis Hand Index™, Dartmouth COOP Chart System) and to assess the feasibility of pharmacists using these questionnaires to monitor OA patients.

The specific objectives were to:
5. improve clinical (eg physical functioning, reduction of perceived pain) and humanistic outcomes (eg quality of life) for patients with OA.
6. demonstrate a role for the pharmacist in optimising the management of OA through evidence-based and quality use of medicines.
7. establish pharmacists as integral members of the primary health care team (including GPs, specialists and physiotherapists) in the seamless management of patients with OA.
8. establish a cost-effective and transportable model for the multidisciplinary management of OA in the primary care setting.

There were four null hypotheses. There will be no statistically significant differences in:
1. the patients’ pain assessment, physical functioning and mobility scores (WOMAC™ and AUSCAN Osteoarthritis Hand Index™ subscales) between the Baseline and Post-Intervention measurements for the Intervention and the Control Group.
2. the degree of patient satisfaction between the Intervention and the Control Group.
3. the patients’ quality of life between Baseline and Post-Intervention measurements for the Intervention and the Control Group as measured by the Dartmouth COOP Chart System.
4. the patients’ pain assessment, physical functioning and mobility scores (WOMAC™ and AUSCAN Osteoarthritis Hand Index™ subscales) over time (10 months), in the intervention group participants.
METHODS
METHODS

This section describes the methods used in conducting this research.

Ethics
The study was approved by the Human Ethics Committee of The University of Sydney. All patients signed an informed consent form and were issued with a subject information sheet (Appendix 3).

Study Design
The original study design proposed for this research was a randomised controlled design in which patients were randomised to either Group one, intervention group (including the delivery of HMR), or Group two, the control group. After study inception, during recruitment stage, researcher obtained permission from the Pharmacy Guild of Australia to include a third group (Group three) who would receive the same “intervention” as patients in the Group one regarding OA and QOL assessments over the 10 month period, but without the HMR (Figure 1). The introduction of this group would allow researchers to determine which part of the intervention (HMR part or OA and QOL assessment part) resulted in change. This third group would provide additional information, useful for describing the individual impact of components of a multifaceted intervention.

Group One: Patients in the Intervention Group were to receive an HMR as well as pain and quality of life assessments using the following standardised and validated measures: WOMAC™, AUSCAN Osteoarthritis Hand Index™ and Dartmouth COOP instruments. These assessments were to be conducted every two months for 10 months, along with counselling on the use of OA medications and the provision of information on non-pharmacological approaches to OA. An assessment of patient satisfaction was to be conducted at the completion of the intervention.

Group Two: Patients in the control group received “standard” care by the pharmacist over a 10-month period. As a part of standard care, pharmacists could choose to
intervene at any stage eg refer patient to their medical practitioner. The evaluation measures used in this group involved the same standardised and validated measures as in Group 1 but only taken at baseline and 10 months.

**Group Three**: Patients in this group received pain and quality of life assessments using the WOMAC™, AUSCAN Osteoarthritis Hand Index and Dartmouth COOP instruments, but no HMR. These assessments were to be conducted every two months for 10 months, along with counselling on the use of OA medications and the provision of information on non-pharmacological approaches to OA. An assessment of patient satisfaction was conducted at the completion of the intervention.

Difficulties in recruiting both pharmacists and GPs from the same location who were involved in the conduct of HMRs for OA patients proved to be a significant recruitment challenge, despite the allocation of a professional fee per patient, consultation with key stakeholders, on-going promotion of the project using a variety of media, and the recruitment of pharmacists willing to participate in this study. Although significant efforts were made, recruitment in the HMR intervention group (one) remained negligible throughout this project and no HMR data were submitted at the time of this report by pharmacists, hence no HMR process or impact indicators were assessed (eg number of HMR referrals, accreditation of community pharmacists for HMR, changes in medications, uptake of HMR recommendations).

Consequently, only data from Group two (Control) and Group three (Intervention) were analysed and reported in this study. Therefore, throughout this report, Group two is referred to as the Control Group and Group three as the Intervention Group.
Figure 1. Study Design

Recruitment of Community Pharmacies

Randomisation into study group

- **Group 1**
  - Training for Pharmacists on Patient Recruitment and Administration of Study Questionnaires
  - Recruited Patients Sent to GP for Diagnosis
  - Baseline Measurement (Pain, mobility, physical function, demographics, QOL)

- **Group 2**
  - Training for Pharmacists on Patient Recruitment and Administration of Study Questionnaires
  - Recruited Patients Sent to GP for Diagnosis
  - Baseline Measurement (Pain, mobility, physical function, demographics, QOL)

- **Group 3**
  - Training for Pharmacists on Patient Recruitment and Administration of Study Questionnaires
  - Recruited Patients Sent to GP for Diagnosis
  - Baseline Measurement (Pain, mobility, physical function, demographics, QOL)

HMR

- Visit 2 Measurement (Pain, mobility, physical function)
- Visit 3 Measurement (Pain, mobility, physical function)
- Visit 4 Measurement (Pain, mobility, physical function)
- Visit 5 Measurement (Pain, mobility, physical function)
- Post-Intervention Measurement (Pain, mobility, physical function, satisfaction, QOL)

- Visit 2 Measurement (Pain, mobility, physical function)
- Visit 3 Measurement (Pain, mobility, physical function)
- Visit 4 Measurement (Pain, mobility, physical function)
- Visit 5 Measurement (Pain, mobility, physical function)
- Post-Intervention Measurement (Pain, mobility, physical function, satisfaction, QOL)

- Visit 2 Measurement (Pain, mobility, physical function)
- Visit 3 Measurement (Pain, mobility, physical function)
- Visit 4 Measurement (Pain, mobility, physical function)
- Visit 5 Measurement (Pain, mobility, physical function)
- Post-Intervention Measurement (Pain, mobility, physical function, satisfaction, QOL)
Study site and participants

Pharmacies

The first phase of recruitment involved a sample of six hundred randomly selected community pharmacies practising within the Sydney metropolitan area. These pharmacies were contacted by telephone by the researchers, who briefly explained the study and invited the pharmacy to take part in it.

The researchers’ approach to recruitment was to randomly select pharmacies and invite them to participate. As initially, patients from one arm of the study were to receive a HMR, researchers attempted to recruit both, pharmacists and GPs who were doing HMRs. However, in many instances pharmacists were keen to participate, but the GPs in the area were not willing to refer patients for HMR. There were also instances where the GPs were keen to participate, but the local pharmacy did not have an accredited pharmacist conducting HMRs.

In total, nine pharmacies took an active part in this study. Table 1 presents the location of pharmacies in the study. Once pharmacies were recruited, pharmacists were then trained on recruitment procedure for enrolling patients with osteoarthritis in the study (the training programme is described later in this report). Pharmacists from participating pharmacies were asked to recruit 10 patients (per pharmacy) to the study.

Table 1. Pharmacies by study group and location

<table>
<thead>
<tr>
<th>Suburb / Town</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gladesville</td>
</tr>
<tr>
<td>Lane Cove</td>
</tr>
<tr>
<td>Manly Vale</td>
</tr>
<tr>
<td>Maroubra</td>
</tr>
<tr>
<td>Mascot</td>
</tr>
<tr>
<td>Picnic Point</td>
</tr>
<tr>
<td>Riverwood</td>
</tr>
<tr>
<td>Rozelle</td>
</tr>
<tr>
<td>Sussex Inlet</td>
</tr>
</tbody>
</table>
The second phase of recruitment was undertaken when it became apparent that the recruitment was taking place at a significantly slower pace than initially expected. In this phase researchers actively attempted to recruit pharmacies they believed would be likely to take part in the study, making it a pre-test/post-test purposive sampling design.

**Patients**
All osteoarthritis patients living in the community were eligible to participate in this study. In most cases patients were identified directly by their community pharmacist when they presented to their community pharmacy with symptoms of OA and/or a request for OA treatments (prescribed, over-the-counter or complementary).

Researchers actively encouraged pharmacists who agreed to take part in the study to recruit eligible patients to the study by regular phone calls and correspondence and also by reminding GPs to refer eligible patients to their preferred local community pharmacy. Altogether, seventy-two patients were recruited and randomly assigned to either an intervention (35) or control group (37).

Patient Inclusion Criteria were:
- Confirmed diagnosis of OA for example in the hip, knee and/or hand (Appendix 4)
- Taking medications for the treatment of OA (prescribed, over-the-counter or complementary)
- ≥ 18 years of age
- Provision of written informed consent

Patient Exclusion Criteria:
- Patients with OA symptoms confined to the axial skeleton, wrists, elbows, shoulders, feet

**Study intervention**
Pharmacies were assigned to either intervention or control groups.

**Intervention Group:** Enrolled osteoarthritis patients recruited at intervention pharmacies were requested to attend a brief assessment sessions with the pharmacist every two
months for a period of ten months in addition to Baseline and Post-intervention measurements (Figure 1). Patients in the intervention group received OA assessment using standardised and validated measures: WOMAC™ and/or AUSCAN Osteoarthritis Hand Index™ (disease specific instruments for osteoarthritis). Quality of life was assessed at baseline and post-intervention using the COOP chart system (general measures of quality of life (QOL). Pharmacists were requested to provide counselling on the use of OA medications and the provision of information on non-pharmacological approaches to OA at each visit. At the final visit a satisfaction questionnaire was administered.

**Control Group:** Patients who were recruited at control pharmacies were requested to be assessed for their osteoarthritis status (musculoskeletal pain, stiffness and physical function) at Baseline and after a period of 10 months (Figure 1) only, using standardised and validated measures: WOMAC™ and/or AUSCAN Osteoarthritis Hand Index™ (disease specific instruments for osteoarthritis). Patients did not receive regular (two monthly) OA assessment. Quality of life was assessed at baseline and post-intervention using the COOP chart system (general measures of quality of life (QOL). Pharmacists were requested to provide “usual care” over the study period (10-month period). At the final visit a satisfaction questionnaire was administered.

**Procedure**
Community pharmacists referred recruited patients to their general practitioners (GPs) to confirm their diagnosis of osteoarthritis. Since this intervention targeted the control of osteoarthritis symptoms (musculoskeletal pain and stiffness), rather than the diagnosis or modification of disease progression (although there may be some contribution to the latter), patients were not excluded on the basis of disease severity. In a proportion of cases, GPs did not indicate the joint/s affected by OA.

**Training of community pharmacists**
All community pharmacist participating in this study received training in pain management and medication counselling. Training was also provided in the administration of the AUSCAN Osteoarthritis Hand Index™, WOMAC™, COOP chart
Training sessions took place on the 8th June 2005. Six pharmacists attended a training session on 8th June 2005. A further 15 pharmacists attended a second training session on 20th August 2005. Training comprised the following (Appendix 5):

- Short didactic presentations on
  - OA: signs, symptoms, management etc
  - Study procedures
- Interactive case study facilitated by researchers

All pharmacists who attended the training provided through this study were awarded 10.5 CPE points from the Pharmaceutical Society of Australia (NSW Branch).

**Sample size**
The original sample size 112 patients per group was computed based on the following assumptions: p=0.05, power=90%, 10 unit change in the WOMAC score (pain subscales), standard deviation of 20 and a two-tailed test. Allowing for a drop out rate of 25%, this would leave 84 patients per group. With permission of the Pharmacy Guild of Australia, due to recruitment difficulties, the sample size was revised downwards to 28 patients per group (total of 56 patients) based on the following assumptions: p=0.05, power=70%, 20 unit change in the WOMAC™ score (pain subscales), standard deviation of 20 and a two-tailed test.

**Data collection and analysis**

*Baseline demographic information.*
The questionnaire to collect demographic and clinical information were devised by the researchers. Using this questionnaire (Appendix 6), researchers gathered the following demographic information:

- Age
- Country of birth
- Language spoken at home
• Gender
• Length of illness (osteoarthritis)
• Health Care Professional consulted
• Health Care Professional who diagnosed osteoarthritis
• Medication taken
• Over-the-counter or complementary/herbal medicines taken

**Evaluation measures**
A range of process and impact measures were used to evaluate the effectiveness of the service, from both the patient and health care professional perspective.

Patient evaluation measures were recorded at baseline and final visit in both groups, including pain assessment, quality of life and patient satisfaction, to allow for the testing of hypotheses.

For the intervention group participants, regular pain and quality of life assessments were conducted by the community pharmacist, every two months for 10-months, to evaluate the impact of the intervention over time.

**Specific process indicators included**
• Number of community pharmacists trained
• Patient satisfaction with the service. [Patient satisfaction with the OA intervention service was measured using a questionnaire developed by the researchers. The questionnaire consisted of 15 questions on various themes related to satisfaction with the service (Appendix 7). Patients were asked to choose responses on five-point Likert scales ranging from “Strongly Agree” to “Strongly Disagree”. The items concerned the amount of contact with the pharmacist, whether the pharmacist was informative, humaneness of pharmacist, technical competence of pharmacist etc.]
Specific impact and outcome indicators

Patient

- Changes in quality of life (COOP chart system)
- Changes in pain perceived (eg WOMAC™ and AUSCAN Osteoarthritis Hand Index™ subscales)
- Changes in patient mobility and physical functioning (WOMAC™ and AUSCAN Osteoarthritis Hand Index™ subscales)

Data Analysis

All data were analysed by SPSS (version 11.5). The data were collected at six periods within a period of ten months (baseline visit, four mid follow-up visits and a final follow-up visit). t-test and a chi-square test were used to compare Intervention and Control patients with respect to demographic and clinical variables. Shapiro-Wilk Test (W-Test) was used to determine if the data was normally distributed. Since the majority of the data were normally distributed analyses were performed using parametric tests. Differences in the mean value of continuous variables were tested using paired / independent t-tests and ANOVA. The null hypothesis was rejected when P < 0.05.

The primary analysis consisted of comparing the changes in perceived pain assessment and in reported mobility and physical functioning (WOMAC™ and AUSCAN Osteoarthritis Hand Index™ subscales) from baseline to final visit in the two groups. Subscale scores (Pain, Stiffness, and Physical Function) were calculated by simple summation of the assigned values scored on component items. Patient satisfaction assessment was also compared between control and intervention groups as were changes in quality of life assessment (COOP chart system).

External consultation and collaboration

A number of key stakeholders were consulted and advice sought regarding the management of this project and specific strategies for recruitment of pharmacies, GPs and patients. These stakeholders were:

- Medication Management Review (Home Medicines Review) facilitators at a number of Divisions of General Practice (Central Sydney, Western Sydney, Bankstown) were
consulted to aid the recruitment process and attended the training programme for pharmacists.

- The state coordinators for medication management at the Pharmaceutical Society of Australia (NSW Branch) (PSA) and Pharmacy Guild of Australia (NSW Branch) were supportive of this project and were consulted on an on-going basis, in particular to aid recruitment. Both attended the training programmes for pharmacists. Specific strategies adopted were to promote health care professional participation in this study via Pharmacy Guild Newsletter and via e-mail (PSA’s Young Pharmacists Group by e-mail. The PSA accredited the research programme and awarded continuing education points for participation in this research.

- The CEO from the Arthritis Foundation (NSW) was consulted throughout this study and attended the training programmes for pharmacists. The Arthritis Foundation represents the peak consumer advocacy body for those with arthritis.

- Written and electronic materials were accessed from NSW Therapeutic Assessment Group (TAG) and National Prescribing Service (NPS) for pharmacist participants.

- The study was also promoted in a number of Divisions of General Practice when members of the research team made invited presentations on other topics (Central Sydney and Bankstown).

- Professor Nicholas Bellamy, distinguished rheumatologist and Director of Centre of National Research on Disability and Rehabilitation Medicine (CONROD), The University of Queensland, was consulted throughout this project particularly in relation to the use of the WOMAC™ and AUSCAN™ Indices.

**Study limitations**
As previously mentioned, a purposive sample rather than a random sample of pharmacies was used due to difficulties in recruiting pharmacies to take part in the study. In addition, statistical analyses were performed only in patients who completed Visit 5 of the study, and, therefore, may not be a reliable estimate. Also, it is reasonable to assume that participating pharmacists may have recruited patients they were familiar with and that they felt would have agreed to take part in the study. This uncontrolled patient selection process could have led to bias in our data set as patients may not have
been a representative subset of OA patients. In addition, the smaller sample size than initially expected may not have allowed for conclusive results.

It should also be noted that not all cases of OA in the study had been confirmed by a general practitioner (GP) despite attempts from researchers to have all patients formally diagnosed. Therefore in some cases the researchers relied on patients’ reports of OA without written confirmation by a GP.

In addition to the challenges involved in recruiting subjects for the study discussed above, following the training programmes provided for pharmacists, several pharmacists withdrew from the study alleging time constraints. The smaller than initially expected sample size precluded the sub analysis of the data by type of osteoarthritis. That is, researchers were not able to examine whether or not different types of osteoarthritis (by joint) lead to different outcomes.

The lower than expected sample size lead to a number of changes in the conduct of the study from those proposed in the Aims and Objectives sections of this report and those actually performed in the study:

- It was not possible to establish pharmacists as integral members of the primary health care team (including GPs, specialist and physiotherapists) in the seamless management of patients with OA as stated in the Objectives Section. The delivery of HMRs to OA patients was central to this objective as it would have allowed for closer liaising with medical practitioners and other healthcare professionals regarding the patient’s pharmacological treatment. The fact that the number of patients recruited for this arm of the study was negligible significantly limited our ability to pursue this objective.

- The lack of HMR data due to negligible recruitment in the HMR intervention group throughout this project also meant that no HMR process or impact indicators were assessed (eg number of HMR referrals, accreditation of community pharmacists for HMR, changes in medications, uptake of HMR recommendations). This lack of
HMR data significantly limited researchers’ ability to pursue the stated objective of demonstrating a role for the pharmacist in optimising the management of OA through evidence-based and quality use of medicines.

- Although an estimated cost of providing the service was computed, the small sample size rendered the study underpowered to detect a possible change in evaluation measures over time. Hence the value in undertaking a cost-effectiveness analysis was limited. Therefore, this study objective was not pursued.

Finally, satisfaction questionnaires were not blinded, which could have altered patients’ reporting.
Results

Withdrawal rate

A total of 23 pharmacists from 16 pharmacies were trained to provide the intervention. One of the pharmacies declined to participate in the study following training since the pharmacists had too many other commitments. A further 6 pharmacies whose pharmacists received training formally withdrew from the study alleging time constraints leaving a total of 9 pharmacies in the study. Pharmacists enrolled in the study were paid a professional fee for each patient recruited to the study and were supported by researchers throughout the study period. Pharmacists found it challenging to recruit patients to this study. Pharmacist participants were asked about the lower than expected recruitment rate with time constraints being mentioned as a barrier. In addition the proportion of enrolled patients who completed the study in the Intervention Group was very low. Only 7 out of 30 expected WOMAC™ questionnaires for the final visit were returned from patients in the Intervention Group pharmacies compared to 35 out of 36 from the Control Group. In relation to the Auscan Osteoarthritis Hand Index questionnaires 7 were returned out 20 expected questionnaires from patients in the Intervention Group compared to 18 out 20 from the Control Group. This smaller than expected sample size is likely to have rendered the study underpowered to test the above hypotheses in a conclusive way.

Demographic data

Table 2 shows the demographic characteristics of patients at study inception. A total of 72 patients recruited from the 9 pharmacies took part in the study. Most of the patients were female (77.8%) with a mean age of 73 years with a high proportion born in Australia (76.4%).
Table 2. Patient demographics

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of females</td>
<td>68.6%</td>
<td>86.5%</td>
<td>77.8%</td>
</tr>
<tr>
<td>Mean Age</td>
<td>73.6 (SD=9.2)</td>
<td>72.6 (SD=9.1)</td>
<td>73.1 (SD=9.1)</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>22 (62.9%)</td>
<td>33 (89.2%)</td>
<td>76.4%</td>
</tr>
</tbody>
</table>

**Age**
A two-tailed independent t-test was used to test for equality of means for age between the Intervention and Control groups. Results showed the pattern of age was similar between the Intervention and Control groups ($t = -0.440; df=70; p = n.s.$).

**Gender**
One-sided Chi-square analysis of patient gender was performed to compare proportion of males and females between the Intervention and Control groups ($\chi^2 (1, N = 72) = 3.340, p = n.s.$) demonstrating similar proportions of males and females between the two groups.

**Country of birth**
Two-sided Chi-square analysis was used to compare proportion of patients born in Australia between the two groups demonstrating a significant difference in proportion of patients born in Australia ($\chi^2 (1, N = 72) = 6.914, p < 0.01$). That is, the rate of patients born in Australia was 11% higher in the Control Group.

**Type of osteoarthritis**
The majority of the patients in the study had OA in multiple joints including OA of the knee (41) or hip (27) followed by back (22), ankle (4), feet (4), neck (3) and leg (1). Other joints affected included shoulder and hand.
Health Care Professional Consulted
A demographic questionnaire was used to examine the types of health care professionals consulted by patients in relation to the management of osteoarthritis. Various healthcare professionals were consulted by patients regarding their osteoarthritis. Table 3 presents overall statistics related to healthcare professionals consulted by patients in the study and Figure 2 presents this statistic by group. Overall, a high proportion of patients had consulted their GP about their osteoarthritis (86.1%) with the pharmacist being the fourth most consulted health professional (29.2%) after, GP, medical specialist (48.6%), and physiotherapist (38.9%) and the second most commonly consulted allied health care professional.

No significant difference was observed between the Intervention and the Control groups in the proportion of patients who consulted general practitioner, specialist medical practitioner, other health professional and no health professional. However, the proportion of patients consulting pharmacists and physiotherapists was significantly higher in the Control Group compared to the Intervention Group \[ \chi^2 (1, N = 72) = 4.766, p < 0.03 \text{ and } \chi^2 (1, N = 72) = 4.974, p < 0.03, \text{ respectively}. \]
Table 3. Number and percentage of healthcare professional consulted by patients by study group

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Intervention Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Practitioner</td>
<td>37 (100%)</td>
<td>32 (91.4%)</td>
<td>69 (86.1%)</td>
</tr>
<tr>
<td>Specialist Medical Practitioner</td>
<td>19 (51.4%)</td>
<td>16 (45.7%)</td>
<td>35 (48.6%)</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>15 (40.5%)</td>
<td>6 (17.1%)</td>
<td>21 (29.2%)</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>19 (51.4%)</td>
<td>9 (25.7%)</td>
<td>28 (38.9%)</td>
</tr>
<tr>
<td>Other Health Professional</td>
<td>3 (8.1%)</td>
<td>4 (11.4%)</td>
<td>7 (9.7%)</td>
</tr>
<tr>
<td>No Health Professional</td>
<td>0 (0%)</td>
<td>1 (2.9%)</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Total Number of Cases</td>
<td>37</td>
<td>35</td>
<td>72</td>
</tr>
</tbody>
</table>
Medicines

The pattern of use of analgesic agents was similar between the Intervention and the Control groups (Table 4) with eighteen types of analgesic agents being taken by patients in both groups, including different combinations. The most commonly used analgesic to treat osteoarthritis was paracetamol (56.9% of patients in the study, n=41) followed by celecoxib (23.9%, n=16) and meloxicam (19.4%, n=13) (Table 4). Only 9.7% (n=7) of patients reported taking paracetamol on a regular basis at a therapeutic dose (2 QID or 2 TDS). The proportion of patients reporting taking paracetamol on a when needed (PRN) basis was 13.8% (n=10).

When paracetamol intake was examined by dose, 38 patients were taking paracetamol 500mg and 3 patients taking paracetamol 665mg. Only 6 patients taking paracetamol 500mg and 1 taking paracetamol 665mg were taking this medication on a regular basis (2 four times daily or 2 three times daily), the dose required for efficacy. Nine patients
were taking paracetamol 500mg and one patient taking paracetamol 665mg were doing so on a when required (PRN) basis.

Some of the patients in the study could be described as polypharmacy patients. Out of the 72 patients enrolled in the study, 24 patients were taking 2 different medicines to treat their osteoarthritis, 7 patients were taking 3 medicines and 2 patients were taking 4 medicines. The high rate of patients taking two medicines or more (46%) medicines to treat their osteoarthritis at study inception may reinforce the need for pharmacists' intervention in the treatment of osteoarthritis.
Table 4. Medicines taken by patients by study group.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Overall Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td>22</td>
<td>19</td>
<td>41</td>
</tr>
<tr>
<td>Celecoxib</td>
<td>5</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>Rofecoxib</td>
<td>0</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Meloxicam</td>
<td>5</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>Tramadol</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Paracetamol + Codeine 30mg</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Paracetamol + Codeine 8mg</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Dextropropoxyphene + Paracetamol</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Naproxen</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Ketoporofen</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Aspirin</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Indomethacin</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Diazepam</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Paracetamol 500mg + codeine 10mg + doxylamine 5.1 mg</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total number of participants using medicines*</td>
<td>31</td>
<td>36</td>
<td>67</td>
</tr>
</tbody>
</table>

* Out of the 67 patients that reported taking medicines for OA, 23 reported taking 2 medicines, 5 reported taking 3 medicines, and 2 reported taking 4 medicines.

**Complementary and alternative medicines**
Of the 72 participants 48 (66.7%) reported taking over-the-counter and complementary / herbal medicines for the treatment of osteoarthritis (Table 5). Most common reported complementary medicine was glucosamine hydrochloride (15 participants) followed by glucosamine (unknown salt) (13 participants). A further four patients were taking
glucosamine combined with chondroitin and five were using a topical preparation.

Table 5. Complementary and alternative medicines taken by participants by study group

<table>
<thead>
<tr>
<th>Complementary/herbal medicine</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucosamine alone salt unknown</td>
<td>4</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>Glucosamine sulphate alone</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Glucosamine hydrochloride alone</td>
<td>10</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Fish oil alone</td>
<td>2</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Salmon oil alone</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Glucosamine sulphate + chondroitin</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Glucosamine hydrochloride + chondroitin</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Topical glucosamine HCL</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Dencorub® Arthritic Cream</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Triethanolamine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elmore oil®</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Tiger balm®</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total number of participants using complementary / herbal medicines*</td>
<td>25</td>
<td>19</td>
<td>44</td>
</tr>
</tbody>
</table>

* Out of 44 patients taking complementary / herbal medicines for OA, 4 were taking two different types of these medicines.

Diagnosis by health care professional
The pattern of diagnosis was similar for the Intervention and the Control groups with similar proportion of patients being diagnosed by GPs, physiotherapists and other healthcare professionals (Table 6). However, the proportion of patients diagnosed by medical specialists was higher in the Control Group (29.7%) compared to the Intervention Group (9.1%) (χ² (1, N = 72) = 5.141, p < 0.03). These results could be indicative of more severe cases of osteoarthritis in the Control Group, however this assumption is not confirmed by results from the WOMAC™ and AUSCAN Osteoarthritis Hand Index™ questionnaires which are discussed later in this section.
Table 6. Health care professional who diagnosed osteoarthritis by study group*

<table>
<thead>
<tr>
<th>Health Care Professional</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Practitioner</td>
<td>30 (90.9%)</td>
<td>34 (91.9%)</td>
<td>64 (91.4%)</td>
</tr>
<tr>
<td>Medical Specialist</td>
<td>3 (9.1%)</td>
<td>11 (29.7%)</td>
<td>14 (20.0%)</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>2 (6.1%)</td>
<td>2 (5.4%)</td>
<td>4 (5.7%)</td>
</tr>
<tr>
<td>Other Health Care Prof.</td>
<td>3 (9.1%)</td>
<td>0</td>
<td>3 (4.3%)</td>
</tr>
</tbody>
</table>

Formal diagnosis by a General Practitioner

Study protocol required that community pharmacists referred recruited patients to their general practitioners for a formal diagnosis of osteoarthritis. Out of the 72 patients enrolled in the study, 45 (62.5%) were formally diagnosed by a general practitioner. Out of these 45 patients, 15 were from the Intervention Group and 30 from the Control Group. That is, 42.9% of patients in the Intervention Group and 81.1% of patients in the Control Group were formally diagnosed as having osteoarthritis.

WOMAC™ Assessment

Table 7 presents analyses conducted by two-tailed independent t-tests to compare Baseline scores for the WOMAC™ subscales and global scores between the Intervention and Control groups. The two groups were similar at Baseline with no subscale or global score indicating a difference.
Table 7. Comparison on **WOMAC™** subscales between Intervention and Control groups at Baseline visit

<table>
<thead>
<tr>
<th>Scales</th>
<th>Study Group*</th>
<th>Intervention Group (Mean ± SE)</th>
<th>Control Group (Mean ± SE)</th>
<th>t-test</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOMAC™ Pain</td>
<td>Intervention (n=35)</td>
<td>18.59 ± 1.98</td>
<td>23.09+ .1.76</td>
<td>.093</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control (n=37)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WOMAC™ Stiffness</td>
<td>Intervention (n=35)</td>
<td>9.37 ± .0.98</td>
<td>10.70 +.0.85</td>
<td>.302</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control (n=37)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WOMAC™ Physical Function</td>
<td>Intervention (n=35)</td>
<td>68.65 + .8.03</td>
<td>72.14 +.7.34</td>
<td>.750</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control (n=37)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WOMAC™ Global</td>
<td>Intervention (n=35)</td>
<td>97.20 + 10.93</td>
<td>107.43 + 10.93</td>
<td>.487</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control (n=37)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Total amount of patients in each group
Table 8 depicts a comparison between Baseline and Post-Intervention scores for the Intervention and Control groups. Results failed to demonstrate differences between these two measurement points for each of the WOMAC™ subscale and global scores.

Table 8. Comparison between Baseline and Post-Intervention scores for the WOMAC™ subscales for the Control and Intervention groups

<table>
<thead>
<tr>
<th>Scales</th>
<th>Study Group*</th>
<th>Mean Difference + SE</th>
<th>Paired t-test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOMAC™ Pain</td>
<td>Intervention (n=5)</td>
<td>-.50±2.87</td>
<td>.873</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td>-1.18±2.29</td>
<td>.609</td>
</tr>
<tr>
<td>WOMAC™ Stiffness</td>
<td>Intervention (n=6)</td>
<td>2.07±1.29</td>
<td>.136</td>
</tr>
<tr>
<td></td>
<td>Control (n=33)</td>
<td>-.93±.95</td>
<td>.331</td>
</tr>
<tr>
<td>WOMAC™ Physical Function</td>
<td>Intervention (n=3)</td>
<td>15.70±8.94</td>
<td>.113</td>
</tr>
<tr>
<td></td>
<td>Control (n=24)</td>
<td>-10.50±7.16</td>
<td>.156</td>
</tr>
<tr>
<td>WOMAC™ Global</td>
<td>Intervention (n=35)</td>
<td>20.00±16.15</td>
<td>.342</td>
</tr>
<tr>
<td></td>
<td>Control (n=37)</td>
<td>-11.91±10.13</td>
<td>.252</td>
</tr>
</tbody>
</table>

* Total amount of patients in each group

Between-group comparisons of the change between Baseline and Final Visit scores for the two groups were also conducted using independent *t* tests. These comparisons failed to demonstrate significant differences between the Intervention and Control groups in global scores, (*t* = - 0.44; df=24; p = n.s.), pain subscale (*t* = 0.48; df=35; p = n.s.), stiffness subscale (*t* = 0.25; df=37; p = n.s.) and physical function subscale (*t* = - 0.41; df=25; p = n.s.).

Distributions were tested for normality and parametric analyses were conducted. Repeated-measures ANOVA was used to study the effect of the study intervention on the score of the WOMAC™ Pain, Stiffness and Physical Function subscales across time (Table 9). Missing data was handled in a casewise deletion fashion. Due to very low response rate in the Intervention Group for the final visit, all Intervention Group patients
who participated in Visit 5 (second last visit) were assessed by using a last observation carried forward analysis (LOCF), in which patient's measurements from Visit 5 were carried forward to the final visit of the study. This allowed a reasonable view of what might have happened had these Intervention Group patients finished the last assessment of the study.

The results of the repeated-measures ANOVA indicated no significant difference among measurement points (visits) on WOMAC™ Pain subscale scores (F(4, 12)=.770; p=.56.) (Figure 3a). Similarly, no significant difference was observed among visits on WOMAC™ Physical Function scales or global scores (F(4, 32)=1.453; p=.24, and F(5, 5)=0.563; p = .728, respectively), indicating that these measurements over the study period (ten months) were not statistically significantly different. However, measures for Stiffness subscale differed significantly across time (F(4, 48)=2.573; p=.05). Patients’ measurements of stiffness improved over the course of the study (Figure 3b). The lower the score in the WOMAC™ Stiffness subscale the lesser the stiffness reported by the patient.
Figure 3a. WOMAC subscale scores for the Intervention Group across measurement points*

* The higher the score the greater the degree of disability
Figure 3b. WOMAC Stiffness subscale scores for the Intervention Group across time*

* The higher the score the greater the degree of disability
Table 9. Distribution of scores for WOMAC™ pain, stiffness and physical function subscales for the Intervention Group*

<table>
<thead>
<tr>
<th>WOMAC™ PAIN</th>
<th>N**</th>
<th>Mean</th>
<th>SE</th>
<th>95% Confidence Interval</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>29</td>
<td>21.2</td>
<td>1.887</td>
<td>15.243 27.257</td>
<td>15.243</td>
<td>27.257</td>
</tr>
<tr>
<td>Visit 2</td>
<td>27</td>
<td>28.2</td>
<td>5.121</td>
<td>11.951 44.549</td>
<td>11.951</td>
<td>44.549</td>
</tr>
<tr>
<td>Visit 4</td>
<td>25</td>
<td>22.5</td>
<td>3.663</td>
<td>10.843 34.157</td>
<td>10.843</td>
<td>34.157</td>
</tr>
<tr>
<td>Visit 5</td>
<td>13</td>
<td>21.7</td>
<td>2.323</td>
<td>14.358 29.142</td>
<td>14.358</td>
<td>29.142</td>
</tr>
<tr>
<td>Final Visit</td>
<td>7</td>
<td>15.5</td>
<td>5.315</td>
<td>-1.415 32.415</td>
<td>-1.415</td>
<td>32.415</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WOMAC™ STIFFNESS</th>
<th>N</th>
<th>Mean</th>
<th>SE</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>30</td>
<td>8.7</td>
<td>1.406</td>
<td>5.052</td>
<td>12.282</td>
</tr>
<tr>
<td>Visit 2</td>
<td>27</td>
<td>9.8</td>
<td>2.358</td>
<td>3.771</td>
<td>15.895</td>
</tr>
<tr>
<td>Visit 3</td>
<td>24</td>
<td>9.8</td>
<td>2.056</td>
<td>4.548</td>
<td>15.119</td>
</tr>
<tr>
<td>Visit 4</td>
<td>25</td>
<td>7.8</td>
<td>2.227</td>
<td>2.108</td>
<td>13.559</td>
</tr>
<tr>
<td>Visit 5</td>
<td>14</td>
<td>8.0</td>
<td>2.145</td>
<td>2.487</td>
<td>13.513</td>
</tr>
<tr>
<td>Final Visit</td>
<td>7</td>
<td>9.0</td>
<td>0.856</td>
<td>6.799</td>
<td>11.201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WOMAC™ PHYSICAL FUNCTION</th>
<th>N</th>
<th>Mean</th>
<th>SE</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>26</td>
<td>49.7</td>
<td>12.333</td>
<td>-3.399</td>
<td>102.733</td>
</tr>
<tr>
<td>Visit 2</td>
<td>23</td>
<td>56.3</td>
<td>8.822</td>
<td>52.539</td>
<td>60.128</td>
</tr>
<tr>
<td>Visit 3</td>
<td>18</td>
<td>50.3</td>
<td>10.398</td>
<td>5.596</td>
<td>95.071</td>
</tr>
<tr>
<td>Visit 4</td>
<td>21</td>
<td>57.3</td>
<td>5.925</td>
<td>31.838</td>
<td>82.829</td>
</tr>
<tr>
<td>Visit 5</td>
<td>11</td>
<td>47.3</td>
<td>9.905</td>
<td>4.715</td>
<td>89.952</td>
</tr>
<tr>
<td>Final Visit</td>
<td>3</td>
<td>69.0</td>
<td>10.583</td>
<td>23.465</td>
<td>114.535</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WOMAC™ GLOBAL SCORE</th>
<th>N</th>
<th>Mean</th>
<th>SE</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>25</td>
<td>69.5</td>
<td>23.500</td>
<td>-229.096</td>
<td>368.096</td>
</tr>
<tr>
<td>Visit 2</td>
<td>3</td>
<td>83.0</td>
<td>7.000</td>
<td>-5.943</td>
<td>171.943</td>
</tr>
<tr>
<td>Visit 3</td>
<td>23</td>
<td>82.0</td>
<td>2.000</td>
<td>56.588</td>
<td>107.412</td>
</tr>
<tr>
<td>Visit 4</td>
<td>18</td>
<td>67.5</td>
<td>11.500</td>
<td>-78.621</td>
<td>213.621</td>
</tr>
<tr>
<td>Visit 5</td>
<td>18</td>
<td>82.5</td>
<td>6.500</td>
<td>-.090</td>
<td>165.090</td>
</tr>
<tr>
<td>Final visit</td>
<td>11</td>
<td>63.5</td>
<td>9.500</td>
<td>-57.209</td>
<td>184.209</td>
</tr>
</tbody>
</table>

* The higher the score the greater the degree of disability
** Total amount of cases used to compute statistics
**AUSCAN Osteoarthritis Hand Index™ Assessment**

Table 10 presents a comparison between the Intervention and Control groups for the AUSCAN Osteoarthritis Hand Index™ subscales and global scores at Baseline using independent t-test. As in the WOMAC™ comparisons, due to low response rate in the Intervention Group for the final visit, comparisons for the AUSCAN Hand Index™ were made using a last observation carried forward analysis (LOCF). All Intervention Group patients who participated in Visit 5 (second last visit) were assessed. Patients’ measurements from Visit 5 were carried forward to the final visit of the study. Results failed to show a difference between the two groups for the Pain and Stiffness subscales and global scores with only the Physical Function subscale indicating a greater degree of physical limitation due to OA of the hand for patients in the Control Group.

Table 10. Comparison on AUSCAN Osteoarthritis Hand Index™ subscales between Intervention and Control groups at Baseline visit

<table>
<thead>
<tr>
<th>Scales</th>
<th>Study Group*</th>
<th>Intervention Group (Mean ± SE)</th>
<th>Control Group (Mean ± SE)</th>
<th>t-test p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUSCAN Pain</td>
<td>Intervention (n=18)</td>
<td>17.17 ± 3.11</td>
<td>22.65 ± 3.27</td>
<td>.182</td>
</tr>
<tr>
<td></td>
<td>Control (n=20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUSCAN Stiffness</td>
<td>Intervention (n=18)</td>
<td>3.33 ± 7.14</td>
<td>4.75 ± .750</td>
<td>.235</td>
</tr>
<tr>
<td></td>
<td>Control (n=20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUSCAN Physical Function</td>
<td>Intervention (n=17)</td>
<td>30.94 ± 5.49</td>
<td>47.25 ± 5.31</td>
<td>.041**</td>
</tr>
<tr>
<td></td>
<td>Control (n=20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUSCAN Global</td>
<td>Intervention (n=17)</td>
<td>51.76 ± 8.65</td>
<td>74.65 ± 8.75</td>
<td>.073</td>
</tr>
<tr>
<td></td>
<td>Control (n=20)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Total amount of cases used to compute statistics

** P < 0.05

Table 11 presents comparisons between Baseline and Post-Intervention scores for all AUSCAN Osteoarthritis Hand Index™ subscales and global scores for the Control and the Intervention groups. Results failed to show a significant difference for any of these
comparisons except for the Physical Function subscale in the Control Group. That is, no change was observed in AUSCAN Osteoarthritis Hand Index™ measurements between Baseline and Post-Intervention visits for any of the study groups except for patients in the Control Group whose physical function ratings deteriorated from Baseline to visit 5.

Between-group comparisons of the change between Baseline and Final Visit global scores for the two groups were also conducted using independent t tests. These comparisons failed to demonstrate significant differences between the Intervention and Control groups in global scores (\( t = 0.093; \text{df} = 21; \text{p = n.s.} \)), pain subscale scores (\( t = 0.15; \text{df} = 21; \text{p = n.s.} \)), stiffness subscale scores (\( t = -1.02; \text{df} = 22; \text{p = n.s.} \)) and physical function subscale scores (\( t = 0.27; \text{df} = 22; \text{p = n.s.} \)).

Table 11. Comparison between Baseline and Post-Intervention scores for the AUSCAN Osteoarthritis Hand Index™ subscales and global scores for the Control and Intervention groups

<table>
<thead>
<tr>
<th>Scales</th>
<th>Study Group*</th>
<th>Mean Difference + SE</th>
<th>Paired t-test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUSCAN Pain</td>
<td>Intervention (n=6)</td>
<td>6.35 ± 4.59</td>
<td>.434</td>
</tr>
<tr>
<td></td>
<td>Control (n=17)</td>
<td>-1.00±.73</td>
<td>.17</td>
</tr>
<tr>
<td>AUSCAN Stiffness</td>
<td>Intervention (n=6)</td>
<td>-.50 ± .32</td>
<td>.062</td>
</tr>
<tr>
<td></td>
<td>Control (n=18)</td>
<td>1.42 ± 1.04</td>
<td>.18</td>
</tr>
<tr>
<td>AUSCAN Physical Function</td>
<td>Intervention (n=6)</td>
<td>.33 ± 2.24</td>
<td>.495</td>
</tr>
<tr>
<td></td>
<td>Control (n=24)</td>
<td>16.30 ± 7.67</td>
<td>.04*</td>
</tr>
<tr>
<td>AUSCAN Global</td>
<td>Intervention (n=6)</td>
<td>-1.00 ± 2.96</td>
<td>.750</td>
</tr>
<tr>
<td></td>
<td>Control (n=17)</td>
<td>-6.64 ± 7.05</td>
<td>.360</td>
</tr>
</tbody>
</table>

* Total amount of cases used to compute statistics
* \( p < 0.05 \)
Repeated-measures ANOVAs were used to compare the changes in the Intervention Group with respect to data from the 6 measurement points in the study. Three repeated measures ANOVAs were done on whether OA intervention delivered by pharmacists across time had an effect on AUSCAN Osteoarthritis Hand Index™ subscale scores across time. Missing data was handled in a casewise deletion fashion. Results showed that there was no significant difference in AUSCAN Osteoarthritis Hand Index™ Pain scores throughout the study period (F(1, 5)=0.993, p = 0.44), no significant difference in AUSCAN Osteoarthritis Hand Index™ Stiffness subscale scores across time (F(5, 25)=2.379, p = 0.06), and also no significant difference in AUSCAN Osteoarthritis Hand Index™ Physical Function scores across time (F(2, 25)=0.174, p = 0.97) (Figure 4, Table 12).
Table 12. Distribution of scores for AUSCAN Osteoarthritis Hand Index™ pain, stiffness and physical function subscales for the Intervention Group*

<table>
<thead>
<tr>
<th>AUSCAN PAIN</th>
<th>N**</th>
<th>Mean</th>
<th>SE</th>
<th>95% Confidence Interval Lower</th>
<th>95% Confidence Interval Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6</td>
<td>12.66</td>
<td>2.76</td>
<td>5.55</td>
<td>19.77</td>
</tr>
<tr>
<td>Visit 2</td>
<td>6</td>
<td>11.16</td>
<td>2.41</td>
<td>4.96</td>
<td>17.37</td>
</tr>
<tr>
<td>Visit 3</td>
<td>6</td>
<td>12.66</td>
<td>2.53</td>
<td>6.14</td>
<td>19.19</td>
</tr>
<tr>
<td>Visit 4</td>
<td>6</td>
<td>12.50</td>
<td>2.32</td>
<td>6.53</td>
<td>18.46</td>
</tr>
<tr>
<td>Visit 5</td>
<td>6</td>
<td>13.33</td>
<td>2.92</td>
<td>5.80</td>
<td>20.86</td>
</tr>
<tr>
<td>Final Visit</td>
<td>6</td>
<td>14.66</td>
<td>3.45</td>
<td>5.79</td>
<td>23.53</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AUSCAN STIFFNESS</th>
<th>N</th>
<th>Mean</th>
<th>SE</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6</td>
<td>2.33</td>
<td>.76</td>
<td>.37</td>
<td>4.28</td>
</tr>
<tr>
<td>Visit 2</td>
<td>6</td>
<td>2.66</td>
<td>.55</td>
<td>1.23</td>
<td>4.10</td>
</tr>
<tr>
<td>Visit 3</td>
<td>6</td>
<td>2.83</td>
<td>.74</td>
<td>.90</td>
<td>4.75</td>
</tr>
<tr>
<td>Visit 4</td>
<td>6</td>
<td>3.16</td>
<td>.54</td>
<td>1.77</td>
<td>4.56</td>
</tr>
<tr>
<td>Visit 5</td>
<td>6</td>
<td>2.66</td>
<td>.80</td>
<td>.60</td>
<td>4.73</td>
</tr>
<tr>
<td>Final Visit</td>
<td>6</td>
<td>3.66</td>
<td>.80</td>
<td>1.60</td>
<td>5.73</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AUSCAN PHYSICAL FUNCTION</th>
<th>N</th>
<th>Mean</th>
<th>SE</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6</td>
<td>27.50</td>
<td>5.07</td>
<td>14.44</td>
<td>40.55</td>
</tr>
<tr>
<td>Visit 2</td>
<td>6</td>
<td>28.33</td>
<td>6.31</td>
<td>12.10</td>
<td>44.55</td>
</tr>
<tr>
<td>Visit 3</td>
<td>6</td>
<td>28.00</td>
<td>6.13</td>
<td>12.22</td>
<td>43.77</td>
</tr>
<tr>
<td>Visit 4</td>
<td>6</td>
<td>27.66</td>
<td>6.42</td>
<td>11.15</td>
<td>44.17</td>
</tr>
<tr>
<td>Visit 5</td>
<td>6</td>
<td>27.83</td>
<td>5.27</td>
<td>14.27</td>
<td>41.39</td>
</tr>
<tr>
<td>Final Visit</td>
<td>6</td>
<td>29.66</td>
<td>6.73</td>
<td>12.36</td>
<td>46.97</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AUSCAN GLOBAL SCORE</th>
<th>N</th>
<th>Mean</th>
<th>SE</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6</td>
<td>42.50</td>
<td>7.71</td>
<td>22.66</td>
<td>62.33</td>
</tr>
<tr>
<td>Visit 2</td>
<td>6</td>
<td>48.00</td>
<td>10.50</td>
<td>20.99</td>
<td>75.00</td>
</tr>
<tr>
<td>Visit 3</td>
<td>6</td>
<td>42.16</td>
<td>8.58</td>
<td>20.08</td>
<td>64.24</td>
</tr>
<tr>
<td>Visit 4</td>
<td>6</td>
<td>43.50</td>
<td>8.81</td>
<td>20.84</td>
<td>66.15</td>
</tr>
<tr>
<td>Visit 5</td>
<td>6</td>
<td>43.33</td>
<td>9.03</td>
<td>20.09</td>
<td>66.57</td>
</tr>
<tr>
<td>Final visit</td>
<td>6</td>
<td>43.83</td>
<td>8.33</td>
<td>22.40</td>
<td>65.26</td>
</tr>
</tbody>
</table>

* The higher the score the greater the degree of disability
** Total amount of cases used to compute statistics
Figure 4. AUSCAN subscale scores for the Intervention Group across time*

* The higher the score the greater the degree of disability

**Functional assessment charts**
Table 13 presents a comparison between the Intervention and the Control Group using independent $t$-test to compare each of the nine subscales of the COOP Functional Assessment Charts. The two groups were similar at Baseline (8 of the 9 subscales) with only the “physical fitness” subscale indicating a significant difference.
Table 13. Comparison on COOP scales between Intervention and Control groups at Baseline visit

<table>
<thead>
<tr>
<th>Scales</th>
<th>Study Group*</th>
<th>Intervention Group (Mean ± SE)</th>
<th>Control Group (Mean ± SE)</th>
<th>t-test p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical fitness</td>
<td>Intervention (n=32)</td>
<td>2.68 ± .229</td>
<td>3.50 ± .196</td>
<td>.008**</td>
</tr>
<tr>
<td></td>
<td>Control (n=31)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feelings</td>
<td>Intervention (n=34)</td>
<td>2.47 ± .180</td>
<td>2.24 ± .198</td>
<td>.388</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily activities</td>
<td>Intervention (n=32)</td>
<td>2.63 ± .189</td>
<td>2.71 ± .155</td>
<td>.741</td>
</tr>
<tr>
<td></td>
<td>Control (n=34)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social activities</td>
<td>Intervention (n=32)</td>
<td>2.00 ± .211</td>
<td>1.85 ± .180</td>
<td>.586</td>
</tr>
<tr>
<td></td>
<td>Control (n=33)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>Intervention (n=32)</td>
<td>3.59 ± .179</td>
<td>3.62 ± .134</td>
<td>.914</td>
</tr>
<tr>
<td></td>
<td>Control (n=34)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in health</td>
<td>Intervention (n=32)</td>
<td>2.88 ± .172</td>
<td>2.94 ± .132</td>
<td>.747</td>
</tr>
<tr>
<td></td>
<td>Control (n=36)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall health</td>
<td>Intervention (n=32)</td>
<td>3.28 ± .150</td>
<td>3.12 ± .145</td>
<td>.436</td>
</tr>
<tr>
<td></td>
<td>Control (n=34)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Support</td>
<td>Intervention (n=32)</td>
<td>2.44 ± .262</td>
<td>2.44 ± .238</td>
<td>.728</td>
</tr>
<tr>
<td></td>
<td>Control (n=35)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td>Intervention (n=32)</td>
<td>2.53 ± .149</td>
<td>2.46 ± .132</td>
<td>.710</td>
</tr>
<tr>
<td></td>
<td>Control (n=35)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Total amount of cases used to compute statistics
** p<0.05

Table 14 presents a comparison between Baseline and Post-Intervention scores for the Intervention and Control groups for each of the COOP subscales using paired t-test. Results failed to show significant differences between Baseline and Post-Intervention scores for all of the subscales scores for the two groups except for the physical fitness.
subscale in the Control Group with physical activity deteriorating from Baseline to Post-Intervention.

Table 14. COOP scales comparison of Baseline and Post-Intervention visits

<table>
<thead>
<tr>
<th>Scales</th>
<th>Study Group*</th>
<th>Mean Difference</th>
<th>95% Confidence Interval</th>
<th>Paired t-test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
<td>Upper</td>
</tr>
<tr>
<td>Physical fitness</td>
<td>Intervention (n=8)</td>
<td>-.38</td>
<td>-1.26</td>
<td>.51</td>
</tr>
<tr>
<td></td>
<td>Control (n=28)</td>
<td>-.54</td>
<td>-.99</td>
<td>-.08</td>
</tr>
<tr>
<td>Feelings</td>
<td>Intervention (n=8)</td>
<td>-.25</td>
<td>-.84</td>
<td>.34</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td>-.03</td>
<td>-.48</td>
<td>.41</td>
</tr>
<tr>
<td>Daily activities</td>
<td>Intervention (n=8)</td>
<td>.13</td>
<td>-1.09</td>
<td>1.34</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td>.09</td>
<td>-.28</td>
<td>.46</td>
</tr>
<tr>
<td>Social activities</td>
<td>Intervention (n=8)</td>
<td>-1.13</td>
<td>-2.50</td>
<td>.25</td>
</tr>
<tr>
<td></td>
<td>Control (n=31)</td>
<td>.23</td>
<td>-.24</td>
<td>.69</td>
</tr>
<tr>
<td>Pain</td>
<td>Intervention (n=8)</td>
<td>-.13</td>
<td>-.42</td>
<td>.17</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td>.06</td>
<td>-.33</td>
<td>.45</td>
</tr>
<tr>
<td>Change in health</td>
<td>Intervention (n=8)</td>
<td>.50</td>
<td>-.13</td>
<td>1.13</td>
</tr>
<tr>
<td></td>
<td>Control (n=34)</td>
<td>-.09</td>
<td>-.50</td>
<td>.33</td>
</tr>
<tr>
<td>Overall health</td>
<td>Intervention (n=8)</td>
<td>.00</td>
<td>-.45</td>
<td>.45</td>
</tr>
<tr>
<td></td>
<td>Control (n=31)</td>
<td>-.10</td>
<td>-.40</td>
<td>.21</td>
</tr>
<tr>
<td>Social Support</td>
<td>Intervention (n=8)</td>
<td>.25</td>
<td>-.14</td>
<td>.64</td>
</tr>
<tr>
<td></td>
<td>Control (n=33)</td>
<td>.15</td>
<td>-.40</td>
<td>.71</td>
</tr>
<tr>
<td>Quality of life</td>
<td>Intervention (n=8)</td>
<td>-.50</td>
<td>-1.13</td>
<td>.13</td>
</tr>
<tr>
<td></td>
<td>Control (n=33)</td>
<td>.03</td>
<td>-.27</td>
<td>.33</td>
</tr>
</tbody>
</table>

* Total amount of cases used to compute statistics
** p<0.05

Table 15 presents between-group comparisons of change from Baseline to Post-Intervention in scores for COOP scales using independent t-test. Results failed to show significant differences in change from Baseline to Post-Intervention scores for all of the
subscales scores for the two groups except for the pain and social support subscales. Patients in the Intervention group reported greater change (improvement) in pain and greater change (improvement) in social support compared to Control Group patients.

Table 15. Between-group comparisons of change from Baseline to Post-Intervention scores for COOP scales

<table>
<thead>
<tr>
<th>Scales</th>
<th>Study Group n*</th>
<th>Mean Difference</th>
<th>95% Confidence Interval</th>
<th>Paired t-test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
<td>Upper</td>
</tr>
<tr>
<td>Physical fitness</td>
<td>Intervention (n=8)</td>
<td>0.160</td>
<td>-0.774</td>
<td>1.096</td>
</tr>
<tr>
<td></td>
<td>Control (n=28)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feelings</td>
<td>Intervention (n=8)</td>
<td>-0.218</td>
<td>-1.140</td>
<td>0.703</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily activities</td>
<td>Intervention (n=8)</td>
<td>0.031</td>
<td>-0.864</td>
<td>0.926</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social activities</td>
<td>Intervention (n=8)</td>
<td>-1.350</td>
<td>-2.426</td>
<td>-0.275</td>
</tr>
<tr>
<td></td>
<td>Control (n=31)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>Intervention (n=8)</td>
<td>-0.187</td>
<td>-0.974</td>
<td>0.599</td>
</tr>
<tr>
<td></td>
<td>Control (n=32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in health</td>
<td>Intervention (n=8)</td>
<td>0.588</td>
<td>-0.306</td>
<td>1.482</td>
</tr>
<tr>
<td></td>
<td>Control (n=34)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall health</td>
<td>Intervention (n=8)</td>
<td>0.098</td>
<td>-0.532</td>
<td>0.726</td>
</tr>
<tr>
<td></td>
<td>Control (n=31)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Support</td>
<td>Intervention (n=8)</td>
<td>0.095</td>
<td>-1.041</td>
<td>1.238</td>
</tr>
<tr>
<td></td>
<td>Control (n=33)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td>Intervention (n=8)</td>
<td>-0.530</td>
<td>-1.193</td>
<td>0.132</td>
</tr>
<tr>
<td></td>
<td>Control (n=33)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Total amount of cases used to compute statistics
** p<0.05
Patient Satisfaction
Of the 72 patients in the study, 45 completed the satisfaction questionnaire (Table 16). Of these 45 patients who completed the questionnaire, 35 were from the Control Group and 10 from the Intervention Group. This lower rate of respondents in the Intervention Group makes it difficult to interpret the significance of the results. Therefore, results must be approached with caution.

The raw distribution data for the satisfaction questionnaire was normal and therefore parametric analyses were conducted on the independent samples by two-tailed t-tests to compare mean satisfaction scores measured at the Final Visit between the Intervention and Control Group. As numerical values had been assigned to each of the five response categories (1 = strongly agree, 2 = agree, 3 = uncertain, 4 = disagree, 5 = strongly disagree) a final score was calculated by simple summation of the assigned values scored on component items. Comparison of global scores between Intervention and Control Group failed to show a significant difference between the two groups (t=0.986, df=40 p = .330.). Out of the 15 individual items in the questionnaire, only 1 was statistically different between the two groups, namely “The pharmacist’s hours are good for me and I can speak to the pharmacist whenever it is convenient for me.” Patients in the Intervention group reported a higher rate of agreement with this item compared with Control Group subjects.

Overall, the vast majority of patients reported that they had been satisfied with all aspects of the osteoarthritis program measured by the questionnaire. Of those patients who completed the satisfaction questionnaire the following responses were observed:
Table 16. Comparison of satisfaction items between intervention and control groups using independent t-test

<table>
<thead>
<tr>
<th>Item</th>
<th>Intervention Group (Mean + SE)</th>
<th>Control Group (Mean + SE)</th>
<th>t-test p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>The questionnaires were too long and time consuming</td>
<td>3.10 ± .348</td>
<td>3.80 ± .158</td>
<td>.051</td>
</tr>
<tr>
<td>The questionnaires were easy to understand</td>
<td>4.20 ± .133</td>
<td>4.23 ± .109</td>
<td>.896</td>
</tr>
<tr>
<td>The questionnaires could be a useful way for the pharmacist to help me manage my Osteoarthritis</td>
<td>3.80 ± .291</td>
<td>4.23 ± .143</td>
<td>.172</td>
</tr>
<tr>
<td>The pharmacist explained the reasons for the study clearly</td>
<td>4.20 ± .133</td>
<td>4.43 ± .085</td>
<td>.197</td>
</tr>
<tr>
<td>The pharmacist advice to me on how to take my medications is valuable</td>
<td>4.60 ± .163</td>
<td>4.54 ± .095</td>
<td>.774</td>
</tr>
<tr>
<td>The pharmacist treats me with genuine interest as a person</td>
<td>4.70 ± .213</td>
<td>4.83 ± .065</td>
<td>.439</td>
</tr>
<tr>
<td>I feel confident that the pharmacist is providing me with correct information with regard to my medications</td>
<td>4.70 ± .153</td>
<td>4.77 ± .083</td>
<td>.686</td>
</tr>
<tr>
<td>I feel confident that the pharmacist is providing me with correct information with regard to my osteoarthritis</td>
<td>4.60 ± .163</td>
<td>4.66 ± .108</td>
<td>.797</td>
</tr>
<tr>
<td>The pharmacist spent plenty of time with me</td>
<td>4.30 ± .213</td>
<td>4.71 ± .105</td>
<td>.075</td>
</tr>
<tr>
<td>The pharmacist is competent and well trained to provide this service</td>
<td>4.50 ± .167</td>
<td>4.80 ± .080</td>
<td>.095</td>
</tr>
<tr>
<td>I feel confident that the pharmacist is keeping my doctor informed about my medications and my osteoarthritis</td>
<td>4.30 ± .213</td>
<td>4.03 ± .161</td>
<td>.401</td>
</tr>
<tr>
<td>The pharmacist listens carefully to what I have to say</td>
<td>4.70 ± .153</td>
<td>4.71 ± .088</td>
<td>.938</td>
</tr>
<tr>
<td>The pharmacist’s hours are good for me and I can speak to the pharmacist whenever it is convenient for me</td>
<td>4.30 ± .213</td>
<td>4.71 ± .077</td>
<td>.029*</td>
</tr>
<tr>
<td>The pharmacy is not private enough to discuss my condition</td>
<td>4.10 ± .233</td>
<td>3.70 ± .197</td>
<td>.297</td>
</tr>
<tr>
<td>The service provided by the pharmacist is beneficial to me and I would be willing to pay for this service</td>
<td>2.50 ± .269</td>
<td>2.56 ± .203</td>
<td>.885</td>
</tr>
<tr>
<td>Global score</td>
<td>62.60 ± 1.68</td>
<td>64.40 ± .87</td>
<td>.330</td>
</tr>
</tbody>
</table>

*p < 0.05
Questionnaires

When asked about satisfaction with the questionnaires used in the study, the majority of patients responded favourably. Sixty-nine percent reported that they either disagreed or strongly disagreed when asked if the questionnaires used in the study were too long and time consuming. Although the current study did not record the length of time taken to complete the assessment questionnaires, previous research demonstrated that the WOMAC™ takes 5-10 minutes to be completed in the pharmacy setting (16). Also 91% of respondents either agreed or strongly agreed that the questionnaires were easy to understand. Finally, 84% either agreed or strongly agreed that the questionnaires could be a useful way for the pharmacist to help the patient manage OA.

Interactions with pharmacist

All respondents agreed or strongly agreed that the pharmacist explained the purpose of the study clearly. The vast majority agreed or strongly agreed that the pharmacist’s advice on how to take the medication was valuable (98%) and that the pharmacist treated them with genuine interest (88%). Finally, 97% agreed or strongly agreed that the pharmacist spent enough time with them and 98% agreed or strongly agreed that the pharmacist listened to what they had to say carefully.

Perceived confidence on the pharmacist

Overall, perceived confidence on services provided by the pharmacist was very high. Ninety-eight percent of respondents agreed or strongly agreed that the pharmacist was providing them with correct information on their medications in general and also with their specific medication for osteoarthritis. Also 98% of respondents agreed or strongly agreed that the pharmacist was competent and well trained to provide osteoarthritis service and that the pharmacist was keeping their doctors informed about their medication and osteoarthritis.

Pharmacy hours and privacy

A majority of respondents indicated they were happy with the hours the pharmacy operated and that they found the pharmacy setting adequate for the osteoarthritis service. Ninety-eight percent of respondents reported to either agree or strongly agree
that the pharmacist's hours were good for them and that they could speak to the pharmacist whenever it was convenient to them. And (67%) disagreed or strongly disagreed that the pharmacy was not private enough to discuss their condition.

**Willingness to pay for service**
When asked whether or not they would be willing to pay for the osteoarthritis service offered to them, the majority of respondents (68%) reported that they would be willing to pay and that they found the service provided by the pharmacist beneficial to them.

**Cost Analysis**
A cost analysis was conducted estimating the main direct costs associated with providing this intervention in community pharmacy (Table 16). The main direct costs were the pharmacist's time in conducting or administering pain and QOL assessments. The original study design also included the costs associated with HMR delivery. Other indirect costs and start up costs associated with service delivery include training and education costs specific to this intervention. The cost of delivering the service to 10 patients for a period of 12 months was estimated along with the cost per patient per consultation.

Table 16 Estimated costs in delivering intervention

<table>
<thead>
<tr>
<th>Estimated costs¹ for intervention</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial group training programme and education for pharmacists (4 hours)</td>
<td>$150.00</td>
<td>-</td>
</tr>
<tr>
<td>Pharmacist’s time per patient per year (@ $60.00 ph)² for 6 consultations with the patient of approximately 15 minutes each</td>
<td>$90.00</td>
<td>$90.00</td>
</tr>
<tr>
<td>Pharmacist consultation with medical practitioner or other health care professional (@ $60.00 ph)² for 1 consultation of approximately 15 minutes</td>
<td>$15.00</td>
<td>$15.00</td>
</tr>
<tr>
<td>Cost to deliver intervention to 10 patients per year</td>
<td>$1200.00</td>
<td>$1050.00</td>
</tr>
<tr>
<td>Cost per patient per consultation&lt;sup&gt;3&lt;/sup&gt;</td>
<td>$20.00</td>
<td>$17.50</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>Estimated costs&lt;sup&gt;1&lt;/sup&gt; for intervention including HMR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial group training programme and education for pharmacists (4 hours)</td>
<td>$150.00</td>
<td>-</td>
</tr>
<tr>
<td>HMR Training (4 days at $300 per day)</td>
<td>$1200.00</td>
<td>-</td>
</tr>
<tr>
<td>Accreditation assessment</td>
<td>$332.75</td>
<td></td>
</tr>
<tr>
<td>Accreditation</td>
<td>$356.95</td>
<td>-</td>
</tr>
<tr>
<td>Re-accreditation</td>
<td>-</td>
<td>$151.25</td>
</tr>
<tr>
<td>Pharmacist's time per patient per year (@ $60.00 ph)&lt;sup&gt;2&lt;/sup&gt; for 6 consultations with the patient of approximately 15 minutes each</td>
<td>$90.00</td>
<td>$90.00</td>
</tr>
<tr>
<td>Pharmacist consultation with medical practitioner or other health care professional (@ $60.00 ph)&lt;sup&gt;2&lt;/sup&gt; for 1 consultation of approximately 15 minutes</td>
<td>$15.00</td>
<td>$15.00</td>
</tr>
<tr>
<td>Cost to deliver intervention to 10 patients per year</td>
<td>$3089.70</td>
<td>$1201.25</td>
</tr>
<tr>
<td>This is off set through the generation of HMR income of $180.00 per patient</td>
<td>-$1800.00</td>
<td>-$1800.00</td>
</tr>
<tr>
<td>Accreditation incentive</td>
<td>-$1500.00</td>
<td>-</td>
</tr>
<tr>
<td>Re-accreditation incentive</td>
<td>-</td>
<td>-$750.00</td>
</tr>
<tr>
<td>Net cost</td>
<td>-$210.30</td>
<td>-$1348.75</td>
</tr>
<tr>
<td>Cost per patient per year&lt;sup&gt;3&lt;/sup&gt;</td>
<td>-$3.51&lt;sup&gt;4&lt;/sup&gt;</td>
<td>-$22.48&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

1. In this study the WOMAC™ and AUSCAN™ Indices were used at no charge to the project, under the Academic User Agreement provided by Professor Bellamy. This cost has not been estimated.
2. The hourly rate has been set at $60 per hour on the basis of the expertise and training required by the pharmacist to administer the intervention.
3. The cost per patient assumes full payment of the service by the patient.
As previously stated, originally a cost-effectiveness analysis was also going to be computed in which both the costs and consequences of the osteoarthritis service on pain and patient satisfaction would be examined. However, because the results from the WOMAC™ and the AUSCAN Osteoarthritis Hand Index™ did not yield changes in global scores for these indices, the value in undertaking a cost-effectiveness analysis was considered to be limited.
Discussion
Traditionally, the role of the pharmacist has been restricted to the supplying of medicines with the training of pharmacists focusing on a product-oriented role with little clinical responsibility. The reliable measurement of osteoarthritis status followed by appropriate counseling provides the pharmacy profession with the opportunity to introduce a new professional service that will be valued by the community, governments and the pharmacy profession.

The dramatic increase of life expectancy in Australia coupled with decrease in fertility rates indicate that the proportion of younger people will decrease, while the proportion of older people will continue to rise (1). As the prevalence of all major forms of arthritis increases with age, the disease burden caused by osteoarthritis will become more prominent in Australian society specially because osteoarthritis typically causes disability for long periods of time (1).

This change in osteoarthritis prevalence due to changes in population demographics has clear implications for the pharmacy profession. The number of people with osteoarthritis will increase leading to greater demand for community-based health services. The current study attempted to be proactive in filling predicted health gaps in the management of osteoarthritis by developing, implementing and evaluating practical methods for the delivery of a specialised pharmacy service for people living with osteoarthritis.

This study was conducted to develop, implement and evaluate a practical method for the delivery of a specialised pharmacy service for patients with osteoarthritis. Pharmacists were required to monitor osteoarthritis patients by carrying out assessments of osteoarthritis status, including pain, stiffness and function using the WOMAC™ and AUSCAN Osteoarthritis Hand Index™ instruments, and also assessments of quality of life, using the COOP instrument. Pharmacists were also required to conduct assessment on satisfaction with OA services using an instrument developed by the researchers. This procedure was believed to facilitate the provision of routine
counseling by pharmacists on the management of OA based on reliable clinical measurement of OA status. In addition, greater understanding of the patient’s OA status placed the pharmacist in a better position to liaise more closely with other healthcare professional to manage the patient’s OA potentially leading to improved health outcomes.

After a few months of recruitment, it became apparent that the recruitment rate was lower than expected and that the pharmacists enrolled in the study did not provide enough potentially eligible patients for the study. Pharmacists in the study were asked about the lower than expected recruitment with time constraints being mentioned as a major issue. In addition the rate of enrolled patients who completed the study was very low in the Intervention Group. Clearly, a number of barriers made recruitment a challenge, in particular the requirement that routine (every second month) assessments were to be undertaken in the intervention group. Although the assessment of OA using the WOMAC™ and AUSCAN™ Indices has previously been shown to be feasible (16), this proved to be a significant challenge. It is noted that previous research on the feasibility of OA services in community pharmacies required pharmacists only to deliver the WOMAC™ and the AUSCAN™ just once (16). In the current study pharmacists were required to deliver more questionnaires more frequently, 6 times over a period of 10 months. Another significant barrier was the lack of referrals for HMR from GPs. Previous research has shown that approximately three quarters (76%) of pharmacies completed fewer than two HMRs per month and that less than half (42%) currently have an accredited pharmacist on staff (27). It is however likely that the rate of uptake of HMR will improve with the recent (April 1st, 2006) announcement of increased remuneration for HMR to $180.00 and one off incentives for pharmacists to gain accreditation ($1500.00) and be re-accredited ($750.00). The on-going support provided by the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia through MMR Facilitators and Practice Support respectively, will remain central to the increased uptake of HMR.

It is noteworthy, however, that this intervention trial was successful in obtaining a recruitment number of 72 consenting patients. However, this smaller than initially
expected sample size reduced statistical power to evaluate the implementation of the pharmacy-based osteoarthritis service provided to patients. Therefore, it is likely that the study was underpowered to achieve its stated objectives conclusively.

**Study hypotheses**
Again, it is noted that results used in the discussion of the hypotheses were derived from a small sample size which limited the researchers’ ability to test these hypotheses in a conclusive way.

$H^1$ was partially supported and partially rejected. In comparing results from Baseline with Post-Intervention visits for patients in the Intervention Group and in the Control group, the Western Ontario and McMaster Universities Osteoarthritis Index scores for the Pain, Stiffness and Physical Function subscales and global scores showed no significant differences between the two measurement points for any of the two groups. For the AUSCAN Osteoarthritis Hand Index™, results failed to show a difference between Baseline and Post-Intervention scores for the Intervention and Control group global scores and all subscales except for the Physical Function subscale whose patients reported deterioration in mobility from Baseline to Post-Intervention phase.

$H_2$ was also mostly supported as there was no statistically significant difference in the degree of patient satisfaction between the Intervention and the Control Group with global scores failing to reach statistical significance. Out of the 15 items in the Satisfaction Questionnaire, only one presented significant results with patients in the Intervention Group rating that they felt that the pharmacist’s hours were good and that they could approach the pharmacist at their convenience at a higher rate than did those in the Control Group.

It should be noted that high levels of satisfaction with the osteoarthritis service provided by the pharmacist were expressed by all respondents. As overall patient satisfaction is a recognised measure of outcome of healthcare processes (22), the results indicate that the provision of the osteoarthritis services could lead to improved health outcomes.
It should also be noted that there may not have been much scope for improvement in satisfaction scores from Baseline to Post-Intervention due to the tendency to ceiling effects of high baseline satisfaction (22). The high satisfaction scores at Baseline may have been indicative that the scores were at ceiling level. In addition, the instrument developed for the current study may not have been sensitive enough to detect small changes in satisfaction with osteoarthritis services.

H₃ was partially rejected and partially supported. Statistical analysis failed to demonstrate a significant difference in quality of life scores for all scales of the COOP Functional Chart between Baseline and Post-Intervention measurements for the Intervention and the Control Group except for the Physical Fitness scale for patients in the Control Group. Results indicated physical activity of patients in the Control Group deteriorated from Baseline to Post-Intervention. Also, patients in the Intervention group reported greater change (improvement) in pain and greater change (improvement) in social support compared to Control Group patients.

H₄ was also partially supported and partially rejected. No significant difference was observed in patients’ assessments over time except for the WOMAC™ stiffness in the Intervention Group patients. Patients’ measurements of stiffness improved over the course of the study.

**Integration of OA service into routine professional practice**

The current study represented the first attempt in Australia, and perhaps globally, to develop, implement and evaluate a method for the delivery of specialized pharmacy service for patients living with osteoarthritis. Although time constraints, from a pharmacists’ perspective, proved to be a barrier to the implementation of the OA service and a smaller than expected sample size limited researchers’ ability to evaluate the service, our results are useful in guiding future pharmacy practice research in the OA area.
The fact that recruitment was a challenge and that many pharmacists in the Intervention Group either withdrew from the study alleging time constraints or failed to complete the study, could have indicated that the OA service in its current format, may not have been entirely suitable for current practice environment. Pharmacists perceived the service as being too time consuming were not able to integrate it to their daily professional activities. This assumption is backed by anecdotal accounts from pharmacists who completed the study that they had made their graduate pharmacist in charge of collecting the data. That is, the service was not conducted as part of their routine daily activities, but as an additional duty. The successful implementation of sustainable cognitive services in community pharmacy requires that pharmacists develop mechanisms to allow them to integrate new professional services into their routine professional practice.

Future study may need to place greater emphasis on inherent time-constraints of community pharmacies in the current practice environment, adapting the current service to be less time-consuming. Reduction in the length and number of questionnaires could enhance pharmacists' motivation to deliver OA services. However, this potentially would comprise the utility of having more routine evaluations.

The fact that pharmacists were not required to assess or to interpret the results from the questionnaires, i.e. questionnaires were delivered to patients in a mechanistic manner for research purpose only, may have had a negative impact on their motivation to incorporate it into their daily professional practice. On the other hand, assessment and interpretation of results may have added to the time spent with the patients rendering the service even less suitable for current community pharmacy practice environment.

It is noted that the significant results observed in this study were all consistent with the assumption that community pharmacists are able to impact on clinical outcomes for patients with OA by conducting pain assessment and counseling on regular basis. However, some statistically significant results were likely to be observed simply due to the sheer number of comparisons made with experimental demand characteristics likely
to have influenced results in the expected direction. Also, these results were derived from a relatively low number of patients, making it difficult to interpret their significance.

**General comments**

A large range of medicines were reported to have been used, however the most common medicine used to treat osteoarthritis was paracetamol (61% of patients in the study). It was pleasing that more than 60% (n=41 patients) of patients were taking paracetamol for their OA, as it is considered the medicine of first choice. Paracetamol, to a maximum daily dose of 4g, is considered first line therapy in mild to moderate OA (28)(3)(29)(30). However, when the dose of paracetamol 500mg was examined, only 6 of the 41 patients (8.3%) were taking paracetamol on a regular basis (2 four times daily or 2 three times daily), the dose required for efficacy. Furthermore, 9 of 41 patients (12.5%) were taking paracetamol 500mg on a when required (PRN) basis. Only one of the 3 (4.2%) patients taking paracetamol 665mg, was taking it in accordance with recommended dosing guidelines of 2 tablets every 6 to 8 hours. Hence there is an important role for pharmacists to improve the prescribing of medicines for OA by recommending appropriate dosing schedules.

The most commonly used analgesic to treat osteoarthritis was paracetamol (56.9% of patients in the study, n=41) followed by celecoxib (23.9%, n=16) and meloxicam (19.4%, n=13) (Table 4). Only 9.7% (n=7) of patients reported taking paracetamol on a regular basis at a therapeutic dose (2 QID or 2 TDS). The proportion of patients reporting taking paracetamol on a when needed (PRN) basis was 13.8% (n=10).

The high rate of patients taking over-the-counter and complementary/herbal medicines for the treatment of osteoarthritis observed could be indicative that study participants were self-medicating in addition to their prescribed medicines for osteoarthritis. It is true that previous studies have found that the medical practitioners do not have a clear indication of many of the drugs taken by patients, specially the elderly (31). The use of several agents to treat osteoarthritis by some of the patients could be of concern as the use of drugs without proper indication is found frequently in polypharmacy. This high
rate of intake of OTC and herbal/complementary medicines reinforces the need for pharmacists’ intervention.

As it is commonly known, there is a place for complementary medicines like glucosamine and chondroitin in the treatment of osteoarthritis, particular for patients who cannot tolerate the side effects of NSAIDs. It is noted that 50% of the study population (36 patients) reported to be taking complementary combinations containing glucosamine. Indeed, evidence suggests these supplements can be of assistance in the treatment of osteoarthritis (32). However, patients need to be made aware of recommended dose (1,500mg daily for glucosamine sulphate) and that it can take up to six weeks before they observe any benefits in order to sustain compliance (32). Patients should also be made aware that although there are a number of complementary medicines that are marketed for the treatment of osteoarthritis, the evidence supporting the use of these products are not as strong as those for glucosamine / chondroitin (32). There is a need for pharmacists’ intervention if patients are going to use complementary medicines appropriately for the treatment of osteoarthritis. As complementary medicines are available outside community pharmacists, treatment for osteoarthritis may not always be monitored appropriately.

Greater involvement of pharmacists in the management of OA appears to have been welcomed by study participants. The vast majority of study participants reported to highly value the pharmacist’s advice on how to take the OA medication and to believe the pharmacist treated them with genuine interest. This acceptance of OA services, places community pharmacists at a prime position for optimising the management of OA through evidence-based and quality use of medicines.

In addition to providing assistance with the pharmacological treatment of OA, the pharmacist is also in an ideal position to educate OA patients about non-pharmacological treatments. It is true that most patients with osteoarthritis seek medical attention because of pain (33). However, alleviation of pain does not alter the underlying disease (33). Attention must also be given to non-pharmacological treatment, such as
weight loss and exercise. The fact that high levels of satisfaction with the OA service were observed in the current study indicates that patients welcome a broader involvement of pharmacists in the management of OA.

Further reinforcement for a role for community pharmacists beyond advice on pharmacological treatment in the management of OA was provided by the high WOMAC™ scores. Although all patients in the study were taking analgesic agents, the WOMAC™ scores indicated that a considerable proportion of patients were still reporting a great deal of pain and disability associated with OA. Again, pharmacists could be of great value not only by providing sound advice on safe and effective use of medicines to treat OA, but also by educating patients on the benefits of non-pharmacological treatments.

Results also point to a role for the pharmacist in the early identification of patients leading to a diagnosis of OA. The fact that only 45 patients in the study (62.5%) were formally diagnosed by a medical practitioner as having osteoarthritis raises concern about the prognosis of the disease. At early stages of osteoarthritis, relief of pain and restoration of function can be achieved in some patients whereas patients with advanced osteoarthritis may eventually require surgery (33). Greater involvement of community pharmacists in the management of osteoarthritis could potentially lead to early referral to a general practitioner with treatment being provided at an earlier stage.

Despite the potential benefits of pharmacists’ involvement in the management of OA, there seems to be a need for community awareness of pharmacy-based services in relation to OA. Although the pharmacy is the prime access point for patients seeking treatment for pain, in this study the pharmacist was the fourth healthcare professional to be consulted regarding osteoarthritis. Whether this was solely for the purpose of collecting medicines or to seek advice is not known. This low rate of pharmacist consultation indicates that the pharmacist’s skills were being underutilised. The pharmacy profession would profit from greater community awareness of the role of
community pharmacy in providing a osteoarthritis service and other professional services.

It is also noted that patients in the study not only valued the involvement of the pharmacists in the management of OA, but also reported being willing to pay for the osteoarthritis service offered by the pharmacist.
**Conclusion**
The vast majority of participants reported to highly value the pharmacist’s advice on how to take their OA medicines and believed that the pharmacist treated them with genuine interest. This acceptance of OA services, places community pharmacists at a prime position for optimising the management of OA through evidence-based and quality use of medicines. However, barriers associated with the integration of the OA service into routine professional practice of community pharmacists may need to be addressed before such services can be successfully implemented in community pharmacy.

**Recommendations**
1. It is recommended that further feasibility studies of the role of the pharmacist in on-going OA management be conducted, in which the use of the standardized instruments are incorporated into routine professional pharmacy services. Such studies will be required before developing a model suitable for dissemination to the broader community pharmacy profession.

2. Osteoarthritis services developed for community pharmacists should place greater emphasis on inherent time-constraints of community pharmacies in the current practice environment, and focus on the integration of professional activities into routine pharmacy practice.

3. In light of the positive satisfaction responses to the OA service from patients who completed the study, it is recommended that the development of an OA service that can be more easily incorporated into the professional services provided by pharmacists, be pursued in the future.

4. Unlike the current study which assessed satisfaction from a patient’s perspective only, satisfaction with OA service also should be assessed from a pharmacist’s perspective in future attempts to develop and implement an OA service.

5. Based on patients’ response about willingness to pay for OA services, once the methodology presented in the current study is refined to better suit the current community pharmacy environment, pharmacists should be encouraged to introduce a fee-for-service for OA services.
References


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Appendices

Appendix 1: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC™) Academic User Agreement

In accordance with this Academic User Agreement it is not possible to reproduce the WOMAC™ or AUSCAN™ Indices used in the conduct of this research.
WOMAC 3.1™ Academic User Agreement

The following agreement defines the conditions under which the WOMAC™ 3.0/3.1, WOMBAT® 3.0, AUSCAN® 3.0 and OGI 8.0 Indices (including their original, alternate language computerised and special feature versions) are provided for use. The conditions are as follows:

1. Use of the Indices is limited to authorised users and their clinical and research associates only.

2. The Indices may not be provided to unauthorised individuals or agencies without prior notification of the originator (Prof Nicholas Bellamy).

3. All copies of the Indices made for research or clinical purposes must bear the Originator’s (Prof Nicholas Bellamy) copyright insignia.

4. Commercialisation and resale of any of the Indices is strictly prohibited.

5. Although the use and publication of data collected on the Indices is not limited in any way, the physical form of the Indices may not be published or otherwise displayed in any publication, on the Internet or any other public access medium.

6. Permission for use is non-exclusive.

7. Only alternate-language forms created under the Originator’s (Prof Nicholas Bellamy) copyright will be used.

8. User agreements will be confirmed in advance, on a protocol by protocol basis.

9. Use outside the agreed protocol is not permitted.

10. The Index will not be modified in any way, or used to create modifications or alternate forms, or other instruments.

11. The Principle Investigator will provide an original copy of the latest version of the Index User Guide to each person supervising the administration of the Index.

I accept all of the aforementioned conditions to use the ___________ Index in a study entitled ____________________________________________

in ______ patients over ______ months

Signed ____________________________ Date ____________________________

* WOMAC is a registered trade-mark (CDN No. TMA 545,986)
Copyright 2004. Prof Nicholas Bellamy. All Rights Reserved
Appendix 2: Dartmouth COOP Functional Assessment Charts
Dartmouth COOP Assessment Charts

PHYSICAL FITNESS
During the past 4 weeks... What was the hardest physical activity you could do for at least 2 minutes?

FEELINGS
During the past 4 weeks... How much have you been bothered by emotional problems such as feeling anxious, depressed, irritable or downhearted and blue?

DAILY ACTIVITIES
During the past 4 weeks... How much difficulty have you had doing your usual activities or tasks, both inside and outside the house because of your physical and emotional health?

SOCIAL ACTIVITIES
During the past 4 weeks... Has your physical and emotional health limited your social activities with family, friends, neighbors or groups?

PAIN
During the past 4 weeks... How much back pain have you generally had?
Appendix 3: Study Consent and Information Sheet
**HEALTH CARE PROFESSIONALS CONSENT FORM**

Medication management and education of osteoarthritis patients: evaluation of a role for community pharmacists

I, ……………………………………………………………………………………………………………………………
(insert full name, underlining family name)

of …………………………………………………………………………………………………………………………..
(insert practice address)

Provider number (medical practitioners only) ……………………………………

have read and understood the “Subject Information Sheet” on the above project and have had the opportunity to discuss it. I am aware of the procedures involved in this study. This project is being conducted by Timothy Chen, Linda Gelgor, and Beata Bajorek, of the Faculty of Pharmacy, University of Sydney.

I understand that my involvement and all data obtained from this project will be treated confidentially and only group data will be published or used in future research. No personal details will be revealed at any time during or after the study. The data will not be used to identify any medical practitioner, pharmacist, pharmacy, other health care professional or patient.

I understand that I may withdraw my consent to participate in the above project at any time by telephoning any of the above researchers, without any negative consequences.

I hereby freely choose to participate in this research study and consent to the release of the above information about me.

Signature…………………………………………………………Date………………………………………………...

Name of Witness………………………………………………..Signature of Witness……………………………...

Any person with complaints about the conduct of a research study can contact the secretary of the Human Ethics Committee, The University of Sydney on (02) 9351 4811.
PATIENT CONSENT FORM

Medication management and education of osteoarthritis patients: evaluation of a role for community pharmacists

I, ………………………………………………………………………………………………………………………
(insert full name, underlining family name)

of ………………………………………………………………………………………………………………………
(insert postal address)

Medicare number…………………………………………. Date of birth …………………………………………

have read and understood the “Subject Information Sheet” on the above project and have had the opportunity to discuss it. I am aware of the procedures involved in this study. This project is being conducted by Timothy Chen, Linda Gelgor, and Beata Bajorek of the Faculty of Pharmacy, University of Sydney.

I authorise my doctor to allow project staff, pharmacists and other health care professionals involved in the project, access to my medical notes. In addition to this I authorise the release of the following information, to the above project:

<table>
<thead>
<tr>
<th>Details regarding the pharmaceutical services provided to me by my usual community pharmacist(s);</th>
<th>Please circle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes / No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmaceutical Benefits Scheme (PBS) data, Repatriation Pharmaceutical Benefits Scheme (RPBS) data and Medicare (MBS) data from the Health Insurance Commission</th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalisation and treatment data from any hospitals I have received treatment.</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Data from the Department of Veteran affairs</td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

I understand that my involvement and all data obtained from this project will be treated confidentially and only group data will be published or used in future research. No personal details will be revealed at any time during or after the study.

I understand that I may withdraw my consent to participate in the above project at any time by telephoning any of the above researchers, without any negative consequences.

I hereby freely choose to participate in this research study and consent to the release of the above information about me.

Signature ……………………………………………………………………Date ……………………………………

Name of Witness ………………………………………………Signature of Witness ……………………………

Any person with complaints about the conduct of a research study can contact the secretary of the Human Ethics Committee, The University of Sydney on (02) 9351 4811.
SUBJECT INFORMATION SHEET- GP, RHEUMATOLOGIST, PHARMACIST AND PHYSIOTHERAPIST (1)

Medication management and education of osteoarthritis patients: evaluation of a role for community pharmacists

In Australia, osteoarthritis is the ninth most common condition managed in general practice and is estimated to cost the community $9 billion per annum. Since there is a lack of disease-modifying drugs for osteoarthritis, symptomatic management of pain is the mainstay of treatment. Given that the community pharmacy is the primary source for obtaining these medications (prescribed and over the counter), pharmacists are ideally placed to play a significant role in the management of OA patients. This study will extend the role of the community pharmacist in providing specialized service to osteoarthritis patients in collaboration with rheumatologists, GPs and physiotherapists practicing in the community.

This project aims to identify a practical system for GPs, rheumatologists, physiotherapists and pharmacists to collaboratively manage patients suffering from osteoarthritis by developing, implementing and evaluating a specialised service. Patients over eighteen years of age with a confirmed diagnosis of osteoarthritis in the hip, knee and/or hand taking medication for their osteoarthritis (prescribed, over the counter or complementary) will be considered eligible to participate in the study and receive this service. This specialised service will be coordinated by the community pharmacy and will involve a comprehensive medication review, medication counseling as well as a pain and quality of life assessment. In some cases the medication review may be conducted in the patient’s home. The pain and quality of life assessments will be conducted in the pharmacy.

The pharmacist will conduct a comprehensive medication review as well as a pain and quality of life assessment using validated and reliable questionnaires and document their findings and recommendations. They will also provide counseling with regard to the management of medications as well as informing patients about availability of non-pharmacological methods for the treatment of their pain. The community pharmacist will make recommendations to the GP on the basis of their findings. If necessary the pharmacist in collaboration with the GP will devise a care plan for the patient. The pharmacist will conduct pain assessment and medication counseling for patients at two monthly intervals over a period of ten months and feed this information back to the GP. The GP may also refer patients to their local pharmacy for participation in the study. The GP will consult with the pharmacist following the medication review and pain assessment at the start of the study and devise a care plan if deemed necessary. Other health care professionals such as, nurses, physiotherapists may have access to the participant’s notes if the GP has provided them or referred the patient to them as part of their care plan. The researchers will also access Health Insurance Commission Data to obtain information relating to utilization of healthcare service such as hospital admissions and medication usage. The GP and/or rheumatologist will be responsible for making any final decisions about patient treatment. A patient satisfaction with the service will be administered at baseline and after 10 months.

All information collected as part of the project will remain confidential, except as required by law, and only group data will be reported.

This project has been funded by the Commonwealth Department of Health and Aging as part of the Third Community Pharmacy Agreement.

Your participation in this project will help us develop, implement and evaluate a practical mechanism for the improvement in care for patients suffering from osteoarthritis. Your involvement is entirely voluntary and you are free to withdraw at anytime. If you require further information or have any other questions, please contact Timothy Chen at the Faculty of Pharmacy on (02) 9351 4440, Linda Gelgor on (02) 9351 4434, or Beata Bajorek on (02) 9351-2359.

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This project aims to identify a practical system for GPs, rheumatologists, physiotherapists and pharmacists to collaboratively manage patients suffering from osteoarthritis by developing, implementing and evaluating a specialised service. Patients over 18 years of age with a confirmed diagnosis of osteoarthritis in the hip, knee and/or hand taking medication for their osteoarthritis (prescribed, over-the-counter or complementary) will be considered eligible to participate in the study and receive this service. This is a randomised controlled study. Each health care practice (eg GP clinic) will be randomised to one of two arms, intervention or control arm. In the intervention arm of the study patients will receive a Home Medicines Review (HMR) at the beginning of the study as well as pain and quality of life assessments. In some cases the HMR may be conducted in the patient’s home. Regular pain assessments will be repeated at two-monthly intervals for a period of 10 months for participants in the intervention arm. The pain and quality of life assessments will be conducted in the pharmacy by the pharmacist. In the control arm, pain and quality of life assessments will be conducted at the beginning of the study and again at the end of the study (after 10 months). All services will be coordinated by the participant’s community pharmacy.

The GP, rheumatologist or physiotherapist may refer patients to their local pharmacy for participation in the study. The pharmacist will conduct pain and quality of life assessment as well as a patient satisfaction survey using validated and reliable instruments at baseline and after 10 months. Should the GP decide that the patient requires a Home Medicines Review (HMR), the pharmacist will undertake one and communicate the outcome to the GP. The pharmacist, as part of standard care, may refer the patient to their GP at any stage during the course of the study. Other health care professionals such as, nurses and physiotherapists may have access to the participant’s notes if the GP has provided them or referred the patient to them as part of their care plan. The researchers will also access Health Insurance Commission Data to obtain information relating to utilisation of healthcare services such as hospital admissions and medication usage. The GP and/or rheumatologist will be responsible for making any final decisions about patient treatment.

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The GP, rheumatologist or physiotherapist may refer patients to their local pharmacy for participation in the study. The pharmacist will conduct pain and quality of life assessment as well as a patient satisfaction questionnaire using validated and reliable instruments at baseline and after again ten months. Should the GP decide that patients require a medication review the pharmacist will undertake one and communicate the outcome with the GP. The pharmacists as part of standard care may refer the patient to their GP at any stage during the course of the study. Other health care professionals such as, nurses, physiotherapists may have access to the participant’s notes if the GP has provided them or referred the patient to them as part of their care plan.

The researchers will also access Health Insurance Commission Data to obtain information relating to utilization of healthcare services such as hospital admissions and medication usage. The GP and/or rheumatologist will be responsible for making any final decisions about patient treatment.

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In Australia, osteoarthritis is the ninth most common condition managed in general practice and is estimated to cost the community $9 billion per annum. Since there is a lack of disease-modifying drugs for osteoarthritis, symptomatic management of pain is the mainstay of treatment. Given that the community pharmacy is the primary source for obtaining these medications (prescribed, over-the-counter or complementary), pharmacists are ideally placed to play a significant role in the management of osteoarthritis patients. This study will extend the role of the community pharmacist in providing a specialised service for osteoarthritis patients in collaboration with rheumatologists, GPs and physiotherapists practicing in the community.

This project aims to identify a practical system for GPs, rheumatologists, physiotherapists and pharmacists to collaboratively manage patients suffering from osteoarthritis by developing, implementing and evaluating a specialised service. Patients over 18 years of age with a confirmed diagnosis of osteoarthritis in the hip, knee and/or hand taking medication for their osteoarthritis (prescribed, over-the-counter or complementary) will be considered eligible to participate in the study and receive this service. This is a randomised controlled study. Each health care practice (eg GP clinic) will be randomised to one of two arms, intervention or control arm. In the intervention arm of the study patients will receive a Home Medicines Review (HMR) at the beginning of the study as well as pain and quality of life assessments. In some cases the HMR may be conducted in the patient’s home. Regular pain assessments will be repeated at two-monthly intervals for a period of 10 months for participants in the intervention arm. The pain and quality of life assessments will be conducted in the pharmacy by the pharmacist. In the control arm, pain and quality of life assessments will be conducted at the beginning of the study and again at the end of the study (after 10 months). All services will be coordinated by the participant’s community pharmacy.

The GP, rheumatologist or physiotherapist may refer patients to their local pharmacy for participation in the study. The pharmacist will conduct pain and quality of life assessment as well as a patient satisfaction survey using validated and reliable instruments at baseline and after 10 months. Should the GP decide that the patient requires a Home Medicines Review (HMR), the pharmacist will undertake one and communicate the outcome to the GP. The pharmacist, as part of standard care, may refer the patient to their GP at any stage during the course of the study. Other health care professionals such as, nurses and physiotherapists may have access to the participant’s notes if the GP has provided them or referred the patient to them as part of their care plan. The researchers will also access Health Insurance Commission Data to obtain information relating to utilisation of healthcare services such as hospital admissions and medication usage. The GP and/or rheumatologist will be responsible for making any final decisions about patient treatment.

All information collected as part of the project will remain confidential, except as required by law, and only group data will be reported.

This project has been funded by the Commonwealth Department of Health and Aging as part of the Third Community Pharmacy Agreement.

Your participation in this project will help us develop, implement and evaluate a practical mechanism for the improvement in care for patients suffering from osteoarthritis. Your involvement is entirely voluntary and you are free to withdraw at anytime. If you require further information or have any other questions, please contact Timothy Chen at the Faculty of Pharmacy on (02) 9351 4440, Linda Gelgor on (02) 9351 4434, or Beata Bajorek on (02) 9351-2359.

Any person with complaints about the conduct of a research study can contact the secretary of the Human Ethics Committee, The University of Sydney on (02) 9351 4811. This information is for you to keep.
Medication management and education of osteoarthritis patients: evaluation of a role for community pharmacists

In Australia, osteoarthritis is the ninth most common condition managed in general practice and is estimated to cost the community $9 billion per annum, this figure will increase as the population ages. Pain is the main reason why patients seek treatment. The community pharmacist is ideally placed together with the rheumatologist, general practitioner (GP) and physiotherapist to play an important role in providing a specialised service for the management of patients suffering from osteoarthritis.

This project aims to put into practice a system for rheumatologists, GPs, physiotherapists and pharmacists to work together to manage patients suffering from osteoarthritis by developing and implementing a specialised service. The specialised service for osteoarthritis sufferers will be conducted in the community pharmacy and includes a comprehensive medication review, medication counseling as well as a pain and quality of life assessment.

Comprehensive medication review refers to a systematic evaluation by the pharmacist of all medications you are taking, including prescribed, over-the-counter and complementary medicines. The pharmacist will also carry out regular pain assessments using questionnaires developed by rheumatologists. The medication review and pain assessment process involve an interview with you in the pharmacy or in some circumstances in your home. Following the interview with you, the pharmacist provides feedback and makes recommendations to your GP either at a case conference meeting or via telephone or facsimile. The pharmacist will conduct pain and quality of life assessments every two months over a ten month period and if necessary will contact your GP to discuss your case further. Pharmacists will also provide you with medication counseling during the study and may suggest you consult other allied health professionals such as physiotherapists. However your GP or rheumatologist will be responsible for making any final decisions about your treatment.

This project will involve your GP, pharmacist and other health care professionals (eg. physiotherapists, nurses), having access to your medical notes and pharmacy records. As part of the project, the researchers will also need to collect other information about you, such as information from the Health Insurance Commission (about your use of Medicare and Pharmaceutical Benefits services) and the Department of Veterans Affairs (if applicable), as well as any recent hospital visits. All information collected will remain confidential, except as required by law, and only group data will be reported.

You will also be asked to complete a questionnaire patient indicating your satisfaction with the service

All information collected as part of the project will remain confidential, except as required by law, and only group data will be reported.

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This project aims to put into practice a system for rheumatologists, GPs, physiotherapists and pharmacists to work together to manage patients suffering from osteoarthritis by developing and implementing a specialised service. The specialised service for osteoarthritis sufferers will be conducted in the community and includes a pain and quality of life assessment.

Your GP will need to confirm that you have osteoarthritis and provide this diagnosis to your pharmacist. The pharmacist will carry out pain assessment using questionnaires developed by rheumatologists at the start of the study and again after ten months. Your pharmacist may refer you to your GP or physiotherapist during the course of the study. If you are taking a lot of medications your GP might ask your pharmacist to conduct a comprehensive medication review, which is a systematic evaluation by the pharmacist of any medication you are taking (including prescribed, over the counter and complementary). Your GP or rheumatologist will be responsible for making any final decisions about your treatment.

This project will involve your GP, pharmacist and other health care professionals (eg. physiotherapists, nurses), having access to your medical notes and pharmacy records. As part of the project, the researchers will also need to collect other information about you, such as information from the Health Insurance Commission (about your use of Medicare and Pharmaceutical Benefits services) and the Department of Veterans Affairs (if applicable), as well as any recent hospital visits. All information collected will remain confidential, except as required by law, and only group data will be reported.

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Appendix 4: GP Diagnosis
GP Diagnosis

Medication management and education of osteoarthritis patients: evaluation of a role for community pharmacists

Dear Doctor,

We are conducting a study for patients with osteoarthritis in community pharmacy. In this study we are investigating the impact of regular pain and quality of life assessment combined with home medicine review (HMR) on patients with osteoarthritis.

This study is being conducted by Professor R. Day of UNSW and St. Vincent's Hospital, Professor J. Brien, Faculty of Pharmacy and St Vincent's Hospital, and Drs T Chen, L. Gelgor, and B. Bajorek, from the Faculty of Pharmacy, University of Sydney.

We would appreciate it if you could please confirm that this patient is, in your opinion suffering from osteoarthritis by completing the form below. Radiographic confirmation is not required.

For further information you can contact your local community pharmacist or any of the researchers directly.

Full Name of Patient: _______________________

Suffers from osteoarthritis of the hip and knee  [ ]

Suffers from osteoarthritis of the hand  [ ]

Suffers from osteoarthritis of the back  [ ]

Other joints (Please specify) _______________________

Doctors Signature: ________________________ Date: __/__/____

Please return to ________________

Pharmacy stamp/sticker
Appendix 5: Training Program for Pharmacists
Medication management and education of osteoarthritis patients: Evaluation of a role for community pharmacists

Dr Linda Gelgor
Dr Beata Bajorek
Dr Tim Chen

Faculty of Pharmacy
The University of Sydney

Presentation:
1) Introduction/Welcome  Tim Chen
2) Osteoarthritis: Case study  Tim Chen / Jo Brien
   - Overview
   - Clinical presentation
   - Management
3) Study Protocol  Linda Gelgor
4) Questions?

Introduction

• Thank you for your interest in our research … your research
• Acknowledge funding body: Third Guild/Government Agreement
• With the support of Arthritis Foundation (NSW)
• Pharmacy Practice Research Group: providing evidence for the value of pharmacy services

Background to Research

• Focus on HMR in my research group
  – Evidence for the value of HMR in the elderly polypharmacy population
  – Currently investigating HMR in specific patient groups
    • OA
    • Chronic pain
    • Mental health
    • Continuity of care – hospital community interface

• Other programmes
  – HMR
  – Continuity of care
  – DSM
  – CMI
  – QUM

Why OA?
• National Health Priority Area
• Decade of bone joint
• Involves many pharmacy clientele
• NO pharmacy data
### Why are we doing this research?

<table>
<thead>
<tr>
<th>Patient perspective</th>
<th>Pharmacist perspective</th>
<th>Research perspective</th>
<th>Government / organisation perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Better outcomes for various disease states</td>
<td>• Under utilised expertise in medication management</td>
<td>• Shift away from product to the supply of a professional service</td>
<td>• Utilise the medication management skills of pharmacists</td>
</tr>
<tr>
<td>• Improved QOL</td>
<td>• Most accessible primary HCP</td>
<td></td>
<td>• Cost effective means of delivering health care</td>
</tr>
<tr>
<td></td>
<td>• Potential for remuneration for providing a professional service – professional interest</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CQI Points (1 to 5)</td>
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</tr>
</tbody>
</table>

### Research Team

- Dr Linda Gelgor, USYD
- Dr Beata Bajorek, USYD
- Prof Joanne Brien, USYD, St Vincents Hospital
- Prof Ric Day, St Vincents Hospital, UNSW
- Dr Tim Chen, USYD

### A Case on Osteoarthritis

**Scenario**

Mrs Marianne Miller (72 years old) presents to the Pharmacy and requests a packet of Nurofen® tablets. She says that her knees are “playing up again”.

**Task:** What questions / information would you ask?

### Information from Mrs Miller

Mrs Miller is an **elderly (72y), overweight, lady.**

She tells you that her knee is getting **painful**, especially in the mornings when getting out of bed. She was diagnosed with OA 12 months ago, but chose not to take the medication recommended by the GP – “too many tablets as it is”. But she did take up some more exercise – “lawn bowls has been great fun”. Nurofen was recommended to her by her lawn bowls partner – she has taken it only once before. She also picked up a bottle of **Arthreze™** on her last trip into the city (last month).

She is feels otherwise healthy, her blood pressure, “sugar”, and cholesterol are “under control” according to her GP. She has not had any problems with her ulcer – that healed up many years ago.

**Task:** Initial thoughts?

### Patient Interview

- How effective do you find the Nurofen®?
- Who recommended the Nurofen®?
- Where is the pain?
- Please describe your pain?
- When did it start? How long have you had it?
- What makes the pain better or worse?
- What have you tried for it already?
- What other medical conditions do you have?
- What other medications are you taking? (OTC, complementary)

### Medical history

- **Osteoarthritis (knees, hip):** 1 year
- Hypertension: 11 years
- Hypercholesterolaemia: 8 years
- Atrial fibrillation: 6 years
- NIDDM: 8 years
- Peptic ulcer disease: 10 years ago
- Non-smoker, social ETOH
Osteoarthritis Study

Training Programme For Pharmacists – Selection Of Slides 3

### Osteoarthritis: brief overview

- Most common form of arthritis
- Progressive, degenerative disease:
  - erosion of articular cartilage
  - due to trauma, 'wear and tear', hereditary
  - remodelling of underlying bone, joint space narrowing, osteophyte formation
- Leading cause of pain and disability in elderly
- Patients with OA often have multiple comorbidities

### Osteoarthritis: clinical presentation

**Signs:**
- Visible deformities in joints:
  - Finger joints
  - Spine
  - Hip and knee
- Radiography: evidence of joint degradation

**Symptoms:**
- Pain is the principal symptom

### Osteoarthritis versus Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Symptom</th>
<th>RA</th>
<th>OA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morning stiffness</td>
<td>&gt; 1 hr</td>
<td>≤ 15 minutes</td>
</tr>
<tr>
<td>Inflammation</td>
<td>Present</td>
<td>Absent or mild</td>
</tr>
<tr>
<td>Disease distribution</td>
<td>Systemic</td>
<td>Local</td>
</tr>
<tr>
<td>Serum RA factor</td>
<td>Frequently +ve</td>
<td>-ve</td>
</tr>
<tr>
<td>ESR</td>
<td>Increased normal</td>
<td></td>
</tr>
<tr>
<td>Swelling</td>
<td>Symmetrical</td>
<td>Irregular</td>
</tr>
<tr>
<td>Subcutaneous nodules</td>
<td>Frequently present</td>
<td>Absent</td>
</tr>
<tr>
<td>Joint involvement</td>
<td>Bilateral, Symmetrical</td>
<td></td>
</tr>
</tbody>
</table>

### Osteoarthritis: management

- **Assessment**
  - WOMAC, AUSCAN
  - (COOP)
- **Non-pharmacological → lifestyle**
  - Strengthening exercises, posture/gait correction, weight loss
- **Pharmacological**
  - Paracetamol
  - NSAIDs → COX-2
  - Complementary medicines

### Osteoarthritis: clinical presentation

**Differentiation from Rheumatoid Arthritis:**

**OA:**
Biomedical disturbance of cartilage → cartilage loss

**RA:**
Inflammation of the synovium → structural damage to joints → articular bone erosions
**Information from Mrs Miller**

Mrs Miller is an elderly (72y), overweight, lady.

She tells you that her knee is getting painful, especially in the mornings when getting out of bed. She was diagnosed with OA 12 months ago, but chose not to take the medication recommended by the GP – “too many tablets as it is”. But she did take up some more exercise – “lawn bowls has been great fun”. Nurofen was recommended to her by her lawn bowls partner – she has taken it only once before. She also picked up a bottle of Arthreze™ on her last trip into the city (last month).

She feels otherwise healthy, her blood pressure, ‘sugar’, and cholesterol are “under control” according to her GP. She has not had any problems with her ulcer – that healed up many years ago.

**Medication history**

- Amlodipine 10mg daily
- Atorvastatin 10mg daily
- Digoxin 125mcg daily
- Metformin 500mg TDS
- Gliclazide 5mg BD
- Aspirin 100mg daily
- Temazepam 10mg nocte

Ibuprofen 200mg TDS prn OTC – Nurofen® (recommended by niece)

Glucosamine prn OTC – Arthreze® (recommended by lawn bowls partner)

**Osteoarthritis: management**

- Assessment
  - WOMAC &/or AUSCAN and QoL
- Exercise – see handout – 10 minutes!
- Non-pharmacological → lifestyle
  - Strengthening exercises, posture/gait correction, weight loss
- Pharmacological
  - Paracetamol
  - NSAIDs → COX-2
  - Complementary medicines

**Osteoarthritis: NSAIDs**

<table>
<thead>
<tr>
<th>Non-selective COX-1 &amp; COX-2 inhibitors</th>
<th>Selective COX-2 inhibitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPIRIN</td>
<td>CELECOXIB</td>
</tr>
<tr>
<td>BENZYDAMINE</td>
<td>ROFECOXIB</td>
</tr>
<tr>
<td>DICLOFENAC</td>
<td>MELOXICAM</td>
</tr>
<tr>
<td>DIFLUNISAL</td>
<td>PARECOXIB</td>
</tr>
<tr>
<td>IBUPROFEN</td>
<td>VALDECOXIB</td>
</tr>
<tr>
<td>INDOMETACIN</td>
<td>ETORICOXIB</td>
</tr>
<tr>
<td>KETOPROFEN</td>
<td></td>
</tr>
<tr>
<td>KETOROLAC</td>
<td></td>
</tr>
<tr>
<td>MEFENAMIC ACID</td>
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<tr>
<td>NAPROXEN</td>
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<tr>
<td>PHENYL BUTAZONE</td>
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<tr>
<td>PROGPRAM</td>
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<tr>
<td>SULINDAC</td>
<td></td>
</tr>
<tr>
<td>TENOXICAM</td>
<td></td>
</tr>
<tr>
<td>TIAPROFENIC ACID</td>
<td></td>
</tr>
</tbody>
</table>

**NSAI DS: Mode of Action**

- Inhibit cyclo-oxygenase (COX) → inhibit synthesis of prostaglandins
- 2 isoforms of COX.
- Inhibition of COX-1
  - impaired gastric cytoprotection & antiplatelet effects
- Inhibition of COX-2
  - anti-inflammatory & analgesic action
- Both COX-1 + COX-2 inhibition → ↓ in GFR & renal blood flow

**NSAI DS: Contraindications**

| Impaired gastric cytoprotection |
| active PUD, Hi of PUD |

| Antiplatelet effects |
| bleeding disorders, haemorrhagic injury/truma, surgery |
| severe hepatic impairment |

↓ in GFR & renal blood flow

| Uncontrolled hypertension and/or CCF |
| moderate to severe renal impairment |

Other

- Sulphonamide allergy (celecoxib)
- Asthma
- G6PD deficiency
- Drug interactions eg warfarin, methotrexate
**NSAIDs: Properties**

- **Properties:**
  - non-specific analgesics → effective in inflammatory pains
  - dose-dependent effects + ceiling dose
  - marked individual variation in response to different drugs
  - drug-to-drug variation in toxicities (COX-1/COX-2 selectivity)

**NSAID: Practice points**

- **Practice Points:**
  - use MED and to minimise dyspepsia:
    - Oral: PC or CC
    - NSAID with lower risk of GI, eg ibuprofen, COX-2
    - mucosal cytoprotective eg misoprostol
    - PPIs, ?? high-dose H2-antagonists
  - no rationale for ≥1 NSAID concurrently (NB/formulations)
  - counselling for ADRs

**Osteoarthritis: COX-2 Inhibitors**

Additional Note:

Relative cost-benefit of COX-2 selective drugs and non-selective drugs combined with gastroprotective therapy is not known.

**Medication history**

- Amlodipine 10mg daily
- Atorvastatin 10mg daily
- Digoxin 125mcg daily
- Metformin 500mg TDS
- Gliclazide 5mg BD
- Aspirin 100mg daily
- Temazepam 10mg nocte
- Ibuprofen 200mg TDS prn OTC – Nurofen®
- Glucosamine prn OTC – Arthreze®

**Osteoarthritis: Complementary Meds**

**Glucosamine**

- occurs naturally in cartilage
- inhibits enzymes that breakdown cartilage
- ADRs: minor GI, headache, rash; caution in diabetes, diuretics
- dose: oral 1.5 g/day (500MG tds)

**Chondroitin:** 800-1,200mg per day (divided doses)

- bleeding, interactions with anticoagulants

**Osteoarthritis: Complementary Meds**

**Glucosamine:**

- Sulfate (SO4) versus hydrochloride (HCl)?
  - most studied
  - more expensive (made from HCl for stability)
  - more dense
  - less sodium

…since sulfate and hydrochloride are not the key building blocks for the production of joint cartilage, it makes no difference whether glucosamine has a sulfate or hydrochloride carrier, in terms of bioavailability. There is no evidence to suggest that glucosamine sulfate offers advantages over glucosamine hydrochloride…

http://www.pillfreevitamins.com/study.htm
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**Osteoarthritis: Complementary Meds**

- **Topical products**
  
  “Rubbing glucosamine and chondroitin is a useless waste of money. Topical glucosamine and chondroitin makes as much sense as trying to improve your vocabulary by resting your head on a dictionary”


  Is there any evidence for topical? …

  - Topical capsaicin has medical evidence to support its use
  - Camphor? Menthol
  - Other CMs: Ginger ✓ Acupuncture ✓ Devil’s Claw ✓

  - short time pain relief, no improvement to joint/s

**Osteoarthritis: Paracetamol**

- aka acetaminophen
- simple analgesic → minimal anti-inflammatory effects

- 1st line analgesic for OA (all grades of OA)

- ADRS rare in therapeutic (max 4g/24hours) doses:
  - no effect on platelet function, no GI effects

Adverse effects:
- renal toxicity
- hepatotoxicity on overdose
  - ↑ risk with liver disease or chronic alcoholism

Dosing: oral 4 grams daily, usually 1g QID, regularly

**Medical history**

- Osteoarthritis (knees, hip)
- Hypertension
- Hypercholesterolaemia
- Atrial fibrillation
- NIDDM
- Peptic ulcer disease
- Non-smoker, social ETOH

- Amlodipine 10mg daily
- Atorvastatin 10mg daily
- Digoxin 125mcg daily
- Metformin 500mg TDS
- Gliclazide 5mg BD
- Aspirin 100mg daily
- Temazepam 10mg nocte
- Ibuprofen 200mg TDS prn
- Glucosamine prn

**Potential problems for Mrs Miller**

- Suboptimal Rx for OA – PRN NSAID
- Suboptimal Rx of OA – dosage of glucosamine for OA
- Drug-Drug Interaction – NSAID + Aspirin
- Drug-Disease interaction – NSAID + Gastric ulcer
- Drug-Disease interaction – NSAID + NIDDM
- Drug-Disease interaction – glucosamine + NIDDM

*Your suggestions?*

**Osteoarthritis: health burden**

- Arthritis major cause of disability:
  - 80,000 years of healthy life lost 2nd arthritis each year
  - National Health Priority 2002

- Most common form of arthritis is OA:
  - 3.1 million Australians affected by OA
  - Prevalence increases with age

- Management and services? Role of pharmacists?

**Osteoarthritis: Role of HCPs**

- A specialized nurse will be able to direct drug monitoring, screen for drug side effects and educate the patient. These nurses are usually only available via the provincial arthritis societies. They can also be available for the family physician for telephone advice

- The pharmacist may help in pointing out possible drug interactions and may warn about potential side effects of medications

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**Osteoarthritis: Pharmacy?**

Survey Pain and your relationship to your pharmacy:

- How would you rate the value of your pharmacist in your health care?
  - one - most important: 15.3%
  - two - very important: 53.6%
  - three - average importance: 15.3%
  - four - not very important: 12.2%
  - five - least important: 5.1%

- Who do you think knows more about pain medication and their effects on patients?
  - doctors: 36.7%
  - nurses: 3.5%
  - pharmacists: 58.9%
  - drug companies: 7.6%
  - politicians: 0%

[http://www.painandhealth.org/cgi-bin/surveytime.cgi?view=archive&id=050910171034](http://www.painandhealth.org/cgi-bin/surveytime.cgi?view=archive&id=050910171034)

**Osteoarthritis: Role of Pharmacy**

- How and when to help?
  - advice on meds, self-management
  - screening and referral
  - ongoing follow-up, monitoring (risk vs benefit)

- Type of service?
  - collaborative, team approach
  - accessible → community-based
  - comprehensive

**Medication management and education of osteoarthritis patients:**

**Evaluation of a role for community pharmacists**

Dr Linda Gelgor
Dr Beata Bajorek
Dr Tim Chen

Faculty of Pharmacy
The University of Sydney

**Study overview**

**Aim**

To develop, implement and evaluate a practical method for the delivery of a specialised pharmacy service for patients with OA.

**Specific objectives**

- improve perception of pain and quality of life
- demonstrate a role for the pharmacist
- primary health care team – pharmacists
- cost-effective and transportable model

**Study overview**

Two groups

- HMR then:
  - OA assessment
  - QOL assessment
- 8, 2,4,6, 8,10 months
- $155 per completed patient

- OA assessment
  - QOL assessment
  - 8 and 10 months
- $75 per completed patient
### Study overview

- Informed consent
- Confirmation of diagnosis
- Demographics
- OA assessment (WOMAC and/or AUSCAN)
- QOL (COOP)
- Satisfaction with service

### Questions ...

### Comments

### Contact Details:

Dr Tim Chen  02 9351 4440  timchen@pharm.usyd.edu.au  
Dr Linda Gelgor  02 9351 4434  lindag@pharm.usyd.edu.au  
Dr Beata Bajorek  02 9351 2359  beatab@pharm.usyd.edu.au  
or  
fax: 02 9351 4391
Appendix 5 (continued): HMR Resources for GPs
OSTEOARTHRITIS – HOME MEDICINES

REVIEW STUDY

Brief Resource Kit for GPs

- HMR Guidelines for identification of patients
- Accessing HMR templates in Medical Director

Further Information:
Dr Linda Gelgor 9351 4434, lindag@pharm.usyd.edu.au
Dr Tim Chen 9351 4440, timchen@pharm.usyd.edu.au

Acknowledgement:
This Project is funded by the Department of Health and Ageing as part of the Third Guild Government Agreement under the name: Medication management and education of osteoarthritis patients: evaluation of a role for community pharmacists.
Guidelines for Identification of Patients for Home Medicines Review (HMR)

RISK FACTORS FOR MEDICATION RELATED ADVERSE EVENTS. PLEASE REFER TO LIST BELOW AS A GUIDE WHEN DECIDING IF A PATIENT REQUIRES A DMMR SERVICE.

- Currently taking 5 or more regular medications
- Taking more than 12 doses of medication/day
- Significant changes made to medication regimen in the last 3 months
- Medication with a narrow therapeutic index or medications requiring therapeutic monitoring
- Symptoms suggestive of an adverse drug reaction
- Sub-therapeutic response to treatment with medicines
- Suspected non-compliance or inability to manage medication related therapeutic devices
- Patients having difficulty managing their own medicines because of literacy or language difficulties, dexterity problems or impaired sight, confusion/dementia or other cognitive difficulties
- Attending a number of different doctors, both general practitioners and specialists
- Recent discharge from a facility/hospital (in the last 4 weeks)
- Other medication issues/problems

Notes:

- Only one of the above guidelines needs to be met.
- HMR is also known as Domiciliary Medication Management Review (DMMR)
- MBS Item 900

Source: http://mail.andgp.org.au/hmr/
How to access HMR templates in Medical Director

Referral template

There are two templates available in Medical director. To generate a referral to a pharmacy using medical director software

Open “patient”

Either

1. From the ‘tools’ menu, select letter writer
2. From file tab select new
3. From the supplied tab, select DMMR form1

OR

1. select the blue “i” icon to go to Medibank Resource Centre
2. From the menu on the left hand margin, double click on the “CPC templates” logo
3. Scroll down the selection and choose “CPC HMR referral”

The referral template will automatically add the current list of medications and disease states for the patient. You need to type in the name of the community pharmacy you wish to send the referral to, and it is useful to the pharmacist undertaking the review if you add relevant information eg vaccination status and pathology results such as biochemistry, blood picture, TFT’s, drug levels, HbA1c.

Medication Management Plan template

To generate a template for the Medication Management plan follow the same process as for a referral but at step 3. Click on CPC HMR Plan

From the report you have received from the pharmacist and in consultation with the patient fill in the Medication Management Plan and provide a copy to both the pharmacist and patient.
(Access to DMMR forms 1 and 2 via letter writer will not be available from the February 2004 updates.)

**Home medicines reviews – Recalls**

Recalls for HMR are generated in the same way as other recalls; generally a recall would be for 12 months time for a further HMR.

1. Open “patient”
2. From the “clinical” menu select “recall”
3. Click the “add” button to open the “add recall” window

A list of the standard recall protocols is displayed at the lower left. If no-one in your practice has added HMR you will need to do this – see next paragraph. Click on a recall protocol to select it. When a recall protocol is selected from the list, the number of weeks, months or years that have been set for that protocol will be shown in the Interval section.

If the desired reason for recall is not in the supplied list, type the name into the 'Reason for Recall' text box, eg type in HMR and set the desired recall interval, usually 1 year. Click the Save Protocol button. The new protocol will be added to the list, and will now be available for all patients.
Appendix 6: Demographic and Clinical Information Questionnaire
PATIENT DEMOGRAPHIC QUESTIONNAIRE

Miss/Ms/Mrs/Mr (Circle) First name_________________ Last Name_________________

Telephone: (H)__________________ (W)_________________ (Mobile)__________________

General Practitioner: Doctor’s Name:______________________________________________
Surgery Address: ____________________________________________
Surgery Phone Number__________________ Fax___________________

Country of birth:_________________________ Language spoken:___________________

Age ____________

Sex
☐ Male   ☐ Female

How long have you suffered from Osteoarthritis?
☐ Less than 1 year   ☐ 1-3 years   ☐ 3-5 years   ☐ Greater than 5 years

Which Health Care Professionals have you consulted previously about your Osteoarthritis?
☐ General Practitioner
☐ Specialist medical practitioner (Rheumatologist)
☐ Pharmacist
☐ Physiotherapist
☐ Other, please specify ____________________________.
☐ Have not previously consulted a health care professional

Which Health Care Professional diagnosed your Osteoarthritis? (You may tick more than one box)
☐ General Practitioner
☐ Specialist medical practitioner (Rheumatologist)
☐ Pharmacist
☐ Physiotherapist
☐ Other, please specify ____________________________
What medications are you taking for your Osteoarthritis? Please provide dose taken as well (eg 1 capsule of 500 mg three times a day)

1. 
2. 
3. 
4. 
5. 

Do you use any over the counter or complementary/herbal medicines for your Osteoarthritis? (Eg. OsteoEze®, Athro-Aid®, Blackmore’s Glucosamine, Omega-3 fish oil, Shark cartilage) Please provide dose taken as well (eg 1 capsule of 500 mg three times a day)

1. 
2. 
3. 
Appendix 7: Patient Satisfaction with Service Questionnaire
Patient Satisfaction with Services Questionnaire

We are interested in your assessment good and bad about the service you have received from the pharmacist in relation to osteoarthritis.

Please tick the most appropriate statement

1. The questionnaires were too long and time consuming
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

2. The questionnaires were easy to understand
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

3. The questionnaires could be a useful way for the pharmacist to help me manage my Osteoarthritis
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

4. The pharmacist explained the reasons for the study clearly
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

5. The pharmacist advice to me on how to take my medications is valuable
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

6. The pharmacist treats me with genuine interest as a person
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

7. I feel confident that the pharmacist is providing me with correct information with regard to my medications
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

8. I feel confident that the pharmacist is providing me with correct information with regard to my osteoarthritis
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

9. The pharmacist spent plenty of time with me
   ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

10. The pharmacist is competent and well trained to provide this service
    ☐ 1 Strongly agree   ☐ 2 Agree   ☐ 3 Uncertain   ☐ 4 Disagree   ☐ 5 Strongly Disagree

Pt code:
Date:
11. I feel confident that the pharmacist is keeping my doctor informed about my medications and my osteoarthritis

1  Strongly agree   2  Agree   3  Uncertain   4  Disagree   5  Strongly Disagree

12. The pharmacist listens carefully to what I have to say

1  Strongly agree   2  Agree   3  Uncertain   4  Disagree   5  Strongly Disagree

13. The pharmacist’s hours are good for me and I can speak to the pharmacist whenever it is convenient for me

1  Strongly agree   2  Agree   3  Uncertain   4  Disagree   5  Strongly Disagree

14. The pharmacy is not private enough to discuss my condition

1  Strongly agree   2  Agree   3  Uncertain   4  Disagree   5  Strongly Disagree

15. The service provided by the pharmacist is beneficial to me and I would be willing to pay for this service

1  Strongly agree   2  Agree   3  Uncertain   4  Disagree   5  Strongly Disagree