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# **An Evaluation Of The Use And Efficacy Of Analgesics In The Management Of Chronic Pain In The Community**

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A thesis submitted in partial fulfilment of the requirements of The  
Robert Gordon University for the degree of Doctor of Philosophy

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**The Robert Gordon University**

**Aberdeen**

**Scotland**



*To my husband Tim, family and friends,  
for their tremendous long-term support and encouragement*

## **Abstract**

The main aims of this research were to evaluate the use and efficacy of analgesics in the management of chronic pain in the community and to investigate the role of the pharmacist in optimising health outcomes relating to chronic pain by assessing the effect of pharmacist intervention on pain control and activities of life.

Cluster samples of patients with chronic non-malignant pain living at home were identified from 3 medical practices in 2 Scottish Health Board areas, using diagnosis of rheumatoid arthritis (RA) and repeat prescription of non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesics as selection criteria. Structured interviews determined patients' use of prescription and non-prescription therapies for pain relief, attitude to medication and perceived side effects.

Outcomes measured were pain relief, influence of pain on activities using a quality of life (QOL) scale and side effects experienced. Pain relief was assessed using the McGill Pain Questionnaire (MPQ) and horizontal visual analogue scales (VAS). Poor outcomes were defined as at least one of the following: poor pain control (VAS average pain greater than 75), total QOL score greater than 35, signs or symptoms of an adverse drug reaction, deliberate therapy change by patient due to lack of awareness of rationale of therapy or patient dissatisfaction. Patients with poor outcomes were given information or advice, referred to their GP and interviewed after 4 to 6 weeks to determine any changes in outcomes.

A total of 109 patients were identified of whom 96 agreed to participate; 42 had RA, 22 had osteoarthritis (OA), 25 had both OA and RA and 7 had low back pain. Seventy-one patients were prescribed NSAIDs, 15 disease-modifying agents (DMARDs), 49 combination analgesics and 27 paracetamol. The majority of OA patients prescribed NSAIDs had no inflammation. Use of other therapies for pain e.g. anticonvulsants, hypnotics and herbal products was significantly higher in RA patients. Documentation of biochemical and haematological parameters in GP records was very limited.

Twenty-eight patients had poor outcomes requiring GP referral, but also had significantly higher expectations of pain relief, higher pain and QOL scores compared to the 68 patients with satisfactory outcomes. Suggestions for changing



therapy in 24 of the 28 patients were discussed with the GP, the other 4 requiring surgery. Although the pharmacist's recommendations were accepted and acted on in 22 of the 24 patients, 7 were unwilling and 3 were too ill to be re-interviewed during the study period. The pharmacist's recommendations were implemented in 12 of the 14 patients who had a follow-up interview. Pain scores and QOL scores improved in 9 and 8 patients respectively after pharmacist intervention. Twenty-four and 38 patients respectively with satisfactory outcomes required advice to improve concordance and to minimise the risk of side effects. Sixty-four patients reported side effects, 5 of whom required GP referral. Although there was a need for referral advice and information, the small number of patients followed up did not allow estimation of the outcome measures' sensitivity to pharmacist intervention, thus the second aim was not fully achieved.

Potential pharmacist role(s) within a primary care chronic pain team were identified using questionnaires sent to a random selection of GPs, community pharmacists and physiotherapists. Most pharmacists wanted to provide more analgesic advice, a finding supported by most GPs and physiotherapists. This study has demonstrated both a need for pharmacist input into chronic pain management and evidence that such input would be welcomed.

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## Abbreviations

ACR	American College of Rheumatology
ADR	Adverse drug reaction
AIMS 1	Arthritis Impact Measurement Scale 1
AIMS 2	Arthritis Impact Measurement Scale 2
Bd	twice a day
CD4	Cluster differentiation accessory molecules on T (helper) cells
CI	Confidence Interval
COX-1	Cyclo-oxygenase enzyme 1
COX-2	Cyclo-oxygenase enzyme 2
CSM	Committee on Safety of Medicines
Df	degree(s) of freedom
DMARD	Disease-modifying antirheumatic drug
DNA	Deoxy-ribonucleic acid
DNIC	Descending noxious inhibitory control
ESR	Erythrocyte sedimentation rate
FBC	Full blood count
GI	Gastrointestinal
GM-CSF	Granulocyte-macrophage colony stimulating factor
GP	General Practitioner
GPASS	General Practice Administrative System for Scotland
H pylori	Helicobacter pylori
H2	Histamine receptor (Type 2)
HAQ	Health Assessment Questionnaire

HLA-DR $\beta$	Human leucocyte Class II antigen (DR beta sublocus)
IL-6	Interleukin 6
Int 1	Interview 1
Int 2	Interview 2
LHCCs	Local health care co-operatives
Mane	in the morning
MHC	Major histocompatibility complex
MOS	Medical Outcomes Study
MPQ	McGill Pain Questionnaire
MYMOP	Measure Yourself Medical Outcome Profile
NHP	Nottingham Health Profile
NICE	National Institute for Clinical Excellence
NHS	National Health Service
NMDA	N-methyl-D-aspartate
NNT	Number needed to treat
No.	Number
Nocte	at night
NSAID	Non-steroidal anti-inflammatory drug
NWC	Number of words chosen
OA	Osteoarthritis
OTC	Over-the-counter
P	Probability
PACT	Prescribing Analysis and Cost Data
PAGM	Periaqueductal grey matter
PCGs	Primary care groups
PCTs	Primary care trusts

PGE1	Prostacyclin
PGE1	Prostaglandin E1
PGE2	Prostaglandin E2
PGI	Patient Generated Index
PPI	Present Pain Intensity
PRI (S)	Pain Rating Index (Scale)
PRI (S) A	Pain Rating Index (Scale) – affective category
PRI (S) E	Pain Rating Index (Scale) – evaluative category
PRI (S) M	Pain Rating Index (Scale) – miscellaneous category
PRI (S) S	Pain Rating Index (Scale) – sensory category
PRI ®	Pain Rating Index (Rank)
PRI ® A	Pain Rating Index (Rank) – affective category
PRI ® E	Pain Rating Index (Rank) – evaluative category
PRI ® M	Pain Rating Index (Rank) – miscellaneous category
PRI ® S	Pain Rating Index (Rank) – sensory category
Prn	as required
Qid	four times a day
QOL	Quality of life
R	correlation coefficient
RA	Rheumatoid arthritis
RA/OA	Rheumatoid arthritis and osteoarthritis
RPSGB	Royal Pharmaceutical Society of Great Britain
Rx	Prescribed medication
SD	Standard Deviation
SEIQoL	Schedule for the Evaluation of Individualised Quality of Life
SF-36	Short Form-36 Health Survey

SIP	Sickness Impact Profile
SODoH	Scottish Office Department of Health
T cells	Thymus-derived lymphocyte cells
TNF- $\alpha$	Tumour necrosis factor-alpha
UK	United Kingdom
UKSIP	United Kingdom Sickness Impact Profile
USA	United States of America
VAS	Visual analogue scale
VAS av	Visual Analogue Scale – average pain over the past month
VAS average	Visual Analogue Scale – average pain over the past month
VAS now	Visual Analogue Scale – pain at time of interview
VAS worst	Visual Analogue Scale – worst pain over the past month
WCC	White cell count
WHOQOL	World Health Organisation Quality Of Life
%	percentage
$\chi^2$	Chi-squared



## **Chapter 1**

### **Chronic pain**

#### **1.1 Definitions of chronic pain**

Pain is defined as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’ (Merskey 1986). Chronic pain is defined as pain that persists for longer than 3 months which recurs on a regular basis or is ongoing on a daily basis, and can be classified into recurrent, malignant or non-malignant pain (O’Hara 1996).

Recurrent pain is episodic with a predicted end, but can recur frequently after pain-free episodes e.g. migraine. Chronic malignant pain is pain which lasts for months or years but does have a finite time span e.g. cancer pain. Chronic non-malignant pain or chronic ‘benign’ pain recurs daily with variable intensity, where the pain has no predictable end and often does not respond to treatment e.g. peripheral neuropathy, low back pain, rheumatoid arthritis, osteoarthritis. The term ‘benign’ is a misnomer, because patients with such pain suffer significant physical and psychological trauma (O’Hara 1996).

#### **1.2 Types and locations of pain**

Pain can be categorised by its source. Superficial pain occurs when the surface tissue receptors are stimulated and is often sharp whereas deep pain can occur deep in the viscera or within muscles or tendons, the latter often poorly localised. Localised pain comes directly from a site of injury whereas referred pain is pain felt in an area remote from site of injury. Projected pain occurs when pain messages are set up at a point along the pain pathway beyond peripheral pain receptors e.g.

phantom limb pain. Patients with psychogenic pain have no detectable organic lesion or stimulation, although the pain is very real to the patient and is thought to be a physical manifestation of a psychological disturbance (O'Hara 1996).

Intractable pain refers to any chronic pain which cannot be controlled effectively by medication. Most patients with chronic pain have pain due to a physical cause, with emotional and behavioural factors influencing their perception and expression of the pain. Such psychological factors have been shown to diminish on appropriate pain management (Sternbach and Timmermans 1975).

### **1.3 Physiology of pain**

There are a number of different components involved in pain processing and response, which affect both pain perception and behavioural outcome i.e. reflex motor/autonomic, sensory-discriminative, cognitive-evaluative and motivational-affective components.

When a painful or noxious stimulus is applied to sensitive tissues in skin, muscle and around joints, specialised afferent nerves called nociceptors are activated. These nociceptors respond to noxious stimuli, which do not always elicit pain. Moreover, pain can arise without nociceptor stimulation (Jones 1997). Non-nociceptive pain is that experienced in neuropathic or psychogenic pain whereas nociceptive pain usually describes inflammatory pain.

Receptor activation translates the heat, chemical or mechanical stimulus into a nerve impulse along the primary afferent nerve. These nerve impulses are then 'coded' and their messages transmitted via synapses with neurones largely within the dorsal horn (specific nociceptor and multi-modal non-specific neurones) and the ventral root of the spinal cord.

When trauma first occurs, the initial sharp, localised pain (epicritic) is quickly transmitted by A-delta fibres after which, the second pain, (protopathic) a more diffuse, dull and throbbing sensation is C-fibre mediated. Activation of the A-beta fibres occurs when rubbing of the skin (cutaneous stimulation) is initiated (Jones

1997). In patients with chronic pain, these components of pain perception may not be readily defined.

Thereafter, some impulses pass directly to motor neurones to initiate a reflex response, while the majority of pain impulses cross to the opposite side of the spinal cord and ascend via the anterolateral spinothalamic tract and the brain stem to the medial and lateral thalamic nuclei of the brain. These spinothalamic tracts project to the somatosensory cortex and are thought to serve the discriminative and sensory aspects of pain providing information about the location and quality of the painful impulse. A less specific pathway, involving the spinoreticular tract, makes widespread and diffuse connections with areas of the forebrain especially the limbic system, and is involved in the affective aspects of pain (Jones 1997).

Jones (1997) has defined central pain transmission in terms of a pain matrix to process both acute and chronic pain. The more frontal cortical structures of the brain are sensitive to the suffering component of chronic pain and may be involved in processing the affective and attentional components of pain (Jones *et al* 1993). Investigations in cortex responses to pain in controlled studies of patients with rheumatoid arthritis and atypical facial pain suggest that response patterns in different types of chronic pain may reflect differences in affective and attentional responses to acute pain (Jones *et al* 1993).

Several chemical compounds have been shown to accumulate near nociceptors after tissue injury has taken place and may either activate nociceptors directly e.g. histamine, bradykinin and potassium or are potent mediators of the pain response e.g. prostaglandins and leukotrienes. Histamine also causes vasodilation, while bradykinin both directly and indirectly stimulates nociceptors causing hyperalgesia (enhanced pain). Prostaglandin E2 (PGE2), prostacyclin (PGI2) and prostaglandin E1 are potent pain inducers and cause hyperalgesia either directly e.g. PGE2 or indirectly via cyclic -AMP activation or via interaction with bradykinin or histamine e.g. PGE1. Leukotrienes also produce hyperalgesia directly and indirectly (Levine *et al* 1984).

Nociceptors have also been shown to release their own pain producing substances e.g. substance P and N-methyl-D-aspartate (NMDA). Substance P, a peptide, released from C fibres excites pain transmission pathways in the dorsal horn and is also a potent vasodilator, releasing histamine which stimulates nociceptors

further (Levine *et al* 1988). Prolonged release of substance P and NMDA probably have a role to play in primary and secondary sensitisation to pain, the latter occurring when both noxious and originally non-noxious stimuli give rise to pain. The importance of neuromodulation of pain in both inflammatory and neurogenic pain is well reviewed by Woolf (1994).

## **1.4 Pain control mechanisms**

Gate control mechanisms, central descending control pathways, opioid receptors and endogenous analgesics all have roles to play in pain control (Reisner-Keller 1992, O'Hara 1996, Jones 1997).

The 'gate-control' mechanism postulated by Melzack and Wall (1965) is still widely accepted to explain how pain signals are obtained, transmitted and interpreted within the central nervous system. The basic concept is that transmissions of stimulated afferent pathways are blocked or filtered by a synaptic gate in the substantia gelatinosa in the dorsal horn of the spinal cord, which contains both inhibitory and excitatory interneurons. The extent to which the gate is opened or closed is controlled by the activity of other afferent inputs to the spinal cord and the descending pathways from the brain stem including the descending noxious inhibitory control (DNIC), located in the periaqueductal grey matter (PAGM). The precise roles of the DNIC are unclear, but it seems to be more involved in increasing pain discrimination rather than painful stimulus suppression (Jones 1997) and inhibits the nociceptive responses at dorsal horn level, possibly stimulating the gate control mechanism (O'Hara 1996).

The role of opioid receptors (mu, delta, kappa and sigma) in pain control is well reviewed by Reisner-Keller (1992) and Yaksh (1984).

Endogenous opioids (enkephalins and dynorphins) help regulate the pain response and appear to act as excitatory transmitter substances which inhibit the nociceptive pathway and close the pain gate. The enkephalins and dynorphins

regulate pain perception largely within the medulla, while the endorphins and enkephalins act within the dorsal horn and the substantia gelatinosa.

Enkephalins and beta-endorphins are potent mu and delta agonists, while dynorphins bind preferentially to kappa receptors (Carmody 1987). Such systems are activated by stress responses to increase enkephalin or endorphin release e.g. eating, drinking, exercise, acupuncture, but such release can be inhibited by prolonged pain and alcohol.

## **1.5 Physical and psychosocial consequences of chronic non-malignant pain**

Chronic non-malignant pain continues beyond the expected healing time of a specific insult and is seldom accompanied by autonomic symptoms including tachycardia and sweating which occur in acute pain. Patients with chronic pain often do not show any underlying pathophysiology, but the pain can arise from viscera, muscle and connective tissue (musculoskeletal disease) or from neurological sites e.g. peripheral neuropathy.

Chronic pain causes significant lifestyle changes e.g. giving up work due to pain, inability to perform everyday tasks such as bathing or cooking and can lead to loss of role and self-esteem (Yelin *et al* 1987). The complex problems faced by patients with chronic pain can be described in terms of a chronic pain model, consisting of physical disability, depression, side effects of medication and dependence on family and the medical profession (O'Hara 1996).

Such patients with chronic pain often have had their pain treated in the traditional 'medical model' where diagnosis of the cause of the pain is expected, the doctor is regarded as the expert, therapy is very 'cure' orientated and patients consequently can feel out of control. People with chronic pain tend to have a lifestyle which consists of times of over-activity and under-activity. When pain has improved, efforts are made to catch up with activities left undone due to pain. When pain exacerbates, patients require rest, medication and consequently become frustrated and depressed (O'Hara 1996).

Pain - related behaviour in patients with chronic pain depends not only on the patient's perception of their own pain, but also the duration of pain and other people's reaction to their pain behaviours. Patients may become absorbed by their pain and this behaviour can become a habit even when pain is less severe, resulting in isolation from family and friends (Skevington 1990).

Skevington (1990) identified psychosocial problems of patients with arthritis which included uncertainty, loss of control of life events and lack of family support. Although depression has been shown to arise as a consequence of arthritis or as a separate psychological problem (Newman *et al* 1989), its prevalence in rheumatoid arthritis may have been overestimated due to the use of self-report questionnaires (Ash 1990). Indeed, Ash (1990) has identified psychosocial factors including social isolation, long term illness of family, and consulting behaviours of patients such as disproportionately frequent or early attendance at clinic, associated with depression in rheumatoid arthritis.

## **1.6 Assessment of chronic pain**

The difficulties associated with pain assessment arise from its subjectivity, multidimensional nature and the numerous personal, psychological, cultural and environmental factors which influence different peoples' perception and response to the same pain stimulus (Tursky *et al* 1982).

A wide variety of subjective and objective methods of pain measurement exist. Subjective methods tend to assess the sensory aspects of pain and the patient's emotional response to that painful experience using intensity scales, while objective methods may try to differentiate the strength of the painful stimulus from the patient's subjective response. The latter technique has been used in clinical studies to determine whether analgesics reduce the pain experience itself or make the patient less likely to call the stimulus painful (McDowell and Newell 1996).

Assessment of pain may involve the use of pain questionnaires, observation of pain behaviour or use of analogue methods. Pain questionnaires tend to concentrate on measuring pain intensity and duration e.g. visual analogue scales and numerical

rating scales (Jensen *et al* 1986) but can also provide a more qualitative description of pain and a measure of the patient's affective response e.g. McGill Pain Questionnaire (Melzack 1975). Behavioural rating scales are also used to assess pain, since pain often causes involuntary or voluntary change in behaviour e.g. reduction in physical function or an involuntary body movement (McDaniel *et al* 1986). Analogue methods try to correlate a patient's 'typical' pain with pain experimentally induced in an attempt to assess individual patients' maximum tolerance level. However, it has been suggested that the results obtained using analogue methods may not mimic what would happen in reality (McDowell and Newell 1996).

McDowell and Newell (1996) have extensively reviewed the most widely used and validated pain scales in terms of their purpose, description, applicability, reliability and validity. Pain scales which are commonly used in clinical practice for the assessment of chronic pain include the Visual Analogue Rating Scale (Scott and Huskisson 1976), the McGill Pain Questionnaire (Melzack 1975), the Brief Pain Inventory (formerly the Wisconsin Brief Pain Questionnaire) (Daut *et al* 1983), the Oswestry Low Back Pain Disability Questionnaire (Fairbank *et al* 1980) and the Pain Perception Profile (Tursky 1982).

Visual Analogue scales (VAS) are simple, sensitive methods to assess subjectively not only pain intensity, but also pain frequency, and have been incorporated into health-related quality of life instruments (McCormack *et al* 1988). Initial and subsequent VAS pain ratings correlate well and the scale can be descriptive (none, slight, moderate or complete relief) or a VAS scale ranging from no to complete pain relief (Scott and Huskisson 1976). An advantage of the pain relief VAS is that each patient has the same extent of potential response whatever his initial pain (Sriwatanakul *et al* 1983). Downie *et al* (1978) suggested that a 10 point numerical rating scale was more reliable than the VAS due to the risk of user error especially those with literacy problems.

Reliability of the VAS when printed horizontally or vertically is good, but correlation of horizontal scores can be slightly less than vertical scores (Scott and Huskisson 1976). However, horizontal scales may have a reduced failure rate, provide less distortion and are generally preferable (McCormack *et al* 1988). The validity of VAS has been investigated and found to be high when compared with a

four-point descriptive pain rating scale (Downie *et al* 1978). The VAS correlated well with a verbal rating scale and was more sensitive than the latter, hence useful in small sample studies. Since both the 10 point numerical rating scale and VAS have similar responsiveness, Guyatt *et al* (1987) have suggested that numerical rating scales should be recommended in small sample studies.

Good correlations have been found between VAS and the McGill Pain Questionnaire (MPQ) scores (McCormack *et al* 1988), the results of which have varied with the type of patient interviewed and scoring used (Perry *et al* 1988).

## **1.7 Rheumatoid arthritis**

### **1.7.1 Aetiology, epidemiology, pathogenesis, diagnosis and clinical findings of rheumatoid arthritis**

Rheumatoid arthritis (RA) is the commonest form of inflammatory arthritis which affects about 1% of the population, affecting more females than males (3:1) and has a peak onset between the ages of 30-50 years, although age of onset is now increasing and incidence is declining, especially among women (Silman 1997).

In RA extensive morbidity is associated with joint destruction and patients have an increased rate of mortality due to cardiovascular, respiratory, renal diseases, infection and medication with estimates of loss of life expectancy varying from 3-18 years (Scott and Symmons 1986). In primary health care, rheumatic symptoms are the most common problems seen by most general practitioners (GPs), representing 15% of all GP consultations i.e. more than 8 million consultations per year (Ashcroft 1997).

The aetiology of the disease is still unclear, but research does suggest that genetic, environmental, hormonal, viral, autoimmune and other factors have a role in causing RA, all of which have been well reviewed (Panayi and Welsh 1988, Yaron 1995).

A genetic predisposition may reside in the major histocompatibility complex molecule (MHC) which binds antigen and presents it to T cells, especially in severe



RA (Emery *et al* 1992). This MHC marker may be able to predict those patients most at risk of severe disease and thus who require early aggressive management (Bensen *et al* 1997), although some studies have found poor predictability (Emery *et al* 1992). No joint specific antigens have yet been found but research suggests that immune mechanisms against 'self' break down to cause joint-specific diseases such as RA. Intracellular signalling pathways regulating DNA sequence-specific transcription factors which turn genes off or on and play a key role in joint erosion and inflammation have been found in patients with RA (Lewis 1997).

Rheumatoid arthritis is characterised by infiltration of the synovium with lymphoid cells such as B and T lymphocytes and macrophages, proliferation of the synovial membrane and joint destruction. Macrophages and fibroblasts dominate the chronic phase of the disease by production of cytokines (small protein messengers that mediate inflammatory and immune responses). They maintain the chronic synovitis and induce matrix metalloproteinases (Buckley 1997) which play a significant role in joint destruction. Genes for cytokine production are over-expressed in patients with RA.

The most pro-inflammatory cytokines released by macrophages are Interleukin 1 (IL-1) and tumour necrosis factor (TNF- $\alpha$ ) and are well reviewed by Maini (1996). IL-1 and TNF- $\alpha$  encourage chemotaxis and stimulate the release of other immunological, enzymatic or inflammatory mediators such as Interleukin 6 (IL-6), granulocyte-macrophage colony stimulating factor (GM-CSF), prostagandin E2 (PGE2), collagenase and substance P. Synovial fibroblasts, after stimulation by IL-1 and TNF-  $\alpha$ , produce collagenase, PGE2 and plasminogen activator. Hyperactivity of T lymphocytes in peripheral blood and synovial fluid develops, which encourages further cartilage degradation and synovial tissue proliferation (Buckley 1997). This destruction ultimately causes limitation of movement, pain and joint destabilisation.

Criteria for classification of RA, such as those developed by the American College of Rheumatology (Arnett *et al* 1988) were originally developed to act as a standard for purposes of investigation. These criteria are not helpful in making an early diagnosis of the disease, which is vital to identify those most at risk of debilitating disease and to optimise therapy (Prouse 1998). Long-term studies of patient groups from arthritis clinics have demonstrated that polyarthritis of the small joints and the presence of serum rheumatoid factor can predict the development of

persistent rheumatoid disease (Emery *et al* 1992). Other features predictive of RA are early morning joint stiffness and fatigue. In individuals, recent studies suggest that accurate and early diagnosis is best achieved by a rheumatological team (Panush *et al* 1995).

There are as yet, no simple and reliable markers of disease severity to help clinicians titrate therapy to each individual and target those patients most in need of aggressive therapy. While studies have demonstrated variable abilities in the presence of rheumatoid factor and the HLA-DR $\beta$  epitope to predict disease severity (Emery *et al* 1992), longer prospective studies have shown that female gender, early development of erosions, greater disability and older age at initial presentation are more reliable predictors of poor functional outcome (Zwillich 1997, Akil and Amos 1995(A)).

Mild to moderate RA is characterised by tenderness on palpation or pain on movement of involved joints usually those of hands, feet, wrists and/or ankles. In patients with moderate to severe arthritis, signs will be more severe with swelling due to synovial proliferation, while progressive disease is characterised by joint malformations and instability with disabling deformity particularly damage to weight bearing joints. Extra-articular consequences of RA, usually indicating more severe disease, are rheumatoid nodules in the lungs and heart, renal problems, anaemia, depression, pericarditis and ocular problems.

### **1.7.2 Management of rheumatoid arthritis**

The aims of rheumatoid arthritis treatment are to improve or maintain existing function, prevent the development of the patient's joint and extra-articular disease and to minimise side effects of therapy. Since there are no disease-specific clinical, immunological or radiological features with which RA can be identified, diagnosis and hence the initiation of appropriate therapy can be delayed (Platt 1997, Prouse 1998). Such a delay is worrying, especially since research has found that the rate of RA progression is greatest in the first 2 years of the disease and during this phase, the inflammatory features are more easily controlled (Platt 1997).

Management of RA can involve both drug and non-drug management strategies. Drug management of RA includes simple analgesics (Boyce 1992), non-

steroidal anti-inflammatory drugs (NSAIDs) (Anon 1994), disease-modifying antirheumatic drugs (DMARDs) (Anon 1998, Medicines Resource Centre 1996), immunosuppressants, corticosteroids, homeopathic and herbal products (Watson and Dieppe 1998, Mills *et al* 1996). Other experimental therapies include minocycline, gene therapies, CD4 antibodies and antibodies to TNF-alpha (Watson and Dieppe 1998, Breedveld 1997).

Non-drug management generally involves patient education, rest, exercise and surgery (Akil and Amos 1995(B), Boyce 1992). Donovan *et al* (1989) demonstrated that patient beliefs very much influenced their concordance with RA drug therapy, while Stenstrom *et al* (1997) identified specific patient factors which promoted compliance with home exercise programmes. Indeed, recent guidelines have recommended that 'all arthritis patients should receive enough information to understand the type of arthritis they have and its likely process together with information on enabling them to learn how to manage their arthritis' (Rowan *et al* 1997). Cognitive behavioural programmes encourage a multidisciplinary input from health care professionals such as physiotherapists, occupational therapists and psychologists, and include muscle relaxation, distraction and imagery techniques to help the individual regain control over his / her life. Such programmes have been shown to increase work, social and leisure activities in patients with RA as well as decrease chronic pain behaviour and anxiety (Anderson *et al* 1985).

Surgery is useful in repairing or replacing damaged joints, correcting ligament or tendon instability, reducing compression of the spinal nerves and the spinal cord. Its applications in RA are well reviewed by Oliver (1997).

Traditionally, the therapeutic management of rheumatoid arthritis has been a 'pyramid approach' whereby NSAIDs were initially used as baseline symptomatic therapy, after which individual DMARDs were prescribed as patients' disease progressed, usually hydroxychloroquine or sulphasalazine first line followed by gold or penicillamine depending on efficacy and side effects (Bensen *et al* 1997). If the disease deteriorated further, third line agents were used including oral corticosteroids and other immunosuppressants (Platt 1997).

This model has been criticised for providing a simplistic approach to a complex disease (Bensen *et al* 1997), assuming that DMARDs were more toxic than NSAIDs and that RA was a 'benign' disease, resulting in DMARDs being initiated

once radiological evidence of damage had occurred. The use of DMARDs in this way, suppressed disease activity and improved function, slowing joint deterioration, but long-term improvements in disability were not frequently obtained (Anon 1993). Fries *et al* (1996) followed up 2888 RA patients prospectively between 1980-90 and found that patients who were more extensively treated with DMARDs showed disability levels which were 40% lower than those of the group who had little DMARD exposure.

New therapeutic pyramids have now been proposed to ensure early, aggressive management of RA such that NSAIDs, DMARDs and steroids as well as health professionals' input are used early in combination, depending on initial severity of disease (Bensen *et al* 1997). Since erosive changes are late markers of RA indicating joint damage, and such joint damage and functional disability occur commonly within the first 2 years of the disease (Egsmose *et al* 1995), DMARDs are now started shortly after a diagnosis of RA has been established to improve long-term outcomes (Anon 1998). Patients with moderate disease may benefit from a combination of DMARDs to improve efficacy and limit drug toxicity (Pratt 1997, Anon 1998). However, much of the clinical evidence for this use has come from small, uncontrolled trials. Some results from randomised, double blind trials suggest that combinations of methotrexate and sulphasalazine or methotrexate with cyclosporin can improve outcomes with no increase in toxicity (Boers *et al* 1997, Tugwell *et al* 1995).

NSAIDs, unlike DMARDs, only provide symptomatic relief by inhibition of prostaglandin synthesis in inflamed tissues and do not influence the acute-phase response or reduce the development of joint erosions. The hypothesis that NSAIDs which inhibit the cyclo-oxygenase enzyme 2 (COX-2) more selectively than COX-1 enzyme may be more effective anti-inflammatory agents with minimal gastrototoxicity than non-selective agents is still under investigation (De Brum-Fernandes 1997). The COX-2 enzyme is thought to be more involved with prostaglandins involved in the inflammatory response, while the COX-1 enzyme controls those participating in gastric mucosa function. Recent evidence using selective COX-2 inhibitors in RA have demonstrated significant improvements in the signs and symptoms of RA (Lipsky and Isakson 1997).

Guidelines for the appropriate choice, use and monitoring of NSAIDs in RA have been developed to maximise efficacy and minimise the toxicity of NSAIDs (Anon 1994, Scottish Medicines Resource Centre 1995, Committee on Safety of Medicines 1994). Pharmacists have adopted strategies to help review NSAID prescribing to ensure that such prescribing is cost effective (Hampal 1997).

The choice of DMARD depends initially on each drug's efficacy and toxicity profile and ease of monitoring (Platt 1997, Anon 1998). The American College of Rheumatology (ACR) has now recommended specific criteria for assessing positive outcomes in terms of joint inflammation, overall disease activity, pain and disability (Felson *et al* 1995). An improvement of at least 50% on the ACR criteria has been recommended as a valid indicator towards achieving complete suppression of the active disease (Anon 1998). Studies have demonstrated that a good response with an NSAID in mild disease is suggestive of a good response with a DMARD (Platt 1997).

In the UK, sulphasalazine and methotrexate tend to be the DMARDs of first choice now (Medicines Resource Centre 1996), with gold use declining due to its toxicity profile (Watson and Dieppe 1997, Anon 1998). Analysis of pooled data suggest that sulphasalazine, methotrexate, intramuscular gold and penicillamine are similar in efficacy but more effective than auranofin or the antimalarials. However, the response to methotrexate seems to occur much earlier than with other DMARDs (Anon 1998). The efficacy of all DMARDs has been recently reviewed (Platt 1997, Anon 1998, Medicines Resource Centre 1996).

Discontinuation of DMARDs is quite common due to their toxicity profile, lack of sustained effect or limited efficacy (Felson *et al* 1990). The toxicity of methotrexate and sulphasalazine is much lower than that of intramuscular gold and their discontinuation rate is lower than that for other DMARDs (Felson *et al* 1990). Other researchers have suggested that patients' psychological wellbeing prior to DMARD use and disease activity are important predictors of discontinuation of initial DMARD treatment (Listing *et al* 1997).

With the increasing early use of DMARDs and thus the need for accurate diagnosis and effective monitoring of therapy, the resources in hospital rheumatology units are increasingly overstretched to meet demands (Platt 1997). Unfortunately, recent studies are indicating that GPs are increasingly unwilling to

initiate DMARD therapy, provide essential information about DMARD therapy and / or are unable to monitor therapy effectively (Anon 1996(A), Anekwe *et al* 1997), thus rheumatology nurses and pharmacists are increasingly required to adopt these roles (Kay 1997, Hill *et al* 1997).

Immunosuppressants such as cyclosporin and cyclophosphamide have until recently been restricted to management of RA which was unresponsive to other treatments (Watson and Dieppe 1998, Anon 1993). Recently, cyclosporin has been licensed for RA use and is suggested to be as efficacious as sulphasalazine when used early in the disease, despite its use being limited by its side effects (Platt 1997).

No clear indications and guidelines have been developed for the use of steroids in RA. They can be given orally, as intravenous pulse therapy and as intramuscular or intra-articular injections (Coombes and Bax 1996). Low dose oral corticosteroids (i.e. 5-10mg prednisolone daily) are used in about 20-30% of RA patients, particularly those refractory to other treatments and in the elderly, in whom steroids may be safer than NSAIDs (Platt 1997, Coombes and Blax 1996). Studies are still inconclusive as to whether steroids have a disease-modifying effect. Although some patients benefit from the addition of low dose oral corticosteroids to existing DMARD therapy, the effect is only sustained for 6-9 months. Moreover, a significant rebound of disease activity can result as the dose is tapered down, making discontinuation difficult and long-term toxicity a potential problem (Coombes and Blax 1996). A recent meta-analysis (Saag *et al* 1996) and a low dose prednisolone study (Kirwan 1995) suggest that low dose corticosteroids do slow down erosions as evidenced by radiological examination, but it is unclear if these benefits are sustained after the treatment period or outweigh long-term side effects.

Intravenous pulse therapy with, for example, methylprednisolone has been used to induce remissions in severe disease prior to onset of activity of a DMARD and to limit the side effects of oral steroids, however cardiac arrhythmias can occur. Intramuscular methylprednisolone or triamcinolone have been used to control acute RA exacerbations and as induction agents with DMARDs (Platt 1997).

Intra-articular steroids have no disease-modifying effect, but provide symptomatic relief by reducing joint inflammation with minimal side effects, but good injection technique is required and the frequency of injections per joint is limited (Coombes and Blax 1996).

## **1.8 Osteoarthritis**

### **1.8.1 Aetiology, epidemiology, pathogenesis, diagnosis and clinical findings of osteoarthritis**

Osteoarthritis (OA), a degenerative disease, is the most common rheumatic disease, although its precise incidence is hard to define due to discrepancies in diagnosis and the low correlation between clinical symptoms and radiological evidence of the disease. Approximately 12% of the general population aged 65 years or older are affected by OA (Watson 1997). The onset of OA begins around middle age and is more common in men before age 45 but more common in women after age 45.

In many people, the disease occurs spontaneously and no previous cause is identified (primary osteoarthritis), and is a generalised arthritis involving multiple joints usually those of knee, hand, hip or spine. In other patients, especially middle aged women, osteoarthritis may start with inflamed Heberden's nodes. Secondary osteoarthritis may demonstrate unusual patterns of joint involvement and may co-exist with rheumatoid arthritis (Hutton 1995).

Researchers suggest that the aetiology of OA is multifactorial with age, genetic, patient-specific and environmental risk factors identified (Mahoney *et al* 1992).

In osteoarthritis, unlike RA, the effects are limited to the joints and result from changes in the biochemical composition of articular cartilage. The articular matrix becomes poorly regulated, associated with cartilage hydration, loss of elasticity and cartilage breakdown. Underlying bone then becomes exposed, sclerotic and prone to hypertrophy, leading to fracture, subchondral cyst and osteophyte development. These osteophytes can then cause joint enlargement, spinal compression and joint

immobility. Chronic inflammation of the synovium is caused by collagen fragments and proteoglycan subsequent to proteolysis of collagen (Mahoney *et al* 1992).

The diagnosis of OA is based primarily on clinical symptoms and radiographical findings. Clinical symptoms may include intermittent pain, the pattern of which depends on the affected joint(s), limited range of movement of an affected joint, stiffness after inactivity, crepitus (where the joint 'crackles' due to bone and cartilage rubbing together) and disability. Radiographical changes diagnostic of OA include the narrowing of joint space, sclerosis of subchondral bone and the presence of subchondral cysts and osteophytes (Hutton 1995).

Recent guidelines from the Primary Care Rheumatology Society 1995, suggest that localised pain, restricted movement, joint stiffness and tenderness and radiographical changes are required to confirm the diagnosis.

### **1.8.2 Management of osteoarthritis**

The aims of OA management are to relieve symptoms, reduce disability, limit further joint damage, preserve existing joint function and maintain a good quality of life (Mahoney *et al* 1992, Primary Care Rheumatology Society 1995). Thus OA treatment programmes include non-pharmacological therapy, pharmacological therapy and surgical intervention, depending on disease severity and patient concordance (Watson 1997).

Non-pharmacological therapy has a very important part to play in OA management and includes patient education, physiotherapy, weight reduction, occupational therapy and use of appropriate aids. Surgical intervention is indicated when pain and joint stiffness and deformity is uncontrolled, performed most frequently on the hip and knee joints via arthroplasty (Anon 1996(B)).

A randomised, controlled trial by Weinberger and colleagues in 1989 demonstrated the importance of ensuring patients are well informed about and agree with the specific management plan for their own OA to maximise outcomes of therapy. Some evidence exists regarding the importance of self-management courses in improving health outcomes and reducing consultations, but this was an uncontrolled study (Lorig *et al* 1993). National management guidelines for both OA



and RA now recommend that patients should be given access to the whole primary care team, primarily the GP, to encourage the development of an individual management plan and to discuss the importance of self-help, physiotherapy, exercise, aids and the benefits and limitations of medication (Primary Care Rheumatology Society 1995, Rowan *et al* 1997).

Randomised controlled studies have demonstrated the benefit of physiotherapy and exercise to improve function, pain and gait pattern in OA patients (Kovar *et al* 1992). Puett *et al* (1994) have reviewed the benefits of specific aids such as walking frames to stabilise joints and compensate for joint length inequalities.

Pharmacological therapy is aimed at alleviating pain and improving joint function and may include the use of topical therapies such as rubefacients, NSAIDs, capsaicin or intra-articular corticosteroids or systemic treatments such as simple analgesics e.g. paracetamol or combination analgesics, oral NSAIDs and low dose antidepressants (Anon 1996(B)).

Topical analgesic preparations in current use can be classified in 3 groups: (1) rubefacients, (2) formulations based on NSAIDs including diclofenac, ibuprofen and piroxicam and (3) a miscellaneous group including benzydamine and capsaicin (Li Wan Po 1997).

Rubefacients, benzydamine and capsaicin are thought to mediate their pain relief by counter-irritancy, depressing the activity of T cells in the spinal cord, but this theory does not help to explain their prolonged effect. Among the latter drugs, only capsaicin has demonstrated clinical effectiveness in randomised controlled trials in OA (Schnitzer *et al* 1995, McQuay *et al* 1997). Capsaicin causes analgesia by depleting sensory neurones of substance P, has been recently marketed for the treatment of osteoarthritis as a 0.025% cream and has been recommended as a useful second line treatment in OA after simple analgesics (Primary Care Rheumatology Society 1995).

Until recently, there was considerable doubt of the superiority of topical NSAIDs over simple rubefacients, despite their wide use in sports injuries, acute soft tissue injuries, rheumatoid arthritis, osteoarthritis and back pain (Anon 1994, Medicines Resource Centre 1997). Well conducted placebo-controlled, double blind studies used to assess topical NSAID efficacy have often had many difficulties

including lack of sensitive and specific outcome measures, lack of consistency of use of the same pain measurement and high placebo responses in patients (Buchanan 1997, McQuay *et al* 1997). Both felbinac and piroxicam gels have been studied in OA of the knee compared to oral ibuprofen, with only limited improvement in efficacy with piroxicam as compared to placebo (McQuay *et al* 1997).

A large recent systematic review comparing topical NSAIDs with placebo, or with oral or other topical NSAIDs on the basis of number needed to treat (NNT), demonstrated that 7 of the 13 placebo-controlled trials involving patients with chronic arthritis showed NSAIDs to be more effective than placebo (NNT=3.1) (Moore *et al* 1998). Moreover, there was no significant difference in the incidence of side effects with topical NSAIDs as compared to placebo in the chronic groups. When 5 studies comparing topical with oral NSAIDs were reviewed, oral therapy did not confer any additional benefit over topical therapy. Such findings may encourage topical therapy to be used in preference to oral NSAIDs especially in high risk groups such as the elderly. At least one large, 2 phase, randomised, controlled trial of a topical NSAID is still needed e.g. ibuprofen, incorporating an early phase to determine effectiveness and a longer phase to establish the efficacy / toxicity profile (McQuay *et al* 1997).

Intra-articular steroids such as methylprednisolone or triamcinolone are commonly used to treat knee and thumb joint synovitis in OA (Anon 1996(B)). Limited trial data exists regarding the efficacy and optimal frequency of administration of such injections (Anon 1995).

Systemic treatments for OA may be required if non-pharmacological and / or topical therapies fail to control symptoms. Paracetamol should be used first line, since the few studies which have compared paracetamol against either NSAID or placebo in OA suggest that paracetamol is as effective as NSAIDs in OA, is cheaper and has an improved side effect profile (Dieppe *et al* 1993(B), Bradley *et al* 1991). However, a 2 year comparative study of naproxen and paracetamol in patients with OA suggested that some patients may require reintroduction of their NSAID in combination with paracetamol to control symptoms (Dieppe *et al* 1993(A)). Some GP prescribing initiatives have suggested that switching patients with OA from NSAIDs to paracetamol is possible without compromising patient outcome (Helliwell *et al* 1994, Swift and Rhodes 1992). Indeed, one recent randomised study

investigating patient satisfaction with NSAIDs in OA identified that less than 60% of patients reported having used paracetamol as first line therapy and only 50% of patients aged 75 or less could recall if they had been provided with information about their NSAID therapy (Long and Wynne 1996).

Oral NSAIDs should only be initiated if inflammation (often a minor component of OA) as well as pain is present, no contraindications to their use exist and NSAID use is reviewed regularly (Primary Care Rheumatology Society 1995). The choice of NSAID should be one least likely to cause gastrointestinal toxicity e.g. ibuprofen or diclofenac, initiated at lowest effective dose to minimise toxicity and with appropriate renal and gastrointestinal monitoring (Anon 1994, Committee on Safety of Medicines 1994).

Many GPs and hospital clinicians prescribe combination analgesics for patients often inappropriately (Hulme *et al* 1996, Dixon *et al* 1995), due to habit (Haigh 1996), preferred patient preference (Sykes *et al* 1996) or when patients fail to respond to paracetamol and / or NSAIDs. Few trials in OA show that combination analgesics confer any clinical advantage over paracetamol alone (Anon 1996(B)). Li Wan Po and colleagues (1997) recently conducted an overview of 26 randomised trials of paracetamol and coproxamol involving 2231 patients including patients with OA and found that there was little objective evidence to suggest that the combination of paracetamol with dextropropoxyphene was more efficacious than paracetamol alone in treating moderate pain.

Evaluation of the use of opioids in chronic non-malignant pain such as OA has largely been via published surveys and open-label clinical trials. Resistance to opioid use in such patients has been due to perceived lack of efficacy, concerns about addiction, side effects and analgesic tolerance (Portenoy 1990). However, a recent, small, but randomised, placebo-controlled trial in arthritis patients suggests that controlled release opioid formulations significantly improve pain scores and functional ability, although constipation is a long-term problem (Arkinstall *et al* 1995).

## **1.9 Low back pain**

### **1.9.1 Aetiology, epidemiology, pathogenesis, diagnosis and clinical findings of low back pain**

Back pain is an increasing problem in the UK with a 7% prevalence in Scotland as estimated by general practice data (Department of General Practice and Primary Care 1998). The peak incidence of back pain occurs at about 40-60 years with chronic back pain more frequent with increasing age. Surveys show that 6% of employed people lost at least 1 working day because of back pain in the past month, which represents about 52 million working days lost in Britain. Back pain is estimated to cost the NHS about £481 million a year, such that a typical GP practice with 5 GPs and 10,000 patients would have consultation and drug costs around £88,000 (Clinical Standards Advisory Group 1994).

Diagnosis of low back pain requires an understanding of back pain syndromes and is made on the basis of a patient's history and examination. Back pain syndromes include mechanical back pain or prolapsed lumbar disc and systemic back pain which may indicate a tumour, spinal stenosis, postural or referred pain. Bad posture is probably the commonest cause of persistent back pain but unequal leg length can also be a contributory factor causing a scoliosis (Jenner and Barry 1995).

Investigations of low back pain may include haematological and biochemical tests (to rule out systemic causes), radiography and other imaging techniques to investigate disc lesions. Electromyography can help identify nerve root degeneration.

Most acute episodes of back pain arise from degeneration of the nucleus pulposus in the lumbar disc, but the pain source may not be the disc itself but facet joints and / or surrounding ligaments which become stressed as a result of the degeneration of the disc. This factor may explain why removal of the disc will not always cure the pain. Acute low back pain is often due to accidents or injuries and pain intensity often relates to the degree of tissue damage experienced. Pain and associated functional disability may last up to 3 months.

True sciatica, where pain and numbness occur via a single lumbar root, may be accompanied by motor, sensory or reflex changes and is most commonly caused by a posterolateral protrusion of a disc impinging on the nerve root.

Chronic low back pain, where pain has been established for more than 3 months (Berman and Singh 1997), has a poor prognosis. Degenerative lumbar disease, osteoporosis, ankylosing spondylitis or neoplasia (Porter and Ralston 1994) may cause chronic back pain. However, there is often little physical evidence of injury, with no radiological evidence and patients experience hyperalgesia i.e. an exaggerated response to a stimulus. Chronic pain has a strong psychological component, often expressed as depression and a lack of coping strategy (Berman and Singh 1997).

### **1.9.2 Management of acute and chronic low back pain**

Management of acute low back pain in primary care has been reviewed (Clinical Standards Advisory Group 1994). Current guidelines now aim to relieve pain and disability. The main aim of treatment of chronic back pain is to help patients come to terms with their pain and for them to accept that they can do much themselves to relieve their own symptoms.

Acute back pain management includes the use of physical therapies (manipulation, early active exercise and physical activity), drug therapy, and psychosocial management (patient ownership of disease, coping strategies) within a multidisciplinary environment. Bed rest should not be recommended for simple low back pain (Clinical Standards Advisory Group 1994). If needed, bed rest should be restricted to a few days, which is as effective as 2 weeks (Deyo *et al* 1986).

Drug therapy for acute back pain should be limited to the use of simple analgesics such as paracetamol, then NSAIDs if necessary and ultimately a combination analgesic. If opioids or muscle relaxants are needed, a short course is recommended (Royal College of General Practitioners 1996).

Recent randomised controlled studies in chronic back pain have demonstrated that appropriate exercise programmes are more effective in relieving and lessening pain intensity than bed rest (Timm 1994). Since negative life experiences including stress affect low back pain, pain management programmes encourage patients to

learn coping strategies e.g. problem solving techniques and relaxation to help patients regain control over their own lives. Indeed, combinations of methods including combined mind-body interventions have significantly improved pain, function and mood of patients with chronic back pain (Berman and Singh 1997, McQuay *et al* 1997). More recently, a meta-analysis of 9 randomised, controlled trials of acupuncture used in back pain has suggested that acupuncture may have more than just placebo effects (Barnes and White 1998).

Pharmacological management of chronic back pain has been reviewed by Porter and Ralston (1994) and includes the use of simple analgesics, NSAIDs, opioids, muscle relaxants and tricyclic depressants.

There has been general reluctance to prescribe opioids in chronic non-malignant back pain due to clinician concerns about addiction, side effects and lack of efficacy (Portenoy 1990). Guidelines in the management of chronic pain with opioids have been proposed by Portenoy (1990) to maximise outcomes and to identify those patients in whom opioid therapy would be inappropriate.

Tricyclic anti-depressants particularly amitriptyline can elevate mood and increase pain tolerance in depressed patients reducing chronic back pain (McQuay *et al* 1997). The analgesic effect of an antidepressant occurs usually within one week, but may be delayed for up to 3 months, occurring at a much lower dose than that for an anti-depressant effect i.e. 10-25mg at night increasing to 100-150mg according to symptoms and/or side effects. Non-tricyclic antidepressants have been shown to be less effective in the management of chronic pain (McQuay *et al* 1997).

## **1.10 Patient outcome measures**

### **1.10.1 Health outcomes**

Various definitions of health outcomes have been proposed by researchers to identify the influence of health care on overall health status (McCallum 1993, Shanks and Frater 1993). McCallum (1993) defined a health outcome as “ a natural

or artificially designated point in the care of an individual or population suitable for assessing the effect of an intervention, or the natural history of a condition". Shanks and Frater (1993) thereafter sub-classified outcomes in terms of outcomes, health outcomes, health care outcomes and health outcomes of health care in an attempt to recognise the variety of desired outcomes identified. The latter researchers defined a health outcome as "an effect manifest as a change in health status", but the cause of the change may not be known i.e. social, economic or environmental factors, whereas an outcome was a result in any sphere of life. The term health outcome is still the most widely used.

Health outcomes are being increasingly used to objectively monitor the progress of patients, evaluate the cost-effectiveness of treatment options by managers, clinicians and other health professionals and to develop research strategies (Shanks and Frater 1993). The most frequently reported health outcome measures include morbidity and mortality rates, adverse reactions to drug therapy, physiological changes, hospital admission and re-admission rates and economic changes, all of which are well reviewed (Bowling 1997, McCallum 1993).

Health outcomes are influenced by many factors such as type of disease state or intervention, and factors not generally considered as 'health', making assessment of health outcomes *per se* difficult. Moreover, health outcomes of patients with chronic disease in primary care need to be realistic and centred on the patient. Consequently, researchers have suggested that health-related quality of life is the most important outcome measurement and should be patient-assessed (Guyatt *et al* 1993, Carr *et al* 1996, Ruta *et al* 1994).

### **1.10.2 Health related quality of life**

Health related quality of life or quality of life is a multidimensional concept which measures not just aspects of physical, mental and social functioning, but also areas such as the patient's well being and life satisfaction including housing and occupation (McDowell and Newell 1996). The WHOQOL Group (1993) consider this measure in their definition of quality of life i.e. "an individual's perception of their position in life in the context of the culture and value systems in which they live in relation to their goals, expectations, standards and concerns". Bowling (1995)

thereafter, defined health related quality of life as “the optimum level of mental, physical, role and social functioning, including relationships, perceptions of health, fitness, life satisfaction and well being”. Comprehensive reviews of health related quality of life have been recently published (McDowell and Newell 1996, Bowling 1997, Guyatt *et al* 1993).

There is no clear differentiation between quality of life, health status or functional status, hence the terms are used often interchangeably (McDowell and Newell 1996) although, MacKeigan and Pathak (1992) have suggested that the concepts should be considered separately.

Health related quality of life measurement provides a large number of benefits all of which have been discussed by a number of researchers (McDowell and Newell 1996, Bowling 1997, Carr *et al* 1996) including their use in medical audit, population surveys of perceived health problems and outcome measures and evaluation of clinical trials. In terms of patient outcomes, quality of life assessment encourages the monitoring of patients’ progress and screening for particular problems using a more extensive number of outcome measures rather than just clinical indicators. Patients’ views on the factors which influence their quality of life and on the efficacy of treatment are also investigated (Ruta *et al* 1994). Moreover, the influence of any intervention on patients’ physical, social and psychological status can be assessed. However, outcomes using clinical indicators often do not correlate with quality of life outcomes as perceived by either clinicians or patients (Fitzpatrick *et al* 1992, Guyatt *et al* 1993).

### **1.10.3 Health related quality of life instruments**

Health related quality of life instruments contain a number of items or questions grouped in domains or dimensions, which represent specific aspects of a person’s state of health e.g. social or physical status.

These instruments can be classified in terms of health profiles or health indices. Health profiles provide separate scores for each domain to be measured and allow the researcher to identify factors and the extent to which they are influenced by ill health. Health indices describe quality of life in terms of a single global score



for well-being and are used to analyse the cost-effectiveness of treatment in economic studies.

Researchers have also classified quality of health instruments as generic, disease specific or domain specific (Fletcher *et al* 1992(A) and (B), McDowell and Newell 1996).

Generic instruments cover a broad range of quality of life dimensions in one instrument commonly mental, physical and social health. Such instruments permit comparisons between different disease groups but may be less responsive than disease or domain specific instruments and thus fail to identify small but significant changes in quality of health. The most commonly used generic instruments of health related quality of life used in primary care include Sickness Impact Profile (SIP) (De Bruin *et al* 1992), Nottingham Health profile (NHP) (Hunt *et al* 1985) and Short Form 36 (SF-36) (Brazier *et al* 1992).

Disease specific instruments include domains specific for one particular disease state e.g. the Arthritis Impact Measurement Scales, AIMS1 and AIMS2, (Meenan *et al* 1980, 1992). Such scales have greater patient acceptability and are more sensitive. Domain specific measures contain only items within one domain, usually severity of symptoms or psychological status, which, like disease specific scales could exclude necessary dimensions or may be too narrow an assessment. Consequently, most researchers advocate the use of an appropriate domain or disease specific instrument in conjunction with a generic instrument to investigate broader measures of quality of life while maintaining responsiveness (Fitzpatrick *et al* 1992, Malek 1997).

Quality of life outcomes can be assessed from both the physician's and patient's point of view, assessment of which can differ significantly between groups (Donovan 1991). The importance of different aspects of quality of life varies among and within individuals over time, thus tools which are too structured may be insensitive.

Quality of life measurement scales have been based largely on concepts devised by health professionals. Patient-focused scales should be encouraged to obtain a more accurate assessment of patients' quality of life. In such scales, the patient may be asked to (1) identify and rank the areas of life which they consider most important to their quality of life (Schedule for the Evaluation of Individualised

Quality of Life, SEIQoL, O'Boyle *et al* 1992) or (2) identify their own experience of a disease state and its influence on their outcome expectations as in the Disease Repercussion Profile (Carr *et al* 1996) or both, as in the Patient Generated Index, PGI, (Ruta *et al* 1994) and the Measure Yourself Medical Outcome Profile, MYMOP (Paterson 1996). As more QOL measures are defined by patients, then treatment outcomes will be able to be predicted and assessed with improved validity and reliability.

Almost all QOL scales measure the negative aspects of health, which does not reflect a person's realistic assessment of his / her quality of life in terms of its advantages and disadvantages. It is hoped that new scales such as that devised by the World Health Organisation, the World Health Organisation Quality of Life instrument, (WHOQOL 1993), will help to identify patients' perceptions of the positive aspects of life such as positive feelings, self esteem and body image, and relate quality of life measures to life satisfaction.

Appropriateness of any new health related quality of life instrument is now measured against defined scientific review criteria consisting of 8 qualities developed by the Scientific Advisory Committee of the United States Medical Outcomes Trust which are validity, reliability, responsiveness, interpretability, a conceptual and measurement model, alternative forms, cultural and language adaptations and respondent and administrative burden (Lohr *et al* 1996). Such attributes have been recommended by other investigators (Fletcher *et al* 1992(B), McDowell and Newell 1996).

Validity and reliability measures have been described extensively by other investigators (Deyo *et al* 1991, Bowling 1995, McDowell and Newell 1996).

Validity is defined as the extent to which an instrument actually measures what it is supposed to measure and can be defined in terms of face, content, criterion and construct validity. Face validity is a subjective measurement of whether the instrument seems appropriate and unambiguous. Content validity considers subjectively the extent to which questions within an instrument actually reflect its aims and are usually determined by panels of experts and appropriate lay people. Criterion validity tests how an instrument compares with the 'gold standard' of the area under research. Since health-related quality of life lacks such a standard, criterion validity is rarely carried out thus making it necessary for construct validity

to be investigated. Construct validity relies on linking the attribute we are investigating to other attributes by separate hypotheses and then testing the resultant constructs using the test instrument in different test samples i.e. multiple validity indicators are created by correlating individual domains of the instrument with other validated instruments. Convergent and discriminant validity should also be demonstrated, the former testing for high levels of correlation between health outcome indicators and the latter testing for limited correlation between indicators which are unrelated.

Reliability is the extent to which an instrument will produce consistent results on different occasions when no change has occurred, and is assessed by internal consistency and test-retest methods. Internal consistency investigates how well individual items are inter-correlated and the extent with which they correlate with overall scores, usually determined by calculating Cronbach's alpha statistic. A minimum score of 0.7 and a maximum score of 0.9 is recommended for group comparisons for all reliability tests (Nunnally 1978). Test-retest is the relationship between scores obtained by the same person on 2 or more occasions and is determined for continuous data with a normal distribution by using the Pearson correlation coefficient or intraclass correlation coefficient. Test-retest for continuous data without a normal distribution is determined using Spearman's rank correlation coefficient (Altman 1991).

Responsiveness has been defined as 'the ability of an instrument to detect minimal clinically important differences' by Guyatt *et al* 1987. However, in health outcomes research, minimal clinically important differences are often not well defined. Many health profiles produce individual domain or dimension scores rather than a total summary score and clinically important differences can vary among the domains.

Investigation of clinically important differences can help sample size calculations in clinical trials. Jaeschke *et al* (1989) defined such a difference as 'the smallest difference in score in the domain of interest which patients perceive as beneficial', using small sample studies, while Deyo *et al* (1991) defined the minimal clinically important difference as the improvement in score after an intervention of predetermined efficacy. The claims of Jaeschke *et al* (1989) have not been

demonstrated in studies with large patient numbers and may be disease-specific. Indeed, responsiveness depends on the extent of floor or ceiling effects of the instrument under investigation (Fletcher 1992(B)).

## **1.11 Roles of the pharmacist in primary care**

### **1.11.1 Pharmaceutical care and pharmaceutical needs assessment**

Pharmaceutical care has been defined by Hepler and Strand 1990, as 'the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life'. In 1997, Hepler redefined pharmaceutical care as a practice in which the pharmacist takes responsibility for a patient's drug-related needs and also holds him or herself accountable for meeting those needs. The outcomes may include cure of a disease, reduction or elimination of symptoms, slowing or stopping the disease process or preventing symptoms or development of a disease. Pharmaceutical care should be integrated within other health care systems and should be negotiated with patients and members of the primary health care team (Hepler and Strand 1990, Hepler 1997). Frameworks for accurate documentation of such pharmaceutical care are vital to be provided to optimise pharmaceutical input (Briggs *et al* 1996), encourage effective communication with clinicians (Wood *et al* 1998), minimise the risk of side effects and /or adverse drug interactions (Rogers *et al* 1994, Whittlesea and Walker 1996) and accurately evaluate the outcome(s) of pharmaceutical care (Lipowski 1996).

A pharmaceutical need is defined by Scottish Clinical Pharmacy guidelines (1997) as 'a patient's requirement for a pharmaceutical product or service'. Pharmaceutical needs can be determined by identifying pharmaceutical risk factors and potential care issues. Pharmaceutical care issues should be identified for both individuals and populations to enable cost-effective use of health care resources available (Krska 1998). As increasing pressure is placed on health boards and authorities to achieve measurable improvements in health care, practical and achievable frameworks for health needs assessment such as pharmaceutical needs assessment, should be used to help purchasers decide on what services they require.

### **1.11.2 Emerging roles of the pharmacist in primary care**

There is currently extensive encouragement to develop the roles of the pharmacist within many different primary care settings to encourage cost-effective prescribing, promote the under-utilised skills of pharmacists and help reduce the ever increasing workload of GPs within a primary care-led NHS (Royal Pharmaceutical Society of Great Britain 1995, Scottish Office Department of Health (SODoH) 1996 (A) and (B), SODoH 1997). Moreover, recent NHS changes including greater emphasis on health promotion, encouragement of GPs to take on more specialised roles, promotion of evidence-based medicine, expansion of the primary health care team and movement of chronic disease management to community care, all further encourage the development of pharmacists' roles in primary care (SODoH 1998).

There is now a 'window of opportunity' for pharmacists to become more fully integrated into the primary health care teams not only as advisers but also as providers of pharmaceutical care to individual patients within Primary Care Groups (PCGs), a multi-disciplinary health care team. Pharmacists are now being encouraged to become members of their local Primary Care Groups to help to 'contribute to health improvement programmes, promote the health of the local population, commission health services, monitor performance and develop primary care' (SODoH 1998).

### **1.11.3 Models of pharmaceutical input to primary care prescribing**

Recent white papers on primary care have encouraged initiatives to improve primary care prescribing, inter-professional co-operation in service provision and greater skill mixing (SODoH 1996 (A) and (B)). The types of prescribing review initiatives which have been implemented by pharmacists have been reviewed by Bradley *et al* (1997) and include review of repeat prescribing (Davidson *et al* 1998), total medication review (Beech and Brackley 1996) and the analysis of PACT data (Bevan 1996). Other collaborative training activities involving pharmacists and GPs have in uncontrolled studies been shown to improve prescribing (Wood *et al* 1997, Roberts *et al* 1997).

Other initiatives include the development, monitoring and updating of practice formularies (Jenkins 1994), the development of prescribing policies (Fisher and Dunning 1998) and prescribing audit by disease (Moorhouse *et al* 1996). As more medicines are re-regulated / deregulated, pharmacists have also developed their advisory role to improve the appropriate use of medicines and the treatment of minor ailments (Whitaker *et al* 1995) and in health promotion (Ghalamkhari *et al* 1997(A)).

Pharmacists are increasingly employed full time or on a contractual basis within GP practices to aid in the control of prescribing budgets by providing appropriate drug information and developing prescribing policies (Mason 1996). Such pharmacists have then been able to establish disease-specific clinics including pain control (MacGregor 1996), anticoagulation (MacGregor *et al* 1996) and *Helicobacter pylori* (*H Pylori*) eradication (Moorhouse *et al* 1996).

Many of these models however, have been small pilot studies, lacking controls with outcome data limited to specific objectives with minimal evaluation of the impact of pharmaceutical care and the cost-effectiveness of such schemes (Lipowski 1996). However, some models have utilised controls (Thompson *et al* 1984).

Pharmaceutical outcome data in primary care research has tended to include process outcomes such as the extent of uptake of pharmacists' recommendations by GPs (Naylor and Oxley 1997) and the number and type of clinical interventions made (Beech and Brackely 1996). The latter have often been evaluated by a clinical expert panel (Caleo *et al* 1996, Begley *et al* 1996). Financial outcome data has included the consequences of medication changes on prescribing costs (Beech and Brackley 1996), financial implications of improved stock control (Dixon *et al* 1995) and the implications of medication changes in preventing hospital admissions or readmissions (Thompson *et al* 1984).

As more primary care pharmacists are getting involved in medicines' management via disease-specific clinics, the impact of pharmaceutical intervention on patient outcome is increasingly being evaluated in terms of validated quantitative clinical indicators. Pharmacists have utilised INR control in anticoagulant clinics (MacGregor *et al* 1996), eradication of *H Pylori* (Moorhouse *et al* 1996) and other biochemical parameters (Broderick *et al* 1992) to evaluate pharmaceutical interventions. Qualitative outcomes are also being investigated such as patient

concordance with medication (Fairbrother *et al* 1993, Naylor and Oxley 1997) and patient satisfaction (Long and Wynne 1996), but few pharmacists have utilised validated tools to assess patients' health related quality of life. Some pharmacists have used validated QOL tools to evaluate the impact of their interventions, but most studies have been using small sample sizes or have questioned the validity of such tools when applied to pharmaceutical care (Stewart 1997, Tully and Cantrill 1998).

#### **1.11.4 Medication review and the role of domiciliary visits**

Medication review can be described as 'the systematic evaluation of medication therapy' (Sommerville 1996). Such a review has been effectively undertaken within patients' homes, domiciliary medication review, (Dixon *et al*, 1995, Beech and Brackley 1996, Naylor *et al* 1997), community pharmacies (Goodyer *et al* 1996) and other care environments such as nursing homes, residential homes or care centres (Somerville 1996, Rees *et al* 1995, Goldstein *et al* 1995).

Pilot projects have, over the last 10 years, evaluated the model of domiciliary medication review as a strategy to identify medication, compliance and storage problems, to provide appropriate drug information or other health advice to patients and carers, and to refer to other health professionals as appropriate (Royal Pharmaceutical Society of Great Britain 1988, Fairbrother *et al* 1993, Goldstein *et al* 1995, Naylor and Oxley 1997).

Patients who have been targeted for such a review have usually been frail, elderly, confused or have special needs (SODoH 1996, The Royal College of Physicians 1997, Thompson *et al* 1984). Such patients are often on multiple medication, are left to manage their medication unaided or often have carers with limited drug information (Goldstein *et al* 1995), whose therapy is poorly monitored leading to hospitalisation (Col *et al* 1990). Other researchers have targeted a specific patient group by identifying those patients on selected repeat medicines (Dixon *et al* 1995).

Controlled studies have assessed the influence of domiciliary medication review by pharmacists on elderly patients recently discharged from hospital (Begley *et al* 1996), or in residential or nursing homes (Rees *et al* 1995, Thompson *et al*

1984). Such studies suggest that pharmacists have a very important role in maximising the efficacy and minimise the toxicity of medication in such patients and reducing hospital admission rates.

The cost-effectiveness of domiciliary intervention has been assessed in terms of reducing costs due to hoarding of medicines (Dixon *et al* 1995), minimising inappropriate prescribing (Mackie 1997, Beech and Brackley 1996) or adverse drug reactions (Begley *et al* 1996) and improving quality of life (Krska 1998). The studies of Begley *et al*, 1996, Krska 1998 and Mackie 1997 were randomised and controlled, the two latter studies using large patient groups.

#### **1.11.5 Roles of the pharmacist in the management of chronic pain in primary care**

Many patients with chronic pain have benefited from management by a hospital-based multidisciplinary pain team (Hardy and Hill 1996).

The role of the pharmacist within a hospital chronic pain clinic (Reisner-Keller 1992) or a rheumatology clinic (Kay 1997) is well established. Such pharmacists provide appropriate drug information to patients, nurses and clinicians, ensure patient compliance with and understanding of their medication prior to discharge and that appropriate therapy is provided and monitored for each patient (Snell 1993).

This role is not unique to pharmacists since a recent randomised controlled trial has demonstrated that nurse practitioners can effectively manage chronic pain using drug therapy, referral to other health professionals and patient education (Hill *et al* 1997). However, this was a small study, which did not identify pharmaceutical needs.

It has been estimated that 50% of the population suffer from chronic pain, (C Smith, personal communication). The majority of these patients are managed in primary care using analgesic and NSAID therapy, often inappropriately and use non-prescription medicines and alternative therapies to improve pain control (Long and Wynne 1996). There would therefore appear to be a need to investigate further the management of patients with chronic pain in primary care, perhaps as part of a chronic pain team (MacGregor 1996). Although pharmacists have encouraged the development of guidelines for the management of chronic pain (MacGregor 1996),



there has been no evaluation of the outcomes of patients with chronic pain in terms of pain control and quality of life using validated measurement scales before and after pharmacist intervention. This study was designed to determine the potential for pharmacist input into the management of such patients, using appropriate outcome measures.

General practitioners and community pharmacists previously expressed mixed views about pharmacist involvement in chronic pain management (Begley *et al* 1994). However more recent work has shown that medication review and the development of pain clinics by pharmacists was rated favourably by GPs (Weir *et al* 1997). In this study, the attitudes of not only GPs and community pharmacists but also physiotherapists towards pharmacists working within a chronic pain team were evaluated to identify the extent of support for the pharmacist's developing role in chronic pain management.

## **1.12 Aims of the Study**

The aims of this research were:

- To evaluate the use and efficacy of analgesics in the management of chronic pain in the community
- To identify the potential role(s) of a pharmacist in the management of chronic pain in the community.

### **1.13 Objectives of the Study**

The objectives of this research were:

- To determine the prescribing patterns for analgesics and other pain-related therapies in a cluster sample of patients with chronic pain living in their own homes
- To determine the extent of patient adherence to prescribed therapy, the influence of patient attitude to pain, medicines and prescribers on this adherence
- To investigate the pain experienced by patients and the differences, if any, between those with different pain diagnoses in terms of intensity, quality and description, using VAS and the McGill pain questionnaire
- To investigate any effect of diagnosis and pain on quality of life
- To investigate the reliability, validity, and sensitivity of the QOL scale used
- To measure any differences between pain experienced at initial and follow-up interview by the patients who had poor outcomes and were referred for review
- To investigate the overall influence of pain on activities of daily living and mood, as experienced by patients, quality of life and the differences between those with satisfactory and poor overall outcomes in pain and quality of life scores
- To identify side effects reported by the study patients and the extent of documentation of monitoring parameters for efficacy and toxicity
- To quantify the types of pharmaceutical input needed by patients with chronic pain in primary care
- To evaluate the attitudes of community pharmacists, GPs and physiotherapists towards the perceived role(s), if any, for the pharmacist within a chronic pain team

## **Chapter 2**

### **Methods**

#### **2.1 Evaluation of chronic pain management in the community**

##### **2.1.1 Ethical Committee and GP sub-committee approval**

Ethical Committee approval was sought and obtained from the Ethics Committee of Lanarkshire Health Board and by the Joint Ethical Committee of Grampian Health Board and the University of Aberdeen. Copies of both letters are included in Appendices 2 and 3.

Approval was sought and obtained from all the general practitioners in the Oldmachar Medical Practice, Burnbank and Strathaven Health Centres, to allow the study pharmacist to access appropriate medical notes and to interview patients in their homes. A copy of the letter which was completed by all selected practices is included in Appendix 1.

##### **2.1.2 GP Practice selection**

Three GP practices were selected for inclusion in the study to investigate analgesic prescribing patterns, patient perception of pain and pain management. Cluster sampling was carried out involving one GP practice in Aberdeen and two practices in Lanarkshire with whom the researcher had previous contact.

One GP within each practice liaised regularly with the study pharmacist during the developmental stages of the project. Wherever possible, the liaison GP was the GP whom the researcher had previously worked with or knew personally.

A synopsis of the demographic and clinical details of each of the 3 GP practices is provided in Table 2.1

<b>Demographic details</b>	<b>Practice 1 (Aberdeen)</b>	<b>Practice 2 (Strathaven)</b>	<b>Practice 3 (Hamilton)</b>
Number of GPs	7	3	5
Number of patients	11345	5211	8494
Number of documented RA patients	74	30	20
Number of documented patients on repeat Rx NSAIDs and / or combination analgesics	647	194	382

**Table 2.1:** A synopsis of demographic details of the 3 GP practices in 1994

**2.1.3 Criteria for poor outcome**

Patient outcomes were defined in terms of pain control, quality of life, experience of side effects and patient attitude. The criteria for a poor outcome were defined as at least one of the following:

- Poor pain control (VAS average greater than 75) (Read 1989) and / or poor quality of life (total QOL score greater than 35) (Williamson *et al* 1993)
- Signs and / or symptoms described by a patient on interview which were suggestive of a significant adverse drug reaction
- Deliberate change in therapy by patient due to lack of awareness of rationale for therapy
- Patient who was dissatisfied with current medication at time of interview and requested alternative management

#### **2.1.4 Criteria for DMARD monitoring**

Appendix 4 details the general protocol with which DMARD monitoring was compared in this study (Medicines Resource Centre 1996), since variations in protocols between practices were very limited.

#### **2.1.5 Patient sample size and patient selection**

A power calculation was made to estimate the sample size required to demonstrate a statistically significant difference in patients' pain or QOL (quality of life) scores after an intervention. It was found that a sample size of 13 patients would be required to achieve a difference of 10 units between pre and post intervention for VAS (mm), QOL or total PRI scores, at a power of 80%,  $p = 0.05$ .

All patients in each practice in whom a definitive diagnosis of rheumatoid arthritis had been made were included in the study. In addition, in each of the 3 practices, every eighth patient from each practice list who was documented as receiving repeat prescriptions for combination analgesics, NSAIDs or any other analgesics was included in the study to provide a random sample of 60 patients from each practice. Patient information was retrieved using the practice computer system (General Practice Administrative System for Scotland, GPASS). Patients who were excluded were those under 18 years of age, patients unwilling to participate or who had malignant pain and those patients considered by their general practitioner to be unsuitable for inclusion e.g. significant mental impairment.

All patients who were eligible for inclusion were sent a patient information leaflet about the project (Appendix 5) and asked to give written consent prior to being interviewed (Appendix 6). All of the patients who did consent to participate were either telephoned or written to by the study pharmacist to arrange a mutually convenient date and time for the first interview.

Wherever possible, the study pharmacist telephoned or wrote a second letter to all patients who were potentially eligible, but who had not replied after the first mailing.

One hundred and nine out of the total 180 patients who were initially sampled from the three practices were identified. Fifteen of the 180 patients were unwilling to participate, 24 were dead, 17 could not be contacted using the address and / or telephone number noted in the respective medical notes and 15 were no longer taking any painkillers.

Initial patient interviews in all three sites took place between July 1993 and June 1994.

## **2.1.6 Development of data collection tools**

### **2.1.6.1 Information retrieval from medical records**

A data collection form was devised to permit retrieval of relevant information from the medical notes of all patients who gave written consent (Appendix 7). The data collection form included:

1. Demographic information : age, sex, marital status and occupation – factors which can directly or indirectly influence pain.
2. Medical information: diagnosis of type(s) of chronic pain, duration of the pain state(s), concurrent disease states, biochemical and haematological data.
3. Drug information: current medication prescribed for chronic pain and any other concurrent disease states and medication history details.
4. Other information relating to the management of chronic pain: present and past use of exercise, physiotherapy and use of aids for daily living.

The form was piloted on 10 hospital inpatients with a diagnosis of RA. Very slight modifications were made to the data collection form in terms of layout i.e. tabulation of biochemical, haematological and other data in one rather than separate tables.

### **2.1.6.2 Development of attitude statements**

Twenty attitude statements in total were developed by the study pharmacist, based on patient, physical and psychological factors which were known to influence

both patient concordance with medication (Britten 1996) and chronic pain management (Reisner-Keller 1992):

Ten attitude statements related to patient concordance with medication including statements which aimed to identify patient attitude to and trust in his / her GP, attitude to prescribed and self-medication, patient health beliefs and awareness of side effects associated with long-term analgesic use. Ten attitude statements related to the management of chronic pain including statements which aimed to identify patient perception of chronic pain, patient understanding of the consequences of chronic pain (depression, lack of complete pain relief, side effects associated with chronic analgesic use), patient perception of the role of medication, exercise and self-management techniques in the management of chronic pain.

#### **2.1.6.3 Development of the pain questionnaire**

A pain questionnaire (Appendix 8) was developed for use by the study pharmacist to assess:

- patients' pain perception in terms of quality and intensity using the McGill Pain Questionnaire (MPQ) and visual analogue scales
- the influence of pain on patients' quality of life, particularly on activities of daily living using verbal descriptors
- patients' attitude to pain, pain management and awareness of the implications of chronic pain (see section 2.1.6.2)

The pain questionnaire included 2 visual analogue scales used to assess each patient's assessment of their 'ideal' analgesic and perceived efficacy of prescribed analgesia (questions 24 and 35).

To assess the impact of chronic pain on patients' behaviour, mood and activities of daily living, statements which had been included within a previously validated questionnaire were used (Williamson *et al* 1993). The whole of the questionnaire could not be used in this study, due to its original length (69 items) and inappropriateness of some of the statements i.e. some statements related specifically to patient perception of chemotherapy.

Thus 14 of the 50 statements used by Williamson *et al* 1993 were incorporated into the pain questionnaire (questions 9-22) covering 4 dimensions of physical, social, occupational and psychological status. The 14 statements were chosen because their individual scores had the highest correlations with their respective dimension scores in that study as compared to the scores of the other 36 statements. This finding suggested that these 14 statements well reflected specific dimensions and could be utilised in an abbreviated form of the original questionnaire.

The 14 statements used to define the 4 dimensions (physical, social, occupational, psychological) were:

- mobility, sleep and appetite (statements 9,11,12 and 19) - physical status
- enjoyment of life, support of friends and planning of activities (statements 17,20 and 21) - social status
- ability to do household chores and any other activities and change in work circumstances, (statements 10,18 and 22) - occupational status
- anxiety, depression, loneliness and frustration (statements 13-16) - psychological status

A Likert descriptive rating scale was used to score each statement, where patients were asked to rate the extent to which each statement applied to them at the time of interview (Williamson *et al* 1993). The ratings were such that 0 = not at all, 1 = a little, 2 = a fair amount, 3 = a lot, 4 = very much indeed. All patients completed their own appraisals independently, and could ask the study pharmacist to clarify any statements if necessary.

The questionnaire also included open questions to assess each patient's analgesic usage and understanding of their analgesic therapy to identify:

- what medication they were receiving for their pain (question 25)
- when and how often they used their medication (questions 26 and 30)
- patients' use of OTC or alternative therapies either instead of or in addition to their prescribed analgesics (questions 32-34)
- patient awareness of side effects with long-term analgesic use (question 37)
- patient concordance with prescribed medication (questions 27-29)



#### **2.1.6.4 Piloting of the attitude statements and pain questionnaire**

In June 1993, the attitude statements were initially piloted on 10 hospital pharmacists, 10 inpatients with a diagnosis of RA in a rheumatology ward in Aberdeen City Hospital and 10 family and friends prior to inclusion into the pain questionnaire. All were asked to identify how well the statements could be understood and read. Responders were also asked to indicate whether they strongly agreed, agreed, were uncertain, disagreed or strongly disagreed with each statement and whether they perceived the statement to be positive or negative. Any ambiguous statements or statements with which responders were consistently 'uncertain' were discarded.

Eleven of the original 20 statements were both clearly understood and described by the majority of responders (at least 24 out of the 30 responders) as positive or negative statements. Four of the 11 statements were related more to knowledge than attitude, with no responders strongly agreeing or disagreeing with the statements. Thus these 4 statements were incorporated within the pain questionnaire with true / false / uncertain options (questions 37-40 of Appendix 8) instead of the graded Likert scale (strongly agreed, agreed, were uncertain, disagreed or strongly disagreed) (questions 2-8 of Appendix 8). Questions 2,3,5,6,7,39 were defined as positive statements whereas questions 4,8,37 and 38 were defined as negative statements.

For questions 2-8, the highest score for positive statements was attributed to those who strongly agreed with the statement, whereas the highest score for a negative statement was attributed to those who strongly disagreed. For questions 37-40, the highest score was given to those responders who answered the statement correctly e.g. for question 38 (Persistent pain can make you depressed), the highest score was given to those responders who indicated 'true'.

At least 60% of responders were uncertain regarding their response to 7 of the 18 statements which were concerned with specific side effects and less well known consequences of chronic pain, thus the statements were discarded.

The pain questionnaire was initially piloted for face and content validity on 10 inpatients with a diagnosis of RA in a rheumatology ward in Aberdeen City

Hospital, a multidisciplinary group of 4 researchers in chronic pain and 10 family and friends. All participants were asked to comment on the relevance and clarity of the questions and the extent to which they perceived the questionnaire's content appeared to examine and include the full scope of chronic pain issues. A few modifications to the sequence of questions and wording of the attitude statements were carried out as a result.

The original questionnaire started with questions relating to medication-taking (questions 4-8) which may have biased the response to question 2 'Doctors know what is right for their patients'. After the pilot, the more general questions about attitude to prescriber and outcome as a result of taking painkillers (questions 2 and 3) preceded questions 4 to 8. The word 'medication' in statements 4 and 5 was changed to medicine after piloting to improve readability.

### **2.1.7 Data collection**

All relevant information from each patient's medical notes was collected 1 – 2 days prior to an interview in the patient's home using the questionnaire. Data collection prior to first interviews in all three sites took place between July 1993 and June 1994.

Assessment of chronic pain was carried out during each interview using the MPQ and visual analogue scales.

The McGill Pain Questionnaire defines pain in terms of three major dimensions i.e. sensory, affective and evaluative, such that the questionnaire consists of 20 categories of words to describe the pain experience (Melzack 1975). Patients were asked to select the categories which they recognised as relevant to their pain at time of interview, and to circle the most appropriate word within each category. If none of the words within a category applied, none were chosen.

Within the MPQ, patients were also asked to rate present pain intensity (PPI) on a 0 to 5 verbal descriptor scale where 0 = no pain to 5 = pain is horrible. All patients were also asked to mark on a body drawing, the areas where he / she actually felt pain to assess the correlation between a patient's perceived pain and the established pain diagnosis.

Visual analogue scales (VAS) were used to record (1) each patient's subjective assessment of pain intensity and (2) each patient's subjective assessment of their 'ideal' analgesic and their perceived efficacy of prescribed analgesia. All VAS scales used were horizontal lines of 10cm.

Appendix 9 details the 3 visual analogue scales used to assess pain intensity at its worst over the past month (VAS worst), pain on average (VAS average) and pain at time of interview (VAS now). Each VAS was marked at one end by zero (no pain) and at the opposite end by 10 (pain as bad as you can imagine). Patients were asked to place a mark on each of the 3 lines at a point which represented the severity of their pain.

Each VAS used to assess pain relief was marked at one end by 0 (no relief) to 100 (complete relief). Patients were asked to place a mark on each of the 2 lines at a point which represented respectively, their 'ideal' pain relief (question 24) and the pain relief achieved with medication (question 35).

During each interview, all patients could discuss more fully the impact of their pain on activities of daily living, if they felt so prompted. The study pharmacist transcribed the patients' verbal accounts of their experiences and feelings immediately after the interview.

For seven of the 11 attitude statements, all patients were asked to indicate whether they strongly agreed, agreed, were uncertain, disagreed or strongly disagreed with each statement. The statements aimed to assess patient attitude to his / her GP (questions 2 and 5), patient attitude to and concordance with medication especially analgesia (questions 3,4,7,8) and patient attitude to pain control (question 6).

The four other statements which were used in the pain questionnaire considered patients' knowledge of chronic pain rather than attitude, in terms of the problems associated with the long-term use of analgesic medication (questions 36) and long-term pain (questions 37-39). For each of the 4 statements, all patients were asked whether the answer was true, false or they were uncertain.

If a discrepancy was found between the medication identified by the patient as currently being taken (analgesic or any other medication), with that documented in the medical notes prior to interview, the pharmacist asked open questions to identify

if the patient had deliberately made changes to his / her therapy, and if so, whether these changes had been discussed with his / her GP.

During the interviews, the patients were asked if they had ever experienced any problems, which they thought could be attributed to their medication. Some prompt words to help define the word 'problem' i.e. stomach upset, constipation, were written in the questionnaire for the benefit of the study pharmacist, but the study pharmacist did not convey these prompt words to any of the patients. Patients could report on side effects attributed to any of their past or current medication.

All patients were given an opportunity to ask any questions relating to their past or current medical problems, past or current drug therapy or any other pharmaceutical query. The study pharmacist provided verbal advice, a manufacturer's patient information leaflet, information leaflets from Aberdeen City Hospital or compliance charts, wherever possible. Referral of patients to any other health care team member was also made where the pharmacist deemed it appropriate.

### **2.1.8 Intervention procedures**

All poor outcomes were referred to the respective GP of each patient. GP referrals included those patients in whom a particular problem had already been identified by the GP, but was not documented in the patient's medical notes prior to the pharmacist's interview with the patient. These problems were acknowledged by each GP verbally by telephone or interview with the study pharmacist.

### **2.1.9 Follow-up of patients with poor outcomes**

A further assessment was made, where possible, during a second interview if patients had had poor outcomes on the first interview. This second interview occurred 4 to 6 weeks after action was taken following the pharmacist's recommendations or 4 to 6 weeks after the first interview if GP did not act on advice. This second interview occurred between September 1993 and September 1994 and was performed by the same study pharmacist using the same assessment

tools i.e. pain questionnaire, data collection form to obtain information from notes, and MPQ and VAS scales as were used during the first interview.

## **2.2 Role of the pharmacist in chronic pain management**

### **2.2.1 Development of attitude statements**

Twelve attitude statements were initially developed by the study pharmacist in November 1995 to identify factors which influenced the attitude of health professionals towards the management of chronic pain such as patient factors and management strategies. The statements were developed from present knowledge concerning patient compliance (Stockwell Morris and Schulz 1992), chronic pain and its management (O'Hara 1996) and attitudes to the developing role of pharmacists in primary care particularly in chronic pain management ( Begley et al 1994). The attitude statements were incorporated into a postal questionnaire.

### **2.2.2 Development of questionnaires**

Postal questionnaires were developed in November 1995 to determine professional details and practice relating to chronic pain management for distribution to GPs, community pharmacists and physiotherapists.

The questionnaires asked responders to identify factors from a specified list within the questionnaire which they believed influenced the management of chronic pain. All responders were also asked to state whether they strongly agreed, agreed, disagreed or strongly disagreed with the list of attitude statements relating to chronic pain management. Attitudes to pain management were assessed to determine whether any differences existed between GP, pharmacist or physiotherapist groups. All groups were asked to identify the potential role(s) of the pharmacist, if any, within a multidisciplinary team and more specifically, in the management of chronic pain.

In addition, the questionnaires sent to GPs were designed to obtain:

- (1) practice details: number of patients in the practice, number of GPs per practice.
- (2) information to assess the current extent of clinical interaction with pharmacists

Questionnaires sent to pharmacists were designed to obtain:

- (1) professional details e.g. work experience, number of pharmacists employed per pharmacy, information about current clinical services provided and those which the pharmacist would be keen to initiate and / or develop.
- (2) information concerning communication with GPs e.g. the type and frequency of queries which they conveyed to GPs, modes of communication employed and the extent of feedback received.

Physiotherapists' questionnaires included professional details such as the main site and source of employment and work experience.

### **2.2.3 Piloting of the questionnaire**

Five general practitioners, 5 community pharmacists and 5 physiotherapists in an area outwith the research areas, were recruited between December 1995 and January 1996 as a pilot group to investigate the questionnaire in terms of clarity, readability and content. All the pilot group completed the initial postal questionnaire. All responders were asked to indicate whether they strongly agreed, agreed, were uncertain, disagreed or strongly disagreed with each statement.

After feedback from the pilot group, some changes were made to the number of attitude statements, wording and layout of the questionnaire. Two of the attitude statements were omitted from the final questionnaire. The majority of the pilot group (11 out of 15) regarded one of the 2 statements 'A patient with chronic pain exaggerates the pain which he / she feels' as ambiguous, while another statement

'Pharmacists should provide appropriate drug information to help optimise pain control' was regarded by 10 of the 15 as too leading a question.

The wording of the instructions for completion of Section B of Appendices 12 and 13 was modified to improve readability i.e. the instruction 'From the list below, decide which, if any of the factors, can prevent optimum control of chronic pain' was modified to 'Please tick any of the factors listed below which you feel are preventing you from optimising control of chronic pain'.

Each of the 3 questionnaires was modified to improve its layout in terms of clarity and readability. Each of the section headings A, B and C of each questionnaire was bolded and enlarged to be more distinctive and additional space was provided within tables.

#### **2.2.4 Selection of study sample**

GPs, community pharmacists and physiotherapists were selected since they have important roles in pain management (Hardy and Hill 1990, Briggs et al 1996).

Lists of the names of GPs and their respective practices, names of community pharmacies and their respective proprietors and names of community physiotherapists and their work bases were obtained from the Health Boards, Chief Area Pharmaceutical Officers and Senior Community Physiotherapists of the Lanarkshire and Grampian regions of Scotland.

Thereafter, 100 GP practices, 100 community pharmacies and 50 physiotherapy work bases were randomly selected in Aberdeen and Lanarkshire, which represented 60% and 63% of the total number of GP practices and 62% and 60% of community pharmacies in Aberdeen and Lanarkshire respectively. Random selection of 50 physiotherapy work bases represented 69% and 92% of the physiotherapy work bases in Aberdeen and Lanarkshire respectively. Every eighth health care professional from each of the lists was selected. Only one practitioner was identified from each of the selected surgeries, pharmacies or physiotherapy sites.

### **2.2.5 Mailing procedures**

A revised questionnaire was then sent to each GP practice, pharmacy and physiotherapy work base (see Appendices 11,12 and 13 respectively), accompanied by a covering letter (Appendix 10).

The postal questionnaire study was run over a 3 month period from January to March 1996 and all health care professionals were given a 4 week deadline for completion and return of questionnaire in the stamped-addressed envelope provided. One further follow up letter was sent to non-responders in April 1996. The initial response rate was 60 out of 100 GP practices, 57 out of 100 community pharmacies and 30 out of 50 community physiotherapist bases. Subsequent response rate improved the final response to 63 GP practices, 59 community pharmacies and 33 physiotherapy work bases.

## **2.3 Data analysis**

### **2.3.1 Analysis of data from medical records**

The data collection forms were used to provide background clinical information and to identify any types and frequencies of discrepancies between documented drug histories in medical records and drug histories obtained at time of each patient interview.

The appropriateness of biochemical and haematological monitoring which was actually documented by the practices, was assessed in terms of each patient's concurrent disease states, current therapy and any local protocols e.g. monitoring of DMARDs. Comparison was made of the documented monitoring of the DMARDs used in the study patients with our criteria as shown in Appendix 4.

### **2.3.2 Patient Groupings**

Patients were categorised in terms of pain diagnoses (RA, OA, OA and RA or back pain). Patients were also grouped in terms of outcome at first interview i.e.



satisfactory or poor outcomes. Data for patients with poor outcomes was further evaluated in terms of those who had high VAS pain scores (greater than 75) and those who were interviewed after pharmacist intervention, to investigate the contribution of VAS scores to the assessment of poor outcomes.

### 2.3.3 Analysis of MPQ data

Pain scores for each patient were calculated in 4 ways, as described by Melzack (1975).

- The sum of the scale values for all the words chosen across all categories, a total Pain Rating Index Score or PRI (S) score, or a PRI (S) score within a category e.g. (PRI (S) evaluative), could be calculated. The median and 95% confidence interval of the median PRI (S) were also calculated for all 96 patients at Interview 1
- Similar Pain Rating Index Scores using rank values instead of weighted scale values were calculated e.g. a total PRI ® score, or a PRI ® score within a category e.g. (PRI ® evaluative). The median and 95% confidence interval of the median PRI ® were also calculated for all 96 patients at Interview 1
- By totalling the number of words chosen (NWC) from the 20 categories within the MPQ, a NWC score was calculated at each interview. The median NWC and 95% confidence interval of the median NWC were also calculated
- The Present Pain Intensity Score (PPI) from 0 to 5 was also determined. The median PPI and 95% confidence interval of the median were also calculated

All patients were given every opportunity to ask the study pharmacist if they were unsure of the meaning of any of the words. Each patient completed the questionnaire only in the presence of the study pharmacist.

The Wilcoxon matched pairs signed rank sum test was used to investigate the within patient differences in NWC, total PRI® and PRI (S) and PPI scores in patients who were interviewed on a second occasion after the study pharmacist's recommendations were carried out. Differences were significant if  $p < 0.05$ .

### **2.3.4 Analysis of VAS data**

VAS scores were calculated by measuring the distance of each patient's mark from the lower end of the scale, measured in millimetres, ranging from 0 to 100. Individual VAS scores were presented as multiples of 5.

Since the distribution of VAS scores is not normal, non-parametric statistical analyses are generally considered more appropriate than parametric analyses (McDowell and Newell 1996). Thus medians and 95% confidence intervals of the medians were calculated to define the average value and explicit uncertainty of the median respectively, of each VAS scale which was used instead of means. Differences were significant if  $P < 0.05$ .

The Wilcoxon matched pairs signed rank sum test was used to investigate the within patient differences in VAS scores in patients who were interviewed on a second occasion after the study pharmacist's recommendations were carried out. Any tied ranks within each set of patients were accounted for. Differences were significant if  $P < 0.05$ .

Reliability of the MPQ and VAS pain scales was assessed by determination of Pearson correlation coefficients for all patients after Interview 1 ( $n=96$ ). Correlations were calculated between VAS average scores and total PRI (S) or PRI ® scores and between NWC and VAS average scores.

Chi-squared tests ( $2 \times 2$ ) were used to compare any differences in VAS pain and pain relief, NWC, PPI and total PRI rank and scale scores between those patients with satisfactory and those with poor outcomes. Differences were significant if  $P < 0.05$ .

### 2.3.5 Analysis of QOL statements

Two quality of life scores were created as discussed by Williamson *et al* 1993 to assess sensitivity and reliability of the scale:

- A total QOL score - the sum of the individual scores achieved for each statement which was appropriate for each patient, divided by each patient's maximum possible score. This score was then calculated as a percentage. (Not all statements were always relevant to all patients i.e. retired patients could not rate the influence of pain on work, thus the maximum possible score varied between patients). A high score indicated poor quality of life. The median total QOL score and 95% confidence interval of the median were calculated
- A dimension score (physical, social, occupational and psychological) – the sum of individual scores achieved for each statement within a specific dimension divided by each patient's maximum possible score. This score was then calculated as a percentage. A high score indicated poor quality of life. The median score and 95% confidence interval of the median were calculated for each dimension
- When the sample size was small, the range was used instead of the 95% confidence intervals for the above QOL scores

Reliability of the quality of life scales was assessed by determination of Pearson correlation coefficients, split-half reliability using the Spearman-Brown 'prophecy' formula and by calculation of Cronbach's alpha (Streiner and Norman 1995). The Spearman-Brown 'prophecy' formula was used to correct for any underestimation of the scale's true reliability when split into 2 sub-scales.

Correlations were calculated between:

- (1) the total QOL score and each dimension score (physical, social, occupational and psychological) for all patients
- (2) each individual QOL statement score within a dimension and the appropriate dimension score
- (3) each individual QOL statement score within a dimension and total quality of life scores

(4) total quality of life scores and total PRI(S) or PRI ® scores and VAS average pain scores

The Wilcoxon matched pairs signed rank sum test was used to investigate the within patient differences in quality of life scores in patients who were interviewed on a second occasion after the study pharmacist's recommendations were carried out. Any tied ranks within each set of patients were accounted for. Differences were significant if  $P < 0.05$ .

Chi-squared tests (2x2) were used to compare any differences in QOL scores between those patients with satisfactory and those with poor outcomes. Differences were significant if  $P < 0.05$ . Yates' correction was used to minimise any bias associated with analysis.

### **2.3.6 Analysis of patient attitude**

A score between 1 to 5 was assigned to each of the 5 potential responses (i.e. strongly agree, agree, uncertain, disagree, strongly disagree) for each of the 7 attitude statements described in questions 2 to 8 of the pain questionnaire (section 2.1.7). A high score implied a positive attitude. The total score achieved was divided by the maximal score for all 7 statements to create a percentage score. This score was then compared to pain control and quality of life scores using correlation coefficients.

### **2.3.7 Analysis of questionnaires**

The Kruskal-Wallis and Mann-Whitney U tests (if appropriate) were used to compare differences, if any, in response to attitude statements to pain management between GPs, community pharmacists and physiotherapists. The same tests were applied to compare differences, if any, in response to attitude statements between patients with RA, OA, RA and OA and back pain. Analysis accounted for tied rankings.

### 2.3.8 Analysis of advice provided

All patient information requests and advice provided by the study pharmacist were collated in terms of types and frequencies of query according to disease state i.e.:

1. Information concerning management of chronic pain. This category included drug information relating to patients' past or current therapy for chronic pain (excluding side effects).
2. Specific side effects associated with patients' therapy.
3. Drug information concerning any other current medical problem of a patient (excluding chronic pain).
4. General drug information requests from patients e.g. compliance aids.

Patient information requests and advice provided by the study pharmacist were also classified as reinforcement, clarification, correction or follow up with the prescriber. The pharmacist's proposed solution to a patient's problem could involve more than one of these categories e.g. A patient may have required clarification **and** correction if he / she was not only confused about how to take the medication, but had also admitted to taking it inappropriately.

1. **Reinforcement**- the pharmacist needed to reassure the patient that he / she was taking her medication correctly and that the therapy prescribed was appropriate.
2. **Clarification**- the pharmacist provided relevant information to solve any patient confusion about his / her therapy.
3. **Correction**- the pharmacist needed to provide advice to prevent a problem from occurring or solve an existing problem.
4. **Follow up with prescriber** - the pharmacist deemed a problem sufficiently serious to refer to the patient's GP. Referrals concerning chronic pain problems were considered separately from any other medical problem which required referral, but all were referred to the patient's GP.

### **2.3.9 Use of computer packages**

Epi-Info 5 software (Dean *et al* 1990) was used to create the pain questionnaire (Appendix 8) and health professional assessment questionnaires (Appendices 11-13) and to analyse their respective results. All 3 main programmes of EPI were used.

A Microsoft Excel spreadsheet was used to calculate medians and confidence intervals of non-parametric data and correlation coefficients between VAS scales, MPQ pain scores and QOL scores.

## **Chapter 3**

### **Use of prescribed and alternative therapies in patients with chronic pain in the community**

#### **3.1 Introduction**

Adherence to guidelines for the management of patients with chronic pain associated with rheumatoid arthritis, osteoarthritis and back pain should encourage more cost-effective prescribing (Anon 1994, 1996 (A) and (B), Clinical Standards Advisory Group 1994).

As mentioned previously, the therapeutic drug management of rheumatoid arthritis has changed recently with rheumatologists now using DMARDs much earlier in the disease.

However, NSAIDs continue to be extensively used and are probably over-prescribed (Audit Commission 1994, Steele *et al* 1987). In addition, Donovan *et al* (1989) and McElnay and McCallion (1996) found that patients were increasingly buying OTC analgesics in addition to or in preference to their prescribed analgesic therapy, suggesting that pain relief and / or patient satisfaction was sub-optimal. This practice may be potentially hazardous if patients, especially those who are elderly, are using multiple analgesics with significant separate or additive toxicities (e.g. prescribed steroid with OTC ibuprofen) or are using duplicate therapies of one analgesic e.g. multiple products containing paracetamol (Whitaker *et al* 1995).

Minor analgesics are the most extensively used over-the counter remedies in Europe, contributing about 20% of the OTC market (Li Wan Po 1990, Roins *et al* 1998) and are widely used by elderly patients (greater than 65 years) who suffer pain. Patient-reported usage rates of OTC analgesics have varied from 18% (McElnay and McCallion 1996), 40% (Chrischilles *et al* 1990) and 96% (Whitaker *et al* 1995) depending on sample size and methodology used. Most studies were retrospective in nature, where the definitive diagnosis, if any, as to the cause of the

patients' pain was either not known or not validated by the investigators, so no evaluation of OTC therapy efficacy could be made.

McElnay and McCallion (1996) recruited 16 community pharmacies to assess prospectively the extent, type of and reasons for purchase of non-prescription medicines which were bought by elderly patients visiting their pharmacy. The study was carried out over 2 periods of 6 and 10 weeks' duration using semi-structured interviews. Chrischilles *et al* (1990) studied a similar age group but a much larger sample of patients in a prospective epidemiological study, which investigated the influence of various social and environmental factors on multiple analgesic drug use. Whitaker *et al* (1995) used pharmacies and semi-structured interviews like those of McElnay and McCallion, but distributed questionnaires to any customers at specified time intervals, rather than just those who were elderly and / or purchased OTC analgesics.

Hanlon *et al* (1996) and Chrischilles *et al* (1990) have investigated factors influencing analgesic use, in large cross-sectional surveys. Analgesic use was more likely in those patients who were female, had a physical, functional problem or had a history of cardiovascular disease, the latter perhaps reflecting the use of aspirin in thrombotic disease. White women, depressed people and those who visited their GP frequently were more likely to be taking three or more analgesics at one time. Depressed patients or those who needed help with basic daily activities were more likely to be using more than 1 analgesic within a therapeutic class.

Various researchers have investigated the prescribed and OTC drug usage patterns in patients with chronic pain who are referred to pain clinics (Leavitt and Sweet 1986, Turner *et al* 1982, Ready *et al* 1982). Such patients often under-reported their drug consumption, especially narcotic analgesics (Ready *et al* 1982) and had problems associated with drug misuse, side effects, drug interactions and dependency. The type(s) of analgesic(s) used were related to social, physical and psychological factors (Turner *et al* 1982).

Drug usage patterns of patients with arthritis in the community have also been investigated. Long and Wynne (1996) studied the use of NSAIDs and alternative therapies in 153 patients with osteoarthritis and found that younger patients were more likely to report using alternative therapies for pain management with 75% reporting at least moderate pain relief with their NSAID. Some patients with



rheumatoid arthritis have reported improved perceived benefit with alternative therapies, even although good evidence of their efficacy is lacking (Pullar *et al* 1982).

One potential reason for the use of both OTC and alternative therapies is failure to use prescribed medication appropriately. The factors which influence the extent of and the methodologies used to assess patient compliance have been well reviewed by Stockwell Morris and Schultz (1992). Researchers who have investigated adherence of patients to their arthritis medication are now aware of the need to understand and appreciate patients' beliefs and attitudes to their disease, its management and implications to their daily lives, before an appropriate patient education programme can be developed (Donovan *et al* 1989, Donovan and Blake 1992).

### 3.2 Objectives

The objectives of this part of the study were:

1. To identify a cluster sample of patients with chronic pain living in their own homes, using the diagnosis of RA or repeat prescriptions of NSAIDs and / or other analgesics.
2. To determine the prescribing patterns for analgesics and other pain-related therapies in this sample related to diagnosis of chronic pain.
3. To determine the patterns of OTC and alternative therapies used by the study sample for relief of chronic pain.
4. To determine the extent of patient adherence to prescribed therapy and the influence of patient attitude to medication and to prescribers on this adherence.
5. To determine the extent and type of discrepancies, if any, between documented medication histories in patients' medical records and information supplied by the patients.

### **3.3 Methods**

A data collection form (Appendix 7) as described in Chapter 2, Section 2.1.6.1 was used to document relevant demographic, medical, drug, and other patient information from each patient's medical notes prior to interview for comparison at time of interview.

A pain questionnaire (Appendix 8) as described in Chapter 2, Section 2.1.6.3, was used to identify patients' self-reported concordance with their prescribed analgesia and other medication and usage of OTC or alternative therapies either instead of or in addition to their prescribed analgesia.

Duration of each patient interview was between 1 and 1.5 hours.

### **3.4 Results**

#### **3.4.1 Demographic details**

A total of 96 patients were identified from the three practices, who agreed to participate in the study. Thirteen patients refused to participate, who showed no differences in terms of number of disease states or drugs prescribed. All thirteen patients refused because they did not want to be interviewed by a pharmacist in their own home.

Of these 96 patients, 42 had RA, 22 had OA, 25 had both OA and RA and 7 had low back pain. The mean age of the 96 patients was 60.4 years (SD 13.8 years, range 29-84 years). Twenty-eight of the 96 patients (29%) were male and 68 (71%) were female. There was no significant difference in age between pain groups. The mean number of medications currently prescribed for patients was 4.9 (SD: 2.8) and the mean number of concurrent disease states (excluding the chronic pain diagnosis) was 3.0 (SD: 1.9). Forty-seven patients had concurrent problems which could exacerbate chronic pain, 21 with documented gastrointestinal problems and 4 with documented chronic headaches or migraine.

There were no significant differences between the mean number of medications which each group of patients were taking. The mean number of medications taken by each patient group were; RA 5.0 (range 0-12), OA 5.2 (range 2-9), back pain 4.3 (range 2-9) and group with RA and OA 4.9 (range 0-12).

### **3.4.2 Drugs used by study patients in the management of chronic pain**

Table 3.1 illustrates the types and frequencies of analgesic therapies prescribed for the study patients by pain diagnosis. There were no significant differences between the 4 groups' prescribed use of NSAIDs, paracetamol or combination analgesics. However, significantly more patients in the RA group were prescribed other therapies ( $\chi^2 = 9.45$ ,  $df = 3$ ,  $p < 0.05$ ). Thirty-three patients (34%) were prescribed other therapies which included cyclosporin, steroids, alternative therapy, hypnotics and anticonvulsants. Cyclosporin was prescribed concurrently with prednisolone for one patient with ankylosing spondylosis. Steroid therapy was prescribed in 10 patients, all of whom suffered RA, nine of whom were prescribed prednisolone therapy. Two of the 10 patients taking steroid therapy were prescribed intra-articular triamcinolone, one of whom was prescribed oral prednisolone concurrently.

Type of drug prescribed	Number of patients for whom drug was prescribed				
	Patients with RA (%) n=42	Patients with OA (%) n=22	Patients with RA and OA (%) n=25	Patients with Back pain (%) n=7	Total (%) n=96
<b>NSAID</b>	35 (83)	17 (77)	15 (60)	4 (57)	71 (74)
<b>DMARD</b>	11 (26)	0	4 (16)	0	15 (16)
<b>Combination analgesic</b>	18 (43)	13 (59)	12 (48)	5 (71)	48 (50)
<b>Paracetamol</b>	15 (36)	4 (18)	8 (32)	0	27 (28)
<b>Dihydrocodeine</b>	2 (10)	2 (10)	3 (12)	1 (14)	8 (8)
<b>Other</b>	18 (43)	4 (16)	6 (24)	5 (71)	33 (34)

**Table 3.1:** Types and frequencies of analgesic and DMARD therapies prescribed for the 96 study patients

Alternative therapy was only prescribed for 2 RA patients. One of the 2 patients was prescribed a combination of rhus tox and evening primrose oil and the other was prescribed Efamast. Both patients were taking NSAIDs concurrently. Although only 2 patients were taking prescribed alternative therapies at the time of study, 40 patients had documented evidence of previous use of alternative drug therapies and / or use of other treatment strategies such as heat. Moreover, 26 of the 96 study patients (27%) reported on interview that they were actually using alternative therapies. Although, more patients with RA as compared to patients with OA or back pain used alternative therapies, this difference was not of statistical significance ( $\chi^2 = 4.67$ ,  $df = 2$ ,  $p < 0.1$ ).

No records of any present or past OTC medication were found in the medical notes of 92 out of the 96 study patients. Documented OTC analgesics were Anadin Extra (2 patients), diclofenac gel (1 patient) and garlic capsules, all of which were being taken in preference to the patients' prescribed analgesic therapy. Although only 4 patient records had any documentation of OTC analgesics, 25 of the study group (26%) during interview reported that they bought OTC preparations to alleviate pain.

Slightly more RA patients used OTC analgesics than patients in the other 3 groups, although this was not statistically significant ( $\chi^2 = 1.76$ ,  $df = 3$ ,  $p > 0.2$ ).

Tables 3.2 and 3.3 detail respectively, the types and frequency of use of alternative and OTC analgesics treatment used by patients to self-medicate at the time of interview.

	Number of patients using alternative therapy						
Type of alternative therapy	Patients with RA	Patients with OA	Patients with RA and OA	Patients with back pain	Frequency of usage of therapy		Total
					Regularly	Prn	
Cod-liver oil	2	1	4	0	5	2	7
Evening primrose oil	2	0	1	0	3	0	3
Homoeopathy / Herbal	4	1	1	0	2	4	6
Hot bath/ shower/ wax	0	0	1	0	0	1	1
Combination of above	3	0	2	0	4	1	5
Acupuncture	0	1	0	0	0	1	1
Faith-healer	1	0	0	0	1	0	1
Other alternative Rx	0	1	1	0	1	1	2
Total	12	4	10	0	16	10	26

Table 3.2: Types, frequencies and usage patterns of alternative therapies in the 4 different patient groups

	Number of patients using OTC therapy						
Type of OTC analgesic therapy	Patients with RA	Patients with OA	Patients with RA and OA	Patients with back pain	Frequency of usage of therapy		Total
					Regularly	Prn	
OTC paracetamol	6	0	1	0	0	7	7
OTC combination analgesic	0	1	0	0	0	1	1
OTC paracetamol / Solpadeine	1	0	0	0	1	0	1
Rubefacient	1	1	1	0	0	3	3
Anadin Extra	1	1	1	0	2	1	3
OTC NSAID	0	0	1	0	1	0	1
Other OTC	4	1	3	1	3	6	9
Total	13	4	7	1	7	18	25

Table 3.3: Types, frequencies and usage patterns of OTC analgesic therapies in the 4 different patient groups

Other prescribed co-analgesic therapy included hypnotics (4 patients) and in 2 patients, diazepam was used as a muscle relaxant.

Out of the 71 patients who were prescribed NSAIDs, 55 reported that they were using them regularly as prescribed by their GP. Seven patients were prescribed 2 NSAIDs concurrently, four of whom were using oral combinations with 3 using a combination of oral and topical NSAID preparations. One of the latter 3 patients was prescribed a combination of 2 oral and 2 topical preparations. Table 3.4 illustrates the range of 17 NSAIDs prescribed in the study.

Type of NSAID	Number of patients prescribed NSAID	Type of NSAID	Number of patients prescribed NSAID
Naproxen	21	Mefenamic Acid	3
Ibuprofen	11	Azapropazone	3
Fenbufen	7	Sulindac	2
Diclofenac	5	Movelat gel	2
Piroxicam	5	Tiaprofenic Acid	1
Indomethacin	5	Benorylate	1
Aspirin	4	Felbinac	1
Nabumetone	4	Ketoprofen	1
Etodolac	1		

**Table 3.4:** Types and frequencies of NSAIDs prescribed

Twenty-six patients were prescribed prophylactic therapy to prevent gastrointestinal (GI) ulceration which included misoprostol (3 patients), omeprazole (5 patients), ranitidine (6 patients), cimetidine (5 patients), antacids (5 patients) and ranitidine plus antacid (2 patients).

In terms of prophylaxis against NSAID- induced gastrointestinal ulceration, therapy was inappropriate in 9 of these patients (Scottish Medicines Resource Centre 1995(B)). The daily dose of H2 antagonist was too low in 4 patients, antacids were used as sole prophylaxis in 4 patients and the omeprazole daily dose in 1 patient was a treatment dose. A further 8 patients, six of whom were taking NSAIDs regularly or as required, had a previous history of gastrointestinal problems, but were not prescribed any prophylactic therapy. In addition, 3 patients prescribed GI prophylaxis were not taking their therapy at time of interview, despite 2 of the patients continuing to take 2 NSAIDs concurrently.

Out of the 48 patients prescribed combination therapy, 30 patients had RA. Fourteen patients were using combination analgesics regularly with one patient

taking 2 prescribed combination analgesics concurrently. The 3 combination analgesics which were most commonly prescribed were coproxamol (30 patients), cocodamol (13 patients) and codydramol (4 patients). Solpadol was prescribed for one patient.

Only 6 of the 8 patients reported to take dihydrocodeine regularly. Three of the patients prescribed dihydrocodeine were also taking combination analgesics concurrently, two of whom were taking combination analgesics regularly.

Only 15 of the 67 patients (22%) in the study with RA, were prescribed disease-modifying antirheumatic drugs (DMARDs). The DMARDs prescribed were sulphasalazine (6 patients), intramuscular gold (4 patients), penicillamine (3 patients), auranofin (1 patient) and hydroxychloroquine (1 patient). All 15 patients reported that they took their DMARD therapy regularly, although one patient did remark that she had lowered her dose of sulphasalazine while on holiday on one occasion. All DMARDs were initiated and monitored by rheumatologists.

None of the 15 patients were prescribed a DMARD as sole therapy. Thirteen of the 15 were taking NSAIDS concurrently with 9 of the 13 prescribed a combination analgesic or paracetamol for background pain in addition. The other 2 patients on DMARDs were prescribed dihydrocodeine and paracetamol (1 patient) and cocodamol (1 patient) due to NSAID intolerance in both patients.

### **3.4.3 Pharmacist assessment of patients' knowledge of and adherence to prescribed medication and attitude to prescriber**

#### **3.4.3.1 Patient awareness of indication for therapy**

Eighty-seven of the 96 study patients (91%) identified all prescribed medications which were being taken by them at the time of interview and could identify their indications.

Two patients had problems identifying their medication and its indication. One of these had no idea of the names and indications of 3 of her prescribed medications, while the other identified Sudafed tablets as being used to treat his constipation. The other seven patients could identify all their medication, but wrongly identified at least one of their therapies for the relief of pain i.e. low dose aspirin (3 patients),

antacid / proton-pump inhibitor (1 patient), choral hydrate (1 patient) and cardiovascular agents (2 patients). Six patients also identified that their anti-rheumatic therapy aided sleep and / or mood.

#### **3.4.3.2 Patient awareness of drug administration details**

Ninety-four out of the 96 patients (98%) could identify how many dosage units of all their medications they took per dose, without being prompted or looking at their medication during interview.

Patient awareness of strength of medication was not so encouraging, especially concerning their analgesic therapy. Thirty-eight out of the 96 study patients (40%) i.e. 16 RA patients, 16 patients with RA and OA, 5 OA patients and 1 back pain patient could not identify the correct dosage of their analgesic therapy. None of the patients who were taking combination analgesics could identify the dosage of paracetamol or any other component within each tablet, but all could identify the maximum prescribed daily dosage of their combination analgesic.

#### **3.4.3.3 Pharmacist assessment of patient adherence to prescribed analgesic therapy and attitude to prescriber**

During the patient interview, patients were asked whether they always took their analgesic medication as prescribed or, if not, how their current regime differed from that prescribed by their GP.

Table 3.5 compares the number of patients who were prescribed regular analgesic therapy by their GP as documented in each patient's medical records with the number of patients who reported taking their analgesic medication regularly at the time of interview. All patients prescribed DMARDs took them regularly as prescribed, but only 5 out of 14 patients prescribed paracetamol regularly actually took it as prescribed. Moreover, slightly fewer patients than predicted from medical records were actually taking their NSAIDs regularly. In total, 60 patients (62%) said that they always took their medication as prescribed, but 36 patients (38%) said that they had recently altered the dose and / or frequency of their current analgesic medication. The reasons patients gave for amending therapy are detailed in Table



3.6. When patients were asked about specific adherence to prescribed individual drug therapies, 46 patients (48%) actually admitted that they did not adhere to the prescribed regimes with 41 reporting that they used a lower dose than prescribed and 5 a higher dose than prescribed.

Patient group	RA		OA		RA and OA		Back pain		Total	
Type of drug prescribed	No. prescribed regular Rx (n)	No. taking regular Rx	No. prescribed regular Rx (n)	No. taking regular Rx	No. prescribed regular Rx (n)	No. taking regular Rx	No. prescribed regular Rx (n)	No. taking regular Rx	No. prescribed regular Rx (n)	No. taking regular Rx
NSAID	32 (35)	29	12 (17)	11	14 (15)	12	3 (4)	3	61 (71)	55
DMARD	11 (11)	11	0	0	4 (4)	4	0	0	15 (15)	15
Combination analgesic	4 (18)	5	0 (13)	4	5 (12)	2	1 (5)	2	10 (48)	13
Paracetamol	11 (15)	2	1 (4)	2	2 (8)	1	0 (0)	0	14 (27)	5
Dihydrocodeine	2 (2)	1	0 (2)	2	2 (3)	3	0 (1)	0	4 (8)	6
Other	13 (18)	14	4 (4)	3	5 (6)	5	4 (5)	3	26 (33)	25

**Table 3.5:** Self - reported patient concordance with prescribed medication

‘N’ in each column refers to the total number of patients prescribed each type of analgesic within each disease category, including those for whom the medicine was prescribed as required.

Reasons for amending dose(s) of analgesics	RA group n=42	OA group n=22	Back pain group n=7	RA and OA group n=25	Total n=96
Reduced pain	1	2	0	2	5
Only took what was needed	4	1	2	3	10
Thought that I did not need them	2	1	0	1	4
Side effects limit the dosage I can take	2	2	0	1	5
Combination of reduced pain/ only take what I need	1	0	0	1	2
Pregnancy	1	0	0	0	1
Increased pain	4	1	0	0	5
Symptoms of another problem worsened	0	1	3	1	4
<b>Total</b>	<b>15 (36%)</b>	<b>8 (36%)</b>	<b>5 (71%)</b>	<b>9 (36%)</b>	<b>36 (38%)</b>

**Table 3.6:** Types and frequencies of reasons for patients amending the dose of analgesia currently prescribed

Most of the 36 patients who had recently altered their current daily dosage of analgesic therapy, were taking a reduced dosage of analgesic compared to that prescribed. Doses were reduced by 15 patients prescribed NSAIDs (21% of those prescribed NSAIDs), 10 prescribed combination analgesics (21%), 9 prescribed other therapy (27%), 3 prescribed dihydrocodeine (38%) and 3 prescribed paracetamol (11%). Four of the 36 patients altered the daily dosage of more than 1 currently prescribed analgesic.

Although 28 patients were assessed by the study pharmacist as having poor pain outcomes, only five patients admitted to currently taking a higher dose of their analgesic therapy than their normal daily dose due to a recent increase in pain (see Table 3.6).

Thirty-three patients (34%), identified that they had required a higher dose than currently prescribed at least once during their disease, largely due to decrease in pain control at the time. Significantly more patients with RA reported such a need than any other pain group ( $\chi^2 = 8.26$ ,  $df = 3$ ,  $p < 0.04$ ). Three patients identified that analgesic requirements had to be increased due to an exacerbation of a concomitant problem.

Patients were also asked if they had ever forgotten to take their analgesia at any time, and if so what had been the perceived consequences. Forty-six patients (48%) admitted to having forgotten to take their medication at some time. Consequently, 15 out of the 46 patients recognised that the pain and stiffness got worse. Twenty-four patients found no problems and either took it as soon as they remembered or forgot that day's dose and continued as normal thereafter, while 7 patients suggested that other disease state(s) became aggravated.

Patients were asked when they took their analgesia in relation to food or times of the day. Although 62 patients identified that they took their NSAID with or after food, 7 patients admitted to taking their NSAID before food on an empty stomach, at any time or just with fluid, one of whom was taking two oral NSAIDs concurrently.

Eleven out of the 15 patients taking DMARDs took their medication with or after food, two of whom were taking penicillamine. Only one of the 3 patients taking penicillamine was taking the medication before food as recommended. Three of the 4 patients on intramuscular gold identified that administration of their DMARD depended on their clinic appointment time. Twenty-five out of 48 patients and nine of 25 patients who were prescribed combination analgesics or paracetamol respectively took their medications with or after food. The other 39 patients prescribed combination analgesics or paracetamol took them 'as required' or at times as GP had prescribed. Six out of the 8 patients taking dihydrocodeine took it with or after food.

Case Study 1 (Appendix 14) illustrates changes in the use of prescribed medication and use of alternative therapy.

When patients' responses to the attitude statements 2 to 8 of the pain questionnaire (Appendix 8) were compared to their self-reported adherence to medication, only one significant difference in attitude was found between those who adhered completely to their GP's advice and those who altered their medication. Patients who agreed or strongly agreed with the statement 'Doctors know what is right for their patients' were more likely to be compliant with their GP's recommendations compared to those who disagreed or strongly disagreed with the statement ( $\chi^2 = 10.70$ ,  $df = 1$ ,  $p < 0.01$ ).

**3.4.3.4 Pharmacist assessment of patients’ awareness of and attitude to drug information leaflets**

Patients were asked if they had ever received an information leaflet about their medication when it was dispensed. Patients who had received an information leaflet were then asked if they read it and if so, in what ways they found it useful. Fifty-seven patients (59%) identified that they had received an information leaflet, 55 of whom, had read it. Twenty-eight of the 55 patients said the leaflets were useful to help explain how the drug worked and 39 that they were useful in aiding identification of potential side effects of their prescribed medication. Nine of these also suggested that leaflets could advise on the action to take if a side effect was experienced. Ten of the 55 patients suggested that the information leaflet clarified dosing and / or administration directions.

Analysis of attitude statements showed that 71 patients (74%) agreed or strongly agreed that doctors knew what was right for their patients, while 23 (24%) disagreed or strongly disagreed and 2 (2%) were uncertain. Although, 84 patients (88%) felt that patients should try to control their own pain, 87 (91%) believed that most patients benefit from taking painkillers for pain. There were largely 2 groups of thought regarding medicine taking. Forty-six patients (48%) thought that taking medicines was unnatural, while 44 (46%) disagreed with the statement.

**3.4.4 Discrepancies between documented medication histories in patient medical records and information supplied by patients**

**3.4.4.1 Discrepancies in prescribed medication for chronic pain**

Table 3.7 details the types and frequencies of discrepancies in prescribed medication for chronic pain.

Seventy-two out of the 96 (75%) patients interviewed had at least one discrepancy present between their documented drug history in their medical record and that obtained by interview concerning therapy for chronic pain. All 72 patients who described the 183 analgesic changes claimed at interview that the changes had actually been recommended or agreed by their GP, but the amendments had not been made in the patients’ records (see Case Study 2 in Appendix 15). There were

discrepancies in 54 patients with RA (81%), 15 with OA (68%) and 3 patients with back pain (43%).

Forty-five of the discrepancies involved chronic pain therapies which had been discontinued without a documentation of the change made in the patient's medical notes. Twenty-five of these were for NSAID therapy, the rest for paracetamol or combination analgesics (6), steroids or DMARDs (7), rhus tox( 5) and others (2).

Type of discrepancy between records and information from interview	Drugs for chronic pain (No. of patients)	Other drugs (No. of patients)	Total number of discrepancies
Change in dosage of currently prescribed medication	32 (23)	8 (8)	40
Change in frequency of currently prescribed medication	48 (39)	14 (13)	62
Change in formulation	9 (9)	0	9
Addition(s) to treatment regimen	49 (36)	31 (26)	80
Discontinued treatment	45 (43)	49 (35)	94
Total	183	102	285

**Table 3.7:** Types and frequencies of prescribed medication discrepancies

Twenty-eight of the 48 discrepancies in dosing frequency between records and information from the patient were for paracetamol or combination analgesics, 12 for NSAIDs and 8 others involving dihydrocodeine. Thirty-six of these 48 differences involved a decrease in dosing frequency.

Additional therapy was prescribed for patients on 49 occasions but not recorded in the notes. Sixteen of these were related to NSAID therapy (10 changes in drug, 4 changes in formulation and 2 cases where an NSAID was added to existing NSAID therapy), 10 additions to combination analgesics where a combination was either added to an analgesic regime (6 patients) or changed (4 patients). Nine and 10 additions respectively, concerned paracetamol and other therapies. Four additions related to OTC preparations.

**3.4.4.2 Discrepancies in over-the-counter (OTC) medication**

Only 4 patients had any OTC medication documented in medical notes. Two of these patients attributed greater efficacy to Anadin Extra as compared to their prescribed combination analgesics, thus used the former in preference to the latter. The two other patients were using garlic capsules and Diclofenac gel respectively. The patient taking garlic had actually been recommended cod-liver oil by his GP,

but the patient preferred garlic in conjunction with an NSAID. Diclofenac gel was being used by the fourth patient to reduce his daily dose of coproxamol from that prescribed. All patients stated that their GP was aware of the changes in medication.

No further follow up was made to verify GP awareness since none of these patients had a poor pain outcome and thus according to study protocol, did not require GP referral.

#### **3.4.4.3 Discrepancies in other medication**

Table 3.7 details the actual number and type of discrepancies found for prescribed medication other than that used in the management of chronic pain.

Ninety-eight of the 102 prescribed medication discrepancies resulted from changes in therapy as recommended by the patients' GPs, but again no written record had been made in patients' notes. In total, 79 (82%) patients interviewed had 102 other prescribed medication discrepancies. The most frequent types of discrepancies found were discontinuation of therapies (48%) and additions to therapy (30%).

Four of the 102 discrepancies arose when patients admitted that they were not taking their medication as prescribed because of intolerable side effects (1 patient) or because they were unconvinced of the need for the treatment (3 patients).



### 3.5 Discussion

It was reassuring to find that 3 of the top 4 most commonly prescribed NSAIDs in this study were those with lowest risk of gastrointestinal side effects (Committee on Safety of Medicines (CSM) 1994). However, indomethacin, piroxicam, and azapropazone were also prescribed, all of which have moderate to high risk of GI toxicity and use of which should be limited and especially discouraged in the elderly. Seven patients were prescribed 2 NSAIDs concurrently, 3 of whom required referral to their GP because of gastrointestinal side effects and pain. Patients with chronic pain should be assessed regularly and concurrent use of more than one NSAID should be avoided to minimise potential serious side effects and maximise therapeutic outcome.

The number of NSAIDs prescribed by a GP should be minimised, such that 5 NSAIDs account for about 70-80% of prescriptions, to encourage familiarity of GP and patients with the NSAID and encourage adherence to CSM guidelines (Scottish Medicines Resource Centre 1995(A)). In this study, 7 to 12 different NSAIDs were used per practice, but as only a proportion of patients in each practice were included, the number of different NSAIDs prescribed may be an underestimate.

NSAID prescribing in the OA group was high (77%). However, 5 of the 17 in this group prescribed NSAIDs used them as required, 3 of whom were using topical NSAIDs. Paracetamol prescribing in this group was much lower (18%) compared to the proportion prescribed an NSAID, which suggests that NSAIDs were overprescribed in this patient group. Some randomised trials have shown that for OA patients, paracetamol is as useful as NSAIDs (Bradley *et al* 1991, Dieppe *et al* 1993(A)) and should be encouraged. In this study, very few OA patients at interview noted inflammation which is not a typical feature of osteoarthritis. Indeed, Swift and Rhodes (1992) have demonstrated that a large proportion of OA patients can be safely changed from NSAIDs to paracetamol without compromising efficacy.

The use of prescribed topical NSAIDs in this study was restricted to 5 patients (2 with RA and 3 with OA). All prescribed topical NSAIDs were used as required,

not regularly, but one other OA patient was purchasing diclofenac gel for osteoarthritis of superficial joints and using it regularly instead of his prescribed oral NSAID. The finding that 3 of the patients using topical NSAIDs were also using oral NSAIDs regularly and that 1 of the 3 was using 2 oral and 2 topical NSAIDs concurrently suggests that these patients were at high risk of gastrointestinal toxicity. None of the OA patients prescribed topical analgesics had used a simple rubefacient previously. Evidence suggests that chronic use of topical analgesics is similar in efficacy to 1200mg ibuprofen (Dickson 1991) i.e. an analgesic not an anti-inflammatory dose of NSAID and is still associated with systemic gastrointestinal side effects. From this study, the use of topical NSAIDs, especially in OA patients, requires to be reviewed. Prescribers should be encouraged to use a rubefacient if needed and a single oral NSAID at an anti-inflammatory dose for a short course for soft tissue inflammation for OA. Otherwise, OA pain and soft tissue injuries should be treated with paracetamol or dihydrocodeine. Dihydrocodeine was seldom used in this study.

Combination analgesics were widely prescribed in preference to paracetamol in all groups. There is no significant evidence to suggest that combination analgesics are superior to individual analgesics of the combination if given alone (Li Wan Po *et al* 1997, Scottish Medicines Resource Centre 1995(C)). They also do not provide dosage flexibility, may encourage unnecessary use of an analgesic and are expensive. Cocodamol, the second most commonly prescribed combination analgesic in this study, with 8mg codeine and 500mg paracetamol per tablet, may cause patients, especially the elderly, to suffer opioid side effects such as constipation (see Chapter 6) with no additional analgesia conferred, but more problems associated with overdose treatment.

Combination analgesics containing higher doses of opioid such as Tylex (paracetamol 500mg, codeine 30mg) which was also prescribed in this study, have been shown to be more effective than codeine alone, but not paracetamol (Bentley and Head 1987), and are more likely to cause dependence. A recent meta-analysis suggests that codeine provides a slight additive analgesic effect to paracetamol but use is limited by side effects (De Craen *et al* 1996). Coproxamol was the most commonly prescribed combination analgesic, a popularity demonstrated in other studies, which may be caused by habit rather than evidence of improved efficacy (Haigh 1996). Although dextropropoxyphene accumulation in chronic use may

contribute to coproxamol's enhanced efficacy (Sykes *et al* 1996), such chronic use should be discouraged, especially since overdoses can be quickly fatal.

The review of drug therapy used in the management of patients with RA and with a combination of RA and OA suggests that the usage of DMARD agents is low. The low incidence of DMARD use can be partially explained by the fact that this study was performed prior to recent evidence suggesting that DMARDs should be initiated early on in the disease process (Egsmose *et al* 1995). Moreover, many RA patients had extensive joint disease, where DMARD therapy would be inappropriate and some patients had to discontinue DMARD therapy prior to the study due to side effects or lack of benefit. However, pharmacists should now be vigilant and identify newly diagnosed RA patients who may respond well to DMARD treatment long-term (Porter *et al* 1994). It was reassuring to find that no patient was prescribed or was using a DMARD as sole therapy. The lack of methotrexate use in this study, a DMARD now considered as first line DMARD treatment along with sulphasalazine (Felson *et al* 1990), reflects the time of the study at which time methotrexate was only just licensed for use in RA.

Although the back pain group only consisted of 7 patients, it can be seen that NSAIDs and combination analgesics were largely prescribed. Simple analgesics should be encouraged in this group of patients wherever possible, with appropriate physical therapy, activity and biopsychosocial assessments (Clinical Standards Advisory Group 1994).

An investigation of patients' usage of OTC and alternative medication was undertaken to identify whether patients were self-medicating and, if the OTC use was additional to or in preference to prescribed medication. Although a high percentage of the study patients believed that they should control their own pain, only 25 patients were using OTC analgesics and 26 were using alternative medication, which suggests that most patients were prepared to tolerate pain or adopt alternative management strategies. The latter is not obvious from the medical records, since only 57 patients had any documentation of other management strategies e.g. physiotherapy, occupational therapy, use of aids or a combination of approaches. Seventy-one study patients agreed or strongly agreed with the statement that 'Doctors know what is right for their patients', which suggests that most

patients preferred to use prescribed medication or other strategies suggested from their own doctor.

The majority of patients using OTC analgesics were using them in addition to their prescribed therapy, with only 4 patients using OTC analgesics in preference to their prescribed analgesic therapy. The findings that RA patients were more likely to use OTC and alternative therapies may reflect not only the chronicity and pathophysiology of RA, but also patients' desires to find other therapies with perceived less side effects than their long-term prescribed medication (Donovan and Blake 1992), as self-medication is encouraged and publicised. It was unclear as to whether the patients who were taking OTC and / or alternative therapies not recorded in their medical notes had actually notified their GPs, emphasising the importance of an agreed and well defined strategy of treatment between GP and patient.

Age of patient did not influence the purchase of OTC or alternative therapies. The age of patients purchasing the latter therapies tended to reflect the mean age of RA patients in this study. Britten (1996) has investigated other factors which may influence the public's perception of herbal remedies or natural products and found that people with unorthodox views about medicines were more likely to be more positive about alternative therapies than prescribed medicines. Such patients were more likely to consider medicines as unnatural. In this study, 24 of the 25 patients who used OTC analgesics and 24 of the 26 patients who used alternative therapies agreed or strongly agreed that taking medicines was unnatural.

Patients' understanding of their medication for chronic pain needs to be improved. The finding that the majority of patients could identify the indications for all their prescribed medications is perhaps not surprising, since many of the study patients had been taking their therapies long-term. Some could also have been prompted to check their understanding prior to the pharmacist's scheduled visit. Fairbrother *et al* (1993) found that a similar percentage of patients knew the indications of their medications, but they were investigating a general group of elderly patients.

It is encouraging that almost all patients could identify how many dosage units they took per dose but worrying to find that 40% could not identify the correct

strength. Pharmacists need to consistently check patients' awareness of dosage of medication, especially if on chronic therapy.

Patient adherence to prescribed analgesic therapy was variable. Deviation from the prescribed dose was largely associated with a reduced analgesic usage due to patients' perception that they only took what was needed, pain was reduced or side effects limited use. These findings illustrated by a case study (Appendix 14) are similar to those of Donovan and Blake (1992), confirming that patients' decisions to comply with therapy are based on their need to take control of their own disease management, after assessing the costs (side effects, stigma of drug-taking, drug regimen) and benefits (improved symptomatic and long-term pain relief, better quality of life) in relation to their own attitudes to their disease state and its management.

The findings that nearly half of the study patients titrated their analgesic requirements to their own daily needs and tended to take no more than half of the daily dose of combination analgesic prescribed, suggest that patients are prepared to experiment with doses and timing of therapy in a similar manner to that observed by Donovan and Blake 1992, Dixon *et al* 1995. Some patients in this study demonstrated a reluctance to take the maximum daily dose of their prescribed analgesic or the dosages recommended by their GPs even when experiencing significant pain.

Only five patients admitted to currently taking a higher dose of analgesic than their normal daily dose due to a recent increase in pain, despite 18 patients requiring referral because of poor pain outcomes. This suggests that some patients with chronic pain prefer to tolerate significant pain rather than increase analgesia (see Chapter 4). Deyo *et al* 1981, found that patients on DMARDs received better information than patients on other drugs and have identified the improved compliance with DMARD therapy as compared to other therapies in this study. This finding emphasises the need for accurate and sufficient information about the rationale of therapy and monitoring requirements to be effectively communicated to the patient at a time convenient to him / her. Patients in the 'bereavement period' of a chronic illness do not respond well to information about their disease state (Donovan *et al* 1989).

A high proportion of patients agreed with the statement that 'doctors know what is right for their patients', yet amended their medication taking according to their own pain experience and understanding of the treatment prescribed. These findings were similar to those of other investigators who have found that when patients were confident about their understanding of their treatment, they modified their own treatment regimes, yet perceived that this was not inconsistent with their GPs' recommendations (Blaxter and Britten 1997). (Chapters 4 and 5 discuss more fully the study patients' attitudes and perceptions of their chronic pain and its management.).

Only about 60% of the study patients were aware of the availability of information leaflets. More patients taking DMARDs were aware of this availability compared to patients on any other medication. This finding may suggest some forgetfulness on the part of the patients, since most of the patients on DMARDs had been taking them for several years. Alternatively, this may also reflect a lack of communication and / or dissemination of information between rheumatologists and GPs, the latter acting in accordance with the consultants' recommendations and less familiar with the availability of information leaflets. Moreover, the study was undertaken prior to recommendations for all original packs to contain package insert leaflets. Assumptions may have been made by health professionals involved that patients already had leaflets or were not interested in obtaining further information as suggested by Donovan and Blake (1992). Many studies have found that patients want specific information about their disease state and its management in order to make informed decisions regarding their own medication-taking behaviour (Farmer and Pepper (1995), Donovan and Blake (1992)).

Patients must be aware of the rationale for monitoring therapy outcomes and who is responsible for carrying out appropriate monitoring procedures. Pharmacists need to be proactive and identify those patients with chronic pain who will benefit from information leaflets in addition to verbal advice. Indeed, encouraging leaflet availability (Ghalamkari *et al* 1997(B)) can enhance patient perception of the skills of pharmacists.

The high number of discrepancies between documented drug histories in medical records and that at time of interview found in this study was worrying, since few medical records of the study patients, especially those for RA patients actually

reflected their present prescribed medication regime. The fact that 60% of discrepancies were concerned with changes in drugs prescribed rather than just dosage or frequency changes, suggests that the risks of clinically significant interactions and side effects are increased, especially since no updated medical record is available for monitoring purposes. Potential toxicities could result as illustrated by Case Study 2 (Appendix 15).

It was not possible to make a rapid assessment of patients' responses to therapy both therapeutic and toxic by appraising medical notes in this study. Such documentation is critical if adverse drug reactions are to be avoided and efficacy optimised. Indeed, four patients had discontinued therapy on their own accord due to intolerable side effects or lack of perceived benefit, none of which was documented in any record.

No evaluation was made of the type or accuracy of medication records held by pharmacists in this study. Pharmacists are well placed to update patients' records as changes are made to patients' therapy and provide appropriate advice, provided these patients regularly attend the same pharmacy. OTC medication use can more easily be included in these records, whereas documentation in medical records was poor in this study. Pharmacists can then use the records to identify (1) any potential overuse of OTC analgesics in addition or in preference to prescribed therapy and (2) the development of any side effects attributed to analgesic therapy, discussing the situation with the patient and their GP (Briggs *et al* 1996).

## **Chapter 4**

### **Patient outcomes in terms of pain control**

#### **4.1 Introduction**

Chronic pain associated with rheumatoid arthritis (RA), osteoarthritis (OA) and back pain is a longstanding problem which has often become a stable element in a patient's life. RA can cause both acute and chronic pain of varying intensity, arising from many sources including local joint inflammation, chronic changes in articular tissue, systemic problems, affective changes and side effects of medication (Reisner - Keller 1992).

The perception of chronic pain is influenced by physical (age, tissue damage, drug toxicity), social (stress), psychological (depression, drug dependence) and emotional (fear, loss of dignity) factors (Reisner - Keller 1992).

Elderly patients have demonstrated altered pain perception, partly due to altered nociceptive responses, such that they may not experience certain types of visceral pain. They also demonstrate altered psychological responses involving an unwillingness to label a noxious stimulus as painful, thus making chronic pain assessment difficult in the elderly (Gloth 1996). Moreover, age-related pharmacodynamic changes and concurrent psychiatric illness can complicate pain control (Newman *et al* 1989).

Patient attitude to pain is an important factor in pain perception and overall management, and can vary depending on severity of pain problems and duration of pain disease state. Older RA patients often present with fewer symptoms than younger patients and tend to report less pain (Deal *et al* 1985). Patient reporting of chronic pain may not be believed, their problem not fully appreciated or the patient can be mislabelled as a malingerer or 'addicted' to medication, all of which damage



patient self-esteem and the patient-physician relationship (Weissman and Haddox 1989).

Studies suggest that analysis of medication usage cannot reliably predict the pain experienced by patients with chronic pain. Work in pain clinics suggests that certain patient groups will underestimate drug usage (Ready *et al* 1982), while patients with rheumatological diseases tend to deliberately limit their medication intake, preferring to tolerate pain (Donovan and Blake 1992).

Patient satisfaction with medication is often closely associated with beliefs about the origin of their pain, with better outcomes being achieved when both physician and patient agree on a pain management strategy (Wooley *et al* 1978).

Assessment of pain in arthritic patients is a critical factor in the determination of their medication usage, over and above any physical or psychological problems (Kazis *et al* 1983) and has a strong influence on general health assessment. The recommended pain scales used in patients with rheumatic diseases and other chronic pain states have been well reviewed (McDowell and Newell 1996).

The McGill Pain Questionnaire (MPQ) is a well-validated tool for the assessment of pain, providing a qualitative profile of three major psychological dimensions of pain (sensory-discriminative, motivational-affective and cognitive-evaluative). The MPQ has been shown to be reliable (Melzack 1975), although the extent of correlation between the three dimension scores depends on the type of pain being evaluated (Perry *et al* 1988). Correlations between MPQ scores and VAS scores have been discussed in Chapter 1. Use of verbal descriptors within the MPQ can help classify patients into particular diagnostic groups (McDowell and Newell 1996), but patients can misinterpret them.

Researchers have mixed views as to whether the MPQ actually reflects the three proposed dimensions of the pain experience as reviewed by McDowell and Newell (1996). Turk and colleagues (1985) reassessed the factorial structure of the MPQ and confirmed the three dimensions, although suggested that the total Pain Rating Index score is the recommended variable for research use.

Few pharmacists have used validated pain assessment tools to evaluate chronic pain management in the community. Most studies by pharmacists investigating outcomes of patients with chronic pain have evaluated outcomes in terms of patient satisfaction with medication (Long and Wynne 1996) or medication usage (Briggs *et*

*al* 1996). Any pharmacist involved in the assessment of chronic pain perceived by patients should be encouraged to use a previously validated pain assessment tool to obtain a more accurate assessment of patients' pain and their perceptions of that pain over a period of time. The results could then be related to patients' medication taking behaviour to obtain a greater understanding of pain outcomes.

## 4.2 Objectives

The objectives of this part of the study were:

1. To identify patients' expectations of pain relief compared to actual pain relief experienced.
2. To investigate the pain experienced by the 96 patients at first interview and the differences, if any, between patient groups in terms of intensity, quality and description, using VAS and the McGill Pain Questionnaire.
3. To measure any differences between pain experienced at initial and follow-up interview by those patients who had poor outcomes and were referred for review.
4. To identify patient attitude to pain and knowledge of pain management and differences, if any, between groups.
5. To investigate the influence of age, duration and diagnosis of chronic pain, patient attitude and knowledge on pain perception.

## 4.3 Methods

Patients' expectations of pain relief as compared to actual pain relief experienced were assessed using visual analogue scales (VAS) as described in Chapter 2, Section 2.1.6.3.

The McGill pain questionnaire (MPQ), its verbal descriptors and visual analogue scales (VAS) (Appendices 8 and 9) were used to assess the quality and intensity of each patient's chronic pain during each interview as described in Chapter 2, Section 2.1.7. The mean time taken for each patient to complete the MPQ was 12 mins.

Pain scores for each patient were calculated in terms of total PRI (S), total PRI ®, NWC and PPI scores as described by Melzack (1975), and noted in Chapter 2 Section 2.3.3.

Visual analogue scales were also used to record each patient's subjective assessment of their 'ideal' analgesic and their perceived efficacy of prescribed analgesia. All VAS scales used were horizontal lines of 10cm.

Patient attitude to pain and knowledge of pain management was assessed using attitude statements within the pain questionnaire as described in Chapter 2 Section 2.1.7.

The influence of age, duration and diagnosis of chronic pain on pain perception was assessed by correlating the patients' responses of age, duration and diagnosis of chronic pain with their respective total PRI pain scores.

4.4 Results : Evaluation of patients’ pain control

4.4.1 Patients’ expectations of pain relief compared to pain relief experienced

Table 4.1 shows the degree of pain relief which patients expected and achieved from their medication(s), assessed on a horizontal VAS scale where 0 = no relief and 100 = complete pain relief (see questions 24 and 35 of Appendix 8).

Expected pain relief (VAS scale 0-100)	Number of patients who expected pain relief	Cumulative frequency (%)	Number of patients who achieved pain relief	Cumulative frequency (%)
0-30	1	1	4	4
31-50	2	3	20	25
51-70	24	28	32	58
71-90	40	70	30	90
91-100	29	100	10	100
Total	96		96	
Mean (95% CI)	82.5 (79.4-85.6)		68.9 (64.9-72.9)	
Median (95% CI)	80 (80-90)		70 (60-75)	

Table 4.1: Patients’ expected pain relief and that actually achieved

Table 4.2 illustrates patients’ expectations in terms of goals of pain relief and that actually achieved (see questions 24 and 35 of Appendix 8). There were no differences of significance between pain diagnoses in terms of expected goals or actual goals achieved, expected pain relief or actual pain relief achieved.

Although 29 patients expected complete relief with their medication(s), only 9 actually reported that they achieved 100% relief with 1 other reporting 95% relief. Sixty-nine patients (72%) expected at least 75% pain relief, yet only 40 patients

(42%) reported to have achieved that relief. The difference in expectations between patients with satisfactory outcomes at Interview 1, patients with poor pain control at Interview 1 and patients with poor outcomes at Interview 1 are shown in Table 4.3. Expectations of pain relief were significantly higher in the poor outcomes patient group as compared to those patients with satisfactory outcomes ( $\chi^2 = 4.30$ ,  $df = 1$ ,  $p < 0.05$ ).

Goal of therapy (Rating on numerical scale)	No. of patients who expected goal of therapy	Cumulative frequency (%)	No. of patients who achieved goal at first Interview	Cumulative frequency (%)
Provide complete relief (1)	22	23	7	7
Relieve pain as much as possible (2)	44	69	30	38
Relieve pain enough to cope with daily activities (3)	21	91	44	84
Relieve pain enough to sleep (4)	1	92	1	85
Other (5)	8	100	14	100
Total	96		96	
Median (95% CI)	(2) Relieve pain as much as possible (2-2)		(3) Relieve pain enough to cope with daily activities (3-3)	

**Table 4.2:** Patients’ expected goals of therapy and goals of therapy actually achieved

<b>Expectations of pain relief</b>	<b>All patients at Interview 1</b>  (n=96)	<b>Patients with satisfactory outcomes at Interview 1</b>  (n=68)	<b>Patients with poor pain control at Interview 1 (VAS average pain &gt;75)</b>  (n=6)	<b>Patients with poor outcomes at Interview 1</b>  (n=28)
<b>Median VAS score</b> <i>(95% CI)</i>	80 <i>(80-90)</i>	70 <i>(70-80)</i>	85 <i>(60-100)</i>	90 <i>(80-100)</i>

**Table 4.3:** Patients' expectations of pain relief in terms of VAS scores for all patients and patient groups

Patients were requested to rate how satisfied they were with their pain control. Six patients (6%) were completely satisfied, 41 (43%) were very satisfied, 44 (46%) were moderately satisfied and 5 (5%) were dissatisfied with their pain relief at that time. There was no statistical difference in patient satisfaction between pain diagnoses groups.

#### **4.4.2 Pain experienced in terms of intensity, quality and description using visual analogue scales (VAS) and the McGill Pain Questionnaire (MPQ)**

All 96 patients were asked to rate the intensity of their average pain at interview over the previous month, using horizontal VAS, (VAS average), the worst pain they had experienced (VAS worst), and the pain experienced at time of interview (VAS present) (Table 4.4). Compared with patients with satisfactory outcomes, patients with poor outcomes had significantly higher VAS average ( $\chi^2 = 9.08$ ,  $df = 1$ ,  $p < 0.01$ ), VAS worst ( $\chi^2 = 5.75$ ,  $df = 1$ ,  $p < 0.02$ ) and VAS now scores ( $\chi^2 = 13.41$ ,  $df = 1$ ,  $p < 0.001$ ).

The results of pain outcomes measured using the MPQ are shown in Table 4.5. Patients with poor outcomes had significantly higher total PRI scale ( $\chi^2 = 6.33$ ,  $df = 1$ ,  $p < 0.02$ ), total PRI rank ( $\chi^2 = 8.18$ ,  $df = 1$ ,  $p < 0.01$ ), NWC ( $\chi^2 = 16.85$ ,  $df = 1$ ,  $p < 0.001$ ) and PPI scores ( $\chi^2 = 19.24$ ,  $df = 1$ ,  $p < 0.001$ ) as compared with patients with satisfactory outcomes.

Patient satisfaction demonstrated significant negative correlations with total PRI rank and scale scores ( $r = -0.34$ ,  $r = -0.32$ , respectively,  $p < 0.001$ ) and with VAS average scores ( $r = -0.57$ ,  $p < 0.001$ ) i.e. the higher the pain or VAS average scores, the lower the patient satisfaction.

Table 4.6 summarises the MPQ scores in terms of patients' disease state(s). The total PRI® and PRI(S) scores for all patients are subdivided into the 4 MPQ categories i.e. sensory (S), affective (A), evaluative (E) and miscellaneous (M). Although the subgroup of back pain patients is small, this group had higher, but not statistically significant, PRI® and PRI(S) sensory scores as compared to the RA, RA and OA and OA groups.

<b>Parameter</b>	<b>All patients at Interview 1 (n=96)</b>	<b>Patients with satisfactory outcomes at Interview 1 (n=68)</b>	<b>Patients with poor pain control at Interview 1 (VAS av pain &gt;75) (n =6)</b>	<b>Patients with poor outcomes at Interview 1 (n=28)</b>
Median score for VAS worst pain (95% CI)	70 (60-80)	60 (60-70)	100 (60-100)	80 (60-90)
Median score for VAS average pain (95% CI)	40 (40-45)	40 (30-40)	80 (80-100)	55 (40-70)
Median score for VAS pain now (95% CI)	30 (30-40)	30 (30-40)	70 (60-100)	50 (30-60)

**Table 4.4:** Patients' pain intensity.

Worst, average VAS scores over past month and present VAS scores at Interview 1 for all patients and patient groups



<b>Parameter</b>	<b>All patients at Interview 1 (n=96)</b>	<b>Patients with satisfactory outcomes at Interview 1 (n=68)</b>	<b>Patients with poor pain control at Interview 1 (VAS average pain &gt;75) (n=6)</b>	<b>Patients with poor outcomes at Interview 1 (n=28)</b>
<b>Median PRI scale (95% CI)</b>	<b>14.5</b> (11.8-18.3)	<b>12.8*</b> (10.3-15.2 )	<b>28.0</b> (10.0-59.0)	<b>22.4*</b> (14.1-29.4 )
<b>Median PRI rank (95% CI)</b>	<b>14</b> (10- 17 )	<b>12#</b> (10-14 )	<b>26.5</b> (8-54 )	<b>21#</b> ( 15-26)
<b>Median NWC (95% CI)</b>	<b>6</b> (4-6 )	<b>5#</b> (3-6)	<b>10</b> (4-20)	<b>8#</b> ( 6-11)
<b>Median PPI (95% CI)</b>	<b>2</b> (2-2)	<b>2</b> (2-2)	<b>3</b> (2-3)	<b>2</b> (2-3)

**Table 4.5: Summary of McGill Pain Scores for all patients and patient groups**  
 (\* = p < 0.02    # = p < 0.001)

**Table 4.6:** Summary of McGill Pain Scores for 96 study patients compared by disease state

Disease state	n	Median PPI (95% CI)	Median NWC (95% CI)	Median PRI ® (95% CI)					Median PRI (S) (95%CI)				
				S	A	E	M	Total	S	A	E	M	Total
RA	42	2 (2-2)	6 (4-7)	9.5 (8-14)	1 (1-2)	1 (0-2)	1 (0-2)	13 (10-20)	8.48 (7.3-12.5)	2.42 (2.4-2.6)	1.89 (0-2.4)	0 (0-2.2)	13.69 (10.6-19.0)
OA	22	2 (2-2)	4 (3-6)	8 (5-12)	1 (0-2)	0.5 (0-2)	1 (0-4)	11.5 (7-16)	7.7 (4.8-10.1)	2.4 (0-2.6)	0.9 (0-2.4)	2.2 (0-2.4)	12.4 (6.3-19.3)
Back	7	2 (2-3)	7 (3-18)	15 (9-26)	1 (0-6)	2 (0-4)	1 (0-9)	24 (9-41)	10.8 (7.9-23.8)	2.8 (0-9.5)	2.4 (0-3.8)	2.2 (0-8.5)	24.6 (8.1-44.2)
RA + OA	25	2 (1-2)	7 (4-8)	11 (8-13)	1 (0-2)	1 (0-2)	0 (0-2)	14 (9-17)	9.4 (7.4-11.6)	2.4 (0-5.2)	1.9 (0-2.4)	0 (0-2.7)	15.2 (9.4-19.8)

Correlations between the scores of VAS average, NWC, PRI® total, PRI(S) total and PPI were calculated for all patients. A high correlation ( $p < 0.001$ ) was found between the PRI(S) total and PRI® total scores ( $r = 0.98$ ) and the number of words chosen (NWC) correlated highly with both PRI(S) total ( $r = 0.98$ ) and PRI® total ( $r = 0.97$ ). VAS average measurements demonstrated a poorer correlation with all of the other scores (range 0.41-0.69) as did the PPI scores. There were good intercorrelations between PRI rank and scale scores for all four categories ( $p < 0.001$ ).

Intercorrelations between the 4 categories of each scoring system were also calculated (Table 4.7). Present pain intensity (PPI) significantly correlated with NWC and the PRI ® for each of the 4 categories (PRI sensory, affective, evaluative and miscellaneous) and the PRI® total, although the correlations were poorer than those between the total PRI rank and scale scores. The Pearson correlations ( $r$ ) between PPI and each of the PRI categories were PRI® sensory = 0.32, PRI® affective = 0.44, PRI® evaluative = 0.50, PRI® miscellaneous = 0.41, PRI(S) sensory = 0.37, PRI(S) affective = 0.44, PRI(S) evaluative = 0.45 and PRI(S) miscellaneous = 0.37.

The frequency of choice of each subclass within categories and words within subclasses were analysed in all patients. Patients used all subclasses at some stage. Only 8 out of the 78 verbal word descriptors available were not used at any time. The verbal word descriptors which were most commonly selected by patients were from the sensory subclasses i.e. throbbing (49 patients), aching (49 patients) gnawing (46 patients), sharp (30 patients) and shooting (25 patients). The most commonly selected verbal word descriptor overall was tiring (52 patients) from the affective category. Only 54 of the 96 patients (56%) chose a word in the evaluative subclass, the most common being 'annoying' (22 patients).

	PRI(S) (95% CI)					PRI(R) (95% CI)			
PRI®	S	A	E	M	T	S	A	E	M
S	0.97 (0.96-0.98)								
A		0.96 (0.94-0.97)				0.54 (0.38-0.66)			
E			0.96 (0.94-0.97)			0.56 (0.41-0.68)	0.6 (0.45-0.71)		
M				0.89 (0.84-0.92)		0.66 (0.53-0.76)	0.7 (0.58-0.79)	0.68 (0.55-0.75)	
T					0.98 (0.97-0.99)	0.93 (0.87-0.95)	0.76 (0.66-0.83)	0.74 (0.64-0.82)	0.86 (0.80-0.90)
PRI(S)	-----								
A	0.68 (0.55-0.75)								
E	0.5 (0.33-0.63)	0.62 (0.48-0.72)							
M	0.66 (0.53-0.76)	0.76 (0.66-0.83)	0.62 (0.48-0.72)						
T	0.92 (0.82-0.95)	0.68 (0.55-0.75)	0.69 (0.56-0.78)	0.86 (0.80-0.90)					

**Table 4.7:** Pearson Correlations between Rank ® and Scale (S) values of the Pain Rating Index (PRI)

The categories are S = sensory, A = affective, E = evaluative, M = miscellaneous, T = total (n=96). All p < 0.001 (hypothesis test for correlations)

#### 4.4.3 Pain control in 14 patients with poor outcomes before and after intervention by the study pharmacist

Individual pain scores of the 14 patients who had poor outcomes as defined by the pre-set criteria at Interview 1 and who were subsequently re-interviewed after pharmacist intervention are shown in Table 4.8.

Patient Code	VAS Average		NWC		PPI		Total PRI ®		Total PRI (S)	
	Int 1	Int 2	Int 1	Int 2	Int 1	Int 2	Int 1	Int 2	Int 1	Int 2
81 ↓	80	50	9	8	3	2	23	19	24.6	21.1
76 ↑	60	40	3	5	2	2	4	8	6.2	11.7
4 ↓	70	50	8	4	3	2	21	9	19.6	9.2
40 ⇔	30	30	7	7	2	2	13	13	14.9	15.0
27 ↓	40	60	9	7	1	1	20	19	21.3	19.2
28 ↓	50	50	17	15	2	2	35	31	43.6	40.3
41 ↑	40	50	6	13	2	3	15	36	18.3	40.5
46 ↓	60	90	10	7	2	4	21	18	25.9	20.5
57 ↓	70	70	15	6	3	1	34	13	44.1	14.0
39 ↓#	100	60	4	3	3	2	8	7	10	7.3
78 ↑#	20	50	8	8	2	2	19	20	20.5	21.6
84 ↓	80	50	7	7	3	2	24	20	25.0	21.1
52 ↓	80	60	15	14	3	3	37	36	39.5	39.0
68 ↓	80	50	20	12	3	2	54	22	59.0	29.3

**Table 4.8:** Patients' pain control prior to (Interview1) and after pharmacist intervention (Interview 2) (n=14)

(Int 1 = Interview 1, Int 2 = Interview 2)

↓ = decrease in pain scores at Interview 2

↑ = increase in pain scores at Interview 2

⇔ = no change in pain scores at Interview 2

# = intervention was not accepted by the GP

The Wilcoxon matched pairs signed rank sum test was used to investigate the within patient differences in pain scores obtained before and after intervention. The PRI rank, PRI scale and NWC scores all showed slight decreasing trends ( $p < 0.1$   $n = 13$ ,  $p < 0.1$   $n = 14$ ,  $p < 0.1$   $n = 11$  respectively). However, there was no statistically significant differences between VAS scores ( $p > 0.2$ ,  $n = 11$ ). When the pain scores of the 2 patients in whom the pharmacist's recommendations were not acted upon were excluded from analysis, changes in total PRI rank and scale and NWC scores were less significant ( $p < 0.2$   $n = 11$ ,  $p < 0.2$   $n = 12$  and  $p < 0.2$   $n = 9$ ). VAS score changes were not statistically significant ( $p > 0.2$   $n = 9$ ).

In terms of clinical improvement, 10 patients demonstrated improvement in pain control after pharmacist intervention, as reflected by the reduced PRI rank and scale and NWC scores at Interview 2. Three patients perceived a decrease in pain control after intervention, as reflected by their increased scores at Interview 2, while 1 patient perceived no change in pain control after intervention.

The PPI scores were less sensitive to changes in pain before and after intervention than the respective PRI and NWI scores. VAS scores were more sensitive to changes in pain than PPI scores. Decreases in VAS scores tended to be associated with decreases in NWC and PRI scores, but some anomalies were found (Patients 27, 46 and 76 in Table 4.8).

The consistency of choice of subclass and words within each subclass chosen from the MPQ was assessed for each of the 14 patients who were interviewed on two occasions. The median consistency of choice of subclass between Interviews 1 and 2 was 75% (range 25-100%), whereas the median consistency of choice of words between Interviews 1 and 2 was 44% (range 22-83%).

At Interview 2, 7 out of the 10 patients who had reduced pain (Patients 28, 46, 52, 57, 68, 81 and 84), chose fewer or an equal number of verbal descriptors with lower scores from the same subclasses, as compared to those descriptors chosen at Interview 1. This finding was reflected by correspondingly lower PRI rank or scale scores. The 3 other patients who perceived reduced pain (Patients 4, 27 and 39) either selected new but fewer words of a higher score within the same subclass or selected new subclasses. Two of the 3 patients who demonstrated increased pain at Interview 2 had higher NWC scores, while one patient showed no change in the number of words chosen.

The most common verbal descriptors chosen in the 14 patients with poor outcomes and pharmacist intervention, correlated highly with those chosen by the total 96 study patients. This sub-group of 14 patients chose more words on average (median NWC= 8) at Interview 1 as compared to that for the total group (median NWC =6), but less than the sub-group who had poor pain relief (median NWC = 10). The 14 patients at Interviews 1 and 2 used all subclasses. The most commonly used words included 'tiring' (13 patients), 'exhausting' (12 patients), 'throbbing' (12 patients), 'aching' (12 patients) and 'sharp' (11 patients). Although the sensory subclasses were more frequently used by the 14 patients as compared to the affective or miscellaneous groups, 12 of the 14 patients chose a word from the evaluative group, the most commonly reported being 'miserable'.

Expectation of pain relief of these 14 patients was similar to that for the total group (median VAS score 80), but scores were within a narrower range (65-100 as compared to 30-100 for the total group). Compared with the total group's pain scores prior to intervention, the group of 14 patients had higher median scores at Interview 1 for VAS worst, average and present pain (80, 65 and 50 respectively) and higher median total PRI rank and scale scores (21 and 23.0 respectively). After intervention, the intervention group's median VAS scores decreased to 70, 50 and 40 respectively, and median PRI rank and scale scores decreased to 19 and 21 respectively. After intervention, 2 patients were more satisfied, 9 were as satisfied as prior to intervention and 3 were less satisfied. All 3 patients who were less satisfied after intervention, had their therapy changed, but their arthritis had progressed as therapy changes were initiated.

#### **4.4.4 Influence of psychological, physical and treatment factors on patients' pain perception**

Patient knowledge and attitude to pain was investigated in the 96 patients to see if any differences existed between the diagnostic groups. The questions used to assess knowledge and attitude and the patient responses obtained are illustrated in Tables 4.9 and 4.10 respectively.

The relationship of pain scores with QOL scores is discussed in Chapter 5.

The results investigating patient knowledge suggest that most patients (84,88%) believed that patients could become addicted to painkillers, although more patients with low back pain disagreed with or were uncertain about the statement.

Moreover, comparatively more patients with back pain (5 out of 7) disagreed with the statement that 'exercise can help chronic pain'. Most of this sub-group did not perceive the benefit of drug therapy or exercise as demonstrated by specific comments:

*I don't take the tablets unless I'm desperate.*

*I only take my tablets when I'm pushed to take them.*

*I don't want to get dependent on them.*

*I don't want to feel drowsy during the day, since I'm driving a lot and want to be alert – get the full benefit of painkillers when really needed.*

*Chronic pain could dominate your life if you let it. You need to assess what activities you'll be able to achieve with the minimum amount of increased pain.*

*Exercise aggravates my pain. (2 patients)*

*Exercise makes my pain worse. (3 patients)*

*Exercise is of no help to me.*

*Gentle exercise helps stretch my spine.*

The statement 'pain can continue after healing has taken place' was used to investigate patients' understanding of the chronicity of the pain in the absence of a pathophysiological cause. In response to the latter statement, over a fifth of the study patients (20, 21%) did not know.

Three out of the 5 patients who disagreed with the statement that 'painkillers help you to cope with a normal life' patients had RA, with or without OA (Table 4.10). Eighty-seven patients (91%) agreed that taking painkillers was beneficial, yet most patients (84, 88%) agreed that patients should try to control their own pain. The results regarding attitude to medication-taking have been reported in Chapter 3.

Older patients (greater than 70 years old) had significantly lower PRI scores (median total PRI scale score = 10.2) than the rest of the study patients ( median total PRI scale score = 15.9), ( $\chi^2 = 7.49$ ,  $df = 1$ ,  $p < 0.01$ ). Duration of chronic pain



and pain diagnosis did not influence pain perceived by patients ( $\chi^2 = 5.47$ ,  $df = 3$ ,  $p < 0.2$ ,  $\chi^2 = 3.18$ ,  $df = 3$ ,  $p > 0.2$  respectively). Mean duration of pain was 13.2 years (SD 10.2, range 1-53 years).

No real assessment was made on the influence of patients' current medication on their current pain, since many of the patients in the study were undertreating their pain, as discussed in Chapter 3.

Statement	Diagnosis	No. of patients			
		Yes	No	Don't know	Total
People can be addicted to painkillers	RA	26	5	1	42
	OA	21	1	0	22
	Back Pain	4	1	2	7
	RA + OA	23	2	0	25
	Total	84	9	3	96
Persistent pain can make you depressed	RA	39	3	0	42
	OA	19	3	0	22
	Back Pain	7	0	0	7
	RA + OA	24	1	0	25
	Total	89	7	0	96
Exercise can help chronic pain	RA	33	8	1	42
	OA	14	4	4	22
	Back Pain	1	5	1	7
	RA + OA	19	6	0	25
	Total	67	23	6	96
Pain can continue after healing has taken place	RA	26	8	8	42
	OA	11	5	6	22
	Back Pain	5	0	2	7
	RA + OA	15	6	4	25
	Total	57	19	20	96

Table 4.9: Assessment of patient knowledge of chronic pain (n=96)

Statement	Number of Patients						
	Diagnosis	Strongly agree	Agree	Uncertain	Disagree	Strongly Disagree	Total
Most patients benefit from taking painkillers for pain	RA	9	30	1	2	0	42
	OA	7	12	2	1	0	22
	Back Pain	0	5	1	1	0	7
	RA + OA	9	15	0	1	0	25
	Total	25	62	4	5	0	96
Taking medicines like painkillers is unnatural	RA	10	8	2	17	5	42
	OA	6	5	2	9	0	22
	Back Pain	2	3	0	2	0	7
	RA + OA	2	10	2	10	1	25
	Total	20	26	6	38	6	96
Patients should try to control their own pain	RA	17	21	0	4	0	42
	OA	9	7	2	4	0	22
	Back Pain	4	2	1	0	0	7
	RA + OA	15	9	0	1	0	25
	Total	45	39	3	9	0	96
Painkillers help you to cope with a normal life	RA	12	23	0	7	0	42
	OA	7	14	1	0	0	22
	Back Pain	1	3	2	1	0	7
	RA + OA	10	11	1	3	0	25
	Total	30	51	4	11	0	96
Taking painkillers for a long time can cause side effects	RA	8	26	5	3	0	42
	OA	5	8	5	4	0	22
	Back Pain	0	4	3	0	0	7
	RA + OA	8	13	2	2	0	25
	Total	21	51	15	9	0	96

Table 4.10: Assessment of patient attitude to chronic pain (n=96)

#### **4.4.5 Case study - patients with poor pain outcomes on Interview requiring referral**

Although all 28 patients had inadequate pain control i.e. VAS average pain more than 50, only 6 of the 28 patients had a VAS average pain greater than 75 (one of the criteria defined as a poor outcome in Chapter 2). Outcome details of all the 28 patients reviewed by the pharmacist are discussed in Chapter 7.

In 14 of the 18 patients who had a second interview, recommendations were made by the pharmacist to the patient's GP and acted upon in 12 patients. Case study 3 in Appendix 16 illustrates the type and quality of poor pain outcomes experienced by the patients who required referral.

### **4.5 Discussion**

The results indicate that patients' expectations in terms of expected pain relief and goals of therapy were much higher than those actually achieved. Fifty percent of patients expected that pain should be relieved as much as possible, yet in reality, half the study patients reported that pain was only relieved sufficiently to cope with daily activities.

Patient satisfaction as a global measurement in this study was found to be relatively insensitive as an outcome measure, since patients after an intervention which improved pain control often rated satisfaction unchanged. This may reflect the narrow rating scale used, the high expectations of patients or may be explained by the fact that pain control is only one contributory factor towards patient satisfaction (Donovan and Blake 1992). Long and Wynne (1996) investigated patient satisfaction in arthritis, but only in global terms of symptomatic relief. They did not evaluate pain relief in terms of a numerical VAS scale or established pain scores as in this study.

The MPQ scores and VAS scores obtained show that pain perception was very variable both within and between groups of patients with different pain diagnoses. However, the high correlations found between MPQ scores for all study patients suggest an internal consistency among the different PRI categories and the three indices of the questionnaire i.e. PRI, NWC and PPI. Similar findings were found by Melzack (1975) using a much larger group of patients with diverse chronic pain diagnoses.

This study's findings suggest that the indices of the MPQ are very valid tools to use in small groups of patients with chronic pain, as in this study, to assess pain intensity and quality, although there are limitations in scoring methods as discussed in Chapter 2.

The high correlations between NWC and PRI® and PRI(S) are not surprising, since the scoring system operates such that the larger the number of words chosen, the higher the PRI. The correlation between PPI and PRI® categories is highest for the PRI® evaluative category in this study, a finding also found by Melzack (1975), who suggested the reason for this was partly related to the PPIs' originating from a large number of evaluative descriptors (Melzack and Torgerson 1971). Moreover, the higher PPI correlation with the PRI® evaluative category suggests that the patient's past pain experience, mood or expectation of pain relief plays a larger part in the overall assessment of pain by patients, compared to the sensory and affective dimensions of pain.

The lower correlations between PPI and NWC and PRI® categories suggest that a large part of the PPI variance may be explained by factors not directly suggested by the verbal descriptors of the PPI scale. One factor which may cause variance is the different interpretations of the same word descriptors by patients i.e. a PPI score of '1' (mild pain) in one person may be interpreted as '2' (discomforting pain) by another person (Melzack 1975, Read 1989). PPI has been influenced by psychological factors at the time of assessment including mood, anxiety and attention (Melzack 1973). In this study, such factors were not controlled, therefore patients may have demonstrated uncharacteristic moods, levels of attention or anxiety at the time of interview.

The higher correlations between PPI and PRI scores for the affective category in either rank ( $r = 0.44$ ) or scale ( $r = 0.44$ ) scores compared to the correlations

between the same scores for the sensory category ( $r = 0.32$ ,  $r = 0.37$  respectively) suggest that pain intensity is influenced more by the affective rather than the sensory dimension. This suggestion is further supported by the finding that the correlation between VAS average scores and PRI® categories was highest for the affective category ( $r = 0.46$ ) and lowest for the sensory category ( $r = 0.35$ ). However, care must be taken when interpreting the PRI scores for individual categories, rather than the total PRI score, especially when patients are grouped according to diagnosis, since the type of pain influences the correlation between the PRI category scores (Perry *et al* 1988). Moreover, subclassification is based on Melzack's proposal that chronic pain has three distinct dimensions (Melzack 1975), a proposal which is still under debate (McDowell and Newell 1996).

Data obtained from the subgroup of 14 patients who had poor outcomes and who were followed up after intervention by the study pharmacist suggests that the MPQ can be used to investigate the influence of a therapeutic intervention on pain perceived by patients. The trends in decreasing PRI and NWC scores after pharmacist intervention suggest that the MPQ may be able to be used by pharmacists to identify changes in intensity, chronicity and quality of the chronic pain experienced.

The number-word categories of the PPI scale clearly meant different pain intensities and qualities to different patients, a finding supported by Melzack (1975) using a much larger study group. These findings suggest that interpretation of PPI scores must be based on each individual patient's pain experience.

Although the visual analogue scales in this study were more sensitive than the verbal rating scales in detecting changes in pain intensity, as previously found by Sriwatanakul *et al* (1983), patient understanding of their use can be a problem and may account for the anomalies found in this study. Patient 76 was slightly confused at Interview 2 and despite higher NWC scores and PRI scores than previously, had a lower VAS score which may have indicated poor ability to use the VAS at the time of Interview 2. The particular word descriptors used by this patient suggested an increase in pain severity.

Melzack (1975) has previously proposed that patients suffering from a specific type of pain state would be expected to show a considerable degree of consistency in the choice of subclasses which characterise that pain state. The consistency of

subclasses chosen by the 14 study patients at both Interviews 1 and 2 was similar to that found by Melzack (1975) i.e. median consistency of 75% in this study as compared to a mean of 70% in the Melzack study. Although these studies were not directly comparable, the consistency suggests that the MPQ verbal descriptors are sufficiently sensitive to report changes in pain intensity and quality over a much longer period of study within a practical clinical setting.

Re-testing using the MPQ after 4-6 weeks also minimised the risk that patients at Interview 2 would have remembered the verbal descriptors they had chosen at Interview 1.

The consistency of word choice within subclasses between Interviews 1 and 2 was lower, reflecting the diversity of pain quality and intensity experienced by patients even over 1 to 2 months. Moreover, almost all the words used within the MPQ subclasses were used by patients to describe their pain. Pharmacists need to appreciate the diversity of patients' pain experiences, which they must be able to identify and act upon.

Care needs to be taken when interpreting the NWC scores in this study, since the changes in PRI scores were not necessarily reflected by a change in NWC. Patients who perceived decreases in pain tended to choose a less intense or highly scored word within that subclass rather than drop the subclass altogether, thus the NWC may not have changed but the change in word chosen influenced the PRI scores. This finding suggests that only partial relief may have been obtained in a large number of the 96 patients. Indeed only 6% of patients were completely satisfied with their pain control. The high correlation between the most commonly used verbal descriptors for the poor outcomes group, and the total group overall suggests that use of a similar MPQ verbal descriptor check list in practice could help to identify the type and intensity of pain perceived by patients. Such a checklist would be especially valuable for pharmacists if patients could not adequately describe their pain, and in particular, it could identify those requiring acute intervention. Time taken for completion of the checklist might limit its uptake in practice. At least 1 hour per patient was required for satisfactory completion of the MPQ in this study.

It is impossible to distinguish any specific influence of the pharmacist in the 14 patients in terms of pain control, since many other factors may have contributed to

the outcome, including natural disease progression, influence of therapy and lack of wash-out period between therapy changes and psychological and social factors. It was however interesting to note that the median VAS scores for pain now at either interview were consistently lower than any other VAS scale measurement, which may reflect the influence of distraction and / or social interaction as a useful coping strategy perceived by patients.

By visiting such patients in their homes and demonstrating specific interest in their needs, the pharmacist may be able to provide a therapeutic benefit. Long-term and regular evaluation of such patients, for at least 3-4 months would be needed to evaluate the influence of therapy changes on pain control, especially in patients using DMARDs.

The results investigating patient attitude to and knowledge of chronic pain suggest that the majority of patients have a good understanding of the potential consequences of chronic pain and its treatment, which may reflect the duration of the chronic pain state, although the latter result was not of statistical significance in this study.

Patients desired to manage their own pain yet recognised the therapeutic benefits of therapy, findings of which are consistent with those of other researchers (Donovan *et al* 1989). The finding that patients with RA and / or OA were less likely to agree to the statement that painkillers help you to cope with a normal life, could reflect their awareness of potentially increased exposure to side effects associated with long-term medication including NSAIDs and DMARDs. Indeed, side effects were more likely to be reported by RA patients in this study (see Chapter 6). Patients are generally worried about the risk of side effects (Donovan and Blake 1992). Pharmacists need to provide accurate information to patients about the likelihood of serious adverse effects arising and encourage frequent monitoring of therapy and appropriate referral.

Some patients, especially those with back pain, do not seem to perceive the benefit of therapeutic strategies such as exercise, which is worrying, since appropriate exercise and physiotherapy are important factors in management. Most of the patients who perceived little benefit from exercise, reported worse pain and were then less keen to persevere with the therapy. Indeed, the pain scores in Table 4.6 suggest that patients with back pain were suffering more pain than patients with



other pain diagnoses. Pharmacists are well placed to confirm and discuss with patients the rationale of established protocols for such chronic pain management (Kay 1997).

## Chapter 5

### Patient outcomes in terms of quality of life measures

#### 5.1 Introduction

Quality of life is a multidimensional concept, as discussed in Chapter 1, which needs to include at least three major components when understanding chronic pain (Van Riel and Van Lankveld 1993). Such components are often inter-related and include:

1. disease related variables such as outcome variables (e.g. pain, functional status, drug side effects), process variables e.g. erythrocyte sedimentation rate (ESR).
2. socio-demographic variables such as age, sex and social network.
3. psychological processes such as adaptation and coping.

Many quality of life studies in rheumatology have not utilised this 3 component model and often measure just one component e.g. depression, often combined with one or more processes influencing quality of life. Initial health indices which were developed to measure quality of life either confused process with outcome measures or only focused on one outcome measure, instead of visualising a multidimensional concept (Carr *et al* 1996).

Evaluation of health outcomes in rheumatic diseases has traditionally consisted of clinical measures, regarded as process measures e.g. the Arthritis Association Scale (Felson *et al* 1995) and outcome measures such as pain (Kazis *et al* 1983). Bowling (1995) has produced a full review of the quantitative outcome measures used in rheumatoid arthritis.

Measures of physical functioning and limitation of activity have been used extensively to assess the outcome of joint disorders. The wide range of functioning scales have been extensively reviewed by Bowling (1995), and their applicability, validity, reliability and sensitivity discussed by McDowell and Newell (1996) and Bowling (1997). However, such scales have not provided a sufficiently detailed assessment of functioning in everyday life in rheumatic diseases, failing to identify social, physical and emotional well being.

Consequently, investigators have developed arthritis-specific functional scales such as the Health Assessment Questionnaire (HAQ) (Fries *et al* 1980) and the Arthritis Impact Measurement Scales (AIMS 1 and 2) (Meenan *et al* 1980, Meenan *et al* 1990). These scales are often used in combination with a generic, non-disease specific scale to assess broader health status rather than just functional status, such as the Sickness Impact Profile (SIP), (Bergner *et al* 1981) or the Short Form-36 Health Survey (SF-36) (Brazier *et al* 1992).

The AIMS covers social, emotional and physical wellbeing and is one of the most widely used outcome measures in arthritis research, with well-established validity and reliability. Although widely used for research purposes, it is suitable for use in the clinical setting (Kazis *et al* 1990). Fries *et al* (1980) using the Health Assessment Questionnaire (HAQ), a tool which is extensively used with well proven validity and reliability (McDowell and Newell 1996), defined the outcome of rheumatoid arthritis patients in terms of discomfort, disability, death, drug toxicity and cost. Researchers are increasingly using more patient-generated scales such as the Patient Generated Index (PGI) to obtain more patient-focused assessments of quality of life in arthritis and back pain (Ruta *et al* 1994).

Rheumatoid arthritis, osteoarthritis and back pain affect patients' quality of life largely by limiting activities due to pain and disability, which also significantly affects social activity (Newman 1996). Pain itself can be regarded as both a process and an outcome variable.

Psychological processes such as depression and coping strategies can influence both pain and functional status such that correlations between functional status or pain with quality of life are poor.

Depression can be a significant problem in patients with chronic pain, arising either as a consequence of the chronic disease or as a separate psychological

problem (Newman *et al* 1989). However, inappropriate tools have often been used to assess the influence of depression on quality of life of patients with chronic pain, ultimately overestimating its influence on quality of life (Van Riel and Van Lankveld 1993).

Patients with chronic pain can often feel that they are a burden to family and friends, that they have lost their independence, yet are determined to cope without help and appear 'normal' (Skevington 1990) thus making determination of quality of life *per se* difficult. Coping strategies are employed by patients through time to minimise the stress associated with such chronic diseases such that in patients with stable disease, the duration of the diagnosis is correlated with patient well-being (Newman *et al* 1990). Coping strategies can be investigated by using validated self-reporting disease-specific measures such as the London Coping with Rheumatoid Arthritis Questionnaire (Newman *et al* 1990) or scales to assess coping with chronic pain itself (Rosenstiel and Keefe 1983).

In this study, it was inappropriate in terms of characteristics of QOL scales required and time available during each interview, to utilise both a generic scale such as SF-36 and a disease specific scale such as AIMS or the Medical Outcomes Study (MOS) Pain Measures (Sherbourne 1992). SF-36 psychological sub-scores, an important component of chronic pain, have been shown to be less sensitive to change compared to AIMS (McDowell and Newell 1996). The AIMS scale could not be used, since it is designed as an outcome measure for arthritis patients and not all patients included in this study had arthritis. Unfortunately, the MOS Pain Measures scale was not sufficiently validated for recommended use as a disease-specific measure at the initiation of this study. Moreover, no patient generated index (PGI) had been published at the time of this study.

Thus a QOL scale had to be created to assess the influence of chronic pain on activities of daily living, which could be easily used and could identify the physical, psychological, social and occupational factors which influenced pain. It would also need to be sufficiently sensitive to detect changes in quality of life over a short period of time.

## 5.2 Objectives

The objectives of this part of the study were:

1. To investigate the reliability, validity, and sensitivity of the quality of life scale used.
2. To investigate the overall influence of pain on activities of daily living and mood, as experienced by the 96 patients at first interview, and the differences between those with satisfactory and poor overall outcomes in total quality of life scores and / or scores for physical well-being, social, occupational and psychological status.
3. To investigate the overall influence of pain on activities of daily living and mood as experienced by the 14 patients who had a second interview and the changes in total quality of life scores and / or scores for physical well-being, social, occupational, and psychological status.
4. To investigate the influence of pharmaceutical intervention on quality of life in patients who had poor outcomes at the time of the first interview.
5. To investigate the influence of age, chronic pain duration, pain diagnosis, concurrent disease states, current medication, patient attitude and satisfaction on quality of life.

## 5.3 Methods

The reliability of the QOL scale used in the study was investigated using the Pearson correlation coefficient and by the determination of split-half reliability using the Spearman-Brown 'prophecy' formula and Cronbach's alpha coefficient as described in Chapter 2 Section 2.3.5.

Face and content validity was assessed during the initial piloting of the pain questionnaire as described in Chapter 2 Section 2.1.6.4. Construct validity of the QOL scale was assessed by proposing a working hypothesis that patients with

satisfactory outcomes should have lower QOL scores than those with poor outcomes. Sensitivity was assessed by investigating the differences if any, in patients' responses to individual statements and by investigating the influence of pharmacist's intervention on quality of life scores.

Fourteen statements from a previously validated questionnaire (Williamson *et al* 1993) were incorporated into the pain questionnaire to assess the impact of chronic pain on patients' behaviour, mood and activities of daily living, as described in Chapter 2 Section 2.1.6.3 and Appendix 8. During each interview patients were free to describe unprompted any other aspect of daily living with which their chronic pain interfered.

Two types of quality of life scores were created, a total QOL score and dimension scores to assess sensitivity and reliability of the scale and the influence of pharmaceutical intervention on quality of life, as discussed by Williamson *et al* 1993 and described in Chapter 2 Section 2.3.5. High scores indicated poor quality of life.

The Wilcoxon matched pairs signed rank sum test and Chi-squared tests (2x2) were used to analyse results, as described in Chapter 2, Section 2.3.5.

## **5.4 Results**

### **5.4.1 Reliability, validity and responsiveness of the QOL scale**

The reliability or homogeneity of the QOL scale used in 96 patients was investigated using the Pearson correlation coefficient as discussed in Chapter 2. Tables 5.1 and 5.2 show the correlations between the individual QOL statement scores (Table 5.1) and the QOL dimensions with total QOL scores (Table 5.2). Table 5.3 gives the correlations between individual statement scores and dimensions. Each individual quality of life statement correlated significantly with its total and specified dimension QOL score ( $p < 0.001$ ) (Tables 5.1 and 5.3 respectively) and significant correlations also existed between each dimension score and total QOL scores ( $p < 0.001$ ) (Table 5.2).

Split-half reliability using the Spearman-Brown ‘prophesy’ formula was found to be 0.87. Internal consistency, as determined by Cronbach’s alpha was 0.87. These results suggest that that the QOL scale has good homogeneity and that the individual statements within the scale are well correlated with each other. The acceptable range for split-half reliability or internal consistency is 0.7-0.9 (Nunally 1978). Too high a result would suggest that 2 different constructs are combined.

Individual QOL statements	Pearson’s correlation coefficient (r) (95% CI)
Walking	0.63 (0.49-0.74)
Housework	0.64 (0.52-0.75)
Sleeping	0.61 (0.45-0.71)
Eating	0.65 0.51-0.75)
Anxiety	0.70 (0.57-0.79)
Depression	0.68 (0.54-0.77)
Loneliness	0.50 (0.32-0.63)
Frustration	0.67 (0.54-0.77)
Enjoyment of life	0.73 (0.63-0.82)
Daily activities	0.64 (0.52-0.75)
Mobility	0.75 (0.67-0.84)
Support to discuss problems	0.39 (0.22-0.56)
Ability to plan activities	0.76 (0.67-0.84)
Influence of pain on work	0.55 (0.4-0.68)

Table 5.1: Pearson correlation coefficients of individual QOL statements with total QOL scores at Interview 1 (n=96, p < 0.001)

QOL dimensions	Pearson’s correlation coefficient (r) (95% CI)
Physical	0.91 (0.87-0.94)
Social	0.86 (0.80–0.90)
Occupational	0.81 (0.73–0.87)
Psychological	0.85 (0.79–0.90)

Table 5.2: Pearson correlation coefficients of QOL dimensions with total QOL scores at Interview 1 (n=96, p < 0.001)

Individual QOL statement	Dimension of QOL	Pearson's correlation coefficient (r)(95% CI)
Walking	Physical	0.70 (0.58–0.79)
Sleeping		0.71 (0.60–0.80)
Eating		0.74 (0.64–0.82)
Mobility		0.76 (0.67–0.84)
Enjoyment of life	Social	0.74 (0.64–0.82)
Friends / family support to discuss problems		0.63 (0.49–0.74)
Ability to plan activities		0.82 (0.74–0.88)
Housework	Occupational	0.72 (0.61–0.80)
Enough daily activities		0.61 (0.45–0.71)
Influence of pain on work		0.78 (0.69–0.84)
Anxiety	Psychological	0.83 (0.76–0.88)
Depression		0.85 (0.79–0.90)
Loneliness		0.68 (0.54–0.77)
Frustration		0.69 (0.57–0.78)

**Table 5.3:** Pearson correlation coefficients of individual QOL statements with QOL dimension scores at Interview 1 (n=96, p < 0.001)

Initial piloting of the questionnaire assessed face and content validity. Construct validity was assessed by investigating if any correlations existed between the QOL scores and other relevant, previously validated health outcome measures i.e. MPQ outcome measures. Total QOL scores correlated significantly (p < 0.001) with total pain rating index scale scores (PRI (S)) (r = 0.39) and total pain rating index rank scores (PRI®) (r = 0.38) for all 96 patients.

A working hypothesis proposed to establish construct validity of the QOL scale was that patients with satisfactory outcomes should have lower QOL scores than those patients with poor outcomes. Table 5.4 shows that patients with



satisfactory outcomes compared with patients with poor outcomes had significantly lower total QOL ( $\chi^2 = 10.41$ ,  $df = 1$ ,  $p < 0.01$ ), physical ( $\chi^2 = 10.63$ ,  $df = 1$ ,  $p < 0.01$ ), social ( $\chi^2 = 7.31$ ,  $df = 1$ ,  $p < 0.01$ ) and psychological dimension scores ( $\chi^2 = 10.04$ ,  $df = 1$ ,  $p < 0.01$ ).

Sensitivity was assessed by investigating the differences if any, in patients' responses to individual statements and by investigating the influence of pharmacist's intervention on quality of life scores. The differences between total QOL, physical, social, occupational and psychological dimension scores for all patients and for subgroups can be seen in Table 5.4.

Individual QOL statement scores in all 96 patients at Interview 1 and the changes in these individual scores in the 14 of the 28 patients who were interviewed after the pharmacist's intervention are shown in Table 5.5. The wide ranges of scores both before and after intervention, suggest that the QOL scores are sensitive to external and internal influences.

<b>Median score for QOL dimensions as a percentage of maximum score</b>	<b>All patients at Interview 1 (n=96)</b>	<b>Patients with satisfactory outcomes at Interview 1 (n=68)</b>	<b>Patients with poor pain control at Interview 1 (VAS average pain &gt;75) (n =6)</b>	<b>Patients with poor outcomes at Interview 1 (n=28)</b>	<b>Patients with poor outcomes interviewed at both Interviews 1 and 2 Result at Interview 1 / Result at Interview 2 (n = 14)</b>
<b>Total QOL</b>	<b>28</b>	<b>24</b>	<b>48</b>	<b>44</b>	<b>50 / 63</b>
<b>(95% CI)</b>	<b>(23-36)</b>	<b>(19-28)</b>	<b>(32- 68)</b>	<b>(36-57)</b>	<b>(32-68 / 27-70)</b>
<b>Physical dimension</b>	<b>31</b>	<b>25</b>	<b>62</b>	<b>56</b>	<b>62 / 50</b>
<b>(95% CI)</b>	<b>(25-38)</b>	<b>(19-31)</b>	<b>(38-69)</b>	<b>(31-62)</b>	<b>( 25-69 / 38-62)</b>
<b>Social dimension</b>	<b>25</b>	<b>25</b>	<b>33</b>	<b>33</b>	<b>40 / 62</b>
<b>(95% CI)</b>	<b>(17-33)</b>	<b>(17-25)</b>	<b>(38-50)</b>	<b>(25-50)</b>	<b>(25-67 / 25-75)</b>
<b>Occupational dimension</b>	<b>33</b>	<b>29</b>	<b>54</b>	<b>46</b>	<b>56 / 54</b>
<b>(95% CI)</b>	<b>(25-33)</b>	<b>(17-33)</b>	<b>(17-92)</b>	<b>(25-58)</b>	<b>(17-83 / 26-67)</b>
<b>Psychological dimension</b>	<b>25</b>	<b>19</b>	<b>56</b>	<b>44</b>	<b>50 / 50</b>
<b>(95% CI)</b>	<b>(19-31)</b>	<b>(12-25)</b>	<b>(19-69)</b>	<b>(25-50)</b>	<b>(25-69 / 19-75)</b>

**Table 5.4: Summary of median quality of life scores and 95% confidence intervals of all patients and patient groups**

Individual QOL parameters	Dimension of QOL	Median scores for all patients at Interview 1 (n=96)	Median score at Interview 1 (n=14) Range (0-4)	Median score at Interview 2 after intervention (n=14) Range (0-4)
Walking	Physical	2 0-4	3 0-4	3 1-4
Sleeping	Physical	1 0-4	2 0-4	3 1-4
Eating	Physical	0 0-4	1 0-3	1 0-3
Mobility	Physical	1 0-4	1 0-4	2 0-4
Enjoyment of life	Social	1 0-4	2 0-4	3.5 0-4
Family support to discuss problems	Social	0 0-4	1 0-4	0.8 0-4
Ability to plan activities	Social	1 0-4	2 0-4	2 1-4
Influence of pain on work	Occupational	2 0-4	3 0-4	2 0-4
Housework	Occupational	2 0-4	2 0-4	3 1-4
Daily activities	Occupational	0 0-4	1 0-4	0.8 0-4
Anxiety	Psychological	1 0-4	2 0-4	2 0-4
Depression	Psychological	1 0-4	2 0-4	1 0-3
Loneliness	Psychological	0 0-4	0 0-3	1 0-4
Frustration	Psychological	1.5 0-4	3 1-4	2 1-2

**Table 5.5:** Median scores and ranges for individual QOL statements in all patients (n=96) and in those interviewed after pharmacist's intervention (n=14)

## **5.4.2 Influence of pain on quality of life**

### **5.4.2.1 Influence of pain on activities of daily living and mood in all patients**

In this study, a high QOL score implies a poor QOL and vice versa. Patients who had satisfactory outcomes at the time of Interview 1 had the lowest QOL scores in terms of total and dimension scores. Fourteen patients who had poor outcomes at Interview 1 and were interviewed after pharmaceutical intervention had the highest QOL scores in comparison to the other groups initially. Although they represent only half of the 28 patients with poor outcomes, total and dimensional QOL scores tend to reflect those of the whole group.

The ranges of scores for both total QOL and QOL dimensions were very wide within and between patient outcome groups. However, the comparatively narrow confidence intervals for all patients at Interview 1 suggest that median QOL scores were not very variable, varying between 17 to 38% of the maximum QOL scores. Indeed, even among patients in whom a poor outcome had resulted at Interview 1, median QOL scores ranged from only 33-62% of the maximum achievable QOL score.

The median scores in Table 5.4 suggest that at the time of Interview 1, occupational problems contributed most to the QOL scores of the total group, followed by physical, psychological and lastly social factors. Patients with satisfactory outcomes had higher occupational scores as compared to other dimensional scores while patients with poor pain outcomes had higher physical scores as compared to other dimensional scores.

Patients' perception of quality of life in terms of individual QOL was again varied within and between patient groups as reflected by the wide range of QOL scores in Table 5.5. For the total patient group, the physical dimension results suggest that, patients in general identified a fair amount of difficulty in walking, a little difficulty in eating and in getting out the house more but did not generally find food unappealing. Within the occupational dimension of quality of life, most patients identified a fair amount of difficulty with household chores and with performance at work. The low median scores for the total patient group regarding enjoyment of life, planning of activities due to pain or family support, suggest that

the social dimension of quality of life was satisfactory for most patients. Frustration contributed most to the psychological problems of the 96 study patients.

#### **5.4.3 Quality of life in 14 patients with poor outcomes before and after intervention by the study pharmacist**

The median scores of those patients who required pharmacist intervention were the highest of the patient outcome groups (Table 5.4). Physical problems contributed most to this group's total QOL scores, followed by occupational, psychological and lastly social factors.

Table 5.5 demonstrates that, prior to intervention, patients who had pharmaceutical intervention after their first interview had a lot of difficulty in walking (physical dimension), felt very frustrated (psychological dimension) and pain had greatly affected their work (occupational dimension). Patients also identified a fair amount of difficulty in sleeping, doing household chores, planning activities and felt fairly anxious and depressed.

After pharmaceutical intervention in 14 patients, there were non-significant increases in total QOL scores, decreases in the median QOL scores for the physical and occupational dimensions, slight increases in median scores for the social dimension and no overall change within the psychological dimension (Table 5.4).

Some of the changes in dimension scores post intervention (Table 5.4) did not reflect changes in individual statement scores (Table 5.5). Although the median physical dimension score decreased after pharmacist intervention, the median score for sleeping increased (Table 5.5). Slight decreases in the median occupational dimension score post intervention reflected increases in activity and a reduction in the influence of pain on work, yet the median score concerning the ability to do housework increased. Social problems increased after pharmaceutical intervention, which was reflected by a decrease in enjoyment of life, despite reduced family support problems. Patients perceived themselves after intervention to be less frustrated and depressed, but rated loneliness as slightly more of a problem (Table 5.5).

Details of changes in total QOL and dimension scores, patient satisfaction and patient attitude in the 14 patients interviewed after pharmaceutical intervention are shown in Table 5.6.

Within patient differences between Interviews 1 and 2 for total QOL scores and physical, social, occupational and psychological dimension scores were not statistically significant ( $p > 0.2$  ( $n = 14$ ),  $p > 0.2$  ( $n = 13$ ),  $p > 0.2$  ( $n = 11$ ),  $p > 0.2$  ( $n = 9$ ),  $p > 0.2$  ( $n = 14$ ), Wilcoxon signed rank sum test).

**Table 5.6: Changes in patient QOL outcomes, satisfaction and attitude as assessed at Interview 2 (n=14)**

Action taken by GP(Pharmacist's recommendation accepted? Yes/No)	Total QOL score (%max)	Physical score (%max)	Social score (%max)	Occupational score (%max)	Psychological score (%max)	Patient satisfaction index	Patient attitude score (%max)
Existing therapy continued with trial course of safflower oil (Yes)	U (32 / 70)	U (25/ 50)	U (25 / 83)	U (58 / 75)	U (25 / 75)	U (2 / 5)	U (74 / 80)
NSAID changed to Ibuprofen. Omeprazole started (Yes)	U (60 / 65 )	U (69 / 75)	U (33 / 67)	S (62 / 62)	D (69 / 56)	S (3 / 3)	D (66 / 60)
Sulphasalazine switched to penicillamine therapy (Yes)	D (71/ 70)	D (62 / 56)	D (67 / 58)	D (83 / 42)	D (75 / 19)	D (4 / 3)	D (83 / 77)
Referred to physiotherapist (Yes)	D (39 / 27)	D (62 / 38)	D (33 / 25)	D (42 / 33)	D (19 / 12)	S ( 3 / 3)	S ( 69 / 69)
Diflunisal stopped. Regular cocodamol and naproxen prn (Yes)	D (70 / 54)	D (81 / 62)	S (67 / 67)	D (83 / 58)	D ( 50 / 31)	S ( 2 / 2)	U ( 71 / 74)
Penicillamine stopped. Safflower therapy started (Yes)	U ( 14 / 16 )	U ( 0 / 19 )	D ( 17 / 8)	S (17 / 17)	D (25 / 19)	S ( 3 / 3)	D ( 74 / 66)
Sulphasalazine restarted. Homoeopathy started (Yes)	U (48 / 86 )	U ( 56/ 94 )	U ( 55 / 75)	U ( 33 / 67)	U ( 31 / 81)	U ( 3/4)	D ( 69 / 60)
DMARD started. Support group and family contact (Yes)	D ( 62 / 43)	D (62 / 38)	S (67 / 67)	S (50 / 50)	D ( 69 / 25)	S ( 3 / 3)	U ( 63 / 71)
One NSAID prn, no ulcer. Misoprostol discontinued and aspirin monitored (Yes)	D ( 57 / 54 )	D (62 / 50)	U ( 33 / 42)	S (50 / 50)	U ( 62/ 69)	S ( 3 / 3)	S ( 77 / 77 )
Coproxamol stopped. Dihydrocodeine and physiotherapy resumed (Yes)	D (68 / 61)	D (69 / 56)	S ( 50 / 50)	D (92 / 83)	D (62/ 56)	D ( 4 / 3)	U ( 49 / 54 )
Changed DMARD. NSAID to be reviewed. (Yes)	D (57 / 34)	D (62 / 50)	D ( 50 / 33)	D (67 / 33)	D ( 50 / 19)	S ( 3/3)	U ( 77 / 80 )
Penicillamine discontinued.Coproxamol started (Yes)	U (10 / 17 )	U ( 6 / 25 )	D ( 25 / 17)	U ( 0 / 8)	U ( 6 / 12)	U ( 2 / 3)	D ( 77 / 71)
Homoeopathy initiated with usual therapy. Surgery (No)	D (42 / 39)	S ( 44 / 44)	D ( 42 / 33)	U ( 17 / 25)	D ( 50 / 44)	S ( 4 / 4)	S (54 / 54)
No change made to medication (No)	U ( 36 / 66 )	U (25 /50)	U ( 25 / 83)	S (58 / 58)	U (38 / 75)	S (2 / 2)	D ( 69 / 63 )

D = decrease in QOL scores at Interview 2

U = increase in QOL scores at Interview 2

S = no change in QOL scores at Interview 2

In terms of patient outcome, 8 patients reported a decrease and 6 reported an increase in total QOL scores. In the 2 patients where the pharmacist's advice was not accepted, the total QOL score decreased in one but increased in the other (Table 5.6).

#### **5.4.4 Influence of psychological, physical and social factors and quality of life**

##### **5.4.4.1 Influence of patient attitude and satisfaction on quality of life**

Patients who demonstrated a high attitude score were regarded as having a good awareness of the rationale of therapy. Although each attitude statement used to create the attitude score was reasonably correlated with the overall attitude score ('r' ranged from 0.24 - 0.63), patient attitude to chronic pain did not correlate with QOL scores for either the total group (n = 96) or the sub-group interviewed on 2 occasions (n = 14). The distribution of the attitude scores for all 96 patients was heavily positively skewed (median 71%, range 46 – 89).

Satisfaction with overall pain management for the 96 patients was however significantly correlated with total QOL scores ( $r = -0.52$ ,  $p < 0.001$ ), with high levels of satisfaction being associated with low total QOL scores.

##### **5.4.4.2 Influence of pain, pain diagnosis, duration of pain, concurrent disease states, age and current medication on quality of life**

Total QOL scores for the 96 patients were positively correlated with all three McGill Pain Questionnaire pain parameters i.e. total PRI rank scores ( $r = 0.38$ ,  $p < 0.001$ ), total PRI scale scores ( $r = 0.39$ ,  $p < 0.001$ ) and VAS average scores ( $r = 0.54$ ,  $p < 0.001$ ). The type of pain diagnosis and number of concurrent disease states were not related to total QOL scores.

Duration of pain showed a weak positive correlation with patient attitude ( $r = 0.24$ ,  $p > 0.2$ ), but no correlation with patient satisfaction or pain scores ( $r = 0.1$ ). Total QOL scores were not influenced by age ( $r = 0.07$ ) or duration of pain ( $r = 0.12$ ).



Since all patients were taking multiple medications, it was not possible to identify the influences, if any, of current medications on quality of life.

#### **5.4.5 Case studies - patients with poor quality of life on interview requiring GP referral**

Appendices 17 and 18 illustrate two case studies in which patients had poor quality of life and required GP referral after intervention by the study pharmacist.

### **5.5 Discussion**

Pharmacists in both primary and secondary care are being challenged to validate and ultimately use quality of life assessment tools to measure the impact of pharmaceutical intervention on patients' quality of life (Williamson *et al* 1993, Salek and Walker 1995, Tully and Cantrill 1998). Quality of life instruments for use by pharmacists in primary care need to be applicable, practical, sensitive and valid for the environment in which pharmaceutical care is being delivered, the patient group(s) involved and intended purpose (Salek and Walker 1995, Tully and Cantrill 1998).

No one tool has yet been demonstrated by pharmacists to be ideal in terms of measuring pharmaceutical influence on quality of life. Since health care professionals' and patients' perceptions of quality of life in chronic disease often differ (Weissman and Haddox 1989), researchers are increasingly investigating the validity and applicability of patient-generated scales, such as the Patient Generated Index (PGI) to obtain a more accurate assessment of the quality of life of patients with arthritis and low back pain (Tully and Cantrill 1998, Ruta *et al* 1994). However, Tully and Cantrill (1998), question the validity of the PGI, since areas of life described by patients as those most affected by their arthritis depended on the severity of their disease. Patients with severe arthritis described many areas of their lives which were affected, yet most often described the areas of life given as examples within the PGI. Patients with mild or inactive arthritis were much more

likely to describe different areas of their life which were affected and chose significantly fewer example areas of the PGI.

Short-form generic instruments such as the Summary UKSIP may be useful in community practice to assess the influence of drug therapy on quality of life between different patient groups (Salek and Walker 1995). However, the Short Form-36 (SF-36) as a generic tool is insensitive to changes in drug therapy after implementing formulary changes (Stewart 1997). Patient-derived scales such as the PGI have also been used by pharmacists to assess quality of life in arthritis patients (Tully and Cantrill 1998) but such indices may need to be further refined to establish their validity prior to clinical use by pharmacists in practice. On the other hand, disease specific scales can be useful in measuring health outcomes resulting from therapy changes even with small sample sizes (Stewart 1997).

The reliability of the QOL scale used was found to be within acceptable standards e.g. Cronbach's alpha coefficient of at least 0.85 (McDowell and Newell 1996). However, it is important to consider that correlation coefficients fail to assess variability well (Deyo *et al* 1991). Ideally, intraclass correlations or a weighted kappa statistic should have been calculated to identify within-patient variations and explicitly dissociate between true variation and random error. Unfortunately, the lack of control groups in this study prevents such statistical analysis.

The content and face validity of the quality of life tool are demonstrated by the facts that all individual QOL statements fell into at least 1 of the 4 physical, social, occupational or psychological dimensions and showed good correlations within their respective dimensions. The halo effect of patient rating of quality of life (Norman and Steiner 1995) was minimised by encouraging patients to assess their QOL in terms of individual statements rather than a global index or score. The wide range of responses for each individual statement and the individual comments made unprompted by patients suggest that the scale was able to identify most of the factors which influence the quality of life of patients with chronic pain. However, the scale did not investigate the influence of pain on sexual activity, which has been shown to be a significant problem (Skevington 1990). Such an omission may not have occurred had a patient-generated index been used to define patient-perceived QOL problems (Ruta *et al* 1994).

Too few questions within each dimension with respect to the dimension's relative importance may also have limited the scale's content validity (Norman and Steiner 1995) and many have contributed to the anomalies seen in QOL statement scores after pharmacist intervention. In the scale used, although the physical and psychological dimensions were each allocated 4 questions as compared to the 2 other dimensions, to reflect their greater contribution to the perception of chronic pain (Anderson *et al* 1985), the scale may have been too brief to ensure validity.

Criterion validity was not assessed in this study. Ideally, the new scale should have been correlated with an already established QOL scale which assessed the impact of pain on activities of daily living e.g. the Medical Outcomes Study Pain Measures (Sherbourne 1992).

The findings that patients who had satisfactory outcomes had statistically significantly lower QOL scores as compared to patients with poor outcomes, and that the QOL scores correlated positively and significantly with all validated McGill pain indices suggest that construct validity of the QOL questionnaire was satisfactorily investigated. If necessary, further exploration could involve 2 extreme groups, one group with chronic pain and the other healthy individuals. It would then be expected that the former group should score significantly higher on the QOL scale to provide further evidence of the QOL scale's construct validity.

The statistically significant results from Interview 1 indicate that the QOL scale may be sufficiently sensitive to distinguish between patients with poor outcomes and those with satisfactory outcomes, using the pre-set criteria for poor outcome. This suggests that the QOL tool did contribute to identifying those patients most in need of help in terms of quality of life. Such a scale may be a useful screening tool in practice to help identify those patients who need health care intervention to improve symptoms in patients with chronic pain. However, it is important when using QOL scales for routine practice to be aware of each dimension score as each could be modified by intervention.

The sensitivity of the scale in measuring changes in quality of life after pharmaceutical intervention appeared to be limited from the results obtained from tables 5.4 and 5.5. However, the small sample size here (14) and lack of control group precludes a valid assessment of sensitivity. The ranges of the dimension

scores before and after intervention were much more reflective of the resultant changes, if any, in scores as compared to median scores.

Such findings again illustrate the lack of sensitivity of a generic scale to assess changes over a relatively short period of time, as in this study, especially when individual scores are compounded into a global score (Carr *et al* 1996). A more disease-specific scale would have been more appropriate as discussed earlier. Indeed, Stewart (1997) found that the generic SF-36 was less responsive to changes in health outcomes after implementing therapy changes in patients with peripheral vascular disease compared to the performance of a disease specific scale.

The changes demonstrated in Table 5.5 after pharmaceutical intervention may reflect the unpredictable nature of the disease state, (especially since most of the patients who were interviewed twice had rheumatoid arthritis), the sub-optimal response of the revised therapy e.g. DMARDs and / or cross-over effects of treatment regimens between the interview times 1 and 2 (Fries *et al* 1997). Ideally, to assess the clinical contribution of a therapeutic change, this QOL scale would need to be used by patients regularly at appropriate 2 to 3 monthly intervals before and after therapeutic changes under controlled conditions.

Patient bias in terms of demonstrating socially desirable responses, different interpretation of response scaling and attitude to management of their chronic pain may have also complicated results. However, careful wording of attitude and quality of life statements were designed to minimise response bias. The results demonstrated more bias to the left of the QOL scale i.e. low scores, rather than a skewed distribution in the middle of the scale as can often occur with patient rating scales (Norman and Steiner 1995). This finding may suggest that patients' response was reflective of their perceived quality of life with patients actually making a judgement rather than just marking the middle of the scale.

In general within the group of 96 patients, patients identified more physical and occupational problems as compared with social or psychological problems. However, as with most QOL scales, this does not accurately reflect the individual patient perception of the relative influence of each factor on their QOL. Ideally, patients should have been asked to rank the statements in order of their perceived importance or to create their own patient-generated index to obtain a more realistic appreciation of patients' own problems (Ruta *et al* 1994). However, limitations have

also been found with this approach as discussed earlier in this chapter (Tully and Cantrill 1998).

Although the results vary widely between patients, low median social scores for all groups suggest that patients have coping strategies to maintain enjoyment of life irrespective of the intensity of their pain. Coping strategies are well documented in patients with chronic pain and vary depending on many external and patient factors (Rosenstiel and Keefe 1983). For example, when patients were asked if they had difficulty in talking to their friends or relatives about their pain, some reported that they did not talk to their relatives about the pain, so it was not perceived as a problem by these patients. Although this was perceived by the study pharmacist as a coping strategy, it may have resulted in overestimating the extent of family and friend support which was provided to the study group and in underestimating the social problems of patients with chronic pain.

It was interesting to note that although patients with satisfactory outcomes, as defined by the pre-set criteria, had the lowest total QOL scores and the lowest QOL scores for all dimensions, the group still identified that their chronic pain caused problems including housework, planning activities and continuing their work. Their pain often resulted in changes in work practices, reflected by high occupational scores. They also identified problems in their ability to eat, sleep, walk and get out of the house. Such limitations have been well documented by Anderson *et al* (1985). These problems need to be appreciated by all health care professionals when assessing the wellbeing of patients with chronic pain, irrespective of perceived pain control.

Patients with poor pain control reported the highest psychological scores as compared to the other groups, which may reflect the psychological distress associated with pain itself, a lack of coping strategies or may indicate that this group had separate psychological problems (Newman 1996), as illustrated by Case Study 5 in Appendix 18. Further investigation of the psychological problems of such a patient group is needed using an appropriate tool to more accurately assess the influence of psychological problems such as depression and coping strategies on quality of life (Van Riel and Van Lankveld 1993).

Patients who had poor outcomes and were interviewed on a second occasion after intervention, had the highest median total, physical and occupational dimension

scores and the highest individual statement QOL scores as compared to the other outcome groups. The large amount of frustration identified by this group (Table 5.5) may well have resulted due to problems of mobility and work, all of which can lower self-esteem (Newman *et al* 1989).

Patient attitude to pain has been demonstrated to influence quality of life such that patients with a very negative attitude to chronic pain have reflected a poor quality of life (Van Riel and Van Lankveld 1993). In this study, the lack of correlation of overall attitude with quality of life may be partly explained by the positively skewed distribution of patient attitude in this group prior to intervention, the lack of sensitivity of the attitude score and the duration of chronic pain in the study group. Knowledge about chronic pain management in this group of patients was high (reflected by high attitude scores) and duration of pain was found to relate to attitude, marked changes in attitude would have been required to effect a change in overall score at Interview 2. The results also demonstrate the problem of potentially masking a change in an attitude statement by creating a global index attitude score from such statements (Norman and Steiner 1995).

Although the type of chronic pain was not found to influence quality of life, pain intensity significantly influenced patients' overall quality of life. Pain in patients with RA, OA and back pain has been reported to be a significant factor in determining patients' quality of life (Reisner-Keller 1992, Kazis *et al* 1983). Pharmacists have an ideal opportunity to try to optimise pain relief where possible and so help to improve quality of life.

## Chapter 6

### Side effects experienced by patients and documentation of monitoring parameters

#### 6.1 Introduction

Patients with chronic disease states such as chronic pain are at high risk of side effects, since many of the patients are on multiple drug therapy, elderly, have concurrent disease and may be non-compliant with their medication. All of the above factors predispose to adverse drug reactions (Cadieux 1989, Kando *et al* 1995, Col *et al* 1990).

Patients prescribed long-term NSAIDs and DMARDs are at high risk of developing side effects (CSM 1994, Fries *et al* 1993) so need to be closely monitored to optimise efficacy and minimise toxicity. Indeed, NSAIDs are responsible for 25% of voluntary adverse effect reporting to the Committee on Safety of Medicines (CSM 1994).

The incidence of adverse drug reactions (ADRs) in hospital ranges from 4 to 30%, depending on the differences in methodology used to detect suspected reactions and the differences in the ADR definition used (Bates *et al* 1995, Seeger *et al* 1996). The few limited well-designed studies of ADRs in the community which have been published, suggest an incidence of 2.6 to 40% (Martys 1979, Mulroy 1973, Cunningham *et al* 1997).

Mulroy (1973) prospectively investigated the number of GP consultations in a practice of 6,200 patients which were assessed as a direct result of iatrogenic disease. One consultation in every 40 was identified as the result of iatrogenic disease. This study had no control group and found problems in defining and measuring some of the side effects of medical treatment. Martys (1979) found a much higher incidence of ADRs in general practice (41%) in a 2 year prospective,

uncontrolled study, which involved more detailed patient interviews and follow-up as compared to the study of Mulroy (1973). Cunningham *et al* 1997 found that over 25% of hospital admissions in the elderly were due to drug related problems, and, unlike the previous researchers, utilised a review panel of health professionals to assess the type(s) of drug related problems and their contribution to the admission.

Spontaneous reporting schemes of ADRs have, until recently, only been permitted for use by doctors, dentists, coroners and pharmaceutical companies via the 'Yellow card scheme'. Recent studies have demonstrated that under-reporting of ADRs in both hospital and general practice has occurred (Smith *et al* 1996). Both hospital and community pharmacists, in pilot studies, have been shown to have adequate resources and ability to participate in such schemes (Edwards *et al* 1989, Wolfson *et al* 1993, Whittlesea and Walker 1996). Moreover, pharmacists have improved the reporting of serious drug reactions (Lee and Beard 1997). Consequently, all hospital pharmacists and some community pharmacists in pilot sites have been recruited recently into the scheme (CSM 1997). The pharmacist's roles in this scheme have been defined recently by Lee and Beard 1997. The community pharmacist is actively encouraged to identify adverse effects associated with OTC medicines, alternative therapies and possibly generic medicines (Whittlesea and Walker 1996). Recent results suggest that ADR reporting by community pharmacists has been of good quality, but not as extensive as originally anticipated from the original response to involvement in the initial pilot study. Reduced uptake of the scheme may have reflected variations in the enthusiasm of the recruited pharmacists as the project proceeded. However the extent of ADR reporting is influenced by appropriate training programmes (Lewis 1998).

Patients are becoming increasingly involved in making decisions about their drug therapy for rheumatological problems, and can be useful sources from whom adverse effects can be identified (Donovan *et al* 1989). However, attribution of the causality of symptoms to an ADR is difficult and limited (Lee and Beard 1997), especially since ADRs can often be masked by other concurrent diseases. Moreover, healthy people not taking any medication can report similar symptoms (Reidenberg and Lowenthal 1968).



Documentation and communication of an ADR to relevant healthcare personnel is vital to minimise further side effects and to maximise the therapeutic outcomes of potentially very toxic agents such as DMARDs and NSAIDs.

Shared care protocols must be developed and agreed by both rheumatology consultants and general practitioners to clearly identify who is responsible for initiating and thereafter maintaining DMARD therapy and who is responsible for the monitoring of potential toxicity (Anekwe *et al* 1997, Anon 1996).

## 6.2 Objectives

The objectives of this part of the study were:

1. To identify patients' awareness of the potential side effects of their medication.
2. To identify side effects reported by the study patients.
3. To investigate the extent of documentation of monitoring parameters for efficacy and toxicity.

## 6.3 Methods

The data collection form as described in Chapter 2 Section 2.1.6.1 and Appendix 7, was used to identify side effects which were both currently or previously experienced by patients and attributed to their medication for the management of chronic pain. These side effects were documented in the patients' medical notes. The question 'Have you ever experienced any problems which you think could be due to your medicine?' in the pain questionnaire (Appendix 8, question 36) was also used during each interview to identify patient awareness of side effects which they attributed to their medication for chronic pain management.

The same data collection form in Appendix 7, was also used to identify the extent of documentation of monitoring parameters for optimising efficacy and minimising toxicity of NSAIDs, DMARDs, immunosuppressants and other therapy.

## **6.4 Results**

### **6.4.1 Types and frequencies of side effects experienced and reported by study patients**

Seventy-three out of the 96 study patients (76%) reported that they had at some time since the diagnosis of their chronic pain experienced at least one side effect which they could attribute to their medication. One hundred and seventy five side effects were reported by the 73 patients, 158 during Interview 1 and 17 at Interview 2, the latter attributed by patients to medication which was prescribed after Interview 1.

Table 6.1 shows the number of RA, RA and OA, OA and back pain patients, who reported side effects. Table 6.2 describes the number of side effects reported related to type of drug therapy.

Five of the 18 patients who had poor pain outcomes, as defined in Chapter 2, were referred to the GP because they were at high risk of or had developed side effects.

No patients reported an ADR to an OTC medicine.

Interview	Number of side effects reported	Number of patients who reported side effects (% of pain group)	Chronic pain disease state (total no. of patients in group)
1	76	35 (83)	RA (42)
	21	13 (59)	OA (22)
	53	20 (80)	RA and OA (25)
	8	5 (71)	Back pain (7)
Total	158	73 (76)	96
2	10	5 (62)	RA (8)
	1	1 (33)	OA (3)
	6	4 (80)	RA and OA (5)
		0 (0)	Back pain (2)
Sub-total 2	17	10 (56)	18
Final Totals	175	83	

Table 6.1: Frequency of side effects reported by 73 study patients

Type of drug	Number of side effects reported (% of total)	Number of patients who reported side effects (% of patients prescribed drug)
NSAID	72 (41)	64 (90)
DMARDs and Immunosuppressants	39 (22)	17 (93)
Combination Analgesics	26 (15)	20 (42)
Opioid analgesics	7 (4)	6 (75)
Others	31 (18)	22 (67)
Totals	175 (100)	

Table 6.2: Frequency of side effects reported by 73 study patients in terms of type of drug

**6.4.2 Types and frequencies of side effects attributed to NSAID therapy**

Table 6.3 lists the 72 specific side effects which 66 different patients attributed to their NSAID therapy. Eight of the 64 patients reported side effects which they attributed to NSAIDs prescribed since Interview 1. Seventy-one of the side effects reported with NSAIDs were known to be associated with NSAID therapy. The most common reported side effects were gastrointestinal side effects (74%). All patients who reported that they had a gastrointestinal bleed had no previous history of gastric ulceration prior to the bleed. Other NSAID side effects reported by 4 patients, included interstitial nephritis, nephropathy (induced by diclofenac), proctitis (indomethacin suppositories), and palpitations induced by etodolac.

Type of side effect	Number of side effects reported	Number of patients who reported the side effect
Nausea	18	16
Vomiting	3	3
Diarrhoea	3	3
Heartburn/ indigestion	17	14
Gastric or duodenal ulcer	8	8
GI bleed	4	4
Constipation	1	1
Dermatological	10	10
Dizziness, euphoria	3	3
Others	5	4
Total	72	66

**Table 6.3:** Types and frequencies of side effects attributed to NSAID therapy by study patients

**6.4.3 Types and frequencies of side effects attributed to DMARD and immunosuppressant therapies**

Seventeen patients attributed 39 specific side effects to their DMARD or immunosuppressant therapies. The most commonly reported side effects included gastrointestinal problems (10 patients), rash (7 patients) and haematological problems (4 patients). Two patients on penicillamine reported that they had developed thrombocytopenia with their therapy, while 2 on sulphasalazine developed leucopenia. Proteinuria was reported by 1 patient on penicillamine and 2 patients on gold. Two patients who had taken hydroxychloroquine in the past reported ocular side effects, fever, malaise and bone pain.

#### **6.4.4 Types and frequencies of side effects attributed to combination analgesics, opioids and other therapies**

The frequency with which side effects were reported to combination analgesics, opioids and other therapies is shown in Table 6.2.

The most commonly reported side effects of combination analgesics were constipation (12) and CNS side effects (9). Opioid therapy was reported to cause constipation in 5 patients, nausea in 2 patients and dizziness or drowsiness in 2 patients.

Thirteen of the 31 other side effects, reported by 7 patients, could not be attributed to any specific drug. The 18 other side effects, attributed to other therapy not associated with chronic pain management included gastrointestinal problems (7), side effects associated with cardiovascular therapy (8), night sweats with tamoxifen (1) and side effects associated with antibiotic therapy (2).

#### **6.4.5 Case studies - patients requiring GP referral due to high risk or development of side effects**

Five of the 18 patients who had poor pain outcomes and who were consequently referred to the GP by the study pharmacist were at high risk of or were experiencing side effects to their prescribed medication. Appendices 19 and 20 detail the case studies of 2 of the 5 patients who required GP referral due to the development of side effects.

Four of the 5 patients were experiencing side effects which both they and the study pharmacist attributed to NSAID therapy. These NSAID side effects included gastrointestinal side effects (3 patients), ranging from dyspepsia to 'spitting blood' and dermatological side effects (1 patient). Two patients developed thrombocytopenia with penicillamine therapy, requiring GP referral, after which penicillamine therapy was discontinued in both cases.

#### **6.4.6 Documentation of biochemical and other parameters to monitor the efficacy and toxicity of therapy**

There was very little documented evidence in medical records relating to the efficacy of treatment in terms of pain relief, either subjectively or objectively.

Little documentation was made of the progression of rheumatoid arthritis in patients. Pain and joint scores were only documented in 1 patient's notes, erythrocyte sedimentation rates in 7 patients' notes and c - reactive protein levels in 1 patient. One patient with diagnosed iron deficiency anaemia had serum iron recorded post therapy, but no haemoglobin, mean cell volume or ferritin documented.

Only 34 of the 96 study patients had any monitoring parameters actually documented in their medical records or on computer, which made it difficult for the study pharmacist to evaluate the potential efficacy or toxicity of patients' medication in terms of objective parameters.

#### **6.4.7 Documentation of parameters to assess the efficacy and toxicity of NSAIDs**

There was no routine monitoring of haematological parameters or renal function documented for any of the study patients. Only 2 patients had renal parameters monitored, which was due to underlying renal disease.

#### **6.4.8 Documentation of parameters to assess the efficacy and toxicity of DMARDs**

Out of the 16 patients who were taking DMARDs or immunosuppressants, only 10 patients had any monitoring parameters recorded. Three of the 5 patients prescribed gold, 2 of the 6 prescribed sulphasalazine and all 3 patients prescribed penicillamine had full blood counts documented. One patient prescribed hydroxychloroquine was due for an initial ophthalmology assessment and 1 prescribed azathioprine had liver function and full blood tests documented. It is thus unclear if any monitoring was actually carried out in the patients with no documented results. No baseline serum biochemistry and haematology results were available to check baseline values prior to DMARD therapy.

Table 6.4 compares the documented monitoring parameters in the above 10 patients with the protocol for monitoring DMARDs and immunosuppressants as defined in Appendix 4.

<b>DMARD</b>	<b>No. of patients with results recorded</b>	<b>No. of patients prescribed drug</b>	<b>No. of records which met criteria</b>	<b>Comments</b>
<b>Sulphasalazine</b>	2	6	2	
<b>Penicillamine</b>	3	3	2	(a)
<b>Sodium Aurothiomalate</b>	2	4	0	(b)
<b>Auranofin</b>	1	1	0	(c)
<b>Hydroxychloroquine</b>	1	1	1	(d)
<b>Azathioprine</b>	1	1	1	(e)
<b>Totals</b>	10	16	6	

**Table 6.4:** Comparison of documented monitoring for the DMARDs and immunosuppressants used in the study patients with data sheet monitoring recommendations and other published advice (Medicines Resource Centre 1996)

- (a) Only 1 patient who developed thrombocytopenia had platelets recorded in GP medical notes after therapy was discontinued.
- (b) Two patients had no documented results, 2 had monthly full blood count results after injection, but no urinalysis.
- (c) No record of WCC or urinalysis monitored.
- (d) Therapy just recently initiated, but ophthalmic check 2 weeks after initiation of therapy.
- (e) Liver function tests, full blood count monitored at 3 monthly intervals.

#### 6.4.9 Documentation of parameters to assess other disease states

When blood pressure results were investigated for assessment of hypertension, it was found that in 7 of the 11 patients with documented blood pressure measurements, a clinical diagnosis of hypertension had been made. Only 1 of these patients had more than 2 blood pressure recordings documented. Three other patients who had blood pressure recorded had cardiovascular disease but were not hypertensive, while another patient had no diagnosis. One patient was diagnosed hypertensive yet no blood pressure measurements were recorded.

## 6.5 Discussion

It is difficult to establish to what extent the study's side effect and adverse drug reaction reporting rates reflected their true incidence in this study group of patients.

Side effect reporting may have included quite a number of false positives, since patients may have reported symptoms of concurrent disease which they had experienced, mistaking them for side effects of drug therapy, or may have been prompted to report a side effect which they were aware could potentially occur. Such information could have been obtained from patient information leaflets, or medication label warnings. Indeed, in this study, 39 of the 55 patients who identified that they had received information leaflets (see Chapter 3), reported that the leaflets were useful in helping patients identify potential side effects. Some researchers have found that specific information cards encouraging ADR reporting have prompted patients to report (Whittlesea and Walker 1996), while others suggest that written drug information alone does not improve patient reporting rate of ADRs (Kitching 1990).

Although the question concerning side effects within the questionnaire was open, asking if patients had ever experienced any problems which they thought could be attributed to their medicines, some patients at interview did need some clarification about the term 'problem', which may have introduced bias. However, the reporting of adverse effects experienced by patients prescribed NSAIDs, DMARDs and immunosuppressants, was unprompted, suggesting that patient awareness of side effects was good.

Conversely, some patients within the study may have under-reported side effects, since it is unclear if the 23 patients who reported no side effects actually had no problems or just had poorer recall. Portable documentation of patients' drug therapy, drug history and adverse drug reactions in the form of smart cards might improve the accuracy of ADR reporting by patients, by reinforcing their awareness of drug information concerning their present and past disease states.



There was very limited evidence in the medical records of any minor side effects which may have been previously reported by patients in this study. Moreover, no evidence was available to indicate that any 'Yellow cards' had been submitted for any of the ADRs documented in the medical case notes. Since ADRs are frequently under-reported (Smith *et al* 1996), pharmacists have a crucial role to try to minimise this reporting problem, by accurately and consistently documenting and reporting potential and actual ADRs associated with a patient's therapy (CSM 1997).

The majority of side effects was reported by patients within the RA and RA and OA groups, associated with NSAID therapy (41%) or DMARD therapy (22%). This finding may reflect not only the toxicity profiles of the medications which they were currently or had been taking for their arthritis management, but also the side effects associated with concurrent medication and / or disease states. The majority of ADRs but not minor symptoms as reported by patients were verified in the past medical history or drug history of their respective notes. This latter finding suggests that patients on long-term therapy can recall significant ADRs accurately and can be a useful source of drug history information relevant to the ADRs experienced, as demonstrated by O'Brien and colleagues (1990). However, the 2 case studies in Appendices 19 and 20 illustrate that patients may not always report significant ADRs to their GP.

The side effect profiles of NSAIDs and DMARDs as reported by patients in this study reflect published data, with gastrointestinal problems most commonly reported with both types of therapy (CSM 1994, Lee and Morris 1997, Felson *et al* 1990). It was interesting to note that all 4 patients who reported a gastrointestinal bleed had no ulcer previously diagnosed and had experienced little if any symptoms. All of these patients were elderly and taking high dose NSAIDs, risk factors now commonly recognised for the development of NSAID-induced ulcers (Lee and Morris 1997). Pharmacists need to be aware of the risk factors for NSAID-induced ulcers and develop strategies within their own practice to minimise NSAID-induced gastrotoxicity.

Three patients attributed diarrhoea to misoprostol, mefenamic acid and diclofenac respectively, all of which have been reported previously (Lee and Morris 1997). The renal adverse side effects reported may be an underestimate of the

problem in this study, especially since interstitial nephritis is a relatively rare ADR and only 2 patients had any renal function parameters documented. Since many of the patients in this study are elderly and on chronic NSAID therapy, such patients should have their renal function monitored regularly (Scottish Medicines Resource Centre 1995(B)).

The case studies demonstrate that patients with chronic pain want to be involved in making therapeutic decisions and they are often intentionally non-compliant with their medication partly because of their perceptions of the side effect profiles of their prescribed drugs.

Case 8 (Appendix 20) demonstrated medication-taking behaviour previously demonstrated by rheumatology patients (Donovan and Blake 1992) in that he took therapy for a short trial period as he thought fit, until side effects (dyspepsia) or lack of effect (no pain relief) occurred. The medication behaviour illustrated in Case 7 (Appendix 19) was less intuitive and needed greater reassurance and information about the risk of side effects from the pharmacist. In both cases, neither patient was prepared to visit their GP despite experiencing significant ADRs. The risk of ADRs and their implications must be discussed with patients to ensure that maximum benefit of therapy is achieved with minimal toxicity, since more studies investigating chronic pain suggest that patients who are more worried about side effects are less likely to comply with therapy (Donovan and Blake 1992, Ward *et al* 1993).

Documentation of biochemical and other parameters in the medical case notes or practice computers was very poor. One explanation for the poor documentation of DMARD therapy is that the GPs were reluctant to be involved in the continued monitoring of second-line therapy. Alternatively, some patients may have had all their monitoring conducted at a local hospital. Blood pressure readings and other laboratory results may have been located in other nursing notes, but some verification of results should be made in the medical case notes. GPs should agree monitoring protocols with their local rheumatologists or health care team, depending on the parameters to be monitored (Anekwe *et al* 1997). Thereafter, whoever is responsible for the monitoring should carry it out as per protocol, act on the results and disseminate any results to relevant members of the healthcare team including patients (Anon 1996, Medicines Resource Centre 1996).

Hospital pharmacists are being encouraged to monitor the efficacy and toxicity of anti-rheumatic drugs (Kay 1997), but pharmacists in primary care are also well placed to carry out similar roles. The finding that 5 of the 18 cases which required considerable pharmacist input and, ultimately, GP referral were associated with ADRs suggests that pharmacists in primary care especially, need to be vigilant to detect any signs or symptoms suggesting an ADR and refer proactively. The use of PMRs to detect and document ADRs with both prescribed and OTC medication is likely to be critical to the success of pharmacists' involvement in ADR reporting, as suggested by recent pilot studies in community pharmacies (Whittlesea and Walker 1996, Briggs *et al* 1996).

The results suggest that patient interviews via domiciliary visits provide very good opportunities to review patients' signs and symptoms, adherence, attitude and tolerance to both past and present prescribed and OTC medications. Much more detail regarding the type of side effect experienced, nature of onset and how the adverse effect was resolved was obtained by interview compared to information in medical notes. Patient reports could provide an additional resource to current ADR databases, as suggested by Jarernsiripornkul *et al* 1997. Such medication reviews could be carried out in the community pharmacy, but time available to both pharmacist and patient may limit outcomes. Such reviews must be interpreted in the light of up-to-date laboratory results and medical case note reports, all of which need to be readily accessible via, for example, computer links between pharmacies and local GP surgeries, to ensure efficient transfer and utilisation of information and optimum monitoring of therapy by all relevant members of the health care team. Community pharmacies may also need computer links with biochemistry and haematology laboratories to facilitate rapid retrieval of laboratory data, if results are not being sent effectively to and communicated from GP surgeries.

## **Chapter 7**

### **Pharmacist interventions and recommendations for patients with chronic pain**

#### **7.1 Introduction**

Domiciliary visiting by pharmacists to review medication is becoming more common (Beech and Brackley 1996, Fairbrother *et al* 1993). Most studies have investigated medication review of the elderly as a general patient group (Dixon *et al* 1995, Hawksworth 1996), since they are often on multiple medication supplied on repeat prescription (Cartwright 1988), at high risk of adverse drug reactions (Royal College of Physicians 1997), and are often housebound with limited access to the primary health care team (Sommerville 1996). Recent national reports have supported these initiatives (Royal Pharmaceutical Society of Great Britain 1988, 1992 and The Royal College of Physicians 1997).

Few studies have however focused on pharmaceutical needs of patients with chronic pain. Dixon *et al* (1995) used chronic compound analgesic usage as a tool to investigate medicine usage of a wide range of patients in their homes. They determined patients' knowledge of their analgesics, but did not identify pharmaceutical needs associated with chronic pain management. Briggs *et al* (1996) investigated the influence of community pharmacists using prescription medication records on the use of analgesics by patients, but again did not investigate chronic pain management.

Most of the studies on domiciliary visits have been pilot projects, with limited evidence to demonstrate the outcomes of such activities in terms of patient and GP benefits. Specific outcome measures must be identified and evaluated to appraise the feasibility and extension of such pharmaceutical services. However, specific and

sensitive outcome measures for pharmaceutical care are not easy to identify, as discussed in Chapters 4 and 5, so measures of process are often used instead of outcomes.

Domiciliary visit outcomes from previous small studies have demonstrated patient, GP and carer satisfaction (Fairbrother *et al* 1993, Begley *et al* 1994), a reduction in the number of visits to the doctor (Hendrikson *et al* 1984), and reduced drug costs and hospitalisation rates by reducing drug usage, risk of side effects and increasing drug efficacy (Hawksworth 1996). No published work on pharmacists involved in domiciliary medicine management has utilised specific qualitative and quantitative indicators to evaluate the implementation of a pharmaceutical care plan on chronic pain management.

Intervention reporting studies in community pharmacy have been used to justify developing the role of the pharmacist (Rogers *et al* 1994, Caleo *et al* 1996). Researchers involved in domiciliary visits have found that although the rate of doctors' acceptance of pharmacists' interventions is often high, the number of therapeutic interventions actually carried out by the prescriber is very variable (Rees *et al* 1995, Grymonpre *et al* 1994). Attitudes of members of the health care team towards the development of the pharmacist's role in chronic pain in primary care, have ranged from being very positive to negative (Begley *et al* 1994). This suggests that there is still a need to demonstrate that pharmacists can provide pharmaceutical care as an integral part of the primary health care team despite evidence that they have good analgesic knowledge (Briggs *et al* 1997).

It is therefore important to record both process in the form of recommendations and outcomes, using appropriate measures, in the provision of pharmaceutical care. The willingness of GPs to implement recommendations generated by this new type of service is also important (Weir *et al* 1997).

## **7.2 Objectives**

The objectives of this part of the study were:

1. To quantify the types of pharmaceutical care issues identified in patients with chronic pain in primary care.
2. To quantify the pharmaceutical input needed to optimise chronic pain management in these patients.
3. To assess the extent of GP acceptance and therapeutic actions actually carried out as a result of the pharmacist's interventions.

## **7.3 Methods**

The study pharmacist collected all relevant information from each patient's medical notes, 1 to 2 days prior to an interview in the patient's home using the pain questionnaire as described in Chapter 2, Section 2.1.7. The study pharmacist made a second visit if patients had a poor outcome on the first interview, as defined in Chapter 2, Section 2.1.3. This second interview occurred 4 to 6 weeks after action was taken by the GP following the pharmacist's recommendations or 4 to 6 weeks after the first interview if the GP did not act on the pharmacist's advice, as described in Chapter 2, Section 2.1.9.

GP referrals concerning problems with chronic pain management were considered separately from referrals due to other medical problems. All referrals were made directly by the study pharmacist by telephone or in discussion with the GP at his / her surgery within 2 days of the pharmacist's first interview. All requests from patients with chronic pain and the advice provided by the study pharmacist were collated in terms of type and frequency of pharmaceutical care issue as described in Chapter 2, Section 2.3.8.

The pharmacist's proposed solution(s) to a patient's problem were also categorised as reinforcement, clarification, correction or follow up with prescriber issues as described in Chapter 2, Section 2.3.8.

Patient requests and pharmacist's solutions for those patients who had satisfactory outcomes were compared with those requests and solutions for patients who had poor outcomes.

GP acceptance and implementation rates of pharmacist's recommendations concerning problems with chronic pain management were also assessed.

## **7.4 Results**

### **7.4.1 Results: Types and frequencies of patient problems and interventions made by the study pharmacist**

Twenty-eight patients (29%) out of the 96 interviewed had poor outcomes requiring referral to their GP, although only 18 of these were re-assessed by a second interview. Out of the 28, 6 patients had VAS average pain greater than 75, 5 had or were at high risk of developing an adverse drug reaction, 14 were generally dissatisfied with their chronic pain management, 5 of whom specifically requested alternative management. (Two patients demonstrated more than 1 poor outcome criteria). The 10 patients who did not receive a second interview to assess the outcomes of the pharmacist's intervention, were either unwilling or unavailable to be interviewed a second time despite agreeing to the study protocol at the outset (7 patients), or were too ill to be interviewed twice during the study period (3 patients).

In 14 of the 18 patients who were followed up, the pharmacist made recommendations to GPs concerning therapy changes. The remaining 4 patients had poor pain control at the first interview, but it was considered that no further recommendation could be made other than the surgical management currently being recommended by the patient's GP. All 14 patients required changes to their analgesic therapy due to reported poor pain control yet only 6 of these patients had

high VAS average pain scales (greater than 75) (see Chapter 4). GPs agreed with and carried out the pharmacist’s recommendations in 12 of the 14 patients. Five of these 14 patients were also referred because of a high risk of the development of side effects (see Chapter 6). Table 7.1 summarises patient outcomes by pain diagnosis, referral rate to the GP and recommendation acceptance rate by GPs.

A further 10 patients were referred to their GP by the study pharmacist due to inappropriate or duplicate therapy. These 10 patients did not have poor outcomes as defined by the criteria of the study.

Pain diagnosis	RA	OA	RA and OA	Back pain	Total no. of patients
No. of patients with satisfactory outcomes	32	17	14	5	68
No. of patients with poor outcomes	11	4	11	2	28
No. of poor outcome patients reviewed by pharmacist at Interview 2	8	3	5	2	18
No. of recommendations accepted by GP	5	3	3	1	12

**Table 7.1:** Summary of patient outcomes in terms of disease state, referral rate to the GP and GPs’ acceptance of pharmacist recommendations

Table 7.2 details the problems identified by the study pharmacist and actions taken by the GPs in the 14 patients in whom recommendations were made. Pain scores in terms of total PRI rank and scale scores and NWC scores decreased in 10 of the 14 patients, remained unaltered in 1 and increased in 3 patients (see Chapter 4).

Out of the 12 patients in whom the pharmacist’s recommendations had been carried out, VAS average pain scores decreased in 6 patients (range of decrease was 20-30mm), increased in 3 patients (range of increase was 10-30mm) and was



unchanged in 3 patients. Total PRI scale and rank scores decreased in 9 patients (range of decrease was 1-30.1), increased in 3 patients (range of increase was 0.7-22.2) and was relatively unchanged in 1 patient. NWC scores decreased in 8 patients (average decrease was 4 words, range 1-9), increased in 2 patients (average increase was 4 words, range 2-7) and unchanged in 2 patients.

The changes in overall mobility, psychological, patient satisfaction and attitude scores were strongly influenced by the changes in overall pain scores in most of the 12 patients after the second interview (see Chapter 5).

In the 2 patients where the GP did not agree with the pharmacist's recommendations, one patient's pain (Patient 39 in Table 7.2) improved subsequent to surgery and the initiation of homeotherapy (VAS average pain score decreased from 100 to 60), while the other patient's pain (Patient 78) worsened with no change made in medication (VAS average pain score increased from 20 to 50). Total QOL scores for Patient 39 decreased while those for Patient 78 increased. However, psychological and social scores in both patients did reflect changes in pain control, while patient satisfaction was unchanged in both patients.

During the first interview, fifty-nine other patients required pharmacist advice on their current medication, but their problems did not fall under the category of a poor outcome as defined in this study. Current medication included any medication (prescribed and OTC) used to treat their pain (analgesic therapy) and other concomitant disease states (other therapy).

Table 7.3 summarises the types and frequencies of problems encountered and the pharmaceutical actions required during the domiciliary visits. A total of 194 pharmaceutical actions were implemented in these 59 patients in the form of advice and counselling for 84 problems. (50 patients (85%) required advice in at least 2 categories.)

Pain group /code	Problem identified by pharmacist	Action taken by GP after pharmacist recommendations	VAS	PRI (scale)	PRI (rank)	NWC	PPI
OA 81	4 NSAIDs prescribed. Patient wanted to limit NSAID therapy and had dyspeptic symptoms.	1 NSAID continued. GI problems reviewed- no ulcer. Misoprostol stopped and aspirin monitored	-30	-3.5	-4	-1	-1
OA 76	Stomach and arthritic pain - taking 2 NSAIDs concurrently with possible haematemesis.	Diflunisal stopped, regular cocodamol and Naproxen continued. Haematemesis unconfirmed	-20	+5.7	+4	+2	⇔
RA/OA 4	Increased pain, requested alternative therapy - already on DMARD. NSAID ADR.	DMARD changed. NSAID re-introduced.	-20	-10.4	-12	-4	-1
RA 40	Thrombocytopenia with reduced penicillamine dosage. Nose bleeds on steroids and NSAID.	Penicillamine discontinued. Analgesia changed to coproxamol	⇔	+0.7	⇔	⇔	⇔
RA 27	Patient keen to conceive and discontinue DMARD. Requested safflower therapy	Penicillamine discontinued Safflower therapy commenced	+20	-2.1	-1	-2	⇔
RA 28	Very depressed due to RA and a recent death - reluctant to start DMARD.	Hydroxychloroquine commenced / social support	⇔	-3.3	-4	-2	⇔
RA 41	Reluctant to restart DMARD, depressed , requested other Rx.	Sulphasalazine and restarted. Homoeopathy	+10	+22.2	+21	+7	+1
RA/OA 46	Patient requested to try alternative therapy- on gold injection / NSAID.	Existing therapy continued - trial of alternative Rx.	+30	-5.4	-3	-3	+2
RA 57	Patient requested improved pain relief and a change in DMARD.	Sulphasalazine changed to penicillamine	⇔	-30.1	-21	-9	-2
Back pain 84	Increased pain - patient requesting alternative therapy - on coproxamol.	Physiotherapy-coproxamol changed to dihydrocodeine	-30	-3.9	-4	⇔	-1
RA/OA 52	Increased RA and GI pain - on NSAID (GI history).	Omeprazole initiated - no ulcer. Ibuprofen started	-20	-0.5	-1	-1	⇔
OA 68	Poor pain control. Required physiotherapy.	Patient referred to physiotherapy	-30	-29.7	-32	-8	-1
RA 39	Awaiting hip surgery, requested homoeopathy - on codydramol.	Surgery performed. Homoeopathy started	-40	-2.7	-1	-1	-1
RA/OA 78	Increased pain - review allopurinol .	No change to medication	+30	+1.1	+1	⇔	⇔

- = decrease in pain scores at Interview 2 + = increase in pain scores at Interview 2

⇔ = no change in pain scores at Interview 2

**Table 7.2:** Problems identified by pharmacist, actions taken by GP and changes in pain scores in 14 patients with poor pain outcomes

Type of problem requiring action	Type of action				Total no. of actions
	Reinforcement	Clarification	Correction	Follow up	
Chronic pain management	1	7	3	0	11
Therapy for pain	7	34	31	3	75
Therapy for other disease states	5	23	26	1	55
Side effect-pain therapy	5	15	20	5	45
Side effects-other therapy	1	1	1	1	4
Management of other disease states	0	2	2	0	4
Totals	19	82	83	10	194

**Table 7.3:** Frequencies of problem areas and pharmaceutical actions implemented by the study pharmacist during the domiciliary visits

The problem areas in the different chronic pain groups are shown in Table 7.4. The majority of the actions were implemented within either the RA patient group or those with RA and OA. Analgesic problems required 131 of the total 194 care actions (68%). There was no significant difference in the type of problems between groups.

Disease State	Type of problem						Total no. of problems	Total no. of actions
	Chronic pain management	Therapy for pain	Therapy for other disease states	Side effects -pain therapy	Side effects -other therapy	Management of other disease states		
RA	2	11	8	9	3	0	33	71
OA	4	0	4	5	0	1	14	27
RA +OA	1	7	9	3	0	2	22	60
Back Pain	1	5	4	4	0	1	15	36
Totals	8	23	25	21	3	4	84	194

**Table 7.4:** Types and frequencies of pharmaceutical actions identified by the study pharmacist within each pain diagnoses.

## 7.4.2 Results of patients with poor outcomes

### 7.4.2.1 Case studies – pharmaceutical care of patients with poor pain outcomes

Appendices 21 and 22 (Case studies 8 and 9 respectively), provide details of 2 patients who required GP referral due to poor outcomes after first interview.

### 7.4.3 Results of patients with satisfactory outcomes

Table 7.5 specifies the types and frequencies of pharmaceutical advice provided to patients who did not have poor outcomes by the study definition, but still required advice to optimise efficacy of their treatment.

Type of problem	Number of patients with problem
Poor pain control due to inappropriate use of prn analgesia	6
Patient taking 2 NSAIDs concurrently	1
Poor understanding of DMARDs – taking it prn or stopped	4
Poor understanding of DMARDs – taking it at wrong time	4
Advice on other treatments to improve pain relief	4
Compliance problems with analgesic therapy	12
Advice to minimise the side effects of analgesic therapy	38
Advice to improve efficacy of therapy for other disease states	14
Advice to minimise the side effects of therapy for other disease states	4
Advice on other treatments to improve other disease states	6
Compliance problems with other therapy	12

**Table 7.5:** Types and frequencies of problems identified in patients with satisfactory outcomes but required advice

## 7.5 Discussion

The wide range of medication-related problems identified by the study pharmacist is similar to those identified by other researchers who have investigated problems associated with chronic analgesic use (Briggs *et al* 1996, Dixon *et al*

1995). This indicates that pharmacists involved in the management of chronic pain via domiciliary visits must be prepared to discuss pharmaceutical problems, ranging from those related to the chronic pain including pain therapy, side effects, drug / drug or drug / disease state interactions to problems associated with other disease states or other pain management strategies. The pharmacist must be prepared to refer patients to other members of the health care team wherever appropriate. Only then will patients more readily perceive the pharmacist as a member of the health care team, not an isolated professional.

The pharmaceutical actions required in this study were mainly advising patients (77%), but a substantial proportion of patients (38, 40%) needed GP referral with or without poor pain outcomes. The different types of advice given both to patients and GPs illustrate the complexity of patients' problems as well as the multiplicity of skills which pharmacists need to acquire and develop to optimise pharmaceutical care (Odedina and Segal 1996).

The failure of 10 of the 28 patients with poor outcomes to agree to a second interview, reduces the value of the results. This lack of support can be partly explained by the unpredictably severe relapses of RA in some of the study patients. A longer follow up period, more selective patient criteria and more explicit information about the study implications may have helped improve patient follow-up.

Despite this, the study suggests that pharmacists have a valuable role in the assessment of and pharmaceutical care of patients with chronic pain. The study pharmacist made interventions in 14 patients, all of whom had poor pain outcomes. Moreover, 131 of the additional 194 pharmaceutical actions (68%) required were related to analgesic problems. The findings that 84% of these analgesic problems (110 out of 131) were clarification and correction issues and that 8 out of the 10 patients without poor outcomes required GP referral due to analgesic problems, suggest that many patients are not achieving optimum pain management. This deficiency may be due to patients' reluctance to request a review of therapy or inappropriate GP prescribing.

There were more problems identified in patients with RA as compared to those with OA or back pain, but no statistically significant difference in types of problems

between chronic pain groups. The fact that RA patients had more problems may be partly explained by the influence which RA has on other disease states.

All available sources of information must be used prior to undertaking a full patient medication review as illustrated by Cases 8 and 9 in Appendices 21 and 22 respectively. These should include the patient, medical notes and any patient medication records. Patient medication records were unavailable as a source of information in this study, but they have been shown to be very useful tools to help evaluate GPs' analgesic prescribing patterns (Paes 1992), identify patients who require improvement in their pain management (Dixon *et al* 1995) and identify patients at risk of drug / disease state interactions with any OTC analgesics (Briggs *et al* 1996).

Since most of the relevant laboratory data including biochemical and haematological parameters required to assess drug efficacy and toxicity was not available, little comment can be made about patient outcomes, particularly those with RA, in terms of standard clinical parameters. It was uncertain in the majority of cases whether GPs were aware of relevant laboratory and OTC drug use data and had just failed to document the details or whether they were unaware of the information. Pharmacists are well placed to aid in the monitoring process, having demonstrated appropriate skills in monitoring anticoagulant therapy outcomes in the community (Hall *et al* 1995).

The acceptance rate of the pharmacist's recommendations by GPs (86%) was similar to that in previous studies (Lobas *et al* 1992, Dorevitch and Perl 1996). However, no external validation of the recommendations was made, which has been shown to help eliminate bias (Begley *et al* 1996). Ideally, the recommendations should have been validated externally, using an expert panel possibly consisting of a rheumatologist, GP and a pharmacist with a specific interest in chronic pain.

In this study, all 12 of the recommendations agreed by the GPs were actually carried out. Other researchers including Rees *et al* (1995), found that, although acceptance rate by GPs was high, only 54% of pharmacists' recommendations were actually carried out. This study's higher rate of completed recommendations may be partly explained by the facts that the patient numbers involved were relatively small, that the study pharmacist was working closely with the GPs for a finite period of time in a relatively academic capacity and had previously worked with 2 of the GPs.

Grymonpre and colleagues (1994) have suggested that the GP / pharmacist working relationship influences GP acceptance rate of intervention. However, Begley and colleagues (1994), found that young GPs were less willing to encourage the role of the pharmacist in chronic pain, and may perceive that community pharmacists do not possess the skills or knowledge to equip them for that role. The evidence of this study and that of Briggs *et al* (1997) suggest that pharmacists have a role to play in the management of chronic pain.

## **Chapter 8**

### **The role of the pharmacist in the management of chronic pain in the community**

#### **8.1 Introduction**

There is currently extensive encouragement both by political and pharmaceutical bodies to develop the roles of the pharmacist within many primary care settings (SODoH 1996(A) and (B), Royal Pharmaceutical Society of Great Britain 1995, 1992). Pharmacists are now developing their skills and knowledge to provide services such as pharmacist-led clinics (MacGregor *et al* 1996, Radley and Hall 1994), GP formulary development and review (Jenkins 1996) and medication review (Westwood and Hudson 1996). As deregulation of medicines increases, pharmacists are developing their advisory role to improve the appropriate use of medicines and the treatment of minor illnesses (Hassell *et al* 1996).

Recent studies have demonstrated pharmacists' involvement in the management of chronic pain in the community (Dixon *et al* 1995, Briggs *et al* 1995, 1996, 1997 and MacGregor 1996). Pharmacists have utilised patient medication records in community pharmacies or medical records in GP practices as useful sources to identify patients, enabling assessment of prescribed and OTC analgesia in the light of patients' concurrent medication and their awareness and understanding of therapy, after which interventions were made to optimise efficacy of treatment (Briggs *et al* 1996, 1997).

Data demonstrating improved outcomes in chronic pain control in patients after pharmacist involvement in the primary care setting is limited. However, the present study has shown that patients with chronic pain can benefit from pharmaceutical intervention to maximise the efficacy of drug regimes, reduce the risk of potential adverse effects and to make appropriate referrals to GPs and other members of the health care team.



Pharmacists in primary care need to be proactive if the outcomes of patients with chronic pain are to be maximised. Analgesics are the most widely used non-prescription medicines, yet their use can often be inappropriate and potentially dangerous (Whitaker *et al* 1995). The elderly must be monitored closely, since they are a high-risk group in terms of analgesic use. This patient group is most likely to overuse analgesics (Whitaker *et al* 1995), is at greater risk of adverse drug reactions (O'Malley *et al* 1971), usually buys any OTC analgesics from a pharmacy but is less likely to ask for advice (Whitaker *et al* 1995).

Most patients with chronic pain have benefited from management by a multidisciplinary team, based in hospital, which includes a pharmacist (Hardy and Hill 1990, Snell 1993). However, the majority of such patients are managed in primary care most frequently by their GPs who may not have such expertise in chronic pain management. Evidence of chronic pain clinics or an established chronic pain team in the community is limited, but a pharmacist-led clinic for neuropathic pain has been recently established (MacGregor 1996). A recent study has suggested that pharmacist involvement in the prescribing of analgesics is much needed and is a role requested by pharmacists themselves (Briggs *et al* 1997).

The present attitudes of GPs, pharmacists and other members of the health care team to the developing roles of pharmacists need to be considered to encourage inter-professional communication, minimise duplication of services and enhance seamless care provision (Begley *et al* 1994). Previous studies have demonstrated that GPs and other health professionals are in favour of pharmacists' developing domicilliary services to encourage review of medication in high-risk patient groups and to provide appropriate drug information (Dixon *et al* 1995, Weir *et al* 1997). However, Begley *et al* (1994) found that although a large percentage of pharmacists were willing after training to provide domiciliary management of pain as a speciality, young GPs and nurses generally did not support this extended role for pharmacists.

## 8.2 Objectives

The objectives of this part of the study were:

1. To determine the current clinical activities of community pharmacists and the extent of their clinical interaction with GPs.
2. To evaluate general practitioners' and physiotherapists' experiences of pharmacists' contribution to patient care especially in chronic pain management.
3. To determine the views of community pharmacists, general practitioners and physiotherapists on the type(s) of patient, disease and management factors which can influence the management of chronic pain.
4. To evaluate the attitudes of community pharmacists, general practitioners and physiotherapists towards the development of chronic pain teams and the responders' perceived role(s), if any, for the pharmacist within such a team.
5. To identify the quantity, type of drug and disease state information requested by patients during domiciliary visits and to investigate the pharmacist's response to information requested.

### **8.3 Methods**

Postal questionnaires incorporating attitude statements as described in Chapter 2 Sections 2.2.1 and 2.2.2, were developed in November 1995. The questionnaires were first piloted on 5 general practitioners, 5 community pharmacists and 5 physiotherapists working in an area outwith the research areas between December 1995 and January 1996 as described in Chapter 2 Section 2.2.3. Feedback from the pilot group revealed that completion of the questionnaire took an average of 5.5 minutes to complete and also resulted in 2 of the original statements being removed from the final questionnaire due to their being ambiguous or leading. Slight modifications to the wording and layout of the questionnaires were made as described in Chapter 2 Section 2.2.3.

100 GP practices, 100 community pharmacies and 50 physiotherapy work bases were randomly selected in Aberdeen and Lanarkshire as described in Chapter 2 Section 2.2.4. Only one practitioner was identified from each of the selected surgeries, pharmacies or physiotherapy sites. A revised questionnaire was then sent to each selected practitioner (see Appendices 11, 12 and 13 respectively),

accompanied by a covering letter (Appendix 10) as described in Chapter 2 Section 2.2.5.

Initially, 60 out of 100 GP practices, 57 out of 100 community pharmacies and 30 out of 50 community physiotherapist bases responded. Non-responders were identified by their code numbers. Subsequent response rate improved the final response to 63 GP practices, 59 community pharmacies and 33 physiotherapy work bases.

The Kruskal-Wallis and Mann-Whitney U tests (if appropriate) were used as described in Chapter 2 Section 2.2.7.

## **8.4 Results**

### **8.4.1 Professional details of GP, community pharmacist and physiotherapist responders**

Replies were obtained from 63 out of 100 GPs (63%) who had been sent a questionnaire, 34 (54%) of whom were from fundholding practices, with an average of 6 GPs (range 2.5 - 12 GPs) per practice. The number of patients per practice reflected the number of GPs per practice (range 3,200 - 22,500).

Fifty-nine out of the 100 pharmacists (59%) who had been sent a questionnaire responded. Fifty-six (95%) of the pharmacists worked full-time and 3 pharmacists (5%) worked part-time. Forty-eight of the responders were the sole pharmacist in the pharmacy, while 10 had 1 colleague and 1 had 2 colleagues working in the pharmacy at the same time.

Replies were also obtained from 33 out of the 50 physiotherapists (66%) based in community practice who received a questionnaire. Limited access to community practice physiotherapists restricted the potential number of responders.

## **8.4.2 Responders' perceptions of present role(s) of the pharmacist in chronic pain management in primary care**

### **8.4.2.1 Current clinical activities of community pharmacists**

All community pharmacists were asked to identify the areas of clinical activity in which they were currently involved. No responder identified specific involvement in the management of chronic pain.

All pharmacists identified their traditional roles of provision of advice about prescribed medicines and over-the-counter (OTC) medicines. Ten pharmacists reported that they were currently involved in the development of treatment protocols, while 25 pharmacists identified the advising of GPs on their prescribing practices as a routine activity. Other clinical activities identified by 6 pharmacists included blood-pressure monitoring (3 pharmacists), stoma care advice (1 pharmacist) and specific nutrition advice (2 pharmacists). Therapeutic drug monitoring activities included blood cholesterol monitoring (2 pharmacists). No pharmacist reported involvement in anticoagulant monitoring.

### **8.4.2.2 Pharmacist assessment of clinical interaction with GPs**

Pharmacists were asked to provide a general estimate of the type and frequency of any clinical interventions made to GPs, to determine the extent and quality of clinical interaction between the pharmacists and their GPs (Table 8.1). Fifty-seven out of the 59 pharmacists (97%) who responded identified that they often requested information from GPs, to clarify a dosage or drug indication (39 pharmacists identified that this was a common problem on most days or at least 2 to 3 times a week). Forty out of the 50 pharmacists who did say that they proposed changes in therapy to try to improve patient outcome, did so infrequently i.e. once a month or less than monthly. Side-effect reporting to GPs was also an infrequent activity. Twelve out of the 50 pharmacists who identified that they reported drug interactions between prescribed and OTC medication did so at least 2-3 times a week.

Type of Intervention	most days	2-3 times a week	once a week	once a month	less than monthly	Total number of interventions
Request information to clarify a dosing regime or drug indication	27	12	12	2	4	57
Propose a change in therapy to improve patient outcome	0	3	7	14	26	50
Report a side effect	0	2	6	8	36	52
Inform a GP about a patient request	6	13	11	6	17	53
Report a prescribed medicine / OTC medicine drug interaction	5	7	11	8	19	50
Total number of responses	38	37	47	38	102	262

**Table 8.1:** Pharmacist estimation of type and frequency of clinical interventions (n=59)

All pharmacists communicated with their GPs by telephone, nineteen pharmacists also visited their GPs personally, five communicated by letter as a third option, while 3 pharmacists used fax machines in addition to the three previous modes of communication.

Fifty-eight of the 59 pharmacist responders (98%) described the feedback which they received from GPs. One responder did not complete this part of the questionnaire. Overall, pharmacists perceived that feedback from GPs was generally poor and sometimes non-existent. Forty pharmacists reported that the feedback which they requested from GPs indicated their recommendations were fully or mostly acted on, but eleven pharmacists said that only a few suggestions were accepted by their GPs. Seven pharmacists said that they did not know if their

suggestions were accepted or not. Comments regarding feedback from GPs were very variable (Table 8.2). Pharmacists who reported limited feedback from GPs were less likely to be currently involved in additional clinical activities ( $\chi^2 = 6.85$ ,  $df = 1$ ,  $p < 0.01$ ).

Certain GPs refuse to answer any queries.

Many GPs adopt the attitude that what they say “goes”. GPs are normally happy with your advice at the time, but the advice is ignored in future.

GPs feedback is not always prompt. Varies from genuine acceptance of advice and/or feedback to hostile resentment.

GPs, even when they do not make any changes, normally thank you for pointing it out anyway.

We do not suggest things to GPs.

Ninety percent of them do not like it. From previous experience, only some suggestions have been received positively.

Feedback from GPs especially is non-existent.

Some GPs can be quite rude about our suggestions, while other GPs are extremely happy we get involved.

**Table 8.2:** Pharmacists’ comments regarding GP feedback

**8.4.2.3 GP assessment of pharmacists’ contribution to patient care**

GPs were asked to identify if and how pharmacists were helpful to them, using a series of closed questions. Sixty-two out of the sixty-three GPs who responded (98%), identified that pharmacists were helpful. Fifty-three of the 62 (86%) recognised the pharmacist’s role as a source of medication supply and drug information to patients while 46 (74% ) and 49 (79 %) GPs respectively, identified that pharmacists were very helpful in ensuring prescription legality and supply of medication to GPs. Twenty-two GPs (36%) were finding pharmacists helpful in

encouraging patient compliance, but only nineteen and twelve GPs respectively had direct experience with pharmacists in discussing treatment options or general practice formulary development. Moreover, only six GPs had had experience or were at present gaining pharmacist input in GP practice research projects.

#### **8.4.2.4 Physiotherapist assessment of pharmacists' contribution to patient care**

No physiotherapist who responded had any direct involvement with a community pharmacist, so a physiotherapist assessment of the current role of the pharmacist could not be made.

### **8.4.3 Factors influencing chronic pain management**

#### **8.4.3.1 Factors identified by responders which may influence the management of chronic pain**

Factors identified by responders which may influence the management of chronic pain are detailed in Table 8.3. All responders completed this section.

There was a significantly greater number of GPs (31) as compared to pharmacists (17) ( $\chi^2 = 5.29$ ,  $df = 1$ ,  $p < 0.05$ ) who believed that patient expectation of pain control influenced management of chronic pain. There were no significant differences between groups with regard to the statement that poor compliance influenced management of chronic pain. Significantly more pharmacists (34) as compared to GPs (21) ( $\chi^2 = 7.26$ ,  $df = 1$ ,  $p < 0.01$ ) felt that limited access to pain specialists or pain clinics influenced patient outcome. Physiotherapists were more likely to identify that limited access to up-to-date drug information was an influencing factor as compared to either GPs ( $\chi^2 = 16.62$ ,  $df = 1$ ,  $p < 0.001$ ) or pharmacists ( $\chi^2 = 10.92$ ,  $df = 1$ ,  $p < 0.001$ ). Significantly more pharmacists (42) as compared with GPs (13) ( $\chi^2 = 29.4$ ,  $df = 1$ ,  $p < 0.001$ ) or with physiotherapists (15) ( $\chi^2 = 4.90$ ,  $df = 1$ ,  $p < 0.05$ ) identified that lack of opportunity limited chronic pain management. Pharmacists were more likely than GPs ( $\chi^2 = 15.68$ ,  $df = 1$ ,  $p < 0.001$ ) to identify lack of expertise in a multidisciplinary team as a limiting factor in pain management.

<b>Factor</b>	<b>No. of GPs who said 'Yes' (%) n = 63</b>	<b>No. of pharmacists who said 'Yes' (%) n = 59</b>	<b>No. of physiotherapists who said 'Yes' (%) n = 33</b>
<b>Patient expectation of pain control</b>	31 (49)	17 (29)	20 (61)
<b>Poor patient compliance</b>	25 (40)	19 (32)	17 (52)
<b>Poor agreement of management with patient</b>	13 (21)	5 (8)	2 (6)
<b>Limited access to pain clinics / specialists</b>	21 (33)	34 (58)	22 (67)
<b>Limited access to up to date drug information</b>	2 (3)	5 (8)	11 (33)
<b>Limited expertise in a multidisciplinary team</b>	10 (16)	28 (48)	9 (27)
<b>Excessive workload</b>	27 (43)	29 (49)	14 (42)
<b>Lack of opportunity for involvement in a multidisciplinary team</b>	13 (21)	42 (71)	15 (45)

**Table 8.3: Factors which may influence the management of chronic pain.**

#### **8.4.3.2 Attitude statement responses**

Table 8.4 summarises the responses to the attitude statements of the 154 responders, since one physiotherapist omitted to tick any of the attitude statements.

One hundred and forty-seven responders (95%) agreed or strongly agreed with the belief that compliance with a pain management strategy was better if patients understood the explanation. Moreover, almost two thirds of the study group (92, 64%) thought that the majority of patients complied with their advice (24 (73%) of physiotherapists, 40 (64%) GPs and 35 (59%) pharmacists agreed or strongly agreed). However, when asked to indicate their response to the statement 'Some



patients want to control their own pain and don't comply with your advice', the responders were more uncertain.

The majority of responders (133, 86%) recognised the negative influence of depression on pain control. Attitudes to patient perception of the pharmacist were significantly different between groups ( $\chi^2 = 27.11$ ,  $df = 2$ ,  $p < 0.001$ ). The majority of community pharmacists (41, 71%) disagreed with the belief that patients generally regarded pharmacists as shopkeepers, but 27 (84%) physiotherapists agreed with the statement. Although 25 (40%) GPs disagreed with this statement, 20 (32%) agreed with the statement and 18 (29%) were uncertain.

Attitudes to treatment plans and guidelines were encouraging. However, there were significant differences between groups concerning the statement 'a treatment plan should be agreed by a multidisciplinary team' ( $\chi^2 = 15.75$ ,  $df = 2$ ,  $p < 0.001$ ). The statement about treatment guidelines disguises the fact that GPs as a group were least in agreement with this statement and were more uncertain than the other two groups in the benefits of treatment guidelines. Only 36 (57%) GPs agreed with this statement, as compared to 45 (76%) pharmacists and 24 (75%) for physiotherapists, but there was no statistical difference between groups ( $\chi^2 = 5.46$ ,  $df = 2$ ,  $p > 0.1$ ).

These attitudes to guidelines were reflected in the results obtained when GPs and physiotherapists were asked about their actual use of treatment guidelines. Treatment guidelines were used by 14 of the 63 GPs (22%), while 17 of the 33 (52%) physiotherapists used guidelines. GPs claimed to use the British National Formulary as a useful source while all 17 physiotherapists, who reported that they used guidelines, only used specific physiotherapy protocols.

<b>Statement</b>	<b>No. of responders who strongly agree/ agree (%)</b>	<b>No. of uncertain responders (%)</b>	<b>No. of responders who strongly disagree/ disagree (%)</b>
<b>Most patients comply with your advice</b>	99 ( 64)	37 (24)	18 (12)
<b>Patient compliance is increased if patients understand you explanation</b>	147 (95)	6 (4)	1 (1)
<b>Some patients want to control their own pain and don't comply with your advice</b>	92 ( 60)	42 (27)	20 (13)
<b>A patient with chronic pain exaggerates the pain which he / she feels</b>	35 (23)	66 (43)	53 (34)
<b>Patients generally view pharmacists as shopkeepers</b>	56 (36)	29 (19)	69 (45)
<b>More patients are self- medicating to improve control of chronic pain</b>	79 (51)	52 (34)	23 (15)
<b>Patients with chronic pain who are depressed often have poor pain control</b>	133 (86)	20 (13)	1 (1)
<b>Patients with chronic pain usually know very little about the management options for chronic pain</b>	108 (70)	31 (20)	15 (10)
<b>A treatment plan for the control of chronic pain should be agreed by a multidisciplinary care team</b>	89 (58)	49 (32)	16 (10)
<b>Treatment guidelines improve cost-effective prescribing</b>	105 (68)	37 (24)	12 (8)

**Table 8.4: Summary of responses by 154 responders to all attitude statements**

#### **8.4.4 Responders' perceptions of future role(s) of the pharmacist in chronic pain management in primary care**

##### **8.4.4.1 Responders' attitude to a multidisciplinary team approach to the management of chronic pain**

Attitudes to multidisciplinary care teams were encouraging. Overall, 89 (58%) responders agreed that treatment plans should be agreed by a multidisciplinary team. However GPs as a group were less positive about the merits of a multidisciplinary approach to pain control.

These attitudes were reflected in the results obtained when GPs and physiotherapists were asked about their involvement in multidisciplinary care teams for chronic pain. Only seventeen of the GPs had a multidisciplinary team already established for the management of chronic pain at the time of study. The composition of the teams, as documented by the GP and physiotherapist responders, varied considerably with a nurse being the most frequently cited team member (14) after the GP (17), while pharmacists and physiotherapists were only involved in 2 and 4 of these GP-led teams respectively. Two of the study physiotherapists were currently involved in a multidisciplinary care team, but other team members in each group were limited to a GP and a clinical psychologist.

None of the pharmacists were involved in a multidisciplinary team themselves at the time of the study. When pharmacists were asked who they thought should be involved in the chronic pain team, 57 out of the 59 responders suggested a GP, 44 suggested a pharmacist and 32 a physiotherapist. Ten responders suggested an anaesthetist, 19 an occupational therapist and 9 recognised the need for a nurse in the team. A patient or representative was suggested by 4 responders as an additional member of the team.

Lack of money (14 responders), interest (17), time (31) and expertise (20) were reasons commonly given by GPs and physiotherapists for not establishing multidisciplinary care for patients with chronic pain. Twelve GPs suggested that there was a lack of need, either due to perceived lack of evidence of benefit (8) or adequate resources at present (4). Four GPs said that a chronic pain team had never been thought of within their practice, while 3 stated that it was not a high priority.

#### **8.4.4.2. Responders' perceptions of the future roles of the pharmacist in chronic pain management**

All of the GPs and physiotherapists stated that pharmacists had a role to play in a multidisciplinary approach to managing patients with chronic pain. Thirty-five GPs (56%) and 21 physiotherapists (64%) recognised a dispensing role for pharmacists, 46 GPs (73%) and 29 physiotherapists (88%) identified the important role in provision of specific drug information to patients and 38 GPs (60%) and 25 physiotherapists (76%) believed that pharmacists should be involved in medication review.

Other responders (8 GPs, 12 physiotherapists) suggested that pharmacists should be involved in drug history taking within a chronic pain clinic. Two physiotherapists and three GPs identified a need for pharmacists not only to act as facilitators to improve multidisciplinary care but also to actively educate health care professionals in the potential contributions which pharmacists can make to improve patient care. Two GPs requested more information from pharmacists regarding the clinical significance of drug interactions associated with chronic pain management. Three GPs suggested that pharmacists should be advising GPs more on substitution of prescribed medicines for pain with over-the-counter products where appropriate.

Fifty-eight out of the 59 pharmacist responders (98%) identified that they wanted to develop their role in chronic pain management, but only thirty-three pharmacists (56%) were keen to become actively involved in pain clinics. Forty-eight and 26 pharmacists respectively wanted to develop patient information services regarding OTC products and prescribed medication for chronic pain management.

#### **8.4.5 The role of the pharmacist as a provider of appropriate drug information to patients**

##### **8.4.5.1 Information requested by patients during domiciliary visits**

A summary of the information requested by patients during domiciliary visits by the study pharmacist is tabulated in Table 8.5.

Table 8.5 shows that 35 different queries were made by 36 of the 96 study patients (38%) resulting in a total of 62 queries, the most frequent of which were about chronic pain.

The requests were made by 14 (36%) of the RA group, 11 (44%) of the group with RA and OA, 7 (32%) of the OA group and 4 (40%) of back pain patients.

The responses to these queries involved reassuring patients on 16 occasions that they were taking their medication correctly, clarifying 19 misunderstandings concerning medication, providing information to correct a potential or existing problem with medication on 14 occasions and referring 13 problems to the patients' GPs which were subsequently followed up. Reinforcement and clarification involved the pharmacist providing patients with written information to emphasise verbal recommendations.

Pain diagnosis	Chronic pain query	Side effect query	Drug info query	Other disease state query	Total no. of different problems	Total no. of patients	Total no. of queries
	No. of queries	No. of queries	No. of queries	No. of queries	No. of queries		
RA	3	1	5	1	10	14	18
RA and OA	3	6	5	0	14	11	26
OA	3	1	1	2	7	7	12
Back pain	3	1	0	0	4	4	6
Total no. of types of queries	12	9	11	3	35	36	62

Table 8.5: Types and frequencies of information requested by patients during domiciliary visits

## **8.5 Discussion**

### **8.5.1 Factors encouraging the development of the pharmacist's role in the management of chronic pain**

Analysis of the results from the questionnaire suggests that there are positive factors to encourage the development of the pharmacist's role in chronic pain management. These are the motivation of pharmacists to develop their role in primary care, current evidence of practice development and a common appreciation and agreement of the current and potential roles of pharmacists by GPs, physiotherapists and community pharmacists. Favourable relationships between GPs and pharmacists and a general enthusiasm to develop multidisciplinary teams to manage chronic pain in the community are also encouraging findings.

An assessment of the study pharmacists' current and potential clinical activities suggests that all pharmacists recognised their roles in the provision of advice concerning both prescribed and non-prescribed medicines and were motivated to develop them. These roles need to be defined and developed (Royal Pharmaceutical Society of Great Britain 1995, Hassell *et al* 1996).

The fact that 98% of pharmacists wanted to develop their role in pain management was encouraging, even although no pharmacist identified his / her involvement in the management of chronic pain at the time of the study. No specific questions were asked to assess the number and frequency of pharmacist interventions / advice to patients and GPs which related to chronic pain management, hence this perceived lack of involvement may be an underestimate of activity. The pharmacists in this study were keen to develop other strategies to improve pain management, especially drug information provision for both OTC and prescribed therapies for pain. Protocols must be developed to ensure that this provision of advice is appropriate, consistent and accurate for optimisation of patient care and the development of the pharmacist's role in chronic pain.

The questionnaire study demonstrated that communication between GPs and pharmacists, although not extensive and related largely to clarification of prescription information, was generally a positive influence on pharmacist role development. Although 50 pharmacists said that they recommended changes in therapy, only 10 pharmacists discussed therapy changes with their GPs at least weekly. Over 50% of the pharmacists reported that the incidence of drug interactions and patient requests which they discussed with GPs was only about one a month. This low reporting rate may be a true incidence of the number of clinically significant problems requiring intervention with a GP, but under-reporting due to lack of pharmacist awareness of a potential problem and / or poor documentation may be precipitating factors (Rogers *et al* 1994).

The finding that all three groups of health care professionals in the study strongly identified with the pharmacists' role as a provider of relevant drug information (pharmacists 81%, GPs 73% and physiotherapists 88%) is a motivating factor towards development of a pharmacist's advisory role. General practitioners have previously defended the development of this role of pharmacists in the areas of rational prescribing and formulary development (Hughes and McFerran 1995). The fact that physiotherapists in this study had no direct experience of pharmacists' contribution to the care of their patients within their workplace, might be partly explained by their lack of accessibility to pharmacists. The majority of physiotherapists were based within GP practices, while the pharmacists were largely based in community pharmacies not attached to a health centre. However, despite their lack of experience working with community pharmacists, they were very positive about the potential roles of pharmacists in the drug management of chronic pain.

The physiotherapists in our study may have had direct clinical contact with hospital pharmacists during their training, which, after qualification, may have influenced their perception of the pharmacist's potential role in the community. It was unclear as to the reason why physiotherapists were more likely than the other groups to identify lack of drug information as a limiting factor to control of pain. The result may reflect physiotherapists' need to gain more relevant analgesic drug knowledge (Stewart *et al* 1995). This finding further validates the need for community pharmacists to establish links with community physiotherapists to identify their drug information needs. Pharmacists have been shown to provide

useful drug information to help physiotherapists appreciate the influence of analgesic therapy on their patient management strategies (Stewart *et al* 1995).

The interest of pharmacists in domiciliary visiting and development of treatment protocols for chronic pain and the multidisciplinary support for pharmacists to undertake medication review in this study may reflect the developing roles of pharmacists in GP surgeries (Mason 1996).

The large number of unprompted patient requests made during patient interviews and the pharmacist interventions made thereafter support the argument that pharmacists need to be readily available and accessible to patients in a location convenient to patients to optimise pharmaceutical care. Thirty-eight of the patients' requests were unrelated to chronic pain management, demonstrating the need for pharmacists to be aware of current therapeutic management strategies for all relatively common chronic disease states and to make appropriate recommendations and interventions.

The finding that 13 unprompted patient queries actually required follow-up with the relevant prescriber is significant, since the problems may not have been detected until symptoms and / or signs prompted the patient to refer them to his / her GP. Pharmacists thus need to be vigilant and utilise good open questioning, listening and other communication skills.

Attitudes to multidisciplinary team management of chronic pain in this study were encouraging. Although only 17 of the GPs had a team at the time of study, and pharmacists were only involved in 2 teams, the majority of responders agreed or strongly agreed that a treatment plan should be agreed by a multidisciplinary team. The findings that pharmacists were more likely to identify limited access to pain specialists or pain clinics and lack of opportunity of pharmacist involvement as limiting factors to optimise pain control confirms the study group's enthusiasm to develop the role in a specified environment within a multidisciplinary team. Chronic pain clinics led by pharmacists but facilitated by GPs and other health care team members are now being developed within a general practice environment (MacGregor 1996).

The attitudes of the study groups to treatment guidelines for chronic pain management were variable and reflected their reported usage. Treatment guidelines were used by only 14 (22%) of the GPs involved in this study, while at least 50% of



physiotherapists utilised them. Patients with chronic back pain problems are often referred to physiotherapists who utilise well-validated exercise strategies for the effective control of pain (DiMaggio and Mooney 1987). Pharmacists must be aware of the importance of appropriate exercise and the limitations of pharmacological therapy in back pain management (Clinical Standards Advisory Group 1994).

### **8.5.2 Factors limiting the development of the pharmacist's role in the management of chronic pain**

The results from the questionnaire study suggest that limited experience and skills of the study pharmacists, limited co-operation by GPs and varying attitudes of health care team members regarding chronic pain management and multidisciplinary team involvement, may limit the development of the pharmacist's role in the management of chronic pain.

Significantly more pharmacists as compared to GPs identified lack of appropriate skills as a factor preventing development of their role. This finding may suggest that pharmacists are becoming increasingly aware of the specific training needs required to develop advisory roles in clinical practice such as reporting of adverse drug reactions (Whittlesea and Walker 1996, Whittlesea *et al* 1995) and interpersonal skills (Hassell *et al* 1996). The latter is critical especially if pharmacist involvement in multidisciplinary teams is to develop, as this research would suggest. Community pharmacists need to be competent in the skills involved with adverse drug reporting, in order to fulfil this developing role, especially with respect to OTC products (CSM 1997) and potentially generic products (Whittlesea and Walker 1996). If physicians perceive that pharmacists do not have the required skills, then role development of pharmacists will not be encouraged by other health care professionals (Begley *et al* 1994).

A lack of feedback from GPs may be another factor contributing to the low intervention rates by pharmacists. Pharmacists who were not currently involved in additional clinical activities with their GPs were significantly more likely to have received limited feedback regarding the outcome of an intervention. The latter result suggests that good collaboration and communication between GPs and pharmacists is necessary to encourage mutual respect and development of roles in the primary

care team. However, clinical service development was not influenced by pharmacist perception of GP feedback, which suggests that other factors are of greater significance in service development. Recently, researchers have identified additional workload and lack of financial remuneration as deterrents to service progression (Bond *et al* 1997).

Differences in attitudes to the development and roles of multidisciplinary teams may limit pharmacists' role development. GPs as a group were less positive about multidisciplinary management of a patient with chronic pain, which may reflect a fear that a treatment plan agreed by a team may confuse or jeopardise the patient-doctor relationship. Specification of defined roles and responsibilities of each team member should alleviate such fears and optimise patient management (Hardy and Hill 1990).

Pharmacists need to be aware of the varying attitudes of other health care professionals towards chronic pain management if their involvement in a pain team is to be valued. Too high patient expectation was identified as a limiting factor in pain control by significantly more GPs than pharmacists or physiotherapists. This finding may reflect the environment in which GPs consult, such that within a 10 minute clinic appointment, patients have limited time to discuss their expectations of treatment, which can result in patients' non-compliance with treatment and a lack of concordance about a treatment strategy established between patient and prescriber (Donovan *et al* 1989). Alternatively, this finding may reflect the prescribing behaviour of GPs, since a recent study demonstrated that GPs' opinions of patients' expectations regarding medication influenced GPs' prescribing practices (Cockburn and Pit 1997).

Pharmacists were less likely to identify too high patient expectation as a limiting factor, perhaps reflecting poorer probing skills and / or lack of awareness of potential patient non-concordance with medication in chronic disease (Donovan and Blake 1992).

Lack of perceived benefit of a chronic pain team in the community may be a limiting factor to pharmacist involvement. The professional and financial viability of a pharmacist working within the team must be evaluated carefully by each pharmacist in consultation with his / her local GPs, pharmacists and other health care professionals.

Physical resources such as the number of pharmacists working in a pharmacy at one time was not found to influence the type of clinical services provided. However, the sample size here was relatively small so the results may not be a true reflection of practice. Indeed, lack of resources, time and expertise were perceived to be more common reasons for lack of development of a pain team in this study, rather than lack of need.

The finding that GPs were less in agreement with the benefits of treatment guidelines in terms of cost-effectiveness, may reflect the GPs' personal experience of treatment guidelines actually increasing costs to the practice. Pharmacists need to be proactive in treatment guideline development and delivery where appropriate, as demonstrated in pharmacist-led neuropathic pain clinics, yet aware of the limitations of treatment guidelines and roles of the rest of the chronic pain team (MacGregor1996).

## **Chapter 9**

### **General discussion**

Previous work investigating the role of the pharmacist in the management of chronic non-malignant pain in primary care focused largely on prescribed and OTC analgesic drug usage (Dixon *et al* 1995, Briggs *et al* 1996) or the influence of therapy on patient satisfaction (Long and Wynne 1996), with little reference to the effect on health outcomes. Dixon and colleagues only examined chronic compound analgesic usage using a domiciliary model to identify patients' medication knowledge rather than assessing pain management as a whole, whereas Briggs and colleagues assessed the need for pharmaceutical intervention and the risk of drug interactions between purchased and prescribed analgesics in community pharmacies. Both the latter studies were small and uncontrolled. The present study, although uncontrolled, aimed to investigate the potential for the pharmacist to improve health outcomes by assessing the effect of pharmaceutical intervention on pain control and activities of life.

This study shows the need for pharmacists to undertake different types of activity such as prescribing advice, advice to patients and measurement of health outcomes.

The study has identified that community pharmacists have a role in the provision of advice to GPs to encourage rational prescribing in chronic pain management especially with regard to NSAID prescribing, gastrointestinal prophylaxis and DMARD prescribing. In this study, primary care guidelines for chronic pain management were followed in only 41 (43%) of the 96 study patients.

The incidence of NSAID prescribing in the study's OA patients was high in relation to those who had symptomatic inflammation, which has also been found by other researchers (Dieppe *et al* 1993(B)). Hawker (1997) suggests that such inappropriate NSAID prescribing will continue to increase as life expectancy increases and thus the incidence of degenerative osteoarthritis will increase, with a

correspondingly increased risk of NSAID toxicity. Indeed, as a result of NSAID use, some OA study patients were placed at risk of side effects as demonstrated in case studies 6 and 7.

Community pharmacists are well placed to assist in the development of treatment protocols for the use of NSAIDs in OA patients and to recommend simple analgesics with or without a rubefacient as initial drug therapy if inflammation is not present. If inflammation is present, the community pharmacist could recommend short-term topical NSAID therapy e.g. ibuprofen in preference to oral therapy.

Where NSAID use was appropriate, gastrointestinal prophylaxis was inappropriate in 12 patients in terms of drug choice and / or daily dosage prescribed of prophylactic therapy and non-existent in 8 other patients who fulfilled the necessary criteria. Moreover the study did not identify whether any of the study patients were *H-pylori* positive, recently identified as a potential risk factor in NSAID-induced gastrointestinal damage (Chan *et al* 1997). Community pharmacists could help to identify patients who had risk factors for the development of NSAID-induced gastrointestinal ulceration and so encourage rational prescribing.

This study was carried out just as initial research evidence encouraged early DMARD use in RA (Fries *et al* 1993). However, the use of DMARDs in patients with early onset RA or mild disease was limited in this study. Methotrexate, in particular, was not prescribed despite its increasing recognition as the DMARD of choice in Europe and the USA (Akil and Amos 1995(A), Cash and Klippel 1994). If the benefits of DMARDs on long-term health outcomes are to be elucidated, all RA patients must be commenced on early DMARD therapy, where appropriate, considering relevant drug, disease and patient factors to minimise toxicity and maximise efficacy. Community pharmacists are well placed to identify a patient presenting with inflammatory symptoms or signs and symptoms of chronic pain and to refer the patient appropriately to his / her GP. Ideally, more GPs should be encouraged to become specialists in rheumatology in primary care to encourage quick and accurate diagnosis and early DMARD treatment where appropriate.

The results in Chapter 8 and the recent findings of Weir *et al* (1997), have demonstrated that GPs have identified a need for such advice from pharmacists, recognising pharmacists' roles in the provision of specific drug information to

patients and individual patient medication review. The results from this study demonstrate that the pharmacist can provide pharmaceutical care for patients with chronic pain in terms of rationalisation of medication and improvement in pain relief.

The results have demonstrated that there is also a need for patient-centred activities. Chewning and Sleath (1996) discussed the need for a client-centred medication review, where patients should be encouraged to make their own decisions regarding treatment choices, frequency and the best times at which they should take their medication. Their own attitudes to medicines and management of their disease should be considered and outcomes fed back to their doctor to encourage patient concordance with therapy. In this study, patients' attitude to medicines and management including attitude to prescriber as described in Chapter 3, were all important factors influencing the extent of patient concordance. The community pharmacist could act as a facilitator in this review process, since he / she does not 'own' the prescription. If decisions are not jointly agreed during a consultation between a doctor and patient, the patient-doctor relationship and final outcome of the consultation can be negatively influenced (Blaxter and Britten 1997). Community pharmacists should be responsible for ensuring that what the patient agrees to do is actually carried out and is involved in monitoring the outcome in terms of pharmaceutical care.

These patient-centred activities need to follow a validated framework of activity before any analysis of their influence on health outcomes can be assessed. In Scotland, national guidelines providing standards for pharmaceutical care are in place for hospital practice (Clinical Resource and Audit Group 1996). New guidelines have yet to be produced to develop a framework for primary care practice.

The information and advice provided by the pharmacist and that requested in this study suggest that patients with chronic pain are a high needs group in terms of drug and disease state information. The case studies in Chapters 4, 5, 6 and 7 demonstrated that clarification and reinforcement of drug information was often needed, especially since such patients were often on multiple therapy with high risk of toxicity, had multiple chronic disease states and were taking concomitant OTC analgesics / alternative therapy.

The importance of an appreciation of patients' perceptions of their disease states and treatment is illustrated by the results particularly of the patients with back pain.

Although the group was small and perhaps not representative of the general back pain population, it did produce some interesting findings. Combination analgesics and NSAIDs were largely prescribed for this group, despite guidelines from the Clinical Standards Advisory Group 1994 suggesting that simple analgesics should be used first line with NSAIDs only used short-term, where symptomatic inflammation is present. All 7 patients with back pain took less than the prescribed maximum daily dosage of their analgesic(s) largely due to fear of side effects e.g. drowsiness rather than describing feeling doped and constipation. The results in Chapter 4 suggest that patients with back pain suffered more pain than patients with other chronic pain states, yet were unwilling to agree with therapy recommendations and did not perceive the benefit of exercise.

Moreover, these patients with back pain reported most of the highest psychological dimension scores in Chapter 5, which may reflect the large amount of psychological distress particularly associated with chronic back pain, a lack of coping strategies or separate psychological problems.

These results suggest that this group of patients have significant needs which are not being fully addressed. Further study regarding not only the pharmaceutical needs but other health care needs of this group should be undertaken, using a larger sample size to identify if the results of this study represent those of the general chronic back pain population. The community pharmacy may be the first port of call for such patients seeking help. Community pharmacists must be able to identify the specific psychological and physical problems of such patients and refer them appropriately to specific health care personnel, depending on specific patients' health care needs. The views of the health care professionals as discussed in Chapter 8 indeed reflect the perception that the community pharmacist is a valuable source of drug information for not only patients but other health care professionals.

The study has shown that there is a need for pharmacists to obtain information about patients in order to undertake medication review effectively. Drug history taking as part of the medication review process in this study was identified as a

major source of information which should be used by the pharmacist to elicit an accurate history of patients' medicine-taking behaviour, although patient medical records and pharmacy medication records can also be used as sources of information. In this study, pharmacy medication records were not used, but have been shown to be useful tools in the identification of potential medicine management problems (Rogers *et al* 1994). However, the large number of discrepancies between medical records and information obtained from patients, as demonstrated in Chapters 3 and 6, indicates that the former are not reliable. Beech and Brackley (1996) found similar problems when undertaking medication review of a small number of patients with multiple disease and medication problems. The discrepancies reported in Chapter 8 by pharmacists further support the finding that pharmacists need accurate information about patients' therapy to undertake medication review.

Community pharmacists could deliver a medication review service for patients with chronic pain within their community pharmacy as demonstrated by Rogers *et al* 1994. However, the extent of patient assessment, in-depth patient discussion and patient confidentiality required within the community pharmacy for a medication review may well be limited by lack of pharmacist availability and / or skills and time. Other limiting factors might include lack of patient presence (a carer e.g. relative or home-help may be collecting the prescription), limited privacy and lack of and accessibility to patient and medical information.

The problems of skills training, manpower, remuneration and accessibility to patients and their medical records need to be addressed quickly to facilitate the development of pharmaceutical care of patients with chronic pain. A process of pharmaceutical needs assessment is essential to enable services to be provided to those patients who need them, rather than those who demand them (Krska 1998). This study has adequately demonstrated a need for improved pharmaceutical services to patients with chronic pain.

A high percentage of the study patients believed they should control their pain yet only 25% of patients were actually using OTC or alternative therapy and the majority of patients took less than the prescribed daily dosage of analgesic. These findings suggest that the study patients were prepared to tolerate pain, use only



medication which was prescribed and / or adopt alternative coping strategies. Although the study's results cannot be directly extrapolated to the general population, the results would suggest that pharmacists need to be especially proactive when providing pharmaceutical care, especially the provision of pharmaceutical information to patients with chronic pain to optimise pain relief. Indeed, Donovan and Blake 1992, interviewed patients with rheumatoid arthritis prior to and following hospital consultations and found that patients with chronic pain were often deliberately non-compliant and developed their own pain management strategies, depending on their own lay beliefs, experiences and information obtained from pharmacists and other health care professionals.

The results suggest that domiciliary visiting is an appropriate means by which health outcomes can be assessed and patient problems identified in an environment which is most convenient to patients, and not just a means of medication review as described by earlier researchers (Beech and Brackley 1996). The unprompted requests made by patients, as described in Chapter 7, after the pharmacist had discussed their present and past use of drug therapy, suggest that patients may have gained a better appreciation and acceptance of the pharmacist's role as the interviews proceeded.

Domiciliary assessment of chronic pain in the community has demonstrated problems in terms of patient accessibility and consent to participate, appropriate skills training of the study pharmacist, time required to prepare for, undertake and intervene after a domiciliary medication review and the variable uptake of pharmacist's recommendations by GPs. These problems have been identified in earlier studies (Beech and Brackley 1996), using similar patient numbers and methodology. In this study, it was however, unanticipated that a number of patients would not want to participate after the first interview, despite the full support of the research pharmacist's activities by all the patients' GPs. Such a finding suggests that these patients preferred being in control of their own pain and may have had limited beliefs or awareness of what the pharmacist could do to help improve outcomes. Although a number of patients with poor outcomes could not be interviewed on a second occasion due to unanticipated deterioration in their overall condition, the

number of patients who had a second interview was sufficient to demonstrate a statistical difference in pain scores.

In this study, a longer study time and an improved communication strategy with patients may have improved the extent of initial patient uptake and continued commitment of patients who required a second interview.

Another problem identified using this model was the lack of documentation. The limited documentation of biochemical and haematological parameters and discrepancies in this study reinforces the need for accurate, regularly updated and easily available records to enable health care professionals such as GPs and community pharmacists to make informed decisions about the cost-effectiveness of therapy (Clinical Resource and Audit Group 1996).

The finding that documentation of relevant biochemical and haematological parameters for all patients on DMARDs was very limited suggests that patients on DMARDs in this study group are at risk of serious toxicities and that GPs may be reluctant to monitor therapy initiated in secondary care. Locally agreed protocols regarding monitoring schedules must be agreed by consultant rheumatologists and GPs to optimise patient outcome and minimise toxicity (Medicines Resource Centre 1996). As community pharmacists develop their skills in adverse drug reporting, they will be ideally placed to play a role in the effective monitoring of DMARD therapy in the community (Committee on Safety of Medicines 1997), a role already developed by hospital pharmacists (Kay 1997). Indeed, it was encouraging to find in Chapter 8, that pharmacists were already involved in the development of treatment protocols and therapeutic monitoring before any directives from the Royal Pharmaceutical Society (1995) or Scottish Office Department of Health (1996(A) and (B)) were publicised.

If such a domiciliary model is to be extended to community pharmacy practice, then community pharmacists should restrict this domiciliary service for example, to those patients with chronic pain who are housebound and / or elderly, a proposal recently endorsed by the Royal College of Physicians (1997). Such a service could be identified as a local priority to optimise the pharmaceutical care of patients with chronic pain within the pharmacist's local health care co-operatives (LHCCs).

Measurement of health outcomes and the recording of these parameters would improve patient care, reinforcing the need for valid and sensitive health measures. The measurement of health outcomes provides an objective means of monitoring patient's progress over time. A disease-specific measure, the McGill Pain Questionnaire, MPQ, was able to detect small changes in pain intensity and quality whereas the generic QOL scale provided much broader measures of health related quality of life by assessing the influence of pain on physical, social, occupational and psychological dimensions. The use of a disease-specific measure combined with a generic measure has been recommended by McDowell and Newell 1996.

Small sample size and relatively short duration time of the study limit extrapolation of the study's health outcome data. The large variability in MPQ, VAS and QOL scores both within and between patient groups demonstrates the need to identify each patient's baseline scores when their chronic pain is relatively stable. This baseline data would encourage a truer evaluation of the significance of changes in pain control and quality of life in patients after a therapeutic intervention. Larger groups of patients are also needed to be able to extrapolate the results to the general chronic pain population in the community. Sources of variation such as current medication and medical problems were not controlled in this study.

The study only looked at outcomes within a relatively short time span of 4 to 6 weeks after a change in therapy or management was made or recommended and may have underestimated the chronic pain or quality of life experienced by patients. Some patients, particularly those with rheumatoid arthritis, may have been experiencing a time of remission and improved pain control during time of first interview, yet experienced acute flare-ups over other times of the year. Moreover, no washout period was considered when patients were changed from one DMARD to another, thus the contribution of specific DMARDs to pain control in some patients cannot be determined. Further work needs to be carried out over a much longer period of time e.g. 4 to 6 months, to assess the chronicity of patients' pain and the impact of treatment changes on pain control and health related quality of life.

In this study there was no assessment of any changes in pain or QOL scores in patients with satisfactory outcomes on medication review. Such analysis should be included if an estimate of the smallest clinically significant score difference is to be made (Guyatt *et al* 1987).

The results of Chapter 5 demonstrate the continued difficulty in assessing quality of life when no gold standard tool for QOL assessment has yet been agreed and the limitations in using only part of a validated QOL scale.

Correlation coefficients were used in this study as an assessment of reliability. Although the QOL questionnaire was found to have a high internal consistency and there were good correlations between pain outcome measures and QOL measures overall, alternative methods of assessing reliability could have been more appropriate. Correlation coefficients may not reflect some types of mismatch between scores such that replicated measurements may be systematically different yet highly correlated (Bland and Altman 1986). A more appropriate measure of reproducibility may be the intraclass correlation coefficient (ICC) (Deyo *et al* 1991), which not only assesses the strength of the correlation, but also whether the slope and intercept vary from those expected when measures are repeated.

The results in Chapter 4 as compared to those in Chapter 5 suggest that the MPQ was the most valid and reliable of the two tools used in this study. The good correlations between pain rating index, number of word descriptors and visual analogue scale scores at Interviews 1 and 2 suggest that the MPQ can be used by pharmacists to investigate the influence of a therapeutic intervention. The MPQ has previously only been used in a clinical setting within a hospital environment, not within a community setting as used in this study. The consistency in choice of subclass by patients suggests that patients in the study could define the quality of their pain well, differing more in intensity over time. However, the poor sensitivity of the PPI parameter suggests that pain intensity only partially reflects an individual's pain experience.

Although Melzack (1975) found that the MPQ was capable of discriminating among different pain syndromes, individual patient responses were not related to pain diagnosis in this study. This finding may be partly explained by the relatively smaller sample size as compared to Melzack's study in 1975, lack of consistency of use of pain language by patients and the difficulties in classification of patients into specific pain syndromes. The choice of scores used by the researcher can also influence the outcome (McDowell and Newell 1996). It must also be noted that the MPQ may not reflect Melzack's original pain theory. Since each word within a

subclass reflects both pain type and intensity, studies in factorial analysis of the MPQ may extract pain intensity factors, pain type factors or both (Leavitt *et al* 1978).

Despite the MPQ's limitations, a checklist for community pharmacists' use could be devised based on the MPQ to identify and assess the progress of patients with chronic pain. However, the time taken to carry out the MPQ (15 to 20 minutes in new patients) may be a limiting factor towards its general usability in community practice. The short-form MPQ (Melzack 1987), which takes 5 to 10 minutes to administer, is reliable, the scores of which correlate well with corresponding scores of the standard MPQ. This revised tool may be an alternative option for community use, having been shown to be sufficiently sensitive to demonstrate similar statistically significant differences in pain scores due to treatment compared with the standard MPQ. The short-form MPQ was not evaluated in this study, nor has it been extensively used in community settings.

Consideration of the results and the QOL tool's limitations in reliability, validity and sensitivity, as previously discussed in Chapter 5, would suggest that the study's QOL tool may not be able to accurately assess quality of life after pharmaceutical intervention. The small sample size, lack of control group and lack of assessment of fluctuations of QOL in stable patients also limit the scale's sensitivity. In addition, while the QOL outcome measures used were evaluated for reliability and validity, only 14 statements out of the 50 statements originally validated by Williams *et al* (1993) were used in this study. Further work would need to be done using the same questionnaire on a much larger patient sample and assessing any differences between self-administered and assessor-led questionnaires, to identify any elements of bias and to investigate test-retest reliability. The responsiveness of the study's QOL measures would also need to be compared with established validated QOL instruments, such as AIMS (Meenan *et al* 1980).

Despite the limitations of the QOL scale, the tool did discriminate between those patients who had satisfactory outcomes and those who had poor outcomes. Patients who had satisfactory outcomes had significantly lower QOL scores as compared to patients with poor outcomes, suggesting that the tool did help to identify those patients who were most in need of improvement in QOL. The results

in Chapter 5 suggest that patients had adopted various coping strategies to maintain quality of life irrespective of pain intensity.

Ideally, an established disease-specific functional scale with proven reliability and validity should have been used to assess the impact of chronic pain on activities of daily living such as the Medical Outcomes Study Pain Measures (MOS) (Sherbourne 1992). The MOS covers pain severity in terms of pain intensity, frequency and duration of pain and records the impact of pain on patient behaviour and moods, which is useful for measuring functional outcomes. Although experience with this measure was very limited at the time of this study, McDowell and Newell (1996) suggest that it is suitable for surveys or for clinical settings when the goal is to assess the impact of pain on daily living rather than to provide a detailed assessment of the nature of the pain. Community pharmacists could use this tool to identify those patients whose chronic pain has significantly influenced their quality of life.

Generic measures have been criticised in that they impose the choice of domains and attached values on the patient, which may not be considered to be most important (Ruta *et al* 1994). They have described a truly valid measure of health outcome as one which measured the effect of medical conditions on those aspects of life considered by patients to be most important, was reliable and responded to change over time. In addition, the measure needed to allow patients to rate the extent to which those aspects of life were affected and was adaptable, simple and brief. This resulted in the patient generated index (PGI) (Ruta *et al* 1994). Comparisons of PGI scores with the generic SF-36 and a validated clinical back pain questionnaire in 359 patients with low back pain, have demonstrated correlations with SF-36 domains of bodily pain, social functioning, role limitation due to physical problems and the back pain questionnaire (Ruta *et al* 1994). However, recent work has suggested that outcomes using PGI tools need to be interpreted with caution (Tully and Cantrill 1998), since patients may be prompted to describe areas of life which are described as examples in a PGI, rather than thinking of their own specific situation.

A similar measure, the 'measure yourself medical outcome profile' (MYMOP) has been described by Paterson (1996) and compared with the SF-36 in a sample of 365 patients in primary care. Results suggest that the MYMOP is more sensitive in

detecting changes in acute rather than chronic conditions, so its use may be limited in chronic pain. However, further work needs to be performed by pharmacists, especially community pharmacists or pharmacists working in the community, to investigate the reliability of PGI measures as assessment tools of health related quality of life.

However, as this study has shown, pharmacists are often working single-handed in community practice and have limited opportunities to fully assess patients' needs. Patients may falsely report compliance or may request help indirectly through family or carers, resulting in sub-optimal appreciation by the pharmacist of patient outcomes (Hassell *et al* 1996). Communication between pharmacists and GPs in terms of personal relationships and reliable, extensive computer links need to be developed to improve understanding of each other's professional agendas, prescribing behaviours and information needs to optimise patient care.

Financial resources need to be more readily available to encourage pharmacists to develop their skills in medication review of patients with chronic pain, the assessment of pain and its influence on their quality of life and in information provision to both patients and other members of the health care team. As professional links between practices and such skilled pharmacists develop, patients will be able to appreciate more readily the contribution which pharmacists can make in a chronic pain team in primary care.

No pharmacist identified his / her involvement in the management of chronic pain at the time of the study, which suggests a lack of chronic pain management experience, although this may have been interpreted as meaning pharmacist involvement in a specific pain clinic. Indeed, appropriate training from and a structured information exchange network with other pharmacists and other health care professionals already involved in chronic pain management, in both primary and secondary care, should encourage pharmacists to become more involved in chronic pain management (Kay 1997). This strategy may involve training of community pharmacists by relevant members of the hospital chronic pain team or rheumatology team in pain management and seamless care strategies.

The findings of Chapters 7 and 8 are encouraging. Health care team members were found to both identify and appreciate the current and potential roles of the pharmacist in the management of chronic pain. The appropriate provision of drug information to both patients and other members of the healthcare team and the development of treatment protocols were well-appreciated roles which could be developed within a multidisciplinary team environment.

The study's findings promote the extension of the role of the pharmacist in chronic pain from a pharmacist-led clinic for the management of patients with a specific type of chronic pain e.g. neuropathic (MacGregor 1996) to a domiciliary or community pharmacy based pharmaceutical management of other types of chronic pain such as arthritis and back pain. Indeed recent studies in asthma and anticoagulation have demonstrated the benefits of pharmacist-led clinics in primary care in terms of improved inter-professional co-operation, communication and patient care (Kennedy *et al* 1994, MacGregor *et al* 1996).

There are difficulties in measuring the impact of the pharmacist on chronic pain, although the inclusion of a control group would have been of benefit. The use of such a control group would have helped to define more specifically the impact of pharmaceutical intervention on the management of chronic pain. The conclusions drawn from the study would have been more generalisable for the chronic pain population studied. However, creation of a matched control group for this study would be very difficult due to the multidimensional aspects of chronic pain itself and patients' multiple disease states and multiple drug therapy. In addition, the fact that the same pharmacist intervened and monitored the outcome may have biased the results. However, there was a clear willingness to involve pharmacists in the management of chronic pain both by GPs and physiotherapists, which will facilitate future developments. The extent of chronic pain in the community (50% of the population), (Smith 1998, verbal communication), suggests that there is a large, currently unmet need for such involvement. However, the inherent chronicity, variability and multidimensional aspects of chronic pain as perceived by patients would still render an analysis of the influence of medication change and advice provision on chronic pain difficult.



Selection of patients who were taking analgesics regularly or those with documented RA, involved the assumption that those who were not taking treatment were not suffering from chronic pain. This study may have underestimated the population who were suffering from chronic pain at the time of the study. Howie *et al* (1994), using random sample groups of 200 patients in Grampian and Tayside who had either shoulder, back, hip or neck pain identified that only about 50% of patients were prescribed analgesic therapy. Recent reports suggest that 2500 (50%) of a patient population within 29 Grampian GP practices suffered chronic pain and expressed a high need for analgesic therapy and GP consultation.

An element of recall bias in terms of reported side effects and concordance with therapy may also have been present in the study. The presence of the study pharmacist in the patients' homes may have encouraged patients to report more adverse drug reactions and side effects. In addition, patients may have been genuinely inaccurate in their recall of drug information. Indeed, open and closed questions on drug use within the pain questionnaire did highlight within-patient discrepancies. Verbal reports were difficult to validate especially when documentation in patients' case notes regarding current OTC and prescribed medications, adverse drug reactions and monitoring was so limited.

Despite these limitations, the study has shown both a need and a demand for pharmaceutical input into the management of chronic pain in the community. The value of using outcome measures to determine the impact of such input has yet to be fully determined.

## **9.1 Recommendations for the role of the community pharmacist in chronic pain**

- 9.1.1** Involvement in the development of treatment protocols for the management of rheumatoid arthritis, osteoarthritis and back pain with GPs, nurses, physiotherapists and other members of the primary health care team involved in chronic pain management
- 9.1.2** Greater involvement in the review of repeat prescribing of analgesics (combination analgesics and NSAIDs) and disease modifying agents
- Regular review with local GPs of NSAID use e.g. types of patient, types of NSAID, appropriate GI prophylaxis
  - Provision of appropriate information to patients and health professionals regarding the appropriate use of topical NSAIDS and combination analgesics and OTC analgesia
  - Facilitation of or direct involvement in DMARD monitoring by developing seamless care strategies with the secondary care health team
- 9.1.3** Development of domiciliary-based medication review involving the monitoring of patient outcomes, especially the efficacy and toxicity of disease modifying agents
- 9.1.4** More extensive and consistent provision of specific drug information to patients with chronic pain including the development of a specific pain information service within community pharmacies concerning the rational use of and side effects associated with prescribed and OTC medications used for chronic pain
- 9.1.5** Development of a formalised referral network for pharmacists to refer patients to relevant members of the primary care chronic pain team to optimise outcomes
- 9.1.6** Development of a checklist for use by pharmacists incorporating MPQ and MOS Pain Outcome indicators to aid in the assessment of chronic pain

- 9.1.7** Increase involvement of patients in the primary care chronic pain team to encourage patient awareness of the importance of concordance with a pain management strategy and timely and accurate feedback to the primary health care pain team
- 9.1.8** Development of a realistic remuneration system to encourage community pharmacists to participate in medication review of patients with chronic pain. The system would need to be sufficiently flexible to consider in particular, the pressures of limited resources especially time and manpower available to deliver such a service at the present time

## **Chapter 10**

### **Conclusion**

The study suggests that the role of the pharmacist in the management of chronic pain in the community is a challenging one. This research has demonstrated not only the many pharmaceutical care needs of patients with chronic pain irrespective of pain relief obtained, but also the practical and patient-specific problems associated with domiciliary medication review.

The study has identified that GP prescribing in the management of chronic pain in the community needs to be improved. Evidence based practices need to be implemented after which further research should be carried out to identify the benefits of pharmaceutical input in these practices. As primary care trusts (PCTs) of local health care co-operatives (LHCCs) in Scotland develop, some PCTs may identify the need to improve the management of chronic pain in primary care within their own local population and to commission a local chronic pain team of at least 1 GP, a consultant rheumatologist, a pharmacist, a nurse, an occupational therapist, a social worker, a clinical psychologist and possibly an osteopath depending on the type of chronic pain identified in the population.

The study identified that the majority of patients with chronic pain made their own decisions regarding treatment choices, frequency and administration times of their prescribed medication such that documented medication records rarely reflected patient concordance with therapy. There is a need for improved documentation of and accessibility to medical records, better communication between primary and secondary health care professionals and between patients and health care professionals. Further research needs to be carried out to identify the most efficient methods of documentation and dissemination of such outcomes to both patient and all health care personnel involved in each patient's care.

The study also identified that more work needs to be carried out on the use of health outcome tools by pharmacists before they can be confidently used to assess the influence of pharmaceutical input on health outcomes such as quality of life. Further research using multi-centred studies should be undertaken to assess the applicability of existing pain measures such as the MPQ as tools to help identify pharmaceutical care needs of patients with chronic pain in domiciliary or community pharmacy environments.

The study also identified both a need for pharmacists and a demand from pharmacists to develop their role in the management of chronic pain. Training needs of both hospital and community pharmacists may be extensive e.g. principles and practices of domiciliary medication review and medicines management in community pharmacies, documentation of care plans, monitoring of outcomes and communication skills. There is a need for further research using control groups to investigate the benefits of specific training schemes on pharmaceutical care outcomes.

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## **Appendix 1: Letter from GPs confirming approval of research**

Strathaven Health Centre  
The Ward  
Strathaven  
Lanarkshire  
ML10 6AS

Dr Janet Krska  
Lecturer in Clinical Pharmacy  
School of Pharmacy  
The Robert Gordon University  
Schoolhill  
Aberdeen AB9 1FR

Dear Dr Krska

I confirm, on behalf of Strathaven Health Centre practice, that we are willing to act as a collaborating establishment for the research study by Miss Rhona Park into the evaluation of the use and efficacy of analgesics in the management of chronic pain in the community.

We are also willing to give permission for Miss Rhona Park to access appropriate medical notes and to interview selected patients in their homes. A suitable work area in the practice will also be provided for the period of the study.

Yours sincerely

Dr Carol Campbell

**Appendix 2: Letter of consent from the Joint Ethical Committee of  
the Grampian Health Board and University of Aberdeen**

Clerk to the Committee:  
Mr Sandy Reid  
Headquarters Administration  
Grampian Health Board  
Summerfield House  
2 Eday Road  
Aberdeen AB9 1RE

1 April 1993

Ms Rhona Park  
Lecturer / Practitioner  
School of Pharmacy  
The Robert Gordon University  
Schoolhill  
Aberdeen AB9 1FR

Dear Ms Park

**An investigation into the use and efficacy of analgesics in the management of  
chronic pain in the community**

The above project was considered at the Joint Ethical meeting on 25 March 1993. I am pleased to confirm that ethical approval for this project has now been granted.

With regards to medical indemnity, I enclose a form which should be completed and returned to either: (1) Dr J Hern, Clinical Director, Aberdeen Royal Hospitals NHS Trust, Foresterhill House, Ashgrove Road West, Aberdeen, (2) Dr R Scorgie, Medical Director, Grampian Healthcare NHS Trust, Westholme, Woodend Hospital, Aberdeen or (3) Clinical Director, Moray Health Services NHS Trust, 317 High Street, Elgin, as appropriate if you wish one of the above Trusts to accept liability for medical indemnity for this project.

I also enclose a standard Joint Ethical Committee proforma for future use.

Thank you for bringing this study to the Committee's attention.

Yours sincerely

S Reid  
Clerk to the Committee

**Appendix 3: Letter of consent from Lanarkshire Health Board  
Ethics of Research Committee**

Lanarkshire Health Board  
14 Beckford Street  
Hamilton  
Lanarkshire  
ML3 0TA  
10 October 1994

Ms Rhona Park  
Lecturer / Practitioner  
School of Pharmacy  
The Robert Gordon University  
Schoolhill  
Aberdeen AB9 1FR

Dear Ms Park

An investigation into the use and efficacy of analgesics in the management of chronic pain in the community

I refer to the above study which was submitted to the Ethics of Research Committee for consideration.

Following discussion with the Chairman of the Committee, I can confirm that as the study is a multi-centre trial and it has been given approval by the Joint Ethical Committee of Grampian Health Board and the University of Aberdeen, Lanarkshire Health Board's Ethics of Research Committee has also approved the study.

If you require any further information, please do not hesitate to contact me.

Yours sincerely

Mrs J Grant  
Assistant Secretary

**Appendix 4: Monitoring schedules for commonly used DMARDs  
and Immunosuppressants (Medicines Resource Centre 1996)**

<b>Drug</b>	<b>Full blood count</b>	<b>Renal Function</b>	<b>Proteinuria</b>
<b>Sodium aurothiomalate</b>	Before each injection	Before starting treatment	Before each injection
<b>Auranofin</b>	Before starting treatment, then at least every month	Before starting treatment	Before starting treatment, then at least every month
<b>Penicillamine</b>	Before starting treatment, weekly or fortnightly for first 8 weeks and in week after any dose increase. Every month thereafter	Before starting treatment.	Before starting treatment, then weekly for first 8 weeks and in week after any dose increase. Every month thereafter
<b>Antimalarials</b>			
<b>Azathioprine</b>	Weekly for first 8 weeks, at least every 3 months thereafter		
<b>Cyclosporin</b>		At least twice before starting treatment, then every 2 weeks for first 3 months. Monthly thereafter	
<b>Methotrexate</b>	Before starting treatment. Every 1-2 weeks for 6-8 weeks or until dose stable. Every month thereafter.	Before starting treatment. Annually thereafter	
<b>Sulphasalazine</b>	Before starting treatment, then every month for first 3 months. Every 3 months thereafter	Before starting treatment	

<b>Drug</b>	<b>Liver Function</b>	<b>Other</b>
<b>Sodium aurothiomalate</b>	Before starting treatment	
<b>Auranofin</b>	Before starting treatment	
<b>Penicillamine</b>		
<b>Antimalarials</b>		Eye examination at baseline. Data sheets advise 3-6 monthly follow-up examination
<b>Azathioprine</b>	Monitor regularly e.g. at same time as full blood count	
<b>Cyclosporin</b>	Monitor regularly if co-administering with NSAIDs	Monitor blood pressure
<b>Methotrexate</b>	Before starting treatment. Every 2-4 months during treatment	
<b>Sulphasalazine</b>	Before starting treatment, then every month for first 3 months. Every 3 months thereafter	

Blood count = Haemoglobin, differential white cell count and platelets.  
Renal function = Urea, electrolytes and creatinine  
Liver function = alkaline phosphatase, gamma-glutamyl transferase and aspartate (or alanine) transferase.

## **Appendix 5: Information leaflet sent to patients providing details of the project**

### **A survey of analgesic use in the treatment of chronic pain in the community**

#### **Patient Information Leaflet**

People take painkillers prescribed by their doctors for many different reasons. We aim to find out how well your painkillers work for you and if there are ways to help you get better results from them.

To do this, we need people who take painkillers to volunteer to take part in our study.

This will involve one or two interviews (about 30 minutes each) asking you questions about:

- the type of painkillers you take
- how often you take them
- how you feel about your treatment
- any side effects you may have noticed

If we think that you may not be getting the best from your painkillers, your doctor and I will try to improve things. I will then come back to see you again to find out if they are working any better.

Please don't worry.

All information collected will be treated in the strictest confidence. There is no need for you to take part in the study if you don't want to. You can pull out at any time and there will be no effect on your future medical care.

But it would be wonderful if you could help us.

If you would like to help, please fill in the form giving your permission, which is attached. I will contact you again in a few days, to find out whether you do want to join the study.

Thank you for your time. I look forward to meeting you, if you decide to volunteer.

Rhona Park  
School of Pharmacy  
The Robert Gordon University

## **Appendix 6: Patient consent form for assessment of analgesic use and efficacy**

**Name of Patient:** \_\_\_\_\_

**Principal Investigator:** Rhona W. Park

I have read the Patient Information Leaflet on the above study and have had the opportunity to discuss the details with Rhona Park and to ask questions.

I understand that these questions are part of a research project to encourage better use of painkillers which has been approved by the Joint Ethical Committee.

I also understand that my General Practitioner has agreed that I can participate in the study and that the study will not affect my continuing medical treatment in any way.

I have agreed to take part in the study as it has been described to me, but I understand that I am completely free to withdraw from the study or any part of the study at any time if I wish.

I hereby fully and freely consent to participate in the study which has been fully explained to me.

**Signature of Patient:** \_\_\_\_\_ **Date:** \_\_\_\_\_

I confirm that I have explained to the patient named above, the nature and the purpose of the questionnaires which will be used in the study.

**Signature of Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Appendix 7: Data Collection Form

Patient number \_\_\_\_\_

Address \_\_\_\_\_

Telephone Number \_\_\_\_\_

Sex                      Male    = 1  
                             Female = 2                      \_\_\_\_\_

Occupation \_\_\_\_\_  
(if not working previous occupation)

Marital status        Single    =     1  
                             Married   =     2  
                             Divorced =     3  
                             Widowed =    4  
                             Separated =   5                      \_\_\_\_\_

Occupation of Spouse \_\_\_\_\_

Name of Doctor \_\_\_\_\_

Education            Left school at 16 years        = 1  
                             Completed school               = 2  
                             College/ University experience = 3  
                             Other                                = 4                      \_\_\_\_\_

Pain Diagnosis        1= RA  
                             2= OA  
                             3= Back Pain  
                             4 = RA and OA                      \_\_\_\_\_

Concomitant disease states  
                             \_\_\_\_\_  
                             \_\_\_\_\_



Previous medical/ surgical history

Date	Previous medical history	Date	Previous surgical history

Prescribed analgesics and co-analgesics

Name	Formulation	Dose and Frequency	Route	Date of initial prescription

Documented OTC analgesia

Name	Formulation	Dose and Frequency	Route	Date of initial prescription

Present programme of treatment (other than drug therapy)

Type of therapy	Yes / No	Details of therapy
Physiotherapy		
Occupational therapy		
Surgery		
Psychological support		
Other		

Previous programme(s) of treatment used (other than drug therapy)

Type of therapy	Yes / No	Details of therapy	Date of therapy
Physiotherapy			
Occupational therapy			
Surgery			
Psychological support			
Other			

Previous alternative drug therapy used for chronic pain

Name of alternative therapy	Formulation	Dose and Frequency	Route	Date of initial prescription

Details of other prescribed medication

Name	Formulation	Dose and Frequency	Route	Date of initial prescription

Social history: \_\_\_\_\_

Relevant Biochemistry

Haematological Data		Biochemistry		Other data	
Date		Date		Date	

**Appendix 8: Pain Questionnaire**

**ID Number:** \_\_\_\_\_

**Date of interview:** \_\_\_\_\_

**Time:** \_\_\_\_\_

**Pain Diagnosis:** \_\_\_\_\_

*Assessment of Pain*

*McGill Pain Questionnaire (Melzack 1975)*

## McGill Pain Questionnaire

Patient's Name \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_ am/pm

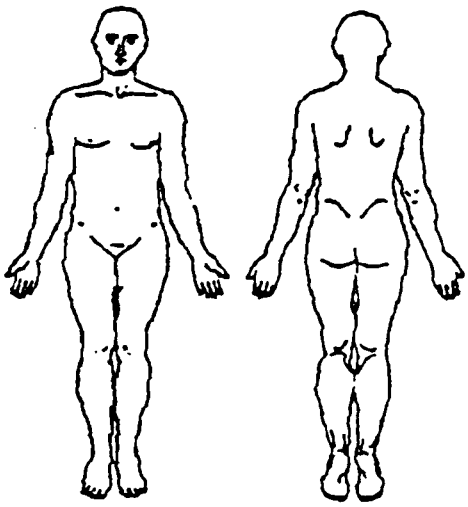
PRI: S \_\_\_\_\_ A \_\_\_\_\_ E \_\_\_\_\_ M \_\_\_\_\_ PRI(T) \_\_\_\_\_ PPI \_\_\_\_\_  
           (1-10)           (11-15)           (16)           (17-20)           (1-20)

<p>1 FLICKERING QUIVERING PULSING THROBBING BEATING POUNING</p> <p>2 JUMPING FLASHING SHOOTING</p> <p>3 PRICKING BORING DRILLING STABBING LANCINATING</p> <p>4 SHARP CUTTING LACERATING</p> <p>5 PINCHING PRESSING GNAWING CRAMPING CRUSHING</p> <p>6 TUGGING PULLING WRENCHING</p> <p>7 HOT BURNING SCALDING SEARING</p> <p>8 TINGLING ITCHY SMARTING STINGING</p> <p>9 DULL SORE HURTING ACHING HEAVY</p> <p>10 TENDER TAUT RASPING SPLITTING</p>	<p>11 TIING EXHAUSTING</p> <p>12 SICKENING SUFFOCATING</p> <p>13 FEARFUL FRIGHTFUL TERRIFYING</p> <p>14 PUNISHING GRUELLING CRUEL VICIOUS KILLING</p> <p>15 WRETCHED BLINDING</p> <p>16 ANNOYING TROUBLESOME MISERABLE INTENSE UNBEARABLE</p> <p>17 SPREADING RADIATING PENETRATING PIERCING</p> <p>18 TIGHT NUMB DRAWING SQUEEZING TEARING</p> <p>19 COOL COLD FREEZING</p> <p>20 NAGGING NAUSEATING AGONIZING DREADFUL TORTURING</p> <p style="text-align: center;">PPI</p> <p>0 NO PAIN 1 MILD 2 DISCOMFORTING 3 DISTRESSING 4 HORRIBLE 5 EXCRUCIATING</p>
---	---

BRIEF  
MOMENTARY  
TRANSIENT

RHYTHMIC  
PERIODIC  
INTERMITTENT

CONTINUOUS  
STEADY  
CONSTANT



E = EXTERNAL  
I = INTERNAL

COMMENTS:

*Visual analogue scales – see Appendix 9*

For the following questions, please indicate whether you **STRONGLY AGREE**, **AGREE**, are **UNCERTAIN**, **DISAGREE** or **STRONGLY DISAGREE** with each statement.

Please circle the box containing your choice

2. Doctors know what is right for their patients

<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
---------------------------	--------------	------------------	-----------------	------------------------------

3. Most patients benefit from taking painkillers for pain

<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
---------------------------	--------------	------------------	-----------------	------------------------------

4. Taking medicines like painkillers is unnatural

<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
---------------------------	--------------	------------------	-----------------	------------------------------

5. Medicines prescribed by your doctor are safe to take

<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
---------------------------	--------------	------------------	-----------------	------------------------------

6. Patients should try to control their own pain

<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
---------------------------	--------------	------------------	-----------------	------------------------------

7. Painkillers help you cope with normal life

<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
---------------------------	--------------	------------------	-----------------	------------------------------

8. Taking painkillers for a long time can cause side effects

<div>Strongly agree</div>	<div>Agree</div>	<div>Uncertain</div>	<div>Disagree</div>	<div>Strongly disagree</div>
-------------------------------	------------------	----------------------	---------------------	----------------------------------

Indicate how much the statements listed below apply to you over the past 4 weeks, using the scale below.

Not a lot	A little	A fair amount	A lot	Very much indeed
0	1	2	3	4

9.

I have difficult in walking
10.

I have difficulty doing household chores
11.

I have difficulty sleeping
12.

I find food unappealing
13.

I frequently feel anxious
14.

I frequently feel depressed / upset
15.

I frequently feel lonely
16.

I frequently feel frustrated
17.

My enjoyment of life is not what it was
18.

I do not have enough activities to fill the day
19.

I would like to get out of the house more
20.

I find friends / relatives have difficulty in talking to me  
about my pain
21.

I have difficulty in planning activities because of my pain
22.

My pain has greatly affected my work

23. What do you think is the cause of your pain?

24. How effective do you think a pain treatment should be in relieving pain?  
*(Mark a point on each of the scales below which you feel best describes the amount of relief a painkiller should provide)*

**No relief**      0    10    20    30    40    50    60    70    80    90    100% **Complete pain relief**

1. Provide complete relief
2. Relieve pain as much as possible
3. Relieve pain enough to cope with daily activities
4. Relieve pain enough to sleep
5. Other \_\_\_\_\_

25. What treatment are you receiving from your doctor for your pain?

26. Do you use this treatment / medicine regularly or just when you feel that you need it?

## Medicine / Treatment

**Regular = 1 / As required = 2**

27. Do you always take the number of tablets/ capsules / volume of syrup etc. per day that your doctor has prescribed? (for each treatment)

Yes / No

## If 'No', is it a higher dose you take?

## If 'No', is it a lower dose you take?

### Reasons for change in dose:

28. Have you ever felt that you needed a dose much higher than the prescribed dose of painkiller? Yes / No

Yes / No

If 'Yes', reasons why:

29. Have you ever forgotten to take your medicine or run out of it before you could get more?

Yes / No

If 'Yes', what happened?

30. When do you take your medicine prescribed by your doctor? (in relation to food / time of day?)

31. When you collect your medicine from the chemist, do you ever get an information leaflet?

Yes / No

If 'Yes', did you read it?

Yes / No

If 'Yes', how useful did you find it in providing information?

32. Do you buy any medicines from your chemist to help pain relief, as well as your prescribed medicines?

Yes / No

If 'Yes', please specify

If 'Yes', how often do you use this medicine?

33. Do you buy any medicines from your chemist to help pain relief, instead of your prescribed medicines?

Yes / No



If 'Yes', please specify

If 'Yes', how often do you use this medicine?

34. Do you buy any alternative therapies e.g. herbal or homeopathic, to treat your pain?

Yes / No

If 'Yes', please specify

If 'Yes', how often do you use this medicine?

35. How much relief do your pain treatments and / or medications provide?  
(Mark on the scales below how much relief you do receive)

No relief      0    10    20    30    40    50    60    70    80    90    100%    Complete pain relief

- 1. Provide complete relief
- 2. Relieve pain as much as possible
- 3. Relieve pain enough top cope with daily activities
- 4. Relieve pain enough to sleep
- 5. Other \_\_\_\_\_

36. Have you ever experienced any problems which you think could be due to your medicine?

*For questions 37-40, please circle your most appropriate answer*

37. People can be addicted to painkillers      Yes / No / Don't know

38. Persistent pain can make you feel depressed      Yes / No / Don't know

39.

Exercise can relieve chronic pain

Yes / No / Don't know
40.

Pain can continue after healing has taken place

Yes / No / Don't know

41.

Are there any other methods of treatment which you would like to find out about to help your pain control?

Yes / No

If 'Yes', please specify

42.

How satisfied are you with your pain control?

<b>Completely</b>	<b>Very</b>	<b>Moderately</b>	<b>Dissatisfied</b>	<b>Very dissatisfied</b>
1	2	3	4	5

**Appendix 9: Visual analogue scales used to assess pain intensity**

**Pain intensity**

1.Please rate your pain by placing a mark on the line at a point which represents your pain at its WORST in the last month (VAS worst)

---

No Pain

Pain as bad as you can imagine

2. Please rate your pain by placing a mark on the line at a point which represents your pain on AVERAGE (VAS average)

---

No Pain

Pain as bad as you can imagine

3.Please rate your pain by placing a mark on the line at a point which represents your pain RIGHT NOW (VAS now)

---

No Pain

Pain as bad as you can imagine

**Appendix 10: Copy of the letter sent to each study pharmacist, GP  
and physiotherapist to assess the role(s) of the healthcare team in  
chronic pain management**

School of Pharmacy  
Faculty of Health and Food  
Schoolhill  
Aberdeen  
AB9 1FR

24 January 1996

Dear Colleague,

I am currently investigating the role of the pharmacist in the management of chronic pain in the community, as part of my research into the management of chronic pain.

Over the last two years, I have been working with GPs in Lanarkshire and Aberdeen, investigating GP management and patient perception of chronic pain. Patients with chronic pain were interviewed in their own homes after I obtained details of concomitant medical problems and relevant drug therapy details from medical notes.

Twenty-eight of the 96 patients had poor pain control and / or quality of life. Recommendations were made to GPs concerning therapy changes in 14 patients, 12 of which were acted on, after which pain control improved in nine patients. The GPs involved in the study, appreciated the pharmaceutical contribution to patient care, especially in the provision of drug information to patients.

I am very interested to find out your views, regarding the present and potential clinical roles of pharmacists in the community, particularly with respect to the management of chronic pain. All information which you will provide will be kept strictly confidential.

I would be grateful if you would complete the enclosed questionnaire and send it to me, in the stamped-addressed envelope provided, by 29 February 1996.

I look forward to receiving your questionnaire. Thank you very much for your time and effort.

Yours sincerely

Rhona W Read  
Teacher- Practitioner

**Appendix 11: Questionnaire sent to community pharmacists to assess the role(s) of the healthcare team in chronic pain management**

**Section A      Personal Information**

In which year did you register as a pharmacist ? \_\_\_\_\_

Do you work as a community pharmacist

full time	<input type="checkbox"/>
as a locum	<input type="checkbox"/>
part time	<input type="checkbox"/>

If part time, do you have other employment as a

hospital pharmacist	<input type="checkbox"/>
academic pharmacist	<input type="checkbox"/>

How many pharmacists work in your pharmacy at any one time? \_\_\_\_\_

**Section B      Your Pharmacy's Current Clinical Activities**

**Please indicate by a tick which of the following services your pharmacy provides:**

Advice on prescribed medicines <input type="checkbox"/>	Advice on OTC medicines <input type="checkbox"/>	Advice to GPs about prescribing <input type="checkbox"/>
Development of treatment protocols <input type="checkbox"/>	Anticoagulant monitoring <input type="checkbox"/>	Involvement in an asthma clinic <input type="checkbox"/>
Therapeutic drug monitoring <input type="checkbox"/>	Involvement in a pain clinic <input type="checkbox"/>	Other (please specify) _____

**Please indicate, by ticking, how often you contact a GP to :**

	most days	2-3 times a week	once a week	once a month	less than monthly
Clarify a dosing regime or drug indication					
Propose a change in therapy to improve patient outcome					
Report a side effect experienced by a patient					

<b>Inform GP about a patient's request</b>					
<b>Report a drug interaction between prescribed and / or OTC medications</b>					

**How do you usually contact a GP about patients' prescribed medicines?**  
(please tick any method which you have used)

telephone ☐      personal visit to surgery ☐      letter ☐      fax ☐

**How many of your suggestions have been received?**

always ignored ☐      acted on a few ☐      acted on most ☐  
acted on all ☐      don't know whether action taken ☐

**Please add any other comments you may have about GP's responses.**

## **Section C      Increasing Your Pharmacy's Clinical Activities**

**Please tick any of the factors listed below which you feel are preventing you from developing your role in the management of chronic pain**

Patient expectation of pain control	<input type="checkbox"/>	Limited access to up-to-date drug information	<input type="checkbox"/>
Poor patient compliance	<input type="checkbox"/>	Limited expertise in a multidisciplinary care team	<input type="checkbox"/>
Poor agreement with patient regarding pain management	<input type="checkbox"/>	Excessive workload	<input type="checkbox"/>
Limited access to pain clinics and / or pain specialists	<input type="checkbox"/>	Limited opportunity to get involved in a multidisciplinary care team	<input type="checkbox"/>

**Which, if any, of the following mechanisms of improving the treatment of patients with chronic pain, would you consider staff in your pharmacy could use?**

Advising patients on their prescribed medicines in the pharmacy ☐

Advising individual patients about OTC or other means of relieving pain ☐

- Advising individual patients about their use of medicines in their own homes ☐
- Contributing to treatment protocols devised by local GPs ☐

**Please indicate by a tick in which of the following areas of pharmaceutical care you would like to be more involved?**

- Inhaler counselling and asthma advice ☐ Drug management of chronic pain ☐
- Involvement in an anticoagulant clinic ☐ Patient compliance ☐
- Nutrition ☐ Other (please specify) ☐

## **Section D Your views on the management of chronic pain**

**Who do you think should be involved in the management of chronic pain?  
(Please tick as appropriate)**

GP ☐ Anaesthetist ☐ Pharmacist ☐ Clinical Psychologist ☐  
Physiotherapist ☐ Occupational Therapist ☐ Other \_\_\_\_\_

For the following questions, please indicate by a tick whether you **STRONGLY AGREE, AGREE, are UNCERTAIN, DISAGREE or STRONGLY DISAGREE** with each statement below.

**Most patients comply with your advice**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patient compliance is increased if patients understand your explanation**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Some patients want to control their own pain and don't comply with your advice**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**A patient with chronic pain exaggerates the pain which he/ she feels**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patients generally view pharmacists as shopkeepers, not part of the health care team**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**More patients are self-medicating to improve control of chronic pain**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patients with chronic pain who are depressed often have poor pain control**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patients with chronic pain usually know very little about the management options for chronic pain**

Strongly agree ☐    Agree ☐            Uncertain ☐            Disagree ☐    Strongly disagree ☐

**A treatment plan for the control of chronic pain, should be agreed upon by a multidisciplinary care team**

Strongly agree ☐    Agree ☐            Uncertain ☐            Disagree ☐    Strongly disagree ☐

**Treatment guidelines improve cost-effective prescribing**

Strongly agree ☐    Agree ☐            Uncertain ☐            Disagree ☐    Strongly disagree ☐

**Thank you for completing this questionnaire**



## **Appendix 12: Questionnaire sent to GPs to assess the role(s) of the healthcare team in chronic pain management**

### **Section A      Personal Information**

How many GPs, in total, work in your practice at any one time? (Please specify number)

\_\_\_\_\_

How many patients are registered in your practice? (Please specify number)

\_\_\_\_\_

Is your practice fundholding?

Yes ☐

No ☐

### **Section B      Management of Chronic Pain**

**Please tick any of the factors listed below which you feel are preventing you from optimising control of chronic pain**

Patient expectation of pain control ☐

Limited access to up-to-date drug information ☐

Poor patient compliance ☐

Limited expertise in a multidisciplinary care team ☐

Poor agreement with patient regarding pain management ☐

Excessive workload ☐

Limited access to pain clinics and / or pain specialists ☐ Limited opportunity to get involved in a multidisciplinary care team ☐

**How often do you refer patients to a pain clinic?**

Never ☐

Occasionally ☐

Frequently ☐

**Do you use treatment guidelines for the management of chronic pain within your practice?**

Yes ☐

No ☐

**If 'Yes', which guidelines do you use?**

British National Formulary guidelines ☐ Pain clinic guidelines ☐  
Local treatment protocol within your practice ☐ Other (please specify)

**Do you have a multidisciplinary team involved in pain control within your practice?**

Yes ☐ No ☐

**If 'Yes', who is involved in your team? (please tick as appropriate)**

GP ☐ Anaesthetist ☐ Pharmacist ☐ Clinical Psychologist ☐  
Physiotherapist ☐

Occupational Therapist ☐ Other \_\_\_\_\_

**If 'No', why is there no team involvement in the control of chronic pain? (please tick the most appropriate)**

Lack of expertise ☐ Lack of interest ☐ Lack of money ☐

No time to create a team ☐ Other \_\_\_\_\_

## **Section C The Role of the Pharmacist**

**What role(s) , if any, would a pharmacist have in a multidisciplinary team? (Please select the most appropriate descriptor(s))**

Dispensing of medication ☐ No role ☐

Provision of drug information to patients ☐ Drug history taking in a clinic session ☐

Reviewing medication ☐ Other \_\_\_\_\_

**Please tick any of the professional situations below, in which you have found a pharmacist helpful**

Ensuring the legality of a prescription ☐ Discussion of treatment options ☐

Supplying of medication for GP use ☐ Development of GP formulary guidelines ☐

Supply of medication or information  
☐ to patients

Practice research projects  
☐

Methods to improve compliance  
☐

## Section D      Your views on the management of chronic pain

For the following questions, please indicate by a tick whether you **STRONGLY AGREE**, **AGREE**, are **UNCERTAIN**, **DISAGREE** or **STRONGLY DISAGREE** with each statement below.

**Most patients comply with your advice**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree    ☐            Strongly disagree ☐

**Patient compliance is increased if patients understand your explanation**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree    ☐            Strongly disagree ☐

**Some patients want to control their own pain and don't comply with your advice**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree    ☐            Strongly disagree ☐

**A patient with chronic pain exaggerates the pain which he/ she feels**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree    ☐            Strongly disagree ☐

**Patients generally view pharmacists as shopkeepers, not part of the health care team**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree    ☐            Strongly disagree ☐

**More patients are self-medicating to improve control of chronic pain**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree    ☐            Strongly disagree ☐

**Patients with chronic pain who are depressed often have poor pain control**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree    ☐            Strongly disagree ☐

**Patients with chronic pain usually know very little about the management options for chronic pain**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree ☐    Strongly disagree ☐

**A treatment plan for the control of chronic pain, should be agreed upon by a multidisciplinary care team**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree ☐    Strongly disagree ☐

**Treatment guidelines improve cost-effective prescribing**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree ☐    Strongly disagree ☐

**Thank you for completing this questionnaire**

**Appendix 13: Questionnaire sent to physiotherapists to assess the role(s) of the healthcare team in chronic pain management**

**Section A      Personal Information**

**In which year did you register as a physiotherapist?** \_\_\_\_\_

**Do you work within a GP practice?** Yes ☐ No ☐

**If ‘Yes’, how many GPs are in your practice?** \_\_\_\_\_

**Is your GP practice within a health centre?** Yes ☐ No ☐

**What is your major source of employment?**

Hospital Trust ☐ (please state division) \_\_\_\_\_

Employed by a GP practice ☐

Other \_\_\_\_\_

**Section B      Management of Chronic Pain**

**Please tick any of the factors listed below which you feel are preventing you from optimising control of chronic pain**

Patient expectation of pain control	<input type="checkbox"/>	Limited access to up-to-date drug information	<input type="checkbox"/>
Poor patient compliance	<input type="checkbox"/>	Limited expertise in a multidisciplinary care team	<input type="checkbox"/>
Poor agreement with patient regarding pain management	<input type="checkbox"/>	Excessive workload	<input type="checkbox"/>
Limited access to pain clinics and / or pain specialists	<input type="checkbox"/>	Limited opportunity to get involved in a multidisciplinary care team	<input type="checkbox"/>

**Mr CF (46) is visiting his GP for the first time, having suffered from intermittent low back pain for the past 6 months. ( no significant medical or surgical history). The pain has been increasing in intensity on bending and lifting over the past 4 weeks. He has been taking regular paracetamol with little effect.**

**What management would you suggest?**

**When should Mr CF be reviewed by you after initial GP referral?**

$\leq 2$  weeks ☐  $> 2 \leq 4$  weeks ☐  $> 4 \leq 8$  weeks ☐  $> 8 \leq 12$  weeks ☐

**How often do you refer patients to a pain clinic?**

Never ☐ Occasionally ☐ Frequently ☐

**Do you use treatment protocols for the management of chronic pain?**

Yes ☐ No ☐

**If 'Yes', which protocols do you use?**

Physiotherapy protocols ☐ Pain clinic guidelines ☐

Local treatment protocol within your practice ☐ Other (please specify) \_\_\_\_\_

**Do you have a multidisciplinary team involved in pain control within your GP practice / health centre ?**

Yes ☐ No ☐

**If 'Yes', who is involved in your team? (please tick as appropriate)**

GP ☐ Anaesthetist ☐ Pharmacist ☐ Clinical Psychologist ☐

Physiotherapist ☐ Occupational Therapist ☐ Other \_\_\_\_\_

**If 'No', why is there no team involvement in the control of chronic pain?  
(Please tick the most appropriate)**

Lack of expertise ☐ Lack of interest ☐ Lack of money ☐

No time to create a team ☐ Other \_\_\_\_\_

**What role(s), if any, would a pharmacist have in a multidisciplinary team?  
(Please select the most appropriate descriptor(s))**

Dispensing of medication	<input type="checkbox"/>	No role	<input type="checkbox"/>
Provision of drug information	<input type="checkbox"/>	Drug history taking in a clinic session	<input type="checkbox"/>
Reviewing medication	<input type="checkbox"/>	Other	<input type="text"/>

## Section C Your views on the management of chronic pain

For the following questions, please indicate by a tick whether you **STRONGLY AGREE**, **AGREE**, are **UNCERTAIN**, **DISAGREE** or **STRONGLY DISAGREE** with each statement below.

**Most patients comply with your advice**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patient compliance is increased if patients understand your explanation**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Some patients want to control their own pain and don't comply with your advice**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**A patient with chronic pain exaggerates the pain which he/ she feels**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patients generally view pharmacists as shopkeepers, not part of the health care team**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**More patients are self-medicating to improve control of chronic pain**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patients with chronic pain who are depressed often have poor pain control**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Patients with chronic pain usually know very little about the management options for chronic pain**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**A treatment plan for the control of chronic pain, should be agreed upon by a multidisciplinary care team**

Strongly agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly disagree ☐

**Treatment guidelines improve cost-effective prescribing**

Strongly agree ☐    Agree    ☐            Uncertain    ☐            Disagree ☐    Strongly disagree ☐

**Thank you for completing this questionnaire**



## **Appendix 14: Case study 1 – Mrs RS (60 years)**

### **Patient concordance with therapy**

**Diagnosis:** Severe RA affecting most hand, knee, hip and shoulder joints.

**Concomitant problems:** hypothyroidism, coeliac disease, dyspepsia / reflux, asthma, eye cysts and constipation.

**Previous adverse drug reactions:** Sulphasalazine (nausea, vomiting and severe headaches), etodolac (palpitations), mefenamic acid (severe nausea, vomiting and diarrhoea), hydroxychloroquine (nausea, diarrhoea and increased muscle pain), penicillin (severe diarrhoea).

**Current therapy for RA:** Fenbufen capsules 300mg tid, coproxamol 2 prn (usually 2 in the morning and 2 at night), traimcinolone injection 20-80mg intra-articularly three times a month if needed and prednisolone 7.5mg daily.

**Concomitant therapy:** Docusate tablets 200mg nocte, Gastrocote tablets 2 prn, thyroxine 200mcg mane, Fybogel Orange 1 sachet twice daily, chloramphenicol eye ointment 1% applied nightly to both eyes, gluten free products.

**Comments from Mrs RS:** 'I have problems relating to my consultant - I feel that I have been badly treated. I'm worried about the side effects of the second line agents which he has recommended. I don't want to try sulphasalazine again. Doctors don't always know what is right for their patients. Taking medicines like painkillers is unnatural but I need them to relieve the pain. I strongly agree that patients should try to control their pain.

I usually take a lower dose of coproxamol than is prescribed to titrate the pain and reduce drowsiness and constipation. I have felt I needed a much higher dose of something at times when the pain is especially bad. I am keen to try some homeopathy products- I'm going to try them daily and get help with the foods I should try to avoid.

**Factors limiting adherence to GP recommendations:** distrust of consultant, previous adverse drug reactions to NSAIDs and DMARDs, side effects of current therapy limiting compliance, keen to self-medicate, reduced dose of prescribed

therapy.

**Action by pharmacist:** Provided more evidence-based information and reassurance regarding the pros and cons of DMARDs in RA. Discussed the implications of starting homeopathic therapy and the evidence available to support its long-term use in RA.

## **Appendix 15: Case study 2 – Mr DF (38years)**

### **Analgesic discrepancies in medical records**

**Diagnosis:** RA associated with peripheral arthritis, ankylosing spondylitis, retinal vasculitis and panuveitis

**Concomitant problems:** glomerulosclerosis.

**Adverse drug reactions:** Interstitial nephritis (secondary to NSAIDs).

**RA therapy documented in medical notes:** Naproxen 500mg bd, coproxamol 2 every 6 hours, prednisolone 10mg daily and cyclosporin 500mg daily.

**RA therapy actually taken at time of interview:** Coproxamol 1 in the morning and 1 at night (2 as a stat dose caused drowsiness), cyclosporin 250mg daily and prednisolone 2.5mg daily.

**Reasons for discrepancies between medical notes and doses taken:** Cyclosporin and prednisolone dosages reduced at last rheumatology clinic visit, but not updated in medical records. Patient's preferences regarding dosage and frequency not documented in records. Naproxen had been immediately discontinued after the diagnosis of NSAID induced interstitial nephritis was made, but again drug details in medical notes were not updated. Both patient, GPs and rheumatologist involved in the patient's care were all aware of the amendments, but no record was available for any other health professional to use to review progress.

**Potential implications of the discrepancies:** Restarting of NSAID and potential exacerbation of renal disease. Continuation of high doses of cyclosporin and prednisolone associated with a risk of increased renal toxicity and immunosuppression.

## **Appendix 16: Case study 3 - Mrs MA (54 years)**

**Pain disease states :** RA, Cervical spondylosis.

**Duration of pain states:** RA (4 years), Cervical spondylosis (9 years).

**Other relevant medical history:** Thrombocytopenia (secondary to penicillamine therapy in 1993), tinnitus (March 1993), tension headaches since 1973, anxiety.

**Relevant drug history:**

Salazopyrin from Aug 1990; Feb 1993 thereafter ineffective.

Prednisolone from Aug 90- Aug 1992 for acute exacerbations.

Penicillamine started in Feb 1993- rash and pruritus developed in March and April 1993. Rash attributed to Nabumetone therapy- discontinued. Thrombocytopenia Oct 93 (penicillamine discontinued). Platelet count recovered- penicillamine restarted in Nov 1993.

Intra-articular triamcinolone - July 93 for acute flare up.

**Risk factors to compliance:** previous adverse drug reactions, otherwise none

**Risk factors which may prevent optimisation of pain control:** anxiety, previous ADR to NSAID (rash), previous ADRs to penicillamine (dizziness, thrombocytopenia, rash), reduced steroid efficacy.

**Risk factors for the development of side effects:** previous ADR history, hiatus hernia.

**Prescribed analgesia and co-analgesia:**

Penicillamine 250mg daily on an empty stomach with water, dihydrocodeine 30mg 2 three times a day and paracetamol 1-2 if required when dihydrocodeine is ineffective. Also uses hand splints periodically. (Used to take cod-liver oil capsules-discontinued a year ago).

**Other concurrent medication:**

Ranitidine 300mg nocte, Daktacort Cream- to be applied three times a day on rash (if needed), Altacite tablets 1 if required.

**Compliance with medication as reported by patient:** All medicines as above, but sometimes took penicillamine after food.

### **Assessment by study pharmacist at first interview**

**Expectations of pain relief:** Mrs MA thought that ideally a painkiller should provide complete pain relief, but that was unrealistic. She would consider 50% pain relief to be effective and that treatment should relieve pain enough to cope with daily activities.

‘ I sometimes still get needling pain. Doctors can’t do miracles- I can’t expect miracles. The doctors are doing their best’.

**Actual pain relief experienced:** Mrs MA complained of increasing pain over the past few months in both wrists, hands, shoulders and legs.’ The pain has been bad over the past couple of

months-sometimes exercise helps. I can't feel I can control the pain at the moment. I can't sit in the bath- have to stand up in the shower- even that is difficult at times'.

'I am moderately satisfied with my pain control. My pain treatments provided 30% pain relief- been good before this past bout. The painkillers have just taken the edge off the pain'.

### **Attitude to pain**

'Patients benefit from taking painkillers for pain, but it takes too long and you get immune. You need painkillers to ease the pain. You have got to try them (the medicines) to ease the pain although you know the side effects. I would try to control the pain if I could'.

### **Assessment of pain using VAS and MPQ at Interview 1 (median score for n=96)**

VAS av = 70 (40), VAS worst over last month = 80 (70), VAS right now = 70 (30),

NWC = 8 (6), PPI = 3 (2), PRI® = 21 (14), PRI(S) = 19.6 (14.5).

Verbal descriptors used to describe the pain were: throbbing, shooting, sharp, aching, tiring, miserable, freezing and nauseating.

### **Patient perception of disease states and medication**

Mrs MA was unsure as to when to take her penicillamine, but was aware of the signs and symptoms of the adverse reactions associated with her past and present medication. Needed clarification regarding the consequences of further adverse drug reactions and the need to monitor therapy closely especially penicillamine. Mrs MA also requested information about eligibility for a car parking ticket.

### **Monitoring efficacy and toxicity of treatment**

Full blood count results were regularly recorded from past rheumatology clinic visits after penicillamine therapy was initiated. Pain scores and joint count scores were recorded at yearly intervals between 1991 and 1993.

### **Advice given to patient**

Advised Mrs MA to continue to take penicillamine before food and to avoid taking antacids at the same time as penicillamine or iron supplements within 2 hours of penicillamine administration. Advised Mrs MA to refer immediately to her GP again if she developed sore mouth, ulcers, bruising, fever, malaise or the rash developed again.

Discussed possible implications of revisions to therapy e.g. change of DMARD therapy due to worsening pain and ADR risks and / or cautious reintroduction of NSAID (the latter to control the acute inflammation). Encouraged Mrs MA to rest more and to use her splints, especially her hand splints more regularly. Provided information re driving eligibility.

### **Pharmacist's recommendations to the GP**

#### **Increased pain**

Made the GP aware that Mrs MA was complaining of increased pain recently and discussed: (1) the implications of changing her DMARD therapy in the light of her worsening pain and risk of thrombocytopenia and (2) introducing an NSAID e.g. diclofenac not nabumetone (previous ADR?) for a short time to control the acute inflammation, monitoring her gastrointestinal status carefully and risk of any rash re-occurrence.

### **GP response to pharmacist's recommendations**

GP accepted all the pharmacist's recommendations and discussed them with the patient's rheumatologist. Penicillamine was discontinued and hydroxychloroquine commenced. Regular dihydrocodeine was continued and paracetamol could be taken regularly if required.

### **Patient outcomes as reviewed by pharmacist at second visit**

#### **Expectations of pain relief**

Mrs MA still reported that she considered pain relief between 50- 60% to be effective and that treatment should relieve pain enough to cope with daily activities.

**Current therapy for pain:** Hydroxychloroquine 200mg /400mg on alternate days, dihydrocodeine 30mg qid and paracetamol 2 at night if required (only took a max of 4 /day if needed).

#### **Actual pain relief experienced**

'I am moderately satisfied with my pain control. My pain treatments provide about 60% pain relief, enough to cope with daily activities. The pain in my fingers has reduced, but I am experiencing headaches a bit more now.'

### **Assessment of pain using the VAS and the MPQ at Interview 2 (comparative score at Interview 1)**

VAS av = 50(70), VAS worst over last month = 80(80), VAS right now = 50(70) NWC = 4 (8) (group median = 7), PPI = 2(3) (group median = 2), PRI® = 9 (21) (group median = 19), PRI (S) = 9.2 (19.6) (group median = 20.8).

Verbal descriptors used to describe the pain were: throbbing, gnawing, tingling and tiring.

#### **Attitude to pain**

Mrs MA's attitude to her pain was slightly more positive post intervention (attitude score increased from 77 to 80).

### **Assessment of QOL at Interview 2 (comparative score at Interview 1)**

Total QOL score 34% (57%), physical score 50% (62%), social score 33% (50%), occupational score 33% (67%), psychological score 19% (50%).

All of Mrs MA's QOL parameters improved and her satisfaction with pain control was unchanged

(moderate). Total number of medications was unchanged (5).

## **Appendix 17: Case study 4 - Mrs DB (56 years)**

**Pain disease states :** Systemic sclerosis with polyarthropathy, synovitis of left knee.

**Duration of pain states:** Systemic sclerosis- 7 years.

**Other relevant medical history:** Breast carcinoma-right mastectomy 1983, depression, deaf, Raynaud's disease, neuralgia due to brachial nerve injury Feb 86.

**Relevant drug history:** Penicillamine started in July 1990 and increased in December 1990. Rash developed which was treated with terfenadine, then penicillamine discontinued Jan 93. Intra-articular triamcinolone (July 87) for acute flare ups in left knee and shoulders.

**Risk factors to compliance:** previous ADR to penicillamine, worried about side effects.

**Risk factors which may prevent optimisation of pain control:** recurring neuralgia, depression, recent bereavement, worry about side effects of therapy, family problems.

**Risk factors for the development of side effects:** regular NSAIDs, previous rash with penicillamine

### **Prescribed analgesia and co-analgesia:**

Codydramol 2 tablets up to 4 times a day if required, nabumetone 1g at night. Mrs D.B. also uses hand splints.

**Other concurrent medication:** none.

**Compliance with medication as reported by patient:**

Nabumetone as above, but Mrs D.B. tends to only take up to 6 Codydramol tablets daily.

### **Assessment by study pharmacist at first interview**

**Expectations of pain relief:** Mrs DB thought that a painkiller should provide complete pain relief with no side effects.

**Actual pain relief experienced:** Mrs DB complained of increasing pain over the past few months in both wrists, hands, shoulders and toes.' The pain has been bad over the past couple of months since my husband died. It can vary from distressing at worst to mild at best. I am moderately satisfied with my pain control. My pain treatments provided 50% pain relief enough to cope with daily activities.'

**Attitude to pain and pain management and influence of pain on activities of**



## **daily living**

'I strongly disagree that doctors know what is right for patients. I strongly believe that patients benefit from taking painkillers, and they are generally safe to take, but I am worried about the side effects. When my consultant spoke to me about starting a new treatment, I didn't tell him or my GP about the worries I had about the possible side effects. My GP was more worried about my depression.

I try to reduce my intake of codydramol according to my daily activities. If I am washing or ironing I need 8 a day, but if I am just sitting I take 4 a day. Once I take the painkillers, I can cope with the activity but feel very tired afterwards and further activity is still limited. I was made aware from the Relifex leaflet that it can cause constipation, which was helpful to know.

## **Assessment of pain using VAS and MPQ at Interview 1 (median score for n=96)**

VAS av = 50 (40), VAS worst over last month = 80 (70), VAS right now = 50 (30)

NWC = 17 (6), PPI = 2 (2), PRI® = 35 (14), PRI (S) = 43.6 (14.5)

Verbal descriptors used to describe the pain were: shooting, pricking, sharp, gnawing, searing, itchy, heavy, tender, exhausting, sickening, fearful, cruel, troublesome, spreading, tight, freezing and nagging.

## **Assessment of QOL at Interview 1 (median score for n=96 as % of maximum score)**

Total QOL score 62% (28%), physical score 62% (31%), social score 67%, occupational score 50% (33%), psychological score 69 (25%).

'I feel pretty depressed at the moment, since my husband died just a few weeks ago. I would desperately like to get out of the house more – my family are a real worry to me'.

## **Patient perception of disease states and medication**

Mrs DB was very wary about restarting a second line agent despite her deteriorating signs and symptoms, unsure of the benefits of DMARD therapy and worried about their potential side effects.

## **Advice given to patient**

Advised Mrs DB to continue to take her nabumetone after food and use up to 8 codydramol per day without undertreating her pain.

Advised Mrs DB to follow her GP's advice and commence a DMARD therapy Discussed the monitoring of and the benefits and problems associated with DMARDs. Encouraged Mrs DB to rest more, contact her family and use her splints more. Provided information about bereavement and support groups.

## **Pharmacist's recommendations to the GP**

### **Increased pain**

Made the GP aware that Mrs DB was less worried about commencing a DMARD therapy and had been given information about local support groups. Discussed the most suitable DMARD in terms of patient and disease factors.

### **GP response to pharmacist's recommendations**

**GP accepted all the pharmacist's recommendations after further discussion with the patient's rheumatologist.**

Hydroxychloroquine was commenced.

### **Patient outcomes as reviewed by pharmacist at second visit**

#### **Expectations of pain relief**

Mrs DB reported that she expected complete pain relief as at Interview 1.

**Current therapy for pain :** Hydroxychloroquine 200mg / 400mg on alternate days, nabumetone 1g at night and codydramol 2 qid pm.

#### **Actual pain relief experienced**

'I am moderately satisfied with my pain control. My pain treatments now provide me with about 50% pain relief.... as much as possible'.

### **Assessment of pain using the VAS and the MPQ at Interview 2 (comparative score at Interview 1)**

VAS av = 50 (50) (group median = 40), NWC = 15 (17) (group median = 7), PPI = 2(2) (group median = 2), PRI® = 31 (35) (group median = 19), PRI (S) = 40.3 (43.6) (group median = 20.8).

Verbal descriptors which had also been used to describe the pain at Interview 1 were: shooting, stabbing, sharp, gnawing, tingling, hurting, tender, exhausting, sickening, cruel, wretched, annoying, piercing, numb and nagging. (The terms 'fearful' and 'wretched' were omitted during Interview 2).

### **Attitude to pain**

Mrs DB's attitude to her pain was slightly more positive post intervention (attitude score increased from 63 to 71). 'I now see that doctors do know what is right for patients, but don't feel that prescribed medicines are always safe to take'.

### **Assessment of QOL at Interview 2 (comparative score at Interview 1)**

Total QOL score 43% (62%), physical score 38% (62%), social score 67% (67%), occupational score 50% (50%), psychological score 25% (69%).

Mrs DB's overall QOL, physical and psychological status had improved, which was reflected in respectively lower total QOL, physical and psychological scores. 'I feel much less depressed at the

moment. The groups are helping me and my family is supporting me more. I don't seem to feel quite as frustrated at the moment and my walking has improved slightly.

Mrs DB was moderately satisfied with her pain control (score of 3 was unchanged), and her attitude to the pain was more positive (attitude score increased from 63 to 71% of maximum score).  
The total number of medications was increased from 2 to 3.

## **Appendix 18: Case study 5 - Mrs AT (62years)**

**Pain disease states:** Seropositive RA.

**Duration of pain states:** Seropositive RA (2 years).

**Other relevant medical history:** Acute closed angle glaucoma Dec 93, dry eye syndrome.

**Relevant drug history:** Sulphasalazine E/C, Traxam gel, cocodamol and cimetidine started in Nov 92. Sulphasalazine daily dosage gradually increased to 2.5g daily as joint pain increased. Intra-articular methylprednisolone (Feb 93) for acute flare up in left knee.

**Risk factors to compliance:** large decrease in FBC at last clinic visit.

**Risk factors which may prevent optimisation of pain control:** none.

**Risk factors for the development of side effects:** Decreased FBC

### **Prescribed analgesia and co-analgesia:**

Cocodamol dispersible tablets 2 tablets every 8 hours if required, nabumetone 500mg in the morning and 1g at night and sulphasalazine e/c 2.5g daily (500mg 5xday).

**Other concurrent medication:** cimetidine 400mg nocte, Tears Naturale 1-2 drops both eyes prn, Pilocarpine 1 % 2 drops in right eye qid.

**Compliance with medication as reported by patient:** As above.

### **Assessment by study pharmacist at first interview**

**Expectations of pain relief:** Mrs A.T. thought that a painkiller should provide 80% pain relief to relieve pain as much as possible.

**Actual pain relief experienced:** Mrs AT complained of increasing pain over the past few months in both wrists, hands, shoulders and toes.' The pain has been increasingly worse over the past few months. It can vary from horrible at worst to discomforting at best. I am dissatisfied with my pain control at the moment and need to get back to the RA clinic. My pain treatments only provide about 55% pain relief enough to cope with daily activities.'

### **Attitude to pain and pain management and influence of pain on activities of daily living**

'I strongly agree that doctors know what is right for patients. Although I believe that patients benefit from taking painkillers, you don't always get relief during acute bouts. You need painkillers to help

the pain- they are not always safe to take. Some NSAIDs cause indigestion but Relifex is OK .... now I have this blood count problem. People with RA know what to do but I don't think we should try to control our pain.

### **Assessment of pain using VAS and MPQ at Interview 1 (median score for n=96 )**

VAS av = 70 (40) , VAS worst over last month = 90 (70), VAS right now = 60 (30) NWC = 15 (6), PPI = 3 (2), PRI® = 34 (14), PRI(S) = 44.1 (14.5).

Verbal descriptors used to describe the pain were: throbbing, boring, sharp, gnawing, wrenching, burning, aching, exhausting, sickening, fearful, vicious, wretched, miserable, spreading and nauseating.

### **Assessment of QOL at Interview 1 (median score for n=96 as % of maximum score)**

Total QOL 71% (28%), physical score 62% (31%), social score 67% (25%), occupational score 83% (33%), psychological score 75% (25%).

'I have been feeling generally unwell recently. I possibly need some changes in my therapy'.

### **Patient perception of disease states and medication**

Mrs AT had a very good awareness of the rationale of treatment (patient attitude score 83% of maximum) and was aware of the deterioration in her symptoms especially pain control and the need to change her DMARD to improve efficacy and minimise any further drop in full blood count.

### **Advice given to patient**

Advised Mrs AT to continue to take her nabumetone after food and use up to 8 codydramol per day to try to control pain while her DMARD therapy was being reviewed.

Advised Mrs AT to report any sort of indigestion or gastric problems to her GP (no previous GI problems).

### **Pharmacist's recommendations to GP**

#### **Increased pain**

Made the GP aware that Mrs AT's symptoms were worsening and referral to Mrs AT's rheumatologist was needed to review DMARD therapy. Discussed the most suitable DMARD in terms of patient and disease factors.

### **GP response to pharmacist's recommendations**

**GP accepted all the pharmacist's recommendations after discussing them with the patient's rheumatologist. Sulphasalazine was discontinued and d-penicillamine was commenced.**

## **Patient outcomes as reviewed by pharmacist at second visit**

### **Expectations of pain relief**

Mrs AT reported that she expected 95% pain relief with treatment (slightly higher expectations than at Interview 1).

**Current therapy for pain:** D-Penicillamine 500mg daily, nabumetone 500mg in the morning and 1g at night and cocodamol dispersible tablets 2 every 8 hours prn.

### **Actual pain relief experienced**

'I am now moderately satisfied with my pain control. I have pain all the time now, it's hard for me to describe how I feel- at the moment it's mild, thank goodness'. I couldn't do without the medication of Relifex and penicillamine. My rheumatologist first put me on them and I have been feeling a lot better. My pain treatments now provide me with about 80% pain relief.... as much as possible.'

### **Assessment of pain using the VAS and the MPQ at Interview 2(comparative score at Interview 1)**

VAS av = 70(70) (group median = 40), NWC = 6 (15) (group median = 7), PPI = 1(3) (group median = 2), PRI® = 13 (34) (group median = 19), PRI (S) = 14.0 (44.1) (group median = 20.8).

Verbal descriptors used to describe the pain were: throbbing, boring, hot, aching, tiring and annoying.

### **Attitude to pain**

Mrs AT's attitude to the pain was less positive (attitude score decreased from 83 to 77% of maximum score). 'I'm now not sure if doctors know what is right for their patients, but believe that the medicines they give you are safe to take--- you've just got to be careful with them long-term. We shouldn't try to control our own pain.'

### **Assessment of QOL at Interview 2 (comparative score at Interview 1)**

Total QOL score 70% of maximum score (71%), physical score 56% (62%), social score 58% (67%), occupational score 42% (83%), psychological score 19% (75%).

Mrs AT's mobility and psychological status had improved, which was reflected in respectively lower physical and psychological scores. Her improved pain control allowed her to do more activities.

Mrs AT was more satisfied with her pain control (score was changed from 4 to 3). The total number of medications was unchanged (6).

## **Appendix 19: Case Study 6 - Mrs RW (65 years)**

**Pain disease state:** OA.

**Other relevant medical history:** Frozen shoulder, reactive hypomania secondary to surgery, anxiety, insomnia, constipation, ankle oedema.

**Risk factors to compliance:** poor English, confusion, anxiety, multiple medication.

**Risk factors which may prevent optimisation of pain control:** more than 1 NSAID prescribed on computer, concurrent CNS depressant therapy, confusion regarding maximum dosage of NSAID therapy, overweight, heavy smoker (more rapid clearance) easily stressed by family, insomnia.

**Risk factors for the development of side effects:** patient use of more than 1 NSAID (GI problems), concomitant use of CNS depressants (increased confusion), late diuretic use (diuresis at night), poor understanding of medication leading to overuse of NSAID.

**Prescribed analgesia and co-analgesia:**

Naproxen tablets 500mg bd, diflunisal tabs 500mg bd, cocodamol 2 daily, mianserin 10mg nocte, nitrazepam 5-10mg nocte, phenobarbitone 30mg bd.

**Other concurrent medication:**

Burinex K 1 bd, Senna 2 nocte, Canesten Cream-Apply as required.

**Compliance with medication as reported by patient:**

Naproxen 500mg bd regularly, Diflunisal 500mg tablets (up to 8 daily if required, but not at the same time as naproxen!) and cocodamol (2 daily but sometimes up to 8 per day if needed). Rest of therapy as above.

**Assessment by study pharmacist at first interview**

**Patient complained of poor sleep, which worsened pain control** - need to review night sedation (nitrazepam) in view of long-term phenobarbitone use and need for twice-daily diuretic. Review serum biochemistry to encourage change from Burinex K to co-amilofruse if serum biochemistry required potassium maintenance.

**Patient described 'spitting blood'** - Mrs RW said that she sometimes took up to 8 diflunisal tablets a day but never took naproxen at the same time as diflunisal. She admitted to taking naproxen 'sometimes first thing on a empty stomach and last thing at night on little more than 1 piece of bread.'

**Patient perception of disease states and medication**

Mrs RW was confused about dosage and administration times of her analgesic therapy. Mrs RW did

recognise that diflunisal could cause heartburn if she took too many, but still admitted to exceeding NSAID daily dosage (as above). She felt that cocodamol had little effect on her pain, so only took 2 tablets daily, despite knowing that she could take up to 8 /day.

She recognised that her legs got very swollen if she did not take her diuretic therapy. Mrs RW felt dependent on her phenobarbitone but requested increased sedation at night to improve sleep and pain.

### **Monitoring efficacy and toxicity of treatment**

No serum biochemistry or haematological data were available in medical notes to assess electrolyte balance or haematological status respectively.

### **Advice given to patient**

Discussed the potential side effects of NSAIDs ( especially gastrointestinal symptoms), combination analgesics ( especially constipation) and side effects associated with long-term anxiolytic use.

Stressed the importance of taking diflunisal as prescribed (not up to 8 per day) after food and discontinue use of naproxen. She was also advised to contact her GP if she coughed up any more blood or had further abdominal pain.

Advised Mrs RW to avoid buying any OTC medication to help her constipation, but continue with her prescribed laxative, improve mobility and monitor fluid intake. Discussed the possibility that cocodamol could worsen her constipation and that her abdominal pain could be related to constipation.

Discussed possible implications of revisions to therapy e.g. change in night sedation, change in diuretic therapy and NSAID dosage changes. Encouraged Mrs RW to avoid taking her diuretic any later than 6pm, since the diuresis may worsen her insomnia.

### **Pharmacist's recommendations to GP**

#### **Spitting of blood and abdominal pain**

Made the GP aware that Mrs RW was taking both naproxen and diflunisal concurrently, since both NSAIDs were still written up as repeat medications.

Reported the recent spitting of blood and abdominal pain described by Mrs RW to the GP. Suggested that all NSAIDs be discontinued until Mrs RW was reviewed, and cause of abdominal pain identified. Thereafter, naproxen could be used as required, provided no GI problems were apparent.

Regular combination analgesic should be encouraged to improve pain control. Laxative therapy may need to be reviewed to include a faecal softener. Haematemesis unconfirmed.

#### **Insomnia**

Discussed the rationale of nitrazepam use. Temazepam had been stopped after the capsule formulation had been discontinued and nitrazepam prescribed.

Advised change back to temazepam (tablets) only for a short period until the acute exacerbation of her anxiety was resolved, then review need for anxiolytic / hypnotic.

#### **Ankle oedema**



Suggested review use of Burinex K and check serum biochemistry.

Suggested change therapy to coamilofruse if patient was hypokalaemic and diuresis was to be encouraged, and to review the need to administer the diuretic twice daily, especially as compliance was a problem with Mrs RW. Possibility of reduced need for diuretic if reduced need for NSAID.

## **GP response to pharmacist's recommendations**

### **GP accepted all the pharmacist's recommendations.**

Diflunisal was discontinued and naproxen continued after the abdominal pain was diagnosed as constipation. Mrs RW was encouraged to take cocodamol and senna and Fybogel regularly. Temazepam was prescribed for a short course and nitrazepam was discontinued by a stepwise approach.

## **Patient outcomes as reviewed by pharmacist at second visit**

### **Assessment of pain using the VAS and the MPQ at Interview 2 (comparative score at Interview 1)**

VAS av = 40(60) (group median = 40), NWC = 5 (3) (group median = 7), PPI = 2(2) (group median = 2), PRI® = 8 (4) (group median = 19), PRI (S) = 11.7 (6.2) (group median = 20.8).

Mrs RW reported that her arthritic and abdominal pain, constipation and insomnia had decreased despite higher PRI scores.

### **Assessment of QOL at Interview 2 (comparative score at Interview 1)**

Total QOL score 54% of maximum score (70%), physical score 62% (81%), social score 67% (67%), occupational score 58% (83%), psychological score 31% (50%).

Mrs RW's mobility and psychological status had improved, which was reflected in respectively lower physical and psychological scores. Mrs RW was satisfied with her pain control (score of 2 was unchanged), and her attitude to the pain was more positive (attitude score increased from 71 to 74% of maximum score).

The total number of medications was reduced from 9 to 7.

## **Appendix 20: Case study 7 - Mr CT (66 years)**

**Pain disease state(s):** OA of knees and shoulders.

**Other relevant medical history:** Hypertension.

**Risk factors to compliance:** multiple analgesic therapies, does not like taking tablets.

**Risk factors which may prevent optimisation of pain control:** obesity (21 stone), recently bereaved, four NSAIDs concomitantly prescribed (3 oral and 1 topical), lack of perceived benefit of physiotherapy (aggravated joint pain).

**Risk factors for the development of side effects:** more than 1 NSAID, smoker, long-term use of NSAIDs, concurrent antihypertensive therapy.

**Drug history for chronic pain management:** Evening primrose oil- took intermittently with some benefit for 3 years. Heat treatment and exercise since 1993.

Variety of NSAIDs (4) since 1983, Traxam gel 1988, coproxamol since 1988 and Arthrotec since October 1993.

**OTC medication:** Snake oil (from South Africa) applied on knees, and Salmon oil capsules 1 daily. Tiger Balm or Ralgex- applied as required to knees and shoulders.

**Prescribed analgesia and co-analgesia:** Arthrotec 1 bd, coproxamol 2 as required (max 8 per day), Brufen Retard tablets 2 at night for 7-10 days, Feldene gel apply to knee as required for 4 days.

**Other concurrent medication:** Aspirin 75mg one in the morning, coamilofruse 5/40 one in the morning and atenolol 100mg daily.

**Compliance with medication as reported by patient:** All as above including coproxamol 4 per day.

**Assessment by study pharmacist at first interview:**

**Patient complained of increased shoulder pain over past few days:** reviewed rationale of Brufen Retard with Arthrotec, Feldene gel and daily aspirin.

**Patient reported dyspeptic symptoms** - reviewed NSAID use in view of possible GI problem(s) and potential change in analgesic e.g. Tylex.

**Control of hypertension:** needed to reassure patient to comply with atenolol and co-amilofruse (if latter still appropriate). No documented indication for co-amilofruse.

**Monitoring efficacy and toxicity**

No serum biochemistry or haematological data were available to monitor potential toxicity of co-amilofruse or NSAID agents respectively. One blood pressure reading, 170/88 (systolic hypertension) taken 5 months prior to interview, was recorded in the medical notes. No other results were available to appraise hypertension control.

### **Patient perception of disease states and medication**

Mr CT had a good awareness of the rationale of all his medication, but was worried about the potential GI side effects with his NSAIDs particularly after reading a patient information leaflet for his newly prescribed Brufen Retard and had recently experienced indigestion. He took his oral NSAIDs and Arthrotec after food. Mr CT decided to take Brufen Retard for a few days to relieve his shoulder pain, then return to his GP. He knew not to take any more than 8 coproxamol daily, but did admit to sometimes taking 4 coproxamol tablets at one time.

Mr CT also worried about loss of efficacy of his antihypertensive therapy with concomitant NSAID therapy, having read his NSAID information leaflet. He admitted to forgetting his antihypertensive therapy occasionally, which had caused him to feel dizzy.

### **Advice given to patient**

Emphasised the importance of continuing his antihypertensive therapy, stop smoking, watch his diet, try to lose weight and take moderate exercise.

Advised Mr CT to discontinue Brufen Retard and continue taking aspirin and Arthrotec after food, unless dyspeptic symptoms got worse. Discussed the potential problems with topical NSAIDs, encouraging Mr CT to use only one sparingly.

Discussed the need to comply with coproxamol dosing and avoid taking any more than 2 tablets per dose. Encouraged the appropriate use of joint exercises and referral to physiotherapy.

### **Pharmacist's recommendations to GP**

#### **Dyspeptic symptoms**

Advised discontinue newly prescribed NSAID in light of new dyspeptic symptoms and review other analgesia.

#### **Increased shoulder pain**

Encouraged physiotherapy referral. Discussed rationale of misoprostol after no ulceration diagnosed. Misoprostol later discontinued.

#### **Rationale of diuretic therapy**

Encouraged cardiological review of Mr CT including serum biochemistry to assess the need for and the efficacy of coamilofruse.

### **GP response to pharmacist's recommendations**

**GP accepted all the study pharmacist's recommendations**

Brufen Retard and misoprostol were discontinued. Physiotherapy was organised, instructions provided re use of coproxamol and sparing use of the topical NSAID. Mr CT was still moderately hypertensive on review - atenolol and coamilofruse were continued.

### **Patient outcomes as reviewed by pharmacist at second visit**

#### **Assessment of pain using the VAS and the MPQ at Interview 2 (comparative score at Interview 1)**

VAS av = 50(80) (group median = 40), NWC = 8 (9) (group median = 7), PPI = 2(3) (group median = 2), PRI® = 19(23) (group median = 19), PRI (S) = 21.1 (24.6) (group median = 20.8).

Mr CT's shoulder pain improved after physiotherapy.

#### **Assessment of QOL at Interview 2 (comparative score at Interview 1)**

Total QOL score 54% of maximum score (57%), physical score 50% (62%), social score 42% (33%), occupational score 50% (50%), psychological score 69% (62%).

Mr CT's mobility in his shoulder had improved, which was reflected in a slightly higher physical score. Mr CT was still moderately satisfied with his pain control (score of 3 was unchanged), and his good attitude to the pain was unchanged (attitude score of 77% of maximum score was unchanged).

Occupational score was unchanged since Mr CT was retired.

The total number of medications was consequently reduced from 7 to 5.

## **Appendix 21: Case study 8 - Mr DM (67 years)**

**Pain disease state(s):** severe RA and OA.

**Other relevant medical history:** Ischaemic heart disease, hypertension, chronic obstructive airways disease, gastro-oesophageal reflux disease and cataracts (both eyes).

**Risk factors to compliance:** lives alone, poor vision and multiple medication.

**Risk factors which may prevent optimisation of pain control:** previous intolerance to NSAIDs (Indocid suppositories caused proctitis), proteinuria with gold, d-penicillamine and cyclosporin and bone pain with high dose hydroxychloroquine, physiotherapy too painful, patient perception that generic indomethacin was less effective than Indocid.

### **Prescribed analgesia and co-analgesia:**

Paracetamol 500mg-1g qid pm, Indocid ® 50mg qid, Movelat gel 1 application at night, hydroxychloroquine 400mg daily (reducing dose). (RA clinic had prescribed Diclomax Retard one at night as well as Indocid, but Mr DM was not taking it).

### **Other concurrent medication:**

Adalat Retard 20mg bd, isosorbide mononitrate 40mg bd, bendrofluazide 2.5mg daily, ranitidine 150mg bd, Flixotide Inhaler 50mcg qid, Volmax tablets 4mg bd, ipratropium bromide nebules 250mcg bd via nebuliser, salbutamol nebules 2.5mg bd and hypromellose eye drops 0.3% 1 drop both eyes pm.

### **Assessment by study pharmacist at first interview**

**Patient complained of abdominal pain** - needed to refer to GP in light of previous history and current NSAID use.

**Patient reported poor pain control** - needed to review rationale for concurrent use of 2 NSAIDs (1 oral and 1 topical) with GI history and Indocid use in hypertension. Limited alternative options, since poor tolerance to hydroxychloroquine and other slow acting agents. Patient wanted to avoid intra-articular steroid injections- worried about side effects. Provided reassurance re rationale of steroids in both RA and respiratory diseases.

### **Monitoring efficacy and toxicity of treatment**

No biochemistry, blood gases or blood pressure measurements found in medical notes. No evidence of previous reports of proteinuria.

### **Patient perception of disease states and medication**

Mr DM had a good awareness of the rationale of all prescribed medications and was moderately satisfied with pain control with a positive attitude to his pain management. Aware of the need to continue NSAID while altering hydroxychloroquine dosing, to monitor gastrointestinal side effects and need for regular eye examinations with hydroxychloroquine. Patient had good inhaler and nebuliser techniques – respiratory symptoms were stable.

### **Advice given to patient**

Pharmacist discussed implications of possible revisions of therapy.

### **Pharmacist's recommendations to GP**

#### **Abdominal pain**

Advised discontinue NSAIDs, review gastrointestinal symptoms with the possible use of a proton pump inhibitor. (Barium meal had been recently performed and results needed chasing up).

#### **Pain control for RA and OA**

Advised a combination analgesic instead of paracetamol and monitor bowel activity, Advised that the GP should discontinue NSAIDs and monitor efficacy and toxicity of hydroxychloroquine- the latter could be carefully increased provided bone pain is monitored by patient, GP and RA clinic.

### **GP response to pharmacist's recommendations**

**GP accepted almost all pharmacist's recommendations apart from initiation of ibuprofen.**

Ranitidine was discontinued and omeprazole initiated to control GI symptoms (barium meal result was negative). Both indomethacin ® and diclofenac were discontinued. Mr DM was commenced on Brufen Retard thereafter and continued with the same dose of hydroxychloroquine.

### **Patient outcomes as reviewed by pharmacist at second visit**

#### **Assessment of pain using the VAS and the MPQ at Interview 2 (comparative score at Interview 1)**

VAS av = 60 (80) (group median = 40), NWC = 14 (15) (group median = 7), PPI = 3(3) (group median = 2), PRI® = 36 (37) (group median = 19), PRI (S) = 39.0 (39.5) (group median = 20.8). Mr DM's abdominal pain had resolved.

#### **Assessment of QOL at Interview 2 (comparative score at Interview 1)**

Total QOL score 65% of maximum score (60%), physical score 75% (69%), social score 67% (33%), occupational score 62% (62%), psychological score 56% (69%).

Mr DM's mobility had become worse, which was reflected in a higher physical score. Mr DM was still moderately satisfied with his pain control (score of 3 was unchanged), but his attitude to the pain

was less positive (attitude score dropped from 66 to 60% of maximum score). Occupational score was unchanged since he was retired. The total number of medications was reduced from 12 to 10.

## **Appendix 22: Case study 9 - Mrs MD (49 years)**

**Pain disease state(s):** OA ankle and foot and cervical spondylosis.

**Other relevant medical history:** Dyspepsia (gastric erosions in 1988 precipitated by OTC aspirin) and irritable bowel syndrome.

**Risk factors which may prevent optimisation pain control:** Depressed because her orthopaedic surgeon could not offer any further treatment, perceived lack of benefit of physiotherapy and poorly fitting corset.

### **Prescribed analgesia and co-analgesia:**

Solpadol caplets 1 – 2 every 8 hours as required (Mrs M.D. took 2 bd)

Naproxen 500mg bd     DHC Continus 120mg bd (up to 1 tid prn).

### **Other concurrent medication:**

Omeprazole 20md bd (since 1992), Mucaïne 5mls prn, Burinex K 1 in the morning as required for knee swelling, Ferrous Sulphate 200mg daily (since 1988) – no record of indication for use of iron.

**Compliance with medication as reported by patient:** As above except Solpadol 2 bd.

### **Assessment by study pharmacist at first interview**

#### **Patient reported poor pain control**

Mrs M.D believed that exercise did not help chronic pain, so was reluctant to continue physiotherapy. Poorly fitting orthopaedic corset prevented her wearing it, despite increasing pain. Advised not to sit for extended periods of time, yet walking also painful. Her consultant was very reluctant to review her opioid therapy – few other treatment options were left.

#### **Monitoring efficacy and toxicity of treatment**

No serum biochemistry or blood results were available to assess any electrolyte status or underlying anaemia. No problems with knee or ankle swelling –diuretic compliance poor. Her appetite was reasonable and she took a well balanced diet.

#### **Patient perception of disease states and medication**

Mrs MD had a reasonable awareness of the rationale of most of her prescribed medications and felt that her diuretic and iron supplement were unnecessary. She was moderately satisfied with pain control and had a reasonably positive attitude to her pain management.' I wouldn't be taking medicines if I didn't have to'. Mrs MD said that she always took her NSAID with or after food and had no recent stomach problems.



### **Advice given to patient**

The benefits in pain relief of appropriate exercise and a better fitting corset were discussed. Mrs MD was made fully aware by the pharmacist of the need to monitor and report dyspepsia, abdominal pain and the amount of antacid required while taking her Naproxen.

### **Pharmacist's recommendations to GP**

#### **Diuretic and iron therapies:**

Since there was no rationale for the treatments, the pharmacist advised the patient's GP to discontinue Burinex K® and iron therapies.

#### **Pain control:**

The pharmacist advised that a review of Mrs MD's opioid therapy be made after further referral to physiotherapy for appropriate exercise and corset alterations.

### **GP response to pharmacist's recommendations**

#### **GP accepted all the pharmacist's recommendations.**

Mrs MD was referred and seen by her physiotherapist, who discussed a revised exercise plan with Mrs MD and provided a new corset.

GP reviewed the opioid therapy and suggested an increase in dihydrocodeine dosage but was unable to convince Mrs MD's orthopaedic surgeon of the benefit.

### **Patient outcomes as reviewed by pharmacist at second visit**

#### **Assessment of pain using the VAS and the MPQ at Interview 2 (comparative score at**

#### **Interview 1)**

VAS av = 50(80) (group median = 40), NWC = 12 (20) (group median = 7), PPI = 2(3) (group median = 2), PRI® = 22 (54) (group median = 19), PRI (S) = 29.3 (59.0) (group median = 20.8).

Mrs MD reported that her arthritic pain had decreased.

#### **Assessment of QOL at Interview 2 (comparative score at Interview 1)**

Total QOL score 27% of maximum score (39%), physical score 38% (62%), social score 25% (33%), occupational score 33% (42%), psychological score 12% (19%).

The total number of chronic medications was consequently reduced from 8 to 6.

Her mobility had improved as reflected in a decrease in her mobility problem score, she was still

moderately satisfied with her pain control (unchanged score of 3) and her attitude to her pain was unchanged (attitude score remained at 69% maximum score).

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# Potential roles of the pharmacist in chronic pain management: a multidisciplinary perspective in primary care

RHONA W. READ and JANET KRSKA

Patients in the community with chronic pain may have poor pain control and use both prescribed and alternative therapies, often inappropriately, to try to optimise pain relief. They may benefit from management by a multidisciplinary primary care team involving a pharmacist. This study used postal questionnaires to determine community pharmacists' attitudes to involvement in pain management and the perceptions of general practitioners and physiotherapists of the current and potential roles of the pharmacist within a chronic pain care team. The three professions' views on factors which could influence chronic pain management were also determined. Sixty-three GPs (63 per cent), 59 community pharmacists (59 per cent) and 33 physiotherapists (66 per cent) responded. None of the pharmacists was currently involved in chronic pain management, but 58 (98 per cent) wanted to develop such a role, especially within pain clinics. Pharmacists and physiotherapists were more likely than GPs to identify that limited opportunity for personal involvement and expertise within a pain team reduced the likelihood of achieving optimal chronic pain management. Only 17 of the GPs had an established multidisciplinary pain care team; two of these had pharmacist involvement. All GPs and physiotherapists agreed that pharmacists had an important role to play in chronic pain management, particularly in the provision of drug information to patients and medication review.

THERE is currently extensive encouragement to develop the role of the pharmacist<sup>1,2,3</sup> within many different primary care settings. Pharmacists are now extending their skills and knowledge to provide services such as pharmacist-led clinics,<sup>4,5</sup> medicine review,<sup>6</sup> general practice formulary development and review<sup>7</sup> and health promotion.<sup>8</sup> As more medicines are deregulated, pharmacists have also developed their advisory role to improve the appropriate use of medicines and the treatment of minor ailments.<sup>9</sup>

Analgesics are the most widely used non-prescription medicines, yet their use can often be inappropriate and potentially hazardous.<sup>10,11</sup> Along with non-steroidal anti-inflammatory drugs (NSAIDs), analgesics are among the most commonly prescribed medicines.<sup>12</sup> The elderly are most likely to overuse analgesics<sup>10</sup> and are at greater risk of adverse drug reactions.<sup>13</sup> NSAIDs have been shown to contribute to hospital admissions in the elderly.<sup>14</sup> The elderly are more likely to obtain analgesia via prescription than purchase,<sup>10</sup> although any analgesics for self-medication are more likely to be bought from a pharmacy than elsewhere.<sup>15</sup> However, the elderly are

less likely than younger patients to ask for advice.<sup>15</sup> Inappropriate use of analgesic therapy may also lead to poor relief of symptoms.<sup>16</sup> Consequently, pharmacists must be proactive if the outcomes of patients with chronic pain are to be maximised.

Controlled studies have shown that pharmacist input into the management of anticoagulant therapy results in improvement of patient outcomes.<sup>4</sup> Patients with chronic pain managed in the community can also benefit from pharmaceutical intervention to maximise the efficacy of drug regimes and reduce the risk of potential adverse effects.<sup>16</sup> Pharmacist referrals to general practitioners and other members of the health care team have been shown to result in an improvement in pain scores.<sup>16</sup>

Many patients with chronic pain have benefited from management by a multidisciplinary pain team, based in hospital, frequently involving anaesthetists.<sup>17</sup> Physiotherapists in particular have a large role to play in improving outcomes in patients with chronic, non-malignant pain, using well-validated manipulative techniques,<sup>18</sup> and are a frequent referral point of GPs. They

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are thus an important group of health professionals, dealing with substantial numbers of patients who are suffering from chronic pain. It has been estimated that 50 per cent of the population aged 25 or over suffer from chronic pain lasting three months or more [W. C. S. Smith, personal communication]. The majority of these patients are managed in primary care by GPs using analgesic and NSAID therapy.

Our previous work showed that large numbers of patients, for example those with rheumatoid arthritis, use non-prescription medicines and alternative therapies to enhance the efficacy of their prescribed analgesia.<sup>16</sup> There is therefore a potential need for pharmaceutical input into the treatment of patients with chronic pain in primary care,<sup>19</sup> perhaps as part of a chronic pain team. GPs previously expressed mixed views on the role of the pharmacist in chronic pain management;<sup>20</sup> however, recent work has shown that medication review by pharmacists was rated favourably.<sup>21</sup>

The purposes of this study were to determine community pharmacists' current input into chronic pain management and to evaluate GPs' and physiotherapists' experiences of pharmacists' contribution to the care of patients with chronic pain. The views of all three professions on factors which limit the management of chronic pain and the role(s) of the pharmacist, if any, within a multidisciplinary chronic pain care team were also determined.

## Methods

Three postal questionnaires were developed to determine the current practice of GPs, community pharmacists and community-based physiotherapists in managing chronic pain. Each contained a list of attitude statements relating to chronic pain and factors potentially influencing its management, developed by discussion with academics and practitioners. All responders were also asked to indicate their level of agreement with the attitude statements, using a five-point Likert scale, and to indicate any of the factors they felt prevented them from optimising control of chronic pain. A range of potential roles for pharmacists in the management of chronic pain were given and responders asked to indicate which, if any, they considered appropriate.

The questionnaires for GPs also requested practice details, the extent of current clinical interaction with pharmacists and strategies used in the management of chronic pain. Questionnaires sent to pharmacists requested professional details, current clinical services provided, especially in chronic pain management, and the pharmacists' attitude to the development of their role in this area. Additional questions asked of physiotherapists requested professional details and information about their management strategies used to control chronic pain.

The questionnaires were piloted by five volunteers from each professional group and minor changes made as a result. None considered a need for changes to be made to the attitude statements. Lists of GP practices, community pharmacies and community-based physiotherapists were obtained from two health boards in Scotland. Questionnaires were sent to 100 GPs, 100 pharmacists and 50 physiotherapists selected at random from these lists, while ensuring that no practitioners working in the same practice received questionnaires. This represented approximately 50 per cent of all practices for each profession in the two boards. The first mailing took place in January, 1996. Prepaid envelopes were provided for return of the questionnaires and one follow-up reminder was sent. Data were analysed using EPI-info 5.0 statistical package. Chi-square and Kruskal Wallis tests were used to compare results between the professions.

## Results

**Demographic details** Replies were obtained from 63 GPs (63 per cent), 34 (54 per cent) of whom were from fundholding practices, with an average of six GPs (range 2.5-12) per practice. The practice list sizes (range 3,200-22,500 patients per practice) reflected the number of GPs per practice. Fifty-nine pharmacists (59 per cent) responded, 56 (95 per cent) of whom worked full-time and the rest part-time. Forty-eight of the respondents were the sole pharmacist in the pharmacy, while 10 had one colleague and one had two colleagues working in the pharmacy at the same time. Replies were also obtained from 33 of the 50 physiotherapists (66 per cent), all independent community practitioners, not associated with general practices.

**Community pharmacists' current clinical activities and involvement with GPs and physiotherapists** All pharmacists indicated that they provided advice about prescribed and non-prescription medicines. No responder identified specific involvement in the management of chronic pain, but 25 (42 per cent) claimed to provide prescribing advice to GPs and 10 (17 per cent) were involved in developing treatment protocols.

Sixty-two GPs (98 per cent) identified pharmacists as helpful, mostly (53 GPs) as a source of medication and drug information to patients. Twenty-two had found pharmacists helpful in encouraging patient compliance, but only 19 and 12 GPs, respectively, had direct experience of involving pharmacists in individualising treatment options or developing a practice formulary.

No physiotherapist who responded had any direct involvement with a community pharmacist at the time of the study.

**Chronic pain management** *Factors preventing optimal management of chronic pain* — The ex-

**Table 1: Extent of agreement with factors which may influence the management of chronic pain**

Factor	Number (per cent) of GPs agreeing (n=63)	Number (per cent) of pharmacists agreeing (n=59)	Number (per cent) of physiotherapists agreeing (n=33)
Patient expectation of pain control	31 (49)	17 (29)	20 (61)
Poor patient compliance	25 (40)	19 (32)	17 (52)
Poor agreement of management with patient	13 (21)	5 (8)	2 (6)
Limited access to pain clinics/specialists	21 (33)	34 (58)	22 (67)
Limited access to up-to-date drug information	2 (3)	5 (8)	11 (33)
Limited [personal] expertise in a multidisciplinary team	10 (16)	28 (48)	9 (27)
Excessive workload	27 (43)	29 (49)	14 (42)
Lack of opportunity for [personal] involvement in a multidisciplinary team	13 (21)	42 (71)	15 (45)

**Table 2: Extent of agreement with attitude statements on chronic pain management (n=154)**

Statement	Number (per cent) who strongly agree/agree	Number (per cent) who don't know	Number (per cent) who strongly disagree/disagree
Most patients comply with your advice	99 (64)	37 (24)	18 (12)
Patient compliance is increased if patients understand your explanation	147 (95)	6 (4)	1 (1)
Some patients want to control their own pain and don't comply with your advice	92 (60)	42 (27)	20 (13)
A patient with chronic pain exaggerates the pain which he/she feels	35 (23)	66 (43)	3 (34)
More patients are self-medicating to improve control of chronic pain	79 (51)	52 (34)	23 (15)
Patients with chronic pain who are depressed often have poor pain control	133 (86)	20 (13)	1 (1)
Patients with chronic pain usually know very little about the management options for chronic pain	108 (70)	31 (20)	15 (10)
A treatment plan for the control of chronic pain should be agreed by a multidisciplinary care team	89 (58)	49 (32)	16 (10)
Treatment guidelines improve cost-effective prescribing	105 (68)	37 (24)	12 (8)

tent to which the three professional groups agreed with factors which may prevent optimal management of chronic pain is shown in Table 1. A significantly greater number of GPs than pharmacists agreed that patient expectation of pain control influenced management of chronic pain ( $P<0.05$ ;  $\chi^2$ ;  $df=1$ ). More GPs than pharmacists also concurred with the statement that poor agreement with patients on a management strategy was a limiting factor ( $P<0.05$ ;  $\chi^2$ ;  $df=1$ ).

Pharmacists were more likely than GPs to agree that limited access to pain specialists/clinics, lack of opportunity to be involved or lack of expertise within a multidisciplinary team limited chronic pain management ( $P<0.05$ ;  $\chi^2$ ;  $df=1$  for all statements). Physiotherapists were more likely than GPs to agree that limited access to pain specialists or clinics was an influencing factor, and more likely than the other two professions to indicate that lack of up-to-date drug information was important ( $P<0.05$ ;  $\chi^2$ ;  $df=1$  for both statements).

**Attitudes to pain management** — Table 2 shows the extent of agreement with a series of statements used to assess the attitudes of respondents towards management strategies for chronic pain, compliance with therapy and other factors which

influence pain and its management. One physiotherapist omitted to complete this section of the questionnaire, thus the total number of respondents was 154.

Few differences were found between the three professions in the extent of their agreement with these statements, the major difference involving the statement that treatment plans should be developed by a multidisciplinary team. Overall, 58 per cent of responders agreed with this statement; however, the proportion of GPs agreeing was lower than that of pharmacists or physiotherapists.

Ninety-five per cent of all responders agreed

**Table 3: Extent of agreement with proposed roles for pharmacists in chronic pain management**

Proposed role	Number (per cent) of responders agreeing	
	GPs (n=63)	Physiotherapists (n=33)
Providing drug information to patients	46 (73)	29 (88)
Medication review	38 (60)	25 (76)
Drug history taking in a chronic pain clinic	8 (13)	12 (30)
Facilitate chronic pain management	3 (5)	2 (6)
Educate health care professionals about use of analgesics	3 (5)	2 (6)

or strongly agreed that compliance with a pain management strategy was increased if patients understood the strategy. While almost two thirds (64 per cent) agreed that the majority of patients complied with their advice, a similar number (60 per cent) agreed that some patients prefer to control their own pain and do not comply.

*Current management of chronic pain* — Treatment guidelines for chronic pain were used by 14 of the 63 GPs (22 per cent), while 17 of the 33 physiotherapists (52 per cent) used guidelines. GPs claimed to use the British National Formulary, while physiotherapists used specific physiotherapy protocols. Only 17 of the GPs (27 per cent) had a multidisciplinary team already established for the management of chronic pain at the time of study.

The composition of the teams, as documented by the GP and physiotherapist respondents, varied considerably, with a nurse being the most frequently cited team member (13) after the GP; pharmacists and physiotherapists were only involved in two and four of these GP-led teams, respectively.

Two of the study physiotherapists were involved in a multidisciplinary pain team, but other team members in each group were limited to a GP and a clinical psychologist. None of the study pharmacists was involved in a team themselves. Lack of resources (30 respondents), time (31) and personal expertise (20) were reasons commonly given by GPs and physiotherapists for not establishing multidisciplinary care for patients with chronic pain, while 22 suggested that there was a lack of need.

*Development of the role of the pharmacist in the management of chronic pain* — All 155 respondents were asked to consider the potential role(s), if any, of a pharmacist in a chronic pain care team. There were no significant differences ( $P>0.05$ ;  $\chi^2$ ) between the responses of GPs and physiotherapists (Table 3), all of whom agreed that pharmacists had a developing role to play in a multidisciplinary approach to managing patients with chronic pain. Further roles for pharmacists suggested by GPs were help with understanding the clinical significance of drug interactions (two respondents) and with the substitution of non-prescription products for prescribed analgesics (three respondents).

Fifty-eight of the 59 pharmacist respondents (98 per cent) identified a desire to develop their role in chronic pain management. Forty-eight pharmacists wanted to develop further patient information services regarding non-prescription products and 46 pharmacists wanted to develop further patient information services for prescribed medication in chronic pain management. Thirty-three pharmacists (56 per cent) indicated they would like to become actively involved in pain clinics.

## Discussion

All pharmacist respondents were currently providing advice concerning both prescribed and non-prescribed medicines, and some were also involved in providing prescribing advice to GPs and developing treatment protocols. Although 98 per cent of pharmacists wanted to develop their role in pain management, the most common desire was to develop further the advice-giving role.

Both GPs (73 per cent) and physiotherapists (88 per cent) also envisaged the pharmacist as a provider of drug information, but were encouraging more clinical and proactive roles for pharmacists in addition. This was despite most previous GP contact with pharmacists involving the traditional supply role and the physiotherapist respondents having no direct contact with pharmacists, as is usual in primary care. There is a possibility that physiotherapists' views may have been influenced by beneficial contact with hospital pharmacists during training.<sup>22</sup>

Sixty per cent of GPs and 76 per cent of physiotherapists felt that pharmacists should undertake review of medication in patients with chronic pain. More than 50 per cent of the pharmacists were keen to review medication, either in pain clinics or via domiciliary visits, the need for which has been shown.<sup>16</sup>

While pharmacists claimed that limited access to pain clinics and the lack of opportunity for involvement were limiting factors to optimising pain control, pharmacist-led chronic pain clinics, involving several health care professionals, are now being developed in primary care (S. MacGregor, personal communication). Meanwhile, there is still much that can be achieved in the community pharmacy. Pharmacists are currently able to use patient medication records to ensure that analgesic overuse does not occur.<sup>10,23</sup> Duplication of NSAIDs and paracetamol-containing preparations<sup>10,11,16</sup> can easily be detected by pharmacists.

Although only 17 of the GPs had a multidisciplinary pain team at the time of study, and pharmacists were only involved in two teams, the majority of respondents felt that a treatment plan should be agreed by such a team. Drug history taking in pain clinics was identified by a number of GPs and physiotherapists in this study as a potential role for the pharmacist. However, there is also a need for the development of local protocols for both prescribed and non-prescription medicines. Recent work has shown that pharmacists have a greater knowledge than GPs of analgesic therapy,<sup>24</sup> which would be of benefit in developing treatment protocols and in the multidisciplinary management of chronic pain.

The low usage of treatment guidelines for chronic pain management was disappointing, but indicates an opportunity for improvements in chronic pain management, which has been

identified by other work.<sup>16,25</sup> The development of treatment guidelines for some chronic disease states has permitted GPs to delegate the operation of specific clinics to pharmacists<sup>4,5</sup> and other health care team members,<sup>26</sup> which has proved popular with patients.<sup>4</sup> This should apply more frequently to chronic pain, given its high incidence and potential for poor outcomes.<sup>16</sup>

High patient expectations, poor compliance and poor patient agreement with a management strategy were all factors limiting pain control with which many respondents agreed. Minimal time for discussing patients' expectations of treatment and developing ownership of the management strategy may result in a reluctance to comply with treatment. This has been shown to be a problem in patients with arthritis.<sup>27</sup> The move to concordance rather than compliance<sup>28</sup> and the involvement of health care professionals other than GPs who may be able to allocate more time to patients could also help to address these factors.

Although the sample size of this study is relatively small, primary health care team members were found both to identify and appreciate the current and potential roles of the pharmacist in the management of chronic pain. The results suggest that there is greater willingness to involve the pharmacist in chronic pain management than was found previously,<sup>20</sup> when many GPs and nurses were not supportive of pharmacist involvement in domiciliary pain management. While fewer GPs than pharmacists and physiotherapists agreed that a treatment plan should be agreed by a multidisciplinary care team in the present study, both GPs and physiotherapists agreed with many potential roles for pharmacists within such a team approach.

The change in GP attitudes may be a reflection of the increasing co-operative working between pharmacists and GPs throughout the United Kingdom, and is in line with more recent findings which suggest that GPs would welcome targeted medication review by pharmacists.<sup>11,21</sup>

We have already shown that there is a need for pharmacists to integrate with the primary health care team, to provide advice and information about analgesic use, to help develop and implement treatment protocols for chronic pain management and to undertake medication review to improve the outcomes of patients with chronic pain.<sup>16</sup>

The results of the present study suggest that these activities will be welcomed by those currently involved in chronic pain management. The opportunity for team approaches to the management of chronic diseases within the current developments in primary care should facilitate the extension of pharmacists' existing input.

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# Targeted medication review: patients in the community with chronic pain

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Patients with chronic pain may be in need of improved pharmaceutical care because of lack of pain relief and lack of understanding of pain management, the potential for drug interaction and adverse effects. This study assessed the need for a pharmacist to review the medication of a population of patients with chronic pain in a domiciliary setting, using specific validated outcome measures to determine any benefits of pharmacist intervention.

Ninety-six patients who had rheumatoid arthritis or were taking regular non-steroidal anti-inflammatory drugs (NSAIDs) or combination analgesics were interviewed after reviewing their medical records. Expectations of pain relief and severity of pain were assessed using McGill pain questionnaire (MPQ), visual analogue scales (VAS) and verbal descriptor scales. Twenty-eight patients required referral to their GP as a result of meeting preset criteria for poor outcome from current therapy; these patients had higher expectations of pain relief than the remaining patients and also higher pain scores. Pain scores using the MPQ and VAS were generally well correlated with each other and both showed changes in the 14 patients who were re-interviewed after pharmacist intervention. A further 59 patients required advice to optimise current therapy and 12 required referral concerning inappropriate therapy. Many patients' medicine use deviated from that prescribed, and a high proportion used alternative medicines in addition. The prescription of drugs for prophylaxis against ulceration was inappropriate in 17 patients and evidence of monitoring in patients on NSAIDs and disease-modifying antirheumatic drugs (DMARDs) was poor.

PHARMACISTS have increasingly begun to undertake reviews of medication in patients living at home, which have resulted in the identification of many medication-related problems.<sup>1,2</sup> Many workers have directed this service at elderly patients taking multiple medicines, although younger patients and those taking fewer medicines may still be at risk of such problems. An alternative method of identifying patients for review is targeting by disease state or by drug group, for example, patients taking ulcer-healing drugs.<sup>3</sup>

Pain is the commonest symptom with which patients present to their GP, and analgesics, including non-steroidal anti-inflammatory drugs (NSAIDs), are among the most commonly prescribed medicines.<sup>4</sup> Patients with chronic pain due to arthritis are also likely to use alternative therapies for pain, including non-prescription medicines.<sup>5,6</sup> Not only could this lead to drug interactions, it also suggests that patients are experiencing incomplete pain relief from their analgesics.<sup>7</sup>

Patients with rheumatoid arthritis (RA) may also be receiving treatment with disease-modifying antirheumatic drugs (DMARDs). Both

NSAIDs and DMARDs have the potential for considerable toxicity, with NSAIDs being responsible for a substantial proportion of drug-related problems contributing to hospital admission.<sup>8</sup> Despite their toxicity, NSAIDs are over-prescribed in the United Kingdom.<sup>9</sup> In addition, patients' knowledge about NSAIDs,<sup>10</sup> analgesics<sup>11,12</sup> and DMARDs<sup>13</sup> has been shown to be poor.

All of these factors suggest that patients with chronic pain may be in need of improved pharmaceutical care, as has been identified in the United States.<sup>14</sup>

The purpose of this study was to identify patients with chronic pain living in the community, to undertake a review of all their therapy for pain and concomitant conditions and to measure pain relief using standard instruments. A definition of poor outcome of therapy for chronic pain was set at the start of the study in order to quantify the likely need for medication review in patients with chronic pain. Action was taken to address any medication-related problems identified during the process, thus enabling the type of action required to improve pain therapy to be quantified.

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## Method

Three medical practices in two health board areas of Scotland agreed to participate in the study. Ethical approval was obtained from both health boards. From each practice all patients with a diagnosis of RA and a systematic random sample of every eighth patient receiving repeat prescriptions for NSAIDs or combination analgesics were selected, using the practice computer system (GPASS). Exclusion criteria were patients aged under 18, patients with malignant pain, patients considered by their GP to be unsuitable for inclusion and patients unwilling to participate. Information about medicines prescribed and medical problems were obtained from practice records. Patients were contacted by letter, followed by a telephone call to determine whether they were willing to be interviewed (by RR) in their own home. Written consent was obtained from all patients who agreed to interview and review of therapy. The study took place between July, 1993, and September, 1994.

A structured interview was used to determine how the patients actually used their prescribed medicines, any non-prescription medicines which they used for pain relief and any complementary therapies used. Perceived adverse effects were determined by asking about any problems ever experienced in relation to any medicines currently being used for pain. Any problems with administration of medicines were also determined during the interview. Patients' knowledge of their medicines was determined without allowing reference to their medicine containers. Knowledge of side effects, disease states and the sources of medicines information used by the patient were also obtained by structured questioning.

Pain relief was assessed using the McGill pain questionnaire (MPQ)<sup>15</sup> and a horizontal visual analogue scale (VAS).<sup>16</sup> The MPQ defines pain in terms of three major dimensions: sensory, affective and evaluative and consists of 20 categories of words to describe the pain experience. Patients were asked to select the categories which they recognised as relevant to their pain at time of interview, and to circle the most appropriate word within each category. If none of the words within a category applied, none were chosen. The MPQ also asks patients to rate present pain intensity (PPI) on a 0 to 5 verbal descriptor scale where 0 = no pain and 5 = pain is horrible. This tool has been widely used and validated in patients with many different types of pain.

Patients were asked to rate their expectations of pain relief, current pain and both average pain and worst pain over the previous month using the 100mm VAS, where 0 = no pain and 100 = pain as bad as it could be. Expectations of pain relief and satisfaction with pain control were also assessed using a validated rating scale with specific verbal descriptors.<sup>17</sup>

A poor outcome of current therapy was de-

fined as one or more of the following problems at the time of interview:

- pain greater than 75mm on the VAS average
- deliberate change in therapy by patient without GP consultation
- presence of potential adverse reaction(s)
- dissatisfaction with therapy.

Actions taken in patients identified as having poor outcomes took the form of providing information and advice or referral to the GP or other health care professional. Patients with satisfactory outcomes but therapy considered to be inappropriate were also referred to their GP. Patients who had been referred due to poor outcomes were subsequently revisited after an interval of four to six weeks to determine any changes in outcomes.

The McGill pain questionnaire was analysed according to the method validated by Melzack<sup>15</sup> and results expressed as:

- Pain Rating Index (scale) score (PRI[S]): the sum of the weighted scale values for all the words chosen within a category or across all categories.<sup>18</sup> A total PRI(S) score and a PRI(S) score within a category, eg, PRI(S) evaluative, was calculated.
- Pain Rating Index (rank) score (PRI[R]): the weighted scale values were replaced by a value which indicated the ranking of the chosen word within a given category and summated to provide a Pain Rating Index score using rank values. A total PRI(R) score and a PRI(R) score within a category, eg, PRI(R) evaluative was calculated.
- Number of Words Chosen (NWC): total number of words chosen (NWC) from the 20 categories within the MPQ were summated.
- The Present Pain Intensity Score (PPI): score of 0 to 5 was also determined from the PPI verbal descriptor scale used within the MPQ.

VAS scores were calculated by measuring the distance of each patient's mark from the lower end of the scale, measured in millimetres, ranging from 0 to 100.

All data were analysed using Epi Info version 5.0. Chi-square tests were used to compare patient subgroups and Pearson's correlation coefficient was used to compare pain scores.

## Results

**Patient population** A total of 109 patients was identified from the three practices, of whom 96 agreed to participate in the study. There were no differences between the 13 patients who refused to participate and those who agreed in terms of number of disease states or drugs prescribed.

Of these 96 patients, 42 had RA, 22 had osteoarthritis (OA), 25 had both OA and RA and

seven had low back pain. The mean age of the 96 patients was 60.4 years (SD 13.8 years, range 29-84 years). Twenty-eight of the 96 patients (29 per cent) were male and 68 (71 per cent) were female. There was no significant difference in age between groups of patients with different chronic pain diagnoses. The average number of medications currently taken by patients was 4.9 (range 0-12) and the average number of concurrent disease states (excluding the chronic pain diagnosis) was 3.0 (range 2-9).

**Use of pain therapies** Seventy-one patients (74 per cent) were prescribed NSAIDs, 15 (16 per cent) DMARDs, 49 (51 per cent) combination analgesics, 27 (28 per cent) paracetamol and eight (9 per cent) an opioid. Other medicines relating to pain, including immunosuppressants, hypnotics and antiepileptics, were prescribed in 33 patients (34 per cent). The average number of medications taken by each patient group were: RA group 5.0 (range 0-12), OA group 5.2 (range 2-9), back pain group 4.3 (range 2-9) and group with RA and OA 4.9 (range 0-12), with no significant differences between groups.

There was a substantial proportion of patients without RA who were prescribed NSAIDs, where their use was less appropriate. In 40 patients there was documented evidence in the records of use of additional therapies, such as physiotherapy, occupational therapy and herbal products, although only two patients were using these at the time of the study. No records of OTC medicines use were found in the majority of patients' notes, although in four there was mention of OTC medicines being used in preference to prescribed medicines.

Comparing the information obtained from records with that obtained from the patients directly at interview, there were discrepancies relating to therapy for chronic pain in 72 patients. Many patients' medicine use deviated from the regimens documented in medical records, although patients claimed GPs were aware of these differences. This was particularly prevalent in patients with RA (54/67, 81 per cent of patients). The type of differences described were medicines having been discontinued (45 instances), dose changed (48 instances) or medicines added (49 instances). Thirty-six patients voluntarily admitted to recently modifying the dose of NSAID or analgesic taken from that prescribed themselves: 31 of these had reduced their dose, while five reported that they had increased their dose of analgesic due to increasing pain. However, more specific questioning revealed that an additional 10 patients used a lower dose than prescribed. Significantly more patients in the RA group reported that they had at some time needed a higher dose of analgesic than that prescribed ( $P<0.05$ ;  $\chi^2$ ;  $df=3$ ).

The use of alternative therapies (homoeopathic or herbal remedies) for pain was significantly

higher in patients with a diagnosis of RA ( $n=22$ , 34 per cent) compared with the others ( $n=4$ , 12.5 per cent) ( $P<0.05$ ;  $\chi^2$ ;  $df=1$ ). These patients also claimed to use allopathic non-prescription medicines more frequently than other patients (20 compared with five) although this difference did not reach statistical significance ( $P>0.05$ ;  $\chi^2$ ).

Duplication of NSAID use was found in seven patients, of whom four used two oral NSAIDs simultaneously, two used an oral and a topical product, and one used two oral and two topical products. One patient was taking two paracetamol-containing combination analgesics concurrently and three prescribed an opioid were also prescribed a combination analgesic. Two patients were taking purchased paracetamol in addition to a prescribed combination analgesic containing paracetamol.

**Prophylaxis against NSAID-induced gastrointestinal ulceration** Twenty-six patients were prescribed prophylaxis against NSAID-induced gastrointestinal ulceration, as follows: misoprostol (3 patients), omeprazole (5), ranitidine (8), cimetidine (5) and antacids (7). Some had two medications. The daily dose of  $H_2$ -antagonist was too low in four patients, antacids were used as sole prophylaxis in four patients and one patient was receiving a treatment dose of omeprazole. A further eight patients, six of whom were taking NSAIDs regularly or as required, had a previous history of gastrointestinal problems but were not prescribed any prophylactic therapy. Moreover, three patients prescribed prophylactic therapy were not taking it at the time of interview, and two of these were continuing to take two NSAIDs concurrently. Elderly patients were no more likely to be receiving prophylaxis than younger patients.

**Monitoring** Documentation of biochemical and haematological parameters in the GP records was very limited, although this information may have been available in hospital records. Only two of the 71 patients who were prescribed NSAIDs had any documentation of renal function testing (serum creatinine in both and urinalysis in one). Two of these 71 patients were also prescribed DMARDs (penicillamine and gold), one was prescribed azathioprine and another patient had pre-existing renal impairment. No baseline urea and electrolyte and haematology results were available in the 15 patients who were taking DMARDs, and only eight of these patients had documented records of monitoring carried out after therapy was initiated.

The study pharmacist needed to intervene in the care of one patient who developed thrombocytopenia due to penicillamine therapy (see Table 2).

**Patient knowledge** The extent of the patients' basic knowledge in relation to their therapy was

**Table 1: Pain scores obtained using McGill pain questionnaire and visual analogue scales in 96 patient with chronic pain**

Patient group	Median scores (95 per cent confidence intervals)						
	VAS score for expectations of pain relief	VAS score for worst pain	VAS score for average pain	VAS score for pain now	PRI scale	PRI rank	NWC
All patients at interview 1 (n=96)	80 (80-90)	70 (60-80)	40 (40-45)	30 (30-40)	14.46 (11.84-18.34)	14 (10-17)	6 (4-6)
Patients with satisfactory outcomes at interview 1 (n=68)	70 (70-80)	60 (60-70)	40 (30-40)	30 (30-40)	12.80 (10.28-15.25)	12 (10-14)	5 (3-6)
Patients with poor outcomes at interview 1 (n=28)	90 (80-100)	80 (60-90)	55 (40-70)	50 (30-60)	22.45 (14.14-29.45)	21 (15-26)	8 (6-11)
Patients with poor outcomes before intervention — interview 1 (n=14)	85 (60-100)	80 (50-100)	65 (40-80)	50 (30-70)	22.96 (14.94-43.57)	21 (13-35)	8 (6-15)
Patients with poor outcomes after intervention — interview 2 (n=14)	80 (80-100)	70 (70-90)	50 (50-60)	40 (30-60)	20.79 (11.70-38.99)	19 (9-31)	7 (5-13)

generally found to be good. Most (91 per cent) identified all prescribed medication, its indication and dosing frequency correctly, 98 per cent correctly identified the number of dosage units they should take, but 40 per cent did not know the strength of all their medication. All patients taking paracetamol or combination analgesics were aware of the maximum dose allowed. Six patients admitted to taking their NSAID on an empty stomach, including one patient taking two NSAIDs concurrently. Two patients took penicillamine after food.

A total of 57 patients (59 per cent) had received an information leaflet about one or more of their prescribed medicines, mostly from hospital clinics or as package inserts. Fifty-five of these had read the leaflet; 28 patients had found it useful for finding out how their medicine worked and 39 had found it useful for identifying potential side effects.

**Adverse effects** Of the 96 patients, 73 (76 per cent) claimed to have experienced at least one side effect at some time which they attributed to their therapy. A total of 175 potential adverse effects were identified by the patients, a rate of 1.8 per patient. Sixty-six patients claimed to have experienced an adverse effect to NSAIDs, citing 72 problems in total, of which the commonest were gastrointestinal symptoms (74 per cent), including four bleeds. Only one of these 72 problems was not a reported adverse effect to NSAIDs. The four patients who had experienced a bleed varied in age (range 49-80 years). The two oldest of these four were still using NSAIDs, one still taking high doses of two NSAIDs concurrently with no GI protection and the other using a topical NSAID as required with antacid cover.

Thirty-nine reactions to DMARDs were identified by patients. Again gastrointestinal problems were commonest (10 patients) followed by rash (seven patients) and blood abnormalities (four patients). Constipation was the commonest problem identified with opioids and combination analgesics, being cited by 17 patients, followed by dizziness or drowsiness (11 patients) and nausea (four patients). Side effects were reported by significantly more patients with RA than those with back pain or OA (55 compared with 18) ( $P<0.05$ ;  $\chi^2$ ;  $df=1$ ), but this was not related to the number of drugs being taken, as the number did not differ between patient groups.

**Pain measurement and satisfaction** Using the MPQ, the most common words selected were from the sensory category, notably throbbing (49 patients), aching (49 patients), gnawing (46 patients), sharp (30 patients) and shooting (25 patients), but 52 patients also selected tiring from the affective category. Using the VAS, the median score for expectation of pain relief was 80 per cent (Table 1). Table 1 also shows median VAS scores for average and worst pain over the previous month and pain at time of interview, which indicate that patients did experience pain despite analgesic therapy.

From the verbal descriptor scales, 29 patients expected complete pain relief and 62 expected very good pain relief. However only 10 patients claimed to obtain complete relief and 36 at least 75 per cent relief. Only six patients were completely satisfied with their pain control, 41 were very satisfied, 44 were moderately satisfied and five were dissatisfied.

Pain relief indices and number of words chosen from the MPQ (PRI[S], PRI[R], NWC) were

**Table 2: Problems identified by pharmacist, actions taken by GP and changes in pain scores in 14 patients with poor pain outcomes**

Pain diagnosis	Problems identified by pharmacist: Action taken by GP	VAS changes	PRI(S) changes	PRI(R) changes	NWC changes	PPI changes
OA	Four NSAIDs prescribed, patient wanted to limit NSAID therapy and described dyspepsia: One NSAID continued, GI problems reviewed — no ulcer, misoprostol stopped, low dose aspirin monitored	-30	-3.5	-4	-1	-1
OA	Stomach and arthritic pain, taking two NSAIDs concurrently, possible haematemesis: Diflunisal stopped, regular co-codamol and naproxen continued, haematemesis unconfirmed	-20	+5.7	+4	+2	n/c
RA/OA	Increased pain, requested alternative therapy — already on DMARD, NSAID discontinued due to rash: DMARD changed, NSAID to be reintroduced cautiously	-20	-10.4	-12	-4	-1
RA	Thrombocytopenia with reduced penicillamine dosage, nose bleeds — on oral steroids and NSAID: Penicillamine discontinued, analgesia changed to co-proxamol	n/c	+0.7	n/c	n/c	n/c
RA	Patient keen to conceive and discontinue DMARD, requested safflower therapy: Penicillamine discontinued, safflower therapy commenced	+20	-2.1	-1	-2	n/c
RA	Marked depression due to RA and recent bereavement — not keen to start DMARD, on NSAID: Hydroxychloroquine commenced and a support group recommended	n/c	-3.3	-4	-2	n/c
RA	Reluctant to restart DMARD, depressed and keen to try alternative therapy: Sulphasalazine restarted and commenced on homoeopathy	+10	+22.2	+21	+7	+1
RA/OA	Patient requested to try alternative therapy — on gold injection/NSAID: Existing therapy continued with a trial course of alternative therapy	+30	-5.4	-3	-3	+2
RA	Patient requested improved pain relief and a change in DMARD: Therapy changed from sulphasalazine to penicillamine	n/c	-30.1	-21	-9	-2
RA*	Awaiting hip surgery, requesting homoeopathy, taking co-dydramol: No change in analgesia, surgery performed and homoeopathy started	-40	-2.7	-1	-1	-1
RA/OA/gout*	Increased pain, inappropriate allopurinol therapy: No change was made to medication	+30	+1.1	+1	n/c	n/c
Back pain	Increased pain, requesting alternative therapy, on co-proxamol: Physiotherapy given, co-proxamol changed to dihydrocodeine	-30	-3.9	-4	n/c	-1
RA/OA	Increased RA and GI pain, on NSAID, previous GI history: Omeprazole initiated — no ulcer, low dose ibuprofen commenced	-20	-0.5	-1	-1	n/c
OA	Poor pain control, required physiotherapy: Referred to practice physiotherapist	-30	-29.7	-32	-8	-1

OA = osteoarthritis; RA = rheumatoid arthritis; - = decrease in pain scores at interview 2; + = increase in pain scores at interview 2; n/c = no change in pain scores at interview 2; \*GP did not fully implement pharmacist's recommendations in these patients

highly correlated with each other ( $r^2=0.941-0.960$ ,  $P<0.001$ ), although the VAS scores and the PPI scores were less well correlated with each other and with the other three pain measures ( $r^2=0.168-0.476$ ,  $P<0.001$ ).

**Patients with poor outcomes** Twenty-eight (29 per cent) patients had poor outcomes fulfilling one or more of the pre-set criteria. Six had poor pain control in terms of VAS average scores greater than 75mm, five were at high risk of or had developed side effects, 14 were generally dis-

satisfied with their treatment and five specifically requested alternative management. Twenty-one of the 28 had RA with or without OA, but there was no significant difference in frequency of poor outcomes between diagnostic groups. In these 28, both expectations of pain relief and the mean VAS pain scores and pain indices from the MPQ were high compared with those of patients with satisfactory outcomes at interview 1 (Table 1). The six with poor pain control (VAS for average pain greater than 75 per cent) also had higher pain indices as measured by the MPQ.

**Action taken by pharmacist** Suggestions for changing therapy were discussed with the GPs for 24 of the 28 patients by the study pharmacist. The remaining four required surgical management rather than changes to medication. Twelve further patients were referred to their GP because of inappropriate or duplicated therapy (13 problems), despite not having poor outcomes. In addition, advice was given to 59 patients by the pharmacist, the purpose being to improve efficacy of prescribed therapy (28 cases), to improve compliance (24 cases), to minimise adverse effects (28 cases) or to improve knowledge of medicines (24 cases) or disease states (11 cases).

Ten of the 24 who required follow-up to assess the outcome of pharmaceutical intervention refused, were unavailable (seven) and too sick (three) for re-interview within the study period. The average pain scores for the 14 remaining patients before and after intervention are shown in Table 1. On follow-up, changes to therapy had been made in 12 cases, most being in line with the pharmacist's recommendations (Table 2). Pain scores (VAS, PRI[S] or PRI[R] scores) decreased in nine of these patients.

## **Discussion**

Evidence-based guidelines are available for the management of patients with chronic pain associated with RA, OA and back pain.<sup>19-21</sup> However, many patients in this study were receiving treatment which was not in line with these guidelines. Only half of the patients who were receiving regular prescribed medication for these conditions were very or completely satisfied with their therapy. This was reflected in a high use of non-prescription analgesics (in 26 per cent of patients) and alternative therapies (in 27 per cent), particularly in patients with RA, and in poor pain scores measured using standard techniques.

Other workers have also found that patients are increasingly buying non-prescription analgesics in addition to, or in preference to, prescribed analgesics<sup>7,22,23</sup> or using alternative therapies,<sup>5</sup> suggesting that pain relief and/or patient satisfaction is less than optimal. The results obtained here confirm this suggestion. Patients with chronic pain who are referred to pain clinics often under-report their consumption of analgesics and have problems associated with inappropriate use of medicines, side effects, interactions and dependency on analgesics.<sup>24,25</sup> Conversely, patients with RA often under-treat their pain.<sup>23</sup> There is thus potential for pharmacist input into the management of these patients. A very high proportion of patients in this study claimed to have experienced side effects, yet there was also duplication of therapy in many cases, which is of concern. In addition, many patients reported they were following a different regimen from that documented in their medical

records, which does not assist the review process and reduces the likelihood of poor pain control being recorded and being adequately managed. A further difficulty for medication review was the lack of information in the general practice records concerning monitoring of therapy. Although this information may have been contained in hospital records, evidence of monitoring having been carried out was scant. Explicit shared care schemes could help to address these problems.

NSAIDs are one of the groups of medicines identified as being over-prescribed in the UK.<sup>9</sup> The elderly, in particular, are at increased risk of gastrointestinal adverse effects and renal impairment, yet the elderly are often prescribed these medicines for OA<sup>5</sup> with little evidence of review. Many patients claim to find benefit from NSAIDs,<sup>5</sup> but require protection from their adverse effects.<sup>26</sup> In this study, four patients were found to be taking two oral NSAIDs concurrently, of whom three experienced gastrointestinal side effects and were referred to the GP, and many were prescribed these drugs for osteoarthritis with no evidence of inflammation identifiable at the time of interview.

Despite extensive use of analgesics and other therapies, pain relief was less than optimal in a substantial proportion of patients, with 29 per cent of patients requiring referral to their GP and 61 per cent requiring advice. The pharmacist was able to provide information to optimise therapy in a high number of patients who did not require prescription changes, despite patients generally having a good basic knowledge of their medicines. Many of these patients had reduced their analgesic consumption and were not using their medicines regularly to obtain maximum benefit. A further 12 patients required referral because of inappropriate therapy. Thus the study demonstrates the potential value of pharmacist input into managing pain therapy whether or not patient outcomes were satisfactory. This was further illustrated by the improvement in pain scores in a small number of patients who were reinterviewed after therapy changes were made. This could usefully be further investigated using a control group to minimise any effect of a domiciliary visit and including an evaluation of outcomes which is independent of the pharmacist making the interventions.

Patients should be involved in treatment decisions and need to agree on a therapeutic strategy,<sup>27</sup> particularly for conditions in which they are most able to monitor efficacy, such as chronic pain. For this to lead to optimal use of analgesics, patients need to be given information about the potential benefits of regular therapy and how to minimise adverse effects, and told which medicines can usefully be combined and which should not. Other work has shown that patients' knowledge of DMARDs is generally good, but only 54 per cent know why they have to under-

go monitoring and 29 per cent could not name one potential side effect of their DMARD therapy.<sup>13</sup> Despite this, many patients have voiced the desire for more information, particularly about side effects.<sup>28</sup>

This study has demonstrated a need for pharmaceutical input into the management of patients with chronic pain. The use of recognised methods of pain measurement enabled the identification of patients with poor outcomes in terms of pain control, of whom few expressed dissatisfaction with their therapy. Both the McGill pain questionnaire and the visual analogue scales are simple to use and their reliability has previously been shown. (While the MPQ may be limited in its usefulness in community pharmacy practice, a shortened version has been developed<sup>29</sup> which remains to be validated in primary care settings.) Both were sensitive to changes in pain following changes in therapy initiated by the pharmacist. The use of such tools should be encouraged, to enable pharmacists to demonstrate their input into patient care on a routine basis.

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