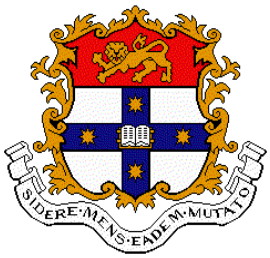
TRAINING COMMUNITY PHARMACISTS IN COGNITIVE-BEHAVIOURAL INTERVENTION STRATEGIES FOR OPTIMISING THE MONITORING OF NON-PRESCRIPTION COMBINATION ANALGESIC PRODUCTS



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B. Sc. (Psychology) Hons

A thesis submitted in fulfilment
of the requirements for the degree of
Doctor of Philosophy
in the Faculty of Science

Department of Psychology
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November, 2000

Abstract

Analgesic products can produce serious side effects. Because potent analgesics are not under medical surveillance but are available to the public without a medical prescription, any attempt to influence consumer behaviour in relation to these products must be via interventions at pharmacist level. The Australian government is now pressuring the pharmacy profession to monitor effectively the use of such non-prescription medication.

The aim of this study was to train community pharmacists on brief intervention strategies for use in a pharmacy setting in relation to combination analgesic products. Focus groups showed that participants had concerns about adopting confrontational counselling styles, as they feared this would antagonise consumers leading to loss of patronage without having an impact on consumer behaviour. This concern was later reinforced by consumer interviews, which showed that a significant proportion of respondents thought that the use of non-prescription analgesics was their responsibility. A protocol for the sales of analgesic products was designed with these issues in mind. The transtheoretical model of change (TTM) and motivational interviewing were selected as theoretical frameworks, as they take into account differences among consumers in motivation and in intention to change behaviour and are congruent with pharmacists' concerns. Consumer-centred intervention strategies were tailored to the individual consumer according to his/her readiness to change. This approach was borrowed from the area of smoking secession in which it has been related to positive clinical outcomes. The assumption was made that TTM-based intervention would also be effective in a pharmacy setting in relation to analgesic products.

In the initial pilot study, community pharmacists who simply attended a workshop in the cognitive-behavioural intervention strategies failed to incorporate the newly acquired skills to their practice and consequently lost their proficiency. In the subsequent pilot study, when the workshop was followed by ongoing on-site training with immediate feedback and coaching through the use of pseudo-patron visits, the investigator was able to shape community pharmacists' practice behaviour in relation to the monitoring of *pharmacist only* analgesic products. The methodology was then refined and in the final study trained

pharmacists were significantly more likely than control pharmacists and baseline to engage in a number of behaviours related to the study intervention. These included handling the sales of *pharmacist only* analgesics themselves, identifying inappropriate use, assessing readiness to change, and delivering an intervention according to the consumer's readiness to change. The results suggested that in pharmacy practice post qualifying therapeutic skill transfer is not achieved by workshop presentation alone. Modelling of the desired behaviour involving reinforcement and feedback is necessary.

Acknowledgments

Thanks are due to my supervisor, McCaughey Professor of Psychology Robert A. Boakes, to my Co-supervisor, Professor of Pharmacy Practice Charlie Benrimoj, and to my Associate Supervisor, Associate Professor of Psychiatry David Kavanagh, for their assistance, advice and friendship for the past five years.

I am grateful too, for the financial assistance provided for this study by Hoechst Marion Roussel, and for the assistance provided by Dr Romano Fois.

PUBLICATIONS RESULTING FROM THIS RESEARCH

Original Papers:

de Almeida Neto, A C, Benrimoj, S I, Gomel M, & Fois, R. Inappropriate Self-Medication Practices: A Pharmacy-Based Intervention. *Journal of Social and Administrative Pharmacy* 1996; 13 (3): 131-138.

de Almeida Neto, A C, Benrimoj, S I, Kavanagh, D J, & Boakes, R A. A pharmacy-based protocol and training program for non-prescription analgesics. *Journal of Social and Administrative Pharmacy* 2000; 17 (3): 183-192.

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de Almeida Neto, A C, Benrimoj, S I, Kavanagh, D J, & Boakes, R A. Shaping Practice Behaviour: A Novel Methodology. *International Journal of Pharmacy Practice* 2001; 9: 203-210.

Unrefereed publications

de Almeida Neto, A C, & Benrimoj, S I. Pharmacy-based intervention strategies. The Australian Journal of Pharmacy 1996; 77: 724.

de Almeida Neto, A C, & Benrimoj, S I. Non-prescription analgesics: a pharmacy perspective. Australian Journal of Pharmacy 1999; 80: 39.

Abstracts

- World Congress of Pharmacy and Pharmaceutical Sciences (Vienna, Austria, 2000). Oral presentation: The pharmaceutical industry as a useful resource for pharmacy education.

- First Annual Postgraduate Research Conference of the Department of Psychology (Sydney, 1999). Oral presentation: Intervention strategies for community pharmacies.

- World Congress of Pharmacy and Pharmaceutical Sciences (Barcelona, Spain, 1999). Poster presentation: Intervention strategies and training programme for pharmacy settings.

- Australasian Pharmaceutical Science Association Conference (Perth, 1999). Poster presentation: Intervention Strategies and Training Programme for Pharmacy.

- Australasian Pharmaceutical Science Association Conference (Hobart, 1998). Poster presentation: Pharmacy-Based Protocol: A Training Mechanism.

- World Congress of Pharmacy and Pharmaceutical Sciences (The Hague, The Netherlands, 1998). Poster presentation: Cognitive-Behavioural intervention for pharmacy setting and training programme.

- The 10th International Social Pharmacy Workshop (Leuven, Belgium, 1998). Oral presentation: Pharmacy-based intervention strategies for optimising the use of non-prescription analgesic products.

- College of Health Sciences and Medical Foundation Research Conference: From Cell to Society (Leura, N.S.W., 1998). Oral presentation: Behaviour change techniques for community pharmacists.

- Australasian Pharmaceutical Science Association Conference (Sydney, 1997). Poster presentation: Pharmacy-based protocols

- Pharmacy Australia Conference (Melbourne, 1996). Poster presentation: Pharmacy-based intervention strategies.

- Australian Pharmaceutical Science Association (Melbourne, 1996). Poster presentation: Intervention strategies for a pharmacy setting.

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CHAPTER ONE

NON-PRESCRIPTION ANALGESIC PRODUCTS IN AUSTRALIA

1.0 Introduction

The Australian Bureau of Statistics in 1989 to 1990 found that more than one-third of Australians consumed analgesic products, of which more than 70 percent were not prescribed (Australian Bureau of Statistics, 1992). This high consumption of analgesic products, of course, is not uniquely Australian. Abbott reports that up to 70% of the population in Western countries uses analgesics regularly (Abbott and Fraser, 1998). Spooner reports that in the United Kingdom, paracetamol was found to be the most widely used medicine, with a consumption of 4,000m tablets annually (Spooner and Harvey, 1993). Similarly, Brune reports that non-prescription analgesics, such as paracetamol, aspirin, ibuprofen, and naproxen sodium, are one of the most widely used classes of drugs in the United States (Brune, 1988).

Despite the large number of persons taking analgesic products, Australian government regulations which require pharmacists to deliver potent analgesics to consumers, allowing for advice on use, have not been enforced (Bowden, 1993). This poses a problem as the abuse of analgesic products in the Australian community seems to be of some concern. Australian surveys have found that up to 45.1% of subpopulations in the Australian community consumed analgesics daily (Australian Bureau of Statistics, 1992) (Carrington-Smith, 1974) (Cullen and Woodings, 1972) (Finnigan and Burry, 1974). It seems that the unrestricted nature of sales of analgesic products has been interpreted by consumers as an indication of the innocuous nature of these products (Coons, Hendricks, and Sheahan, 1980). However, although most analgesic products are remarkably safe, serious side effects can occur when these products are taken inappropriately.

One of the most serious side-effects of analgesic misuse is renal toxicity (Duggan, 1974), which occurs in up to 5% of individuals taking these agents for prolonged periods of time (Whelton and Hamilton, 1991). In patients considered at risk, the incidence of analgesic-induced renal toxicity is approximately 20% (Bush, Shlotzhauer and Imai, 1991). This results in a substantial number of people being affected due to the overall number of

people taking analgesics being high (Whelton, 1995). Following the belief that non-prescription analgesic products are harmless, some consumers have tended not to seek information about these products and have been unaware of usage situations that may be regarded as inappropriate (Christopher, Crooks and Kilgallong, 1979). An unpublished Australian study found that 20% of surveyed consumers of non-prescription analgesics were not using these products according to label specifications (Benrimoj and Chetcuti, 1994). This, again, is not unique to Australia. In Great Britain analgesic products were found to be one of the most abused non-prescription medications (Wills, 1993).

Some non-prescription combination analgesic products contain codeine, which can act on the central nervous system to produce an euphoric effect and thus makes these products even more susceptible to abuse (Ling and Wessen, 1990). Although non-narcotic analgesic products act on the peripheral nervous system, they may also have some activity on the central nervous system (Payne, 1990). In addition, some non-prescription analgesic products are combined with doxylamine, an antihistamine that acts as a sedative helping the person to sleep. This may also increase the risk of misuse (Charupatanapong, 1994). Benrimoj and Chetcuti found that a considerable proportion of consumers of combination analgesics were either using these products as stress management tablets or as sleeping pills (Benrimoj and Chetcuti, 1994). When people are emotionally distressed, they are more likely to engage in substance abuse in order to cope with their distress (Chaney and Roszell, 1985) (DiClemente, Gordon and Gilbertini, 1983) (Marlatt and Gordon, 1980) (Castellani, Wedgeworth, Wootton and Rugle, 1997). It could be the case that some consumers are taking combination analgesic as a substitute for benzodiazepines (Benrimoj and Chetcuti, 1994).

Given the high rate of consumption and the health risks associated with abuse of analgesic products, there is a good basis for training community pharmacists on pharmacy-based interventions specific to these products. However, before examining this issue it is necessary to review in more detail the potential problems associated with self-medication of analgesic products, the availability of these products in Australia, current patterns of analgesic use and the monitoring of these products in Australia.

1.1 Types of non-prescription analgesics

Table 1.1 describes 3 groups of non-prescription analgesics available from a community pharmacy in Australia:

Table 1.1. Non-prescription analgesics available in community pharmacies

a. Single ingredient analgesics:	· paracetamol · aspirin · ibuprofen · naproxen · mefenamic acid
b. Combination analgesics:	· paracetamol and codeine · aspirin and codeine
c. Combination analgesics containing codeine and an antihistamine:	· paracetamol, codeine and doxylamine

SINGLE INGREDIENT ANALGESICS

1.2 NSAID (non-steroidal anti-inflammatory drug)

The antipyretic properties of willow bark have been known for centuries and Salicin, the active ingredient of the bark, was first isolated between 1826 and 1829 by Italian, German and French scientists (Edner and Everts, 1998). Acetylsalicylic acid (aspirin) was derived from salicin and was first introduced into medicine by Hoffman in 1897 (Pinn, 1998). By the turn of the century it had gained worldwide recognition in the treatment of pain and rheumatological disorders (Pinn, 1998). Reports on adverse events relating to gastrointestinal intolerance and bleeding appeared early, but were largely neglected until the 1950s (Edner and Everts, 1998). Today, salicylates are still widely used as analgesic, antipyretic and anti-inflammatory drugs. Aspirin is the original NSAID (non-steroidal anti-

inflammatory drug) and in the last 30 years there have been numerous new drugs developed using it as a standard. NSAIDs are used clinically for the analgesic, anti-inflammatory, anti-platelet and antipyretic actions. They are the most widely used class of drugs in medical history and have revolutionised the treatment of musculoskeletal and other inflammatory disorders (Harrison and Benrimoj, 1995).

1.3 Paracetamol

Paracetamol has been widely used as an analgesic and antipyretic for almost half a century and is now recommended by many as the first-line medication of choice for relieving mild-to-moderate pain and fever in both children and adults. When used in recommended doses, it has few side effects and is well tolerated (Zacharias and Watts, 1998) (Elliott, 1993).

1.4 Opioid analgesics (eg. codeine)

The ancient Greeks used as an analgesic and as a social drug the liquid extract of the opium poppy (Papaver Somniferum) at least as far back as the third century BC (Nencini, 1997). However, the psychological effects of opium may have been known to civilisations existing way before this time. It is known that the opium poppy was imported from Cyprus to Egypt in the early part of the 18^{th} Dynasty (1551 – 1436 BC) (Nunn, 1989). However, this is not accepted by Bisset, Bruhn, Curto, Holmstedt, Nyman and Zenk (1994). The pure alkaloids of the opium poppy including morphine and codeine, were first extracted in Europe in the early nineteenth (Haller, 1989). By the middle of the nineteenth century the medical use of opium alkaloids was widespread (Haller, 1989).

Today the term "opioid analgesic" includes all drugs that have pharmacological effects similar to those of morphine. This includes the original alkaloids derived from the poppy and many synthetic derivatives. Opioid analgesics display a wide range of effects, including analgesia, drowsiness, mood changes, respiratory depression, decreased gastro-intestinal (GIT) motility, nausea and vomiting. Various members of this class display analgesia to different degrees. Morphine is the standard by which other opioid analgesics are measured.

Codeine is often classified as the "weak opioid analgesic". It is sold in Australia without a medical prescription in combination with other analgesics. As a single agent, codeine is not available from community pharmacies without medical prescription.

1.5 Efficacy

The differences between analgesics lie mainly in their efficacy in different applications, indications for use and in special precautions for use in particular patients. It is important to note that different types of pain respond better to different sorts of analgesics. Pain with an inflammatory component responds well to aspirin or the other NSAIDS, whilst opioid analgesics are more effective for visceral pain.

Aspirin, ibuprofen and naproxen inhibit the synthesis of prostaglandins and are useful anti-inflammatory agents. Therefore they can be very effective analgesics in acute pain states associated with prostaglandins and inflammation (eg. sporting injuries). They are also useful in period pain due to their inhibitory action on prostaglandins.

Paracetamol does not have a strong anti-prostaglandin sensitivity and is not an anti-inflammatory agent. It is not as effective in the treatment of sporting injuries associated with inflammation or in the treatment of period pain.

1.6 Precautions

Aspirin, ibuprofen and naproxen have been associated with gastro-intestinal (GIT) damage and haemorrhage, and are contraindicated in-patients with GIT bleeding disorders. Aspirin, ibuprofen and naproxen have been associated with increasing bleeding times. A single 325 mg dose of aspirin can prolong bleeding time for five days after its ingestion. This is because aspirin irreversibly binds to the cyclo-oxygenase enzyme in the platelets. Aspirin should be discontinued at least seven days before surgery. Naproxen has less effect on platelets and bleeding time than aspirin. The effects are reported to have ceased 96 hours after a single dose. Ibuprofen has a transient effect on bleeding time (less than 24 hours).

These effects are important when considering the use of non-prescription NSAIDS in dental pain. Dental pain may require dental surgery and prolongation of bleeding time is undesirable. Aspirin should not be used for treatment of dental pain. Ibuprofen is the least

likely non-prescription NSAID to cause prolongation of bleeding time after dental surgery. Aspirin, ibuprofen and naproxen should be used with caution in asthmatic patients as they can induce asthmatic attacks in susceptible patients. Aspirin is contra-indicated for use in children due to the increased risk of Reyes syndrome.

1.7 Indications of use

The five active ingredients are approved for similar indications in Australia (Table 1.2).

Table 1.2. Indications for use of simple non-prescription Analgesics

Paracetamol	**Aspirin**	**Ibuprofen**	**Naproxen**	**Mefenamic Acid**
· pain · fever · headache · migraine · muscular aches · rheumatic pain · neuralgia · period pain · teething · colds and flu	· pain · fever · headache · migraine · muscular aches · rheumatic pain · neuralgia · period pain · toothache · colds and flu	· headache · dental pain · acute inflammatory pain · period pain · common cold · arthritis	· migraine · acute inflammatory pain states · period pain · rheumatic pain	· period pain short term relief of mild to moderate pain such as dental and soft tissue pain

COMBINATION ANALGESICS

1.8 An overview on combination analgesics

Combination analgesics are formulations that contain more than one analgesic in a single dosage unit. They are very frequently used as both prescription and non-prescription medications. It is necessary that such a combination product be devised along rational guidelines. That is, there should be a therapeutic basis for the inclusion of more than one analgesic into a particular tablet, such as different mechanisms of action, to include drugs to treat other symptoms or disease, to increase patient compliance, etc. There should also be controlled clinical trials to demonstrate that the product is clinically useful.

Combining analgesic products can at times cause problems, such as patients may receive drugs that are unnecessary, certain ingredients may be included at sub-therapeutic doses, the half-lives of the active ingredients may be mismatched, there may be difficulties identifying which analgesic is causing adverse effects, etc. Compound products currently available in Australia are listed in Table 1.3 and the properties of their main constituents are summarised in Table 1.4.

1.9 Analgesic combinations containing codeine

The combination of analgesic/antipyretic analgesics such as paracetamol, aspirin or ibuprofen with codeine has a sound rational basis. They have different mechanisms of action and are thus likely to address the problem of pain from different angles. They also have similar half-lives and the problem of accumulation is not an issue. In general, an additive effect is achieved when these drugs are combined (Harrison and Benrimoj, 1995).

The problem with the codeine-containing non-prescription products is that the dose of codeine (8 to 21 mg) has not been shown to be therapeutically effective (Giles, Hill, Sheperd, Stwart and Pickvance, 1986): 30 mg of codeine has been shown to be approximately equianalgesic to 650 mg of aspirin or 1000 mg of paracetamol and in single dose studies it has been shown to be an effective adjunct to paracetamol, ie. it provides a significant increase in analgesia.

However, there is insufficient evidence from clinical trials to show that a dose of less than 30 mg of codeine in combination with therapeutic doses of non-opioid analgesics (paracetamol 1000 mg or aspirin 600 mg) gives significantly more analgesia than the non-opioid analgesics alone (Frame, Fisher, Pickvance and Skene, 1986) (Klein, Barworth, Birkenfeld, Dyde, Rehm, Toberich and Cierpka, 1986). Furthermore, it has not been established that a dose of less than 30 mg of codeine produces significantly more analgesia than a placebo in a single dose (Klein et al., 1986).

Table 1.3. Some non-prescription combination analgesic products available in Australia (1999) excluding home brands

Products Containing:	Ingredients
Paracetamol and codeine	
Panadeine	Paracetamol 500mg, codeine 8mg
Codalgin	Paracetamol 500mg, codeine 8mg
Panamax Co	Paracetamol 500mg, codeine 8mg
Codral Pain Relief	Paracetamol 500mg, codeine 8mg
Codapane	Paracetamol 500mg, codeine 8mg
Mersyndol®Daystrength	Paracetamol 450mg, codeine 9.75mg
Dymadon Co	Paracetamol 500mg, codeine 8mg
Aspirin and codeine	
Veganin	Aspirin 325mg, codeine 8mg
Codiphen	Aspirin 250mg, codeine 9mg
Aspalgin	Aspirin 300mg, codeine 8mg
Codis Solcode	Aspirin 500mg, codeine 8mg
Disprin Forte	Aspirin 500mg, codeine 9.5mg
Decrin Powders	Aspirin 650mg, codeine 10mg
Aspirin and dihydrocodeine	
Codox	Aspirin 300mg, dihydrocodeine 7.5mg
Paracetamol, codeine and an antihistamine	
Panalgesic	Paracetamol 500mg, codeine 8mg, doxylamine succinate 5mg
Fiorinal	Paracetamol 500mg, codeine 8mg, doxylamine succinate 5mg
Codral Tension Headache	Paracetamol 500mg, codeine 8mg, doxylamine succinate 5mg
Fiorinal Fiorinal-Dental	Paracetamol 500mg, codeine 10mg, doxylamine succinate 2mg
Mersyndol	Paracetamol 450mg, codeine 9.75mg, doxylamine succinate 5mg
Dolased	Paracetamol 500mg, codeine 10mg, doxylamine succinate 5.1mg
Paralieve Plus	Paracetamol 500mg, codeine 9.6mg, doxylamine succinate 5.1mg
Chemadeine Plus	Paracetamol 450mg, codeine 9.75mg, doxylamine succinate 5.1mg
Rapideine Plus	Paracetamol 450mg, codeine 9.75mg, doxylamine succinate 5mg

Table 1.4. Overview of pharmacology of compounds contained in non-prescription analgesics

Compound	**Usual OTC dose available**	**Onset of action**	**Duration of analgesic** action	**Half life**
Aspirin	300 to 650 rng q3-4 h	15 to 30 min	4 hours	2.5 to 4 hours
Codeine	8 to 21 mg q3-4 h	30 to 60 rnin	4 hours	2.5 to 4 hours
Doxylanine	2 mg to 10 mg	30 min	3 to 8 hours	10 hours
Ibuprofen	200 to 400 mg q4h	15 to 30 min	4 to 6 hours	1.5 to 2 hours
Mefenamic acid	500 to 1000 mg tds	60 min	6 to 8 hours	2 hours
Naproxen	275 to 550 mg	60 min	7 hours	13 hours
Paracetamol	500 to 1000 mg	15 to 30 min	4 hours	2 to 4 hours

Another potential problem with non-prescription codeine-containing analgesics is their potential to cause constipation. Codeine, being an opioid analgesic, can reduce gastric motility, prolong gastric emptying time, increase the tone of the anal sphincter, and reduce the normal sensory stimuli to defecation, resulting in constipation (Mikus, Trausch, Rodewald, Hofmann, Richter, Gramatte, and Eichelbaum, 1997). It requires significantly less opioid analgesic to affect the gut and produce constipation than it does to produce analgesia (Harrison and Benrimoj, 1995).

1.10 Analgesic combinations containing codeine and an antihistamine (doxylamine)

Doxylamine succinate is an antihistamine with a pronounced sedative effect. The onset of action is 30 minutes and the effects last for 3 to 8 hours. It is available in Australia in combination with opioid and non-opioid analgesics (e.g. *Mersyndol,*

Fiorinal, Panalgesic). Doxylamine itself has no direct analgesic effect. It is normally combined with other analgesics because of its sedative and anti-nauseant properties. The sedative effect of doxylamine is reported to be useful in relieving pain in patients with anxiety or stress. However, drowsiness can also be an unwanted side effect from this medication. In many cases the use of a simple analgesic may be preferable to provide analgesia without drowsiness.

Doxylamine, paracetamol and codeine combinations (eg. *Fiorinal, Mersyndol)* contain products with differing half-lives. The recommended dosing interval is every 4 to 6 hours. This is because the analgesic effects of the paracetamol and the codeine have ceased. Doxylamine succinate, however, is still present and active in the body. By taking a second dose the effects of doxylarnine succinate become additive and patients may experience more sedation with subsequent doses (Harrison and Benrimoj, 1995). From the point of view of half-life this is not a rational dosing regime.

1.11 The toxicity of analgesic products

Perhaps the Greek word pharmakon best conceptualises the meaning of toxicity in respect to drugs, in that it carries simultaneously the notions of medicine and poison. In therapeutics, a drug typically produces numerous effects, but usually only one is sought as the primary treatment, the other effects being referred to as undesirable or side effects of that drug for that particular therapeutic indication. The toxic effects of drugs and their incidence and seriousness are related, at least over some range, to the concentration of the toxic chemical in the body (Klaassen, 1990). The words of Paracelsus (1493-1541) are worth recalling: "All substances are poisons; there is none which is not a poison. The right dose differentiates a poison from a remedy" (O'Brien and Kursch, 1987). Drug toxicity may therefore result from drug usage contexts ranging from medical supervision to abuse or suicide attempt. In this section, the nature of analgesic-induced disease is explored.

THE ADVERSE EFFECTS OF ANALGESIC PRODUCTS

1.12 Analgesic nephropathy

Analgesic nephropathy is a form of renal disease characterised by renal papillary necrosis (RPN) and chronic interstitial nephritis caused by prolonged and excessive consumption of analgesic mixtures. Analgesic nephropathy patients who continue to abuse analgesics have progressive renal failure, and renal function tends to improve or stabilise when patients stop taking analgesics (Steele and Edwards, 1971) (Smith, Rabkin, Stables, Thatcher and Eales, 1975) yet irreversible renal impairment may occur (Whelton and Hamilton, 1991) (Jick and Derby, 1993) (Murray and Brater, 1993).

Experimental RPN is readily produced in laboratory animals by most nonsteroidal anti-inflammatory analgesics, and the pathological and functional changes seen are identical to those in clinical analgesic nephropathy (Abel, 1971) (Kincaid-Smith, 1978) (Nanra, 1983).

1.13 Analgesic syndrome

The renal disease associated with analgesic abuse is part of a much wider clinical syndrome – the analgesic syndrome. The other aspects of the analgesic syndrome are neuropsychiatric disorders, cardiovascular and cerebrovascular complications, gastrointestinal disorders (predominantly gastric ulcer and its complications) anaemia, gonadal and pregnancy-related problems, pigmentation, and premature aging (Duggan, 1974) (Schreiner, McAnnaly and Winchester, 1981).

1.14 Self-poisoning

"In bygone days, arsenic was used as a tonic, albeit of doubtful efficacy, and as a successful murder weapon. Today, many of our important therapeutic agents are poisons, with the only distinction between efficacy and poisoning being the dose" (Pond, 1995). It is commonly known that overdose of non-prescription analgesics can be life threatening. With paracetamol, generally more than 15 g can cause acute hepatic failure or renal failure (Elliott, 1993). In the case of overdose of NSAIDs (non-steroidal anti-inflammatory drugs) serious toxicity occurs including hypotension, apnoea, coma,

metabolic acidosis and renal failure (Smolinske, Hall, Vandenberg, Spoerke and McBride, 1990).

Deliberate self-poisoning, accounts for about 5% of all admissions to Australian hospitals, resulting in significant morbidity and use of resources (Buckley, Whyte, Dawson, McManus and Ferguson, 1995). However, the overall rate of self-poisoning is not known as surveys of self-harm suggest that a significant proportion (5% - 15%) of poisonings do not present for medical care (Platt, Bille-Brahe and Kerkhof, 1992). In an investigation of 1969 hospital admissions after deliberate self-poisoning in the Newcastle area (Australia), Buckley et al. (1995) found that analgesics were one of the most frequently ingested substances leading to morbidity and mortality. In England, a study comparing the number and type of substances taken in deliberate self-poisoning, found that non-prescription analgesics, minor tranquillisers and antidepressants accounted for about 70% of substances taken, irrespective of outcome. Among self-poisonings with a single substance, antidepressants and paracetamol-opiate combinations were over-represented in fatal-outcome cases (Neeleman and Wessely, 1997).

1.15 Analgesic headache

Analgesic headache has been described as headache occurring during daily intake of medication for symptomatic headache (Diener, Tfelt-Hansen and welch, 1993). It occurs when drugs given for the treatment of headache aggravate symptoms (Symon, 1998). It has been found that ergotamine, narcotics, and even mild analgesics may all aggravate tension headache and migraine when taken daily (Spooner and Harvey, 1993). The condition occurs daily or almost daily, but disappears within a few weeks after withdrawal of medication (Diener and Tfelt-Hansen, 1993).

1.16 Drug interactions

Drug interaction can be defined as "the pharmacological or clinical response to the administration of a drug combination different from that anticipated from the known effects of the two agents when given alone" (Jankel and Fitterman, 1993). A drug interaction is said to occur whenever the therapeutic, prophylactic, or diagnostic action of a drug is altered by the presence of a second chemical in the body (Cadieux, 1989).

Thus one drug may alter the intensity of pharmacological effects of another drug given concurrently. The net result may be enhanced or diminished effects of one or both of the drugs or the appearance of a new effect, which may be idiosyncratic, that is, not seen with either drug alone (Cadieux, 1989) (Jankel and Fitterman, 1993). See Appendix 1 for drug drug interactions related to analgesics.

1.17 Analgesic misuse in the elderly

In Australia, 40% of the elderly use analgesics (Mant, Whicker and Kwok, 1992). Other community-based Australian data have shown that 29% of elderly men and 44% of elderly women use two or more concurrent non-prescription medications (Simons, Tett, Lauchlan, McCallum, Freidlander and Powell, 1992). NSAIDS, taken on a regular basis by more than 20 per cent of the population aged over 65 years, are one of the biggest causes of drug-induced hospitalisation in Australia due to their role in causing serious gastrointestinal damage (Pharmacy Guild of Australia, 1999). In the United Kingdom, a study found that the elderly were at most risk of problems as they took analgesics more often, for longer periods, and in combination with a greater number of prescribed medicines (Whitaker, Wilson, Bargh, Chapman and Dudley, 1995). They were least likely to seek advice from a pharmacist. In the United States, Hershman and colleagues found in a survey of 488 elderly volunteers that the most commonly used classes of medications were cardiovascular drugs and analgesics (Hershman, Simonoff, Frishman, Paston and Aronson, 1995). Similarly, in rural Pennsylvania, Stoehr and colleagues examined self-reported use of non-prescription medications in the elderly (n=1059) and found that analgesics was the non-prescription category used the most (66.3% overall) (Stoehr, Ganguli, Seaberg, Echment and Belle, 1997).

1.18 The classification of drugs and poisons in Australia

Each state and territory in Australia has its own legislative framework and processes to determine the scheduling or classification of medicines and poisons (Matthews, 1989). Each Schedule has restrictions on the sale and supply of its members. The National Drugs and Poisons Schedule Committee (NDPSC) is a Standing Committee of the Australian Health Ministers' Advisory Council (AHMAC). The Decisions of the NDPSC in relation to the Standard for the Uniform Scheduling of Drugs and Poisons

(SUSDP) have no force in the Commonwealth law but are recommended for incorporation into State and Territory legislation regarding drugs and poisons. The SUSDP has published descriptions of each Schedule (AHMAC, 1997). However, only the Schedules of medicines that are available from community pharmacies will be discussed. Unscheduled and Schedules 2 and 3 products do not required a medical prescription for their sales. Unschedule products are also available to the public outside a community pharmacy like in supermarkets for instance. Schedule 2 products are also called *pharmacy only* products as their availability is restricted to pharmacy only. Schedule 3 products (*pharmacist only* medication) are only available to the public from community pharmacies and legislation restricts their sales by pharmacists only. Schedule 4 products are those whose sales require a medical prescription. Below there is a more detail description of the schedules of medicines that are available from a community pharmacy (AHMAC, 1997).

Schedule 2

Description

Schedule 2 poisons are substances or preparations for therapeutic use, which are substantially safe in use, but where advice or counselling is available if necessary for minor ailments or symptoms, which can be easily recognised by the consumer and do not require medical diagnosis or management.

Purpose

To allow effective drugs or preparations, for which pharmacist advice on use may be required by the consumer, to be available to the public, without a prescription, from a pharmacy or where a pharmacy service is not available, from a licensed person.

Assessment Factors

Characteristics of the drug

The drug or preparation in normal use should have the following characteristics: suitability for self treatment of a minor ailment or symptom capable of being monitored by the consumer; extremely low abuse potential; low potential for harm from inappropriate use; low or well characterised incidence of adverse effects or side effects,

and contra-indications for which advice or counselling is available; only minor or well characterised interactions with commonly used substances or food for which advice or counselling is available; a wide Therapeutic Index; low risk of masking a serious disease; and low risk of compromising medical management of a disease.

Indications for use

The ailment or symptom(s) to be treated should: not require ongoing or close medical diagnosis or management; be easily recognised by the consumer; be amenable to short term treatment; or be capable of being monitored and self managed by the consumer, with advice and counselling if necessary.

Schedule 3

Description

Schedule 3 poisons are substances and preparations for therapeutic use which are substantially safe in use but require professional advice or counselling by a pharmacist, and the use of which requires pharmacist advice, management or monitoring. These substances should for ailments or symptoms which can be identified by the consumer and verified by a pharmacist and do not require medical diagnosis or only require initial medical diagnosis, and do not require close medical management.

Purpose

To allow effective drugs or preparations that require professional advice on use to be made available to the public from a pharmacist without a prescription.

Assessment Factors

Characteristics of the Drug

The drug or preparation, in normal use, should have the following characteristics: low abuse potential; low potential for harm from inappropriate use; low incidence of severe adverse effects or side effects which are likely to require medical intervention; only interactions with commonly used drugs or food, which can be managed by a pharmacist; medium to wide Therapeutic Index; the risk of masking a serious disease or

compromising medical management of a disease can be managed by a pharmacist; only contra-indications that can be dealt with by a pharmacist; and safety in use with counselling by a pharmacist.

***Indications for* use**

The ailment or symptom(s) to be treated should: not require close medical management or direct supervision by a doctor; be easily recognised with assistance from a pharmacist; and be amenable to short term treatment or capable of being monitored by the consumer with assistance from a pharmacist.

Schedule 4

Description

Schedule 4 poisons are substances and preparations for therapeutic use. The use of these substances requires professional medical, veterinary or dental management or monitoring which are for ailments or symptoms that require professional medical, veterinary or dental diagnosis or management, the safety or efficacy of which may require further evaluation and substances which are new.

Purpose

To make available drugs or preparations the use, supply and prescribing of which should be by registered medical, veterinary or dental practitioners and supply of which by a pharmacist should be on prescription.

Assessment Factors

A drug or preparation may be classified as a Schedule 4 poison if: it has low to moderate abuse potential; its use may produce serious side-effects; it has a narrow Therapeutic Index; its use requires professional medical, veterinary or dental management or monitoring; its activity, safety, efficacy or side-effects requires further evaluation.

Indications for Use

The ailment or symptom(s) it is used for requires professional medical veterinary or dental diagnosis, management or monitoring.

1.19 The scheduling of analgesic products

In order of most restricted to least restricted, community pharmacists deal predominantly with analgesics included in Schedules, 2, 3 and 4. Schedule 4 analgesics are those which must be supplied on a prescription from a medical, dental or veterinary practitioner (eg. Mersyndol Forte®, Panadeine Forte®), while non-prescription analgesics may be in either Schedule 3 (eg. Mersyndol®, Dollased®) or Schedule 2 (eg. Panadeine®, Nurofen®). Analgesics in Schedule 3 (pharmacist only) or Schedule 2 (pharmacy only) can only be obtained from pharmacies. Analgesic products may also be classified into two or more Schedules as the quantity for sale, strength of preparation, dose, or formulation changes. For example, paracetamol tablets are unscheduled in packs containing not more than 25 tablets and in any other circumstances they are Schedule 2. Ibuprofen 200mg tablets are classified as Schedule 3 in packs containing not more than 50 tablets, however, in packs containing more than 50 tablets or 400mg tablets are available only on prescription (Schedule 4).

Analgesic products containing doxylamine and some analgesic products containing codeine are placed in the Schedule 3 category. The SUSDP guidelines for scheduling a product containing these substances in the Schedule 3 category are as follows (AHMAC, 1997):

Codeine: "when compound with aspirin, paracetamol or any one of their derivatives and no other analgesic substance, in divided preparations containing 10 mg or less of codeine per dosage unit and with a recommended dose not exceeding 15 mg of codeine (equal to 19 mg of Codeine Phosphate), except when included in Schedule 2".

Doxylamine: "in oral preparations except when included in Schedule 2".

1.20 Counselling

As seen above, the 1997 Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) described Schedule 3 as “Substances and preparations for therapeutic use

which are substantially safe in use, but require professional advice or counselling by a pharmacist" (AHMAC, 1997). The national recommendations allow the pharmacist to give either verbal or written advice. These recommendations are open to individual interpretation and pharmacists are able to use their professional discretion to determine the type of advice they feel is necessary to provide at the time of sale. This seems a more appropriate method, as each counselling situation should be considered separately, and may require varying depths of discussion on the different issues regarding the use of the medicine.

1.21 Pharmacists' adherence to counselling guidelines

Pharmacists in the past have approached these Regulations more as a legal reminder to pharmacists about their professional responsibilities (Bowden, 1993). However, with an increasing number of medicines being rescheduled from prescription only (Schedule 4) to pharmacist only (Schedule 3), pharmacists are required to assume a more significant counselling and medication-tracking role (Morgan and Cohen, 1995). As reasonably potent drugs are no longer under medical surveillance, governments are now pressuring the pharmacy profession to monitor the use of non-prescription medication. The Industry Commission into the Pharmaceutical Industry recommended that the current scheduling for Pharmacy (Schedule-2) and Pharmacist Only (Schedule-3) medication should only be retained, "pending further research into the role of pharmacist counselling in ensuring improved health outcomes and the monitoring of the extent of such counselling" (Industry Commission Report, 1996). Indeed, the Government is now monitoring the extent of pharmacist counselling through the Pharmaceutical Benefits Branch of the Department of Health and Family Services (AHMAC, 1997).

1.22 Summary

Although analgesic products available over the counter are safe the abuse and misuse of these products can lead to serious adverse events. When taken in large dosage, analgesic products can be fatal leading to hepatic failure. In Australia, analgesic products containing codeine and doxylamine are in the Schedule 3 category whose sale is restricted to pharmacists. These Schedule 3 analgesics are susceptible to abuse due to their sedative effect and narcotic properties. There is a complex set of legal restrictions

associated with the sale and supply of these medicines. These encompass the supply of the medicine to the client and counselling. There has been no study of whether or not such restrictions achieve their goal or the impact that they have on pharmacists' professional practice. Pharmacists in the past have approached legal restrictions as a reminder of their duties (Bowden, 1993). However, governments are now pressuring the pharmacy profession to monitor the use of non-prescription medication. This has introduced pharmacy to a phase in which pharmacists would profit from training on behavioural interventions. The aim of the current study is to train community pharmacists on a cognitive/behavioural intervention specific for analgesic products.

CHAPTER TWO

THE CONCEPT OF READINESS TO CHANGE

2.0 Introduction

The need for counselling techniques in the area of pharmacy practice in relation to *pharmacist only analgesics* was discussed in the previous chapter. The aim of this chapter was to identify counselling techniques that could be used in a pharmacy setting to optimise the use of these products.

A consumer centred intervention was developed allowing community pharmacists to tailor intervention strategies to the individual consumer according to his/her level of motivation to change dysfunctional behaviour in relation to *pharmacist only* analgesic products. The Transtheoretical Model of Change (TTM) proposed by Prochaska and DiClemente (Prochaska and DiClemente, 1986) and motivational interviewing (MI) developed by Miller and Rollnick (Miller, 1983) (Miller and Rollnick, 1991) provided the conceptual framework for the development of this intervention. Both, TTM and MI were developed in the area of addiction research and are based on the concept of readiness to change, advocating that people at different levels of readiness to change a particular health behaviour would need different types of help. Before describing the intervention strategies the TTM and MI are discussed in this chapter.

2.1 Background of the TTM

Because research has failed to find consistent differences in the effectiveness of various kinds of therapies (Luborsky, Singer and Green, 1975) (Parloff, 1979), the assumption was made that effective therapies shared commonalities. In the 1970s, professionals in the area of addictive behaviour engaged in what was known as the "combination debate" which aimed to integrate different systems of psychotherapy (Davidson, 1992). This movement was reinforced by a seminal paper on commonalities across different therapeutic orientations, presented by Goldfried in 1980 (Goldfried, 1980). Efforts were then made to create treatments for addictive behaviours which met competing demands rather than sticking to parochial approaches to therapy (Prochaska, 1984). To achieve this aim, clinicians tried to gain a better understanding of how

people change, from the time someone becomes aware a problem exists to the point a problem no longer exists.

It was in this theoretical climate that Prochaska and DiClemente developed what they named the transtheoretical model of change (TTM) (Prochaska and DiClemente, 1984). A set of behaviour change techniques (processes of change) were selected from different theories, which explain the term *transtheoretical,* to be used in accordance with the patient's level of readiness to change. The model recognises that not everybody who engages in dysfunctional behaviours is ready to change. Individuals can be located anywhere on a continuum of change (stages of change) which starts with a state of being unaware or unwilling to change, then goes to contemplating change, preparing to change, taking action, and finally maintaining behaviour change. Prochaska and DiClemente argued that most treatments for addictive behaviours only catered for those who are ready to change and do not take into account the covert changes that take place before a person changes overtly. The TTM has three organising constructs: stages of change, the processes of change, and the levels of change.

2.2 Stages of change

As seen above, the TTM conceptualises change as a process, not an event, in which individuals go through distinct stages on the way to changing behaviour. DiClemente and Prochaska define the stages of change as "a way of segmenting the process of change" (DiClemente and Prochaska, 1998, p. 4). Five sequential stages have been identified, Table 2.1 displays a brief description of the five stages of change of the TTM. Once the interventionist finds out what stage the individual is in, he/she then applies a change technique that is specific for somebody at that level of readiness to change.

DiClemente and Prochaska first described the stages of change in a study conducted in 1982 comparing 29 self-changers with 36 smokers participating in smoking cessation programs. They reported that both, self-changers and therapy-changers, went through four common stages of change as identified by principal component analysis, in the process of quit smoking (Prochaska and DiClemente, 1982). The stages were then identified as precontemplation, contemplation, action, and maintenance (the preparation stage had not been identified yet). In 1983, in a study of 150 general psychiatric outpatients beginning therapy, McConnaughy, Prochaska, and Velicer again found four

reliable and well-defined stages of change, in relation to readiness to undergo psychotherapy: precontemplation, contemplation, action, and maintenance (McConnoghy, Prochaska and Velicer, 1983) as measured by the Stages of Change (SOC) Scales. This finding was then replicated in another study involving 350 psychiatric patients (McConnaughy, Prochaska, Velicer and DiClemente, 1984).

Table 2.1. Brief Description of the Stages of Change (DiClemente and Prochaska, 1998)

Precontemplation	Individuals are either ignorant of the nature and extent of a problem needing to be changed or are unwilling to change the problematic behaviour.
Contemplation	Involves thinking seriously about change and includes a decision-making evaluation of the pros and cons of both the problem behaviour and the change.
Preparation	Represents resolution of the decision-making task and a commitment to a change plan to be implemented in the near term.
Action	During the Action stage the change plan is implemented, active coping is initiated, and the actual behaviour change is made.
Maintenance	If successful action is sustained for a period of three to six months, the individual moves into the maintenance stage, in which behaviour change must become integrated into lifestyle. Once this change becomes completely integrated into the lifestyle, the individual can exit from or terminate this process of change.

In a later formulation of the stages of change model, the contemplation stage was subdivided to create a preparation stage (DiClemente, Prochaska, Fairhurst, Velicer, Velasquez and Rossi, 1991). Prochaska and Velicer et al. (1991) reported having misinterpreted data from principal component analyses in their original work (Prochaska and DiClemente, 1982), which consistently found only four scales. However, in the same study, cluster analyses had identified groups of individuals who scored high on both the contemplation and action scales, i.e. those in the preparation stage.

2.3 The five stages of change

Since 1983 when Prochaska and DiClemente first described the TTM (Prochaska and DiClemente, 1983), the stage aspect of the model has evolved as its key component (DiClemente and Prochaska, 1998). A more comprehensive description of the five stages of change, based on Prochaska, DiClemente and Norcross (1992) is provided below.

1. Precontemplation stage

Precontemplators are described as individuals who have no intention of changing dysfunctional behaviour in the foreseeable future, usually being unaware or underaware of their problems. As G.K. Chesterton cited in Prochaska, DiClemente and Norcross (1992) puts it "It is not the case that they can't see the solution. It is that they can't see the problem" (p.1103). However, those who are close to them are often reported to be well aware that a problem exists. When precontemplators seek help, they often do so due to pressure from others. As Prochaska, DiClemente and Norcross (1992) put it, "they usually feel coerced into changing behaviour by a spouse who threatens to leave, an employer who threatens to dismiss them, parents who threaten to disown them, or courts who threaten to punish them" (p.1103). They may even demonstrate change as long as the pressure is on. Once the pressure is off, they are reported to return quickly to their old ways.

Hallmark

Resistance to recognising or modifying a problem is the hallmark of precontemplation.

Criteria

Individuals who are seriously intending to change the problem behaviour in the near future, typically within the next six months, are categorised as contemplators. Those who are not, are classified as precontemplators.

Measurement items

Questionnaires have been devised to identify an individual's stage of change (McConnaughy, DiClemente, Prochaska and Velicer, 1989) (Miller and Tonigan, 1996) (Rollnick, Heather, Gold and Hall, 1992). Items that are used to identify precontemplation include "As far as I'm concerned, I don't have any problems that need changing" and " I guess I have faults, but there's nothing that I really need to change." (McConnaughy, DiClemente, Prochaska and Velicer, 1989).

2. Contemplation stage

Contemplation is the stage in which individuals recognise that a problem exists and are seriously thinking about changing behaviour, but have not yet made a commitment to take action.

An important aspect of contemplation stage is the weighing of the pros and cons of the problem and the solution to the problem. Velicer et al. (1985) found that one's smoking behaviour is partially based on the relative weight given to the pros and cons of smoking. Their analysis of a measure based on Janis and Mann's (1977) model of decision-making yielded two orthogonal components which were labelled "The pros of smoking" and "The cons of smoking" (Velicer et al., 1985). Also, cross-sectional analysis indicated that measures of decisional balance vary as a function of stage of change. Precontemplators were found to score high on the pros and low on the cons of smoking, whereas long term maintainers scored low on both the pros and cons of smoking. In short, on the one hand there is what the individual perceives as the positive aspects of changing behaviour and on the other the amount of effort, energy, and loss involved in overcoming the problem (Velicer et al., 1985) (DiClemente, 1991) (Prochaska and DiClemente, 1992).

Studies have shown that people can remain in the contemplation stage for long periods of time. For example, Prochaska and DiClemente (1985) followed a group of 200 smokers in the contemplation stage for two years. The modal response of this group was to stay in the contemplation stage for the two years without ever making any significant attempt to change.

Criteria

Individuals who assert they are seriously considering changing the problem behaviour within the next six months are classified as contemplators.

Measurement items

Examples of questionnaire items used to identify contemplators are "I have a problem and I really think I should work on it" and " I've been thinking that I might want to change something about myself" (McConnaughy et al., 1989).

Hallmark

Ambivalence about changing is the hallmark of contemplation.

3. Preparation stage

Usually, individuals who are preparing for action report some minor behavioural changes, such as reducing substance use, for instance (DiClemente, Prochaska, Fairhurst et al., 1991). Although they have made some reductions in their problem behaviours they do not reach criteria for effective action, such as abstinence from substance use. However, they do intend to take action in the near future.

Criteria

The preparation stage of change combines cognitive and behavioural criteria. Individuals in this stage intend to take action within the next month and have usually made a serious attempt at modifying behaviour in the past 12 months.

Measurement items

In questionnaires used to identify the individual's stage of change people in the preparation stage score high on both questions related to contemplation and action (see below for examples of the latter).

Hallmark

Intention to take action in the near future.

4. Action stage

Action is the stage at which individuals modify their behaviour, experiences, or environment to overcome their problems (Prochaska, DiClemente and Norcross, 1992). This stage requires the most overt behaviour change and requires considerable commitment of time and energy. In the action stage behaviour change is most visible and recognised. Prochaska, DiClemente and Norcross (1992) point out that action is not to be equated with change. Changers require requisite work to prepare them for action and much effort to maintain the change following action.

Criteria

Individuals are classified in the action stage if they have sustained change from one day to six months.

Measurement items

Example of questionnaire items that identify individuals in the action stage are "I'm really working hard to change" and "Anyone can talk about changing; I am actually doing something about it (McConnaughy, et al., 1989)."

Hallmarks

Modification of the target behaviour to an acceptable criterion and significant overt efforts to change are the hallmarks of action.

5. Maintenance

Maintenance is the stage in which people work to prevent relapse and consolidate the gains attained during action (Prochaska, DiClemente and Norcross, 1992). Maintenance is not a static stage, it is a continuation, not an absence, of change. For addictive behaviours this stage extends from six months to an indeterminate period past the initial action. For some behaviours maintenance can be considered to last a lifetime.

Criteria

Being able to not engage in the dysfunctional behaviour and being able to consistently engage in a new incompatible behaviour for more than six months are the criteria for considering someone to be in the maintenance stage.

Measurement items

Examples of representative maintenance questionnaire items are "I may need a boost right now to help me maintain the changes I've already made" and "I'm here to prevent myself from having a relapse of my problem" (McConnaughy, et al., 1989).

Hallmarks

Stabilising behaviour change and avoiding relapse are the hallmarks of maintenance.

2.4 Progression through the stages of change

In his critique of the stages model, Davidson argued that it was not at all clear what proportion of people, who successfully deal with dysfunctional behaviour, progress in an orderly fashion through the posited stages (Davidson, 1992). Shortly after, in a summary of research supporting the stage model, Prochaska, DiClemente, Velicer and Rossi (1992) reiterated a previous finding that linear progression was possible, but relatively rare in the area of addictive behaviours. It was clearly recognised that relapse and recycling through the stages were integral components of the change process (Prochaska, DiClemente and Norcross, 1992). Indeed, it has been widely documented that people trying to change dysfunctional behaviour, especially in the area of substance use, do not maintain their gains on their first attempt (Schachter, 1982) (Brownell, Marlatt, Lichtenstein and Wilson, 1986) (Donavan and Marlatt, 1988) (Kamarck and Lichtenstein, 1985) (Lichtenstein and Brown, 1982). Prochaska, DiClemente, Velicer et al. (1992) recognised that most addictive and health behaviours movement through the stages of change occur in a cyclical way with most successful behaviour change requiring several cycles through the stages of change. They then reiterated a previous claim that the TTM was a spiral model of stage (Figure 2.1).

Figure 2.1. Spiral model of the stages of change

Source: Prochaska et al. In Search of How People Change. American Psychologist 1992;47: 1102.

2.5 Processes of change

Proponents of the TTM argue that interventions can progress a lot more smoothly if both the patient and the interventionist are focusing on the same stage of change. That is, using particular change processes during one stage and not during others. They argue that action-oriented therapies may be quite effective with individuals who are in the preparation or action stages. However, these same programs are said to become ineffective or even detrimental with individuals in precontemplation or contemplation stages. DiClemente and Prochaska (1998) have recently defined the processes of change as "the engines that facilitate a movement through the stages of change" (p. 4). They represent a type of activity that is initiated or experienced by an individual in modifying affect, behaviour, cognitions, or relationships (Table 2.2).

Ten basic processes of change were first identified by Prochaska (1979) in a comparative analysis of the leading systems of psychotherapy. Prochaska selected the 10 processes of change (Table 2.2) by examining recommended change techniques across different theories. Subsequent research has provided extensive validity and reliability data on the processes of change (Prochaska, Velicer, DiClemente and Fava, 1988) (Norcross and Prochaska, 1986) (Prochaska, Velicer, Guadagnoli, Rossi and DiClemente, 1991). For instance, Prochaska et al. (1988) recruited 970 subjects representing the different stages of change in relation to smoking cessation and found that a 40-item questionnaire provided highly reliable measures of the 10 basic processes of change. Six months later, analysis of responses from 770 subjects confirmed the 10-process model and also revealed two secondary factors, Experiential and Behavioural, which will be further discussed in a later section.

2.6 Experiential and Behavioural Processes

Several studies have reported that the ten individual processes of change (Table 2.2) represent two second-order factors with a set of five labelled cognitive/experiential processes and another set of five labelled behavioural processes (Table 2.3) (Prochaska and DiClemente, 1992) (Prochaska, Velicer et al, 1988) (Perz, DiClemente and Carbonari, 1996).

As early as 1982, research in the area of addictive behaviours found that verbal change processes, such as feedback and education, were critical variables in making the decision to change, whereas the action processes, such as stimulus control and counterconditioning were more effective in terminating smoking (Prochaska and DiClemente, 1982). Indeed, several studies support the hypothesis that in the initial stages of change the key help needed is experiential/cognitive whereas in the later stages behavioural strategies are critical.

Table 2.2. Processes of change, definition, and sample items from questionnaire (Prochaska, DiClemente, Velicer, Ginpil and Norcross, 1985)

Consciousness raising	Increasing information about self and problem. Eg. *"I look for information related to smoking."*
Self-reevaluation	Assessing how one feels and thinks about oneself with respect to a problem. Eg. *"My depending on cigarettes makes me feel disappointed in myself."*
Environmental reevaluation	Assessing how one's problems affects physical environment. Eg. *"I stop to think that smoking is polluting the environment."*
Dramatic relief	Experiencing and expressing feelings about one's problems and solutions. Eg. *"Warnings about health hazards of smoking move me emotionally."*
Social liberation	Increasing alternatives for non-problem behaviours available in society. Eg. *"I notice that public places have sections set aside for non-smokers."*
Self-liberation	The belief that one's own efforts play a critical role in succeeding in the face of difficult situations. Eg. *"I tell myself I am able to quit smoking if I want to."*
Counterconditioning	Substituting alternatives for problem behaviours. Eg. *"I do something else instead of smoking when I need to relax."*
Stimulus Control	Avoiding or countering stimuli that elicit problem behaviour. Eg. *"I remove things from my place of work that remind me of smoking."*
Reinforcement management	Rewarding one's self or being rewarded by others for making changes. Eg. *"I am rewarded by others if I don't smoke."*
Helping relationship	Being open and trusting about problems with someone who cares. Eg. *"I have someone who listens when I need to talk about my smoking."*

Table 2.3 Experiential and behavioural processes of change

EXPERIENTIAL/COGNITIVE	BEHAVIOURAL
Conscious-raising	Self-liberation
Dramatic relief	Counterconditioning
Self-reevaluation	Stimulus Control
Social-reevaluation Social liberation	Contingency Management Helping relationship

2.7 Levels of Change

The third basic dimension of the model, the levels of change, represent five psychological problems which are addressed in treatment. These are organised hierarchically and are believed to be interrelated (see below). They recognise that individuals have multiple problems that interact with the processes of change. According to the model, individuals are in different stages of change with respect to problem areas. The five levels of change identified in the transtheoretical model are:

1. Symptom/situational
2. Maladaptive cognitions
3. Interpersonal problems
4. Systems/family problems
5. Intrapersonal

The symptom/situational is the level in which the transtheoretical model advocates initial intervention as it is more conscious and it represents the reason for which the individual requires intervention. The further down the hierarchy the level, the further removed from awareness are the determinants of the problem likely to be. Prochaska and DiClemente (1986) predict that the deeper the level that needs to be changed, the longer and more complex the treatment is likely to be.

The stages and the processes of change are the basic constructs of the TTM (DiClemente and Prochaska, 1998) and are potentially useful in the development of pharmacy-based interventions. The levels of change are beyond the scope of brief opportunistic interventions and will not be discussed further.

2.8 Motivational interviewing

A client-centred style of counselling known as motivational interviewing was developed in the addiction fields by Miller and Rollnick which facilitates movement from one stage of change to the next (Miller, 1983) (Miller and Rollnick, 1991). In Miller's words, motivational interviewing is best understood in the context of the TTM as it recognises that not all individuals who engage in dysfunctional behaviour are in a state of readiness to change. Within a motivational interviewing framework, the role of the interventionist is to assess in what stage of change the individual is and then trigger the unfolding of the process of change using techniques that are specific to the patient's stage of change. To do these effectively the interventionist needs to develop good empathic relationship with the client through basic listening skills and respect for the client.

The key motivational process begins as awareness of negative consequences in a non-threatening client-centred environment with informational strategies, such as objective assessment feedback. The process of Conscious-raising is used in the early stages of motivational interviewing. This combines with the continuing dysfunctional behaviour to form a state of psychological discomfort (cognitive dissonance). Various possible solutions to the dissonance are then proposed. Description of motivational interviewing principles and techniques are provided below.

2.9 Verbalisation as a motivator

An important feature of motivational interviewing is that the interventionist manipulates the client to convince him/her that a problem exists. According to Miller, one of the most effective attitude change methods is to have the individual verbalise him/herself the need and willingness to change. This assertion is based on a well-established principle in social psychology: *"I learn what I believe as I hear myself talk"* (Miller, 1983). This means that eliciting arguments for change from the individual will make him/her more committed to changing behaviour.

The role of the interventionist in motivational interviewing is to guide individuals in discussing their own concerns about the behaviour and why change is needed. It is not the interventionist's task to persuade the client to change. According to motivational interviewing principles, providing strong advice to an individual who is not ready to change will most likely make her/him argue to defend her/his behaviour. Moreover, when an individual perceives that his or her personal freedom is being reduced or threatened a predictable pattern of emotion and behaviour occurs (Brehm, 1966). The individual is likely to deny the accuracy of what has been said in order to assert his/her personal freedom. Based on the social psychology principle mentioned above, eliciting opposing arguments from the patient is the worst thing the interventionist can do as it will make behaviour change less likely to occur.

2.10 Motivation as a two-sided scale

In Miller's terms, motivation is conceptualised as a balance, a two-sided scale (Miller, 1983). In the area of substance use, usually individuals feel in two ways about their behaviour. On the one hand there is the recognition of a problem, on the other there is avoidance of change due to what the individual sees as the positive aspects of the behaviour. In motivational interviewing the interventionist raises the patient's awareness about the inappropriate behaviour and then assists him/her in the process of weighing the costs and benefits of the behaviour in question in order to facilitate a decision on whether or not to continue it. The interventionist places weight on the positive change-seeking side of the scales, and gently removes weight from the negative change-avoiding side of the balance. This is accomplished by applying 4 key principles and several operational techniques. These are described below.

2.11 Key principles of motivational interviewing

The principles and strategies mentioned below (Miller, 1983) (Miller and Rollnick, 1991) are consistent with the client-centred style of motivational interviewing. They aim to help clients feel comfortable about verbalising for themselves the reasons for concern and the arguments for change and they also help to show empathy and respect for the client.

i. De-emphasis on labelling

Motivational interviewing emphasises the problems the person is having in relation to the substance used, and what needs to be done about them. No value is placed on persuading the individual he/she is an addict.

ii. Individual responsibility

Motivation interviewing places responsibility on the client to decide for him/herself how much of a problem there is and what needs to be done about it. The interventionist just presents information and perspectives, alternatives, and possibilities.

iii. Internal attribution

This is very much related to the principle of individual responsibility. Clinical research has suggested that change which is attributed internally, ie. the individual sees him/herself as being responsible for the change, tends to be more long lasting. If, on the other hand, the change is attributed to the interventionist or some other external factor, the individual feels less responsible for it. Consequently, the change may not be maintained.

iv. Cognitive dissonance

Cognitive dissonance is a state of psychological discomfort created when an individual's behaviour (eg. taking too many tablets) is discrepant with their beliefs, attitudes, feelings about him/herself (eg. I am in control of my life and I look after my health). A motivational condition emerges (psychological discomfort) which motivates the individual to bring about change to the framework in order to restore consistency. In motivational interviewing, the interventionist heightens the cognitive dissonance by highlighting the inconsistency between behaviour and attitude and then directs the dissonance so that the result is changed behaviour rather than modified beliefs. The techniques described below are used to accomplish this goal:

2.12 Directing dissonance towards change

1. Increase self-esteem

It is important to express respect for the individual overtly and covertly in order to enhance self-esteem. If the individual maintains a position of low self-esteem, then the dissonant quality of self-destructive behaviour is decreased (Miller and Rollnick, 1991).

2. Increase self-efficacy

Self-efficacy refers to a person's belief in his/her ability to carry out and succeed with a specific task (Bandura, 1977). In motivational interviewing, the interventionist enhances perception of self-efficacy in order to maintain dissonance and motivate the individual to change.

3. Increase dissonance

The interventionist increases dissonance between the dysfunctional behaviour and the individual's beliefs and knowledge. A way of achieving this is to increase perception of discrepancy between where the client is and where she/he wants to be.

2.13 Direct dissonance reduction toward behaviour change

Provide accessible and effective means for behaviour change to take place by making the individual aware of the number of different approaches that are available and that have been shown to be helpful.

2.14 Strategies of motivational interviewing

The assumption in this section is that the client is ambivalent about change and the strategies described below are used to build up motivation to change. These strategies are mainly basic counselling skills derived from client-centred counselling. They are used in MI to get the client talking about the behaviour exploring their ambivalence and verbalising reasons for changing (Miller and Rollnick, 1991).

1. Ask open-ended questions

Open-ended questions are used to get client to start talking about the dysfunctional behaviour. It encourages the client to do most of the talking in the early stages of the

interaction. Closed-ended questions are de-emphasised in the early stages of motivational interviewing.

2. Affirmation

It is important to affirm and support the client. This can be done in the form of compliments and statements of appreciation and understanding. The process of reflective listening can be quite affirming. The interventionist listens empathically to what the client has to say and attempts to reflect it back.

3. Reflective listening

The interventionist reinforces the client's statements of self-perceived problems in order to increase the client's awareness of these problems and encourage him/her to continue talking about them. The interventionist also restructures the content of information that he/she does not want to reinforce, to place it in a perspective that is more consistent with change.

4. Awareness

Consciousness-raising is directed toward the increasing of dissonance by placing the information on the side of the balance favouring change. It is important that the interventionist provide information on the negative aspect of the behaviour in a non-confrontational manner.

5. Eliciting self-motivational statements

By the attributional principle that "I learn what I believe as I hear myself talk", the interventionist evokes from the client statements that will motivate him/her to change. The main purpose of this strategy is to help the client to resolve ambivalence. The interventionist can directly ask the client for these statements, ask the client to elaborate on the topic, or elicit them as part of a decisional balance exercise.

6. Integrating objective assessment

The interventionist presents to the client feedback of the results of assessment interpreting findings and helping the client to understand his/her situation. The decision of what to do is left to the client.

7. Summarising

The interventionist sums up all of the client's self-motivational statements, phrasing these as reflections of what the client has said. The client is then asked to comment on this summary in an attempt to elicit self-statements on the need for change. Summaries reinforce what has been said, show that the interventionist has been listening carefully, and prepare the client to move on.

8. Alternatives

When the client reaches a point of dissonance which motivates him/her to act upon the dysfunctional behaviour, the interventionist's task is to present alternatives and helping the client to evaluate them.

2.15 Decisional balance

It can be helpful to have the client discuss the positive as well as the negative aspects of his/her dysfunctional behaviour. Miller and Rollnick suggest that the interventionist asks the client what he/she likes about the behaviour as a preface to inquiring about the negative side. This shows the client that the interventionist understands that there is a positive side to the behaviour (empathy) and reduces resistance when it is time to talk about the negatives.

2.16 Integration of motivational interviewing with the TTM

According to Miller, motivational interviewing is best understood within the context of the TTM (Miller, 1983). Miller argues that in the area of substance use treatment focus on the action stage and motivation is left exclusively to the individual together with maintenance of change after treatment. Motivational interviewing is presented as a set of strategies intended to put individuals through the process of change, i.e. from precontemplation to action. Awareness-increasing and affirmation strategies and the appropriate forum helps the movement from precontemplation to contemplation. These strategies continue through the contemplation stage aiding transition to the preparation stage at which point alternatives are posed and change strategies are negotiated.

2.17 Support and critique of the TTM

The sections above described what in the area of addiction has been one of the most influential frameworks for therapy, the TTM and motivational interviewing. The next sections examine evidence for the effectiveness of TTM approach and some criticisms.

2.18 Evidence supporting the TTM

A number of studies have supported the claim that behaviour change in the area of substance use occurs in a segmentable sequence (stages) and as a function of certain coping activities (processes of change). The first was conducted by Prochaska, DiClemente, Velicer, et al. (1985) involving 872 smokers and ex-smokers. Ratings on the Process of Change Questionnaire items (Prochaska, DiClemente, Velicer and Zwick, 1981) were obtained from 5 groups of participants (precontemplators, contemplators, recent quitters, long-term quitters, and relapsers) at the initiation of the study and at 5-6 month intervals over two years. Results showed that the processes of change could be used to predict an individual's progression from one stage of change to the next. For example, processes oriented more toward environmental events, such as dramatic relief and social liberation, tended to predict failure or no progress, whereas more experientially oriented processes predicted progress. Results also showed that the use of some of the processes investigated in the study were detrimental in some cases. For example, self-reevaluation was a critical activity, however optimal use depended on the stage of change. Recent quitters who relapsed tended to have higher self-reevaluation process with little social support. Low levels of self-reevaluation in the precontemplators and relapsers lead to more entrenched smoking, while greater self-reevaluation predicted progress for contemplators. Dramatic relief and social liberation tended to predict no change or regression.

Since 1985 a number of studies have supported the central theme of the TTM and MI that particular processes of change are emphasised most during particular stages of change. In a study of 388 smokers Perz et al. (1996) provided data that strongly support the hypothesis that successful stage transitions involve “doing the right thing at the right time”: engaging in experiential process activities during contemplation and preparation stages and shifting to behavioural process activities during action. Tejero and colleagues tested the processes of change using a self-report measure designed to assess the frequency of use of the processes of change by opiate addicts (n=178). It was found

that 8 processes, i.e. all but dramatic relief and social liberation, correctly identified 78% of the total sample (Tejero, Trujols, Hernandez, de los Cobos, Perez and Casas, 1997). Milstein, in 1998, reported that the processes of change appear to be integral components of the strategies which women at high risk of HIV infection use in order to progress toward consistent condom use with male (Milstein, Lockaby, Fogarty, Cohen and Cotton, 1998).

However, the strongest support for the interaction between stages and processes of change comes from a cross-sectional and longitudinal study of self-changers in relation to smoking conducted by Prochaska et al. (1991). In this classic study the frequency of use of 10 processes of change by 14 profile groups was investigated. Meaningful patterns of use could only be discerned when the change processes were organised across groups representing different stages of change. Three experiential processes, consciousness raising, dramatic relief, and environmental re-evaluation, were found to follow a pattern of low use during precontemplation, high use for those making the transition from contemplation to action, followed by a decline in use during the action and maintenance stages, eventually returning to precontemplation levels.

The first process to reach a peak was social liberation in the precontemplatio n stage, declining gradually throughout the remaining stages. Dramatic relief was the next process to peak, which occurred early in the contemplation stage. Prochaska et al. (1991) interpreted it as the emotional trigger required for change to occur. Helping relationship also peaked early in contemplation and it was interpreted as the seeking of social support needed for the anticipated difficult life change. Consciousness raising peaked halfway through contemplation with information about the problem and how to solve it being viewed as the central process for the contemplation stage. Environmental reevaluation peaked at the end of contemplation or beginning of action. Recognition of the effects of the behaviour on the immediate environment occurred at the same time as the decision to do something about the behaviour.

During the action stage, reinforcement management was the first process to peak. Perceived or expected rewards for changing were seen as a final motivational incentive to take action. Self-reevaluation and stimulus control peaked in the middle of action. They were viewed as the central processes for the action stage. Counter-conditioning and self-liberation peaked at the beginning of the maintenance stage. Unlike the above-mentioned processes, social liberation was high in precontemplation and decreased from

precontemplation to maintenance. Five behavioural processes (self-liberation, stimulus control, reinforcement management, counter conditioning, and helping relationship) followed a pattern of low use in precontemplation, increased use during contemplation, and a peaking in action. Self-liberation and stimulus control remained high throughout maintenance; the authors noted these processes were probably being used as strategies to prevent relapse. Reinforcement management peaked early in action and gradually declined during maintenance. Counter conditioning remained high early in maintenance and then declined later in maintenance.

2.19 Critique of the TTM

Davidson has published "a critical overview" of the TTM (Davidson, 1998). He points out that claims about the empirical support for the TTM would be more impressive if there was more independent supporting evidence (Davidson, 1998). It is true that most of the supporting research comes from the Prochaska's research. As mentioned above, Davidson had also previously argued that it was not clear what proportion of people, who successfully deal with dysfunctional behaviour, progress in an orderly fashion through the posited stages (Davidson, 1992). In response, Prochaska, DiClemente, Velicer et al. (1992) reiterated a previous finding that linear progression was possible, but relatively rare in the area of addictive behaviours.

Davidson's basic argument is that stages are artificial segmentation of a naturally occurring continuum of change. It is not unreasonable to divide a spectrum, but the point he makes is whether or not this division is completely arbitrary. Sutton, Bandura and Davidson (Davidson, 1998) argue that the five stages of change are determined by arbitrary time cut offs. That is, the precontemplator has not stated the intention to change in the next *6 months*, the contemplator intent to change in the next *6 months* and those in the preparation stage intend to do so in the next *30 days*. They also argue that the action and maintenance stages are just arbitrary temporal divisions with those who have changed less than *6 month* ago being placed in the action stage and those who have changed for longer in the maintenance stage. As pointed out by Sutton and Bandura (Davidson, 1998), in this case an individual can evolve from action to maintenance simply with the passage of time with no real change to his/her psychological state.

Prochaska and DiClemente argue that the time frame adopted by the TTM is based on clinical approximations of what seems to be the usual time period in which

transformational change occurs, but they do not explain why. That is, an individual does stop dysfunctional health behaviour just because he/she goes from preparation to action. The stage itself is not the cause of the behaviour. Beside the time frame aspect of the model, Prochaska and DeClemente argue that the stages can also be isolated through other methods like questionnaires that were specifically designed to measure an individual's stage of change. The University of Rhode Island Change Assessment Scale (URICA) is given as an example of a questionnaire that has been shown to have good psychometrically properties. However, Davidson argues that the psychometric properties of the questionnaire are due to the same item being phrased in different ways resulting in large inter-item correlations that inflate the reliability coefficients. For instance, the following items were taken from the precontemplation subscale of the EURICA: 1) As far as I'm concerned I don't have any problems that need changing; 2) I guess I have faults, but there is nothing that I really need to change.

Another argument put forward by Davidson is that human behavioural and attitudinal change is too complex to be simplified into discrete categories. Bandura is cited as arguing that the TTM describes pseudo-stages as if they were genuine transitions. However, Bandura's own argument that human behaviour is too complex can also be used in favour of the TTM. It is true that human motivation cannot be dissected scientifically the same way a cell can be placed under a microscope. It may be that clinical observations are the best one can do in relation to determining stage and time frame in relation to motivation to change.

2.20 Conclusion of critique

The general idea propositioned by the TTM and MI that effective processes for changing behaviour depend on the motivational state of an individual does have face validity. It is very intuitive, appealing, and common sensical. However, this should be differentiated from the model itself, which gives specific stages with frames and strategies to be employed in accordance with these stages. As noted by Stockwell, the notion of there being discrete stages of change is an over-simplification; individuals will make the decision to change in different ways over different time courses. A continuum of preparedness to change, however, is a more reasonable concept (Stockwell, 1992).

The criticisms about the TTM cannot be dismissed, especially in relation to its time frame. The empirical question of whether or not the time periods reflect changes in

processes has not been answered conclusively. There is little evidence they do so. The model seems to still be in its infancy in terms of validating its theoretical background. However, as noted by Stockwell (Stockwell, 1996) and quoted by Davidson, perhaps the precise details of the model do not matter much. The TTM has made an important contribution to the area of health behaviour directing attention to the importance of intention and motivation in treating addictive behaviours. It has been widely used in the area of health behaviours providing therapists with a framework to treat individuals who otherwise would be regarded as lost causes in action-oriented paradigms. However, the longevity of the TTM rests not only on the face validity of their proposition, but also on clinical outcomes. Interventions based on the TTM have shown to be effective in facilitating behaviour change (Chapter 2). This is one of the reasons why the TTM has been chosen as a framework for developing pharmacy-based intervention in relation to analgesic consumption.

CHAPTER THREE

THE CONCEPT OF READINESS TO CHANGE AND THE PHARMACY ENVIRONMENT

3.0 Introduction

Chapter One noted the need for training community pharmacists on brief psychological interventions that can be used in relation to non-prescription analgesic products. Chapter Two presented a framework for developing intervention strategies based on the concept of readiness to change. The current chapter will examine this concept in relation to a community pharmacy setting.

3.1 The pharmacy as an intervention setting

Since potent analgesics are available to the public at community pharmacies without a medical prescription, any attempt to influence consumer behaviour in relation to these products must be via interventions at pharmacist level. Pharmacists have a high rate of contact with consumers of analgesic products. This places the pharmacy profession in a good position to deliver brief interventions. In addition, pharmacists have been found to be the most trusted health professionals according to a 1993 Gallup Poll survey conducted in the US (Gallup Poll, 1993) and can potentially counsel consumers. However, there seems to have been no study addressing the training of community pharmacists on intervention strategies aimed to optimise the use of non-prescription analgesic products. Training pharmacists in procedures for influencing the behaviour of analgesic users may allow the pharmacy to become an effective setting for significant behaviour change.

3.2 Existing protocols

In an attempt to improve professional standards with respect to the use of non-prescription medication, pharmacy-based protocols have been devised to encourage high standards of professional practice (Haynes, 1997) (Thomson and Lavender, 1995). In 1994 the Royal Pharmaceutical Society of Great Britain required that pharmacies have written protocols defining procedures for the sale of non-prescription medication (Anonymous, 1994). This protocol endorsed by the Royal Pharmaceutical Society of

Great Britain focussed on providing pharmacy assistants with guidelines on when to refer a customer to the pharmacist (Sharpe, Norris, Ibitt, Staton and Riley, 1994). The protocol advocates use of a questioning method known as "W-WHAM" which stands for a series of five questions that consumers need to be asked (Sharpe et al., 1994):

Who is the patient?
What are the symptoms?
How long have the symptoms been present?
Action already taken?
Medication already being taken?

The manual accompanying the W-WHAM protocol warns pharmacy assistants that many customers will not understand why they need to ask so many questions, and are instructed to explain why it is important to obtain the information (The Royal Pharmaceutical Society of Great Britain, 1994). However, explaining the importance of questioning to the consumer may not be sufficient to deal with a potential clash between the patron's expectations about the interaction and the demands of the protocol. It has been reported that consumers do not expect to be questioned when buying non-prescription medication and that they typically believe that decisions about non-prescription medication are their responsibility (Anonymous, 1997). A partial solution would be to introduce assessment techniques that do not rely on interrogatory methods.

The style of delivery of a relatively inflexible protocol like the W-WHAM may also become a problem. Bissell, Ward and Noyce (1997) note that that rigid application of the W-WHAM protocol did not lead to meaningful dialogue between staff and customer. It was reported that at times the method was applied "in a rather wooden or unresponsive manner, with sometimes the next question being asked even before the customer had answered the former" (p. 13). This highlights the need for pharmacy-based protocols to be flexible.

There is also the issue that, to be effective, the interaction needs to avoid conflict or embarrassment, and needs to be conducted in privacy. Achieving the required examination within the context of a public pharmacy transaction is difficult, particularly when the demands of a busy pharmacy and the need to preserve customer loyalty are

taken into account. The protocol mentioned above, which has been an influential protocol in pharmacy, takes little account of these issues.

A further problem with existing protocols is that they often imply a naive approach to behaviour change. It is as if it is sufficient for a pharmacist to identify inappropriate medication use and tell the consumer how to use the medication correctly. The implicit assumption is that consumers will immediately accept this advice and change their behaviour. Research on behaviour change in other domains, such as problem drinking, suggests that advice from a medical authority can sometimes be effective in changing behaviour, but the proportion of people who make an enduring change is typically modest (Wilson, Wakefield, Steven, Rohrsheim, Esterman and Graham, 185). Effects from simple advice require that the person readily accepts that their current behaviour is dysfunctional and that they already have the requisite skills and confidence to initiate and maintain behaviour change (Bandura, 1986). DiClemente and Prochaska (1998) argue that health professionals need to abandon paradigms which assume behaviour change to be an event that can occur quickly, immediately, discretely, and dramatically.

3.3 The TTM and counselling on non-prescription combination analgesics

Evidence for the robustness of the TTM across different settings is provided by the fact that researchers have been able to replicate the hierarchical structure of the TTM across a diversity of behaviours, such as alcoholism (DiClemente and Hughes, 1990) (Isenhart, 1994), risky sexual behaviour (Bowen and Trotter, 1995), weight control (O'Connell and Velicer, 1988), head injury rehabilitation (Lam, McMahon, Priddy and Gehred-Schultz, 1988), regular physical exercise (Marcus, Rossy, Selby, Niaura and Abrams, 1992) (Marcus, Selby, Niaura and Rossi, 1992) (Booth, Macaskill, Owen, Oldenburg, Marcus and Bauman, 1993) (Marcus, Banspach, Lefebvre, Rossi, Carleton and Abrams, 1992) (Marcus and Owen, 1992) (Marcus, Rakowski and Rossi, 1992), psychological distress (Prochaska and DiClemente, 1985), HIV risk reduction (Milstein et al., 1998), and adolescent delinquent behaviour (Prochaska, DiClemente, Velicer et al., 1992) (Velicer et al., 1992).

Most research supporting the TTM comes from the area of substance addiction, such as smoking and alcohol dependence. However, as seen above, whether or not the behaviour in question is drinking, lack of exercise, smoking, low self-esteem or risky sexual behaviour, the structure of change appears to be the same. Individuals go from

being unaware or unwilling to do something about the behaviour to contemplating change, then to preparing themselves to change, taking action, and finally maintaining behaviour change. Insofar as the model is concerned with differentiating people in their preparedness to change, rather than the idiosyncrasies of the behaviour itself, it seems reasonable to think the model should not only apply to substance addiction, but to a broader range of high-risk behaviours, including non-prescription analgesic misuse.

The TTM could be used to assist people who use combination analgesic products inappropriately. Traditionally pharmacists have viewed the population of analgesic consumers as a dichotomy. Appropriate users and inappropriate users categories have been used almost exclusively to represent the population of consumers. Another possibility would be to approach inappropriate analgesic consumption the same way as researchers have approached smoking cessation (Prochaska and DiClemente, 1983) (Pechacek and Danaher, 1979), ie. as a process rather than a dichotomy.

Since we started researching the concept of readiness to change in relation to counselling on non-prescription analgesics, its practical value has been recognised in the pharmacy area in relation to smoking cessation. In 1995, Hudmond and Berger suggested that pharmacists could use the TTM to categorise patients by their stage of change and then use an specific process of change, thus individualising the intervention. Since then, other studies have been conducted using the TTM as basis for counselling on smoking cessation in a pharmacy setting (Sinclair, Bond, Lennox, Silcock and Winfield, 1997) (Sinclair, Bond and Lennox, 1999).

3.4 The TTM and the Pharmacy environment

In the addiction literature there are a large number of interventions for dealing with substance misuse, but they are prescriptive interventions, i.e. they are action-oriented intervention appropriate for individuals who are ready to change. These interventions would not be appropriate for a pharmacy setting. Surveys in the area of substance use suggest that stage distribution is approximately 40% in precontemplation, 40% in contemplation, and 20% in preparation, but this distribution can very dramatically between different populations (Dijkstra, DeVries, and Bakker, 1996) (Fava, Velicer and Prochaska, 1995). Because pharmacists deal with the entire population of inappropriate non-prescription analgesic users, it could be the case that an action-oriented intervention would be suitable for less than 20% of this population. One of the great attractions of a

stage-matched intervention is its universal application to anyone in the situation of wanting to influence someone else's dysfunctional behaviour (Stockwell, 1992). This means that pharmacists may be able to deliver intervention strategies appropriate to all types of consumers.

The consequences of indiscriminate delivery of an action-oriented intervention in a community pharmacy could go beyond the failure to change dysfunctional behaviour. Such an action would not only lead to loss of the opportunity to facilitate behaviour change, but also to a potential loss of business. Treating precontemplators as if they were ready to change could lead to a decline in patronage.

It should be noted that health professionals have tried to deliver action-oriented interventions to an entire population of patients irrespective of their level of readiness to change. This was done in a managed care organisations in the U.S. (Lichtenstein and Hollis, 1992). Physicians recruited smokers to sign up to a smoking cessation program. In cases when the physicians were unsuccessful, nurses spent 10 minutes trying to get the smokers to enrol for the program followed by 12-minute counselling from a health educator and a phone call at home. Of the total sample of smokers recruited 35% were precontemplators, 3% of them showed up, 2% finished the program and none of them quit smoking. In a study in which investigators proactively recruited smokers from the general population and delivered stage-specific interventions, precontemplators continued in the study at the same rate as those who were in the preparation stage (Prochaska, DiClemente, Velicer and Rossi, 1993).

Another potential benefit of delivering stage-matched pharmacy-based intervention is that pharmacists would be able to set realistic goals for brief encounters with inappropriate analgesic users, which could potentially sustain motivation to intervene. DiClemente and Prochaska (1998) note that when health professionals are trained in a stage-matched approach to the addictions, there is a dramatic increase in their morale. Health professionals were reported to be able to see progress with the majority of their patients instead of failure when immediate action was the only criteria of success.

3.5 Current status of research on TTM counselling in pharmacy

Because the application of TTM-based counselling in pharmacy is new, there is a lack of research examining its impact on consumers. A study reported by Sinclair et al. (1997) appears to be the only one of this kind. In a randomised controlled trial of

counselling by pharmacists and their staff for cessation of smoking, Sinclair et al. (1997) reported that more intervention subjects were not smoking at three follow-up points: one month ($p = 0.59$); four months ($p = 0.021$); and nine months ($p = 0.089$). Although cessation rates were not statistically significant for all follow-up points, this study suggests that training on the stages of change model had a positive impact on consumers.

3.6 Assessing the stages of change in a pharmacy setting

In order to employ TTM-based counselling, pharmacists would need to be able to identify the level of readiness to change of a consumer. Assessment methods used in clinical settings, such as the URICA (McConnaughy et al., 1989), SOCRATES (Miller and Tonigan, 1996), and RTC (Rollnick, Heather, Gold et al., 1992) questionnaires are not applicable in a pharmacy setting due to time constraints faced by pharmacists. Also, consumers may not view this type of assessment as being the pharmacist's role. If the TTM is to be of any benefit in the area of non-prescription analgesic misuse, pharmacists need to be able to assess readiness to change verbally within a very short period of time and in a non-confrontational way.

Miller and Rollnick (1991) advocate the use of a single question to assess readiness to change, namely asking the individual directly about the willingness to change. In the area of smoking cessation, individual's responses to specific questions (eg. "Are you seriously considering quitting smoking in the next six months?") have provided discrete classification of their stage of change. However, Rothflesich (cited in DiClemente and Prochaska, 1998) points out that these types of measures have not worked well in clinical settings due to demand characteristics that make affirmations of unwillingness to change or of ambivalence about change problematic for most clients. DiClemente and Prochaska (1998) note that in situations where there is no strong pressure to feign readiness, individuals can be assessed using even a single-item continuous measure that allows the individual to indicate readiness to change on a continuum from not at all ready to change to very ready to change, or taking action. They also claim that single-item measures are useful, as long as there is some assessment of attitudes and intentions to change a specific behaviour and it is clear what constitutes successful action (cessation to smoke, adherence to diet, reduction of drinking). This way the preaction stages can be distinguished from the action and maintenance stages. DiClemente and

Prochaska (1998) also state that individuals earlier in the process of change differ from those who are in the later stages of change, no matter what system of classification one uses (specific stage, stage-related or continuous measure).

Measuring the stages of change in a pharmacy setting might be accomplished by using a single-item continuous measure that allows the individual to indicate readiness to change in relation to analgesic misuse. In a community pharmacy, there would be reduced demand characteristics for the individual to indicate willingness to change, as it may not be perceived by consumers as a clinical setting. Consumers' response to a single question about how they feel about their use of analgesics may be indicative of their level of readiness to change.

3.7 Assessment of appropriateness of the analgesic consumption

Most health professionals are trained to be passive-reactive, ie. to passively wait for the patient to seek service and then react (DiClemente and Prochaska, 1998). Common sense suggests that pharmacists would provide counselling mainly to sufferers of acute conditions, as the discomfort of such conditions motivates the person to seek help. The greatest problem with a passive-reactive approach in a pharmacy setting is that most patients with problems of substance misuse do not seek help (DiClemente and Prochaska, 1998). In chronic conditions caused by lifestyle disorders like substance abuse, of which analgesic misuse could be an example, delay, indecision, and ambivalence are reported to interfere with seeking help (DiClemente and Prochaska, 1998).

Pharmacists would potentially be able to monitor analgesic consumption more efficiently if they adopted a proactive approach to identifying inappropriate analgesic user. As seen in chapter two, pharmacy-based protocols have relied on interrogatory methods of obtaining information from consumers. They make use of closed-ended questions, which in most cases, limit the patient's response to "yes" or "no". Close-ended questioning methods in a pharmacy setting may also elicit defensiveness from patients. In contrast, an approach which uses open-ended questioning methods would encourage patients to do most of the talking and would potentially allow the pharmacist to obtain the same information interrogatory methods would with additional data.

An important communication skill is learning to ask questions in a way that elicits needed information from patients without using closed-ended questions. This technique

is called "probing" (Tindall, Beardsley and Kimberlin, 1994). It could be the case that a simple probe from pharmacists would make most patients feel welcome to talk about their medication consumption. This would be a rapid method of obtaining information from consumers while minimising their feelings of being interrogated. As seen earlier in this chapter, consumers do not like to be interrogated by pharmacists (Anonymous, 1997). Making use of probing techniques would also have the added benefit of helping to build up a degree of rapport between the pharmacist and the consumer. In addition, a positive perception of the pharmacist may foster consumer loyalty and return, thus enabling the pharmacist to monitor non-prescription analgesic use. Moreover, after eliciting information from the consumer, pharmacists would be in a position to tailor the provision of information to that particular consumer and to avoid providing unnecessary or ineffective information.

It may be the case that pharmacy-based protocols would be more effective in assessing the appropriateness of the medication consumption if they restricted the use of closed-ended questions to situations in which the patient fails to provide the pharmacist with the desired information after being asked an open-ended question.

3.8 Summary and conclusion

Existing pharmacy protocols for non-prescription medication adopt a naive approach to the misuse of non-prescription medication. It assumes that patients will follow the pharmacist's advice promptly and start using the medication appropriately. It is naive to believe that all patients who misuse analgesic products enter the pharmacy in a state of readiness to change. Due to the robustness of the TTM across a diversity of behaviours it is reasonable to believe its hierarchical structure would also apply to analgesic misuse. The TTM could provide the theoretical framework in which patients at different level of readiness to change inappropriate analgesic use could be provided with individualised counselling depending on their readiness to change.

After reviewing the literature on the concept of readiness to change, it was proposed to develop pharmacy-based intervention strategies in which the patient's readiness to change, and pharmacists' and patients' attitudes toward pharmacy-based interventions were taken into account.

CHAPTER FOUR

QUALITATIVE STUDIES

4.0 Introduction

The development of satisfactory pharmacy-based interventions needs to take into account community pharmacists' and consumers' attitudes to the monitoring of analgesic products. This chapter aims to examine these attitudes. The current chapter is divided into two parts: the first reports on focus groups conducted with community pharmacists in relation to the monitoring of *pharmacist only* analgesic products; and the second reports on brief interviews conducted with consumers of analgesic products at time of purchase.

PART I: SEMI-STRUCTURED FOCUS GROUPS WITH COMMUNITY PHARMACISTS

Community pharmacists' self-reported behaviour and attitudes to the monitoring of *pharmacist only* analgesic products are presented in this part of this chapter. The purpose was to investigate these attitudes and behaviours with a view to exam how congruent they are with the theoretical background. In addition, the researcher wanted to identify any effective strategy already being used by pharmacists in the monitoring of *pharmacist only* analgesics for the purpose of incorporating them to the study intervention.

4.1 Participants and setting

The qualitative study with community pharmacists on the monitoring of *pharmacist only* analgesics was conducted at the Department of Pharmacy, University of Sydney, in the form of semi-structured focus groups. The Human Ethics Committee of the University of Sydney approved the study protocol (Appendix 2), and all participants read an information sheet describing the study and signed consent documents agreeing to take part in it (Appendices 3 and 4).

The purposeful sampling strategy was used in the current investigation. Purposeful sampling is used when the objective of the study is to understand selected cases without

the need to generalise to the entire population (Patton, 1980). The researcher selected pharmacists that he thought he would learn the most from. That is, only pharmacists with a history of participating in continuing education programs, according to the Pharmaceutical Society of Australia, were selected. The assumption was made that these pharmacists would be more willing to discuss the monitoring of "pharmacist only" analgesic products.

Twenty-eight community pharmacists were invited to take part in focus groups. The researcher telephoned the community pharmacists and explained the study and the purpose of conducting the focus groups. Of the 28 pharmacists, 21 agreed to take part in the study. Of the 7 pharmacists who did not agree to take part in the study, all alleged time constraints, including clashes with other commitments, as the reason for not participating. All pharmacists were given a reminder call from the researcher the day before the focus group in order to maximise attendance.

Twelve of the participants were females and 9 males. Their mean age was 34.8 years (Range = 24 to 48). Fourteen of the participants came from independently owned pharmacies and 8 were from pharmacies linked to marketing groups. All participants came from pharmacies located in the Sydney Metropolitan Area, either in suburban shopping centres (6) or local neighbourhood shops (15).

4.2 Sample size

The 21 pharmacists were conveniently allocated to 3 groups (n=7) according to availability. The size of the groups was based on Walker's review of focus groups (Walker, 1985) which argues that it is impossible to run a good focus group with more than 10 people present and suggests 6 or 7 as the optimum size of a group. According to Walker, more than 10 participants makes the group hard to manage, fragmented with different subgroups, the quality of the discussion deteriorates, and more timid participants become inactive. It was believed that 3 groups would be a reasonable amount to obtain the information needed for the development of the intervention strategies.

4.3 Material

Because combination analgesic products containing antihistamine (Codeine, paracetamol, doxylamine) are more likely to be abused and misused, the study focused on the monitoring of these products.

A focus group plan was designed consisting of a series of open-ended questions with prompts to identify community pharmacists' practice in relation to the monitoring of *pharmacist only* analgesic products and their attitudes to pharmacy-based intervention (Appendix 5).

4.4 The group facilitator

It was decided that an experienced community pharmacist with research skills was necessary to facilitate the focus groups. This decision was made on the basis that the facilitator needed to be able to understand the day-to-day functioning of a community pharmacy, being able to make decisions as to whether a given topic was proving useful and worth pursuing, or fruitless to be headed off. This had to be done in the light of his understanding of pharmacy and hence possible relevance or irrelevance of particular kinds of information. An experienced community pharmacist with a Ph.D. in pharmacy practice was selected to facilitate the 3 focus groups.

4.5 Data analysis

There is no formal rule for researchers to follow in respect to analysing qualitative data. The researcher read through the transcripts for each focus group and established a data index, as suggested by Patton (1980). The data index consisted of an inventory of the major categories, descriptions, and examples provided by participants during the focus groups. Lincoln and Guba (1985) emphasise that the analyst must read through focus group transcripts and notes to identify units of information. A unit may be as little as a sentence or as much as a paragraph. Data from the transcripts were firstly organised into different topics. This was done following Lincoln and Guba's guidelines (p. 347): "*The essential tasks of categorising are to bring together into provisional categories those cards that apparently relate to the same content; to devise rules that describe category properties and that can, ultimately, be used to justify the inclusion of each card that remains assigned to the category as well as to provide a basis for later tests of replicability; and to render the category set internally consistent. Note that the category*

set that emerges cannot be described as the set; all that can reasonably be required of the analyst is that he produces a set that provides a 'reasonable' construction of the data. 'Reasonable' is most easily defined as a judgment that might be made subsequently be an auditor reviewing the process." After categorising the data, the researcher described and interpreted the data.

4.6 Results

Each focus group lasted for approximately 2 hours. They were audiotaped, transcribed, and content analysed. The questions asked during the focus groups are presented below together with examples of participants' answers.

Question I: ***How do you assess whether or not somebody is misusing non-prescription analgesics?***

Two types of pharmacists' assessment were mentioned: a) observing frequency of purchase; b) questioning consumers about their intake of analgesics. Examples of these are:

a) *"It doesn't matter whether it's Mersyndol or your own home brand, it's all the same. The same person comes once a week and says the same thing. It's the same scenario."*

b) *"Well, I think it's a pretty hard thing to assess in the first place. First thing I do is to ask questions to find out whether or not they are taking it correctly."*

Question II: **Could please describe how you intervene in your daily practices when you believe consumers are misusing non-prescription medication.**

Straightforward advice giving appeared to be widely used. Examples of this are:

- *"I tell the customer there may be something more appropriate that they may be able to swap it to, if they are willing and then go from there."*

- *"Sometimes, instead of combination analgesics I tell them to take straight paracetamol."*

Providing consumers with alternatives to misusing the analgesic product was also reported to be a common way of intervening. Examples of this are:

- *"To suggest alternatives to them is very important. We have to get thinking about their condition. Get them to think about the cause of the condition that they have come to see you for rather than just sort of a blank cure. If you can explain how these things act. It helps them to take more responsibility to their own health. "*

- *"There is one thing that I feel that is important, it's to provide alternatives."*

Perception that the pharmacist cares about the consumer was mentioned by some of the participants as an important factor contributing to a successful intervention. Examples of this are:

- *"I approach people on a 'I care about you' type of approach, not strictly in these words. Because I care about you therefore this could cause you problems. I try to look at it from that sort of approach."*

- *"To be a successful community pharmacist you have to like people. You have to care about people and this is a prime pre-requisite for a successful pharmacist."*

Refusal to supply the analgesic product was raised as a way of intervening, although some of the participants believed it did not solve the problem. An examples of this is:

- *"I just refuse to supply. I have done that a number of times. It's very confrontational, it makes your heart beat real fast. I know it doesn't solve the problem, they just go around the corner and buy it, but it helps with your own ethics."*

Participants did not seem to think that restricting the sales of *pharmacist only* analgesics would provide a solution to the problem of misuse. Examples of this are:

- *"Imposing further restrictions on pharmacist only analgesics would not solve the dependence problem and it would increase social problems."*

- *"No, I just think that would make people do things that are illegal and try to get them some other way. I don't think it would solve the problem of the dependence."*

Although some participants agreed that restrictions would not solve the problem of inappropriate use, others viewed the easy availability of "pharmacist only" analgesic as a problem. An example of this is:

- *"This is really one area that I think is very difficult because of its availability and I don't think that restricting the availability will solve anything."*

Lack of information about a patient's illness was raised as a barrier to counselling. Examples of this are:

- *"You wouldn't be able to intervene like you do to asthma with analgesics. With asthma you can assess appropriate usage you know when the patient is puffing too much Ventolin, but with analgesics it's so variable that you just don't know what constitute too much analgesics. You don't know the frequency or the intensity of the pain. Without a thorough examination taking the full history of the patient it is very hard to assess what is appropriate and what is not appropriate."*

- *"With analgesics, if you question the patient about frequent usage, they may say I've had a migraine since Monday. You don't know whether or not that's a real situation, you don't know that much about migraine. "*

Referral to other health professionals seemed to occur when treatment required knowledge of the consumer's clinical condition. An example of this is:

- *"Well, if they say they are in that much pain you should really refer them to see somebody who is more qualified to help or say whether or not that's the best drug there is for them."*

Although participants acknowledged that, at times, further knowledge of the consumer's condition was needed, some of the pharmacists were reluctant in making referrals to general practitioners. This was due to what they perceived as a potential for abuse. Examples of this are:

- *"If you send them back to a doctor, they'll come back for a script for a stronger medication."*

- *"Sometimes I sent 'pharmacist only' analgesic users back to the doctor and they came back with a script for something stronger."*

- *"I've suggest for them to try a natural product instead. They say I've tried all of that and it doesn't work and you don't want send them to a doctor to get them onto benzos."*

Three barriers to counselling were identified: a) Consumers' negative attitude to pharmacist counselling; b) a general perception that the dispensary has higher priority than non-prescription medicines; c) and management requirements. Examples of these are:

a) *"When you go to the front the customer asks: "what are you doing?" Aren't you meant to be back there?"*
" I do get out more than the other pharmacists, but they know that the dispensary is where you usually are. You are the pharmacist you are meant to be up there."

b) *"I try to treat everyone equally, but I think that people waiting for scripts have the perception that they are special people and I can understand that. It is hard to juggle. It also depends on how understaffed you are."*
"Most of it is the time factor. Sometimes we have time to go down there and have a quick conversation, but after that there is pressure to get back to the dispensary and serve somebody else. We can't just leave them waiting with your boss there."

c) *"That's the owner and his requirements. You have to really juggle how long you spend with the customer at the shop and check how busy the dispensary is. You can't really just concentrate on one at the expense of the other. It's a case of constantly be watching the two with the back taking priority."*

Participants acknowledged the difficulties involved in trying to change the behaviour of those who use "pharmacist only" analgesics regularly. Examples of this are:

- *"The ones that we see very regularly, they don't want to know about changing their behaviour. You can sit and discuss it with them: "Have you been to see a doctor?" "Have you tried this and this?" They don't want to know about it, they'll be back in a couple of days."*

- *"I just explain that that's not really what the drug is for, but they just don't listen to me."*

- *"I speak to them several times and they say 'Yeah, yeah, so what.'"*

Question III: **What would be the most practical way of intervening when a consumer is believed to be misusing non-prescription analgesic products?**

Training on communication skills specific to medication misuse was mentioned as an essential requirement for intervening appropriately. Examples of these are:

- *"Communication is the tool that we use and we are continually educating ourselves on that, but we should be provided with more knowledge on how to communicate as pharmacists. At the moment we have nothing, no training."*

- *"Personally, communication is a big deal because it's alright communicating with people in general, but when it comes to people who are addicted to something it's really hard to try to talk to them and to get a change in their behaviour. That's the sort of communication skills that we need, dealing with people who have problems."*

Participants agreed that training on behavioural intervention was inadequate. Examples of this are:

- *'We do not receive formal training on interventions."*

- *"The whole area of drug dependence needs to be very well done at a university level. Kids come out from uni and have absolutely no understanding of how someone who is dependent on the drug would feel. The social aspects of it as well, they may understand it from a pharmacological perspective, but that doesn't tell you very much. You are giving these drugs to people, you are dealing with people all the time."*

In New South Wales, Australia, pharmacists are recommended to record the sales of β agonists, for the treatment of asthma, on a card which is held by the consumer. The "asthma card" was viewed by some of the pharmacists as a way of facilitating communication with the consumer enabling them to follow a protocol. Some of the pharmacists believed the same system should be applied to "pharmacist only" analgesic products, whereas others disagreed.

Examples of arguments for recording sales of analgesics are:

- *"Maybe we need some type of trick like the asthma card. You see, before the asthma card it was really hard to try to keep the patient there long enough for you to ask*

question and get to a stage of counselling whether they should go back to the doctor or not. Now they can't just walk in and say I want that and walk out. They have to take the time to fill in the card. The same sort of intervention may work."

- *"I'm always trying to intervene in some way or another. When you're giving the asthma cards out you have an extra minute to spare and you ask how they're going with it. Before you had to try a lot harder now they have an excuse to stop and listen to you. It does open up the way."*

Examples of arguments against recording sales of analgesics are:

- *"I think it's irrelevant. If the pharmacists wants to enter a dialogue they can without having to record anything."*

- *"You have to get them to wait in the queue. You can't just provide the information like you used to do before. Now you have to ask their names and how to spell them and blah, blah, blah, whatever that is."*

It was argued that little would be gained by developing pharmacy-based intervention if pharmacists did not believe counselling is part of their role. The asthma card was used to illustrate the point:

- *"Look at the example of the asthma card. There are some pharmacists who are very angry about the asthma card and they just fill them in in anger. They are just handing them out and doing no more than they were doing before. They are still not asking the right questions because they are very angry at having to do something they don't want to do. If they did it the right way that would be a help, but we haven't changed the way pharmacists look at it. So, this whole asthma campaign has not worked."*

- *"The pharmacists that you need to aim these strategies at, are the ones that don't do all those things. With this asthma thing, it somehow has missed all these pharmacists completely. The point has missed them completely, but the idea is to*

enhance the wellbeing of the patients, it's not a policing role, but that's how they see it."

Pharmacists' lack of self-efficacy in handling medication misuse was mentioned as a barrier to intervening. Examples of this are:

- *"Pharmacists shouldn't be afraid of handling the situation. You know how some pharmacists straight away tell the person to go and see someone else 'Go and see a physio or go and see a chiropractor' and then they lose everyone."*

Time constraints relating to the retail nature and daily activities of a community pharmacy were also mentioned as barriers to counselling.

- *"Most of the time there are two of us, but most of the time we have heaps of scripts waiting, somebody wanting Ventolin, someone else wanting Mersyndol and something like that. It's very hard."*

- *"So, you really have to address the issue of how to provide pharmacists with the time to do counselling."*

Participants believed they should be paid for counselling. Examples of this are;

- *"My boss complains, 'we don't get anything for it, it reduces the amount of business we have'. The only way you will get pharmacists to be interested in an intervention program will be if it attracts remuneration to them."*

- *"I once went to a public health seminar and someone came up with a fantastic phrase 'behavioural change follows subsidy' and that's probably applicable to everyone out there."*

4.7 Discussion

Participants' belief that further restriction to non-prescription combination analgesics would not solve the problem of misuse reinforces the need for community pharmacists to have the necessary skills to influence consumer behaviour. However, the focus groups provided little indication that pharmacists receive adequate training on the monitoring of combination analgesic products. Assessment of appropriateness of use was based on either observation or interrogation. Participants reported a low sense of self-efficacy in dealing with consumers they believed used analgesics inappropriately and believed that in a number of cases intervening would lead to loss of patronage. Interventions were mainly prescriptive, with the pharmacist telling consumers what to do irrespective level of readiness to change. Time constraints and participants' perception that management and the general public expect the pharmacist to give priority to the dispensary over counselling on non-prescription medicines indicate that pharmacists would profit from behavioural skills that can be applied in a short period of time.

The belief that interventions were more successful in changing behaviour when consumers perceived that the pharmacist cared about them is consistent with the notion proposed earlier (Chapter 3) that a consumer-centred approach to developing commitment to changing behaviour would be appropriate for a community pharmacy setting. Participants' perception that some consumers have a negative attitude to counselling and do not listen to them, is also consistent with the notion of "precontemplators" posited by the TTM and supports the notion that action-oriented interventions cannot be applied to all consumers who misuse analgesics (Chapter 3). The raise in morale reported by health professionals upon being trained on the TTM (Chapter 3) could be used to remedy the low self-efficacy in dealing with misusers reported by participants. It could potentially give community pharmacists a greater sense of mastery in dealing with consumers they perceive as being "difficult".

Strategies already in place, such as providing alternatives and showing empathy, are strategies advocated by the TTM (counterconditioning, helping relationship). However, it could be the case that these strategies would have a more powerful impact on consumer behaviour when applied at the "right time", ie. according to the consumer's level of readiness to change, as has been found in the smoking cessation area (Chapter 2). Training on the TTM could also provide a partial solution to the belief that

intervening would lead to loss of patronage. As discussed in Chapter 3, matching the intervention to the consumer's readiness to change would be less confrontational than a prescriptive intervention potentially leading to retention of patronage.

The fact that participants felt that, at times, they did not have the expertise in the consumer's condition to provide adequate counselling has implications for the development of pharmacy-based interventions. Any intervention to be used by community pharmacist would have to be a flexible one allowing for the screening of consumers who should be referred to another health professional.

Another important issue identified in the focus groups was the belief that little would be achieved in the area of non-prescription analgesics if pharmacists were not paid for providing counselling. This suggests that training on pharmacy-based intervention strategies would be more effective if it also addressed motivational issues which would sustain interest in counselling other than monetary incentive.

4.8 Summary and research direction

Content analyses of focus groups suggested that the development of pharmacy-based intervention should take into account the following: that not all misusers are ready to change; time constraints; consumers' perception of empathy; flexibility, allowing for referrals to other health professionals; and payment. Some strategies advocated by the TTM are already being used by pharmacists in a trial-and-error fashion. Motivational issues should be addressed when training pharmacists in intervention strategies. The main barrier to counselling appeared to be consumers' negative attitude to it, which was perceived as potentially leading to loss of patronage.

PART II: CONSUMER INTERVIEWS

4.9 Introduction

In Part One of this chapter, it was seen that focus group participants perceived misusers of non-prescription analgesic products as having a negative attitude to pharmacy-based counselling. In order to satisfy the need for relevant local data on consumers' perception of this type of counselling, it was decided to conduct brief

interviews with consumers of non-prescription analgesic products at the time of purchase. The aim was to assess their attitude to pharmacy-based counselling. Consumers' responses to interview questions are described in this part of the chapter.

4.10 Targeted analgesic products

Optimally only consumers of combination analgesic products would have been interviewed, as these products are more prone to misuse. However, obtaining an adequate sample size of consumers of these products would have been too time-consuming due to the limited resources available to the researcher. It was decided that consumers of non-prescription analgesic products in general would be approached for a brief interview.

4.11 Participants and setting

Three different areas were selected on the basis of income per capita (1991 census data), as settings for the interviews. Walker (1985) argues that the sampling procedures for qualitative research need not have the rigours of quantitative research, but should consist of a cross-section of the population to be studied. Resources and time available allowed for 75 interviews in the three socio-economic areas to be conducted which was considered to be an adequate sample size to provide the researcher with the information needed. The brief interviews were conducted with consumers of non-prescription analgesic products at pharmacies in three suburban shopping centres in the following locations: Blacktown (lower income area); Hurstville (mid income area); and Chatswood (higher income area).

4.12 Recruitment

After a sale of a non-prescription analgesic product had been finalised, the researcher approached the consumer, explained he was from the University of Sydney and was conducting a survey on pharmacists' counselling on painkillers, and that he would only ask two brief questions. To reach the target number of 75 interviews 107 consumers were approached. The most common reason given for not taking part in the survey was time constraints.

4.13 Demographics

To maximise survey participation, demographic data apart from gender and location were not collected, as it was thought that consumers could perceive it as being too intrusive and time consuming. The researcher recorded participant's gender and location of the interview at the time of data collection. Out of the 75 consumers interviewed, 49 were female and 26 male.

4.14 Material

A standard questionnaire consisting of two open-ended questions was designed to identify consumers' attitudes towards information provision and towards being questioned by pharmacists on their intake of non-prescription analgesic products. The interview questions were as follows:

1. How do you feel about pharmacists giving information about non-prescription painkillers?

2. How would you feel about the pharmacist asking you about how you are taking the painkiller you buy?

4.15 Results

Seventy-five interviews were conducted, 25 per location, during the months of June and July, 1995. Each interview lasted approximately 4 minutes on average. The researcher wrote down the main points as the consumer spoke.

The vast majority participants responded favourably when questioned about the way they felt about pharmacists providing information on non-prescription analgesic products (Question1). By and large respondents made positive statements about information provision by pharmacists. The main reason for wanting verbal counselling was a willingness to increase their knowledge about the medication that they are taking. Examples of this are:

"I respect them like doctors and would be happy if they gave me more information"

"People should ask for information, if not the pharmacist should provide it."

"I'd be happy. He's explaining things to me."

"I'd listen in case I find something new."

A minority of survey respondents made negative statements about information provision on non-prescription analgesics. The most frequently cited reasons for not wanting verbal information were: 1) lack of time to listen to the pharmacist; 2) perception that non-prescription analgesic products are harmless; 3) belief that decisions about non-prescription medication are their responsibility; 4) and a perception that people already have adequate knowledge about analgesic products. Examples of these are:

"I wouldn't listen. Usually when I go to a pharmacy I'm in a hurry."

"I would mind if it's non-prescription."

"It's got nothing to do with him."

"I wouldn't be happy, people know plenty already."

Respondents were divided on their approach to being questioned by pharmacists about their self-medication practices (Question 2). Most respondents indicated they would not mind being questioned by the pharmacists. However, a considerable proportion of respondents approached pharmacist's questioning negatively.

Most respondents made positive statements about being questioned by pharmacists when buying non-prescription analgesics. It was thought that it is important for pharmacists to ensure appropriate use of these products. Examples of this are:

"I'd be happy, I think a lot of them are more helpful than the local doctor."

"I'd be happy, he's showing interest and would, perhaps, be able to suggest something else."

"I'd be happy, he would be just ensuring that you are taking it properly."

"I'd like the pharmacist to ask questions. It's good to know if you can take other tablets with pain killers."

A minority of respondents made negative statements about being questioned by pharmacists on non-prescription analgesics. The survey identified the following reasons for not wanting to be questioned by pharmacists: 1) reasons for taking analgesics may be personal; 2) belief that non-prescription analgesic taking is their responsibility; 3) the belief that it is outside the call of the pharmacists' duties; 4) the belief non-prescription analgesic products are harmless. Examples of these are:

"I'd feel put out although it's a good idea. It's too personal"

"I'd tell him to mind his own business."

"I wouldn't be happy, that's for the doctor to do, not the pharmacist."

"I wouldn't be happy if it's just pain killers."

4.16 Discussion and conclusions

Results were consistent with the notion that pharmacy-based intervention should be individualised. The majority of consumers reported they did not mind the pharmacist providing information on non-prescription analgesics or questioning on their use, but some stated they did mind. These results are consistent with findings of the focus groups that showed respondents believed some consumers did not like to be counselled on non-prescription analgesics. This supports findings reported in the literature that consumers do not expect to be questioned when buying non-prescription medication and that they typically believe that decisions about non-prescription medication are their responsibility (Anonymous, 1997).

The reported negative perception of being questioned supports the view put forward in chapter two, which suggests that an assessment approach that encourage consumers to do most of the talking, like open-ended questioning, would be more appropriate for a pharmacy setting. This way, consumers would not feel like they are being interrogated.

CHAPTER FIVE

DESIGN OF THE PROTOCOL

5.0 Introduction

In this chapter, a description is given of the designing of a patient-centred protocol for the sales of *pharmacist only* analgesic products. This protocol was based on the TTM and on principles of motivational interviewing and was divided into a number of steps. These are described below:

5.1 STEP ONE: Introducing oneself

It was hypothesised that if a consumer were actively made aware he/she is talking to the pharmacist, as opposed to a pharmacy assistant, she/he would feel more comfortable talking about the medication intake. To achieve this, the protocol instructs pharmacists to introduce themselves to the consumer as the pharmacist. For example, "Hi, my name is Richard. I'm the pharmacist."

5.2 STEP TWO: Proactive information gathering

It was decided that the pharmacist would take a proactive approach to counselling prompting the consumer to talk about the analgesic intake (chapter two). Like in motivational interviewing (chapter two), training emphasised the use of open-ended questions to get the consumer talking about his/her medication taking. Participants were trained to ask questions like **"How do you find these tablets?"** or **"How is it going with these tablets?"** (Figure 5.1). It was hypothesised that it would enable the pharmacist to start the interaction in a friendly manner and in a number of instances it would also enable the pharmacist to obtain information without having to question consumers directly thus minimising consumers' negative feelings about being interrogated (chapter two). Pharmacists participating in the study were instructed only to use closed-ended questions if the consumer failed to provide him/her with the desired information after being asked an open-ended question.

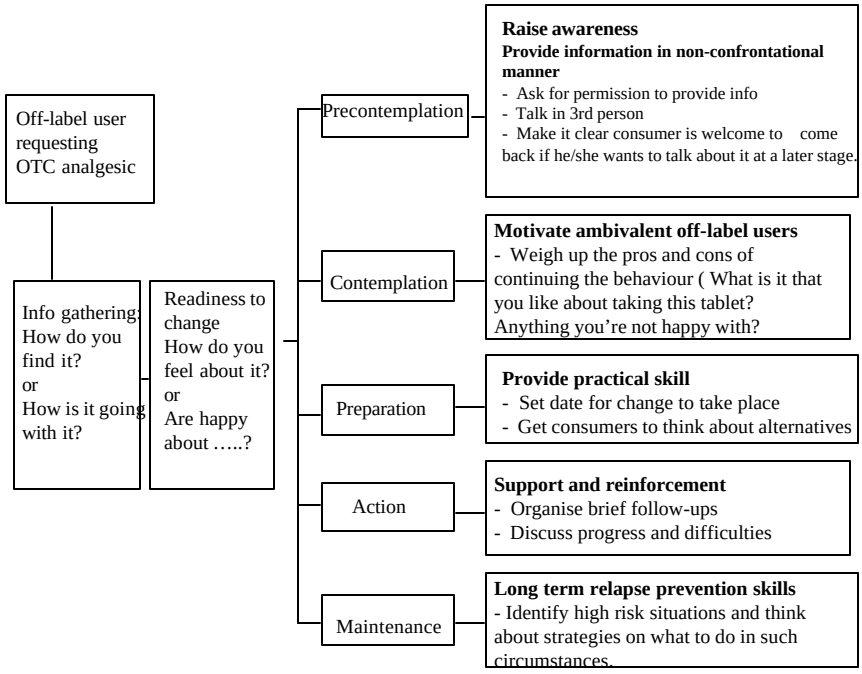
It was thought that starting the interaction with an open-ended question also would have the added benefit of helping to build up a degree of rapport between the

pharmacist and the consumer fostering consumer loyalty and return, thus aiding the pharmacist to monitor non-prescription medication use over time.

5.3 STEP THREE: Intervention strategies for inappropriate users

If the consumer is believed to be misusing the medication, it was proposed that the pharmacists delivered a brief intervention taking into account consumers' readiness to change (Figure 5.1). This intervention represents an adaptation of Miller and Rollnick's Motivational Interviewing method (Miller and Rollnick, 1991) and Prochaska and DiClemente's model (Prochaska and DiClemente, 1986) for use in a pharmacy setting.

Figure 5.1 Pharmacy-based intervention strategies



5.4 Assessment of readiness to change

If it was established that the consumer is using the non-prescription analgesic inappropriately, the next step was to assess his/her readiness to change. As seen in chapter three, readiness to change in a pharmacy setting could be measured by using a single-item-continuous measure, which allows the inappropriate consumer of analgesics to indicate readiness to change. Pharmacists were trained to ask a very simple question: *How do you feel about ……*.(mention drug-related problem)?. For instance, *How do you feel about taking stronger doses than recommended?* (Figure 5.1). The consumer's

answer may be indicative of his/her level of readiness to change. This would allow the pharmacist to deliver intervention strategies specific to the individual. These are described below.

5.5 Intervention for precontemplators

Those who use medication inappropriately and indicate they are not even thinking about change (precontemplators) will most likely resist any attempt from the pharmacist to discuss the problem behaviour. The question to be asked in this situation is "How do we as interventionists facilitate progression from a state of not thinking about change to a state of contemplating change?

One of the strategies used in MI to facilitate movement from the stage of precontemplation to that of contemplation is to raise awareness about the behaviour (Miller, 1983), i.e. making the individual more aware of his/her inappropriate behaviour (consciousness raising). The pharmacist's job is to make the consumer aware of the behaviour and its consequences. Precontemplators need to be provided with more information about their self-medication practices and its consequences in a non-threatening manner (chapter two). Study participants were instructed simply to provide the consumer with insight into his/her inappropriate behaviour being aware that strong argumentation for change may cause the consumer to take up the other side becoming more committed to the inappropriate behaviour (Miller, 1983). Participants were instructed to ask for permission to provide information in order to minimise resistance to information provision. The protocol instructs pharmacists to provide information in third person to minimise confrontation, i.e. talk about what happens to people rather than to the individual him/herself. For example, *"Experts have found that people that take this medication for a prolonged period of time run a greater risk of developing liver damage."* Pharmacists are instructed to encourage the consumer to think about the information and make it clear that he/she will be there, if the consumer decides to talk abut it at a later stage (Figure 5.1).

5.6 Intervention for contemplators

When individuals enter the contemplation stage of change the negative aspects start to outweigh the positive aspects of the behaviour, although both are still very important for the individual (Prochaska and DiClemente, 1986). On the one hand is recognition of

a problem, on the other is avoidance of change due to what the consumer perceives as being the benefits of the inappropriate behaviour.

Those who indicate they are thinking about change (contemplators) need to be helped on working through the ambivalence about behaviour change. A decisional-balance exercise, which is used in motivational interviewing, can best do this (chapter two). The protocol instructs the pharmacist simply to ask the consumer about the positive aspect of taking the medication the way he/she does. For instance *"What is it that you like about taking these tablets every day?"* The pharmacist starts by asking about the positive aspect of the behaviour in order to minimise resistance and to motivate the consumer to subsequently talk about the negative aspect of the behaviour. Talking about the positive aspect of the behaviour first also helps the pharmacist to demonstrate empathy, recognising that there is also a good side to inappropriate use of the medication.

Once the consumer finishes talking about the positive aspect of taking the medication inappropriately, the pharmacist briefly summarises it and then get the consumer to talk about the negative aspects of taking the medication inappropriately by asking *"Is there anything you are not happy about with this tablets?"* The pharmacist then prompts the consumer to elaborate on the not so good things about the inappropriate medication consumption by asking questions, such as "How does it affect you?"; "What else?"; "What don't you like about it?" According to motivational interviewing principles, if the consumer verbalises the need to change often enough, he/she will experience a greater propensity to act upon it. Simply by allowing the patient to talk about the willingness and the need to change the pharmacist will be facilitating behaviour change.

Another important aspect of this exercise is to generate cognitive dissonance (chapter two). One of the pharmacist's goals is to heighten the psychological discomfort experienced by the consumer by highlighting the inconsistency between the medication misuse and the consumer's concerns about it. Pharmacists will be instructed to do it by succinctly summarising the positive and the negative aspects of the behaviour. For example, "So, taking analgesic products helps you to relax when you are under pressure and really feeling fed-up. On the other hand, you feel you are spending too much money on tablets and also that you are getting hooked on it." According to motivational interviewing, the psychological discomfort created by contrasting the individual's

behaviour with his/ her attitude is one of the forces that will help the consumer to act upon the inappropriate use (chapter two).

5.7 Intervention for those in the preparation stage of change

If the consumer indicates she/he is ready for change, the limited time available to the pharmacist may be better spent providing practical advice on how to go about making the change rather than on further boosting his/her motivation. Within a MI framework, the pharmacist's task is to help the consumer determine the best course of action to be taken in order to change the inappropriate self-medication practices (chapter two). A good way of starting is to set a date for the behaviour change to occur. If the medication misuse is being caused by misinformation, the consumer may commit him/herself to change upon being provided with information on how to use the product appropriately. However, in the case of chronic users and abusers the consumer will most likely need a few days to prepare him/herself for changing behaviour.

In cases of long term use, consumers will need to learn a new set of skills that will enable them to cope with the change. The cognitive-behavioural approach, which is used in motivational interviewing (chapter two), advocates the replacement of the inappropriate behaviour with more adaptive ways of satisfying the needs that it fulfilled. Pharmacists were trained to encourage consumers to think about alternative behaviours to taking the medication inappropriately. An example was to encourage those who use analgesics as a sleeping tablet to think about other ways of ensuring a good night's sleep, such as relaxation techniques, meditation, hot bath before bed, etc. If appropriate, the pharmacist should also provide the consumer with self-help materials. For instance, somebody who uses analgesics for their calming effects will profit from materials on stress management techniques and referrals.

5.8 Intervention for consumers in the action stage

In the action stage patients put into practice the skills acquired in the preparation stage. Within a MI framework, support from the pharmacist is crucial in this stage: it is important for patients to have someone with whom to discuss the progress and difficulties encountered in making the change (helping relationship process of change).

Reviewing successful attempts to change will help to increase the consumer's self-esteem and sense of mastery of the changing process. Pharmacists were encouraged to arrange follow-up visits of 3 to 5 minutes to assess consumer's progress and reinforce success.

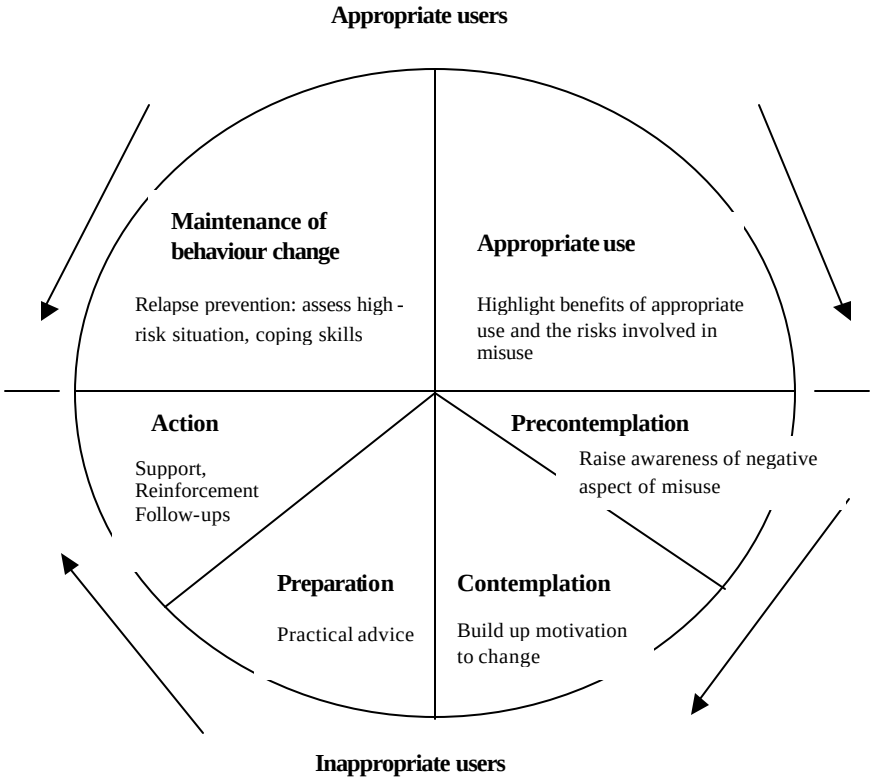
5.9 Preventive intervention

The stages of change model provided the framework for matching consumers with medication-related problems to different types of interventions to improve outcome. However, it should be noted that solving analgesic-related problems is not the only reason for monitoring these products. Maintaining the behaviour of those who use non-prescription combination analgesics appropriately is just as important as changing the behaviour of those who do not. Pharmacy practice requires a model that not only addresses behaviour change, but also addresses prevention. A framework should be provided on the basis of which patients who use medication appropriately can be optimally matched to preventive interventions.

Unlike the stages of change model, the model presented here includes two stages of appropriate use, an extension of the Prochaska and DiClemente model as applied to medication consumption (Figure 5.2). It is important to make a distinction between those appropriate medication users who have misused the non-prescription analgesic regularly in the past and those who have not, as this will provide the basis for selecting preventative intervention strategies. That is, relapse prevention strategies, in the case of former misusers, or simply misuse prevention, in the case of those who do not have a history of medication misuse. It is well known that in the area of substance use relapse is the rule rather than the exception (Saunders and Roche, 1991). An individual who is known to have inappropriately used a substance in the past is more likely to misuse it again in the future than someone who has never engaged in inappropriate use. An appropriate user in the maintenance of behaviour change stage, i.e. who has gone through a process of inappropriate use, will need to be encouraged to acquire long term relapse prevention skills, such as assessing situations in which inappropriate use of medication is likely to occur and think about responses that will minimise the chances of it taking place; strategies to escape or avoid situations where misuse may occur; and problem solving skills. However, these skills would be of less value for those who have never misused the medication (appropriate use); for the latter it would be more effective

to deliver an educational-based intervention strategy which highlights the benefits of using the product appropriately and increases the individual's perception of risks and problems related to inappropriate use. Therefore, pharmacists should assess the appropriateness of the consumer's self-medication practices and readiness to change and then deliver the intervention accordingly (Figure 5.2)

Figure 5.2 Pattern of analgesic consumption and intervention methods.



5.10 Intervention strategies for proxy consultations

If the medication is for a third party, the pharmacist shows the purchaser the Consumer Medicine Information (CMI) or other written information about the medication and asks him/her to give it to the consumer to read.

CHAPTER SIX

PRELIMINARY STUDY

6.0 Introduction

As a preliminary test of the protocol described in Chapter 5, a pilot study was undertaken. Eight community pharmacists were trained in a workshop and asked to incorporate these strategies to their practice. The impact of the training procedure was evaluated by conducting short follow-up interviews.

6.1 Ethical considerations

The study protocol was approved and monitored by the University of Sydney Human Ethics Committee (Appendix 2). All participants were required to read an information sheet explaining the nature, purpose and duration of the study prior to study inception and required to sign a consent form (Appendices 6-9).

6.2 Subjects and recruitment

After examining the study protocol the Pharmaceutical Society of Australia agreed to cooperate with the recruitment of community pharmacists. The investigator was provided with a list of 1,500 community pharmacists in the Sydney Metropolitan Area. The investigator contacted only pharmacists with a history of participating in continuing education programs who had accrued a total of 20 or more Continuing Pharmacy Education (CPE) points. A total of 73 telephone calls were made in which the researcher briefly explained the research protocol and invited the pharmacist to take part in the study. Fifteen pharmacists agreed to take part. They were randomly allocated to either an intervention (n=7) or a control group (n=8). There were 3 males and 5 females in the intervention group and 5 males and 2 females in the control group. Three of the pharmacists in the intervention group were from independent pharmacies and 5 were from pharmacies linked to marketing groups. In the control group 4 of the pharmacists were from independent pharmacies and 3 were from pharmacies linked to marketing groups. All the pharmacists in the study worked on a full time basis.

6.3 Procedure (pharmacists)

All the 8 pharmacists in the intervention group were trained on the intervention described in Chapter 5 (Figure 5.1) over a 2-day weekend workshop conducted at the Department of Pharmacy, The University of Sydney. A comprehensive manual was given to participants containing the workshop materials and additional reading (see Appendix 10 for content). The workshop started with a discussion of the importance of the study for the pharmacy profession. This was done in an attempt to remedy the low motivation to deliver behavioural intervention, which had been identified in the focus groups (Chapter 4). The study was presented as an opportunity for pharmacists to show that they could monitor the use of *pharmacist only* medication, which would help in the retention of non-prescription medicine in community pharmacies. The remainder of the workshop comprised of presentation of the stages of change model, motivational interviewing techniques, intervention strategies for optimising the use of non-prescription analgesic products, role plays and research procedure. During role-playing sessions, the investigator coached the pharmacists on the delivery of the intervention. All pharmacists were asked to evaluate the workshop using a standard questionnaire from the Department of Pharmacy, University of Sydney. No training was provided in the control condition. All intervention pharmacists were provided with a laminated algorithm of the study intervention (Appendix 11), which was to be placed on the wall in the dispensary with the purpose of reminding pharmacists of the intervention strategies. The algorithm was printed on bright green paper.

Pharmacists in the intervention group were asked to deliver the intervention upon selling *pharmacist only* analgesics that contained paracetamol, codeine and doxylamine. Control pharmacists were instructed to continue their practice as usual. The investigator intended to conduct follow-up visits to intervention group pharmacists on a weekly basis for a period of 4 weeks to ask how the implementation of the intervention affected their practice. It was further intended to conduct role-plays during the follow-up visits to ascertain continued proficiency and also coach pharmacists on any aspect of the intervention that needed refinement. Control group pharmacists were only be asked about the consumer aspect of the study, which is described below.

6.4 Procedure (consumers)

A pilot consumer questionnaire was designed to record characteristic of the product purchased, pattern of analgesic intake, knowledge about the product, readiness to change, health status, and consumer demographics. Pharmacists from intervention and control groups were asked to give consumers of *pharmacist only* analgesics the study information sheet (Appendix 8) after a purchase had been finalised. If the consumer agreed to take part in the study the consent form was provided for the consumer to sign (Appendix 9). After consenting to take part in the study, consumers were then given the study questionnaire to be filled out in the pharmacy. The investigator contacted the consumer 2 - 4 weeks after purchase and asked questions about readiness to change, pattern of product intake and knowledge about the product.

6.5 Workshop evaluation

Table 6.1 displays participants' assessment of the training workshop on the study intervention.

Table 6.1 Participants' evaluation

	Very Good	Good	Average	Poor	Very Poor
Lecturing	6	2	0	0	0
Subject matter	7	1	0	0	0
Materials	4	3	1	0	0
Relevance to my practice	5	3	0	0	0
Value to me	7	1	0	0	0

Pharmacists were asked to state what features of the workshop they liked. Five participants answered this question and three abstained from doing so. The following answers were obtained: 1) All; 2) The classification of people into "Not Ready", "Unsure" and "Ready" and how to deal with each group; 3) Subject matter and relevance to day to day practice; new knowledge about brief motivational interviewing and how to assess patients. I had thought about precontemplators before; 4) I found the whole course very good; the course was very practical. Lecturing was kept to a minimum. The material was relevant to my work situation; 5) Differentiation of stages of change amongst misusers, reflective listening skills and questioning techniques. Use

of open-ended questions and importance of it; the course has taught me how to be organised and predictive of patients' behaviour and also how to communicate effectively. All the eight pharmacists stated that they would recommend the workshop training to others.

When asked about the features of the course they found of no particular value, the following answers were obtained: 1) I thought there was some value in all aspects as it all had to do with communication with patients and this is after all the fundamental role we play; 2) Much of communication skills section was much familiar - while revision was useful, perhaps too much time was spent on this subject.

Summary of workshop evaluation

Pharmacists who participated in the training workshop rated it as being highly relevant to their practice and found the concept of readiness to change of particular value in dealing with "pharmacist only" analgesic product.

6.6 Drop out rate

Immediately after the workshop three pharmacists withdrew from the study leaving a total of five pharmacists in the intervention group: two reported that the pharmacy proprietors preferred that the research procedure was not carried out in their pharmacies; and a third pharmacist (proprietor) subsequently took part in another pharmacy practice study and reported not having enough time to be involved in the current study.

6.7 Evaluation of pharmacists' performance

During the workshop, pairs of pharmacists were asked to role-play interactions between consumers of "pharmacist only" analgesic products and pharmacists. By the end of the second day of training, all of the pharmacists were able to assess readiness to change and select strategies from Figure 5.1 that were suitable for specific consumers. A week after the training workshop the investigator started conducting follow-up visits to inquire about consumer recruitment, evaluate the efficacy of the training program, and to do on-site role-plays and ascertain that the community pharmacists were still proficient in delivering the intervention. Out of the five pharmacists who had been trained, only one was found to still recall the study intervention. The main reason given

by the intervention group pharmacists for not delivering the intervention was time constraints. Control group pharmacists were only inquired about the recruitment of consumers.

6.8 Discussion and Conclusions

The inability of pharmacists in the intervention group to recall an intervention after they had demonstrated proficiency in the workshop suggested that simply conducting workshops and providing pharmacists with a written protocol was, in this case, not sufficient to change pharmacists' practice. Despite workshop evaluation indicating that participants perceived the intervention strategies as highly relevant to their practice, pharmacists failed to put into practice the newly acquired skills and consequently lost their proficiency. It was concluded that traditional methods were not effective in developing maintained behaviour change by the pharmacists. Similar problems with generalisation of workshop training have been encountered in other health care settings, such as training general practitioners to provide advice to stop smoking (Copeman, Swannell, Pincus and Woodhead, 1989), training mental health staff to deliver family intervention (Kavanagh, Piatkowska, Clark, O'Halloran, Manicavasagar, Rosen and Tennant, 1993) or training health workers to develop and record behavioural patient goals (Kavanagh, 1994). Together, these data suggested the need for a different approach to training. Moreover, Rollnick, Heather and Bell (1992), note that the provision of a single workshop has serious limitations. It is easier for learning to take place when training is spread over a series of small sessions during a number of weeks (Rollnick et al., 1992). It was also concluded that the collection of data on the impact of the intervention upon consumers was a fruitless exercise given the fact that pharmacists were not delivering the study intervention.

CHAPTER SEVEN

DEVELOPMENT, IMPLEMENTATION AND EVALUATION OF A PILOT TRAINING PROGRAM FOR COMMUNITY PHARMACISTS

7.0 Introduction

The preliminary study described in the previous chapter suggested that simply providing a workshop was not sufficient to induce a change in practice behaviour. A brief literature view on the training of health care professional on motivational interviewing is reported in the first section of this chapter. The purpose of this literature review was to verify whether or not the failure to generalise workshop skills was consistent with the literature. A study is then reported, which aimed to increase generalisation and maintenance of workshop skills in the natural setting. A training program was developed using pseudo-patrons (mystery shoppers) after workshop training to assess participants' performance and shape practice behaviour through the provision of immediate feedback and coaching.

7.1 Training on Motivational Interviewing Methods

To my knowledge, specific training on motivational interviewing and the stages of change has only been addressed by Rollnick, Mason, and Butler (1999). They advocate that training on motivational interviewing needs to be based on the principles of the method itself. That is, the trainees' right to make their own decision about whether or not to change the way they practice should be upheld at all times. Their training model also acknowledges that it may take more than one training session for someone to gain the motivation and the confidence to put a new way of working into practice. They also argue that it is necessary to provide trainees with "a solid injection of real-world clinical problems". The aim of this section will be to view their approach to this approach.

7.2 The need for on-going training

In writing on the training of health professionals on stage-based interventions, Rolllnick, Mason, and Butler note that sustained change in practicing behaviour will not be achieved by a dose of anything, be it a workshop or a spectacularly good

consultation. They refer to the knowledge of this reality as "the most important training guideline" (p. 169). According to the authors, training is not a matter of replacing one bag of tools with another, but of subtle alterations to a repertoire, which needs gradual and ongoing fine-tuning to meet the needs of the shifting.

7.3 Knowledge about trainees' work needs

Trainer will be more successful if they do not try to change the value based of the practitioners, but to work with their language and values to accommodate the kind of methods might be of use to them. It is important to listen carefully to how they describe their everyday work problems. It should then be able to design training that is congruent with their needs.

7.4 Understanding training from practitioner's point of view

According to Rollnick et al., not all practitioners who come to a motivational interviewing workshop want to learn how to motivate patients to change their behaviour. There may be a need to motivate them to consider changing their behaviour in their consultations. It is important, therefore, to understand the training situation from their point of view. Trainers are advised to find out whether or not there are incentives for trainees to learn the new approach. Have the trainees have been sent on the course or have they chosen to be there? In other words, is the course hoops through which trainees have to jump in order to achieve something else? Is there anything in it for them to learn the new approach.

If trainees do not appear to be ready to adopt the new style of intervention being taught, the trainer is advised to ask him/herself how can he/she apply some of the principles of motivational interviewing itself to addressing their motivation? A purely skills-based workshop might meet with resistance because, for some of the practitioners, there is a more fundamental problem: they do not see the value of the method in the first place. Enhancing this perception of value might require a focus on their knowledge and relevant scientific evidence, and their attitudes towards behaviour change consultations.

Rollnick et al. notes that "patients have freedom of choice: it is not appropriate to force our views upon them and the practitioner's role is to help patients to make decisions within their own frame of reference" (p.176). According to the authors this can also applies to the importance of working in a way that is congruent with individual

workshop participant's level of readiness to change. It is true that health care professionals attend training for a variety of reasons. The fact that they are attending it does not equate to a high level of readiness to change practice behaviour. Rollnick et al. emphasises that the point that, like patients, trainees need time to think about change and to consider its importance and their confidence to take action.

They suggest that to present ideas and then create opportunities for trainees to consider their own ambivalence about them as model for workshops. Obviously, in their method, trainees are encouraged to discuss whether or not they consider an idea valid or useful and whether they can imagine themselves changing their practice to incorporate the method. In summary, the training of practitioners on motivational interviewing methods should be compatible with the principles the trainer is trying to teach.

7.5 Need for trainees to feel comfortable with workshop approach

The authors note that how comfortable the trainees are with patient-centred approach has to be taken into consideration. The table below describes their approach to familiarising trainees with the workshop procedure

Table 7.1 Approach for motivational interviewing training workshop

- describe a model for understanding changing lifestyle behaviours
- raise the issue of lifestyle change with a patient in a way that does not elicit resistance
- use an agenda-setting strategy to help a patient decide what changes he or she might talk about
- use the model and associated visual aids to assess a patient's feelings about change (readiness, importance and confidence)
- assist a patient in exploring the importance of a particular behaviour change and the confidence to achieve it
- use a range of active listing skills to enable a patient to clarify his or her own feelings about lifestyle change
- conduct a consultation in such a way as to leave the responsibility for change, and the right to decide whether or not to change, clearly with the patient
- give accurate and appropriate information about lifestyle and health in a neutral way and enable the patient to interpret the implications for his or her own situation
- describe how they handle their own frustrations when working with patients who do not, at present, want to change; and how they avoid attempting to impose their own timetable for change upon the patient
- describe an overview of the mothod's tasks and strategies
- use a menu of strategies for guiding the consultation.

Source: Rollnick, S., Mason, P., and Butler, C. Health Behavior Change: A Guide for Practitioners. Page 173.

7.6 Training and everyday practice

The authors emphasise the need of the content of the workshop to be related as closely as possible to the participants' everyday practice. As mentioned previously, this requires the trainer to have a great deal of knowledge about the practitioner's work. They suggest demonstration of situations that are closely related to trainees' work as a useful resource in training.

7.7 Pseudo-patron studies

This literature review will now focus on pseudo-patron studies as this methodology was of value in developing on-going training for pharmacists on workshop skills.

Pseudo-patient/patron studies are those which employed people to enter the health setting, not to seek treatment, but to observe and/or test the health care process. In contrast to the current study, which proposes to use pseudo-patron methodology as an educational tool, previous pseudo-patron studies have focussed primarily on assessment of the practitioners' skills.

Numerous pseudo-patient studies have been conducted with the intent of assessing practitioners' performance. A classic example is the study reported by Rosenhan (1973), in which eight pseudo-patients were instructed to enter mental hospitals and feign one symptom of schizophrenia, i.e. hearing voices. All but one of the pseudo-patients were diagnosed as schizophrenics and admitted to hospital.

These direct observations have a number of strengths as assessments of practitioner behaviour. They are conducted in the naturalistic environment, rather than in artificial testing settings (such as role-played assessments in a workshop context). They focus on the key behaviours to be tested, rather than on proxy measures such as file records of interventions that are made by the practitioner. When the practitioner is not aware that the person is not a real patient, the method also minimises the risk of the assessment being reactive, as can occur when an observer is present or the interview is being taped (Roethlisberger and Dickson, 1939). However, the issue often induces some anxiety or

resentment among practitioners, and Rosenhan's study elicited controversy concerning both the merit of his conclusions and the competence or otherwise of the staff involved (Rabichow and Pharis, 1974) (Wolitzky, 1973).

Such resentment is particularly prone to occur if the observation is very critical or was undertaken without prior consent. It is true that pseudo-patient research often results in very critical reports of practitioner behaviour. More recently, in a Dutch study, 4 pseudo-patients visited 39 general practitioners complaining of headaches, diarrhoea, shoulder pain and diabetes. General practitioners' performance was reported to have been "substandard" (Rethans, Sturmans, Drop and Van der Vleuten, 1991).

This type of research, of course, is not unique to medicine. Pharmacists have also been criticised on the basis of pseudo-patient/patron studies. For example, in a British study pseudo-patrons posed as parents requesting community pharmacists for advice on the treatment of children with diarrhoea. It was reported that 70% of the pharmacists recommended inappropriate treatment (Goodburn, Mattosinho, Mongi and Waterston, 1991). In Australia, an article was published describing a pseudo-patron study conducted by a consumer magazine. According to the article, out of 200 pharmacies visited by pseudo-patrons seeking treatment for asthma, half gave poor or even negligent advice (Creswell, 1997).

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7.8 Pseudo-patron methodology and evaluation of training

Pseudo-patron studies have also been conducted to evaluate training. For example, in a study in which pharmacy staff was trained in a 8-hour workshop to provide brief interventions aimed at raising AIDS awareness and preventing STDs, pseudo-patrons visited pharmacies to assess the rate of delivery of the intervention. It was found that training did not lead to behaviour change (Pick, Reyes, Alvarez, Cohen and Craig, 1996). It was concluded that the workshop increased short-term knowledge about AIDS and STDs, but was less successful in achieving longer retention and transfer of knowledge to clients.

Another pseudo-patron study in pharmacy went a step further and provided pharmacists with feedback from the assessments (Krska, Greenwood and Howitt, 1994), but this was delayed. In this study, volunteer pharmacists set the standards for adequate advice to be given in a number of symptom based scenarios. Pseudo-patrons were used to assess the rate of delivery of standard advice. Once data collection had finished, participating pharmacists were sent the data for their own pharmacy and for the group.

7.9 The use of pseudo-patrons as an educational tool

Continuing education of health professionals tends to rely on workshop training as a primary means of skill development. However, as noted in the previous chapter, workshops often have little impact on the day-to-day practice of participants. The data cover areas as diverse as training general practitioners to provide advice to stop smoking (Copeman et al., 1989), and on rates of reminders about Pap smears (Ward and Sanson-Fisher, 1996), training mental health staff to deliver family intervention (Kavanagh et al., 1993) and training health workers to develop and record behavioural patient goals (Kavanagh, 1994).

There are several possible reasons for this failure to generalise skills. In some cases, participants may not be committed to skill acquisition when they attend the workshop; the procedure that is taught may not be suitable for implementation, or there may be insufficient incentives for implementation when participants attempt it in the field

(Kavanagh et al., 1993). Alternatively, the workshop may not include sufficient opportunity for skills practice with corrective feedback, or the skills practice may not be in a sufficiently similar context. Preliminary data reported in the previous chapter reinforced the notion that a keen group of participants and a practical procedure were not enough to ensure continued application of the skills in the field. In the pilot study reported here, the investigator examined a strategy to increase skills and incentives in the natural environment using pseudo-patrons.

7.10 Training program: theoretical underpinning

Behavioural theorists have found that practice will result in more effective learning and retention when spread over successive days rather than concentrated in a workshop session (Skeff, Berman and Stratos, 1988). This is consistent with Rollnick et al. (1999) revised in Section 7.2. Moreover, reinforcement and feedback seem to be necessary to transfer skills acquired in workshops to the practice setting (Kavanagh, 1994). This implies that pharmacists are not likely to acquire intervention skills by discovering them, by being told about them, or by observing them. Practice over a period of time, supported by feedback, may be necessary.

The investigator predicted that an approach based on behaviour change theory that provided feedback to pharmacists on the use of the intervention with their own pharmacy consumers over time would maximise generalisation and maintenance of the skills. The study included visits by pseudo-patrons (mystery shoppers) as part of an educational program. By integrating pseudo-patron assessment into a training program, the investigator was able both to assess changes in clinical practice and to use feedback from assessments as a basis for further skills acquisition. It was intended that the feedback would also act as a powerful incentive to continue applying the skills (Bandura, 1986), especially if they could not easily predict when an assessment would take place. Moreover, if feedback emphasised positive attainment as well as providing some corrective information, it would increase pharmacists' confidence in their skills (Bandura, 1986) and help maintain their commitment to the program.

Undoubtedly, feedback on performance of newly acquired skills in the natural setting is an important factor in the acquisition of knowledge. Behaviourist theorists argue that it is critical for a person to receive information about the closeness of his/her actual performance to a predefined desired behaviour (Skeff et al., 1988). Feedback is normally more effective when provided immediately after the behaviour. When provided with immediate feedback, pharmacists and their staff should still have clear recollection of their actual performance and this allows for correction. An educator could potentially shape practice behaviour by assessing true to life performance and providing immediate feedback and coaching. Feedback would relate to how close the pharmacist's performance was to the desired behaviour and coaching would address what the pharmacist could do to improve his/her performance.

The present study incorporated the assessment advantages of the pseudo-patron methodology and used it in a collaborative manner to promote further skill development through the provision of immediate feedback after pseudo-patron visits.

7.11 Pseudo-patron as a training mechanism

The current study randomly allocated pharmacists to a group that received training that comprised a workshop plus performance feedback from pseudo-patrons, or to a control group who received neither form of training. Pharmacists' behaviour was measured at Baseline, Post and at a 14-week Follow-Up. Where the pharmacists already had a required behaviour in their repertoire - such as the requirement that they personally deliver "pharmacist only" medication to purchasers, or the delivery of standard warnings on medication effects - we expected that their awareness of impending pseudo-patron visits would be sufficient to change their behaviour without further training (i. e. that an equal degree of change would occur in control and training groups). Since we had no measure of pharmacist adherence before the study began, a Baseline assessment of pharmacists' adherence to guidelines on supply or medical warnings might overestimate their usual adherence level, since they would be aware of the assessments and would have very recently given their consent for them to occur. We expected that there may be some decay in this reactivity to assessment over the course of the study as their anxiety about the pseudo-patron visits habituated.

Where we predicted that prompting or additional training was required before the pharmacist reliably produced the target behaviour - as in the identification of misusers - the training group was expected to improve more than the controls. Consistent delivery of rewards for appropriate performance of these training foci and delivery of corrective feedback during the training phase was expected to motivate skill acquisition. Whether the behaviour changes were maintained at Follow-up was expected to depend on whether sufficient naturalistic incentives for the behaviour were present, once the consequence of performance feedback was withdrawn.

7.12 Method

Ethical considerations

The study protocol was approved and monitored by the University of Sydney Human Ethics Committee (Appendix 12). Participants gave written consent to conduct pseudo-patron visits during baseline, training phase, and follow-up phase at an unpredictable time within a period of six months. All pharmacists taking part in the study were required to read an information sheet explaining the nature, purpose and duration of the study prior to study inception and required to sign the consent form (Appendices 13 and 14).

Subjects

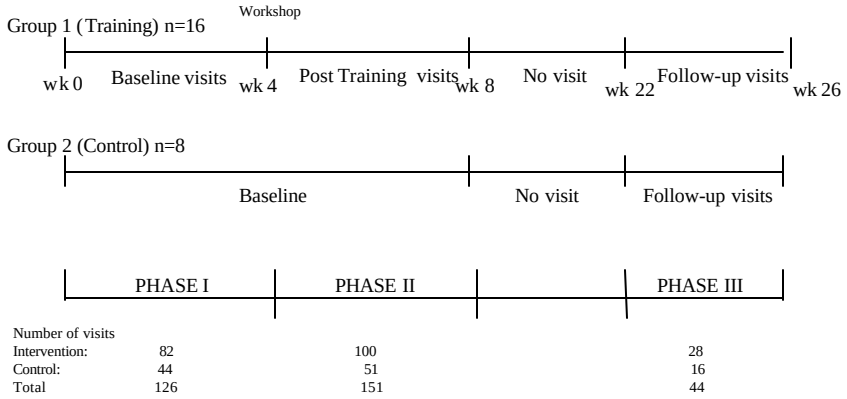
The study protocol was endorsed by the Pharmaceutical Society of Australia and the Central Coast Pharmaceutical Association who provided the investigator with lists of pharmacists who had a history of participating in continuing education programs. Twenty-four pharmacists from 24 pharmacies were recruited to take part in the study, after contacting pharmacists from the above-mentioned lists. Twenty-two of the 24 pharmacists were randomly allocated to either a training group (n=16) or a control group (n=8). The remaining two pharmacists stated time constraints would not allow them to attend training workshop and, therefore, were allocated to the control group making it a quasi-random design. Twelve of the 24 pharmacists (8 intervention and 4 control pharmacists) were recruited from the Central Coast (approximately 80 km from Sydney) and the remaining 12 (8 intervention and 4 control pharmacists) from the Sydney Metropolitan Area. Fourteen of the pharmacies were independently owned and ten were from 3 different marketing groups. Seven of the pharmacies were located in

shopping centres and considered to be of high volume, with the remaining 17 pharmacies being of lower volume.

Procedure

Throughout the study, practice was monitored in both control and intervention pharmacies through the use of pseudo-patron visits. Confederates of the researchers went to the pharmacies and made test purchases of non-prescription products without disclosing their identity and then transcribed the interaction with the pharmacists. Figure 7.1 summarises the phases in this study. There were three 4-week assessment periods: an initial Baseline period in which usual practice was observed in the pharmacies, a period immediately after a training workshop (Post) during which the training group received performance feedback, and after a further interval of 14 weeks (Follow-Up), during which participants were unaware of when further observation would take place.

Figure 7.1 Study Design



The initial training was provided to Intervention Group pharmacists in a 3-hour workshop. First, they were engaged in a discussion on the importance of the research project for the pharmacy profession. Discussion covered topics such as government policy on *pharmacy only* medication, the role of pharmacist counselling in maintaining the *pharmacist only* category of medication, and the need to record the extent of pharmacist counselling. The Stages of Change Model was discussed, the recommended

protocol was presented and skills were practised in role-plays. Pharmacists were requested to use the protocol for sales of *pharmacist only* analgesics - those containing paracetamol, codeine and doxylamine.

The concept of pseudo-patron visits was presented to pharmacists as an integral part of the training program with the purpose of coaching pharmacists in the process of developing the intervention skills. All pseudo-patrons were instructed to play the role of an inappropriate analgesic repeat user. Three scripts were chosen and rotated throughout the study: (1) dosage above manufacturers' recommendation, (2) inappropriate indication of medication, and (3) prolonged use without adequate supervision. The scenarios were based on the findings of previous research discussed in Chapter 1, which identified them as areas of pharmacist concern (Benrimoj and Chetcuti, 1994). All three scenarios were expected to trigger an intervention to help patrons reduce or stop their intake of the medication, restricting its use to appropriate circumstances and seeking medical advice to deal with problems that may lead to inappropriate use.

Pseudo-patrons were recruited by placing notes at the Student Employment Office at the University of Sydney and by emailing staff from the Department of Pharmacy offering casual employment to their relatives and friends. Seventy two percent of the 23 pseudo-patrons were women, and their mean age was 28.4 years (Range = 19 to 58). All pseudo-patrons were instructed to provide information about medication behaviour only if the pharmacist inquired about it. If the pharmacist asked an open-ended question, pseudo-patrons were to provide all relevant information about their drug taking behaviour. In the case of close-ended questions, pseudo-patrons were to provide only information pertaining to the question. All pseudo-patrons were trained prior to visiting the pharmacies, using role-plays with provision of feedback. Pseudo-patrons visited a particular pharmacy only once during the study, in order to avoid being recognised as a pseudo-patron. Four "pharmacist only" analgesic products were randomly purchased by the pseudo-patron throughout the study: Mersyndol®, Fiorinal®, Dolased®, and Panalgesic®.

Immediately following a pseudo-patron visit, the investigator walked into the pharmacy and provided the pharmacist with positive feedback, highlighting segments of the protocol that were correctly performed. Then the investigator offered corrective

feedback or coaching that addressed how the pharmacist could improve performance further.

A total of 321 pseudo-patron visits were made to the pharmacies in the study (Figure 7.1). Of these, 126 visits were conducted during baseline (Group1=82 and Group 2=44), 151 during training phase (Group1=100 and Group2=51), and the remaining 44 visits occurred 14 weeks after training had ceased (Group1=28 and Group2=16).

The pseudo-patron visits provided observations on 9 measures. Two of these were expected to change more strongly in the training group than the controls: They were identification of misuse and discussion of alternative medication. Seven others were expected to be already within the pharmacists' knowledge and skill repertoire: personal delivery of medication by the pharmacist, asking if the consumer had used the medication before, provision of warnings about drowsiness, alcohol interactions and driving, information on correct dosage, and suggesting that the patron consult their doctor. These were not expected to change differentially as a result of training, even though the workshop included reminders about some of these elements. Instead, awareness of the pseudo-patron visits over the course of the study was expected to make a temporary impact on pharmacist adherence to these behaviours across both groups.

7.13 Statistical methods

Because of variations in the number of visits across phases of the study, the primary analyses of changes in pharmacist behaviour use the proportion of visits in each phase when each behaviour was observed. Sample sizes were calculated to detect a 20% difference between intervention and control groups in rates of identification of inappropriate (off-label) use of the analgesic product with 80% power and a 5% significance level for a two-tailed test.

Distribution were tested for normality and MANOVAs were conducted to examine variables pertinent to pharmacist behaviours over the course of the study. Terms were tested against the pooled within-cells and residual sum of squares by use of the default standard method. Homogeneity of variance was tested by use of the Bartlett and the Cochran homogeneity tests. For comparison of proportions between groups (eg proportion of visits pseudo-patron was identified as a misuser, etc) chi-square tests were used.

7.14 Results

Of the 24 pharmacies two withdrew from the study during baseline phase. One pharmacist enrolled to take part in another intervention study and another pharmacist failed to attend the training workshop, leaving the intervention group with 14 pharmacists and the control group with 8 pharmacists.

As explained before, because of variations in the number of visits across the 3 phases of the study, the primary analyses of changes in pharmacist behaviour used the proportion of visits in each phase when each behaviour was observed. Mean results of pharmacy observations are displayed in Table 7.2.

Control variables

The most basic expectation of the pharmacists was that they adhere to the legal requirement that they personally deliver the "pharmacist only" analgesic medication to the purchaser. This was expected to be well known to pharmacists before the study and we predicted that it would be responsive to pharmacists' awareness that assessment would occur at unpredictable intervals during the study. At Baseline the whole sample delivered the medication personally to an average of 83% of purchasers. All of the pharmacists were adhering to this requirement on at least one visit. The rate of adherence rose further to 94% at Post ($F(1,20) = 8.30$, $p < .01$), and there was no additional effect from training ($F(1,20) = 0.04$, n. s.). However the high rate of personal service fell substantially from Post to Follow-Up to 57% ($F(1,20) = 17.19$, $p < .001$), suggesting that the previously high level was probably not reflective of normal practice, and that the effect of the pseudo-patron visits was temporary. There was a similar drop in adherence in both groups ($F(1,20) = 0.03$, n. s.). However there was still a substantial rate of partial adherence to the requirement at Follow-Up, with 77% of the pharmacists personally handling the sale of the medication during one or more of the pseudo-patron visits.

Table 7.2. Means of proportions of pseudo-patron visits where selected Pharmacist behaviours were displayed over the course of the study.

	Mean (s.d.)					
	Control Group			Training Group		
	Baseline	Post	Follow-Up	Baseline	Post	Follow-Up
Targets of Training						
Correctly identified misuse	.06 (.18)	.12 (.14)	.13 (.35)	.11 (.15)	.46 (.28)	.29 (.43)
Discussed alternate Medication	.00 (.00)	.05 (.07)	.06 (.18)	.01 (.04)	.25 (.18)	.32 (.46)
Control Variables						
Medication delivered by pharmacist	.81 (.19)	.91 (.13)	.56 (.42)	.83 (.24)	.95 (.12)	.57 (.39)
Discussed						
Drowsiness	.48 (.19)	. 22 (.10)	.25 (.27)	.55 (.23)	.29 (.25)	.64 (.41)
Driving risk	.24 (.18)	.22 (.28)	.06 (.18)	. 24 (.22)	.10 (.13)	.18 (.32)
Alcohol interaction	. 02 (.06)	. 02 (.05)	.00 (.00)	. 11 (.26)	.02 (.05)	.11 (.29)
Asked about previous use of the medication	.63 (.26)	.54 (.26)	.50 (.46)	.68 (.24)	.62 (.17)	.54 (.37)
Recommended that see a doctor	.04 (.12)	.05 (.10)	.06 (.18)	.06 (.09)	.04 (.09)	.00 (.00)
Information on dosage	. 00 (.00)	. 02 (.05)	.00 (.00)	.18 (.27)	.24 (.22)	.07 (.18)

Results are based on 8 control and 14 trained pharmacists.

As expected, a differential effect of training was also not observed on standard warnings about medication effects and on suggestions to consult a doctor. These behaviour domains were not specifically targeted by the intervention and the need to warn about side-effects was expected to be well-known to pharmacists. From Baseline to Post, groups did not differ on warnings of drowsiness ($F(1, 20) = 0.01$, n. s.), alcohol interaction ($F(1, 20) = 0.98$, n. s.) or driving ($F(1, 20) = 2.70$, n. s.), or on recommendations of medical consultation ($F(1, 19) = 0.38$, n. s.). Warnings about drowsiness and about driving were already given to pseudo-patrons on at least one Baseline visit by 95% pharmacies and 73% pharmacies respectively. However, only 18% of pharmacies warned about a possible interaction with alcohol on any Baseline visit and only 23% suggested a medical consultation.

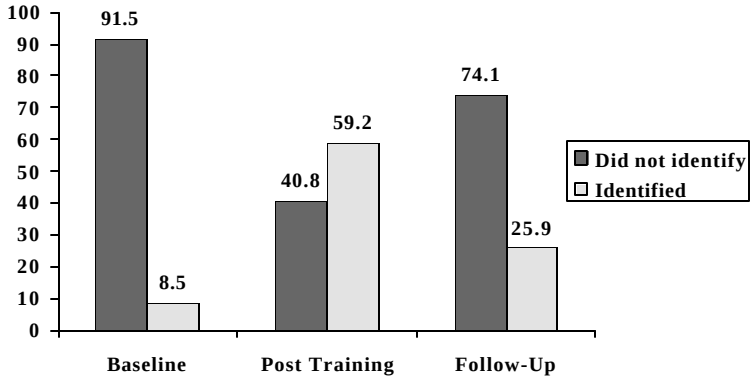
Surprisingly, both groups reduced the frequency with which they warned about drowsiness ($F(1, 20) = 34.27$, $p < 0.001$) and about driving ($F(1, 20) = 4.70$, $p < 0.05$) from Baseline to Post. By Follow-Up, the rate of warnings about drowsiness had substantially recovered (Post vs Follow-Up: $F(1, 20) = 4.70$, $p < 0.05$): As Table 7.2 shows, this recovery was particularly prominent in the training group, although the interaction with group did not reach the .05 significance level (Post vs. Follow-Up by Group: $F(1, 20) = 3.24$, $p < 0.09$). At Follow-Up, 68% of the total sample mentioned this side effect on at least one pseudo-patron visit. Warnings about driving remained relatively low from Post to Follow-Up ($F(1, 20) = 0.46$, n. s.), with only 23% of the total sample mentioning driving risks during one or more pseudo-patron visits at Follow-Up. However as in the case of drowsiness, there was an apparent trend for the training group to show some recovery in warning about driving while taking the medication ($F(1, 20) = 3.89$, $p < 0.07$).

There was no significant change over the study in warnings about interactions with alcohol (Baseline to Post: $F(1, 20) = 1.09$, n. s.; Post to Follow-Up: $F(1, 20) = 0.47$, n. s.) or recommendations of medical consultation (Baseline to Post: $F(1, 20) = 0.02$, n. s .; Post to Follow-Up: $F(1, 20) = 0.30$, n. s.) Nor were there any interactions of these Post to Follow-Up effects with Group (alcohol warning: $F(1, 20) = 1.05$, n. s.; Medical consultation: $F(1, 20) = 0.84$, n. s.). At Follow-Up, only two pharmacists (9%) warned about interactions with alcohol on any of the visits, and only one (5%) recommended a medical consultation.

Provision of information on dosage to be taken did not differ over the study (Baseline vs Post by Group: F(1, 20) = 0.04, n. s.; Post vs Follow-Up by Group: F(1, 20) = 0.03, n. s.). However, there was a significant fall from Post to Follow-up in the intervention group, from 24% to 7% (Group x Time effect: F(1, 20) = 0.17, $p < 0.05$).

In order to tell how much information to provide about a medication, pharmacists would be expected to ask whether the medication had been used before. On average, this question was asked at a high rate at Baseline (on an average of 67% of visits, across groups, and on at least one visit, by 100% of pharmacists in the sample). The question continued to be asked frequently at the Post and Follow-Up assessments (Baseline vs Post: F(1, 20) = 1.20, n. s.; Post vs Follow-Up: F(1, 20) = 0.42, n. s.). Nor did the two groups differentially change over the study on this measure (Baseline vs Post by Group: F(1, 20) = 0.03, n. s.; Post vs Follow-Up by Group: F(1, 20) = 0.04, n. s.). The question was still being asked by 73% of the total sample on at least one of the Follow-Up visits.

Figure 7.2. Percentage of visits in which the pharmacist identified the patient was an off-label user by study phase



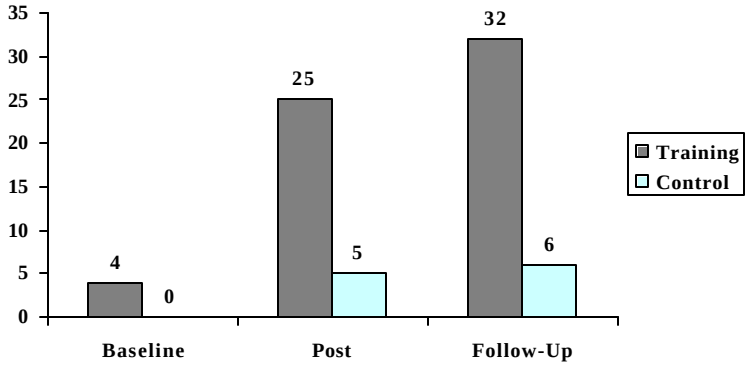
Targeted pharmacist behaviours

In contrast to the results on the previously discussed measures, changes in the two variables expected to be most likely to respond to training (identification of misuse and recommendations of alternate medication), did indeed show a differential training

response. Results on these two variables are shown in Table 7.2 and Figures 7.2 and 7.3. Across groups, there was a significant improvement from Baseline to Post in the proportion of visits on which misuse of medication was detected ($F(1, 20) = 17.26$, $p < 0.001$). This effect was primarily due to an increase in detection by the training group rather than to changes in controls (Group x Time effect: $F(1, 20) = 8.63$, $p < 0.01$). At Post (when workshop training was completed and performance feedback was being given), the training group correctly identified the patron as a misuser on an average of 46% visits, as against an average of 12% for the control group. The misuser was identified on one or more pseudo-patron visits at Post, by 100% of pharmacists in the training group, but only by 50% of the control pharmacists (χ^2 (1) = 8.56; $p< 0.01$). The improvements in detection were maintained from Post to the 14-week Follow-Up: Despite an apparent drop in the average proportion of clients detected by pharmacists in the training group (Table 7.2), neither the main effect for Post vs Follow-Up ($F(1, 20) = 1.61$, n. s.), nor the interaction of Time with Group: ($F(1, 20) = 1.70$, n. s.) were significant. However, the misuser was identified on at least one Follow-Up visit by only 36% pharmacists in the training group, and this figure did not significantly differ from the proportion of controls who did so (12.5%; χ^2 (1) = 1.38; n. s.).

Similar changes in performance were obtained on discussion of alternative medication (Figure 7.3). There was a significant increase across the whole sample from Baseline to Post in the proportion of visits on which an alternative medication was discussed by the pharmacist ($F(1, 20) = 15.76$, $p < 0.001$). While the controls showed little improvement, alternate medicine was discussed by the training group on 25% visits at Post, compared with 1% at Baseline ($F(1, 20) = 6.53$, $p < 0.02$). Alternate medication was discussed during at least one of the visits by 86% of the training group at Post, as compared with 38% of the control pharmacists (χ^2 (1) = 5.46; $p< 0.05$). There was no significant change from Post to Follow-Up, either across groups ($F(1, 20) = 0.22$, n. s.), or differentially in the two groups ($F(1, 20) = 0.12$, n. s.). However, the proportion of training Group pharmacists who discussed alternate medication on at least one pseudo-patron assessment was only 36% at Follow-Up, compared with 13% in the control group (χ^2 (1) = 1.38, n. s.).

Figure 7.3. Percentage of visits in which the pharmacist recommended an alternate medication by group and phase



7.15 Discussion

The results support the notion that reinforcement and feedback are necessary to transfer skills acquired in workshops to the practice setting (Kavanagh, 1994), discussed earlier in this chapter. Providing community pharmacists with workshop training followed by feedback and coaching effectively shaped practice behaviour of community pharmacists during the study period. Pharmacists in group 1 were more likely to detect inappropriate use of non-prescription medication, discussing this with consumers and providing alternatives. Fourteen weeks after training these effects on average performance were substantially maintained, although the proportion of the trained pharmacists who met criteria on one or more visits was almost half the proportion at Post.

Effects on pharmacists' behaviour were not seen in domains that were already in their repertoire of knowledge and skills or that were not specifically targeted in the training. So, although the training reviewed requirements for direct delivery of the analgesics by the pharmacist, this did not result in a substantial increase in personal delivery above the effect of pharmacists knowing they were being observed. This was

presumably because the requirement was already known to them - as evidenced by the fact that pharmacists in the control group personally handed the medication to an average of 91% of the pseudo-patrons at Post. Adherence to this requirement appeared to be substantially affected by habituation, with the rates dropping by almost 50% during the Follow-Up period.

The performance feedback did not target the provision of information about side effects or drug interactions. Perhaps partly as a result, there was a temporary decrease in provision of information about drowsiness or driving that recovered at Follow-Up. While interactions of these time effects with Group were not significant with the sample size used in the current study, the results suggest that training to increase pharmacist intervention for changes in consumer behaviour should ensure that basic clinical tasks are not neglected in the process. In retrospect, the low level of warning about interactions of analgesic mediation with alcohol suggests that this clinical issue should have been a particular focus of training, because of the significant risks that are posed by this drug interaction. We recommend that further studies examine this issue as an important target for behaviour change by pharmacists. There were other limitations to current methodology: data collection did not allow for analysis per scenario; there was no control for reliability of pseudo-patrons' transcripts; no control for reliability of scoring methods; feedback provision was not standardised; and the design was quasi-random as opposed to random. There were also concerns about the pseudo-patrons, as a large proportion of them was comprised of students from the University of Sydney, which could have made it easier for pharmacists to identify them.

Questions about long-term sustenance of behaviour are still to be answered. However, the fact that 14 weeks after training the effects of training were still detectable indicates that continuous application of the intervention skills may lead to their incorporation to practice behaviour.

CHAPTER EIGHT

HYPOTHESIS TESTING: REFINEMENT OF A TRAINING METHODOLOGY

8.0 Introduction

In light of the satisfactory results obtained in the study described in the previous chapter it was decided to conduct a randomised control trial to replicate findings after refining the methodology. In the study reported in this chapter more pharmacies were recruited (30); a greater number of pseudo-patron visits were conducted (453); the training period was extended to 6 weeks; audiotaping was used for greater accuracy of performance feedback; feedback was standardised; variables relating to assessment of readiness to change and the delivery of intervention strategies accordingly were also recorded and measured; training not only focused on behavioural techniques, but also stressed clinical warning about medication side effects; and pseudo-patrons were recruited from the general population in an attempt to minimise identification. In addition, this final study also attempted to assess the impact on consumers of this training of pharmacists.

8.1 Method

Ethical considerations

Prior to initiation of the study, the study protocol was approved and monitored by the University of Sydney Human Ethics Committee (Appendix 15). Each person taking part in the study (pharmacists, pharmacy assistants and consumers were required to read an information sheet explaining the nature, purpose and duration of the study prior to study inception and required to sign a consent form (Appendices 16-21).

Subjects

Thirty pharmacies whose pharmacists were perceived by their peers as being "clinically minded" were conveniently sampled to take part in the study. Pharmacy managers were firstly contacted by telephone with a researcher briefly explaining the study. When the pharmacy manager permitted an appointment was made to see him/her. If pharmacy manager agreed, pharmacists were approached and given the study information sheet (Appendix 16) and invited to take part in the study. If they

agreed to do so, they were asked to fill out the consent form (Appendix 17). Forty-three pharmacists from the 30 pharmacies were conveniently recruited to take part in the study. They were randomly allocated to either a training group (n=15 pharmacies) or a control group (n=15 pharmacies). Rondomisation procedure consisted of pressing the "random" button of a portable calculator after pharmacists from a particular pharmacy agreed to take part in the study. In the advent of an even number the pharmacy was allocated to the intervention group and an odd number to the control group. Of the 43 pharmacists from the 30 pharmacies, 22 were control and 21 intervention group pharmacists. Eighteen of the 30 pharmacies were from the Sydney Metropolitan Area and remaining 12 were from regional centres in commuting distance of Sydney (80 - 100 km north). Twenty-three pharmacies were independently owned and 7 were linked to marketing groups. Eleven of the pharmacies were located in busy shopping centres and considered to be of high volume, with the remaining 19 pharmacies being of lower volume.

Intervention

The intervention strategies adopted in this study were a simplified version of those described in chapter six. However, they were revised to make it more suitable for community pharmacist use. The results in Chapter 6 showed that pharmacists failed to recall the study intervention a few days after workshop training. The investigator predicted that an approach that was based on only two stages of change, namely whether or not the consumer was ready to change, would lead to better chances of memory retention, but still be effective.

The Precontemplation and Contemplation stages were collapsed into one, "Not Ready Stage" and the preparation and action stages into "Ready Stage". The theoretical rationale for collapsing these stages of change into two was provided by research reported in Chapter 2, which reported that the processes of change represented two second-order factors: cognitive/experiential and behavioural (Prochaska and DiClemente, 1992) (Prochaska, Velicer, DiClemente et al., 1988) (Perz et al., 1996). That is, verbal change processes (cognitive/experiential), such as feedback and education, were found to be critical variables in making the decision to change, whereas the action processes (behavioural), such as stimulus control and counterconditioning were more effective in terminating dysfunctional behaviour (Prochaska and

DiClemente, 1982). In this study, community pharmacists were trained to assess whether or not the consumer was ready to change and then provide feedback and education (cognitive/experiential processes) to misusers who appeared not to be ready to change and practical behavioural advice (behavioural process) to those who appeared to be ready to change.

Pharmacists assessed consumer's readiness to change by either asking how the consumer felt about the particular behaviour or asking whether or not he/she was happy about the behaviour (Figure 8.1) eg. *How do you feel about taking more than 8 tablets a day?* or *Are you happy about taking more than 8 tablets a day?*. The consumer's answer gave the pharmacist an indication of whether or not s/he is ready to change. The appropriate strategy could then be used: if the consumer was not ready to change, the pharmacist was trained to provide information about the inappropriate use in a non-confrontational manner in order to motivate the consumer to change; if the consumer was ready to change, the pharmacist was trained to provide him/her with practical advice on how to go about changing (Figure 8.1).

As in the previous study, at the beginning of the interaction, pharmacists prompted consumers to talk about the medication intake by asking an open-ended question, *"How is it going with these tablets?"* or *"How do you find these tablets?"* Closed-ended questions were only asked if consumers failed to provide relevant information after being asked an open-ended question.

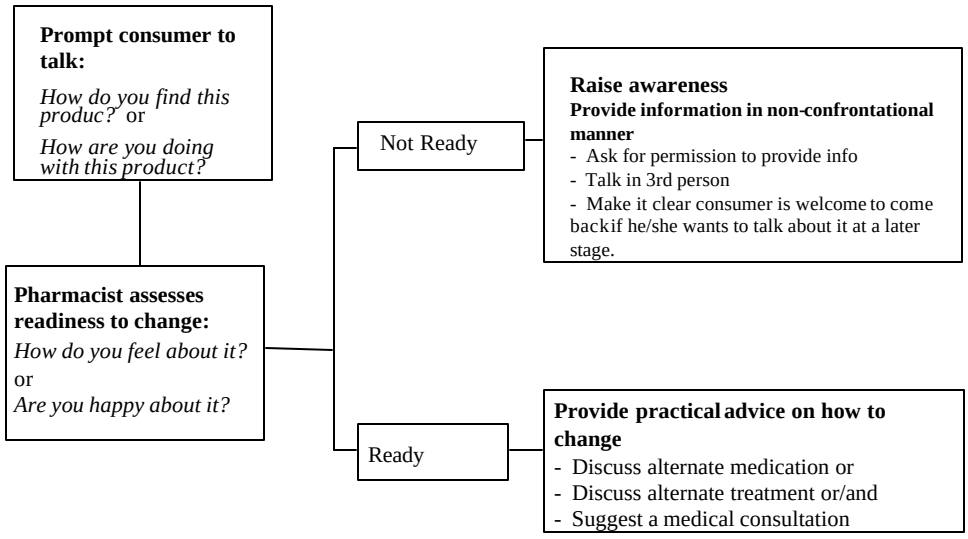
Workshop: training of pharmacists

As in the previous study, initial training was provided to Intervention Group pharmacists in a 3-hour workshop. First, they were engaged in a discussion on the importance of the research project for the pharmacy profession in order to build up motivation to adhere to the study protocol. Discussion covered topics such as government policy on *pharmacy only* medication, the role of pharmacist counselling in maintaining the *pharmacist only* category of medication, and the need to record the extent of pharmacist counselling. The Stages of Change Model was discussed, the recommended protocol (Figure 8.1) was presented and skills were practised in role-plays. Results from the previous study concerning clinical warning about side effects were presented and pharmacists were sensitised to the issue of replacing clinical warning by the study intervention. Pharmacists were requested to use the protocol for

sales of *pharmacist-only* analgesics - those containing paracetamol, codeine and doxylamine.

Figure 8. 1.

Intervention strategies for inappropriate users



Training of educators

Four hundred and fifty-three visits to pharmacies were conducted during the current study. It is noted that pharmacies in the study were in different locations in the Sydney metropolitan area and in regional centres outside the metropolitan area (80 - 100 km north). There was a need to employ two "educators" on a casual basis to help the investigator with the research procedure.

A 27-year old female psychologist who was completing her final year of a Ph.D. at the University of Sydney and a 43 year old female former bank manager were interviewed and hired as "educators" to assist the investigator. A total of 40 hours of training was provided to the educators. Training consisted of theoretical underpinning of the intervention used, pseudo-patron methodology, and research procedure including feedback provision and role-plays. The educators were trained to provide feedback in a respectful manner talking about the positive aspect of the pseudo-patron/pharmacist

interaction first and then inquiring about the aspect of the interaction in which the participant needed to improve on by asking how the pharmacist was finding it. For example, *How are you finding the assessment strategies?* The two educators were also required to attend the pharmacist-training workshop and were encouraged to interact with participants to establish a certain degree of rapport prior to commencing the data collection.

Procedure

Pseudo-patrons were recruited by placing advertisements on bus stops and shopping malls. Throughout the study, practice was monitored in all the pharmacies through the use of pseudo-patron visits. Confederates of the researchers went to the pharmacies and made test purchases of non-prescription products without disclosing their identity. Again, the concept of pseudo-patron visits was presented to pharmacists as an integral part of the training program with the purpose of coaching pharmacists in the process of developing the intervention skills. The methodology was negotiated with the pharmacists prior to study commencement and signed consent to collect the data was obtained from all pharmacists in the study (Appendix 17). It should be noted that pharmacists' awareness of pseudo-patron evaluation was an integral component of the training program. This awareness was needed to motivate continued application of the workshop skills in the field.

There were 2 assessment phases: during an initial 3-week Baseline period; and for six weeks immediately after workshop training when training group pharmacists received performance feedback (Post). The responses of control pharmacists to the pseudo-patrons were assessed in the same way as for the training group, but no feedback on performance was given. All interactions with the pharmacists were audiotaped using a small taperecorder concealed by the pseudo-patron. Pseudo-patrons transcribed the interaction immediately after leaving the pharmacy.

All pseudo-patrons were instructed to play the role of an inappropriate medication user. Three scripts were chosen and rotated throughout the study: (1) dosage above manufacturers' recommendation, (2) inappropriate indication of medication, and (3) prolonged use without adequate supervision. The scripts were based on the findings of previous research (see Chapter 1), which identified these scenarios as areas of pharmacist concern (Benrimoj and Chetcuti, 1994). For each of the script the pseudo-

patrons were trained to display one of two levels of readiness to change*: ready to change* and *not ready to change*, totalling 6 scenarios. The *ready to change* scenario consisted of the pseudo-patron accepting pharmacist's advice (eg. buying a product other than the one requested on pharmacist's advice). In the *not ready* scenarios pseudo-patrons were instructed not to take pharmacist's advice (eg. refuse to lower the dosage as recommended by the pharmacist).

All pseudo-patrons were instructed to provide information about medication behaviour only if the pharmacist inquired about it. If the pharmacist asked an open-ended question, pseudo-patrons were to provide all relevant information about their drug-taking behaviour. In the case of close-ended questions, pseudo-patrons were to provide only information pertaining to the question. All pseudo-patrons were trained prior to visiting the pharmacies, using role-plays with provision of feedback. In order to avoid being recognised as a pseudo-patron, confederates visited a particular pharmacy only once during the study. Four "pharmacist only" analgesic products were randomly purchased by the pseudo-patron throughout the study: Mersyndol®, Fiorinal®, Dolased®, and Panalgesic®.

Immediately following a pseudo-patron visit, one of three researchers from the University of Sydney walked into the pharmacy and provided the training group pharmacist with feedback, emphasising positive features of the pharmacist's performance. Then the researcher offered corrective feedback or coaching that addressed how the pharmacist could improve performance further. A feedback sheet was designed highlighting essential features of the intervention (clinical assessment, assessment of readiness to change, and use of an appropriate strategy) to facilitate provision of standardised feedback (Appendix 22). Pharmacists got a tick for the components of the intervention they performed well and the ones requiring further training were left blank. A carbon copy of the assessment sheet was given to the pharmacist.

The time and day of pseudo-patron visits were randomly rotated in every week of study to avoid participants being able to predict the visits. A total of 453 pseudo-patron visits were conducted. Of these, 153 visits were conducted during Baseline (median = 6, range = 4 – 6 per pharmacy) and 300 during the training period (median = 12, range = 8 – 13 per pharmacy).

The pseudo-patron visits provided observations on 11 measures. The measures that were directly related to the intervention and therefore were expected to change more strongly in the training group than the controls were: 1) use of open-ended questions; 2) identification of misuse; 3) assessment of readiness to change; 4) provision of information on misuse; 5) discussion of alternate medication; 6) and suggesting that the patron consult a doctor. Five others were expected to be already within the pharmacists' knowledge and skill repertoire: 1) personal delivery of medication by the pharmacist; 2) asking if the consumer had used the medication before; 3) warning about drowsiness; 4) warning about alcohol interactions; 5) and warning the patron not to drive. These were not expected to change differentially as a result of training, even though the workshop included reminders about some of these elements. Instead, awareness of the pseudo-patron visits over the course of the study was expected to make a temporary impact on pharmacist adherence to these behaviours across both training and control groups.

After training had finished, acceptability of the pseudo-patron procedure was measured by sending to each pharmacist in the training group a survey questionnaire and pre-paid addressed envelope. To minimise bias, the responses were anonymous. A question about the pseudo-patron methodology was embedded in a set of more general questions to conceal the main purpose of the survey. The survey asked for some ratings on how much they liked the overall training, the practicability of the intervention, how much they liked the pseudo-patron training and feedback, and how much they liked the study intervention. Two open-ended questions were also asked: "What did you like about the training?" and "What did you NOT like about the training?".

To determine interater reliability, an independent assessor re-coded 15% of pharmacist/pseudo-patron interactions. The investigator who did the coding also re-coded 15% of his data to determine intra-rater reliability. Reliability was calculated by *k* statistic (Altman, 1991).

8.2 Statistical methods

As in the previous study, because of variations in the number of visits across the baseline and training phase of the study, the primary analyses of changes in pharmacist behaviour were based on the proportion of visits in each phase when a particular behaviour was observed. Sample sizes were calculated to detect a 15% difference

between intervention and control groups in rates of identification of inappropriate (off-label) use of the analgesic product with 80% power and a 5% significance level for a two-tailed test.

Distributions were tested for normality and MANOVAs were conducted to examine differences in participants' behaviour between experimental and control groups at pre- and post-workshop. Terms were tested against the pooled within-cells and residual sum of squares by use of the default standard method. Homogeneity of variance was tested by use of the Bartlett and the Cochran homogeneity tests. For comparison of proportions between groups chi-square tests were used (eg. sex). Where an unpaired comparison was appropriate, the Wilcoxon rank sum test was used (eg. age versus gender).

8.3 Pre-training characteristics of subjects

There was no significant difference between the ages of pharmacists in the intervention and control groups (df = 1, χ^2 = 1.34, n.s.). There was no significant difference between the 2 study groups in terms of the gender proportions of pharmacists in each group (df = 1, χ^2 = 1.98, p = 0.14). Male pharmacists were significantly older than their female counterparts (Wilcoxon rank sum test Z value = -5.71, p = 0.001).

8.4 Results

Withdrawal rate

Of the 30 pharmacies three withdrew from the study during baseline phase. One pharmacist withdrew for health reasons and 2 because of time constraints, leaving the training group with 13 and the control group with 14 pharmacies.

Assessment of information needs

The use of open-ended questions replaced the closed question about past use, and allowed the pharmacist to obtain the same information, but with additional data about the consumer's misuse. Pharmacists in the study generally asked if the consumer had taken the medication before. On average, this question was asked at 59.5% of visits at Baseline, across groups. The frequency of this question decreased at Post to an average of 44.2% of visits ($F(1, 25) = 8.95$, $p < 0.05$). This was primarily due to a decrease in

the frequency of this question in the training group (Group x Time effect: $F(1,25) = 7.33$, $p < 0.02$). Mean results of pharmacy observations are displayed in Table 9.1.

As predicted, the use of open-ended questions increased from 0.03% at Baseline to 39.5% at Post ($F(1,25) = 113.32$, $p < 0.001$). This was mainly due to an increase in the use of open-ended questions by the training group From 0.03% at Baseline to 68.0% at Post (Group x Time effect: $F(1,25) = 63.72$, $p< 0.001$).

Legal requirement

The most basic expectation of the pharmacists was that they adhered to the legal requirement that they personally deliver the *pharmacist only* analgesic products to the purchaser. As this should be well known to the pharmacist before the study, we predicted that it would be responsive to pharmacists' awareness that assessment would occur at unpredictable intervals during the study. At Baseline the whole sample delivered the medication personally to an average of 75.7% of purchasers. The rate of adherence was 82.1% of purchases at Post ($F(1,25) = 3.64$, n.s.) and there was an additional effect from training (Group x Time effect: $F(1,25) = 9.01$, $p < 0.01$) with the rate increasing in the training and decreasing in the control group (Table 8.1).

Misuse identification

Across groups, there was significant improvement from Baseline to Post in the proportion of visits on which misuse of medication was identified ($F(1, 25) = 55.80$, $p<0.001$). As expected, there was an effect of training ($F(1,25) = 32.97$, $p > 0.001$), which was primarily due to an increase in the rate of misuse identification by the training group from 16.2% at Baseline to 66.9% at Post.

Readiness to change

Once misuse was identified, pharmacists assessed the consumer's readiness to change by asking how s/he felt about the behavior in question. Out of the 67% of Post visits to the training group in which misuse was identified, readiness to change was assessed 69.1% of the time with a significant effect of training ($F(1,25) = 14.58$, $p < 0.001$).

Table 8.1 Proportion of pseudo-patron visits where selected Pharmacist behaviours were displayed over the course of the study.

	Mean (s.d.)			
	Control Group		Training Group	
	Baseline	Post	Baseline	Post
Used an open-ended Question	. 03 (.10)	. 13 (.17)	. 02 (.06)	. 68 (.24)
Correctly identified misuse	.10 (.23)	. 17 (.19)	. 17 (.26)	.67 (.20)
Assessed readiness to change	. 00 (.00)	. 09 (.24)	. 01 (.04)	. 47 (.26)
Provided information on misuse	.12 (.19)	.13 (.19)	.19 (.16)	.59 (.24)
Discussed alternate medication	.04 (.18)	.14 (.19)	.12 (.18)	.51 (.23)
Provided practical advice	. 12 (.21)	. 19 (.24)	. 13 (.18)	. 66 (.23)
Recommended that see a doctor	.06 (.12)	.11 (.17)	.04 (.08)	.33 (.19)
Medication delivered by pharmacist	.81 (.17)	.77 (.18)	.70 (.31)	.88 (.18)
Discussed				
Drowsiness	. 57 (.22)	. 49 (.20)	. 55 (.27)	.26 (.15)
Driving risk	. 18 (.21)	. 17 (.18)	. 36 (.31)	.15 (.14)
Alcohol interaction	. 02 (.06)	.03 (.07)	.15 (.21)	.04 (.14)
Asked about previous use of the medication	.61 (.24)	.59 (.19)	.58 (.26)	.28 (.18)

Results are based on 14 control and 13 trained pharmacists.

The training and control group differed in the rate of misuse identification when the pseudo-patron played the role of a consumer who was ready to change, "ready scenarios" (Table 8.2, $F(1,25) = 21.56$, $p<0.001$). This was due to an increase in the rate of identification from Baseline to Post ($F(1, 25) = 26.85$, $p<0.001$) with the training group presenting a greater rise over time ($F(1, 25) = 14.16$, $p<0.001$).

A similar result was observed with the "not ready scenarios". The rate of identification of misuse differed between the two groups (Table 8.2, $F(1, 25) = 8.00$, $p<0.01$) with an increase from Baseline to Post ($F(1, 25) = 58.14$, $p<0.001$). Again, a greater rise over time was observed in the training group ($F(1 ,25) = 37.99$, $p<0.001$).

Table 8.2 Average percentage of visits per type of scenario on which misuse was identified.

	Control Group (n=14)		Training Group (n = 13)	
	Baseline	Post	Baseline	Post
Scenario				
Ready to change	9.5%	17.0%	20.5%	68.0%
Not ready to change	10.7%	16.3% 1	0.3%	62.6%

Results are based on a total of 543 visits to pharmacies.

Intervention for medication misuse

Once the pharmacist determined whether or not the consumer was ready to change he/she would then either provide information on misuse of the medication to those who were not ready and practical skills on how to go about changing to those who were ready. Changes in performance were obtained on the provision of information about the particular medication misuse ($F(1,25) = 29.96$, $p < 0.001$) with an effect of training (Group x Time effect: $F(1,25) = 28.04$, $p < 0.001$). In 76.2% of visits to the training group on which misuse was identified and the pseudo-patron was not ready to change,

information on the misuse was provided in 76.2% of time. Such information comprised of: warning about the addictive or constipating properties of codeine when taken in excess of label specifications; or/and explaining what the substances in the tablets were for (paracetamol, codeine and doxylamine), especially in case of non-analgesic use of the medication; or/and risks of hepatic side effects.

There was also a significant increase across the whole sample from Baseline to Post in the proportion of visits on which an alternate medication was suggested by the pharmacist ($F(1,25) = 32.58$, $p < 0.001$). The use of an alternate medicine was discussed by the training group on 51.5% of visits at Post, compared with 11.8% at Baseline (Group x Time effect: $F(1,25) = 12.94$, $p < 0.001$). Out of the visits at Post to training group pharmacists on which the pseudo-patron was ready to change, a more appropriate medication was suggested 65.45% of time.

At Baseline only 0.05% of the whole sample suggested that the pseudo-patron consult a general practitioner. This rate rose to 21% at Post ($F(1,25) = 28.86$, $p < 0.001$). This effect was primarily due to an increase in the rate of suggestion to see a General Practitioner by the training group rather than to changes in controls (Group x Time effect: $F(1,25) = 15.33$, $p > 0.001$). However, practical advice, which encompassed suggesting a medical consultation, suggesting an alternate medication or treatment, was provided on 69.60% of visits when the pseudo-patron played the role of a consumer who was ready to change.

Specific warnings about effects of the medication

As in the previous study, a differential change across the groups from Baseline to Post was observed in the provision of specific warnings about medication effects, ie possible interaction with alcohol ($F(1,25) = 5.25$, $p < 0.05$), risk of driving a motor vehicle ($F(1,25) = 9.22$, $p < 0.01$) and about the drowsiness effect ($F(1,25) = 19.64$, $p < 0.001$). These effects were due to a greater decrease in warning by the training group than in controls (Group x Time effect: $F(1, 25) = 6.25$, $p < 0.02$; $F(1,25) = 7.95$, $p< 0.01$; $F(1,25) = 6.93$, $p< 0.02$, respectively).

Inter- and intrarater Reliability

The κ values for inter-rater reliability exceeded 0.8 for all items on the rating scale. The κ values for intra-rater reliability also exceeded 0.8 for all items.

Acceptability of pseudo-patron procedure

Out of 17 questionnaires sent to pharmacists in the training group (Appendix 23), 10 were returned to the researchers. Pharmacists were asked to rate on a 11-point likert scale how much they enjoyed the pseudo-patron and feedback training (0 = not at all and 10 = very much). Ratings had a median of 9 (Range = 3-10), and nine of the ratings were at 5 or above.

8.5 Consumer methodology

Pharmacy assistants were required to recruit consumers of *pharmacist only* analgesic products after a purchase had been finalised. They were paid at a rate of $25.00 for every 10 consumers recruited. Two 10-minute phone interviews were conducted 2 – 4 weeks after recruitment. All consumers who agreed to take part in the study were paid for their participation at a rate of $10.00 per interview. Pharmacists were not involved in the recruitment procedure in order to avoid contamination of the interview.

Difficulties in recruiting consumers of *pharmacist only* analgesic products led to the recruitment of a small sample size (N=90) precluding meaningful statical analysis of the data. It was not possible to gauge the impact of the training of community pharmacists upon consumer behaviour due to a lack of statistical power therefore the data will not be reported. In addition to the small sample size, recruitment rate varied greatly among pharmacies, this meant that an even bigger sample size was needed than initially estimated. Results showed that 45.6% of subjects were recruited from 4 of the 27 pharmacies in the study with six pharmacies not recruiting any subject at all and three recruiting only one each. Moreover, anecdotal reports from pharmacy assistants indicated that regular users of these products were highly reluctant to join the study. Nevertheless, the full description of the consumer methodology and results are given in the next chapter.

8.6 Conclusions

In direct contrast to previous pseudo-patron studies (Chapter 7), a high proportion of pharmacists accepted the procedure. As the procedure had been negotiated with pharmacists, there was no sense of betrayal. Instead, participants recognised they would also profit from the procedure by further developing their professional skills.

The results were consistent with the notion that when a workshop is combined with on-site performance feedback, it enhances in the natural setting practitioners' adherence to protocols. Trained pharmacists showed significant improvement on all components of the protocol.

Consistent with the previous study, there was a decrease in the rate of provision of clinical information about the analgesic product, i.e. interaction with alcohol, drowsiness and the risk of driving, despite the fact that training emphasised provision of such information. This was not caused by differences in number of sales of *pharmacist only* analgesic products pre- and post workshop as no significant interaction was detected between volume of sales and training. This effect may be due to limits on the time that a pharmacist spends with a patient. There may need to be a prioritising of what is needed at the moment of analgesic purchase. Another possibility is that trained pharmacists were correctly identifying patients who needed information on adverse effects, and only gave such information to those consumers. However, a further possibility is that, in focusing on the need to change dysfunctional use, pharmacists neglected important clinical information. This has shown to be a robust effect as it happened even after pharmacists had been sensitised to it during workshop training.

Contrary to prediction, the results did show an effect of training on legal requirements that pharmacists personally deliver the "pharmacist only" analgesic product. For ethical reasons there could be no true baseline measure of personal provision of the medication, in which the pharmacists were unaware of the assessment. The differential effect across groups was best explained by an initial inflation of performance that was related to awareness that they were being assessed and a subsequent decline in the control group due to habituation to the assessment. The same habituation did not occur in the training group because the workshop and post-workshop feedback maintained a sensitisation to assessment. The results for personal delivery of the medication were in contrast to the previous study, which had shown a sustained increase. It could have been the case that in the previous study a third assessment phase at an unpredictable time period sustained sensitisation to assessment for a longer period of time. Additional research is needed to establish whether this explanation is accurate. It also remains to be seen whether or not a change in behaviour would be observed when using a random sample of pharmacists instead of a self-

selected sample. Only then would one be comfortable in generalising the conclusions of this study to pharmacists as a whole.

The results also show an effect of training on referrals to medical practitioners. The area of analgesic misuse is an inter-professional one, requiring collaboration between community pharmacists and general practitioners. Greater involvement of pharmacists in the health care chain may lead to an improvement in health outcomes.

CHAPTER NINE
CONSUMER METHODOLOGY AND RESULTS

9.0 Introduction

The methodology regarding measurement of the impact of the study intervention upon consumers is presented in this chapter together with results. However, as indicated in the previous chapter, difficulties in recruiting consumers of "pharmacist only" analgesic products led to the recruitment of a small sample size precluding meaningful statical analysis of the data. Consequently, data obtained from the consumer questionnaires are reported descriptively.

9.1 Sample size

A sample size of 200 consumers per group would provide 80% power to detect a difference (α= 0.01) of 15% between consumers recruited from the intervention and control groups in proportion of pharmacists giving information about the product sold to pseudo-patrons. The total number of subjects the investigator needed to recruit was approximately 400.

9.2 Recruitment

Consumers of "pharmacist only" analgesic products were to enrol at the time of purchased and two 10-minute phone interviews were to be conducted. A series of assessments were out, these are described in a later section. Pharmacy assistants recruited the consumers after a purchase had been finalised. Pharmacy assistants were paid at a rate of $25.00 for every 10 consumers recruited. At enrolment, consumers were asked to fill out an enrolment card, which contained his/her name, telephone number and best time to be contacted. All consumers who agreed to take part in the study were paid for their participation at a rate of $10.00 per interview. Pharmacists were not involved in the recruitment procedure in order to avoid contamination of the interview.

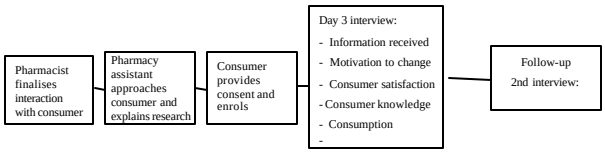
9.3 Inclusion and exclusion criteria

The inclusion criteria consisted of: consumers purchasing analgesic products for their own use; consumers who were 18 years of age or above; ability to communicate in the English language; and consumers who provided written consent to participate in the study. At the enrolment point consumers were given information about the study including interview points. Consumers who indicated inability to complete the two interviews were excluded.

9.4 Procedure

Figure 9.1 displays the consumer methodology. Consumers from intervention and control pharmacies were to be interviewed by phone within three days of purchasing the analgesic product. A second interview was to be conducted: a) two weeks after purchase, for those who reported buying analgesics more than once fortnightly; b) or 4 weeks after purchase for those who reported buying analgesics less frequently than fortnightly. The interviews were conducted by 3 independent researchers blinded to study condition. The following behaviours and attitudes were to be assessed during the first interview; 1) motivation to change; 2) consumer knowledge about analgesic products; 3) consumer satisfaction with the interaction; 4) information received; 5) and analgesic consumption. These are described later in this chapter. Because the number of off-label users was very small, data on motivation to change were not reported in the results. Some demographic data were also collected with the intent of testing them for outcome prediction. The second interview did not include demographics, satisfaction scale nor did it include knowledge questionnaire (Appendix 24).

Figure 9.1: Study design in relation to consumers



9.5 Consumer behaviour and product purchased

The consumer questionnaire included a series of questions on consumer behaviour and product purchased (Appendix 25). This consisted of consumer's current health status and drug taking behaviour. These questions aimed to help the investigator determine whether or not the consumer was taking the medication according to label instructions.

9.6 Assessment of motivation to change: Readiness to Change Questionnaire

Only consumers who were believed to be using analgesic products contrary to label specifications (off-label users) were to be assessed on their level of readiness to change. This was to be done by using 12 questions adapted from the "Readiness to Change Questionnaire" (Appendix 25) which is an instrument for measuring the "stage of change" reached by an excessive drinker of alcohol. All questions were modified to be used in the area of medication consumption. Items representing each of the stages of change (Precontemplation, Contemplation, and Action) are regarded as scales measuring the extent to which the subject endorsed that stage of change. Because in developing the questionnaire researchers found that items representing the Maintenance

stage of change had not been answered by subjects in a reliable and valid manner the Maintenance stage was left out of the questionnaire. Allocation of subjects to one of the stages of change is based on the highest raw score obtained among the three scales. It should be stressed that the suggestion that the questionnaire can be used for measuring stages of change in relation to medication consumption has not yet been tested. This was the first study that was going to test the validity and reliability of the questionnaire when used for measuring stages of medication consumption. The questionnaire was also be used to assess any changes in motivation which had taken place over time. This was to be accomplished by giving the "Readiness to Change Questionnaire" shortly after the intervention was delivered (first interview) and also at the second phone interview which took place a few weeks later. However, due to the low number of off-label users recruited (9) analysis of the above questionnaire became pointless.

9.7 Assessment of knowledge

At the first and second phone interviews consumers were asked four questions concerning safety, adverse effects and indications of analgesic products (Appendix 25). Performance of respondents from the intervention group was to be compared to that of the control group.

9.8 Satisfaction

Because the motivational interviewing techniques used in this study are comparable with patient-centred intervention styles found to be related to good outcome (Rollnick, 1992) there were certainly good grounds for testing the hypothesis that ratings of satisfaction with the interaction would not significantly decline in the intervention group. At the first interview, consumers were requested to rate satisfaction with the interaction with the pharmacist on a 11-point Likert scale (Appendix 25). It should be pointed out that the current study is concerned with satisfaction with the particular interaction with the pharmacist.

9.9 Data analysis

The primary end-points of the study were whether or not pharmacists provided consumers with information about the medication being purchased and whether or not there was a shift in motivation to change behaviour among off-label users. Secondary

end-points consisted of whether or not there was a difference between the intervention and control group in: consumer satisfaction with the interaction; level of consumer knowledge about analgesic products; and patterns of analgesic consumption. Between proportion were going to be analysed using Chi-squared ((2) statistics and difference between means would be compared using t tests. Logistic regression (W) were also going to be used to find predictors of outcome.

9.10 Results

Ninety-seven consumers of "pharmacist only" analgesic products were recruited to take part in the study (54 from intervention pharmacies and 43 from control pharmacies). Out of the 97 consumers, 12 withdrew from the study before the second interview was conducted and 7 met exclusion criteria (purchased the medication for someone else) and were excluded from data analysis leaving a total of 78 subjects. A further 16 subjects could not be contacted for the follow-up with only 61 participants undergoing the second interview. As mentioned earlier, the small sample size did not allow for meaningful statistical analysis, therefore results are presented descriptively. Another factor precluding meaningful analysis was the wide variation in recruitment rates among pharmacies in the study. Results showed that 45.6% of subjects were recruited from 4 of the 27 pharmacies in the study with six pharmacies not recruiting any subject at all and three recruiting only one each (Table 9.1). This had the effect of making the sample less representative of the population of consumers of "pharmacist only" analgesic products inflating the sample size needed for meaningful analysis. Any attempt to compare the two groups probably would have been heavily influenced by these 4 pharmacies. Between group and comparisons between consumers and pseudo-patron data were kept to a minimum. It should be noted that pseudo-patron data were representative of the whole sample of pharmacies in the study whereas consumer were not.

Table 9.1 Number and percentage of subjects recruited by pharmacy*

Harmacy Number	No. of subjects	Percentage of subjects
1	6	6.7
2	2	2.2
3	8	8.9
4	3	3.3
5	7	7.8
6	1	1.1
7	1	1.1
9	1	1.1
10	9	10.0
11	0	0
12	0	0
13	15	16.7
14	7	7.8
15	2	2.2
16	2	2.2
17	0	0
18	3	3.3
19	0	0
20	2	2.2
21	2	2.2
22	3	3.3
23	3	3.3
24	0	0
26	0	0
27	9	10
28	4	4.4
Total	90	100

* Subjects who later on withdrew from the study were included in this table

9.11 Consumer demographics

For the reasons mentioned above, demographic data could not be tested as predictors of outcome, as previously intended. However, these data are presented in this section descriptively. It could the case that females were over represented, 90% of the sample (81) was composed of females. The age distribution is displayed on Table 9.2 and the educational level on Table 9.3.

Table 9.2 Percentage of participants by age

Age bracket	Percentage of participants
<31	13.3
31 to 40	24.5
41 to 50	24.5
51 to 60	26.6
>60	7.8
Missing	2.2

Table 9.3 Education level by number and percentage of study participants

	No. of consumers	Percentage of consumers
None	13	14.4
School certificate	49	54.4
Higher School Certificate	14	15.6
Associate Diploma	5	5.6
Undergraduate Diploma	3	3.3
Bachelor Degree	6	6.7
Total	90	100.0

9.12 Product purchased

Eleven of the 90 subjects (12.2%) who were eligible to enter the study purchased the "pharmacist only" analgesic product for the first time. Seventeen of the subjects (18.9%) reported their doctors not to be aware of their analgesic consumption. Reported frequency of intake at time of purchased varied from 22.2% of consumers taking the medication daily to 15.6% taking it less than monthly (Table 9.4). Thirty-one consumers (34.4%) reported buying other types of analgesic products with Panadol® (paracetamol) being the most popular one (Table 9.5). The most common reason for purchasing the "pharmacist only" analgesic product was migraine/headache (66.3 % of consumers), this is displayed on Table 9.6.

9.13 Inappropriate use

Out of the 90 consumers initially recruited, 9 (10%) were believed not to be taking the analgesic product according to label specifications. At the follow-up point (second interview), 19.7% of participants (12) were found not to be taking the analgesic product according to label specifications. The types of off-label use is displayed on Table 9.7. Seven out of these 12 subjects were off-label users identified at the first interview.

9.14 Pharmacist involvement and information provision

Seventy percent of respondents (63) reported having been served by the pharmacist, 26.7% (24) by the pharmacy assistant, 2.2% (2) did not know and 1.1% (1) reported having been served by both, pharmacist and pharmacy assistant. Seventy six percent of respondents (68) reported having received information about the product purchased from the pharmacist. Out of these consumers, 67.3% reported having been warned about drowsiness effects, 37.4% about the effects of alcohol, and 26.9% reported having been asked if they had taken the medication before. See Table 9.9 for a more detail description of the content of the pharmacist/consumer interaction as reported by questionnaire respondents. Of these consumers who reported receiving information from the pharmacists 40.3% (27) reported that the pharmacist prompted them to talk about the medication by asking how they were going with the tablets or how they found the tablets (34.5% of the total sample).

Table 9.4 Reported frequency of analgesic intake at time of purchase

Frequency of intake	No. of cnsumers	**% of consumers**
Daily	20	22.2
Weekly	25	27.8
Fortnightly	10	11.1
Monthly	21	23.3
Less than monthly	14	15.6
Total	90	100

Table 9.5 Number and percentage of consumers who reported to buy other analgesics by product.

	No. of consumers	Percentage
Panadol	13	40.6
Mersyndol	1	3.1
Naprosyn	6	18.8
Voltarin	1	3.1
Indocid	1	3.1
Panadeine Forte	1	3.1
Paralieve	1	3.1
Feldine	1	3.1
Nurofen	4	12.5
Sudafed Plus	1	3.1
Efexort	1	3.1
Panamax	1	3.1
Total	32	100

Table 9.6 Condition the analgesic product was being taken for by number and percentage of consumers*

Product Name	No. of consumers	% of consumers
Period Pain	8	9.0
Migraine	33	37.1
Headache	26	29.2
Muscle pain	5	5.6
Insomnia	2	2.2
Insomnia + pain	1	1.1
Back pain	3	3.4
Kidney pain	3	3.4
Pain from cancer	1	1.1
Toothache	1	1.1
Arthritis	3	3.4
Post-operative pain	1	1.1
Pinched nerve	1	1.1
Neuralgia	1	1.1
Total	89	100.0

*There was one missing data

Table 9.7 Type of off-label use by number of consumers and percentage of the total sample at fist interview.

	No. of consumers	% of the total sample
Non-analgesic use	4	4.4
Dosage above recommendation	4	4.4
Prolonged use without supervision	1	1.1
Total	9	10.0

Table 9.8 Type of off-label use by number of consumers and percentage of the total sample at follow-up point

	No. of consumers	% of the total sample
Non-analgesic use	4	6.6
Dosage above recommendation	5	8.2
Taking more than one analgesic	1	1.6
Prolonged use without supervision	2	3.3
Total	12	19.7

Table 9.9 Content of pharmacist/consumer clinical interact as reported by consumers by number and percentage of consumers

	No. of consumers	Percentage of consumers
Drowsiness*	10	14.9
Drowsiness and alcohol	16	23.9
Drowsiness and dosage	3	4.5
Drowsiness, alcohol, dosage**	5	7.5
Drowsiness, not to operate machinery or drive	4	6.0
Drowsiness and before***	4	6.0
Drowsiness, before, alcohol	2	3.0
Drowsiness, not to operate machinery and dosage	1	1.5
Alcohol	2	3.0
Before and alcohol	2	3.0
Before	8	11.9
Before and dosage	2	3.0
Dosage	3	4.5
Recommended something else	2	3.0
Warned it was for severe pain only	2	3.0
Warned about constipation, liver damage, drowsiness, addictive properties	1	1.5
Total	67	100.0

*Warned about drowsiness
**Warned about alcohol
***Asked if consumer had taken it before

9.15 Knowledge

The knowledge section of the questionnaire was composed of five items. For the first item, "When taken with alcohol the tablets I bought many cause ……", 66.7% of respondents indicated "drowsiness" was correct. For the second item, "It isn't safe to take more than ….", 8.9% of respondents answered "8 tablets a day" was correct, with the vast majority of consumers (35.6%) indicating "6 tablets a day" was correct. The third item was the same as the previous one, but referred to a single dosage, "It isn't safe to take more than….. ", with 70% of respondents answering "true" to "2 tablets at a time". For the fourth item, "What are the unwanted effects of codeine?", 45.6% of respondents answered constipation was correct; 58.9% answered drowsiness was correct; and 47.8% answered "true" for "increases the effects of alcohol". For the final knowledge item " Which of the following pain killers can cause liver damage if used in large doses?" 35.6% of respondents indicated "aspirin" was correct.

9.16 Satisfaction

Ratings of satisfaction with the interaction with the pharmacist were 8.92 (SD=1.56) for the intervention group and 9.13 for the control group (SD=1.28).

9.17 Discussion

Based on the data collect from 90 consumers from intervention and control pharmacies it was not possible to gauge the impact of the training of community pharmacists upon consumer behaviour due to a lack of statistical power. In addition, as mentioned earlier, the fact that recruitment rate varied greatly among pharmacies, meant that an even bigger sample size was needed than initially estimated.

It is also not possible, based upon the current data, to get a true estimate of the proportion of consumers of analgesic products who was not using these products in accordance to label specifications. It could be the case that the proportion of off-label users was deflated by the unwillingness of those who misuse analgesic products to participate in the study. Anecdotal reports from pharmacy assistants indicated that regular users of these products were highly reluctant to join the study. If, indeed, pharmacy assistants were right on their account of consumer recruitment, the non-accessibility of regular users poses a big barrier to studying this sub-group of users.

Data on product purchase should also be approached with caution. It is true that 34% of consumers reported buying other types of analgesic products. However, this does not mean consumers were taking both types of analgesics concurrently. At hindsight, the questionnaire should have been more specific and included an additional question related to intake. Further research is needed to determine whether or not consumers take other analgesic products in addition to combination analgesics. However, it should also be noted that paracetamol (Panadol®) was the most popular second analgesic, which is one of the safest analgesics in terms of poisoning and toxicity.

Despite the fact that data obtained from consumers are biased, as previously discussed, mostly coming from a few pharmacies, it may be worth it cautiously mentioning that 70% of respondents reported having been served by the pharmacist compared to the 82.1% figure obtained from pseudo-patron data post training. It could be the case that the population of consumers differed from the population of pseudo-patron in terms of familiarity. If, indeed, there is a difference in proportions reported by pseudo-patrons and consumers, this could be explained by inflation of performance that was related to unfamiliarity, i.e. unfamiliar faces were suspected of being pseudo-patrons leading to a higher rate of personal delivery of the medication to this group. However, additional research is needed to establish whether there is a significant difference between these two groups.

The study also attempted to measure satisfaction with the interaction with the pharmacist. Clearly, satisfaction is a very broad topic and it was not the researcher's intention to conduct any in-depth study of it. A satisfaction scale was included in the questionnaire in order to get an indication of whether or not the intervention had a negative impact on consumers' perception of the pharmacy. This was done because focus group (Chapter 4) showed that fear of decline in patronage was a barrier to counselling on "pharmacist only" analgesics. It is true that the sample size was too small, however a larger sample size could not necessarily guarantee a meaningful comparison between the two groups. Satisfaction is a very complex area of study and one cannot assume that satisfaction with an interaction with the pharmacist is mutually independent from overall satisfaction which is a multidimensional construct (Passmore, 1990) encompassing many different facets of a community pharmacy being beyond the scope of the current study.

Data on consumer knowledge about analgesics showed a large proportion of consumers not to be aware of important information about dosage and side effects related to analgesic products. This reinforces the need for training pharmacists on intervention strategies specific for analgesic products.

Low recruitment rate despite the fact that both recruiters (pharmacy assistants) and consumers were being paid for their participation in the study, highlights the difficulties involved in researching consumers of "pharmacist only" analgesic products. Effective methodology for investigating consumer behaviour among off-label users needs to be developed to throw light in the area of analgesic misuse. However, for the time being, the effectiveness of stage-matched counselling in other areas of substance use like smoking secession, provides a sound basis for continuing to train community pharmacists on the techniques used in the current study.

CHAPTER TEN

GENERAL DISCUSSION

10.0 Introduction

The present study supports the notion that reinforcement and feedback are necessary to transfer skills acquired in workshops to the practice setting (Kavanagh, 1994) (Chapter 7). In the initial pilot study (Chapter 6), community pharmacists who were trained through means of workshop alone, failed to incorporate the newly acquired skills to their practice and consequently lost their proficiency. In the subsequent pilot study (Chapter 7), when workshop was followed by ongoing on-site training with immediate feedback and coaching through the use of pseudo-patron visits, the investigator was able to shape community pharmacists' practice behaviour in relation to the monitoring of *pharmacist only* analgesic products. This is also consistent with claims by behavioural theorists (Chapter 7) that practice results in more effective learning and retention when spread over successive days rather than concentrated in a short period of time (Skeff, 1988).

The methodology was then refined and in the final study trained pharmacists were significantly more likely than control pharmacists and baseline to engage in a number of behaviours related to the study intervention. These included handling the sales of *pharmacist only* analgesics themselves, identifying inappropriate use, assessing readiness to change, and delivering an intervention according to the consumer's readiness to change.

The most innovative feature of the current study was the introduction of performance feedback and coaching as an integral part of training. Before the development of the current training techniques, continuing education of community pharmacists used to rely on workshop training alone, which has been found to be ineffective in changing the practice behaviour of health professionals. A powerful incentive for pharmacists to practice the study intervention with their own consumers was provided by their awareness of the impending pseudo-patron visit.

Performance feedback was provided in a respectful manner with educators delivering positive reinforcement first, i.e. talking about the positive aspect of the pseudo-patron/pharmacist interaction first, and then inquiring about the aspect of the interaction

in which the participant needed to improve on. The fact that the researchers were adequately trained in feedback provision and that the study emphasised the pseudo-patron methodology as an educational exercise may have had an impact on participants' approach to the study. This may have lead to the high degree of acceptance and satisfaction with the methodology reported by participants (Chapter 9). Moreover, because all participants were fully aware of and consented to the methodology, there was no sense of betrayal. However, one should be cautious in attributing the high rate of protocol adherence solely to the pseudo-patron methodology. The client-centred approach aspect of the study intervention also may have been a factor in pharmacists' motivation to deliver the intervention. It is reasonable to assume that the pseudo-patron methodology provided the means by which pharmacists became proficient in the intervention and the consumer-centred features of the intervention acted as a motivator for pharmacists to intervene. It is important to approach the training mechanism and the intervention strategies as part of a whole rather than isolated features of the study.

It is noted that the high rate of delivery of intervention strategies reported in Chapters 8 and 9 supports the assumption made in Chapter 3 that the delivery of stage-matched intervention could lead pharmacists to set realistic goals for encounters with inappropriate analgesic users sustaining motivation to intervene. These results are also consistent with the principle of self-efficacy (Bandura, 1977): the stage-matched intervention may have lead pharmacists to experience a greater sense of mastery of the situation when encountering inappropriate analgesic users which could have contributed to sustaining motivation to keep on delivering the intervention strategies. The results are also in line with DiClemente's et al. claim that a stage-matched approach to behaviour change is related to an increase in morale, since health professionals can see progress with the majority of their patients, instead of failure when immediate action is the only criterion for success (Chapter 3). It is also the case that the intervention strategies were congruent with pharmacists' concerns expressed in focus groups (Chapter 4), it also may have contributed to pharmacists' adherence to the protocol.

Another factor that may have contributed to the success of the study as a whole was the endorsement given to the project by the Pharmaceutical Society of Australia, the Central Coast Pharmaceutical Association and by the Faculty of Pharmacy, University of Sydney.

10.1 The study intervention

Background,

The brief consumer-centred intervention strategies used in this project was based on the TTM and principles of motivational interviewing, as applied to a public retail situation, and was developed specifically for use with consumers of *pharmacist only* analgesic products. Focus groups showed that participants had concerns about adopting confrontational counselling styles, as they feared this would antagonise consumers leading to loss of patronage without having an impact on consumer behaviour. This concern was later reinforced by brief consumer interviews, which showed that a significant proportion of respondents thought that the use of non-prescription analgesics was their responsibility. The protocol for the sales of analgesic products was designed with these issues in sight.

Experts in the area of brief interventions in health settings may see the intervention used in the final study as being too simplistic, as only two levels of readiness to change were used, *ready* and *not ready*. It is important to note that when devising pharmacy-based interventions, one has to take into account the retail nature of a community pharmacy and its daily activities, which do not allow for complex intervention procedure. It should also be kept in mind that most pharmacists have not had any exposure to cognitive/behavioural approaches to intervention. Moreover, it is well known in professional circles that community pharmacists are happy to deliver a brief intervention, but do not want to become counsellors. The present project did not intend to train pharmacists in motivational interviewing, but to train them to deliver a brief intervention based on motivation interviewing principles.

Wider application

Application of the intervention techniques used in the current study has the potential to improve routine care by community pharmacists in a variety of therapeutic areas. This has been acknowledged by one of the authors of the TTM, Prochaska, who has recently cited the current study in a manuscript on pharmacy care practice (Johnson, Grimley and Prochaska, 1998). It is noted that the intervention strategies used in this study are generalisable and could be used with other non-prescription medication whose misuse may lead to adverse reactions. Examples of these are laxatives, as abuse has been shown to be associated with severe water-electrolyte disorder (Milliez and Meyer,

1966) and diphenhydramine as its abuse can lead to poisoning (Aderjan, Bosche and Schmidt, 1982). Vitamins are another good example. Current trends toward healthy lifestyles and the prevention of disease have fostered the abuse of vitamin/mineral supplementation raising concerns about bioavailability of nutrients in supplements, possible nutrient imbalances, and potential toxicity with misuse and overuse (Couris, 1994).

Impact of the study intervention

As a result of the current project, the more comprehensive intervention strategies described in Chapter 6 have now been incorporated to the pharmacy curriculum of the University of Sydney. Consequently, young pharmacists are starting to take into account the importance of intention and motivation in the management of inappropriate medication use. This has potentially increased the prospects of effective prevention and management of inappropriate analgesic use. As young pharmacists enter the workforce, the more familiar the profession will be with the TTM and principles of motivational interviewing. This will increase the likelihood of pharmacists in the near future being able to deliver brief intervention addressing the full spectrum of change, as described by Prochaska and DiClemente, rather than only the two stages used in the final study of this project. Moreover, concepts of motivational interviewing and the TTM have been incorporated to the Standards for the provision of *pharmacist only* and p*harmacy* medicines put out by the Pharmaceutical Society of Australia (Appendix 24) as a result of the current study. Every registered pharmacist in Australia has been mailed a copy of the standards of practice, which may lead to a greater focus on intention and motivation in current pharmacy practice.

10.2 Pseudo-patron methodology

The training techniques developed in this project have been taken up by other researchers in the area of behaviour modification in a pharmacy setting and have now been used in a wide range of studies. These are described below.

The use of pseudo-patron methods on the training of pharmacy assistants

Once the current study demonstrated the effectiveness of pseudo-patron methodology as an educational tool, researchers at the University of Sydney progressed

to extend this technique to pharmacy assistant training (Kelly, 1998). Protocols for non-prescription medicines were developed to encourage pharmacy assistants to elicit information from consumers more frequently and refer to the pharmacist as appropriate. In this study, pseudo-patron methodology allowed researchers to monitor and successfully shape behaviour of pharmacy assistants after workshop training. The frequency of pharmacy assistant protocol application increased in test sites from 18% to 74% of pseudo-patron visits pre- to post-intervention with statistical significance (χ^2 = 23.88, $p<0.001$).

The University of Sydney has now been commissioned to train pharmacy assistants from the Boots pharmacy chain in the United Kingdom on pharmacy-based protocols for non-prescription medication. This will be done using the pseudo-patron methodology developed in the current study. A researcher from this university will be going to the United Kingdom in January 2000, to implement a protocol specific for pharmacy assistants for a period of six months.

Pseudo-patron methodology and the establishment of standards of practice in Australia

Once the effectiveness of pseudo-patron methodology in shaping behaviour was well established, the next step was to train both groups, pharmacists and their staff, concurrently. This was done in relation to the development of standards of practice (Benrimoj, Gilbert, Crampton and Quintrell, 1998). These included items, such as human and financial resources, time spent with consumer, screening and referral systems, care and counselling provided to consumers, etc. Once standards had been developed, protocols for pharmacy staff were developed to encourage compliance. Thirty-nine pharmacies were conveniently sampled to participate in the protocol implementation trial. Pharmacists' and pharmacy assistants' behaviour was shaped over a period of 6 weeks after workshop training through the provision of feedback and coaching immediately after pseudo-patron visits. Protocol application for all participating pharmacies increased from an average of 26.9% during baseline to 51% at the end of training phase ($p<0.0001$).

More recently, The University of Sydney and The University of South Australia were given funds from the Guild/Government Community Pharmacy Agreement to raise the standard of pharmacy practice in Australian community pharmacies relative to

the supply of pharmacy and pharmacist only medicines. The standards of practice developed in the study described in the previous paragraph will be implemented in New South Wales, Victoria, Queensland and South Australia, again using the pseudo-patron methodology developed in the current study. The project is due to commence in January 2000, and will last for a period of two years. It should also be noted that, as mentioned above, the pharmacy protocol used in the standards of practice uses the concept of readiness to change from the TTM and motivational interview and was based on the protocol developed in the current study (Appendix 24).

Pharmaceutical industry as a resource for pseudo-patron methods

Although the previous studies provided support for the effectiveness of pseudo-patron methodology in shaping behaviour, large-scale implementation of pharmacy-based protocols would be costly. Educators and pseudo-patrons would have to be trained and remunerated, transport organised and the process of shaping behaviour may be time consuming. However, the utilisation of resources and infrastructure already available in the pharmaceutical industry overcame these problems. This was done in two collaborative studies between the University of Sydney and the pharmaceutical industry. The first study aimed to monitor consumers of antacids and anti-reflux agents for the treatment of heartburn and indigestion and to switch them to more effective medication like H_2 antagonists when appropriate.

Eleven sales representatives from Warner Lambert were trained as educational representatives to provide training to pharmacists and pharmacy assistants from ninety-nine pharmacies in the main metropolitan cities in Australia. Following the initial training sessions in which the current author took part, the "educational representatives" took six pseudo-patrons to pharmacy over a period of 12 weeks. The methodology developed in the current project was used by the educational representatives to shape the behaviour of pharmacists and pharmacy assistants.

There were two main outcome measures in this study, product sales and behaviour of pharmacy staff. Average weekly sales of H_2 antagonists significantly increased from 0.55 product sales during the baseline period to 0.89 product sales after delivery of the training ($p<0.05$). Practice behaviour was assessed by frequency of protocol application during the pseudo-patron visits. Immediately after the initial training, 35% of pharmacy assistants were found to refer the pseudo-patron to the pharmacist as required. This

increased to 59% of pharmacy assistants by the end of the study. Similarly, pharmacists' practice behaviour also improved with 78% of pharmacists conferring with the final pseudo-patron about their condition and medications.

The second study was then conducted by the current author and Professor Benrimoj in which sales representatives from Hoechst Marion Roussel were trained as educational representatives to assist in a program aimed to optimise the management of analgesic products. Following an initial training workshop on protocols specific for analgesics, the educational representatives took six pseudo-patrons to pharmacy over a period of 7 weeks. Pseudo-patrons were coached in standardised scenarios: they either requested a treatment for pain or a specific product. Educational representatives provided the pharmacists and pharmacy assistants with feedback and coaching immediately after the pseudo-patron visits. Practice behaviour was assessed by frequency of protocol application during the pseudo-patron visits. Both pharmacists and pharmacy assistants were found to achieve a high level of protocol application and improvements were noted with each pseudo-patron visit. Immediately after the initial training, protocol adherence by pharmacy assistants was 25%. This increased to 68% by the end of the study. Pharmacists' adherence to the study protocols was high throughout the study with an average of 74.5% adherence. In addition, anecdotal reports indicated an improvement in relationships between pharmacists and sales representatives. Hoechst Marion Roussel is now examining a proposal to extend the training in the year 2000 to a greater number of pharmacists in New South Wales and Queensland.

These were pioneer studies in the sense that the role of sales representatives was extended to that of an educator. While industry sponsorship enabled wide distribution of the training, there was variability on the ability of each representative to achieve a high level of protocol application.

The international perspective: Changing Swiss Pharmacists' and Pharmacist-Assistants' practice in dealing with Non-Prescription Analgesics

The present studies were conducted in Australia. The next step was to test the pseudo-patron training methodology internationally. This was done in a study in which pseudo-patron methodology was used to implement an innovative pharmacy-based protocol based on the stages of change and health belief models in pharmacies in the Swiss province of Neuchâtel (Sigrist, 1999). Twenty-seven pharmacies were recruited

to take part in the study and randomly assigned to either an intervention group (n=14) or a control group (n=13). Pseudo-patron visits measured practice behaviour in intervention and control sites pre- and post-training workshop (n=189). A researcher provided feedback and coaching to pharmacy staff immediately following each of 70 pseudo-patron visits to the training group pharmacies.

A scoring system was developed to evaluate the impact of the program on practice behaviour. One-way analysis of variance detected statistically significant differences in mean protocol scores between intervention and control pharmacies post-training ($F(1,25)>7.19$, $p<0.013$). Higher scores were also reported in intervention sites for each of the three elements within the theoretical framework when these were computed separately.

Concluding remarks on the pseudo-patron methodology

The above section reported the refinement of an existing observational technique through the extension of its use as a behaviour change mechanism post workshop training. Once enough evidence was gathered as to the effectiveness of the pseudo-patron methodology as a behaviour change tool, other researchers used it to train not only pharmacists, but their staff as well. The methodology was also found to have international application. The issue of pseudo-patron methodology being resource intensive in nature, was overcome by having educational representatives from the pharmaceutical industry delivering the program in the training of pharmacists and their staff. It should be noted that all studies mentioned above also used a consumer-centred stage-matched approach to counselling. As in the current study, this may have contributed to the high rate of protocol adherence.

The methodology was reported by researchers to have been well accepted by participants in all the studies mentioned above. Subjects knew that they would profit from learning new skills and that practicing them in the natural setting would assist them in daily interaction with consumers. It is also noted that, as the studies above show, the training technique developed in this study has now been used in several therapeutic areas including non-prescription analgesics, cough-cold medicines, and H_2-antagonists optimising the monitoring of these products. With the advent of greater accountability training that, like the pseudo-patron methodology, has clearly defined

outcomes and can be monitored and modified is vital to promote best practice and thus facilitate safe, effective self-medication.

The study methodology can potentially be expanded to domains other than pharmacy. As mentioned in Chapter 6, problems with generalisation of workshop training have been encountered in other health care settings, such as training general practitioners to provide advice to stop smoking (Copeman et al., 1989), training mental health staff to deliver family intervention (Kavanagh et al., 1993) or training health workers to develop and record behavioural patient goals (Kavanagh, 1994). The training programme developed in this study could be adapted to the medical domain to facilitate change in practice behaviour in the training of doctors and nurses.

10.3 The study and the current environment

The literature has consistently reported the likelihood of adverse reactions related to the abuse of analgesic products (Chapter 1). Because potent analgesics are not under medical surveillance but are available to the public without a medical prescription, any attempt to influence consumer behaviour in relation to these products must be via interventions at pharmacist level. The Australian government is now pressuring the pharmacy profession to monitor effectively the use of non-prescription medication. As seen in Chapter 1, the Industry Commission into the Pharmaceutical Industry has recommended that the current scheduling for *Pharmacy* and *Pharmacist Only* medication should only be retained "pending further research into the role of pharmacist counselling in ensuring improved health outcomes and monitoring of the extent of such counselling". The results from the current study are of particular importance for the pharmacy profession in the sense that it is a response to the Industry Commission recommendation. The methodology developed in the current study is now widely used in Australia and abroad to train pharmacists and pharmacy assistants on pharmacy-based protocols.

10.4 Direction of future research

As previously mentioned (Chapter 8), it remains to be seen whether or not a change in practice behaviour would be observed when using a random sample of pharmacists instead of a self-selected sample. Studies like the above-mentioned one on the

standards of practice, which is due to start in 2000, will most likely answer this question.

Lack of resources also precluded the investigation of sustenance of behaviour change beyond training period in the final study. It is true that the study reported in Chapter 7 found that 14 weeks after training the effects of training were still detectable. However, monitoring of behaviour change over a longer period of time is necessary for an evaluation of whether or not the continuous application of the intervention skills leads to their incorporation to practice behaviour.

The current study has other limitations. Although the consumer-centred intervention has a sound theoretical basis (Chapters 2 and 3) there is no assurance it has an impact on consumers of *pharmacist only* analgesic products. Had more resources and time been allocated to the current study, the next step would have been to develop means whereby consumers are assessed on the impact of the intervention strategies. It may well have been the case that lack of statistical power was not the only barrier to investigating consumer behaviour. A larger sample size would not necessarily enable researchers to do so as it may not be representative of the population of consumers of *pharmacist only* analgesic products. As anecdotally reported by pharmacy assistants, regular users of pharmacist only analgesic products were reluctant to take part in the study (Chapter 8). A methodology in which consumer concerns about joining a study of this nature can be identified and dealt with would need to be developed, not only to improve recruitment rates, but also the representativeness of the sample.

There is no study reported in the literature that identifies the proportion of patients who successfully abstain from benzodiazepines and take up codeine and doxylamine combinations. It could be the case that *pharmacist only* analgesic products are being used as substitutes for benzodiazepines with consumers being too frightened to disclose their behaviour as they would perceive it as a threat to their accessibility to these products.

The issue of pharmacists decreasing warning about side effects with training in the intervention strategies still remains to be solved. The final study tried to address this by emphasising the provision of such warning to consumers during training. It should be noted that the feedback sheet used in this study did not contain items on clinical warning about side effects (Appendix 22). This may have lead pharmacists to focus on

the intervention strategies leaving aside the clinical warning. However, this is an assumption, I recommend that further studies examine this issue.

10.5 Final remarks

The current study represented the first attempt in Australia, and perhaps globally, to train community pharmacists in intervention strategies specific for *pharmacist only* analgesic products. Although it only provided a partial solution to the misuse of these products in Australia, it has taken the issue a step forward. It has made the training of pharmacists more effective and it has introduced the concepts of intention and motivation to change to the practice of pharmacy in relation to analgesic products. With the current trend towards rescheduling of *prescription only* medicines to *non-prescription* status there will be greater demand for studies of this nature in the pharmacy literature.

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Appendix 1

Drug Drug Interactions Involving Analgesic Products

Interactions with NSAIDs

Corresponding to their increasing use there has been a rise in the number of adverse reactions attributed to this group of analgesics. As with all drugs, these drugs may interact with other drugs causing unwanted effects. The relative benefits and risks of the NSAIDs must be continuously reviewed.

Some of the drugs NSAIDs intereract with are listed below:

1. Anticoagulants (eg. warfarin, heparin, streptokinase)

NSAIDs may potentiate the effect of oral anticoagulants leading to an increase in clinical effect of warfarin, i.e. increased bleeding time. Concurrent use may predispose the patient to gastro-intestinal tract bleeding and ulceration.

2. Anti-diabetic agents (sulphonylureas, insulin)

NSAIDs may potentiate the hypoglycaemic effect of these medications.

3. Antihypertensives (Beta-blockers, ACE inhibitors, vasodilators)

Concurrent therapy with NSAIDs and antihypertensives can result in decrease antihypertensive effect due to the inhibition of renal prostaglandins.

4. Corticosteroids

Corticosteroids also inhibit the synthesis of prostaglandins (and many other inflammatory mediators) and concurrent use may significantly increase the likelihood of GIT ulceration and perforation.

5. Digoxin

Concurrent use of digoxin and NSAIDs may result in an increase in serum digoxin levels and an increase in the lielihood of gitalis toxicity. This is clinically significant in elderly patients with pre-existing renal disease.

6. Diuretics

NSAIDs can decrease the diuretic effects of both loop and thiazide diuretics and possibly those of potassium-sparing diuretics. Patients may experience an increase in blood pressure.

7. NSAIDs

Concurrent therapy with more than one NSAID may increase the risk of GIT bleeding and ulceration.

8. Lithium

NSAIDs may decrease the renal clearance of lithium, thereby increasing the plasma concentrations and possibly the pharmacological effects and toxicity of lithium.

9. Methotrexate

Concomitant use of NSAIDs and methotrexate can result in methotrexate toxicity, as NSAIDs can decrease the renal elimination of methotrexate.

10. Valproic acid

The combination of aspirin and valproic acid may result in an increased, possibly toxic effect of valproic acid.

Interactions with Paracetamol

Paracetamol is well tolerated in therapeutic doses and adverse effects are rare. However, paracetamol may interact with other drugs increasing the risks of adverse effects. The drugs listed below may increase the potential hepatotoxicity of paracetamol (concomitant usage may lead to an increased production of the toxic metabolite of paracetamol). They may also decrease the therapeutic effect of paracetamol by decreasing its half-life. The risk is greatest when regular use of the following drugs occurs with large intake of paracetamol. These drugs are:

1. Alcohol
2. Barbiturates
3. Carbamazepine
4. Phenytoin
5. Rifampicin
6. Sulfinpyrazone

Interactions with opioid analgesics

The term "opioid analgesic" includes all drugs that have pharmacological effects similar to those of morphine. Codeine is the only opioid analgesic that is sold in Australia without a medical prescription. It interacts with the following drugs:

1. CNS (central nervous system) depressants

Concurrent use of other CNS depressants (eg. antidepressants, alcohol, antihistamines, benzodiazepines) with codeine may result in increased CNS depressant, respiratory depressant and hypotensive effects.

2. Antihypertensives and /or diuretics

Concomitant use of codeine with agents that lower blood pressure may result in potentiation of the hypotensive effect. Patients may be predisposed to an increased risk of orthostatic hypotension.

3. Anticholinergics

Concomitant use of codeine and anticholinergics (eg. atropine, propantheline) or drugs with anticholinergic activity (eg. tricyclic antidepressants, antihistamines) may result in severe constipation and intestinal complications.

4. Histamine H_2 antagonists

Histamine H_2 antagonists may enhance the actions of codeine analgesics, resulting in symptoms of overdose.

5. Naloxone

Naloxone is a specific opioid antagonist, ie. It binds to the opioid receptor without activating it and acts to reverse the effects of codeine.

Appendix 2

Letter From the Human Ethics Committee

Appendix 3

Information Sheet for Focus Group Participants

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

STUDY INFORMATION

The easy accessibility of analgesics in the Australian community is believed to foster the erroneous belief about the harmless nature of these products increasing their potential for misuse and abuse. Regulators, pharmacists and pharmaceutical manufacturers have expressed concern about how over-the-counter (OTC) analgesic products are being used in the Australian community. In order to address the issue of inappropriate analgesic use, the University of Sydney is conducting a focus groups in order to discuss with community pharmacists the monitoring of OTC analgesics.

You are invited to take part in this focus groups. The study is being conducted by Mr Abilio Neto, Professor Charlie Benrimoj, Assoc. Prof. John Saunders and Dr Michelle. If you agree to take part in the study your involvement will be: to sign a consent form; to participate in a discussion session which will be held at the University of Sydney.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and if you do participate - you can withdraw at any time.

When you have read this information, a researcher will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Abilio de Almeida Neto, Senior Researcher, on 935 136 48.

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 351 4811.

Appendix 4

Consent Form for Focus Group Participants

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

CONSENT FORM FOR FOCUS GROUP PARTICIPANTS

I, _____, (please, print your name) have been invited to participate in a discussion group, which is part of a study conducted by the University of Sydney, Pharmacy and Psychiatry departments on THE MONITORING OF PAIN RELIEVERS. In relation to this study, I have been informed of the following:

1. The University of Sydney Human Ethics Committee has given approval for this study.
2. The aim of the study is to help consumers to use pain-relieving products appropriately.
3. My involvement in this project will be participate in the discussion group. I understand that I can withdraw from the project at any time.
4. I understand that any information I give or collect will not be published so as to reveal anybody's identity.
5. I am / am not (circle one) taking part in any other research project. If I am the details are as follows:
6. _____

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 351 4811.

After considering all these points I hereby agree to participate in this study.

NAME (print) _____ **SIGNATURE** _____

(Participant)

NAME (print) _____ **SIGNATURE**_____

(Witness)

DATE _____

Appendix 5

Focus Group Plan

FOCUS GROUP PLAN

Question I: ***How do you assess whether or not somebody is misusing non-prescription analgesics?***

Prompts:

- Does it always work?
- Please, give me an example.
- How do consumers eel?

Question II: **Could please describe how you intervene in your daily practices when you believe consumers are misusing non-prescription medication.**

Prompts:

- Does it always work?
- How do consumers feel?
- How often does it happen?
- What do you do when consumers do not respond favourably?

Question III: **What would be the most practical way of intervening when a consumer is believed to be misusing non-prescription analgesic products?**

Prompts:

- Why?
- Have you used it before?
- What made you think of it?

Appendix 6

Information Sheet for Pharmacists

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

STUDY INFORMATION

The easy accessibility of analgesics in the Australian community is believed to foster the erroneous belief about the harmless nature of these products increasing their potential for misuse and abuse. Regulators, pharmacists and pharmaceutical manufacturers have expressed concern about how over-the-counter (OTC) analgesic products are being used in the Australian community. In order to address the issue of inappropriate analgesic use, the University of Sydney is conducting a study aimed at developing a pharmacy-based intervention to be used by pharmacists when patients are believed to be misusing OTC medication and to prevent misuse among appropriate users.

You are invited to take part in this research. The study is being conducted by Mr Abilio Neto, Professor Charlie Benrimoj, Assoc. Prof. John Saunders and Dr Michelle. If you agree to take part in the study your involvement will be: to sign a consent form; to participate in a training workshop, to provide consumers of S3 analgesic products with a verbal intervention and to recruit consumers of S3 analgesic products to take part in the study.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and if you do participate - you can withdraw at any time.

When you have read this information, a researcher will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Abilio de Almeida Neto, Senior Researcher, on 935 136 48.

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 351 4811.

Appendix 7

Consent Form for Pharmacists

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

CONSENT FORM FOR PHARMACISTS

I, _____, (please, print your name) have been invited to participate in a study conducted by the University of Sydney, Pharmacy and Psychiatry departments on THE USE OF PAIN RELIEVERS PURCHASED FROM COMMUNITY PHARMACIES. In relation to this study, I have been informed of the following:

7. The University of Sydney Human Ethics Committee has given approval for this study.
8. The aim of the study is to help consumers to use pain-relieving products appropriately.
9. My involvement in this project will be: to recruit patients purchasing analgesic products to take part in the study; I will be requested to provide the patient with a questionnaire and; then deliver a brief psychological intervention.
10. I understand that I can withdraw from the project at any time.
11. I understand that any information I give or collect will not be published so as to reveal anybody's identity.
12. I am / am not (circle one) taking part in any other research project. If I am the details are as follows:
13. _____

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 351 4811.

After considering all these points I hereby agree to participate in this study.

NAME (print) _____ **SIGNATURE** _____

(Participant)

NAME (print) _____ **SIGNATURE**_____

(Witness)

DATE _____

Appendix 8

Consumer Information Sheet

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

SUBJECT INFORMATION SHEET

RESEARCH STUDY INTO PHARMACY-BASED INTERVENTION STRATEGIES FOR OPTIMISING THE USAGE OF NON-PRESCRIPTION ANALGESIC PRODUCTS IN THE COMMUNITY

You are invited to take part in a research study into the usage of analgesic products aimed at optimising the usage of non-prescription analgesics. The study is being conducted by Professor Charlie Benrimoj, Associate professor John Saunders, Dr Michelle Gomel and Mr. Abilio Neto.

If you agree to participate in this study, you will be required to fill out a questionnaire after signing a consent form and thereafter, a researcher will contact you by phone twice and ask questions about the tablets you are about to purchase. The first call will be made a week after and the second call 4 weeks after agreeing to take part in the study.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time. Whatever your decision it will not affect your medical treatment or your relationship with mdical/pharmaceutical staff.

When you have read this information, your pharmacist will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Abilio de Almeida Neto, Senior Researcher, on 351-3648.

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 351 4811.

Appendix 9

Consumer Consent Form

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

I, _____, (please, print your name) have been invited to participate in a study conducted by the University of Sydney, Pharmacy and Psychiatry departments on THE USE OF PAIN RELIEVERS PURCHASED FROM COMMUNITY PHARMACIES. In relation to this study, I have been informed of the following:

14. Approval for this study has been given by the University of Sydney Human Ethics Committee.
15. The aim of the study is to help consumers to use pain relieving products appropriately.
16. My pharmacist or pharmacy-assistant will provide me with a questionnaire. My involvement in this project will be to complete a written survey and to answer two follow-up telephone surveys approximately one and four weeks later.
17. I understand that I can withdraw from the project at any time without affecting my medical care.
18. I understand that any information I give will not be published so as to reveal my identity.
19. I am / am not (circle one) taking part in any other research project. If I am the details are as follows: _____

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 351 4811.

After considering all these points I hereby agree to participate in this study.

NAME (print) _____SIGNATURE _____

(Participant)

NAME (print) _____ SIGNATURE _____
(Witness)

DATE _____

Appendix 10

Table of Contents From Workshop Manual

Workshop facilitator: Abilio de Almeida Neto

PROGRAM - SATURDAY

9:00 Coffee and Tea

9:30 Welcome and Introductions

10:00 Stages of Change

11:00 Stages of Change Exercise

12:30 Lunch

01:30 An Overview of Motivational Interviewing Techniques

03:00 Afternoon Tea

03:15 Motivational Interviewing Step by Step

04:00 Close

PROGRAM - SUNDAY

09:00 Review

09:30 Counselling Microskills

11:00 Morning Tea

11:15 Counselling Microskills

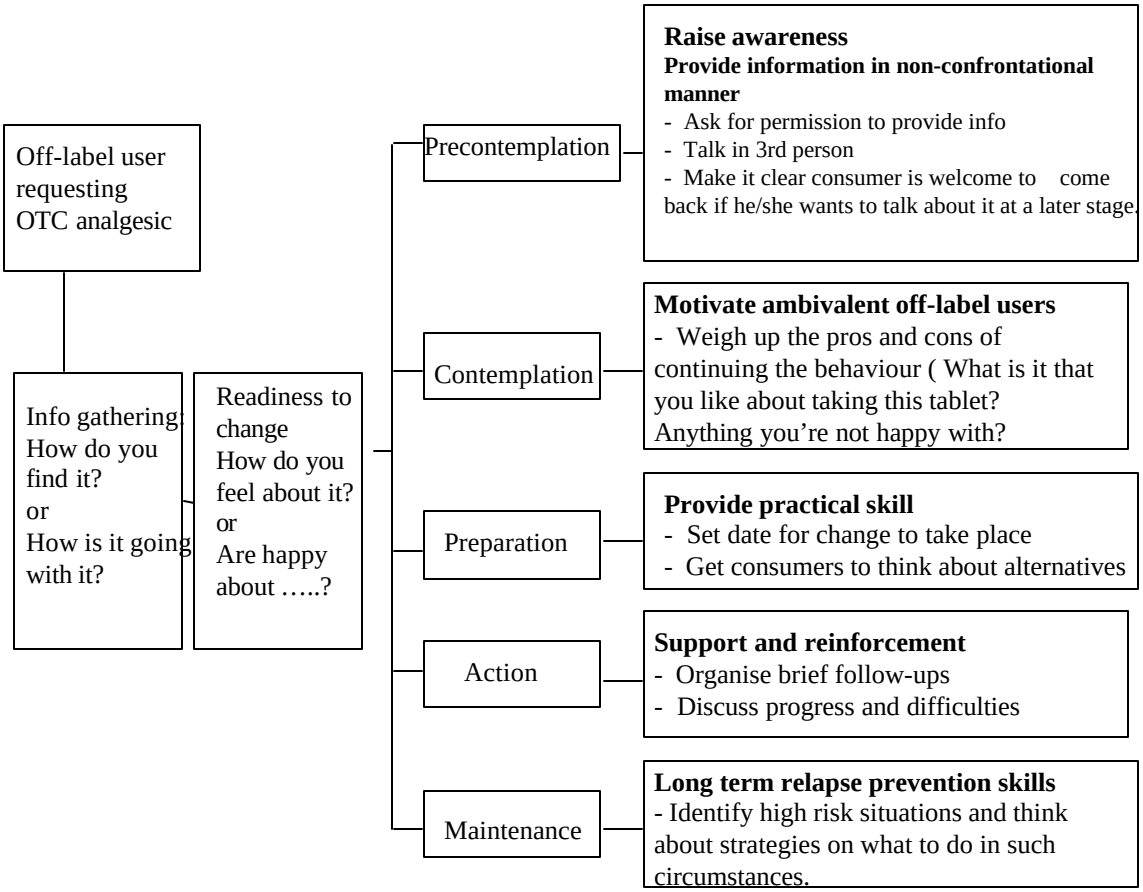
12:30 Lunch

01:30 Putting Motivational Interviewing into Practice

03:00 Research Methods

Appendix 11

Algorithm of Intervention Strategies


Off-label user requesting OTC analgesic
Info gathering: How do you find it? or How is it going with it?
Readiness to change How do you feel about it? or Are happy about …..?
Precontemplation
Raise awareness
Provide information in non-confrontational manner
- Ask for permission to provide info
- Talk in 3rd person
- Make it clear consumer is welcome to come back if he/she wants to talk about it at a later stage.
Contemplation
Motivate ambivalent off-label users
- Weigh up the pros and cons of continuing the behaviour (What is it that you like about taking this tablet? Anything you're not happy with?
Preparation
Provide practical skill
- Set date for change to take place
- Get consumers to think about alternatives
Action
Support and reinforcement
- Organise brief follow-ups
- Discuss progress and difficulties
Maintenance
Long term relapse prevention skills
- Identify high risk situations and think about strategies on what to do in such circumstances.

Appendix 12

Letter from the Human Ethics Committee

Appendix 13

Information Sheet for Pharmacists

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia
Tel: (02) 9351 3347
Fax: (02) 9351 2603

INFORMATION SHEET FOR PHARMACISTS

STUDY INTO: PHARMACY-BASED INTERVENTION STRATEGIES FOR OPTIMISING THE USE OF NON-PRESCRIPTION ANALGESIC PRODUCTS IN THE COMMUNITY

You are invited to take part in a research study into pharmacy-based intervention strategies aimed at optimising the use of non-prescription analgesic products. The study is being conducted by Mr. Abilio Neto, Professor Charlie Benrimoj, Professor Bob Boakes, and Associate Professor David Kavanagh.

If you agree to take part in the study you will be randomly allocated to either the Intervention Group or the Control Group. Pharmacists in the Intervention Group will be asked to attend a short workshop on pharmacy-based intervention strategies and then deliver these strategies to patients purchasing S3 analgesic products.

Researchers will be making a series of purchases of S3 analgesic products from all pharmacies in the study without identifying him/herself as being from the University of Sydney up to six month after commencement of the study. Pharmacists in the Intervention Group will be provided with immediate feedback from the pseudo-patron visit for a period of four weeks: after the purchase is made a researcher will walk into the pharmacy and discuss progress and difficulties in order to coach the pharmacist in the process of acquiring the intervention skills. Pharmacists from the Control Group will not be provided with feedback after the pseudo-patron purchase. All data collected will be treated with strict confidentiality, and neither the names of pharmacists, pharmacy assistants, or the name of the pharmacy will be recorded on the data form. Please find attached, for your information, a copy of a data collection form that will be used in the study.

The project has been approved by the University of Sydney Human Ethics Committee. All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time. If you would like to know more at any stage, please feel free to contact Abilio de Almeida Neto, Senior Researcher, on 9351-3648.

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

Appendix 14

Consent Form for Pharmacists

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

CONSENT FORM FOR PHARMACISTS

I, _____, (please, print your name) have been invited to participate in a study conducted by the University of Sydney, Pharmacy and Psychology departments on PHARMACY-BASED INTERVENTION STRATEGIES. In relation to this study, I have been informed of the following:
Approval for this study has been given by the University of Sydney Human Ethics Committee.

1. The aim of the study is to help consumers to use pain relieving products appropriately.
2. My involvement in this project will be to: a) either deliver a brief intervention to consumers of S3 analgesic products if I am allocated to the Intervention Group; b) or to simply deal with sales of S3 analgesic products as I usually do if I am allocated to the Control Group.
3. I understand that researchers from the University of Sydney will be making a series of purchases of S3 analgesic products from this pharmacy without identifying him/herself up to six months after commencement of the study and I give researchers consent to use these data.
4. I understand that I can withdraw from the project at any time.
5. I understand that any information I give or collect will not be published so as to reveal anybody's identity.

I am / am not (circle one) taking part in any other research project. If I am the details are as follows: _____

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

After considering all these points I hereby agree to participate in this study.

NAME **(print)**_____
SIGNATURE_____
(Participant)

DATE _____

Appendix 15

Letter From the Human Ethics Committee

Appendix 16

Information Sheet for Pharmacists

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia
Tel: (02) 9351 3347
Fax: (02) 9351 2603

INFORMATION SHEET FOR PHARMACISTS

STUDY INTO: PHARMACY-BASED INTERVENTION STRATEGIES FOR OPTIMISING THE USE OF NON-PRESCRIPTION ANALGESIC PRODUCTS IN THE COMMUNITY

You are invited to take part in a research study into pharmacy-based intervention strategies aimed at optimising the use of non-prescription analgesic products. The study is being conducted by Mr. Abilio Neto, Professor Charlie Benrimoj, Professor Bob Boakes and Associate Professor David Kavanagh.

If you agree to take part in the study you will be randomly allocated to either the Intervention Group or the Control Group. Pharmacists in the Intervention Group will be asked to attend a short workshop on pharmacy-based intervention strategies and then deliver these strategies to patients purchasing S3 analgesic products.

Researchers will be making a series of purchases of S3 analgesic products from all pharmacies in the study without identifying him/herself as being from the University of Sydney. Pharmacists in the Intervention Group will be provided with immediate feedback from the pseudo-patron visit: after the purchase is made a researcher will walk into the pharmacy and discuss progress and difficulties in order to coach the pharmacist in the process of acquiring the intervention skills. Pharmacists from the Control Group will not be provided with feedback after the pseudo-patron purchase. All data collected will be treated with strict confidentiality, and neither the names of pharmacists, pharmacy assistants, or the name of the pharmacy will be recorded on the data form. Please find attached, for your information, a copy of a data collection form that will be used in the study.

The project has been approved by the University of Sydney Human Ethics Committee. All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time. If you would like to know more at any stage, please feel free to contact Abilio de Almeida Neto, Senior Researcher, on 9351-3648.

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

Appendix 17:

Consent Form for Pharmacists

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia
Tel: (02) 9351 3347
Fax: (02) 9351 2603

CONSENT FORM FOR PHARMACISTS

I, _____, (please, print your name) have been invited to participate in a study conducted by the University of Sydney, Pharmacy and Psychology departments on PHARMACY-BASED INTERVENTION STRATEGIES. In relation to this study, I have been informed of the following:

Approval for this study has been given by the University of Sydney Human Ethics Committee.

1. The aim of the study is to help consumers to use pain relieving products appropriately.
2. My involvement in this project will be to: a) either deliver a brief intervention to consumers of S3 analgesic products if I am allocated to the Intervention Group; b) or to simply deal with sales of S3 analgesic products as I usually do if I am allocated to the Control Group.
3. I understand that researchers from the University of Sydney will be making a series of purchases of S3 analgesic products from this pharmacy without identifying him/herself and I give researchers consent to use these data.
4. I understand that I can withdraw from the project at any time.
5. I understand that any information I give or collect will not be published so as to reveal anybody's identity.

I am / am not (circle one) taking part in any other research project. If I am the details are as follows: _____

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

After considering all these points I hereby agree to participate in this study.

NAME **(print)**_____
SIGNATURE_____
(Participant)

DATE_____

Appendix 18

Information Sheet for Pharmacy Assistants

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia
Tel: (02) 9351 3347
Fax: (02) 9351 2603

INFORMATION SHEET FOR PHARMACY ASSISTANTS

STUDY INTO: PHARMACY-BASED INTERVENTION STRATEGIES FOR OPTIMISING THE USE OF NON-PRESCRIPTION ANALGESIC PRODUCTS IN THE COMMUNITY

You are invited to take part in a research study into the usage of analgesic products aimed at optimising the usage of non-prescription analgesics. The study is being conducted by Mr. Abilio Neto, Professor Bob Boakes, Professor Charlie Benrimoj and Associate Professor David Kavanagh.

If you agree to participate in this study, we would like you to recruit consumers of S3 analgesic products to take part in the study. We would like you to approach consumers after an analgesic purchase has been made and explain the study and enrol the consumer on the spot if he/she agrees. It is important that that consumers are only approached once the sale has been finalised, i.e. **after** payment has been made and consumer is ready to leave. You will be paid $25.00 for every 10 subjects you recruit. A researcher from the University of Sydney will be visiting your pharmacy twice a week to collect forms.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants and on people helping with the study. Names of pharmacy assistants, pharmacists, or the name of the pharmacy will not be recorded on data forms. A report of the study may be submitted for publication, but individual participants or pharmacy assistants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time. If you would like to know more at any stage, please feel free to contact Abilio de Almeida Neto, Senior Researcher, on 9351-3648.

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

Appendix 19

Consent Form for Pharmacy Assistants

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

CONSENT FORM FOR PHARMACY ASSISTANTS

I, _____, (please, print your name) have been invited to participate in a study conducted by the University of Sydney, Pharmacy and Psychology departments on PHARMACY-BASED INTERVENTION STRATEGIES. In relation to this study, I have been informed of the following:

1. Approval for this study has been given by the University of Sydney Human Ethics Committee.
2. The aim of the study is to help consumers to use pain relieving products appropriately.
3. My involvement in this project will be: to recruit consumers of S3 analgesic products only after a purchase has been finalised, e.i. after the consumer has paid for the product and is ready to leave the pharmacy.
4. I understand that I will be paid for recruiting consumers at a rate of $25.00 for every 10 consumers recruited to take part in the study.
5. I understand that I can withdraw from the project at any time.
6. I understand that any information I give or collect will not be published so as to reveal anybody's identity.

I am / am not (circle one) taking part in any other research project. If I am the details are as follows:

_____

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

After considering all these points I hereby agree to participate in this study.

NAME (print)_____ SIGNATURE_____

Participant)

DATE _____

Appendix 20

Consumer Information Sheet

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

PARTICIPANT INFORMATION SHEET

RESEARCH STUDY INTO: PHARMACY-BASED INTERVENTION STRATEGIES

You are invited to take part in a research study into the usage of pain killers aimed at optimising the consumption of these products. The study is being conducted by Mr. Abilio Neto, Professor Bob Boakes, Professor Charlie Benrimoj and Associate Professor David Kavanagh.

If you agree to participate in this study, we would like you to sign a consent form and answer two telephone survey which will last approximately 15 minutes each. You will be paid for the time spent on the telephone answering the survey questions at a rate of $10.00 per interview. The first telephone interview will be made within three days after enrolling in the study and the second phone interview within four weeks after enrolling in the study.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time. If you would like to know more at any stage, please feel free to contact Abilio de Almeida Neto, Senior Researcher, on 9351-3648.

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

Appendix 21

Consumer Consent Form

The University of Sydney

Departments of Pharmacy and Psychology
University of Sydney
NSW 2006 Australia

Tel: (02) 9351 3347
Fax: (02) 9351 2603

PARTICIPANT CONSENT FORM

I, _____, (please, print your name) have been invited to participate in a study conducted by the University of Sydney, Pharmacy and Psychology departments on PHARMACY-BASED INTERVENTION STRATEGIES. In relation to this study, I have been informed of the following:

1. Approval for this study has been given by the University of Sydney Human Ethics Committee.
2. The aim of the study is to help consumers to use pain relieving products appropriately.
3. A pharmacy assistant will provide me with information on the study. My involvement in this project will be to answer two telephone surveys which will last for approximately 15 minutes each.
4. I understand I will be paid for the time spent on the telephone answering the survey questions at a rate of $10.00 per interview.
4. I understand that I can withdraw from the project at any time.
5. I understand that any information I give will not be published so as to reveal my identity.
6. I am / am not (circle one) taking part in any other research project. If I am the details are as follows:
   _____

Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Ethics Committee, University of Sydney on (02) 9351 4811.

After considering all these points I hereby agree to participate in this study.

NAME (print)_____ **SIGNATURE**
_____
(Participant)

DATE _____

Appendix 22

Feedback Sheet

Appendix 23

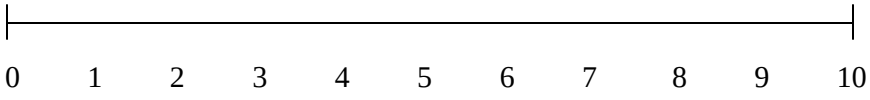
Questionnaire sent to participants to measure acceptability of pseudo-patron methodology

1. Please rate on the following scale how much you liked the overall training on the study intervention.

Not at all Very much

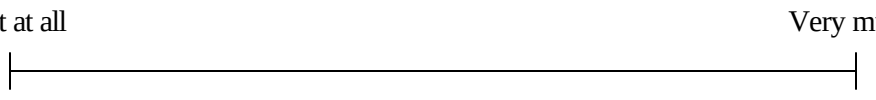
2. Please rate on the following scale how practical it was to do the intervention.

Not at all Very much



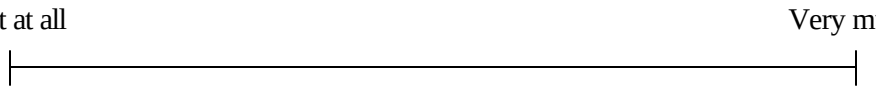
3. Please rate on the following scale how much you liked the pseudo-patron (mystery shopper) training and feedback.

Not at all Very much



4. Please rate on the following scale how much you liked the study intervention.

Not at all Very much



5. What did you like about the training?

_____

_

_____

_

6. What did you NOT like about the training?

_____

_

_____

_

Appendix 24

Consumer Questionnaire

Assessment of Readiness to change questionnaire

Assessment of motivation to change

The following questions are designed to identify how you personally feel about taking the products you bought when you enroled at this study. Please listen to the following questions carefully, and then decide whether you agree or disagree with the statements.

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
a. I don't think I take too much of the tablets I bought.	☐	☐	☐	☐	☐
b. I am trying to take less of these tablets than I used to.	☐	☐	☐	☐	☐
c. These tablets make me feel better, but sometimes I take too much of them.	☐	☐	☐	☐	☐
d. Sometimes I think I should cut down on the amount of these tablets.	☐	☐	☐	☐	☐
e. It's a waste of time thinking about the way I consume these tablets.	☐	☐	☐	☐	☐
f. I have just recently changed the way I take these tablets.	☐	☐	☐	☐	☐
g. Anyone can talk about wanting to do something about his/her medication habits, but actually doing something about it.	☐	☐	☐	☐	☐
h. I am at the stage where I should think about taking less of these tablets.	☐	☐	☐	☐	☐
i. The way I take these tablets is a problem sometimes.	☐	☐	☐	☐	☐
j. There is no need for me to think about changing the way I take these tablets.	☐	☐	☐	☐	☐
k. I am actually changing the way I take these tablets right now.	☐	☐	☐	☐	☐
l. Taking less of these tablets would be pointless for me	☐	☐	☐	☐	☐

Scoring the Readiness to Change Questionnaire:

The Precontemplation items are numbers 1,5,10 & 12, the Contemplation items are numbers 3,4, 8 &9, and the Action items are numbers 2,6,7 & 11. All items are to be score on a 5-point rating scale ranging from:

To calculate the score for each scale, simply add the item scores for the scale in question. The range of each scale is -8 through 0 to +8. A negative scale score reflects an overall disagreement with items measuring the stage of change, whereas a positive score represents overall agreement. The highest scale score represents the Stage of Change Designation.

Note: If two scale scores are equal, then the scale farther along the continuum of change (Precontemplation - Contemplation - Action) represents the subject's Stage of Change Designation. For example, if a subject scores 6 on the Precontemplation scale, 6 on the Contemplation scale and -2 on the Action scale, then the subject is assigned to the Contemplation stage.

Note that positive scores on the Precontemplation scale signify a lack of readiness to change. To obtain a score for Precontemplation which represents the subject's degree of readiness to change, directly comparable to scores on the Contemplation and Action scales, simply reverse the sign of the Precontemplation score (see below).

If one of the four items on a scale is missing, the subject's score for that scale should be pro-rated (i.e. multiplied by 1.33). If two or more items are missing, the scale score cannot be calculated. In this case the Stage of Change Designation will be invalid.

Assessment of knowledge about analgesics

1. When taken with alcohol the tablets I bought may cause:

☐ Diarrhoea ☐ Constipation

☐ Drowsiness ☐ All of the above

2. It isn't safe to take more than:

☐ 6 a day ☐ 8 a day

☐ 10 a day ☐ None of the above

3. What are the unwanted effects of codeine?

☐ It can cause constipation ☐ It can make you drowsy

☐ It increases the effects of alcohol ☐ All of the above

4. Which of the following pain killers can cause liver damage if used in large doses?

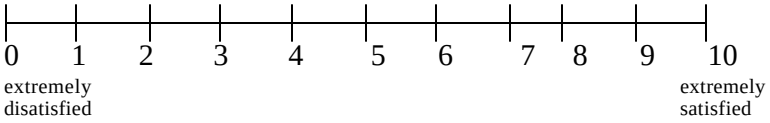
☐ Codeine ☐ Paracetamol

☐ Aspirin ☐ All of the above

Assessment of satisfaction with the interaction

Please rate the following statements how you feel about the pharmacy you enrolled at.

How satisfied were you with the way the pharmacist handled the sale of the pain killer when you enrolled for this study?



Consumer behaviour and product purchased

1. What is the name of the pain killer (s) purchased when you got our research card?
_____

2. Did you purchase the product for yourself? Yes No

3. Was it the first time you bought this product?
   Yes ⇒ Go to question 7
   No ⇒ Go to question 4

4. For how long have you been using this product? _____

5. How often do you purchase this product?

   Weekly Fortnightly Monthly
   Every 2-3 months Other (please specify) _____

6. How often do you take these tablets?
   daily or almost daily Weekly Fortnightly
   Monthly Less than monthly, please specify _____

7. Do you buy other types of pain killers including arthritis medication or anti-inflammatory drugs? No
   Yes ⇒ which ones?
_____

   ⇒ How often do you take them?
_____

_____

8. Is your doctor aware that you are using the product you purchased when you got our research card? No Yes

9. What condition did you buy this product for (product bought when you joined the Research)?
_____

10. Please fill in one table for each day that you took the pain killer you bought (**up to 3 days**
for label users and up to 5 days for off-label users)

Day 1

Time of day	**No. of tablets taken**	**Time of day**	**No. of tablets taken**	**Time of day**	**No. of tablets taken**
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
f9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Day 2

Time of day	**No. of tablets taken**	**Time of day**	**No. of tablets taken**	**Time of day**	**No. of tablets taken**
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am 9 am		4 pm 5 pm		12 midnight 1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Day 3

Time of day	**No. of tablets taken**	**Time of day**	**No. of tablets taken**	**Time of day**	**No. of tablets taken**
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
f9 am		5 pm		1 am	
10 am 11 am		6 pm 7 pm		2 am 3 am	
12 noon		8 pm		4 am	

Day 4

Time of day	No. of tablets taken	Time of day	No. of tablets taken	Time of day	No. of tablets taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Day 5

Time of day	No. of tablets taken	Time of day	No. of tablets taken	Time of day	No. of tablets taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
f9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

11. Was the period of time you've just described typical in terms of amount of pain killers you take? Yes

No ⇒ How is it different? _____

12. When you bought this product, did you receive:

a) a package insert No

Yes, Have you read it?

No

Yes

b) Verbal information No

Yes

13. Have you purchase this product again since you enrolled in this study?

Yes No

If yes, how many times?_____when? _____

Did you get it from the same pharmacy? Yes No

14. Did the pharmacist ask you any of the following questions?

a) How did you find this product? Yes No

b) How do you feel about the way you take it? Yes No

c) Did the pharmacist talk to you about these tablets? Yes No

If yes, what did s/he say?

_____

_____

_____

Demographics

1. Sex: Male Female

2. How old are you? _____

3. What is the highest educational qualification you have obtained?

None	Undergraduate Diploma
School Certificate (Year 10)	Bachelor Degree
Higher School Certificate (Year 12)	Post Graduate Diploma
Associate Diploma	Higher Degree

Second interview

1. How often are you taking the product you purchased when you joined the study?
   daily or almost daily Weekly Fortnightly
   Monthly Less than monthly, please specify _____

2. Have you bought any other types of pain killers including arthritis medication or anti-inflammatory drugs since your last interview?
   No
   Yes ⇒ which ones?

_____

⇒ How often do you take them?

_____

_____

3. Is your doctor aware that you are using the product you purchased when you got our research card? No Yes

4. Please fill in one table for each day that you took the pain killer you bought (**up to 3 days for label users and up to 5 days for off-label users**)

Day 1

Time of day	**No. of tablets taken**	**Time of day**	**No. of tablets taken**	**Time of day**	**No. of tablets taken**
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
f9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Day 2

Time of day	No. of tablets taken	Time of day	No. of tablets taken	Time of day	No. of tablets taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Day 3

Time of day	No. of tablets taken	Time of day	No. of tablets taken	Time of day	No. of tablets taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
f9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am 12 noon		7 pm 8 pm		3 am 4 am	

Day 4

Time of day	No. of tablets taken	Time of day	No. of tablets taken	Time of day	No. of tablets taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Day 5

Time of day	No. of tablets	Time of day	No. of tablets	Time of day	No. of tablets

	taken		**taken**		**taken**
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
f9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

5. Was the period of time you've just described typical in terms of amount of pain killers you take? Yes No ⇒ How is it different?
   _____

6. Have you purchase this product again since you enrolled in this study?
   Yes No (if no, do not ask question 7)

If yes, how many times?_____when? _____

Did you get it from the same pharmacy? Yes No

7. Did the pharmacist ask you any of the following questions?

   a) How did you find this product? Yes No

   b) How do you feel about the way you take it? Yes No

c) Did the pharmacist talk to you about these tablets? Yes No

If yes, what did s/he say?

_____

_____

IF CONSUMER IS BELIEVED TO BE MISUSING THE PRODUCT, GO THROUGH READINESS TO CHANGE QUESTIONNAIRE.

Appendix 25

Standards for the provision of *pharmacist only* and p*harmacy medicines*

(Protocols)