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*Australia's National Research Centre
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Responding to pharmaceutical drug misuse problems in Australia

A Matter of Balance

A review of the literature supporting the development of
Australia's National Pharmaceutical Drug Misuse Strategy

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Foreword

A National Pharmaceutical Drug Misuse Strategy (NPDMS) is being developed at the request of the Ministerial Council on Drug Strategy (MCDS) and is funded through the MCDS Cost Shared Funding Model. The strategy development is being undertaken by a consortium led by the National Centre for Education and Training on Addiction (NCETA) at Flinders University. The project is being overseen by the Victorian Department of Health.

This literature review was prepared as part of the development of the NPDMS. Its purpose is to inform and guide the development of the Strategy. Specifically, the review examines the extent and nature of the existing evidence base of relevance to the NPDMS.

The literature review focuses primarily on opioids, benzodiazepines and codeine-containing analgesics as the Strategy, at the request of the MCDS, focus on these drugs.

The review is structured in several parts, as follows. First some broader frameworks, strategies, policies, initiatives, perspectives and paradigms which impact upon the development of the Strategy are considered. This is followed by an examination of the Australian situation and then the international situation. The review then examines issues surrounding the quality use of opioids and benzodiazepines. Next issues surrounding medication shopping are considered. Finally, the review examines some of the potential responses to pharmaceutical misuse.

In assessing the quality of evidence that supports these responses, the Australian National Health and Medical Research Council's evidence assessment framework will be relied upon. This involves various levels of evidence¹. Responses to complex social problems, such as

¹ Level 1 consists of evidence obtained from a systematic review of all relevant randomised controlled trials. Level 2 consists of evidence obtained from at least one properly-designed randomised controlled trial. Level 3-1 consists of evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method). Level 3-2 consists of evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group. Level 3-3 consists of evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group. Level 4 consists of evidence obtained from case series, either post-test or pre-test/post-test (National Health and Medical Research Council, 2000).

pharmaceutical drug misuse, cannot always be fully informed by high-level evidence. Potential responses to this problem (such as prescription monitoring programs or coordinated medication management systems, for example), do not lend themselves to evaluation by randomised controlled trials.

Therefore, where possible, the measures ultimately proposed in the NPDMS will be based on high-level evidence, but on the understanding that with complex issues such as this, high-level evidence is not always available.

A critical factor in the development of the NPDMS will be ensuring that a balance is achieved between diverse perspectives and interests. There is also a need to ensure continued medical access to these medications and maximising their appropriate use, while minimising opportunities for misuse. These medications are highly beneficial to many individuals and there is a need to ensure that the clinically appropriate supply of these medications is maintained and use is in no way stigmatised.

There is also a need to have measures in place to minimise the harm from any unsanctioned use of these medications. This includes use by those other than for whom the drugs were prescribed, or at doses, or via routes of administration, that were unintended by the prescriber.

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Abbreviations

ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
ACCC	Australian Competition and Consumer Commission
ACSQHC	Australian Commission on Safety and Quality in Health Care
ADF	Abuse Deterrent Formulations
AGREE	Appraisal of Guidelines, Research and Evaluation
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AHPRA	Australian Health Practitioner Regulation Agency
ANZCA	Australian and New Zealand College of Anaesthetists
ANZCAFPM	Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine
AOD	Alcohol and other drugs
APAC	Australian Pharmaceutical Advisory Council
APS	Australian Psychological Society
ARF	Abuse Resistant Formulations
BPS	British Pain Society
CASA	Center for Addiction and Substance Abuse
CAMH	Centre for Addiction and Mental Health
CBT	Cognitive Behaviour Therapy
CDS	Centers for Disease Control and Prevention
CMMS	Coordinated Medication Management System
CNMP	Chronic Non-Malignant Pain
CNS	Central Nervous System
DCPC	Drugs and Crime Prevention Committee of the Parliament of Victoria
DoHA	Australian Government Department of Health and Ageing
DMMR	Domiciliary Medication Management Review
DRUMS	Drug Monitoring System
DUMA	Drug Use Monitoring in Australia
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
FDA	Food and Drug Administration
GOA	United States General Accounting Office
GP	General Practitioner
HIC	Health Insurance Commission
HMR	Home Medication Review
IGCD	Inter-Governmental Committee on Drugs
IDRS	Illicit Drug Reporting System
IDU	Injecting Drug User
INCB	International Narcotics Control Board
KASPER	Kentucky All Schedules Prescription Electronic Reporting

MA	Medicines Australia
MCDS	Ministerial Council on Drug Strategy
MSIC	Medically Supervised Injection Centre
NABP	National Association of Boards of Pharmacy
NASPER	National All Schedules Prescription Electronic Reporting
NCETA	National Centre for Education and Training on Addiction
NCHECR	National Centre in HIV Epidemiology and Clinical Research
NDS	National Drug Strategy
NHRMC	National Health and Medical Research Council
NICE	National Institute for Health and Clinical Excellence
NMP	National Medicines Policy
NPDMS	National Pharmaceutical Drug Misuse Strategy
NPS	National Prescribing Service Ltd
NSP	Needle and Syringe Program
NSDUH	National Survey of Drug Use and Health
NSQUM	National Strategy for the Quality Use of Medicines
OST	Opioid Substitution Therapy
OTC	Over the counter
PBS	Pharmaceutical Benefits Scheme
PMP	Prescription Monitoring Program
PPD	Psychotropic Prescription Drugs
PTSD	Post Traumatic Stress Disorder
QUM	Quality Use of Medicines
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RFID	Radio Frequency Identification
RANZCP	Royal Australian and New Zealand College of Psychiatrists
RCT	Randomised Control Trial
RFID	Radio Frequency Identification
RPBS	Repatriation Pharmaceutical Benefits Scheme
RUM	Returning Unwanted Medicines
SAMHSA	Substance Abuse and Mental Health Service Administration
SIGN	Scottish Intercollegiate Guidelines Network
SES	Socio-economic Status
SNRI	Serotonin-Noradrenaline (norepinephrine) Reuptake Inhibitors
SSRI	Selective serotonin reuptake inhibitors
TCA	Tricyclic Antidepressants
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

Glossary of Medicines

Adrenalin	Local anaesthetic used in routine dental procedures and oral surgery, emergency treatment of severe anaphylaxis
Alprazolam	Benzodiazepine used to treat anxiety, anxiety associated with depression, panic attacks and phobias
Barbiturate	Potent central nervous system depressant
Benzodiazepines	Group of drugs used to treat anxiety, insomnia, muscle spasm and spasticity, seizures, and alcohol withdrawal
Buprenorphine	Partial opioid agonist used to treat moderate to severe pain and opioid dependence
Clonazepam	Partial benzodiazepine used in the treatment of epilepsy
Codeine	Opioid analgesic used to treat moderate to severe pain
Diazepam	Benzodiazepine used to treat anxiety, acute alcohol withdrawal, muscle spasm and spasticity
Dextropropoxyphene	Opioid analgesic used to treat mild pain
Fentanyl	Opioid analgesic used to treat chronic breakthrough pain, commonly used in cancer patients, post operatively and also for short duration analgesia in anaesthesia
Flunitrazepam	Benzodiazepine used to treat severe insomnia
Gabapentin	Anticonvulsant, also used in the treatment of pain
Hydrocodone	Opioid analgesic used to treat moderate to severe pain and is used as a cough suppressant
Hydromorphone	Opioid analgesic used to treat moderate to severe pain
Ibuprofen	Non steroidal anti-inflammatory drug
Kapanol®	A slow release form of morphine used in the treatment of chronic pain unresponsive to non-narcotic analgesia
Methadone	Synthetic opioid analgesic used to treat opioid dependence and severe pain
Morphine	Opioid analgesic used to treat severe pain
MS Contin®	Controlled release opioid analgesic to treat chronic severe pain
Nalbuphine	Opioid analgesic used to treat moderate to severe pain
Nalproxen	Non steroidal anti-inflammatory drug used for the treatment of conditions involving, pain, fever and inflammation
Naltrexone	Opioid receptor antagonist used in the management of alcohol and opioid dependence
Nortriptyline	Tricyclic antidepressant used to treat major depression, chronic pain and bedwetting
Opioid	A scientific term that refers to both natural and synthetic drugs whose effects are mediated by specific receptors in the central and peripheral nervous systems commonly used in pain relief
Oxazepam	Benzodiazepine used to treat anxiety and anxiety associated with depression

Oxycodone	Opioid analgesic used to treat moderate to severe pain
OxyContin®	Slow release oxycodone used to treat moderate to severe chronic pain
Pethidine	Opioid analgesic used to treat moderate to severe pain
Physeptone	A tablet form of methadone used primarily to treat severe pain
Pregabalin	Anticonvulsant, used in the treatment of seizures and as an adjuvant medication for neuropathic pain
Propoxyphene	Analgesic used to treat mild to moderate pain
Pseudoephedrine	Nasal decongestant used in the general treatment of cold/flu symptoms
Temazepam	Benzodiazepine used to treat insomnia
Tramadol	Centrally acting synthetic opioid-like analgesic used to treat moderate-severe pain
Zolpidem	Non-benzodiazepine used to treat insomnia
Zopiclone	Non-benzodiazepine used to treat insomnia

Glossary of Terms

Adjuvant drugs are medications often used in the management of persistent pain, although their usual role is for conditions other than pain.

Chronic non-malignant pain is pain that is non-cancerous in origin and that persists beyond normal tissue healing time, which is assumed to be approximately three months.

Controlled drugs are medicines with a high potential for misuse which are on Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons in Australia.

Coordinated medication management systems/prescription monitoring programs are systems to record the prescription, dispensing and/or supply of defined medications to individuals, to be provided to prescribers and/or pharmacists at the time of prescribing, dispensing or supply, and can also be used for monitoring the supply of these medications by regulatory authorities.

Drug dependence: the term implies a need for repeated doses of a drug to feel good or to avoid feeling bad. It also refers to a cluster of cognitive, behavioural and physiologic symptoms that indicate a person has impaired control of psychoactive substance use and continues use of the substance despite adverse consequences.

Pharmaceutical drug misuse is the use of prescription or over-the-counter drugs by individuals, using routes of administration or at dosages that were unintended by the prescriber or pharmacist at the time of prescribing, dispensing or supply, or use to deliberately obtain an intoxicating effect.

Iatrogenic dependence is dependence stemming from medical treatment or advice.

Inappropriate prescribing is the prescribing of medications in a manner that is inconsistent with their quality use.

Non-medical use of pharmaceutical drugs occurs in order to induce or enhance a drug-related experience, for non-clinically indicated performance enhancement or for cosmetic purposes.

Opioids are chemicals that bind to opioid receptors in the body and result in effects such as analgesia, euphoria, sedation, respiratory depression and constipation. Opioids can be classified as natural, semi-synthetic, fully synthetic or endogenous.

Pharmaceutical drugs are drugs available from pharmaceutical sources, (i.e. manufactured by the pharmaceutical industry or made up by a pharmacist) which are intended for use in the diagnosis, cure, treatment, or prevention of disease.

Psychopharmacology is the study of drug-induced changes in mood, sensation, thinking, and behaviour.

A psychoactive drug is a chemical substance the use of which results in changes in perception, mood, consciousness, cognition or behavior.

Unsanctioned use is use of a substance that is not approved by a society or by a group within society.

1 The broader policy context

1.1 Introduction

The National Pharmaceutical Drug Misuse Strategy (NPDMS) is being developed at the request of the Ministerial Council on Drug Strategy (MCDS). This project has been funded through the MCDS Cost Shared Funding Model. The strategy document is being prepared for consideration by the Inter-Governmental Committee on Drugs (IGCD). It will ultimately be forwarded for Ministerial endorsement.

The Strategy will have potential relevance to a wide variety of prescription and over the counter (OTC) pharmaceutical drugs which are subject to non-medical use, misuse and/or diversion. The prescription drugs of relevance include opioids, benzodiazepines, psycho-stimulants, anti-depressants, anti-psychotics and performance and image enhancing drugs. The OTC drugs of relevance include codeine-containing analgesics, pseudoephedrine and anti-histamines.

Currently in Australia the medications associated with the greatest levels of harm include the pharmaceutical opioids, benzodiazepines and over the counter (OTC) codeine-containing analgesics. Consequently, at the request of the MCDS, the NPDMS will focus on these drugs. The strategy will also use these drugs as strategy development 'prototypes', because many of the responses developed to address actual and potential problems with these drugs will also have applicability to other drugs of concern. In addition, much work has already been undertaken to address problems with some of these other medications.²

There are a number of pharmaceutical drugs that can be subject to misuse. Medicines are divided into 8 schedules in the Standard for the Uniform Scheduling of Drugs and

² For example a considerable amount of work has been undertaken in Western Australia to address problems associated with the misuse of pharmaceutical amphetamine type stimulants.

Poisons in Australia. Schedule 4 drugs are available only on prescription but are not required to be authorised by jurisdictional health authorities. This schedule includes benzodiazepines and most antidepressants. Schedule 8 drugs are drugs that have a high potential for abuse and are often referred to as controlled substances, and in some jurisdictions 'drugs of addiction'. There are a number of controls around these drugs. They include the need to obtain approval from jurisdictional departments of health for ongoing use. They include single ingredient codeine, methadone and buprenorphine, most other opioids, and most amphetamines and amphetamine analogues. Schedule 3 drugs are 'pharmacy only medicines' that require pharmacist monitoring or management but not a prescription. This includes over the counter combination codeine products such as paracetamol-codeine and ibuprofen-codeine. There are also restrictions on the advertising to the public of products containing medicines listed on Schedules 3, 4 or 8.

The strategy will focus on a number of key issues, including:

1. medication monitoring and regulatory processes and their interface with the clinical environment
2. the healthcare workforce development needs required to enhance quality use of these medicines, especially the workforce development needs of prescribers and pharmacists and guidelines for the treatment of chronic non malignant pain
3. where necessary, recommending the development and implementation of guidelines to enhance the quality use of medicines (QUM) in relation to conditions such as chronic non-malignant pain, anxiety and insomnia
4. examining the regulatory, monitoring and investigative resources that might be required to effectively address medication shopping and the illicit supply of pharmaceuticals for profit, including consideration of timely and appropriate information exchange between health and police agencies
5. national data availability concerning the extent and nature of misuse of these medications and

6. the measures required to minimise the harm from unsanctioned use of these medications.

The Strategy will also address a range of structural issues; such as the complex array of ways in which pharmaceutical drug misuse problems interact with Australia's social environment, including its health and welfare systems and the structural determinants of the health of Australians.

Australian's expectations of medicines will form the backdrop to the Strategy. Many Australians may have developed unrealistic expectations of what medications can offer in terms of ameliorating pain, discomfort and dysphoria. Over-reliance on medications may have resulted in their use as a first line response when often non-pharmacological interventions may be more appropriate. The Internet may have also contributed to the development of an increasingly well informed and assertive generation of patients who present to prescribers with predetermined medication treatment requests, expectations or demands. Australia's population is also ageing and, as this occurs, more individuals are likely to experience pain, anxiety and insomnia. This is likely to increase the demand for drugs such as opioids and benzodiazepines.

A critical factor in the development of the NPDMS will be achieving a balance between diverse perspectives and interests. There is also a need to assure continued medical access to these medications and maximising their quality use, while minimising opportunities for their misuse. In maintaining continued access to these medications there is also a need to ensure that those who use them appropriately are in no way stigmatised by that use.

As is evident, the development of the NPDMS is undertaken in the context of a range of other strategies, policies, initiatives, perspectives, paradigms and organisational perspectives. Acknowledgement of this diverse and multi-faceted context is important for several reasons. First is the inter-related nature of these concurrent contextual factors

and the common underlying social determinants of problems they address. Second is that each provides a slightly different lens through which to view the problem of the misuse of pharmaceuticals. The third issue is that taking a broad approach to the issue of pharmaceutical drug misuse is more likely to lead the development of a Strategy which balances a range of perspectives.

As a result of the diverse range of issues that impact the development of the NPDMS, this literature review takes a very broad approach to understanding the problems Australia faces and to identifying possible solutions.

1.2 Key stakeholders

The NPDMS is of relevance to a wide range of stakeholders. They include:

- all Australian citizens
- a range of prescribers including general practitioners and pain, addiction and psychiatric specialists
- pharmacists
- regulators of drugs and poisons
- the pharmaceutical industry at a range of levels
- government-funded bodies such as the National Prescribing Service Ltd and the Australian Commission on Safety and Quality in Health Care
- members of the peak pharmaceutical advisory bodies such as the Pharmaceutical Benefits Advisory Committee, the National Medicines Policy Executive and the National Medicines Policy Committee
- policing and other law enforcement agencies
- drug treatment providers
- other health and human service providers including psychologists, physiotherapists, nurses and counsellors
- individuals suffering from chronic pain, mental health problems, social disadvantage and their respective advocacy groups and
- current misusers of these drugs.

Figure 1 provides an indication of the diversity of groups involved as key stakeholders in the development of the NPDMS.

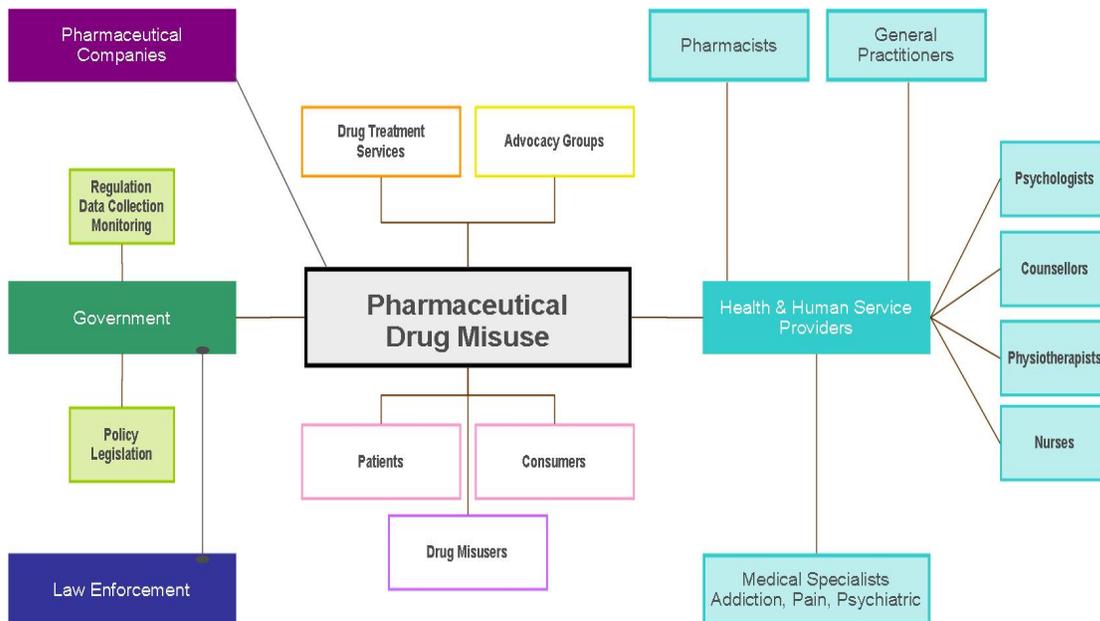


Figure 1. Key stakeholders with a role in the development of the NPDMS

The strategy will seek input from these groups and will endeavour to balance the diverse perspectives involved.

1.3 Key paradigms and documents impacting on the development of the NPDMS

1.3.1 The importance of a systems approach

In seeking to address problems associated with the misuse of pharmaceutical drugs, it is important to adopt a systems approach. This allows problems to be seen in the context of the broader health care and human service systems in which they occur and illuminates ways in which systemic factors may be contributing to these problems. Systemic factors may also be brought to bear in the alleviation of these problems.

Key systemic factors include:

- the relative availability and cost of pharmacological versus non-pharmacological treatments for conditions such as chronic non-malignant pain, insomnia and anxiety
- the level of controls placed on prescribers, pharmacists, the pharmaceutical industry and other commercial interests
- the scope for patients in Australia to attend as many prescribers or pharmacists as they choose
- the potential influence of current patterns of prescriber remuneration on the prevalence of pharmacological versus non-pharmacological treatments
- the adequacy of access to and provision of opioid substitution therapy
- the relative costs to consumers of receiving opioid substitution therapy versus opioid prescriptions via the Pharmaceutical Benefits Scheme
- the fact that many of the most effective non-opioid adjuvant drugs used in the treatment of pain are not approved by the Pharmaceutical Benefits Scheme for that purpose
- the extent to which general practitioners have access to addiction specialists to assist with the care of patients who are misusing medication and the extent to which sufficient time can be devoted to managing these often difficult cases
- the capacity of the health care system to support multi-disciplinary, shared care for patients with pain or substance misuse issues
- the extent to which pain patients can access specialist pain services
- the nature of the links between in-patient hospital care and community-based care, including the provision and ongoing management of discharge medications and
- increasingly well informed patients who may present to prescribers with predetermined medication treatment regimes.

Some of these factors are discussed in more detail later.

1.3.2 Social determinants of health

Over the past decade, there has been an increased global focus on the importance of the social determinants of health (The Marmot Review, 2010). This entails the conditions in which people are born, grow, live, work and age, including the health system, and the influence of these factors on health quality. These influences are often shaped by the distribution of money, power and resources. The social determinants of health are increasingly seen as major contributory factors in a range of health-related issues (Commission on the Social Determinants of Health, 2008).

Little research has been conducted into the social determinants of pharmaceutical misuse. Research conducted into pharmaceutical opioid-related deaths suggests a link with socio-economic disadvantage. Following a study of deaths involving oxycodone in Victoria, it was found that that drug toxicity deaths did not occur uniformly across the spectrum of socioeconomic advantage/disadvantage. The majority (55.2%) of unintentional drug toxicity deaths reported to the Victorian Coroner between 2000 and 2009 occurred in the regions which made up the lowest two quintiles of socioeconomic disadvantage. Only 39.5% of the Victorian population live in these areas. Similarly, while 27.1% of the Victorian population live in rural areas, a disproportionately high percentage of unintentional drug toxicity deaths (41.4%) occurred in these areas (Rintoul, Dobbin, Drummer, & Ozanne-Smith, 2010).

Hall et al. (2008) noted similar findings in their United States' (US) study of non-intentional pharmaceutical overdose deaths in West Virginia in 2006. Risk factors for prescription drug deaths included being male, having less education and living in the most impoverished counties of the state. Likewise, in Washington State between 2004 and 2007, Medicaid³ recipients were far more likely to die from pharmaceutical opioid overdose than non-Medicaid recipients. The age adjusted death rate was 30.8 per 100,000 in the Medicaid enrolled group versus 4.0 per 100,000 in the non-Medicaid group, an age adjusted risk of 5.7.

³ Medicaid is the US health program for eligible individuals and families with low incomes and resources.

There is increasing recognition that factors such as socioeconomic status significantly influence health problems such as chronic pain, levels of mental illness and illicit drug use. Australians who experience chronic pain, for example, are more likely than the population overall to have a lower level of completed education and to not have private health insurance. Those who experience chronic pain are also much more likely to be in receipt of government benefits, have poor self-rated health status and experience high levels of psychological distress (Blyth et al., 2001). Having little control over one's work is particularly related to an increased risk of low back pain (as well as sickness absence and cardiovascular disease) (Wilkinson & Marmot, 2003). In short, the experience of chronic pain is strongly associated with markers of social disadvantage (Blyth et al., 2001).

Similarly, social determinant factors also impact significantly on levels of mental illness. Chronic anxiety, insecurity, social isolation and lack of control over home and work life have powerful effects on mental health. The lower people are in the social hierarchy of industrialised countries, the more prevalent these problems (Wilkinson & Marmot, 2003).

There is also a strong correlation between socioeconomic status (SES) and use of illicit drugs, with lower SES groups more prevalent users of illicit drugs (Roche et al., 2008) and heavier users of related treatment services.

Complex cause and effect relationships exist between social disadvantage and the experience of chronic pain, mental illness and illicit drug use. Nonetheless, experiencing chronic pain, mental health problems or previous illicit drug use may increase the risk of patterns of medication usage that are inconsistent with quality use. Consequently, in developing the NPDMS it will be important that the misuse of pharmaceuticals is not seen exclusively as a medical problem and that it is also seen in its broader social context.

1.3.3 Prevention: Primary, secondary, tertiary and quaternary

Prevention is a pivotal issue in the development of the NPDMS. A comprehensive approach to prevention is required to address the multi-faceted issues of relevance. Four levels of prevention have been identified as shown below.

Primary prevention	Primary prevention is directed towards preventing the initial occurrence of a disorder: such as using non-pharmacological interventions as a first treatment of choice and ensuring that medications are not prescribed for longer than medically required. Primary prevention also incorporates appropriate monitoring systems to ensure early alert and sentinel systems are in place, as well as constraints over product pricing and commercial promotional activities. Primary prevention in relation to NPDMS also involves appropriate professional education and support strategies.
Secondary prevention	Secondary prevention strategies attempt to diagnose and treat a problem in its early stages of development before it results in significant morbidity. Examples include appropriate non-medication based pain management regimes; benzodiazepine withdrawal regimes for patients who have been taking these drugs for some time; and multi-disciplinary care plans.
Tertiary prevention	Tertiary prevention seeks to arrest or retard existing disease and its effects through appropriate treatment; or to reduce the occurrence of relapses and the establishment of chronic conditions through, for example, effective rehabilitation (World Health Organization [WHO], 1998). One example is opioid substitution therapy for opioid dependent patients.
Quaternary prevention	Quaternary prevention seeks to identify patients at risk of over-medicalisation, to protect them from new medical invasion, and to suggest ethically acceptable alternatives (Kuehein, Sohedoni, Visentin, Gervas, & Jamoule, 2010). This fourth level of prevention is particularly relevant to the area of preventing pharmaceutical drug misuse. The ability for prescribers to identify patients at risk of misusing their medications and to respond appropriately is likely to form a key plank in the response to pharmaceutical drug misuse problems. Foremost in this regard is the adoption of universal precautions, or regarding all patients taking medications such as benzodiazepines or opioids as being at risk of addiction (Gourlay, Heit, & Almahrezi, 2005).

In summary, all four levels of prevention should be addressed to adopt a balanced approach to pharmaceutical drug misuse.

1.3.4 National Medicines Policy/National Strategy for the Quality Use of Medicines

A further important strategic framework is the National Medicines Policy (NMP, Commonwealth of Australia, 1999). The NMP represents a partnership consisting of state, territory and Australian governments, health educators, health practitioners, other health care providers and suppliers, the medicines industry, health care consumers and the media. The overall aim of the NMP is to ensure that medication and related service needs are met in Australia, so that optimal health outcomes and economic objectives are achieved. The NMP is consistent with a broader shift of emphasis from healthcare program inputs to quality health outcomes.

The NMP seeks to ensure:

- that Australians have timely access to the medicines that they need, at a cost individuals and the community can afford
- that medicines meet appropriate standards of quality, safety and efficacy
- the quality use of medicines, and
- maintenance of a responsible and viable medicines industry.

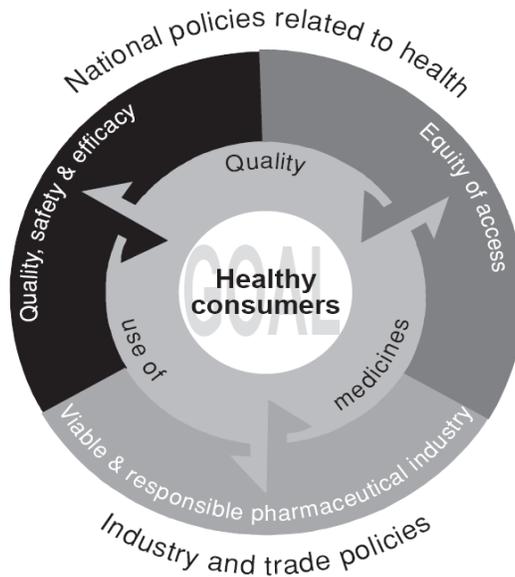


Figure 2. The inter-related nature of the aims of the National Medicines Policy

Source: (Commonwealth of Australia, 2002).

The Policy also recognises the fundamental role consumers have in reaching these objectives and that there needs to be a commitment from all partners to ensure that consultation occurs with consumer representatives (Commonwealth of Australia, 1999).

More information about the NMP is available here:

<http://www.health.gov.au/internet/main/publishing.nsf/content/National+Medicines+Policy-1>.

Sitting within the framework of the NMP is the National Strategy for the Quality Use of Medicines (NSQUM, Commonwealth of Australia, 2002). The quality use of medicines is one of the aims of the NMP. The goal of the NSQUM is to make the best possible use of medicines to improve health outcomes for all Australians.

The five objectives of the NSQUM are to:

1. improve the QUM by healthcare consumers
2. improve QUM by health practitioners, healthcare providers and health educators
3. gain the commitment of the medicines industry (including manufacturers and distributors) to QUM
4. gain the commitment of governments to QUM and
5. improve the commitment of healthcare consumers, health practitioners and educators, the medicines industries, the media, healthcare facilities, funders and purchasers, and Australian, state and territory governments, to working in partnership to achieve QUM.

Five key principles underpin the NSQUM. These were developed in consultation with all partners and in the context of the problems Australia currently faces in achieving QUM. These principles are as follows.

- *The primacy of consumers.* The NSQUM recognises both the central role consumers play in attaining QUM and the wisdom of their experience. Consumers must be involved in all aspects of the NSQUM.
- *Partnership.* Active and respectful partnerships are essential to achieving QUM in Australia.
- *Consultative, collaborative, multi-disciplinary activity.* To attain QUM, activities must be consultative, collaborative and multidisciplinary. Therefore, key partners must be involved at all stages in designing, implementing and evaluating QUM programs. At the local level, the value of the health care team in achieving QUM needs to be promoted and consumers recognised as active members.
- *Support for existing activity.* Wherever possible, initiatives within and across all groups need to be stimulated and supported, and support given to existing groups that are already developing initiatives. Actions taken to improve QUM should heed the ethical and legal rights, obligations and responsibilities of all partners.

- *Systems-based approaches.* To achieve QUM it is necessary to adopt systems-based approaches that will: develop behaviours that support QUM; and create a supportive environment that encourages QUM. Multiple activities and strategies are needed to raise awareness about issues related to QUM. Attitudes, knowledge, skills and behaviours that support QUM need to be developed and maintained. There is also a need to inspire community, organisational, legal and political efforts to create an environment that supports QUM.

The NSQUM identifies all of the partners, which influence the QUM and outlines their responsibilities. It also lists six building blocks that support QUM which are based on evidence and expert opinion about interventions, regulatory efforts and programs to improve medication use. They are:

- policy development and implementation
- facilitation and coordination of QUM initiatives
- provision of objective information and assurance of ethical promotion of medicines
- education and training
- provision of services and appropriate interventions, and
- strategic research, evaluation and routine data collection.

More information about the NSQUM is available here:

<http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm>

1.3.5 National Drug Strategy

The National Drug Strategy (NDS) is a cooperative venture between Australian, state and territory governments and the non-government sector. It aims to improve health, social and economic outcomes for Australians by preventing the uptake of harmful drug use and reducing the harmful effects of licit and illicit drugs in our society. The NDS has

an overarching approach of harm minimisation, which has guided the NDS since its inception in 1985. The current iteration of the Strategy (2010-2015) retains its existing three pillars, while also placing increased emphasis on pharmaceutical misuse. The Strategy is available at:

http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/con_sult.

The three pillars are described below.

- **Supply reduction** to prevent, stop, disrupt or otherwise reduce the production and supply of illegal drugs; and control, manage and/or regulate the availability of legal drugs.
- **Demand reduction** to prevent the uptake and/or delay the onset of use of alcohol, tobacco, illegal and other drugs; reduce the misuse of alcohol, tobacco, illegal and other drugs in the community; and support people to recover from dependence and reintegrate with the community.
- **Harm reduction** to reduce the adverse health, social and economic consequences of the misuse of drugs.

The supply, demand and harm reduction pillars of the NDS are of central importance to the development of the NPDMS.

Supply reduction could involve such measures as:

- ensuring that medications are prescribed and used in ways that are not in excess of medical need
- reducing opportunities for theft, diversion and medication shopping
- enhancing Australia's capacity to monitor the prescription and supply of drugs through online technologies, and
- focusing law enforcement efforts on the illicit trade in pharmaceutical drugs.

Demand reduction strategies could include:

- enhancing the health literacy levels of the broader community in relation to the quality use of pharmaceutical drugs
- ensuring that treatment opportunities are available for those who experience difficulties with pharmaceutical drugs, and
- ensuring access to treatment for co-occurring problems such as anxiety, sleep problems, depression and chronic pain to reduce the need for medication.

Harm reduction strategies could include:

- disseminating information to problematic misusers of pharmaceutical drugs about the harms associated with using these medications in ways that were unintended by the manufacturer and prescriber, and
- providing access to filters to reduce the harms associated with the injection of medications that are not intended to be injected.

1.3.6 The National Health Reform Agenda

The development of the NPDMS is occurring at the same time as the Australian Government has established a major health reform agenda to address significant challenges facing the health system. These challenges include:

- the ageing of Australia's population (including healthcare workers themselves)
- an increasing number of people living for many years with chronic medical conditions such as heart disease, diabetes and arthritis
- the fact that many of these chronic diseases are largely preventable and can be attributed to modifiable risk factors such as smoking, excessive alcohol consumption, obesity and lack of physical exercise, and

- the fact that without any policy change, expenditure on health and aged care in Australia is forecast to rise sharply from 9.3% of gross domestic product in 2002-2003 to 12.4 per cent within two decades (Commonwealth of Australia, 2009).

Three key reports were commissioned by the Australian Government through its health reform process and released in 2009 and 2010. These were the:

- National Health and Hospitals Reform Commission – A healthier future for all Australians
- National Primary Health Care Strategy – Building a 21st century primary health care system, and
- National Preventative Health Taskforce – Australia: The healthiest country by 2020.

These reports are likely to have a wide range of implications for the health system. The timing of their release means that the development of the NPDMS is occurring at a time of considerable flux and uncertainty within the health care system.

Their implications for the development of the NPDMS are outlined below.

National Health and Hospitals Reform Commission – A healthier future for all Australians

The final report of the National Health and Hospitals Reform Commission (Commonwealth of Australia, 2009) contained three central aims.

1. To address prominent equity and access issues that affect health outcomes for people, in particular: among Aboriginal and Torres Strait Islander people; people with serious mental illness; and people living in rural and remote areas. It also sought improvements to dental health care and to improve timely access to quality care in public hospitals.

2. To redesign the health care system to meet emerging challenges by: embedding prevention and early intervention into every aspect of the health system; connecting and integrating health and aged care services; and undertaking a major revision of Medicare.
3. Creating an agile and self-improving health system for long-term sustainability by: strengthening consumer engagement and voice; having a modern, learning and supported workforce; by making smarter use of data, information and communication; well-designed funding and strategic purchasing; knowledge-led continuous improvement, innovation and research; reforming governance; and implementing and funding reform.

More information is available from:

<http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report>

National Primary Health Care Strategy – Building a 21st century primary health care system

The National Primary Health Care Strategy has five key building blocks:

1. Regional integration whereby local governance, networks and partnerships connect service providers to planned and integrated services, identify and fill service gaps and drive change.
2. Information and technology, including E-Health information and technology. This includes E-Health electronic health records and use of new technologies to integrate care, improve patient outcomes, and deliver capacity, quality and cost-effectiveness.
3. A skilled workforce which is flexible, well-trained, with clear roles and responsibilities built around core competencies and which works together to deliver best care to patients cost-effectively and continues to build their skills through effective training and team work.

4. A physical infrastructure that supports different models of care to improve access, support integration and enable teams to train and work together effectively.
5. Financing and system performance arrangements that build on the strengths of the system, identify and fill local service gaps and focus on cost-effective interventions. System performance is a core concern across the service system with up to date information used to drive individual practice and system outcomes.

The Strategy also has four key directions for change:

1. Improving access and reducing inequity whereby primary health care services are matched to peoples' needs and delivered through mainstream and targeted programs across an integrated system.
2. Better management of chronic conditions whereby continuity and coordination of care is improved for those with chronic disease through better targeted chronic disease management programs linked to voluntary enrolment and local integration.
3. Increasing the focus on prevention by having strengthened, integrated and more systematic approaches to preventive care involving regular risk assessments which are supported by data and best use of workforce.
4. Improving quality, safety, performance and accountability by implementing a framework for quality and safety in primary health care with improved mechanisms for measurement and feedback to drive transparency and quality improvement.

More information is available from:

<http://www.health.gov.au/internet/yourhealth/publishing.nsf/Content/report-primaryhealth>

National Preventative Health Strategy. Australia: The healthiest country by 2020

The National Preventative Health Strategy was released by the National Health Preventative Taskforce in June 2009. It is a comprehensive approach to prevention and has seven strategic directions:

1. Shared responsibility – developing strategic partnerships at all levels of government, industry, business, unions, the non-government sector, research institutions and communities.
2. Acting early and throughout life – working with individuals, families and communities.
3. Engaging communities – acting and engaging with people where they live, work and play; at home, in schools, workplaces and the community. Informing, enabling and supporting people to make healthy choices.
4. Influencing markets and developing coherent policies – for example, through taxation, responsive regulation, and through coherent and connected policies.
5. Reducing inequity through targeting disadvantage – especially low socioeconomic status (SES) population groups.
6. Contribute to closing the gap between the health status of Indigenous and non-Indigenous Australians.
7. Refocusing primary healthcare towards prevention.

The Strategy has four goals, namely to:

- halt and reverse the rise in overweight and obesity
- reduce the prevalence of daily smoking to 10% or less
- reduce the proportion of Australians who drink at short-term risky/high-risk levels to 14%, and the proportion of Australians who drink at long-term risky/high-risk levels to 7%, and
- contribute to the 'Close the Gap' target for Indigenous people, reducing the life expectancy gap between Indigenous and non-Indigenous people.

In summary, the National Health Reform Agenda has a range of implications for the development of the National Pharmaceutical Drug Misuse Strategy. These implications include:

- the emphasis placed on problem prevention and early intervention
- the reshaping of Medicare to better reflect the value of non-pharmacological interventions undertaken by clinicians
- better integration of health care services among multi-disciplinary providers
- enhancing the extent to which relevant evidence bases inform practice
- improved use of strategies such as E-Health information and technology. This includes the use of E-Health electronic health records and other new technologies to integrate care and improve patient outcomes, including the quality use of medicines.

More information is available from:

<http://www.health.gov.au/internet/preventativehealth/publishing.nsf/Content/discussion-healthiest>

1.3.7 National E-Health Strategy

In 2008, Australian Health Ministers, through the Australian Health Ministers' Advisory Council (AHMAC), commissioned the development of a strategic framework and plan to guide national coordination and collaboration in E-Health.

National action in this area will be focused in four key areas:

1. **implementing the national 'health information highway'** infrastructure and rules to allow information to be seamlessly accessed and shared across the Australian health system
2. **stimulating investment in high priority computer systems and tools** that can deliver tangible benefits to Australian consumers, care providers and health care managers

3. **encouraging health sector participants to adopt and use high priority systems and tools** as they become available and
4. **establishing an E-Health governance regime** to enable effective coordination and oversight of national E-Health activities.

The aims of these E-Health initiatives are to:

- ensure the right consumer health information is made available electronically to the right person at the right place and time to enable informed care and treatment decisions
- enable the Australian health sector to more effectively operate as an inter-connected system, overcoming the current fragmentation and duplication of service delivery
- provide consumers with electronic access to the information needed to better manage and control their personal health outcomes
- enable multi-disciplinary teams to electronically communicate and exchange information and provide better coordinated health care across the continuum of care
- provide consumers with confidence that their personal health information is managed in a secure, confidential and tightly controlled manner
- enable electronic access to appropriate health care services for consumers within remote, rural and disadvantaged communities
- facilitate continuous improvement of the health system through more effective reporting and sharing of health outcome information
- improve the quality, safety and efficiency of clinical practices by giving care providers better access to consumer health information, clinical evidence and clinical decision support tools, and
- support more informed policy, investment and research decisions through access to timely, accurate and comprehensive reporting on Australian health system activities and outcomes.

The Strategy contains examples of the anticipated impacts of E-Health on consumers, care providers and managers. See Table 1 below.

Table 1. Implications of the E-Health Strategy for stakeholders

Stakeholder Group	Current State	Future State
Consumers	<ul style="list-style-type: none"> • Largely responsible for coordinating their own care delivery and acting as the integrator of health care information across the health system • Spend time repeating the same information to multiple care providers and/or receiving duplicate treatment activities • Poor, and in most cases zero, access to personal health information which is stored in multiple, fragmented silos across the health system • Limited security of personal health information or ability to control who accesses it • Heavily reliant on individual care providers for access to reliable health information • Unequal access to health care services, particularly in remote and rural communities 	<ul style="list-style-type: none"> • When consumers interact with the health system, <i>care providers will know who they are</i> and have access to relevant details of their health information • Will rely on the <i>health system to effectively coordinate</i> their care regimes and treatment activities • Will have an ability to <i>access their own health records</i> and maintain a personal health diary • Will have confidence that their <i>health information is managed securely and confidentially</i> • Will have the ability to <i>better manage their own health</i> through access to reliable and accredited sources of health information • Will have technology enabled <i>access to a broader and deeper range of health services from within rural and remote communities</i> • Will be supported in the management of their care through <i>automated monitoring of their health status</i> and <i>access to individual care plans</i>
Care Providers	<ul style="list-style-type: none"> • Work with incomplete and fragmented information when providing care to consumers • Spend time collecting consumer information and duplicating treatment activities • Manually coordinate care with other providers and exchange information in an inefficient, incomplete and ad hoc manner • Risk the occurrence of adverse events through incomplete information and a lack of access to decision support tools at the point of care • Limited ability to interact with consumers remotely • Limited means to monitor effectiveness of service delivery outcomes 	<ul style="list-style-type: none"> • Will have an <i>integrated and complete view of consumer health information</i> at the point of care • Will be able to <i>share information electronically in a timely manner across different geographic locations and all parts of the health sector</i> • Will have access to data that allows them to <i>more effectively monitor and evaluate service delivery outcomes</i> • Will be able to <i>electronically order tests, prescribe medications and refer individuals to other providers</i> • Providers' care decisions will be supported by <i>access to appropriate information sources and decision support tools</i> at the point of care • Will be able to <i>electronically interact with consumers regardless of where they are geographically located</i> • Will be able to <i>collaborate with other professionals</i> by more easily sharing expertise and evidence • Will have <i>easy access to clinical knowledge and evidence sources</i> to assist with skill development
Health Care Managers	<ul style="list-style-type: none"> • Rely on incomplete, fragmented and untimely information when trying to make decisions • Spend time trying to collect and manually integrate information from many different data sources • Limited ability to share clinical and administrative management information across the health sector • Very difficult to meaningfully understand the national impact of strategic, operational or clinical treatment decisions 	<ul style="list-style-type: none"> • Will have <i>access to timely and complete information about health system activities and outcomes</i> • Will have a <i>reliable and comprehensive evidence base</i> to inform and monitor the impact of clinical, policy, investment and administrative decisions • Will be able to <i>better respond in the case of emergencies</i> through real time monitoring of public health indicators • Will be able to <i>rapidly assess the national impact of particular treatment regimes</i> via access to nationally aggregated clinical datasets

Source: Victorian Department of Human Services (2008, p.6).

The measures described in the E-Health health Strategy mesh well with the kinds of tools that prescribers require to make better decisions about the quality use of medicines for their patients.

The NE-HS is available at: <http://www.ahmac.gov.au/site/home.aspx>.

1.3.8 National Pain Strategy

The National Pain Strategy was released in 2010 and was led by the Australian and New Zealand College of Anaesthetists' Faculty of Pain Medicine, the Australian Pain Society and Chronic Pain Australia. The mission of the Strategy is to improve quality of life for people with pain and their families, and to minimise the burden imposed by pain on individuals and the community. The Strategy has a number of goals and priority objectives.

Goal 1: People in pain as a national health priority

The priority objectives are to:

- establish a national body involving all stakeholder groups to identify partnerships, frameworks and resources required to build capacity and deliver the proposed outcomes of the National Pain Strategy
- de-stigmatise the predicament of people with pain, especially chronic non-cancer pain, and
- achieve federal and state government recognition of chronic pain as a chronic disease in its own right.

Goal 2: Knowledgeable, empowered and supported consumers

The priority objectives are to:

- improve community understanding of the nature of chronic pain and best practice management, and

- provide easily accessible information and support programs to assist people with pain, carers and other supporters, and practitioners to understand and be more proactively involved in managing pain.

Goal 3: Skilled professionals and best-practice evidence-based care

The priority objectives are to:

- train and support health practitioners in best practice pain assessment and management, and
- establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain.

Goal 4: Access to interdisciplinary care at all levels

The priority objectives are to:

- develop and evaluate patient-centred service delivery and funding models for pain management in the community which provide interdisciplinary assessment, care and support as a part of comprehensive primary health care centres and services, and
- ensure meaningful communication about pain management between practitioners and patients, and between practitioners.

Goal 5: Quality improvement and evaluation

The priority objectives are to:

- ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use, and
- improve standards in pain management by developing national benchmarking of outcomes.

Goal 6: Research

The priority objectives are to:

- enable pain research at a national level, and
- identify information gaps underpinning all National Pain Strategy objectives.

The NPS is available at: <http://www.painsummit.org.au/strategy/>.

1.3.9 National Mental Health Strategy

The National Mental Health Strategy is a commitment by Australian governments to improve the lives of people with a mental illness. It was endorsed in April 1992 by the Australian Health Ministers' Conference (AHMC) as a framework to guide mental health reform. The National Mental Health Policy 2008 sits within the Strategy. The aims of the Policy are to:

- promote the mental health and wellbeing of the Australian community and, where possible, prevent the development of mental health problems and mental illness
- reduce the impact of mental health problems and mental illness, including the effects of stigma, on individuals, families and the community
- promote recovery from mental health problems and mental illness and
- assure the rights of people with mental health problems and mental illness, and enable them to participate meaningfully in society.

The National Mental Health Plan (2009-14) was developed to fulfil the vision of the Policy. The Plan has a number of priority areas and outcomes.

Priority area 1. Social inclusion and recovery

Outcomes

- The community has a better understanding of the importance and role of mental health and wellbeing, and recognises the impact of mental illness.
- People with mental health problems and mental illness have improved outcomes in relation to housing, employment, income and overall health and are valued and supported by their communities.
- Service delivery is organised to provide more coordinated care across health and social domains.

Priority area 2. Prevention and early intervention

Outcomes

- People have a better understanding and recognition of mental health problems and mental illness. They are supported to develop resilience and coping skills.
- People are better prepared to seek help for themselves and to support others to prevent or intervene early in the onset or recurrence of mental illness.
- There is greater recognition and response to co-occurring alcohol and other drug problems, physical health issues and suicidal behaviour.
- Generalist services have support and access to advice and specialist services when needed.

Priority area 3. Service access, coordination and continuity of care

Outcomes

- There is improved access to appropriate care, continuity of care and reduced rates of relapse and re-presentation to mental health services.
- There is an adequate level and mix of services through population-based planning and service development across sectors.

- Governments and service providers work together to establish organisational arrangements that promote the most effective and efficient use of services, minimise duplication and streamline access.

Priority area 4. Quality improvement and innovation

Outcomes

- The community has access to information on service delivery and outcomes on a regional basis. This includes reporting against agreed standards of care including consumer and carer experiences and perceptions.
- Mental health legislation meets agreed principles and, in conjunction with any related legislation, is able to support appropriate transfer of civil and forensic patients between jurisdictions.
- There are explicit avenues of support for emerging and current leaders to implement evidence-based and innovative models of care, to foster research and dissemination of findings, and to further workforce development and reform.

Priority area 5. Accountability measuring and reporting progress

Outcomes

- The public is able to make informed judgements about the extent of mental health reform in Australia and has confidence in the information available to make these judgements.
- Consumers and carers have access to information about the performance of services responsible for their care across the range of health quality domains and are able to compare these to national benchmarks.

The National Mental Health Strategy is available at:

<http://www.health.gov.au/internet/main/publishing.nsf/content/mental-strat>.

1.3.10 The perspective of the Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (ACSQHC, 2010) noted that current priorities for the health care system are dealing with complex problems and community concerns stemming from a number of key areas including: healthcare rights; medication safety; open disclosure; and information strategies. Each of these areas involves primary care, mental health, and allied health systems. The Commission has developed a Framework that specifies three core principles, i.e. that care is:

- consumer centred
- driven by information, and
- organised for safety.

Each of these principles is applicable to the misuse of pharmaceuticals and strategies and solutions to address this issue.

In this context, medicines are the most commonly used healthcare treatment in Australia. They relieve symptoms, improve quality of life and prevent or cure disease.

Because they are commonly used, medicines are associated with more errors, and more adverse events, than any other aspect of health care (Leong, Murnion, & Haber, 2009; The Royal Australasian College of Physicians [RACP], 2009). It is estimated that around 2-3% of all hospital admissions are medication-related, with as many as 30% of unplanned geriatric admissions associated with an adverse drug event (Kuehein et al., 2010). Around half of these admissions are considered potentially avoidable (range 32-77%) (Kuehein et al., 2010). In 2006-07 there were 101,003 hospital separations associated with an adverse medicine event in Australia (Cicero, 2007). The cost of medication-related admissions to hospital in Australia is estimated at \$660 million per year (Paulozzi & Ryan, 2006).

Medication safety has been identified by the Commission as a priority area for activity. There are many organisations actively working at both national and local levels to improve the safety and quality of medication use in Australia. In 2008, the Commission undertook a medication safety and quality scoping study to understand how it could best apply its resources to such a large therapeutic domain (Paulozzi, Budnitz, & Yongly, 2006). The study found that while there is much activity to improve medication safety and quality in Australia, including with consumers, much of the work is uncoordinated, there is duplication of effort, and some important patient safety activities are either not occurring or are being implemented inconsistently. The study recommended that the Commission provide national leadership and strategic direction for a national approach to reducing patient harm from medicines. It also recommended 45 specific actions to improve national medication safety and quality.

The Commission systematically analysed the 45 recommendations and prioritised them along five key themes:

1. Standardisations and system improvements
2. Continuity of medicines management
3. Reducing gaps in practice
4. Using technology
5. Advocating safety and quality.

Given the extent to which the Commission is currently focussing on issues of medication safety, this is another issue that warrants consideration in the preparation of the NPDMS.

1.3.11 Other Australian Government Initiatives

The Australian Government aims to provide reliable, timely and affordable access to cost-effective, sustainable and high quality pharmaceutical services and medicines.

Central to achieving this aim is the Pharmaceutical Benefits Scheme (PBS) which subsidises the cost of certain medicines. Continued access to these medicines, within the context of quality use of medicines principles, is important as they are highly beneficial to many individuals. While an extremely valuable program, a key issue is whether improved drug affordability through the PBS leads to the preferential use of medications by prescribers rather than non-medical alternatives, regardless of their respective efficacy.

The Australian Government also provides advice to health professionals and consumers on the quality use of medicines. This includes funding the National Prescribing Service (NPS) to provide independent, evidence-based information on various drug and therapeutic topics. NPS information and resources supplement a range of other resources available to health professionals to improve prescribing and dispensing. These resources include information on medicines provided by pharmaceutical companies, guidelines such as those prepared by medical colleges and other sources such as Therapeutic Guidelines and the Australian Medicines Handbook.

Medicare Australia is responsible for administering the Australian Government's national health programs. Medicare Australia's compliance approach involves risk detection including identifying, assessing and prioritising risks to the integrity of the programs they administer. One of the primary risks to the PBS is the prescription of PBS medicines to patients who do not meet the requirements for these medicines. Prescribers have an important role in deciding who is eligible, in particular, for restricted and authority medicines.

Medicare Australia also researches and monitors prescribing. A major focus is on supporting prescribers to understand their obligations. Drugs of dependence are a particular area of concern and focus. In exceptional circumstances, the Practitioner Review Program may review specific prescribing patterns considered as potentially

inappropriate. Further review may lead Medicare Australia to refer a case to the Director of the Professional Services Review for peer review.

The Professional Services Review plays an important role in educating practitioners and deterring inappropriate practices. The *2008-09 Professional Services Review: Report to the Professions* (Professional Services Review [PSR], n.d.) found that inappropriate prescribing of controlled drugs and benzodiazepine drugs was a significant issue in a number of GP referrals. Patient demand for these drugs, as well as an over readiness by some practitioners to prescribe them, is seen as an ongoing problem.

1.3.12 The policing perspective

It is not just the health sector that is impacted by problematic pharmaceutical misuse. As Nicholas (2002) asserted, the diversion of pharmaceuticals represents a complex series of problems for policing, including:

- providing an additional dynamic to the already complex illicit drug markets
- the behavioural problems associated with intoxication with pharmaceutical drugs
- crime committed while under the influence of pharmaceutical drugs or in order to obtain them; and
- driving while under the influence of pharmaceutical drugs.

Fry et al. (2007) highlighted a range of other issues that pharmaceutical opioid and benzodiazepine markets pose for police. These include:

- the difficulties associated with distinguishing licitly and illicitly held prescription pharmaceuticals
- the requirement for police to have knowledge of relevant scheduling and legislative considerations

- the need for police to have an understanding of psychopharmacology of benzodiazepines and prescribed opioids, their interactions with illicit drugs, and the implications for behaviour; and
- the fact that similar policing responses are required regardless of whether intoxication is due to use of licit or illicit drugs.

Trafficking in illicit pharmaceutical drugs is a major emerging problem for police in some jurisdictions. The relative ease with which these drugs can be cheaply obtained and the potential profits made from their illicit sale is encouraging entrepreneurs to enter the illicit pharmaceuticals market. It may include, for example, patients who ‘use a bit and sell a bit’, through to those making considerable profits from the enterprise. This trend is becoming particularly prevalent in some rural areas, but is also evident in urban settings. Police increasingly encounter individuals travelling from town to town, sometimes across several jurisdictions to obtain substantial quantities of opioids and other pharmaceuticals from a variety of doctors and pharmacies. These drugs are then on-sold in the community.

From a policing perspective, this is very problematic because the information police require to respond to these problems is held by the health sector and, at times, by different state/territory and national jurisdictions. Hence the data is not easily or readily accessible to police. As a result, it is only possible for police to access relevant information once a problem with illicit supply has already caused significant levels of harm in the community. This is a major barrier to the investigation of these crimes.

A further difficulty is that crimes related to the diversion of pharmaceutical drugs are rarely reported to police and, even when they are, the offences are difficult to prove.

A further issue of concern for police is crime committed while under the influence of pharmaceutical drugs. This includes violent and property crime. Crime committed to obtain pharmaceuticals is also problematic. This includes:

- the forgery and alteration of prescriptions; and
- robberies and thefts from pharmacies, hospitals and points of wholesale, manufacture and transport.

Many of the responses required to reduce the misuse of pharmaceutical drugs are ‘upstream’ responses, which include measures such as enhancing the QUM. Nevertheless, if police are not given appropriate tools to respond to the ‘downstream’ problems associated with those profiting from the illegal sale of these drugs, then this would be a major gap in Australia’s strategic response to these problems.

Pharmaceutical drugs have historically not featured prominently on the ‘policing radar’ of illicit drug problems. This is, however, changing and pharmaceutical drugs are likely to become increasingly problematic in coming years (Nicholas, 2010).

1.3.13 Development of clinical guidelines

A range of guidelines exist internationally to provide prescribers with measures designed to enhance the quality use of medicines. These too need to be taken into consideration in the development of the NPDMS. These guidelines include:

- Benzodiazepine Guidelines (The Royal Australian College of General Practitioners [RACGP], 2000)
- Prescribing benzodiazepines. Ongoing dilemma for the GP (National Prescribing Service [NPS], 2002)
- General Principles for Rational Use of Opioids in Chronic or Recurrent Pain (NSW Therapeutic Assessment Group, 2002)
- Opioids in the Treatment of Non-Cancer Pain: An Update of the American Society of the Interventional Pain Physicians Guidelines (Trescot et al., 2008)
- Guidelines for use of Benzodiazepines in Psychiatric Practice (The Royal Australian and New Zealand College of Psychiatrists [RANZCP], 2008)

- Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain (Chou et al., 2009) on behalf of the American Pain Society–American Academy of Pain Medicine Opioids Guidelines Panel
- The Prescription Opioid Policy (RACP, 2009)
- Opioids for Persistent Pain: Good Practice (The British Pain Society [BPS], 2010)
- A Planned Approach to Prescribing Opioids (National Prescribing Service Limited [NPS], 2010b)
- Principles Regarding the use of Opioid Analgesics in Patients with Chronic Non-Cancer Pain (Australian and New Zealand College of Anaesthetists [ANZCA] Faculty of Pain Management, 2010)
- Guidelines Regarding the use of Opioid Analgesics in Patients with Chronic Non-Cancer Pain (ANZCA Faculty of Pain Management, 2010).

1.3.14 Summary

In summary, the development of the NPDMS will necessitate consideration of a wide range of existing strategies and policies. It will be important to ensure that the NPDMS accommodates the perspectives of a range of key stakeholders.

2 What's the problem?

The extent and nature of pharmaceutical drug misuse in Australia

2.1 Knowledge gaps

Before describing the extent and nature of pharmaceutical drug misuse in Australia, it is important to emphasise that substantial knowledge gaps exist in this area.

Consequently, the description of what is known needs to be seen in the context of the much larger picture of what is missing. Pharmaceutical drug misuse has not been a substantial focus of research attention in Australia. Much of what is known about this issue stems from incidental findings of research and data collections intended to illuminate other issues. This 'patchy' understanding is particularly concerning in the light of emerging evidence that pharmaceutical misuse is rapidly emerging as a drug problem in Australia and overseas.

Currently it is not possible to accurately quantify or comprehensively respond to problematic pharmaceutical use, and prescription opioid use in particular, in Australia because:

1. existing monitoring systems cannot identify and track medications to the individual patient level
2. many existing monitoring systems do not cover all prescription drugs, cannot track prescriptions to the individual patient and/or cannot do so in a timely manner
3. the regulation of pharmaceutical opioids varies between jurisdictions, which impedes the implementation of strategies to deal with problematic opioid use and facilitates individuals seeking these drugs across state/territory borders

4. at times, discrete information is held by different agencies (such as health and law enforcement agencies) and across different jurisdictions, which is not usually merged to form a comprehensive picture
5. although there is little evidence that international Internet pharmacies are currently a significant source of these medications, they have potential to further weaken regulatory controls over prescription opioids and other medications
6. research into pharmaceutical misuse in Australia has been very limited
7. inadequate monitoring systems make fraudulent presentation for opioid prescriptions difficult to identify and address in health settings (e.g. general practice, community pharmacies and emergency departments) (RACP, 2009, p. 8)
8. police do not have access to the data they require to effectively respond to the misuse of pharmaceuticals that involves the illicit sale of medications
9. the national registration of health practitioners and the subsequent ability for Schedule 8 prescriptions written in one jurisdiction to be filled in another is an emerging area of concern.

In all jurisdictions, other than NSW and Victoria, there are formal systems in place to monitor overall trends in the prescribing of controlled drugs. In NSW and Victoria, monitoring is undertaken by individual officers visiting pharmacies and manually inspecting a relatively small sample of prescriptions. Tasmania, on the other hand, is moving towards a real-time reporting system. Under this program, prescribers, pharmacists and regulators will have instantaneous access to the prescription receipt and filling history of patients. Other jurisdictions, such as South Australia, have developed systems to transmit data electronically, but the data is generally retrospective. Typically, existing jurisdictional monitoring systems rely on paper-based processes which are not necessarily linked to other systems. (Nous Group, 2008).

A further difficulty in monitoring controlled drugs is lack of assurance about the identity of the person named on a prescription. Individual patients could, for example, use

borrowed or stolen Medicare cards which would enable prescriptions to be obtained using identity fraud (Nous Group, 2008).

The Parliament of Victoria Drugs and Crime Prevention Committee (DCPC, 2007) pointed out other difficulties in obtaining information on the misuse of pharmaceuticals. The key source of information in this area, the Drug Utilisation Sub-Committee of the Australian Pharmaceutical Benefits Advisory Committee, does not currently provide data that permits observations to be made about trends in the prescription of specific drugs and the potency of those drugs. Data is also rarely disaggregated to give 'snapshots' of prescription drug misuse among particular groups, such as Indigenous Australians, culturally and linguistically diverse communities, people living in rural and region areas or prison populations (DCPC, 2007).

Knowledge gaps concerning the extent and nature of problematic pharmaceutical drug misuse among Indigenous Australians is particularly concerning. Anecdotal evidence presented to DCPC (2007) from a number of agencies indicated that medication misuse, and in particular medication mismanagement, was impacting significantly on Indigenous people due to the high level of medications many Indigenous people were prescribed. Nicholas (2010) reported similar findings.

In recent years considerable effort has been made to increase access of Indigenous Australians living in remote areas to prescription medicines. Pharmacists are now subsidised to provide pharmaceutical services to remote Indigenous communities. The average expenditure by the Australian Government on the Pharmaceutical Benefits Scheme per person for the Indigenous population almost doubled between 1995-96 and 1998-99, and increased by a further 64% between 1998-99 and 2004-05 (Australian Institute of Health and Welfare [AIHW], 2008d). There is a concern that some of this represents misuse and inappropriate prescribing. Given the extent to which many Indigenous Australians are already vulnerable to alcohol and other drug misuse, this will be an important issue to monitor.

The data available from the Pharmaceutical Benefits Scheme (PBS) provides some useful insights into drug prescription trends in Australia, but it does need to be seen in the context of its limitations. The data only includes medications which are eligible for a PBS benefit. It also only records information about medications for which the pharmacist requires re-imburement from the PBS. Currently, Australians who do not hold a concession card pay up to \$34.20 per script for medications covered by the PBS (Department of Health and Ageing, 2010). The PBS meets any remaining costs. Therefore any prescriptions filled for non-concessional patients that cost less than \$34.20 do not appear in PBS data because the PBS does not contribute to their cost. Similarly, patients with a concession card pay \$5.60 per script (Department of Health and Ageing, 2010) and any drugs that cost less than this also do not appear in the PBS data for similar reasons.

An examination of the PBS expenditure on prescription drugs for the year 2008-09 indicates that the average cost of analgesics supplied under the PBS in that year was \$24.86. The average cost of codeine phosphate/paracetamol (30 mg & 500 mg respectively) was \$8.45 and the average cost of diazepam was \$7.58 (Department of Health and Ageing, 2008). As at January 2009, the maximum cost to non-concession card holders of medications available on the PBS was \$32.90 (CHERE, 2009). Since the cost of many of these medications falls well below the non-concessional maximum patient payment level, they would not appear in the PBS data. Consequently, while the PBS data provides some insight into the trends of drug prescription it does not necessarily provide a picture of the levels of prescriptions.

The paucity of information available on private prescriptions is also problematic. Private prescriptions are non-PBS or non-Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions which can be provided by prescribers. The patient pays the full (non-subsidised) price for the drugs and the prescription does not appear on PBS/RPBS monitoring schemes. Private or non-PBS prescriptions for alprazolam, for example,

comprised on average an additional 32% of prescriptions per year, based on estimates from the Australian Statistics on Medicines (as cited in Monheit, 2010).

A range of other difficulties are associated with monitoring the problematic misuse of pharmaceutical drugs (Bruno, as cited in Topp, 2006), including:

- problems with timely access to existing databases
- inconsistency in the coding of drugs in these data sets (brand names, generic names, or an overall drug class), and
- privacy concerns related to integrating health and law enforcement data on issues such as the identification of prescription shoppers.

In addition, very little is known about the extent and nature of misuse of over the counter pharmaceuticals (OTCs). Over the counter pharmaceuticals are less closely controlled than prescription drugs and current understanding of their misuse at a population level is scant.

2.2 Levels and patterns of use

2.2.1 Information from population studies

The 2007 National Drug Strategy Household Survey⁴ (AIHW, 2008c) found that 7% of Australians aged 14 years and over had used painkillers, tranquilisers, barbiturates and/or steroids for non-medical purposes in their lifetime and about half of these had done so in the past 12 months. Painkillers/analgesics were used for non-medical purposes by 2.5% of this population in the past 12 months. In the same year, 1.3% of Australians aged 12 years or older had used tranquillisers or sleeping tablets for non-

⁴ Examples of painkillers/analgesics listed in the NDSHS questionnaire included aspirin, paracetamol, Mersyndol®, Panadeine Forte®, and Nurofen Plus®. As such, respondents may not have included other drugs such as oxycodone or fentanyl in their responses, which were not listed thereby understating the self-reported use of these substances.

medical purposes (AIHW, 2008b). While males were more likely than females to have used pharmaceuticals for non-medical purposes in their lifetime (7.6% versus 6.4%), equal proportions of males and females (3.6%) had used these drugs in the past 12 months.

In 2007 Australians aged 20-29 years were more likely than other age groups to have used pharmaceuticals for non-medical purposes in their lifetime (10.3%), in the previous 12 months (5.4%) and in the previous month (2.4%). The AIHW (2008a) reported that Tasmania and the Northern Territory had the highest rates of non-medical use of painkillers/analgesics. These two jurisdictions have historically had low availability of heroin and there appears to be an inverse relationship between heroin availability and levels of pharmaceutical opioid misuse (Fry et al., 2007).

Recent use of tranquillisers/sleeping pills declined from 3% of the Australian population aged 14 years and over in 1998 (Adhikari & Summerill, 2000) to 1.4% in 2007 (AIHW, 2008b).

2.2.2 Specific population survey data

The use and problematic misuse of pharmaceutical drugs is very common among illicit drug users in Australia. Stafford and Burns (2010), reporting the results of the national Illicit Drug Reporting System (IDRS)⁵, found that 42% of respondents had injected morphine in 2009. Recent use of morphine had declined, however, from 50% in 2008 to 44% in 2009. The use of morphine was highest in the NT and TAS, jurisdictions where heroin has traditionally not been freely available.

⁵ The IDRS is an annual study of illicit drug use in Australia. In 2009 it involved a quantitative survey of 881 people who inject drugs (80-152 per jurisdiction) semi-structured interviews with key experts who work with illicit drug users; and analyses of indicator data sources related to illicit drug use.

Four percent of the national IDRS sample reported recent injection of oxycodone obtained legally by themselves and approximately one-quarter reported recent injection of 'illicitly' obtained oxycodone.

Almost half of the national sample reported recent use of methadone (in any form, i.e. 'licitly' and/or 'illicitly' obtained methadone or Physeptone (methadone tablets) and, of those, over half reported recent (last six months) injection.

Eight percent of the national sample reported use of licitly obtained buprenorphine in the six months preceding interview and 18% reported use of illicit buprenorphine. Equal proportions (12%) reported using licitly or illicitly obtained buprenorphine-naloxone in the previous six months.

A further 38% of the national sample reported using over the counter codeine on a median of 12 days in the last six months. Eight percent of the national sample reported recent use of 'other' opioids (e.g. prescription opioids other than methadone and buprenorphine) on a median of nine days. The most commonly used 'other' opioid was tramadol. Recent injection of these preparations was low at 1%.

The use of benzodiazepines is also common among IDRS respondents. Consistent with previous iterations of the IDRS, Stafford and Burns (2010) reported that approximately two-thirds of the national sample had recently used some form of benzodiazepine on a median of 58 days (approximately two and half times per week) in the preceding six months. Forty-four percent of the national sample reported having used 'licitly' obtained benzodiazepines and 'illicitly' obtained benzodiazepines in the six months preceding interview.

The results of the IDRS need to be interpreted cautiously in light of the relatively small number of interviewees involved in each jurisdiction. Nevertheless they indicate that the misuse of pharmaceutical drugs is widespread in this population.

Nielsen et al. (2008) also found evidence of extensive pharmaceutical misuse among illicit drug treatment clients in Queensland, Tasmania, Western Australia and Victoria.⁶ They reported that among their study group in the month prior to entering treatment:

- two-thirds had used pharmaceutical opioids in a manner not as prescribed
- long-acting morphine was used by 41% and long-acting oxycodone products by 30% and these two products were also the most likely to be injected
- 13-15% percent of participants used methadone and buprenorphine in a manner not as prescribed
- almost 70% of participants reported use of benzodiazepines in a manner not as prescribed and the most commonly prescribed benzodiazepines were diazepam (55%) and alprazolam (30%)⁷
- 23% of participants reported misuse of OTC analgesics.

Respondents reported a range of problems as a result of misuse of pharmaceutical drugs including memory problems, injection-related harms, dependence and withdrawal.

Use and injection of pharmaceutical opioids appears more common among injecting drug users (IDU) in rural areas compared with metropolitan areas. Day et al. (2005) reported that:

- 80% of rural IDUs had ever used morphine compared with 66% of metropolitan IDUs
- 77% of rural IDUs had ever injected morphine compared with 52% of metropolitan IDUs
- 50% of rural IDUs had injected morphine in the past six months compared with 21% of metropolitan IDUs.

⁶ The clients for this study were selected on the basis of self-reported misuse of pharmaceuticals and, as such, the researchers did not intend the sample to be representative of all drug treatment clients, or misusers of pharmaceuticals who do not seek treatment.

⁷ The misuse of alprazolam was particularly associated with adverse outcomes in a range of domains such as crime and traffic accidents.

Day et al.'s findings echo the point made earlier that prescription opioid misuse appears to be inversely associated with the availability of heroin.

There also appears to be links between the use and misuse of pharmaceuticals and offending, given the disproportionately large number of police detainees testing positive for opioids and benzodiazepines. The 2008 Drug Use Monitoring in Australia (DUMA) survey of police detainees noted that 15% of adult detainees who provided a urine sample tested positive for an opiate metabolite not identified as heroin.⁸ Eleven percent of female detainees and 5% of male detainees tested were positive for methadone. Of those who tested positive, 34% reported having used methadone illegally. Eight percent of tested adult detainees were positive for buprenorphine. In addition, 23% of detainees who provided a urine sample in 2008 tested positive for benzodiazepines. Urinalysis does not differentiate between prescribed and non-prescribed use of prescription drugs. Consequently, detainees were asked to report if, in the past fortnight, they had taken any medication prescribed for them. In 2008, 21% of detainees reported that they had taken benzodiazepines prescribed for them in the past fortnight. Of this group, one in four also reported using non-prescribed benzodiazepines in the past 30 days (Gaffney, Jones, Sweeny, & Payne, 2010).

Using 1999-2005 DUMA data, Loxley (2007) examined benzodiazepine use and harms among police detainees. She reported that 15% had used illicit benzodiazepines in the previous year and 9% had done so in the last 30 days. Thirteen percent had used prescribed benzodiazepines in the last fortnight, most commonly diazepam, but also temazepam, oxazepam, flunitrazepam and alprazolam.

2.2.3 Health intervention program data

Recent data from the Sydney Medically Supervised Injection Centre (MSIC, 2010) indicate that opioids other than heroin are now the most commonly injected drugs at the

⁸ This could have been a prescribed opioid or an OTC opioid.

facility. From mid to late 2006 the percentage of injections of other opioids exceeded heroin and now significantly exceeds the proportion of heroin injections.

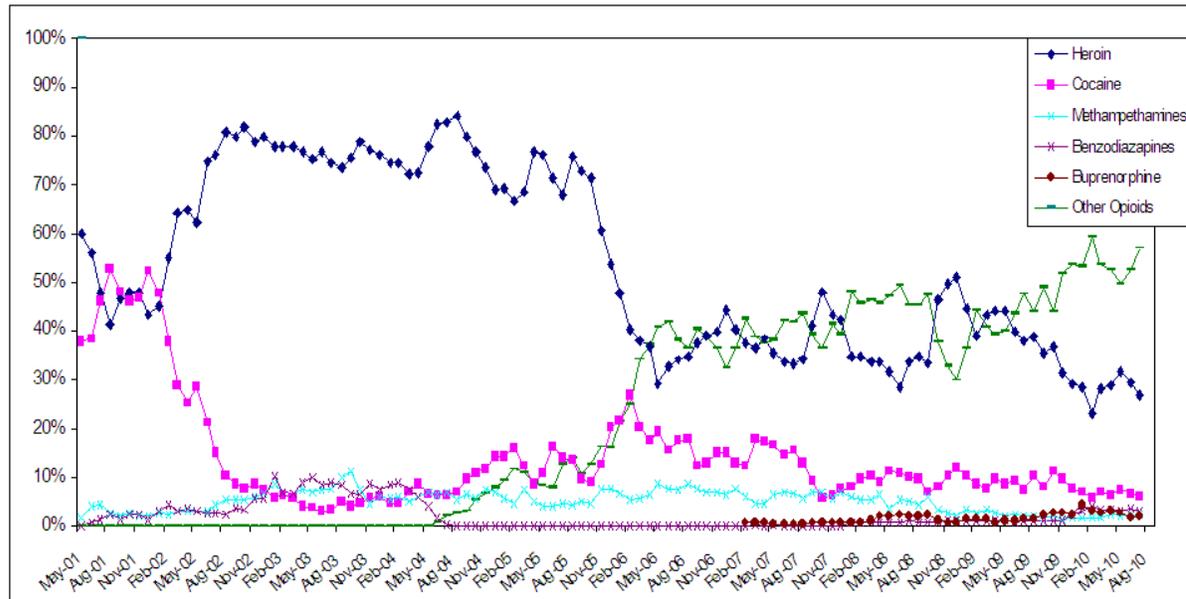


Figure 3. Percentage of all drug injections at the Sydney Medically Supervised Injection Centre by drug type, May 2001 to August 2010

Source: Dobbin (personal communication, February 21, 2011)

Australia-wide, a significant and increasing proportion of people accessing needle and syringe programs (NSP) inject pharmaceutical opioids. In 2005, 9% of respondent NSP users indicated that their most recently injected drug was a pharmaceutical opioid (other than methadone or buprenorphine). By 2009, this had risen to 16% (National Centre in HIV Epidemiology and Clinical Research [NCHECR], 2010).

Problematic misuse of pharmaceutical drugs now also features prominently in Australian alcohol and other drug treatment statistics. The report on the national minimum dataset for alcohol and other drug treatment services in 2008-09 (AIHW, 2010) indicated that the problematic misuse of morphine and methadone now accounts for almost 20% of all publicly-funded treatment episodes for opioid problems.

The Queensland Drugs of Dependence Unit reported that between 2001 and 2006 the Unit experienced a decreasing proportion of individuals seeking pharmacotherapy who reported that their primary drug of concern was a non-pharmaceutical opioid and a concomitant increase in the proportion of those seeking treatment for pharmaceutical opioids (as cited in Dobbin, 2009) (Figure 4).

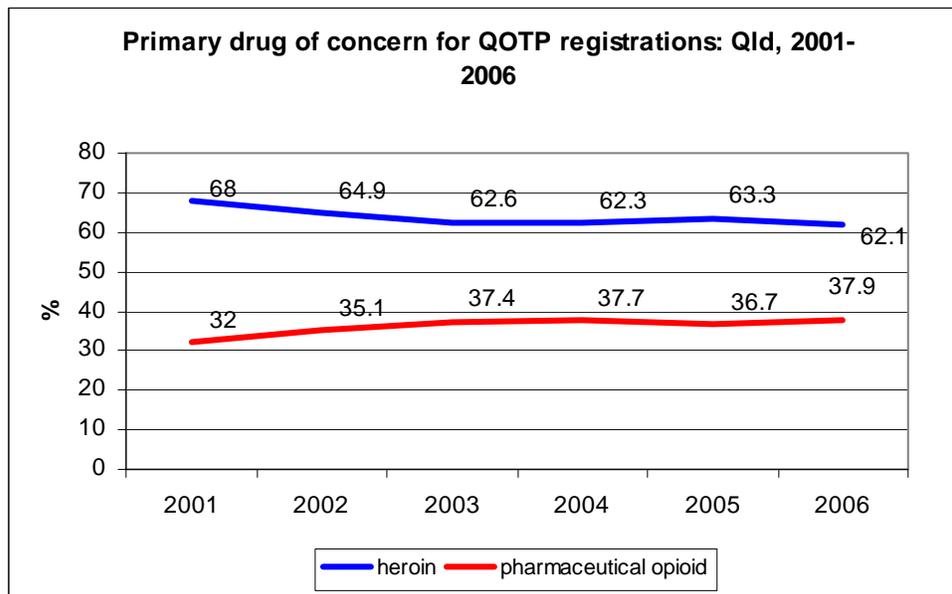


Figure 4. Primary drug of concern for Queensland Opioid Treatment Program Registrations, 2001-2006

Source: Dobbin (2009)

2.3 Psychotropic prescription drugs – supply patterns

2.3.1 Opioids

The availability of pharmaceutical opioids has substantially increased in recent years. Data provided by Dobbin (2009) demonstrates the extent of this increase (Figure 5). Most notable is the exponential increase in the supply of oxycodone over the past 5-6

years and a concomitant decrease in pethidine since the late 1990s. The decline in the per-capita consumption of pethidine is a result of a recognition in the mid-1990s that the drug had no therapeutic advantages over other narcotic analgesics and more toxic side effects (for example see Clark, Wei, & Anderson, 1995). Pethidine has also been removed from the PBS which has further contributed to a decline in its use.

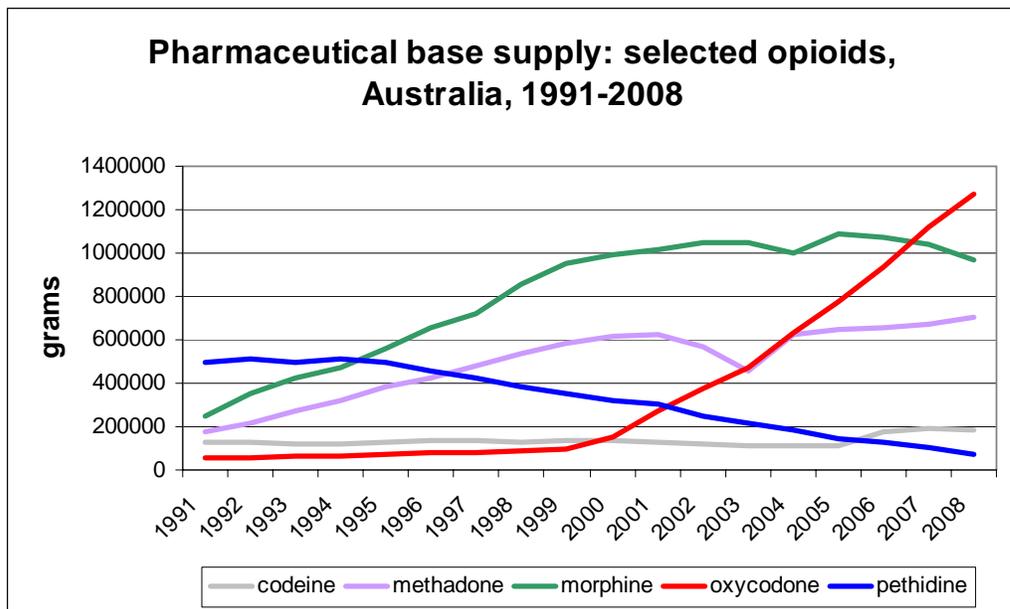


Figure 5. Pharmaceutical base supply: selected opioids, Australia, 1991-2008

Source: Dobbin (2009)

Leong, Murnion and Haber (2009) used Pharmaceutical Benefits Scheme data to examine trends in Australian opiate use between 1992 and 2007.



Figure 6. National opioid use, 1992-2007

Source: Leong et al. (2009)

These data show a steady increase in morphine prescriptions and a dramatic increase in tramadol, oxycodone and fentanyl prescriptions. However, these data do not include private prescriptions, government and private hospital prescriptions or prescriptions for which the cost is less than the PBS co-payment (Leong et al., 2009) and thereby underestimate overall levels of use.

Tramadol is a synthetic opioid analgesic used in the treatment of moderate pain. Its effects and addictive properties are not as intense as other opioid drugs, such as OxyContin. Accordingly, it is not believed to be widely misused in Australia at present, in spite of a substantial increase in its level of use over the past decade (Dobbin, personal communication, November 9, 2009).

Other data supports the observation that there has been a very substantial increase in the prescription of oxycodone in Australia in recent years. The Pharmaceutical Benefits Scheme (Department of Health and Ageing, 2008) reported a 20.1% increase in the

prescription of oxycodone between 2005/06 and 2006/07 (1,087,412 and 1,306,152 annual prescriptions, respectively). This contrasts with 473,292 prescriptions in the year ending December 2002. In Australia, the supply of oxycodone increased from 95.1 kg in 1999 to 1270.7 kg in 2008 (Dobbin, 2009) – a 13 fold + increase. Oxycodone supply to Victoria alone has increased nine-fold from 7.5 mg per capita in 2000 to 67.5 mg per capita in 2009 (Rintoul et al., 2010).

Degenhardt et al. (2006) examined the Drug Monitoring System (DRUMS) data managed by the Australian Government Department of Health and Ageing and reported an 89% increase in the average number of milligrams of morphine prescribed per person aged 15-54 years between 1995 and 2003. The magnitude of the increase differed between jurisdictions. In 1995, the number of milligrams prescribed per person was similar across jurisdictions; however, by 2003, there were dramatic differences. The largest change was in the Northern Territory where there was a 507% increase in the number of milligrams prescribed per person between 1995 and 2000. This then fell by 38% during 2000-2003. The decrease was attributed to actions undertaken in the Territory to constrain morphine prescription after the identification and monitoring of high levels of prescribing by general practitioners. The authors also noted that September 2002 saw the introduction of methadone and buprenorphine maintenance treatment in the NT, which is also believed to have contributed to this decrease.

It is important to note that the increase in supply and use of these drugs is not, of itself, a negative outcome or directly indicative of problematic use. The increase in the level of supply/use could also be indicative of more widespread, clinically appropriate, use of these medications for painful conditions. It could also be a result of an increasing requirement for these medications, as a result of Australia's ageing population. The central issue is not the level of use per se, but rather the extent to which that level is consistent with the quality use of these medicines. It is imperative that this distinction is made. Otherwise, there is a risk of introducing measures that aim to achieve a generalised *reduction in use*, rather than measures which seek to promote *quality use*.

2.3.2 Benzodiazepines

There have also been important changes in the patterns of benzodiazepine prescribing in recent years. Benzodiazepines' sedative, hypnotic, and anxiolytic properties are used for various psychiatric and medical conditions. These include anxiety, sleep, seizure and movement disorders, and muscle spasticity. They are used in anaesthetics and for the symptomatic treatment of agitation associated with other psychiatric and neurological disorders including psychotic, mood, and cognitive disorders. They are also the preferred treatment for agitation from stimulants. Overdoses are almost never fatal unless occurring in combination with other sedative agents such as alcohol or opiates (el-Guebaly, Sareen, & Stein, 2010).

When first introduced in the 1960s, benzodiazepines were seen as a valuable alternative to barbiturates which were used for similar purposes but associated with dependence and implicated in intentional and accidental overdose. While benzodiazepines were clearly an improvement over barbiturates, their use can still have serious consequences. Tolerance and dependence can occur quickly and the drugs' effects and negative consequences can be exacerbated if combined with other central nervous system (CNS) depressants (DCPC, 2007).

Harms that can arise from use of benzodiazepines include:

- sedation, particularly at high doses, which can contribute to concentration and memory problems and to chaotic behaviour and disorganisation
- anterograde amnesia when the memory of events occurring after taking benzodiazepines is affected, whilst long-term memory remains intact
- contribution to overdose when consumed with other CNS drugs
- that dependence can occur quickly and the benzodiazepine dependence syndrome is very difficult to treat
- paradoxical aggression or the so called 'Rambo effect' - while benzodiazepines are frequently prescribed for their tranquillising effect in the relief of insomnia and

anxiety, paradoxically, they can trigger incidents of central nervous system stimulation, which manifests as talkativeness, mania, anxiety, restlessness and sleep disturbances and nightmares

- adverse impacts on driving (DCPC, 2007).

A significant problem associated with benzodiazepines, particularly in the elderly, is falls and other injuries (Bartlett, Abrahamowicz, Grad, Sylvestre, & Tamblyn, 2009).

Table 2: Pharmaceutical Benefits Scheme prescriptions for benzodiazepines, 2002-2009

	Diazepam	Oxazepam	Temazepam	Alprazolam*	Total
2002	1,576,635	1,220,936	2,237,733	324,110	5,359,404
2009	1,639,952	1,015,080	1,840,222	413,526	4,908,780
% change	+4%	-17%	-18%	+28%	-8%

*Private or non-PBS prescriptions for alprazolam comprised on average an additional 32% of prescriptions per year, based on estimates from the Australian Statistics on Medicines.

Source: Australian Government published PBS data cited in Monheit (2010)

Table 2 shows a substantial reduction in the overall number of PBS prescriptions for benzodiazepines between 2002 and 2009, but a substantial increase in prescriptions for alprazolam. The misuse of alprazolam is particularly problematic from a range of perspectives. It appears to be disproportionately associated with problems such as seizures and rage responses among users, as well as traffic accidents and crime-related harms (DCPC, 2007; Nielsen et al., 2008).

2.4 Evidence of harms

Dobbin (2009) examined hospital separations associated with poisoning from a range of substances (AIHW, n.d.). Separations for heroin decreased while those for opioid analgesics increased in recent years, with a substantial acceleration in the rate of increase from 2005-06. Dobbin noted that it was not possible to distinguish separations attributable to problematic/recreational opioid use from cases arising from an adverse effect of the drug used therapeutically to treat pain. Nevertheless, the increase in opioid analgesic cases from 2006 onwards is striking.

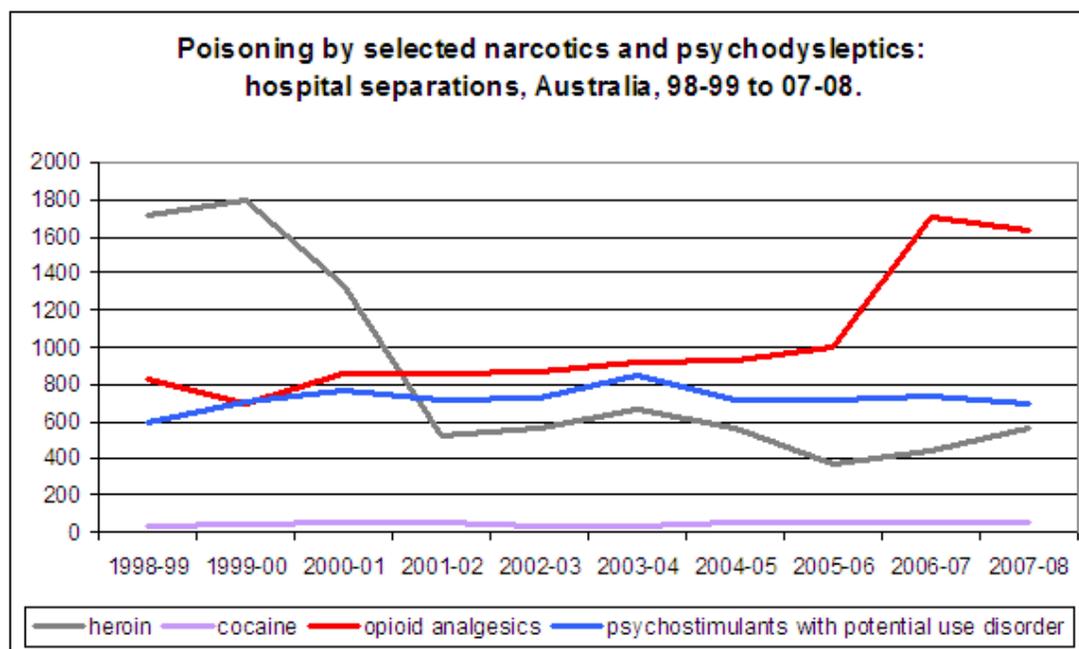


Figure 7. Poisoning by selected narcotics and psychodysleptics: hospital separations, Australia, 1998-99 to 2007-08

Source: Dobbin (2009)

Rintoul et al. (2010) found that the detection of oxycodone in deaths reported to the Victorian Coroner has increased from 4 (0.08/100,000 population) in 2000 to 97 (1.78/100 000 population) in 2009. This represents a 21-fold increase in deaths where

oxycodone was present. Of 320 cases examined by Rintoul et al. (2010), 54% (172) were the result of drug toxicity. Of these, 52% were unintentional and 20% intentional self-harm. The remaining 28% were either still under investigation by the coroner or intent of the deceased was unknown. The authors found that drug toxicity deaths were overrepresented in rural areas and areas indexed with high levels of disadvantage. They concluded that the increase in the number of deaths involving oxycodone was strongly and significantly associated with the increase in supply.

The combined use of pharmaceutical and illicit drugs can also have adverse outcomes. For example, Woods, Gerostamoulos and Drummer (2007) found that of the heroin-related deaths that occurred in Victoria between 2002 and 2006 55% involved benzodiazepines.

The problematic misuse of benzodiazepines by clients receiving opioid substitution therapy (OST) is also common. Nielsen, Dietze, Lee, Dunlop and Taylor (2007) reported that, in their sample of 250 individuals with a history of buprenorphine or methadone treatment, benzodiazepine use and misuse was common. The majority of those individuals obtained their benzodiazepines from a source other than their OST prescriber. This is concerning, given the risk of overdose from a combination of OST and benzodiazepines. Overdose-related symptoms were common among those on OST and were more common among those using a combination of methadone and benzodiazepines compared with those using buprenorphine and benzodiazepines.

Internationally, there has been a recent emergence of individuals seeking treatment for opioid dependence who primarily use prescription opioids, rather than heroin.⁹ No similar evidence is available from Australia, but if this trend is reflected in this country then this could have very significant implications for the provision of opioid replacement treatment

⁹ Rosenblum et al. (2007), for example, documented this phenomenon in a multi-state survey of 5,663 opioid dependent persons enrolling in 72 methadone maintenance treatment programs in the US. Likewise, Sigmon (2006) following a retrospective review of intake data from 75 patients consecutively admitted to an outpatient methadone maintenance treatment program in Vermont, found that 49% of the patients were primary pharmaceutical opioid users.

and other drug treatment services. It is possible that a large, though currently unquantifiable, number of people without a history of injecting drug use may have escalated their use of pharmaceutical drugs beyond recognised therapeutic doses. Such individuals may have also developed related problematic behaviours, including drug-seeking from multiple prescribers and pharmacists. There is little information about this 'hidden' population, because they are not captured by any current research, unlike injecting drug users, where information about unsanctioned use of prescription opioids is comparatively relatively well described (RACP, 2009).

The harms associated with pharmaceuticals are not confined to prescription drugs. Over the counter or non-prescription drugs are also an emerging problem. Foremost among these are codeine-containing analgesics. Problematic drugs include combinations of codeine with paracetamol or ibuprofen which contain up to 15 mg of codeine. In late 2007, it became evident that a number of Victorians were being hospitalised with life-threatening complications due to taking very high doses of ibuprofen. Complications included gastro-intestinal bleeding and/or perforation, renal failure, low potassium levels, anaemia, opioid dependence and death. These clinical presentations derive from the consumption of large amounts of ibuprofen-codeine combination preparations. The preferential misuse of these tablets was attributed to their high codeine content as they contain the highest level of codeine available in any non-prescription analgesic (Dobbin, 2008).

2.5 Law enforcement data

In order to better understand the extent to which pharmaceutical misuse impacts upon policing, six police jurisdictions extracted data concerning pharmaceutical-related offences. In one case (Qld) these data were collected for one year. Other jurisdictions provided data for the years 2001 to 2009 (or subsets of these years). Particular emphasis was placed on the years 2001, 2004, 2007 because they correspond with the years in which the National Drug Strategy Household Survey was undertaken. The year

2001 was selected as the first year of data collection because it marked the commencement of the heroin 'shortage' which has had a significant impact on use patterns and the illicit drug market (Degenhardt, Day, & Hall, 2004).

The ease with which these data were able to be extracted varied between jurisdictions. In some jurisdictions this was relatively straightforward, with systems already established to record incidents concerning pharmaceuticals. In others it was necessary to undertake a random selection of drug-related incidents and assess the extent to which pharmaceutical drugs featured in these events in each year.

In considering these police data it is important to be mindful of their limitations. As with any data source, it is possible that it is not complete. It can also be influenced by levels and patterns of policing activity and does not necessarily reflect actual community trends.

2.5.1 The trend data

Five jurisdictions, NSW, ACT, WA, SA and NT, were able to provide trend data covering all or some of the years between 2001 and 2009.

Data from NSW estimated that police were almost twice as likely to encounter pharmaceutical drugs in 2009 compared with 2001. In the ACT the number of pharmaceutical drug detections increased from 77 in 2001 to 144 in 2007, declining to 95 in 2009. In WA the number of detections increased from 621 in 2004 to 897 in 2009, although a substantial proportion of this increase was associated with precursor drugs.¹⁰ In SA the number of detections increased from 118 in 2001 to 144 in 2009. In the NT detections increased from 18 in 2004 to 60 in 2009.¹¹

¹⁰ This refers to pharmaceutical drugs such as pseudoephedrine used as precursors in the production of illicit methamphetamine.

¹¹ It is important to note that a wide variety of drugs were included in the NT data. These included MDMA, kava, ketamine, MDA, mushrooms etc.

The estimated number of detections of opioid analgesics in NSW between 2001 and 2004 increased by approximately 280%. In the ACT, opioid analgesic seizures increased from 16 in 2001 to 70 in 2007 before declining to 35 in 2009. In WA the number of pharmaceutical opioids detected increased from 203 in 2004 to 244 in 2009. In SA, the number of opioids detected increased from 28 in 2001 to 45 in 2008, before declining to 32 in 2009. In the NT in 2004, there were six detections of pharmaceutical opioids and eight in 2009.

The estimated number of benzodiazepine seizures decreased by 27% in NSW between 2001 and 2009. In the ACT, the number of seizures of benzodiazepines was stable between 2001 (22) and 2009 (21). In WA, the number of benzodiazepine seizures declined from 135 in 2004 to 130 in 2009. In SA, the number of benzodiazepine seizures increased from 23 in 2001 to 30 in 2009. In the NT in 2004 there was one seizure of benzodiazepines compared with two in 2009.

2.5.2 Data from 2009

In 2009, the most frequently seized/detected pharmaceutical drugs identified were, in order of frequency:

- NSW: benzodiazepines, opioid analgesics and antipsychotics
- ACT: opioid analgesics, benzodiazepines and anti-psychotics
- WA: opioids, benzodiazepines and CNS stimulants¹²
- SA: opioids, benzodiazepines and steroids
- NT: opioids and benzodiazepines, and
- Qld: opioids, benzodiazepines and steroids.

These data indicate an increase in the number of police detections and seizures of pharmaceutical drugs over the past decade. In all jurisdictions that provided data there

¹² The third most commonly detected drug was actually under the heading of precursors which is of less relevance to the NPDMS.

was an increase in the detection of pharmaceutical opioids over this period. In almost all of these jurisdictions the number of seizures of benzodiazepines has been stable or has declined. In addition, opioids are now the most commonly seized/detected drug in most of these jurisdictions.

2.6 Which groups are misusing pharmaceutical drugs in Australia?

Before focussing on the misuse of these pharmaceutical drugs, it is important to emphasise that they are also widely and appropriately used in the community and can bring great benefit to their consumers. The fact that they are also subject to misuse in no way detracts from these benefits. This emphasises the importance of their continued clinically appropriate availability without any associated stigma.

Nevertheless a wide range of individuals misuse pharmaceuticals in a diverse range of contexts. As Wodak and Osborn pointed out in their submission to DCPC (2007):

It is important to separate out the very different problems arising in different age groups and populations in terms of developing effective interventions. Very different problems arise in quite different settings [such as] young polydrug users; middle aged people with severe chronic illnesses; and the elderly. (p. 6)

Three profiles of patients who may attempt to access prescription drugs illegitimately have been described by Dr John Galloway, the then chief pharmacist at the Tasmanian Department of Health, in his submission to the DCPC (2007):

1. **The dependent patient** who may have genuine pain problems. Some patients have come to rely on drugs to improve their mood and how they feel. Others have general difficulties coping with life's problems. In general, they have become more interested in continuing and increasing their supply of drugs rather than in the resolution of their medical and other problems.

2. **The drug misuser** who has a history of drug abuse but also may have some evidence of pain. They may also have social or drug trading connections with others who abuse drugs. They are likely to be injecting prescribed and other drugs. Since prescription drugs have a high value on the black market, these patients work hard at developing their presentations to doctors and obtaining drugs for personal use or trading, and this is a high priority in their lives.
3. **The drug seller** who attends doctors with the primary aim of obtaining drugs to sell or trade. This group may include some from the second subgroup. They may also be scammers who use stolen or forged ID documents. Some may be apparently ordinary patients who have come to rely on the income that can be made from selling a proportion of their medication (some of these patients may be elderly or even have cancer). They may also be patients who intimidate or threaten doctors and who may have some evidence of a pain condition.

There is a wide spectrum of patients covered in this typology. Dependent patients, for example, may be deliberately or inadvertently misusing their medications. They may have developed an inadvertent iatrogenic dependence as a result of factors such as inappropriate prescribing, limited health literacy, poorly worded medication instructions or poor communication by health care providers. Patients misusing their medications may also 'use a bit and sell a bit' or they may be obtaining their medications exclusively for resale.

It is important to note that there is a spectrum of non-adherence with opioid treatment and that this spectrum is distinct for pain patients versus those who use these medications for non-medical purposes. In Figure 8 below, non-medical users can be seen as self-treating personal issues, purely as recreational users, or as having a more severe and consistent substance use disorder or addiction. On the other hand, pain patients are more complex and their behaviours might range from strict adherence to chemically coping to an overt addiction (Passik & Kirsh, 2008).

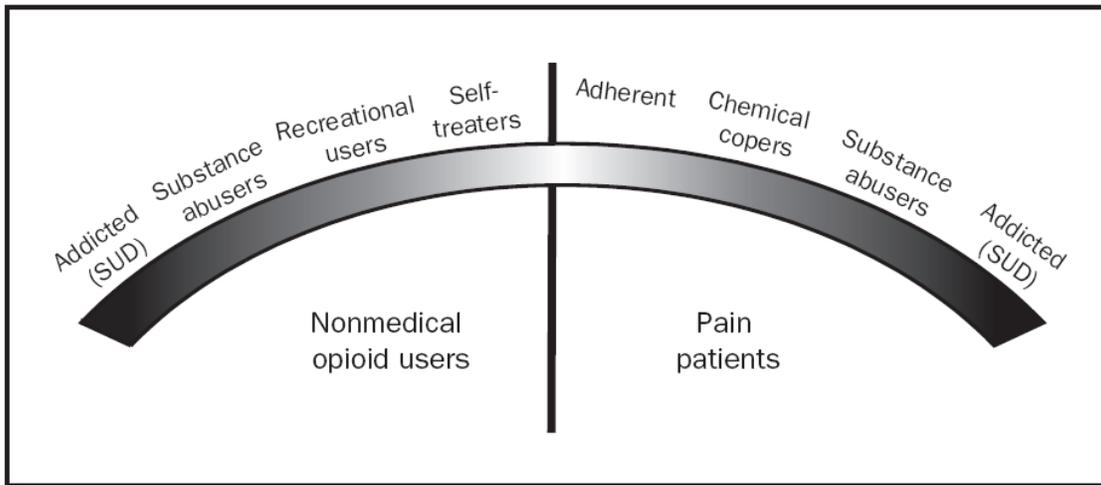


Figure 8. The spectrum of adherence for pain patients versus the spectrum of illicit use by non-medical users

Source: Passik and Kirsch (2008, p. 401)

In addition to those who intentionally misuse opioid or benzodiazepine medications, there is likely to be a large number of Australians using these medications as prescribed but where those prescriptions do not represent a quality use of those medicines. Patients may have been using these medications for some time and, particularly in the case of benzodiazepines, withdrawal from them may be very difficult.

2.7 How are the drugs obtained?

The DCPC (2007) described a range of ways in which these pharmaceuticals might be obtained. These included:

1. stealing, forging or altering prescriptions
2. burglaries of surgeries and pharmacies and private homes
3. medication shopping (presenting to several doctors and obtaining prescriptions for imaginary or exaggerated symptoms)

4. the prescription of drugs in larger quantities than are needed for managing a patient's condition, providing an opportunity for the patient to sell the excess to others
5. purchasing on the black market or on the Internet, and
6. health workers self-prescribing or otherwise misappropriating the drugs through their work.

There is also a range of supply-side dynamics that impact upon the ways in which these medicines are obtained for misuse. Poor prescribing practices, in which patients are prescribed levels of medications well in excess of their medical need, undoubtedly contribute to this. Also important in this regard are poor dispensing practices, in which some pharmacists knowingly dispense levels of medications to individuals which are also in excess of medical need. Despite the presence of a valid prescription, pharmacists also have a responsibility to contribute to the QUM by not knowingly dispensing excess medications.

An examination of illicit prescription drug markets in Melbourne, Hobart and Darwin found they were predominantly driven by a large number of small-scale diversions that included legitimate prescriptions, medication shopping and, to a lesser extent, forged prescriptions (Fry et al., 2007). Organised burglaries/thefts from pharmacies, point of wholesale/manufacture, or via other sources (such as Internet pharmacies, importation and inter-jurisdictional trafficking) were less important sources of supply.

Similarly, a recent NSW study examined offences between 1995 and 2007 involving the theft of prescription pads, presentation of forged or altered prescriptions to pharmacies and theft of prescription drugs, (Rodwell, Ringland, & Bradford, 2010). Over this period only a relatively small number of offences were detected. Fraud events exceeded all other offence categories. Fraud offences peaked in 1998 and have since been in decline. All other offence categories remained relatively stable over this period. Rodwell et al. (2010) pointed out that there may be some difficulties with the extent to which

pharmaceutical crimes are detected and reflected in police statistics. Nevertheless, they suggested that the low number of offences probably indicates that thefts of this kind comprise a relatively small part of the diversion of pharmaceuticals, particularly compared with medication shopping.

Internet pharmacies have been cited as a potential source of psychotropic pharmaceutical drugs. After examining the literature on this issue, Nielsen et al. (2008) reported that the Internet was not currently a major method used by drug misusers to obtain these drugs. This is because obtaining prescription supplies over the Internet has a number of disadvantages, including the potential for: seizure of the drugs by Customs; the purchaser to be identified as a drug misuser; and pharmaceuticals from overseas Internet pharmacy sites to be counterfeit. While these potential disadvantages of Internet supply exist, and while subsidised medicines are relatively easy to acquire from prescribers, Internet derived supplies may remain a small part of the total market. Nicholas (Nicholas, in press), in a review of evidence concerning the extent and nature of pharmaceutical supply via rogue Internet pharmacies in Australia, came to similar conclusions.

2.8 Problematic patterns of misuse of pharmaceutical drugs

One of the key issues in relation to the problematic misuse of pharmaceutical drugs is that they are often administered in ways that are unintended by the prescriber and manufacturer. The medications can be crushed or chewed and taken orally so as to circumvent slow release formulations. They can also be crushed and snorted or injected to increase the rate of absorption. In addition they can be stockpiled and taken in large quantities to increase the effect (Sproule, Brands, Li, & Catz-Biro, 2009).

The injection of pharmaceutical drugs, especially those intended for oral administration, is particularly problematic. It can lead to infection as a result of unsterile injection procedures, the deposition of pharmaceutical materials in blood vessels or organs, or

the occlusion of blood vessels. Talc pulmonary granulomatosis is a serious problem that is associated with the injection or snorting of pharmaceuticals intended to be taken orally. When taken orally as a component of pharmaceutical drugs, talc (magnesium silicate) is a harmless substance. When it is injected or snorted, however, minute particles lodge in the lungs and create an inflammatory reaction that can result in emphysema. Small talc particles can also lodge in and block the arteries in the retina of the eye, causing blindness (DCPC, 2007).

The injection of pharmaceutical drugs by some illicit drug users is very common. Stafford and Burns (2010) reported that among the 2009 national sample of illicit drug users surveyed as part of the Illicit Drug Reporting System:

- 42% reported recent (last six months) injection of morphine
- 26% reported recent injection of methadone
- 19% reported recent injection of oxycodone
- 8% reported recent injection of benzodiazepines, and
- 4% of the national sample reported recent injection of 'licit' buprenorphine
- 14% reported injection of 'illicit' buprenorphine.

A range of measures have been introduced to reduce the harm associated with the injection of medications intended to be taken orally. These include the provision of:

- specifically designed filters (or at least cotton wool for filtering processes)
- large-bore syringes for injection and
- sterile water and spoons (Anex as cited in, DCPC, 2007).

Consequently it is not just that pharmaceutical drugs are taken in dosages, or by persons, that were not intended; it is also that the drugs can be taken in ways that were not intended by prescribers and manufacturers.

2.9 Illicit sale of pharmaceutical drugs

The illicit sale of pharmaceutical drugs in Australia can be very lucrative.

As at 1 January 2011, for example, consumers paid up to \$34.20 for most PBS medicines or \$5.60 with a concession (Department of Health and Ageing, 2011). The Australian Government paid the remaining cost. These drugs cost considerably more on the illicit market resulting in significant profits to be made through the sale of these medications. No doubt this acts as a significant incentive for their diversion.

2.10 Potential demographic and systemic factors impacting on the current and future levels of pharmaceutical drug misuse in Australia

This section of the literature review addresses a range of factors that may act as causal and/or contributory factors to the rapid and significant increase in the use of prescription and OTC drugs. Emphasis is given to factors within the Australian context, drawing where appropriate on international experience and research evidence.

2.10.1 The multiple formulations of opioids, especially slow (or controlled, or modified) release forms

An important factor influencing the availability of pharmaceutical opioids in Australia has been the emergence of multiple formulations available for prescription. The number of prescription opioid compounds available on the PBS has doubled from four in 1992 to eight in 2007. There has been an even larger increase in the number of opioid formulations available on the PBS from 11 in 1992 to 70 in 2007 (Leong et al., 2009). Most prominent among these are the slow-release formulations, particularly those containing oxycodone and morphine. In Australia, controlled release morphine tablets (MS Contin®) were introduced in 1991 and capsules (Kapanol®) in 1992. Over the period 1990 to 2006, the total number of morphine tablets and capsules provided in Australia increased from 651,360 to 32.8 million, representing a 40-fold increase and

consisting almost entirely of an increase in slow release preparations. The picture is similar for oxycodone, with most of the increase in its use occurring since the introduction of oxycodone hydrochloride slow release tablets (OxyContin®) in 1999 (RACP, 2009) (See Figure 6 above).

These slow release formulations represent a definite improvement over their shorter acting predecessors for the treatment of certain conditions. The longer acting formulations can avoid large fluctuations in blood plasma levels of opioids. The high points of these fluctuations can lead to excessive analgesia and euphoria, while the plasma troughs can lead to the return of pain and dysphoria. Shorter acting opioids are also more strongly reinforcing than longer acting opioids (RACP, 2009). These drugs were also marketed on the basis of being less dangerous and addictive than regular oxycodone and morphine. This was not the case. Indeed, in 2007, the manufacturer of OxyContin®, Perdue Pharma, was fined \$US634 million for misrepresenting the addictive and pleasure-producing qualities of the drug (NPR News, 2007). They can also be tampered with to bypass their slow release characteristics.

In summary, the availability of a broader range of opioid pharmaceutical drugs is not necessarily a bad thing of itself. It allows prescribers to better tailor their prescribing practices to individual patient needs. Nevertheless, the poor quality use of these medications can be highly problematic.

2.10.2 The ageing of Australia's population and the potential impact of this on prescription patterns

As with most developed countries, Australia's population is ageing as a result of sustained low fertility and increasing life expectancy. As a consequence, there are proportionally fewer children (under 15 years of age) in the population. The median age (i.e. the age at which half the population is older and half is younger) of the Australian population has increased by 4.8 years over the last two decades, from 32.1 years at 30 June 1990 to 36.9 years at 30 June 2010. The proportion of the population aged 65

years and over increased from 11.1% to 13.5% between 30 June 1990 and 30 June 2010 (Australian Bureau of Statistics [ABS], 2010).

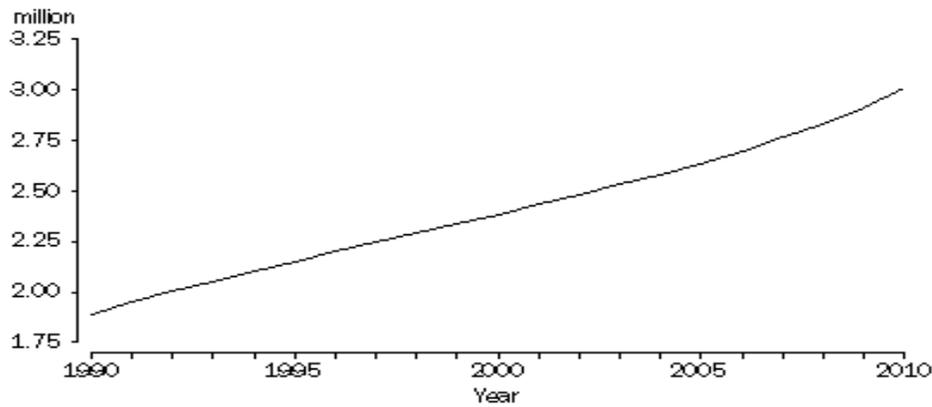


Figure 9. The number of Australians over the age of 65 years, 1990-2010

Source: ABS (2010)

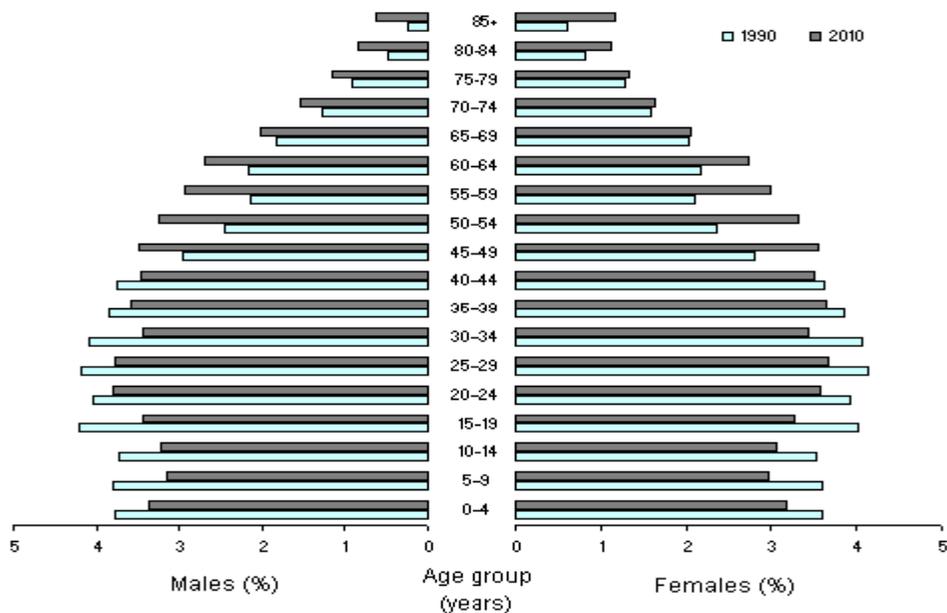


Figure 10. Population structure, age and sex, Australia, 1990 and 2010

Source: ABS (2010)

Figure 10 illustrates that between 1990 and 2010 there was a decrease in the percentage of the population in every age group between 0-4 years and 40-44 years. There was a corresponding increase in the percentage of the population in every age group between 45-49 years and 85 years and above. There is also a 'population bulge' with the largest percentage of the population being in the age groups 35-54. Over the next two decades this 'population bulge' will move into the older age brackets.

This is significant in the context of the problematic misuse of pharmaceutical drugs as the prevalence of a range of conditions including chronic pain increases as the population ages (Access Economics, 2007). As the prevalence of chronic pain increases, the demand for prescription and non-prescription medications can similarly be expected to increase.

In 2007, it was estimated that approximately 3.2 million Australians (1.4 million males and 1.7 million females) were experiencing chronic pain. This was expected to grow to 5.0 million by 2050. The prevalence of chronic pain is projected to increase for men from 13.9% to 15.4% and for women from 16.5% to 18.4% over this period. In 2007, it was estimated that the 50-54 age group contained the largest number of women with chronic pain (190,426), while the 55-59 age group had the highest number of men with chronic pain (166,368) (Access Economics, 2007).

The 1997 NSW Health Survey contained questions concerning pain. In reporting on the findings of this survey, Blyth et al. (2001) found that, among the 15,543 respondents, 17.1% of males and 20.0% of females reported experiencing chronic pain. For males, prevalence peaked at 27.0% in the 65-69 year age group and for females prevalence peaked at 31.0% in the oldest age group (80-84 years). Experiencing chronic pain was significantly associated with older age, female gender, lower levels of completed education and not having private health insurance.

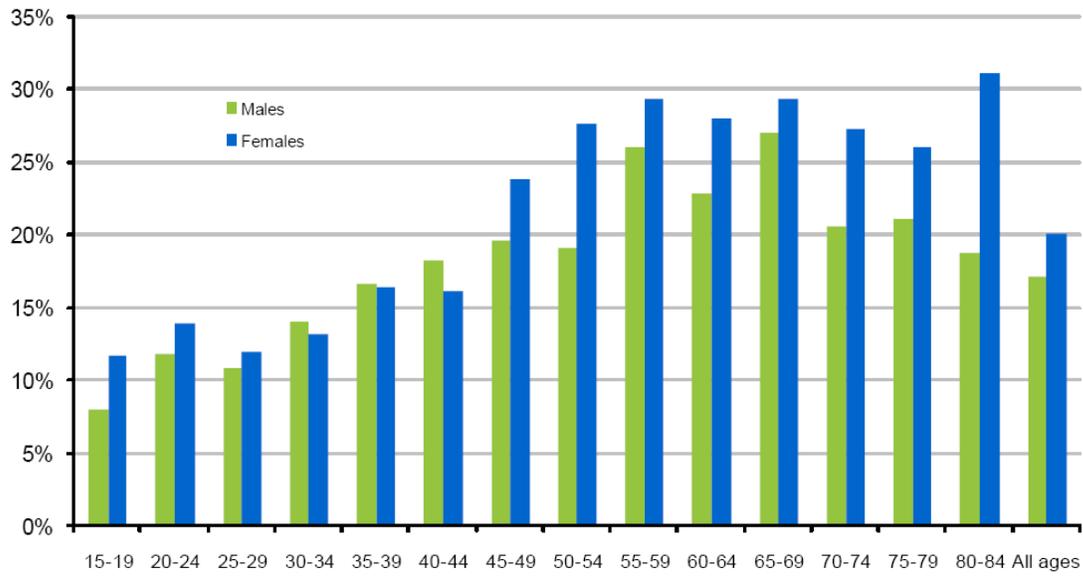


Figure 11. The proportion of the NSW population experiencing chronic pain by age and gender, 1997

Source of Figure: Access economics (2007)

In a similar study conducted in the Northern Sydney Health Area in 1998 (Blyth, March, & Cousins, 2003) reported that 22.1% of the sample of 2,092 respondents reported experiencing chronic pain. Women had a higher adjusted prevalence than men (24.1% versus 19.9%). The prevalence of chronic pain was highest in the 70 years and over age group for men (26%) and the 60-69 year age group for women (36%).

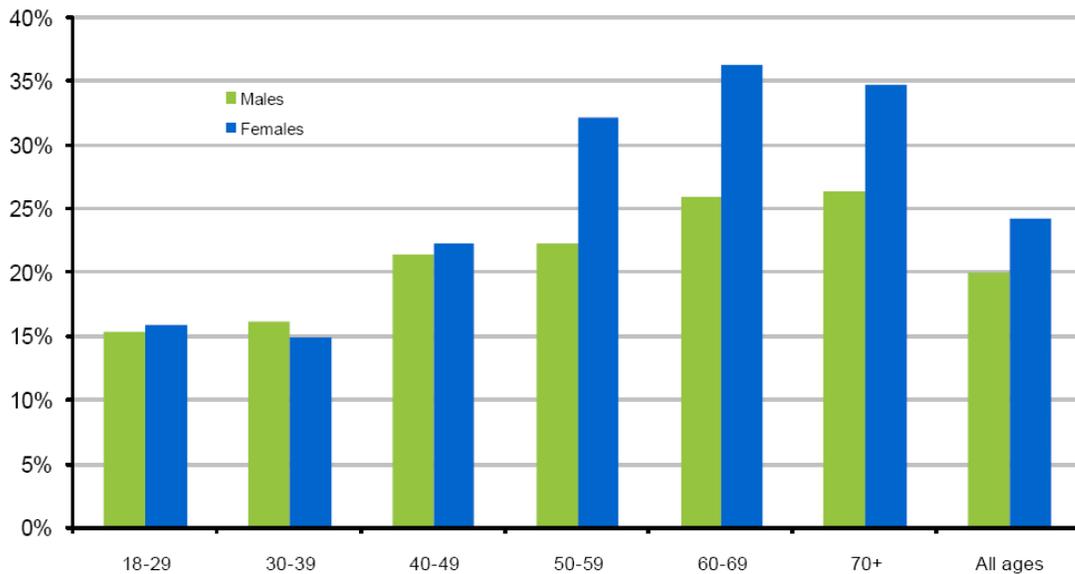


Figure 12. Proportion of NSW population experiencing chronic pain by age and gender, 1998

Source of Figure: Access economics (2007).

Available evidence therefore suggests that the prevalence of chronic pain peaks in later life. An ageing population and a ‘population bulge’ approaching later life can be expected to result in an increase in the prevalence of chronic pain, and a concomitant increase in the population-level demand for analgesics.

In addition to increases in chronic pain and the demand for appropriate medication as the population ages, there is also a concomitant increase in the prevalence of anxiety disorders. Anxiety disorders are the most prevalent mental health disorder and they occur most frequently among middle-age groups (ABS, 2007). Anxiety disorders are also commonly associated with pharmaceutical misuse problems, especially inappropriate use of the benzodiazepines (Lingford-Hughes, Potokar, & Nutt, 2002). Anxiety disorders commonly manifest as sleep disturbance (Ohayon & Roth, 2003) which is also a candidate condition for benzodiazepines.

The rate of use has declined slightly in recent years in part due to better education around anxiety management and more appropriate and judicious use of benzodiazepines over the last 10 years.

The population bulge that coincides with the peak of anxiety problems in the population may be further exacerbated by social problems such as increased rates of divorce around this time, which is also linked to increased anxiety. A further phenomenon is returning service men and women who are susceptible to post traumatic stress disorder (PTSD). PTSD is often treated with drugs with misuse potential.

2.10.3 Ageing opioid substitution clients

Demographic changes are also occurring among the group of Australians receiving opioid substitution therapy (OST) for opioid dependence. This is a group of particular interest in the context of the problematic misuse of pharmaceutical drugs. There has been a substantial increase in the number of Australians receiving this therapy over the past decade. In 1998, 24,657 individuals were receiving OST for opioid dependence. By 2009 this had grown to 43,445 (AIHW, 2010). This does not necessarily imply that Australia now has more opioid dependent people than it did in 1998, but there are more individuals in treatment at any point in time.

In 2009, 30-39 year olds made up the largest proportion of OST clients (40%). Over the last decade there has been a decrease in the proportion of those clients aged 29 years or younger and an increase in the proportion of those aged 40 years and over. In 2006, for example, 7.6% of those receiving opioid pharmacotherapy treatment were aged 50-59 years. By 2009, this had grown to 12.5% (AIHW, 2010).

As discussed, the proportion of older Australians who experience chronic pain is greater than that of younger Australians. As the population receiving OST ages, it is probable that they too will experience a similar if not higher prevalence of chronic pain than the general population. Indeed there is evidence that illicit opioid dependent individuals are

far more likely than the general community to experience chronic pain. Jamison, Kauffman and Katz (2000), for example, found that 61% of patients in methadone maintenance treatment in Massachusetts suffered chronic pain. Similarly, Rosenblum et al. (2003) found that 37% of patients on a methadone program in New York experienced severe chronic pain. This compares with estimates which suggest that 14.6% of the US population (Hardt, Jacobsen, Goldberg, Nickel, & Buchwald, 2008) and 17.1% of males and 20% of females in Australia (Blyth et al., 2001), experience chronic pain. Thus, Australia has a cohort of OST clients who are entering an age when chronic pain is more prevalent and who already have a high prevalence of this problem. In addition, as discussed above, the number of OST clients has increased substantially over the last decade.

Two further factors complicate the picture of individuals receiving opioid substitution therapy in Australia. The first is opioid-induced hyperalgesia¹³. This term refers to:

- a decline in analgesic efficacy during opioid treatment for pain, and
- an increased sensitivity to stimuli in individuals with opioid addiction.

The existence of, and the mechanisms associated with, opioid induced hyperalgesia remain somewhat controversial as it is difficult to distinguish between opioid-induced hyperalgesia and opioid tolerance (RACP, 2009). This notwithstanding, long-term opioid therapy is likely to complicate pain management.

The second factor of relevance to problematic pharmaceutical drug misuse is that individuals receiving opioid substitution therapy already have a high prevalence of pharmaceutical use/misuse (Nielsen et al., 2008; Rosenblum et al., 2007).

¹³ See section 4.2.2 where hyperalgesia is discussed more fully.

Consequently, the population of individuals in Australia receiving opioid substitution treatment:

- is now much larger than it was a decade ago
- is ageing and entering later life when pain is more prevalent
- already has a higher prevalence of chronic pain than the general population
- is likely to experience the pain treatment difficulties and complications that are associated with being on long-term opioid substitution therapy, or from illicit opioid use, and
- already have a high prevalence of pharmaceutical drug misuse.

In summary, the impact of demographic changes in the Australian population in general, and in OST clients in particular, warrant careful consideration in the development of the NPDMS. The prevalence of chronic pain in the community is likely to increase over time, which could lead to more population-level demand for the prescription of pharmaceuticals.

2.10.4 Hospital discharge planning arrangements

An issue likely to impact on the quality use of opioid analgesics and benzodiazepines is hospital discharge medication planning. Especially important in this regard is the extent to which medications commenced in hospitals are continued after discharge. The Australian Pharmaceutical Advisory Council (APAC) has developed guidelines to achieve continuity in medication management between hospital and the community (APAC, 2005). The extent to which these are adhered to is unclear.

2.10.5 The delays and difficulties in accessing comprehensive pain management

The National Pain Strategy (Australian and New Zealand College of Anaesthetists [ANZCA], 2010) highlighted significant deficiencies in Australia's current approaches to

pain treatment. This can result in people with pain getting 'stuck' in the system as they are referred to multiple practitioners, and for multiple investigations, in pursuit of a diagnosis of a potentially non-existent site of tissue injury and/or pain relief. Patients may receive ongoing physical and pharmacological treatment, and may also be recommended for one or more procedures. This cycle may continue for months or years, with some people receiving long-term and/or ineffective treatments, while others are unable to access treatments which are effective but not covered by Medicare. A second issue relates to difficulties in accessing specialist pain clinics. Many of those who are referred to such a service will receive high-quality care, but waiting times for an appointment are typically long and there is great variability in access and service models.

Interim results from the Australian Pain Society's *Waiting in Pain* study (as cited in ANZCA, 2010) estimated that more than a quarter of patients referred to chronic pain management services annually would remain on waiting lists for more than one year, though most services had a process to accommodate the most urgent referrals. The mean waiting time for a publicly-funded chronic pain management service was 184.3 days. The range was large, with the shortest wait time at 34 days and the longest 575 days. Waiting times at private pain clinics were found to be shorter, with a mean waiting time of 50.7 days, but these services were less likely to be multidisciplinary pain management centres that involve several disciplines, education and research.

As well as long waiting times, an additional barrier to access to specialist pain services is that some people may not be referred to such services at all. This can occur because primary care practitioners may not know that pain clinics exist, or may not think it is worth referring to them. A further problem in the current delivery of care occurs on discharge from a pain clinic. There is a need to improve systems for patient transition, and communication between care providers, across care settings, and to develop an adequate relapse strategy. There is a need for a comprehensive model of care which focuses on the primary health care sector and its integration with interdisciplinary pain clinics in the tertiary sector (ANZCA, 2010).

2.10.6 National registration of health practitioners

In July 2010, the state-based system of registration for health practitioners was superseded by the national Australian Health Practitioner Regulation Agency (AHPRA). AHPRA is responsible for the registration and accreditation of 10 health professions across Australia, including the medical, dental, pharmacy, podiatry and nursing professions. The change in legislation means that for the first time there are nationally consistent registration requirements for the 10 professions that come under AHPRA. Consequently, prescribing rights remain regulated at the state and territory level while the ability to practise is now a national responsibility.

One significant implication of the move from state-based to national registration is the extent to which prescriptions for Schedule 8 controlled drugs and certain Schedule 4 drugs written in one jurisdiction can be filled in another. Under the previous arrangements, a prescription for an S8 drug could only be filled in the same state that it was prescribed. As of 1 July 2010, pharmacists are able to fill prescriptions written by any prescriber registered under the AHPRA, regardless of the jurisdiction of the prescriber. Exceptions to this are Tasmania, Western Australia and the Northern Territory which have legislated to prevent the dispensing of Schedule 8 poisons unless the prescriber is practising in that state or territory (Department of Health Victoria, 2010). There is a risk that this change could loosen the restrictions on the availability of these medications and reduce the ability to clinically monitor patient health.

Variations in arrangements between jurisdictions can also make it very complex for doctors prescribing methadone or buprenorphine for OST while their patients are on interstate holidays.

- As noted above, in three jurisdictions Tasmania, Western Australia and the Northern Territory, the authorised prescriber, although registered nationally, is unable to prescribe for their patient while the patient is interstate.

- In two states, Victoria and South Australia, no further authorisation is required to prescribe for the client and there is no restriction on the time for this interstate prescribing.
- Two jurisdictions, ACT and NSW, require an application and Health Department approval to prescribe, and the period for such approval is limited to four weeks.
- In Queensland the prescribing doctor is required to gain approval to prescribe, to use a designated form and the period of time for the prescribing is limited to three weeks.

In addition the five jurisdictions where interstate prescribing is permitted have different requirements.

- Two jurisdictions (ACT and NSW) require the script to conform to the jurisdictions' Opioid Treatment Guidelines.
- In two states (Vic and SA) the guideline requirement is not stipulated.
- In one state, Qld, the prescription need not conform to the state guidelines.

From a dispensing point of view, two states, Victoria and South Australia, allow the prescription to comply with the requirements for writing a drug of addiction prescription in the originating jurisdiction, while the other states require the prescription to meet the requirements of the state in which it is to be dispensed.

As is evident, the implications of AHPRA, coupled with different prescribing and dispensing guidelines in different jurisdictions significantly complicate the processes of prescribing and dispensing. The situation for both prescribing doctors and dispensing pharmacists would be greatly helped by a National Drug and Poisons Act and Regulation (Lawrance, personal communication, February 9, 2011).

2.10.7 The intimidation of prescribers by patients

Unfortunately prescribers in Australia commonly experience violence and intimidation from patients. General practitioners (GPs) are particularly at risk and alcohol and other drug-related issues are a prominent causal factor in this. In a survey conducted in 2004 among NSW GPs, 63.7% had experienced violence in the previous year. The most common forms of violence were 'low level' violence including verbal abuse (42.1%), property damage/theft (28.6%) and threats (23.1%). A smaller proportion of GPs had experienced 'high level' violence, such as sexual harassment (9.3%) and physical abuse (2.7%). Those who were most likely to be subject to violence included females and younger and less experienced GPs. Also at risk were GPs working among practice populations with:

- larger numbers of alcohol and other drug-related problems
- greater social disadvantage and
- larger numbers of mental health problems (Magin, Adams, Sibbritt, Joy, & Ireland, 2005).

Tolhurst et al. (2003) came to similar conclusions in their study of Australian rural GPs. They reported that verbal abuse was commonly associated with drug-seeking behaviour, alcohol intoxication and specific diagnostic indicators such as personality disorder. Alexander and Fraser (2004), in their survey of NSW health professionals, found that alcohol and other drug issues, such as drug-seeking and intoxication, were the most prominent factors associated with violence perpetrated against GPs. Magin et al. (2006) in their study of violence and aggression perpetrated against GPs in NSW, also highlighted the extent to which the practitioners regarded drug-seeking patients as particularly dangerous. The GPs responded to this by such measures as:

- actively discouraging drug-seeking patients from attending
- increasing the price of consultations (however, this has the effect of displacing drug-seeking patients to bulk billing practices), and

- acceding to patient demands.

The findings concerning violence perpetrated against GPs is consistent with the international literature (for example see Koritsas, Coles, Boyle, & Stanley, 2007).

The extent to which violence, or the threat of it, impacts on prescribing practices is unclear. Nevertheless, the findings of the research in this area serve to highlight one of the difficulties faced by prescribers. It also highlights the range of skills and supports required by practitioners to enhance the quality use of medicines.

2.10.8 Access to drug treatment, opioid substitution therapy options, access and dispensing fees

A proportion of those individuals misusing medications including opioids and benzodiazepines will need specialist drug treatment services. Australia currently has a shortage of specialist addiction physicians (Hotham, Roche, Skinner, & Dollman, 2005; Roche & Pidd, 2010) which can impact on their accessibility. It is also not clear whether Australia's drug treatment services are appropriately oriented to meet the needs of misusers of pharmaceutical drugs who are not also injecting drugs users. If treatment services are developed, or reoriented, to meet the needs of this 'new' group of drug misusers, it will be important that this does not further stigmatise the existing group of illicit drug users with a history of injecting drugs.

An issue which may also be impacting on pharmaceutical misuse is the accessibility and available range of OST for opioid dependent individuals. If OST is not readily accessible, either in terms of an individual being able to gain a place on an OST program, or the ease with which individuals can avail themselves of the program, then this could act as a barrier to its uptake. In this case, obtaining opioid medications from other prescribers, or illicitly, could present fewer difficulties compared with being on OST. This, in turn, could exacerbate the misuse of pharmaceutical opioids.

One of the most contentious issues concerning OST in Australia is the dispensing fees paid by therapy clients. While the cost of the OST drugs themselves is funded by the Australian Government, there is a dispensing fee that is not subsidised. It has been estimated that 80% of pharmacotherapy clients (with the exception of clients in certain categories, such as those who are pregnant or have the human immunodeficiency virus) pay for dispensing. This cost is approximately \$5.00 per dose (Chalmers, Ritter, Heffernan, & McDonnell, 2009). If dosing is required on a daily basis, as is usually the case with methadone, this can amount to a substantial cost.

Clients also incur other costs associated with OST such as the gap between the fees charged by medical practitioners and the Medicare benefit and travel costs to the site of the OST. Although these costs are substantially less than the costs associated with using illicit drugs, many clients struggle to meet these fees, and this can impact on future access to OST (via debts or blacklists). This fee is therefore highly likely to adversely impact on entry into and retention in treatment (Ritter & Chalmers, 2009).

The Australian Government has financial responsibility for providing pharmaceutical services through the PBS. It achieves equity of access through subsidising the price of prescription drugs, with this price incorporating both the cost of the drug and dispensing costs. The methadone and buprenorphine used in OST are both PBS-approved drugs, and are provided to clients for free. Yet the Australian Government does not subsidise the dispensing costs associated with these drugs. A substantial proportion of OST is dispensed from community pharmacies at a cost of approximately \$35 per week (Ritter & Chalmers, 2009).

The cost of OST in Australia therefore potentially provides an incentive to obtain PBS opioid medications instead. As noted above, the cost of OST is approximately \$35 per week; compared to the cost of a PBS opioid prescription (at a concessional cost of \$5.60 up to the yearly threshold amount of \$336.00 after which further prescriptions are free) (Department of Health and Ageing, 2010). Alternative opioid drugs are less suitable for OST and when they are provided outside an OST program they are not dispensed in a

single dose in a supervised environment (World Health Organization, United Nations Office on Drugs and Crime, UNAIDS [WHO/UNODC/UNAIDS], 2004).

Opioid substitution treatment clients are already at risk of misusing pharmaceuticals (Nielsen et al., 2008; Rosenblum et al., 2007). Therefore the comparative cost disincentives associated with being on OST are likely to lead to an increase in the overall levels of pharmaceutical misuse among this group.

Modelling undertaken by (Chalmers et al., 2009) also suggested that, if the dispensing costs were to be met by the Australian government, this expenditure would compare favourably with the estimated health and crime cost savings.

2.10.9 The availability of adjuvant drugs on the PBS

Adjuvants are medications often used in the management of persistent pain, although their usual role is for conditions other than pain. They include antidepressants, anti-epileptics, anxiolytics and corticosteroids. The most commonly prescribed antidepressant adjuvants include tricyclic antidepressants (TCAs) and serotonin-noradrenaline (norepinephrine) reuptake inhibitors (SNRIs) (Barber & Gibson, 2009).

A difficulty associated with the use of adjuvants is that some of the best examples of these drugs (such as the anti-epileptics gabapentin and pregabalin and the SNRIs) are not approved for prescription under the PBS for the relief of pain. This compares with a range of opioids which are approved for this purpose. Therefore there is a disincentive to prescribe these drugs because the patients would have to pay the full un-subsidised price. It is further noted that non-pharmacological treatments for pain are also not available on Medicare. This is likely to be an important dynamic influencing the preferential prescription of opioid drugs for chronic non-malignant pain.

2.10.10 The national Returning Unwanted Medications (RUM) Project

The RUM project is an important mechanism through which unwanted and out-of-date medicines are collected from consumers in Australia. It is managed by the National Return and Disposal of Unwanted Medicines Ltd and is funded by the Australian Government Department of Health and Ageing. This project acts to reduce the availability of these drugs for accidental or intentional misuse. Consumers can take their medications to pharmacies for safe disposal and the program collects approximately 400 tonnes of medications annually (Department of Health and Ageing, 2010). A secondary benefit of the Program is that it provides an insight into patterns of wastage of pharmaceutical drugs in Australia.

The large amount of unwanted medicines collected annually by the program provides some indication of the significant level of unwanted and out of date medications in the community.

3 International developments

3.1 Global issues

The widespread misuse of pharmaceuticals is a relatively recent international phenomenon. Hence, examination of patterns, problems and potential solutions for Australia also need to be examined in relation to international developments. A major change has been a substantial global increase in consumption of prescribed opioids (Rintoul et al., 2010), among other substances such as benzodiazepines, amphetamines and OTCs.

The misuse of opiates occurring in many developed countries represents a fundamental paradigm shift away from heroin as the opioid of choice (Fischer & Rehm, 2006). Moreover, the International Narcotics Control Board reports that use of and trafficking in prescription drugs has exceeded that of illicit drugs in some countries (International Narcotics Control Board [INCB], 2010). The Board reported that these drugs have become a drug of first choice in many cases and are not being used as a substitute for illicit drugs.

Global consumption of pharmaceutical opioid analgesics increased by more than two and a half times during the past decade, an increase that occurred mainly in Europe and North America. In 2006, European countries and North America together accounted for the global consumption of approximately:

- 96% of fentanyl
- 89% of morphine and
- 97% of oxycodone (INCB, 2008).

Clearly not all of this increase is due to the problematic use of these drugs, but the INCB (INCB, 2008) pointed out that there is a strong correlation between the extent of

problematic use of various pharmaceutical preparations and their availability on the illicit market. Ironically, the Board is also concerned about the undersupply of opioid analgesics to many developing countries which is significantly limiting the capacity of these countries to effectively manage their citizens' pain-related problems.

While there has been an increase in the *use* of these prescription drugs in the European Union, in contrast with North America, the *misuse* of prescription drugs (with the exception of opioid substitution drugs) has not been regarded as a major problem in this region. This is partly due to existing regulatory frameworks and prescribing practices, both of which differ from those of the US (European Monitoring Centre for Drugs and Drug Addiction, 2010).

Degenhardt et al. (n.d.) undertook an examination of the extent and nature of pharmaceutical opioid misuse and injection globally. Their findings are summarised below.

1. United States

The United States appears to have the largest per capita problem in the world in terms of extra-medical use, injection and diversion. It accounted for half (49%) the world's estimated morphine consumption in 2005, while only comprising 4.7% of the world's population. Controlled-release oxycodone is widely misused, and accounts for 99% of worldwide consumption. It was estimated that prescription opioid misuse cost US\$8.5 billion in 2009; a figure that is likely to be larger today. Dependence, and non-fatal and fatal overdoses related to pharmaceutical opioid misuse continue to increase across the country. Multiple formulations of various opioids are available. Many appear to be easily obtained from GPs for diffuse, non-specified pain conditions.

2. Canada

In Canada, there has been sustained research and community attention directed to misuse and injection of pharmaceutical opioids among regular illicit opioid users, with

evidence of increasing use and injection of pharmaceutical opioids, probably related to inconsistent heroin supply in most areas of the country. There is no national monitoring system in place to track diversion and extra-medical use of prescription drugs, although district-level systems are in place.

3. Western Europe

In Western Europe there is less consumption of pharmaceutical opioids compared to Canada and the United States, and it is not related to OST coverage. Some countries have notably low levels of pharmaceutical opioid consumption (such as Albania, Andorra, Serbia, and Montenegro), and no data were located on the existence or extent of misuse or diversion in these countries. Misuse and diversion is occurring in Western Europe. Although very good monitoring occurs through the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), routine reporting does not appear to consistently differentiate between heroin and pharmaceutical opioids. As a result, it is not clear in some countries to what extent these pharmaceuticals are a concern. In Finland, there have been high levels of diversion of buprenorphine from OST for some years. Since the introduction of buprenorphine-naloxone, many injecting drug users (IDUs) have reported injecting the drug. In France, a similar problem has been reported in relation to buprenorphine, but much of the misuse appears to be among users enrolled in OST, which is widely available and dispensed through pharmacies.

4. Eastern Europe and Central Asia

1. In Belarus, injection of methadone is increasingly common.
2. In the Czech Republic, methadone is rarely diverted, but buprenorphine is frequently diverted, and in some locations is more commonly injected than heroin.
3. In Georgia, injection of buprenorphine, believed to be diverted from nearby countries where it's legally available, has recently been reported as increasingly common among IDUs who perceive it to be a preferable alternative to heroin.

5. South Asia

Some South Asian countries have seen marked problems related to pharmaceutical opioid misuse and, increasingly, injection, particularly India, Nepal and Bangladesh. A shift from heroin smoking to pharmaceutical opioid injection is speculated to be related to i) reduced availability or increased cost of heroin, ii) low cost and easy availability of pharmaceuticals, and iii) legal controls introduced in India to address heroin supply. Pharmaceutical opioids misused in this region are typically lower in potency such as codeine, nalbuphine and dextropropoxyphene, in contrast to the pharmaceutical opioids being used by IDUs in other regions around the globe which include oxycodone and morphine, and high dose buprenorphine. These problems have occurred despite very low levels of licit opioid medication available for medical purposes; suggesting that misuse has not been avoided simply through limited medical supplies.

A recent UNODC report (UNODC Regional Office for South Asia, 2005, as cited in Degenhardt et al., n.d.) concluded that diversion of pharmaceutical opioids for misuse and trafficking is occurring on a large scale both within and outside the region, primarily because of limited enforcement of pharmaceutical regulations. India reportedly accounts for significant large-scale diversion within the country and the region, and further afield through illegal online pharmacies based in India.

6. East and South East Asia

Few reports of pharmaceutical opioid diversion or injection were reported in this region, with the exception of Singapore. This was in contrast to the prominence of heroin as a drug of dependence in this region. Singapore previously had widespread and relatively poorly regulated availability of buprenorphine as an OST for heroin dependence, leading to a significant problem with injection of the drug, sometimes by persons who had been initiated to injecting with this drug.

7. The Caribbean region

Few data were located on the extent of pharmaceutical opioid misuse, injection or diversion from this region. Given the low levels of consumption, it seems likely that the extent of pharmaceutical opioid misuse and diversion is not great, but there is a need for much better coverage of opioid medications for the treatment of pain and for OST.

8. Latin America

The availability of pharmaceutical drugs in general is poor in many countries of Latin America. In response to the high cost of drugs, some countries in the region have developed methods for encouraging generic brands of these medications and ensure swift medication registration. Few mentions of pharmaceutical drug misuse in this region could be found, with most focus on cocaine production, trafficking and use. Access to opioid medication is very low. The use and injection of opioids in general (including heroin) is thought to be low in this region.

In 2008, the South American countries with the highest prevalence of opioid use were Brazil and Chile (0.5% of the population between 15 and 64 years, with corresponding numbers of 640,000 and 57,000, respectively). In both cases, prescription opioids constituted the key pattern of opioid use.

9. Oceania and the Pacific

Pharmaceutical opioid misuse was not noted as an issue in most countries in this region. This is almost certainly because of very minimal availability of these drugs for medical use. Most countries in this region have minimal levels of opioid consumption reported to the INCB. The two exceptions to this are Australia and New Zealand. These countries have comparatively high opioid consumption, including comparatively good levels of coverage for pain treatment. Markets for diverted opioids in Australia have been described as “small scale” and “disorganised” and diversion seems typically to occur sporadically among established heroin injectors, and is probably related to the availability of their preferred opioid (heroin).

10. Middle East and Northern Africa

Pharmaceutical preparations containing controlled substances are easily obtained on unregulated markets in this region, with considerable unregulated sale of pharmaceuticals over the counter without prescriptions occurring. Misuse of these preparations is reported to be taking place but no data were available to quantify this. Drug control legislation is in place in most countries, but it is often not adequately implemented and enforced. Due to insufficient funds, there is apparently a shortage of trained pharmacists and pharmacy inspectors in many African countries.

11. Sub-Saharan Africa

There are significant structural barriers to the provision of medication in some countries, and doubtless fear of limited capacity to control diversion adds to difficulties in achieving change. An added issue is the fact that many African countries now serve as routes for the trafficking of illegal drugs, including heroin, through to the richer markets of Europe. It is likely that countries such as India may account for significant and/or increasing supply of diverted pharmaceutical opioids to this region; this needs to be addressed.

3.2 North America

Much of the relevant literature is drawn from the US, and to a lesser extent Canada. The US has the most systematic data available on this topic due to extensive research and substance misuse control infrastructure in that country (Fischer, Gittins, & Rehm, 2008). A comparison of patterns and prevalence of the misuse of pharmaceuticals in countries such as the United Kingdom also warrants attention given their similarity with Australia in many respects. There are, however, some significant differences between Australia and these other countries in terms of the nature of the health care system and scope for consumer access to pharmaceuticals.

In 2002, Canada and the United States were among the highest consumers of controlled drugs worldwide. Between 2002 and 2006, the use of licit narcotic drugs increased by more than 80% in Canada and by more than 60% in the United States. Clearly not all of this increase is due to the problematic use of these drugs, as it could also be related to more aggressive treatment of painful conditions. In the same period, the consumption of pharmaceutical amphetamines doubled in Canada and increased by 42% in the United States. In Canada, heroin has become an increasingly marginal form of drug use, having been largely replaced by pharmaceutical opioid use (Fischer, Rehm, Patra, & Firestone Cruz, 2006). The Substance Abuse and Mental Health Services Administration (SAMHSA, 2008b) reported in 2008 prescription opioids were then ahead of cocaine and heroin and second only to marijuana in levels of misuse in the US.

The National Center on Addiction and Substance Abuse (CASA, 2005) reported that between 1992 and 2002:

- the US population increased by 13%
- prescriptions for non-controlled drugs rose by 57% and
- prescriptions for controlled drugs climbed by 154%.

The largest increases in prescriptions for controlled drugs between 1992 and 2002 were for:

- stimulants (369%)
- opioids (222%)
- central nervous system (CNS) depressants (48%).

For the similar time period (1992-2003), there were increases in self-reported misuse of prescription opioids of 141%, CNS depressants of 45%, and stimulants of 42%.

Misusers of controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003, a 94% increase (seven times faster than the US population increase).

The 15.1 million people who reported current misuse of prescription drugs in 2003 was

greater than the number using cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (0.3 million), combined.

SAMHSA (2008b) reported that, in the 2002 American National Survey of Drug Use and Health (NSDUH) an estimated 29.6 million Americans had used pain relievers (essentially pharmaceutical opioids) non-medically over their lifetime. By 2005, the number had increased to 32.7 million. In addition, between 2002 and 2005, more Americans initiated non-medical use of pain relievers than had initiated cannabis use.

The rate of increase of pharmaceutical misuse appears to be much higher among younger people compared with older people. CASA (2005) found a 212% increase from 1992 to 2003 among 12-17 year olds misusing controlled prescription drugs, and that an increasing number of teens were trying these drugs for the first time. The initiation of misuse of prescription opioids among teens also increased 542%, more than four times the rate of increase among adults. Two point three million teens between the ages of 12-17 years (9.3%) admitted misusing a prescription drug in the past year, and 83% of these admitted misusing opioids. Younger teens were more likely to misuse only prescription drugs while older teens were more likely to also misuse alcohol or illicit drugs.

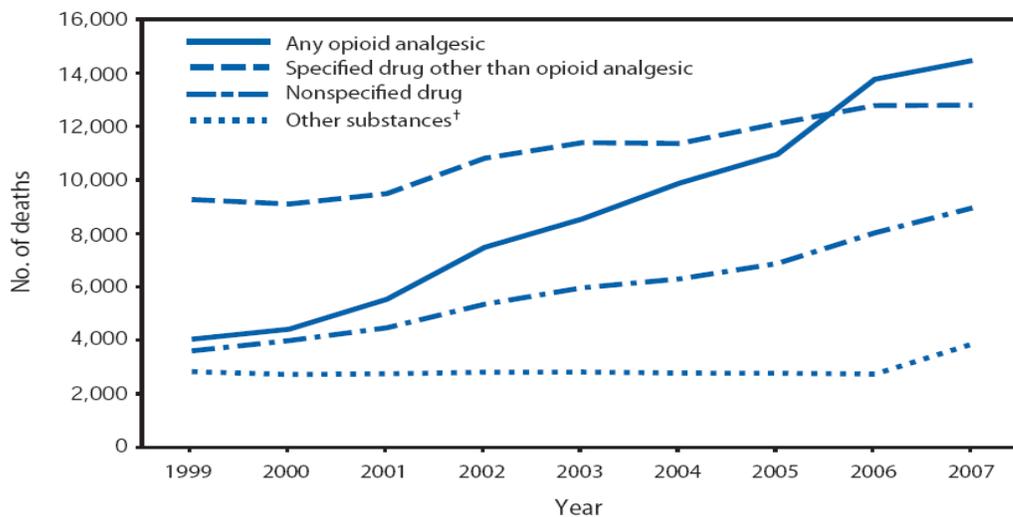
Likewise, SAMHSA (2008b) reported that young people aged 12-17 years and young adults aged 18-25 were most likely to initiate non-medical use of prescription psychotherapeutic drugs. In 2005, there were 526,000 new non-medical users of OxyContin® alone. Of particular concern is that Americans aged 18-25 years reported higher lifetime non-medical use of pain relievers, benzodiazepines, and muscle relaxants than did other age groups. Between 2004 and 2005 there was a substantial increase in the number of people in this age group who used hydrocodone, oxycodone, methadone, clonazepam, or alprazolam.

Poisoning deaths involving opioid analgesics have also increased sharply in the US in recent years. The Centers for Disease Control and Prevention (2010) reported that from

1999-2007 the number of US poisoning deaths involving any opioid analgesic (e.g. oxycodone, methadone, or hydrocodone) more than tripled, from 4,041 to 14,459. This comprised 36% of the 40,059 total poisoning deaths in 2007; whereas in 1999, opioid analgesics were involved in only 20% of the 19,741 poisoning deaths.

There have also been substantial increases in prescription drug-related emergency department visits in the US (SAMHSA, 2008a) and in prescription drug-related deaths (Paulozzi, 2006).

Number of Poisoning Deaths* Involving Opioid Analgesics and Other Drugs or Substances — United States, 1999–2007



* Poisoning deaths include those resulting from drug overdose, those resulting from other misuse of drugs, and those associated with solid or liquid biologics, gases or vapors, or other substances. Poisoning deaths are from all manners, including unintentional, suicide, homicide, undetermined intent, legal intervention, and operations of war. Among deaths with poisoning as the underlying cause, the following *International Classification of Diseases, Tenth Revision* (ICD-10) codes were used to indicate whether drugs were involved and the type of drug involved in poisoning deaths: any opioid analgesic (any of the codes T40.2–T40.4); nonspecified drug (T50.9 only); specified drug other than opioid analgesic (any of the codes T36–T50.8 other than T40.2–T40.4); or other substances (none of the codes T36–T50.9).

† Poisoning deaths associated with only solid or liquid biologics, gases or vapors, or other substances, and exclusive of drug involvement.

Figure 13. Number of poisoning deaths involving opioid analgesics and other drugs or substances, United States, 1999-2007

Source: Centers for Disease Control and Prevention (2010, p.1026)

The high prevalence of problematic misuse of pharmaceutical opioids is also impacting on demand for US and Canadian drug treatment services. In the US, the number of treatment admissions for opioids other than heroin has increased more than 450%, from 16,274 to 90,516, over the ten years between 1997 and 2007. It shifted from contributing to just 6% of opioid admissions in 1997 to 27% in 2007 (United Nations Office on Drugs and Crime [UNODC], 2010).

A similar situation is found in Canada. Treatment demand for prescription opioids in Canada has been greater than for heroin/opium over recent years, and continues to increase. Treatment demand data from Ontario, for example, show that the number of admissions for opioids increased 55% between 2004/2005 and 2008/2009, or from 15% to 19% of all drug treatment demand (excluding alcohol and tobacco). This shift is attributed to the 68% rise in admissions for prescription opioids/codeine (UNODC, 2010).

A 2005 study of 679 regular illicit opioid users from seven Canadian cities found heroin to be virtually absent from four of the seven sites and the most commonly used opioid in only two (Fischer et al., 2006). Prescription opioids (e.g. hydromorphone, morphine and oxycodone) were the opioids predominantly used. Heroin use had declined by 24% across all sites since 2001, together with reductions in key risk behaviours such as drug injection, needle sharing and overdoses. Overall, Fischer et al.'s data suggested that heroin use has become an increasingly marginal form of drug use among opioid users in Canada, particularly outside Vancouver and Montreal (two major coastal importation points for heroin). Heroin use had largely been replaced by pharmaceutical opioid use. They also found that, while the heroin users predominantly obtained their heroin from dealers, the majority of the prescription opioid users obtained their drugs directly or indirectly from the medical system.

It is clear that the US, in particular, has major difficulties with the problematic misuse of pharmaceutical drugs. This raises questions in regard to factors that might contribute to

the emergence of such difficulties which could, in turn, have valuable lessons for Australia. Ballantyne (2010) has highlighted a number of possibilities in this regard.

Firstly, recognition of the role pharmaceutical opioids can play in relieving human suffering led to substantial efforts in the US over the past 10 years to remove stigma associated with their prescription. This push firmly established opioids as an effective and safe therapy for chronic pain, particularly chronic non-malignant pain. This move received strong support and assistance from the pharmaceutical industry, which has a particularly strong influence in the US. All of this occurred at the same time as the development of slow-release forms of opioids which made them a more attractive prescription option.

Secondly, in the US illicit drug laws are particularly strictly enforced and attract severe penalties. This is likely to make prescription drugs more attractive than illicit drugs because of the lesser penalties that detected misuse might attract. In addition, the US comprises a large federation of states and prescription regulation is a state-based issue, which creates challenges for cross-border control.

Thirdly, while the US probably has more comprehensive data on drug misuse than any other country, its national healthcare statistics and measurement of healthcare outcomes are relatively poor. This is further compounded by measures to protect civil liberties and privacy, which prevent collection of comprehensive national health-care data. The limitations of healthcare data collection, Ballantyne (2010) argued, inhibited development of feedback loops on the extent to which the widespread prescription of opioids was achieving desired treatment outcomes and the burgeoning nature of problems.

A further contributory factor was the introduction of the concept of pain as the ‘fifth vital sign’¹⁴ by the (US) Joint Commission on the Accreditation of Healthcare Organizations in

¹⁴ Also see Part 4 which further addresses issues related to pain, pain management, prescribing and multi-disciplinary care.

2001. In other words, in addition to assessing patients' other vital signs (pulse, temperature, respiration and blood pressure), pain was also to be assessed. This conceptual shift was an effort to increase awareness of pain experienced by hospitalised patients and thereby improve treatment of that pain. Trescot et al. (2008) argued that emphasis on pain assessment as the fifth vital sign has resulted in potential overmedication of a group of patients.

At a general level, the US health care system has also become intolerant of under-treated pain. In 2001, a Californian jury found a doctor guilty of elder abuse for under-treating the pain of a dying man and was ordered to pay \$US1.5 million to the patient's surviving family members. A second similar case was settled and resulted in the Medical Board of California formally sanctioning the doctor. While doctors in the US have long been concerned that prescribing opioids for prolonged periods, or for large amounts, could lead to disciplinary actions taken against them, the opposite may be just as punishable. This is likely to be a further factor in the expansion of opioid prescribing in the US (Fishman, Papazian, Gonzalez, Riches, & Gilson, 2004).

Other speculations about why the US has developed such significant problems in this area include:

- a lack of education among all segments of the community including doctors, pharmacists and the public about the limitations of opioid therapy, particularly for chronic non-malignant pain
- ineffective and incoherent prescription monitoring programs and
- a lack of funding for the implementation of a national prescription monitoring program (Manchikanti, 2007).

3.3 The global promotion of pharmaceuticals

Controlled drugs with potential for misuse and diversion pose different public health risks when over promoted and highly prescribed. Such drugs present public health risks that are different to and, it has been suggested, more problematic than uncontrolled drugs when over promoted and highly prescribed (Van Zee, 2009).

The promotion of OxyContin® is instructive in this regard. When Purdue Pharma introduced OxyContin® in 1996 it was aggressively marketed and highly promoted. Sales grew rapidly from \$48 million in 1996 to almost \$1.1 billion in 2000. By 2004, OxyContin®, with high levels of availability and abuse and diversion potential, had become a leading drug of misuse in the US (Van Zee, 2009).

The promotion and marketing of OxyContin® occurred during a period of liberalisation of the use of opioids in the treatment of pain, particularly for chronic non-malignant pain. The potential market for opioids in treating chronic non-malignant pain is a much larger than the market for treating cancer-related pain.

Purdue pursued an 'aggressive' campaign to promote the use of opioids in general and OxyContin® in particular. In 2001 alone, the company spent \$200 million in an array of approaches to market and promote OxyContin®. The heavy promotion of OxyContin® resulted in a 10-fold increase in this drug for chronic non-malignant pain; from about 670,000 prescriptions in 1997 to about 6.2 million in 2002 (Van Zee, 2009).

There were several important features about the way OxyContin® was so successfully marketed and promoted. These offer important potential lessons that may be applied in prevention efforts to curtail ongoing problems and prevent similar patterns occurring in settings such as Australia. These features include the following:

1. Intensive promotion

Messages about the new product were promoted with an unusually high level of intensity, in spite of the product itself having no particular special or superior features over similar products that warranted such intense promotion.

2. Profiling prescribers

Prescriber profiles were used to target high-opioid prescribers.

3. Incentives

Lucrative incentives were used, together with other strategies such as free starter coupons.

4. Messages regarding safety

A consistent feature of the marketing of OxyContin® was the systematic effort to minimise the risk of addiction in the use of opioids for chronic non-malignant pain.¹⁵

5. Academic detailing and other medical education

Academic detailing refers to face to face education of prescribers by other health professionals in an effort to encourage them to prescribe certain drugs.

¹⁵ This subsequently led to criminal charges of Purdue Pharma company executives, to which they pleaded guilty, for misbranding OxyContin® and claiming that it was less addictive and less subject to abuse and diversion than other opioids.

4 Good practice in opioid prescription and pain management¹⁶

4.1 Introduction

As discussed, over the past thirty years there has been a significant increase in the therapeutic use of opioids in many developed countries. There has also been a decrease in the therapeutic use of short-acting injectable opioids and an increase in the use of orally ingested, well absorbed, longer acting opioids. These longer acting and sustained release opioids result in less fluctuation in blood plasma levels of analgesics. This, in turn, has led to improvements in the ability to control chronic pain and fewer effects resulting from excessively high or low opioid levels during treatment (RACP, 2009).

The role of opioids in the treatment of acute pain (such as post-operative pain) and malignant (cancer) pain is relatively uncontroversial. These drugs have a long-established and well-understood role in these conditions (BPS, 2010). Their role in the treatment of opioid dependence is also relatively uncontroversial (Mattick, Breen, Kimber, & Davoli, 2009).

4.2 The role of opioids in the treatment of chronic non-malignant pain

The use of opioids in the longer-term treatment of chronic non-malignant pain (CNMP) is a controversial issue and has been the subject of considerable debate in recent times.

¹⁶ 'Opioid' is a term which includes drugs containing natural opiates derived from the opium poppy and a range of synthetic and semi-synthetic substances. These drugs have effects upon the opioid receptors in the brain. The immediate effects of all opioids include analgesia (relief from pain) and euphoria (feeling of wellbeing). A large number of pharmaceutical opioids have been developed for medical use. Those used most commonly in the management of acute and chronic pain include morphine, oxycodone, hydromorphone, dextropropoxyphene, fentanyl, pethidine and codeine. Methadone and buprenorphine are the drugs most commonly used in Australia for the management of opioid dependence (Degenhardt et al., 2008).

This controversy is due to concerns regarding long-term effectiveness and safety, particularly the risk of tolerance, dependence, or abuse (Noble et al., 2010). The extent to which longer acting opioids are prescribed for chronic non-malignant pain in Australia is unclear, but in America 95% of these drugs are prescribed for CNMP (RACP, 2009).

Broadly, there are two issues of concern in relation to the longer-term prescription of opioid drugs for CNMP. The first is the extent to which the expanded prescription of these drugs for CNMP has facilitated leakage or diversion for use by persons other than those for whom they were prescribed. There is little doubt that a strong correlation exists between the extent of misuse of various pharmaceutical preparations containing narcotic drugs and the availability of those preparations on the licit market (INCB, 2008). This leakage can also lead to the use of (typically) oral drugs in more dangerous ways, such as injection (DCPC, 2007).

The second issue relates to whether the practice of prescribing opioids for CNMP longer-term is clinically sound and beneficial to patients. The latter is addressed below.

Concern about the extent and nature of prescription opioids for CNMP has led to a number of meta-analyses and development of position papers surrounding the prescription of opioids for CNMP. The key findings of these are described below. Before doing so, however, it is important to contextualise the problem of CNMP and to outline some of the difficulties experienced by prescribers in responding to this problem.

There are three main overlapping groups of people who experience pain and/or require extended opioid treatment. These are:

1. those with malignant pain
2. those with CNMP and
3. problematic and illicit users (RACP, 2009).

Patients who use pharmaceutical opioids cannot be simplistically divided into two groups, i.e. those who have a legitimate need for such drugs and those who do not. As Hurwitz (2005) has highlighted, patients cannot be divided into those who have physical and/or psychological pain and are honest and reliable; and those who are without pain who are dishonest and divert and abuse their medication.

The clinical reality presents a more complex picture. Having a painful condition is no guarantee of honesty or reliability in the control of prescribed medications. Nor does a history of addiction or criminality prevent the emergence of painful conditions or mandate non-compliance with medical instructions. (Hurwitz, 2005, p.158)

Some (e.g. Monheit, 2010) maintain that there is a distinction between physical dependence and addiction and that all patients on longer term opioid treatment become physically dependent to some extent and experience withdrawal symptoms if they cease their medication, but that this does not mean the patient has an 'addiction'¹⁷. According to some definitions, other problematic behavioural manifestations, such as continued drug-seeking and inappropriate drug prioritisation, would need to be evident for the condition to be regarded as one of addiction.

A major problem in establishing the efficacy of opioids in the long term management of CNMP is the difficulty entailed in conducting double blind studies in this area.

Challenges include the impracticality of providing placebo drugs to patients in pain and the heterogeneity of the patient population (RACP, 2009).

Noble et al. (2010) conducted a Cochrane Collaboration review to assess safety, efficacy, and effectiveness of opioids taken long-term for CNMP. They reviewed 26 studies with 27 treatment groups that enrolled a total of 4,893 participants. Twenty-five

¹⁷ There is a substantial literature devoted to the differentiation between the concept of 'dependence' and 'addiction'. Clearly this is a contested area, but some conceptual clarification is required in the current context to address issues raised in relation to prescribed opioids. The new DSM may also change its terminology to distinguish addiction vs dependence as separate phenomenon and separating physical and psychological dependence. But this distinction and terminology is not universally applied.

studies were case series or uncontrolled long-term trial continuations and the other was a randomised controlled trial (RCT) comparing two opioids. The authors concluded:

- that many patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events, or insufficient pain relief
- weak evidence suggests patients who are able to continue opioids long-term, experience clinically significant pain relief
- evidence concerning improvement to quality of life or functioning is inconclusive
- many minor adverse events (like nausea and headache) occur while taking opioids, but serious adverse events, including iatrogenic opioid addiction, were rare, and
- that appropriate management of opioid therapy in well-selected patients with no history of substance addiction or abuse can lead to long-term pain relief for some patients with a very small risk of developing addiction, abuse, or other serious side effects.

However, they also concluded that the evidence supporting these conclusions is weak, and that longer-term studies are needed to identify patients most likely to benefit from treatment.

A further Cochrane Review was undertaken to establish the evidence for use of opioids for neuropathic pain (Eisenberg, McNicol, & Carr, 2006).¹⁸ Twenty-three trials met the inclusion criteria and were classified as short-term (less than 24 hours; n = 14) or intermediate-term (median = 28 days; range = eight to 70 days; n = 9). The short-term studies provided equivocal evidence regarding the efficacy of opioids in reducing the intensity of neuropathic pain whereas the intermediate-term studies demonstrated significant efficacy of opioids over placebo, which is likely to be clinically important. Reported adverse events from opioids were common but not life-threatening. The

¹⁸ This refers to pain stemming from nerve damage.

authors called for further randomised controlled trials to establish the long-term efficacy, safety (including addiction potential), and effects on quality of life.

A systematic review was also conducted in the development of the Canadian Guidelines for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain (National Opioid Use Guidelines Group, 2010). It concluded that opioids were more effective than placebo for pain and function, irrespective of the type of opioid (strong or weak) or mechanism of pain (nociceptive¹⁹ or neuropathic). The effect sizes of opioids over placebo were medium for pain and small for function. In other words, the use of opioids was more effective at reducing pain than in improving function. They found that acetaminophen (paracetamol), non-steroidal anti-inflammatory drugs and non-pharmacological treatments are often effective for patients with low back pain and other common musculoskeletal problems. They also reported that opioids are usually not indicated for migraine or tension headaches, or for patients with functional gastro-intestinal problems such as irritable bowel syndrome.

A systematic review of the evidence of the efficacy of longer term opioid therapy for CNMP was conducted on behalf of the American Pain Society and the American Academy of Pain Medicine (Chou et al., 2009) . Although evidence is limited, their expert review panel concluded that chronic long-term opioid therapy can be effective for carefully selected and monitored patients with CNMP. They also found that opioids are also associated with potentially serious harms, including opioid-related adverse effects and outcomes related to the misuse potential of opioids. They concluded that safe and effective long-term opioid therapy for CNMP requires clinical skills and knowledge in both the principles of opioid prescribing and on the assessment and management of risks associated with opioid abuse, addiction, and diversion. They also concluded that the evidence of efficacy is limited in many areas related to use of opioids for CNMP and they developed a range of guidelines to assist practitioners based on their systematic review of the available evidence.

¹⁹ This refers to pain emanating from tissue damage.

A review undertaken on behalf of the American Society of Interventional Pain Physicians (Trescot et al., 2008) also concluded that evidence for the effectiveness of long-term opioids in reducing CNMP and improving functional status for six months or longer is variable. They reported that opioids may be effective for short-term pain relief. Treatment effectiveness over six months or longer, however, was found to be variable. The quality of the evidence of effectiveness ranged from moderate for transdermal fentanyl and sustained release morphine, to limited for oxycodone, and was indeterminate for hydrocodone and methadone.

The RACP (2009) also conducted a review of the literature and concluded:

- opioids are effective in the treatment of CNMP over short periods, being associated with reduced pain and improved functional outcomes compared with placebo
- opioids are more effective than placebo for nociceptive and neuropathic pain
- strong opioids (oxycodone and morphine) are statistically superior to naproxen²⁰ and nortriptyline²¹ (respectively) for pain relief but not for functional outcomes
- weak opioids (propoxyphene, tramadol and codeine) did not significantly outperform non-steroidal anti-inflammatory drugs or tri-cyclic anti-depressants for either pain relief or functional outcomes and
- clinically and statistically, only constipation and nausea were significantly more common with opioids.

Passik and Kirsch (2008) called for prescribers to embrace the concept of rational pain management and to assess patients for risk both before writing the first opioid prescription for them and thereafter. In addition, they pointed out that good pain management should lead to some decreases in pain perception for the patient, combined with a corresponding increase in ability to function. These authors proposed a

²⁰ Naproxen is a non-steroidal anti-inflammatory drug.

²¹ Nortriptyline is an anti-depressant medication.

novel concept designed to provide clinicians prescribing opioids with an early opportunity to review the status of a particular patient. This concept of monitoring opioid prescribing proposed that prescribing patterns could be viewed as either 'in or out of the box'. Prescribing 'in the box' refers to the prescribing of opioids in a usual and customary fashion similar to that of their colleagues. Conversely, prescribing 'out of the box' refers to prescribing opioids in a manner that deviates from the usual habits of the majority of prescribers writing opioid prescriptions.

Passik and Kirsch (2008) emphasised that there is not necessarily anything inherently wrong with prescribing 'out of the box' and there may be excellent reasons to do so. However, this concept may be helpful as a mechanism to alert certain prescribers to the fact that they are no longer in line with the usual prescribing practice of the majority of their colleagues and so may decide to increase the degree, amount, or rigour of documentation or patient monitoring. Although experienced experts in pain medicine may 'know' when they are prescribing 'out of the box', novices and health care providers from other disciplines of medicine may not. Thus, the authors proposed clearly creating criteria that define 'in and out of the box' prescribing in an attempt to be helpful to those clinicians.

4.2.1 Universal precautions

The need to adopt a cautious approach in the prescription of opioids has led to calls for the application of the framework of universal precautions to the area of pain management. In utilising this framework, all chronic pain patients are screened for past or present substance misuse problems, or psychiatric disorders, and extra support is provided to those at risk (Monheit, 2010).

This approach highlights:

- the importance of a comprehensive substance use history and family history to identify people at risk of developing problems
- the usefulness of urine drug toxicology to assist in identifying at-risk patients
- a treatment agreement based on informed consent regarding the risks of dependence and
- clear boundaries surrounding the use of opioids (RACP, 2009).

Under this approach, the selection of opioids for chronic pain is always on the basis of a trial of their usefulness, and subject to ongoing evaluation. This approach has potential for prevention and early identification of problematic opioid use as well as appropriate 'triage' into levels of specialist care as needed, including pain and addiction specialist care. It may have particular utility for GPs (RACP, 2009).

4.2.2 Hyperalgesia

A further confounder in regard to pain and longer-term opioid use is the relationship between long-term opioid use and hypersensitivity to pain - hyperalgesia (Angst & Clark, 2006; Chang, Chen, & Mao, 2007; White, 2004). The term 'opioid-induced hyperalgesia' has been used to refer to a decline in analgesic efficacy during opioid treatment for pain and an increased sensitivity to stimuli in individuals with opioid dependence. It is difficult to distinguish between 'opioid-induced hyperalgesia' and opioid tolerance as the cellular mechanisms have much in common and are also similar to those associated with neuropathic pain (with the latter traditionally considered to be nonresponsive to opioids) (RACP, 2009).

4.2.3 Cost effectiveness of general practice care for low back pain

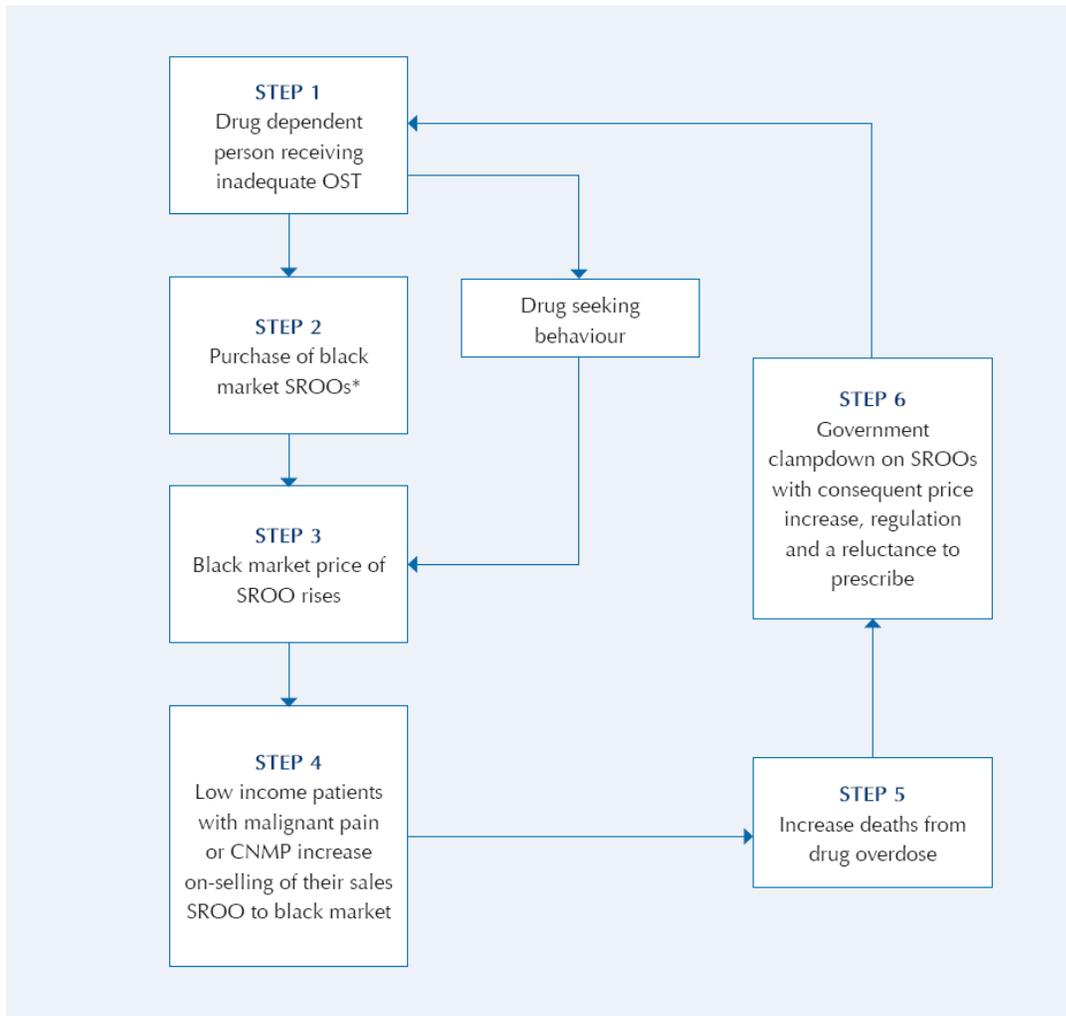
Much of the misuse of prescribed drugs and especially opioids originates with chronic non-malignant pain, a substantial proportion of which involves lower back pain problems. Lin, Haas, Maher, Machado and van Tulder (2011) undertook a systematic review to

evaluate the evidence of the cost-effectiveness of GP care for non-specific low back pain. They found that GP care alone did not appear to be the most cost-effective treatment option for low back pain. Cost-effectiveness of care was improved by referring patients for additional services such as advice and exercise or by the GP providing such services themselves. In addition, one study investigated the cost-effectiveness of guideline-based GP care and found that adding exercise and/or spinal manipulation was more cost-effective than guideline-based GP care alone.

4.2.4 Summary

There is little doubt that the management of CNMP is a difficult issue for prescribers. The problems associated with conducting research in this area make it difficult to draw conclusions about the role of opioids in the treatment of CNMP. Available evidence suggests that opioids can be effective, at least in the short and medium term, in providing symptomatic improvement in a variety of CNMP conditions. However, the efficacy and safety of opioids in the longer term is uncertain, as is the propensity for these drugs to lead to problems of tolerance, dependence and addiction. There is a plethora of interactions between factors involving pain, addiction, opioid substitution therapy, the black market for opioid pharmaceuticals, government policies and addiction. These are summarised in Figure 14.

In conclusion, however, the benefits of opioid treatment for CNMP therefore need to be balanced against burdens of long-term use, as this therapy may need to be continued for months or years (BPS, 2010).



* Sustained release oral opioids

Figure 14. Postulated steps for interaction between the different groups of people who require opioid treatment

Source: RACP (2009, p.13)

5 Good practice in benzodiazepine prescription

Benzodiazepines are primarily used for their sedative and anxiolytic effects, particularly in the treatment of anxiety, agitation and insomnia and as a premedication for medical or dental procedures. The safety profile of this drug is very high compared to its predecessors in the barbiturates family, but the risk of dependence is high and withdrawal from this medication can be protracted (RACGP, 2000). As is discussed below, there is little evidence in the literature for the benefits of long-term use of benzodiazepines.

5.1 Insomnia and use of benzodiazepines

Several prescription guidelines are available to assist prescription of benzodiazepines for insomnia. The NPS provides some such outlines but before doing so details a range of 'first line' responses to this problem (NPS, 2010a). They include:

- investigating and treating the primary causes of insomnia including psychosocial, physical and environmental stressors, medical conditions, psychiatric disorders, poor sleep practices, substance use and the use of medicines
- using non-drug therapies to manage insomnia including good sleep practices, regular daytime exercise, keeping a set sleep/wake time and a bedroom environment conducive to sleep
- discussing the benefits of non-drug management with patients and carers, and
- treating persisting sleep difficulties with at least one behavioural and cognitive therapy, such as cognitive restructuring, stimulus control, sleep hygiene techniques and relaxation training.

The guidelines suggest avoiding prescribing hypnotic medicines whenever possible. If this is not possible, a short-acting benzodiazepine (e.g. temazepam) or other related drug (zolpidem or zopiclone) should only be considered if:

- immediate short-term symptom relief is required
- sleep difficulties are expected to be short-lived (acute insomnia) and non-drug therapies cannot be implemented readily, or
- chronic insomnia has not responded to non-drug therapies alone.

The guidelines suggest that if treatment is required, then this should occur for less than two weeks and ideally intermittently (e.g. 2-5 nights per week). This is because prolonged hypnotic medicine use (for greater than four weeks), especially at high doses, increases the risk of dependence. The guidelines highlight the importance of engaging patients and carers in the limited use of these drugs at the time of the initial prescription. In particular there is a need for prescribers to check the need for and duration of hypnotic medicines initiated during hospital admission and in aged care facilities. This treatment is usually intended to be short-term and should be ceased.

For patients already on longer term benzodiazepine treatment, the NPS guidelines suggest actively pursuing discontinuation. This is because these medicines have the potential to cause harm and stopping their use improves alertness, cognition and sleep quality. Older people in particular are at greater risk of adverse effects including memory impairment, falls, fractures and motor vehicle accidents.

5.2 Anxiety and use of benzodiazepines

Generally, international guidelines recommend that benzodiazepines are used for short periods (less than four weeks) and only for severe distress, unless the patient is dependent in which case management of the dependence by initially continuing prescription and then gradual withdrawal by dose reduction is recommended (e.g., Department of Health (England) and the Devolved Administrations [DOHDA], 2007).

The use of psychological approaches as first line treatment prior to or in conjunction with prescribing has been recommended. There are highly effective psychological therapies

for anxiety problems, including cognitive behaviour therapy (The Australian Psychological Society [APS], 2010).

5.3 Prescribing for withdrawal

The UK drug misuse and dependence guidelines note that general good practice in withdrawal from benzodiazepines is to initially convert any sedative hypnotic to an appropriate dose of diazepam, a longer acting benzodiazepine, aiming for the lowest dose that will prevent withdrawal symptoms. Benzodiazepines can be withdrawn at a rate of between $1/10$ and $1/4$ each fortnight, depending upon patient withdrawal symptoms; at each dose reduction, the dose should be maintained until withdrawal symptoms improve (DOHDA, 2007).

5.4 Use of benzodiazepines in opiate dependent patients

Some caution has been recommended when prescribing for people using other drugs, including illicit opioids. Most illicit drug users do not require long-term replacement prescribing or in high doses (more than 30mg) (DOHDA, 2007). Benzodiazepine use among OST patients, especially those being prescribed methadone, has been associated with increased harms, respiratory depression, greater subjective effects and impaired memory (Lintzeris & Nielsen, 2009).

Lintzeris & Nielsen (2009) recommend particular caution in prescribing benzodiazepines among people in OST, especially those who have current or previous benzodiazepine-related problems, and those with conditions that increase the vulnerability to benzodiazepine-opioid interactions, including cognitive or memory impairment, respiratory depression, those using other sedatives and those with reduced hepatic clearance for example, patients with cirrhosis and the elderly.

6 Medication shopping

In contrast to the section above that addressed challenges confronting prescribers in relation to the appropriate use of prescribed pharmaceuticals, this section addresses consumer behaviours. One of the most overt and problematic manifestations of consumer demand for pharmaceutical products is in the form of ‘doctor shopping’ or more precisely ‘medication shopping’. While not all issues of relevance to consumers stem from medication shopping, this is nonetheless an important area, and other aspects of the consumer perspective will be addressed later.

6.1 A note on terminology

Many terms have been used to describe people who ‘shop around’ in order to obtain large quantities of medication, including traditionally ‘doctor shoppers’ and more recently ‘prescription shoppers’. These are people who visit several prescribers with the aim of obtaining multiple prescriptions in quantities greater than their therapeutic need. The drugs may be for personal use and/or diverted onto the illicit drug market. More specifically, Medicare Australia uses the term ‘prescription shopper’ to refer to someone who has seen six or more prescribers in a three month period, a total of 25 or more target PBS items and/or 50 or more PBS items (Medicare Australia, 2011).

In this review we have replaced the terms ‘doctor shopping’ and ‘prescription shopping’ with **medication shopping** to apply to a broader range of behaviours for a number of reasons.

First, OTC codeine products have recently come into focus as a public health issue, with many people using these products and many of those intentionally or unintentionally over-using or abusing these drugs (Nielsen, Cameron, & Pahoki, 2010). The term ‘prescription shopping’ limits the focus to those medicines available on prescription, but

in Australia, OTC medications are vulnerable to misuse in a similar way to prescription drugs.

Second, we have used a quality use of medicines²² framework in this review and the term 'medication shopping' both broadens and shifts the focus of pharmaceutical drug misuse away from either the prescriber or the user to the appropriate use of medication itself.

Third, there is an increasing number of professionals who are able to prescribe medications, beyond medical doctors. New prescribing rights by nurse practitioners and allied health professionals, such as dentists and podiatrists, have broadened range of strategies required in the quality use of medicines.

6.2 Evidence concerning medication shopping

Relatively large numbers of people have been identified as prescription shoppers. In 2005-6 there were close to 55,000 individuals²³ identified as prescription shoppers by Medicare Australia (as cited in Dobbin, 2011, p.9).

Medication shoppers account for significant proportions of all prescriptions filled on the PBS. In a submission to the Drugs and Crime Prevention Committee (DCPC) Parliamentary Inquiry into the Use of Benzodiazepines and other Drugs (DCPC, 2007), Dobbin, using unpublished data from the PBS, noted that between 5% and 20% of all prescribed codeine preparations, and between 4% and 16% of all prescribed benzodiazepine preparations, were prescribed to people who had been identified as 'prescription shoppers'.

²² Quality use of medicines is one of the main objectives of the Australian National Medicines Policy and includes: selecting management options wisely, choosing suitable medicines if a medicine is considered necessary and using medicines safely and effectively.

²³ It is important to note that this figure includes people who exceed the thresholds set by Medicare Australia but whose medicine usage is clinically appropriate.

In 2007, the medications most commonly prescribed to those on the prescription shopping program were diazepam 5 mg tablets (227,203 prescriptions supplied) and codeine phosphate paracetamol 30 mg / 500 mg (224,070 prescriptions supplied) (DCPC, 2007). The number of prescription shoppers identified on the program increased between 2003 and 2005 and the numbers of supplies to those on the program reduced by about 10% over that time (DCPC, 2007).

Unfortunately these data are now more than four years old. More recent data does not seem to be readily available. A lack of published data hinders the ability to monitor and respond to the situation.

6.3 Reasons for and methods of medication shopping

These medications are sought for a range of reasons, including self-medication of pain, heroin or other drug withdrawal, anxiety and depression, for their psychoactive effects or for financial reasons.

Fountain, Griffiths, Farrell, Gossop and Strang (1998) and others have identified a number of ways in which medication seekers obtain multiple prescriptions. These included: exaggerating dependency or other symptoms; gaining sympathy; bargaining; feigning dependence; presenting to prescribers where they are not known; using altered or stolen prescriptions; and acquisition from family and friends.

Thompson, Harney and Lee (2008) reported that a common strategy used by illicit drug users to obtain larger than required amounts of codeine products was 'pharmacy shopping'. Many respondents also noted that they often ask family or friends to purchase OTC codeine products on their behalf.

There is some evidence to suggest that many people misuse OTC medications unintentionally (Nielsen et al., 2010) and lack of control over the distribution and poor

education of users of these medications may lead to users inadvertently consuming more medication or for longer periods than recommended.

6.4 The Medicare Australia Prescription Shopping Program

The Medicare Australia Prescription Shopping Program is designed to identify those who are obtaining pharmaceuticals in excess of medical need. As discussed above it defines prescription shoppers as anyone within any three month period that has had supplied to them PBS items prescribed by six or more different prescribers (including nurse practitioners and midwives but excluding specialists and consultant physicians) and/or a total of 25 or more target PBS items and/or a total of 50 or more PBS items (Medicare Australia, 2011). The Program can then contact and disclose some details to the prescriber if their patient has been identified under the Program. The Medicare Australia's Prescription Shopping Information Service has also been set up for prescribers who, once registered with the scheme, can call a hotline to find out if their patient has been identified under the Program and receive information about the amount and type of PBS recently supplied to that patient.

The Program has a number of limitations. Some of these are similar to the limitations that apply to PBS data more generally, namely:

- that data is only collected on medications which are eligible for a PBS benefit and where the pharmacist requires re-imburement from the PBS²⁴
- this system will not detect those visiting multiple pharmacies for over the counter codeine preparations

²⁴ These data do not include those who are receiving non-PBS medications (including private prescriptions and those administered by other bodies, such as Transport Accident Commission (TAC) and Department of Veterans Affairs (DVA), or medicines below the cost of PBS subsidies. It also does not capture those who may be using multiple identities or Medicare cards.

- the threshold to meet the HIC prescription shopping criteria is high and potentially means that many people at risk because of over, or improper, use of medication are not captured by these data
- the data is collected retrospectively
- there is a lag time after the data is available during which the data is analysed and
- prescribers must be registered to use the system and pharmacists cannot use it at all.

The limitations of the Medicare Australia Prescription Shopping Program were brought into stark relief by the findings of a 2007 Victorian Coronial Investigation into the death of a 32 year old woman. The death occurred as a result of an overdose of a range of pharmaceutical drugs including morphine. Between December 2003 and September 2005 the deceased had received approximately 400 prescriptions for 27 different drugs. Added to this were a further 600 repeat prescriptions. On the 25th of January 2006, a decision was made to conduct an intervention in relation to the deceased under the Prescription Shopping Program. One of her prescribers was contacted in this regard on the 31st of January 2006. This was five months after she had died from an overdose (State Coroner Victoria, 2007).

Previously, the PBS data for the Prescription Shopping Program was compiled quarterly. Prescribers were only able to obtain information about prescription shopping that occurred in the current (unfinished) quarter or in the latest (finished) quarter. More recently the data is compiled on a rolling quarter basis and prescribers can obtain information about the medication usage of their patients over the preceding three months. While this is an improvement, it falls well short of 'real time' monitoring and, as discussed above, only includes PBS-subsidised medicines.

6.4.1 Medication shopping online

The extent of medication shopping via local and overseas online pharmacies is unknown (Nielsen & Barratt, 2009) nor are the types of drugs purchased through these pharmacies known (St George, Emmanuel, & Middleton, 2004). Letkiewicz and Górski (2010) reported that approximately 10% of pharmaceuticals worldwide are sold online, but how much of this is through legitimate pharmacies compared with 'rogue' websites is unclear and how much is for medication misuse is also unknown. Although prescription drugs are easily accessible through legitimate vendor websites, 'rogue' non-prescription websites have been difficult to control (Nielsen & Barratt, 2009) and there has been little real-time monitoring of online prescriptions.

In a qualitative study of benzodiazepine use among illicit drug users (Thomson et al., 2008), online pharmacies were reported as a source of OTC codeine products, but many respondents were concerned about the potential recording of their purchases and the 'trail' they may leave, and reported that they did not frequently use this source of supply for medication shopping. Monitoring may therefore provide a potentially important deterrent to illegitimate pharmaceutical use.

While online pharmacies are a relatively small component of the current pharmaceuticals market and are unlikely to overtake traditional sources of medication supply in Australia in the immediate future, the existence of overseas online pharmacies, such as those based in Mexico and Thailand, raise important issues at the consumer level about access and quality. The ease with which these pharmacies, even the legitimate ones, are susceptible to medication shopping is unclear.

In addition, consumers may not be aware of the caution required when purchasing from online pharmacies and, with the absence of face-to-face advice through a pharmacist may be putting themselves at risk. Ivanitskaya et al. (2010) showed that even young university students in the US, a group considered well educated and literate, were

generally poor at identifying danger signs and were easily misled by the professional appearance of websites selling pharmaceuticals online.

The monitoring and regulation of these pharmacies can be complex and needs to involve a range of organisations working together, including local and federal police, customs and Australia Post and other mail carriers (Nicholas, in press).

Australia has a well-developed range of mechanisms which control the sale and supply of pharmaceuticals. Online pharmacies, however, are subject to the laws of the countries in which they are based. In the US, a study of online pharmacies found that 97% of them appeared to operate outside compliance with American state and federal laws, or established patient safety and pharmacy practice standards, 93% did not require a valid prescription, 25% did not secure patients' personal information and 61% offered foreign drugs which are not approved by the US Food and Drug Administration (FDA), and which according to federal law are not legal to sell in the US (National Association of Boards of Pharmacy [NABP®], 2008).

Just as technology plays an increasingly important role in drug acquisition, Nielsen and Barratt (2009) noted that it can also be used to enhance the monitoring and prevention of prescription drug misuse.

7 Responses

7.1 Introduction

This section outlines a range of potential response strategies that could be employed to address issues related to the misuse of pharmaceuticals. Some of these strategies have already been given consideration and have been applied in part. Others have yet to be fully examined and/or implemented. Whichever strategies are employed to address this issue, it is clear that no single response strategy will suffice. What is required is a comprehensive array of preventive strategies that are well thought through and inter-related.

As indicated previously, the NPDMS will be informed by Australia's approach to quality use of medicines and the broader National Medicines Policy. An effective strategy is likely to require contributions from consumers, practitioners, providers and educators, the medicines industry and governments.

Six main areas are addressed below:

1. infrastructure, research monitoring and systems issues
2. clinical responses
3. workforce development responses, including guidelines
4. consumer responses, including health literacy
5. harm reduction issues
6. technological responses
7. market forces and commercial aspects issues.

This is a non-exhaustive indicative list of some of the issues that need to be addressed in a comprehensive preventive response.

7.2 Infrastructure, research monitoring and systems issues

7.2.1 Prescription monitoring programs/coordinated medication management systems

As discussed earlier, there are major gaps in Australia's capacity to monitor the prescription and dispensing of Schedule 4 and Schedule 8 pharmaceutical drugs. This is because:

- existing monitoring systems cannot identify and track opioid prescriptions to the individual patient level and
- the regulation of pharmaceutical opioids varies between jurisdictions, which impedes the implementation of strategies to deal with problematic opioid use, and facilitates individuals seeking these drugs across state/territory borders.

In addition, inadequate monitoring systems make fraudulent presentations for opioid prescriptions difficult to identify and respond to in health settings (e.g. general practice, community pharmacies and emergency departments) (RACP, 2009).

Prescription monitoring programs (PMPs) or coordinated medication management systems (CMMS) are surveillance systems that record prescription and/or dispensing details of defined prescription drugs. They are either paper-based, or increasingly electronic and real time data-monitoring processes. They are designed to identify irregularities in agreed treatment (such as excessive prescription amounts or early repeat dispensing and medication shopping). They are used as a basis for implementing investigation and/or enforcement measures (Fischer, Bibby, & Bouchard, 2010).

Dobbin (2010) described the four generations of PMPs.

1. The first generation involves inspection by regulatory authorities of copies of filled prescriptions retained at pharmacies.

2. The second generation involves paper-based collation of prescriptions sent from pharmacies to a centralised point to be analysed by regulatory staff, and decisions are made about the need to communicate with prescribers and/or pharmacists about problematic patients or prescribers.
3. The third generation involves the electronic transmission of prescription information but not in real time.
4. The fourth generation is best described as a CMMS as it is far more comprehensive and involves the instantaneous or real-time transmission of prescription information to prescribers, pharmacists and regulators and has a QUM focus. It is also important that this approach is underpinned by a sound regulatory framework.

One of the problems with first, second and third generation PMPs is the ability of regulatory staff to deal with the volume of prescriptions and the time delay in identifying problematic prescribing or drug-seeking.

Most Australian jurisdictions utilise first, second and third generation PMPs, with Tasmania moving towards finalisation of a fourth generation CMMS at the time of writing.

In assessing the efficacy of PMPs/CMMS it is essential to be mindful of which generation of PMPs is being considered; as Dobbin (2010) noted, each generation of PMP is more effective than its predecessor. The third generation of PMPs, for example, is less effective than the CMMS as:

- it only provides a historical perspective of prescriptions filled
- it has less ability to identify individuals
- the responsibility to notify practitioners lies with regulators who may not have sufficient information or resources to hand, or appropriate criteria to do so effectively, and

- it does not provide immediate access to information which would allow prescribers and pharmacists to make safer, better informed decisions.

Dobbin (2010) has also pointed out that the second generation of PMPs has all of the disadvantages of the third, including the cost of data entry into electronic spreadsheets from paper copies of prescriptions. In addition there are further problems. The evaluations of the second generation of PMPs suggest that they can actually lead to less appropriate prescribing and substitution of less appropriate drugs in place of those which are covered by the PMP. This may occur where prescribers are more aware that each prescription may be scrutinised, and they may be exposed to censure concerning their prescribing practices as a result of increased prescription monitoring. Second generation PMPs do not provide any immediate additional information about their patients upon which to base prescribing decisions.

It is important to note that most evaluations of PMPs discussed here emanate from the United States (US) and involve the second generation of PMPs; hence, what follows needs to be seen in that context.

The impetus for improved prescription monitoring derives in part from an imbalance between the onus of responsibility placed on prescribers to prescribe appropriately and the extent to which they are provided with the tools to do so. A similar level of regulation applies to the whole supply chain for prescription drugs. Drug manufacturers, distributors, prescribers and dispensers are highly regulated and are accountable under the law and/or under their professional codes of practice. Consumers, on the other hand, are free to obtain prescriptions from any prescriber and have them filled at any pharmacy. They can also change prescribers and/or pharmacies at will. Without centralised monitoring processes it is impossible to identify which patient has acquired what medication, from which pharmacy and under the authority of which prescriber. Drug seekers can exploit any resultant lack of integration of information in order to obtain quantities of drugs from different providers that no single doctor or pharmacist would allow (Brushwood, 2003).

Prescription monitoring programs and CMMS aim to redress this regulatory imbalance by providing information to health practitioners and regulators that is designed to reduce the possibility of consumers obtaining more medication than is medically required.

Effective and safe PMPs/CMMS are a necessary part of responses to problematic pharmaceutical drug misuse. To be considered effective, these programs must actually reduce problematic misuse of pharmaceuticals. To be considered safe, the programs must avoid unintended adverse consequences. Such adverse consequences could include invasion of patient privacy, or interference with legitimate medical use of pharmaceuticals for the treatment of pain or other pathological conditions (Brushwood, 2003). As with most aspects of responses to problematic pharmaceutical drug misuse, achieving a balance between safety and effectiveness is critical.

Australia already has in place jurisdictionally-based PMPs which track prescriptions for Schedule 8 drugs. Unfortunately, there is a lack of uniformity in the monitoring of these drugs across jurisdictions and in most jurisdictions it does not generally take place in real time. There is also a paucity of data sharing between jurisdictions. The only common link occurs in the collation of Pharmaceutical Benefits Scheme (PBS) data, and this is only a subset of all prescription medication in Australia (although it undoubtedly is the majority of medication dispensed).

Prescription monitoring programs have been widely implemented in the US. As of June 2010, 42 of the US states had promulgated laws authorising the establishment of PMPs, and 33 states had implemented them. In the US, PMPs are most commonly operated by state boards of pharmacy (14 out of 33), but in some states they are operated by health, law enforcement, consumer protection, or attorney-general agencies (Blumenschein, Fink, Freeman, James, et al., 2010). States with PMPs also differ in the ways in which they identify and investigate cases (Simeone & Holland, 2006). Some states have reactive PMPs which generate reports only in response to a specific inquiry made by a prescriber, dispenser, or other party with appropriate authority. Others have proactive PMPs which identify and investigate cases, generating unsolicited reports whenever

suspicious behaviour is detected. States also differ in their scope of medication coverage; at one extreme including only Schedule II drugs and, at the other extreme, including Schedule II-V drugs.²⁵ Blumenschein, Fink, Freeman, James, et al. (2010) reported that different states also have very different thresholds that trigger unsolicited reports. States with proactive PMPs also tend to be more law enforcement-oriented in their approach to prescription drug problems (Simeone & Holland, 2006).

In 2005, the US Government passed the National All Schedules Prescription Electronic Reporting (NASPER) system which provided for establishment of a controlled substance monitoring program in each US state, with communication between state programs.

NASPER is intended to provide:

- doctors and pharmacists with access to monitoring programs
- monitoring of (US) schedule II to IV drugs, and
- information sharing across state lines (Manchikanti, 2007).

However, NASPER did not receive funding until 2009 (Blumenschein, Fink, Freeman, James, et al., 2010). In addition, NASPER does not ensure that collected information would be available to doctors at the time of treating patients. Finally, NASPER does not ensure that the authority to monitor prescribing is given to agencies responsible for health, rather than law enforcement (Fishman, 2006).

Of the 33 US states that have PMPs, 19 have laws that impose no expectation on practitioners to access the PMP prior to prescribing or dispensing controlled drugs. These laws provide immunity from liability for accessing, or failing to access, prescription information contained in the PMP.

²⁵ This refers to the US, not the Australian, scheduling system. Under the US scheduling system, Schedule II drugs are those which have a high potential for misuse and includes OxyContin® (slow release oxycodone) and Percocet® (oxycodone and paracetamol). Schedule III drugs have a misuse potential that is less than for Schedule II drugs and include Vicodin® (hydrocodone and paracetamol). Schedule IV drugs have a lower misuse potential again and include those from the benzodiazepine group (Valium®, Xanax®, Rohypnol® etc.).

The average cost of implementing a PMP in the US has been approximately \$350,000 per state with annual operating costs estimated to range from \$US100,000 to \$US1million. Most states with active PMPs have employed external providers to collect prescription drug information from pharmacies. This is then transmitted to the centralised PMP. For most states, dispensers are required to provide prescription data to the PMP every 7-14 days. Thus, with a lag time of up to 14 days, this is not real-time monitoring (Blumenschein, Fink, Freeman, Kirsh, et al., 2010), and cannot be regarded as CMMS.

The US National Drug Intelligence Center (2009) reported that the introduction of PMPs has reduced the diversion of controlled prescription drugs by reducing the level of prescription shopping. Likewise in their 2006 evaluation of US PMPs. Simeone and Holland (2006) found that:

- the presence of a statewide PMP reduced per capita supply of prescription pain relievers and stimulants and this, in turn, reduced the probability of misuse of these drugs
- states that are proactive in their approach to regulation may be more effective in reducing per capita supply of prescription pain relievers and stimulants than states that are reactive in their approach to regulation
- a statistical simulation showed that (by 2003) the rate of pain reliever misuse would have been 10.1% higher and the rate of stimulant abuse would have been 4.1% higher in the absence of these proactive regulatory controls and
- analgesic misuse is higher in states that have PMPs than in states that do not have these systems (hence their implementation), but in the absence of such programs the probability of problematic use would be higher still.

Curtis et al. (2006) came to similar conclusions. They reported the existence of a 12-fold variation in benefit claims for Schedule II oral opioid analgesics between US states. They found that the presence of a statewide prescription monitoring program and the

proportion of the population aged between 15-24 years and 65 years and older were independently associated with less benefit claims for these analgesics.

In Canada, a similar situation exists with considerable inter-provincial variation in regard to levels of prescription of opioid analgesics (Morgan, Raymond, Money, & Martin, 2008, cited in Fischer et al., 2010). Provinces with PMPs in place had significantly lower rates of prescription of these drugs than those without.

The PharmaNet system in British Columbia (BC), for example, is perhaps the most comprehensive prescription monitoring system in Canada. The system is managed by the BC Ministry of Health and collects data on patient drug profiles including drugs dispensed, drug allergies, clinical conditions, patient demographics and claim information. The program has a broad application in BC, covering all drugs dispensed (not just controlled substances) and for all those on the provincial health care plan. Individual pharmacists, the colleges of physicians and pharmacists, the Ministry of Health, emergency physicians and authorised medical practitioners in private practices, hospitals and mental health facilities have access to data on PharmaNet. According to the Ministry of Health, PharmaNet prevents potential drug interactions by providing profiles of medication usage to doctors prescribing medications and pharmacists dispensing medication. The system also prevents fraud by tracking duplication of prescriptions (CAMH, 2010).

The US General Accounting Office (GAO, 2002) in its 2002 report on PMPs in the US concluded that they can be effective in reducing the misuse of these drugs. The GAO found that US states with PMPs have realised a range of benefits in their efforts to reduce drug diversion. This included improving the timeliness of law enforcement and regulatory investigations. As an example, the GAO report indicated that prior to the implementation of the PMP in Kentucky it took investigators an average of 156 days to complete investigations of an alleged doctor shopper. This dropped to 16 days after the program was established. In addition, law enforcement officials in Kentucky and other

states viewed the program as a deterrent to prescription shopping, because potential diverters are aware that any physician from whom they seek a prescription may first examine their prescription drug utilisation history based on PMP data.

The evidence is therefore strong about the influence of PMPs on the level of prescription of drugs such as opioid analgesics. It is important to note that, while the presence of prescription monitoring programs appears to lower the rate of prescription of certain drugs, this does not necessarily equate with lower rates of diversion and misuse (Fischer et al., 2010). These authors argued that if PMPs are implemented merely to reduce the level of prescription of controlled drugs monitored by the program then they clearly achieve that objective. They were, however, concerned that given the extent to which pain is undertreated in the US, merely reducing the extent of prescription of controlled drugs is at odds with the needs of the population that continues to suffer from pain. From this perspective, any claim that PMPs are successful by virtue of decreasing the number of prescriptions, should be balanced against an assessment of whether this impacts adversely on the needs of patients in pain.

Fischer et al. (2010) also pointed out that much of the diversion of these drugs occurs among families and friends of the patient to whom they are prescribed. Yet the PMPs are not able to monitor the fate of the drugs after they have been prescribed.

.... current medical practice does not control whether PPDs (psychotropic prescription drugs) dispensed to consumers in the community are consumed as prescribed or what happens with them if they are not; nor are their firmly regulated or mandated measures (e.g. legislated requirements to keep PPDs under 'lock and key' as required, for example for firearms or other dangerous goods) or controls for safe drug keeping or discarding. (p. 2066)

As discussed above, PMPs may have the unintended consequence of reducing the availability of pain and other medications for those who have a legitimate need for them.

The use of benzodiazepines and other psychoactive drugs among vulnerable populations in New York was monitored following the introduction of a PMP. It was found that as a result of the implementation of the program there was a substantial reduction in the prescription of benzodiazepines, particularly among patients with a seizure disorder (for which benzodiazepines are an effective treatment). It was concluded that, overall, the monitoring program had reduced the use of benzodiazepines among chronically ill patients for whom these drugs represent an effective treatment. In addition, many of the patients who were previously receiving these drugs did not receive any alternative pharmacological intervention (Simoni-Wastila et al., 2004). Wagner and colleagues (2003) came to similar conclusions when assessing the impact of the program on the post-hospitalisation prescription of benzodiazepines. They reported that major reductions in prescriptions occurred particularly among patients hospitalised for acute ischemic cardiac events and cancer.

A number of concerns have been raised about the impact of opioid regulation on the prescription of these drugs in the US. These included:

- the adverse impact on the legitimate prescribing of these drugs
- a tendency for doctors to 'not be bothered' to prescribe these drugs because of the extra paperwork involved or because of the fear of having the specialised prescription pads stolen
- doctors being concerned about being labelled as an over-prescriber, or feeling that drugs requiring a monitored prescription must be more dangerous and therefore their prescription should be avoided at all cost ('the chilling effect')
- patients' concerns regarding a loss of confidentiality and stigmatisation concerning having their names tracked as well as the requirement for more frequent doctor visits because of the availability of shorter-term prescriptions and
- doctors substituting alternative, less clinically appropriate, but less closely monitored drugs instead of the opioid alternatives (Fishman et al., 2004).

Blumenschein, Fink, Freeman, James, et al. (2010) cautiously concluded that it was the older, multiple-copy prescription form PMPs that had resulted in a 'chilling effect' on patients' access to pharmacological treatment in the US. This was particularly the case for patients requiring opioids for pain management and in jurisdictions in which Schedule II but not Schedule III drugs were being monitored. This suggests a substitution effect, in which prescribers switch from prescribing Schedule II to the less closely monitored Schedule III drugs. Overall, these researchers could not reach a clear consensus about whether all PMPs (in particular the more recent iterations) have an adverse effect on patients' access to pharmacologic treatment.

In their evaluation of the Kentucky PMP (the Kentucky All Schedule Prescription Electronic Reporting program, (KASPER)) Blumenschein, Fink, Freeman, Kirsh et al. (2010) found that a 'chilling effect' may have occurred soon after the program's implementation. Their review of data from multiple sources did not suggest that there has been any long term 'chilling effect', however. Rather, they found that it is more likely that the ultimate outcome of KASPER has been an increase in practitioner confidence in making prescribing and dispensing decisions when patients have a legitimate medical need. This is because the practitioners can be more assured that patients are not prescription shopping. Overall, based on their interviews and surveys of key stakeholders, their evaluation found that KASPER is an effective program. That said, it is being hampered somewhat by the relatively low uptake of the program by prescribers and pharmacists.

Several jurisdictions in the US are seeking to move towards real-time reporting. This refers to automatic, or at least daily, transmission of information at the point of dispensing. A further aim is for different states to share PMP data in order to stop problematic prescription drug users from crossing state lines to obtain and fill prescriptions (Blumenschein, Fink, Freeman, James, et al., 2010).

The potential for PMPs to have a 'chilling effect' on the appropriate prescription of controlled drugs is clearly an issue that warrants consideration in any potential expansion and improvement of PMPs in Australia. Nevertheless it is also important to recognise the important structural differences between the Australian and US contexts when assessing the implications of the North American research.

It is important to note that the evaluations of the introduction of PMPs described above essentially involved 'starting from scratch' and implementing monitoring programs where none had previously existed. Australia is not in the situation of 'starting from scratch' because it already has monitoring systems for Schedule 8 drugs in place.

Also important is the fact that the introduction of PMPs in the US has been in many cases led or instigated by the law enforcement sector. In other words, the flavour of its implementation was more likely to be influenced by a law enforcement perspective, rather than by a perspective which seeks to optimise the quality use of medicines or outcomes for patients.

Brushwood (2003) provided a series of principles for the implementation of safe and effective electronic PMPs. These are summarised below.

1. Comprehensiveness

PMPs should monitor all drugs with a propensity for misuse or over-prescription. Monitoring only a limited number of psychoactive drugs is unlikely to provide a deep understanding of the problem of pharmaceutical misuse. This would also almost inevitably lead to prescription substitution as doctors prescribe non-monitored drugs in preference to monitored drugs. The program must also be sufficiently flexible to allow program operators to also collect data on any other non-controlled medication that has also been implemented in harmful problematic use. In addition the PMP should include all pharmacies to which patients would have access. This includes mail-order Internet pharmacies and pharmacies outside of a patient's home state.

2. Expert analysis

The agency responsible for conducting electronic PMPs should have sufficient expertise to evaluate the significance of evidence that may arise from aggregated data. In other words, the host agency should be a health, rather than a law enforcement, agency. It would also be highly desirable to have an expert committee in place to periodically review both specific cases and general trends.

3. Timely and meaningful feedback

Prescription monitoring programs need to provide doctors and pharmacists with a complete record of medications provided to the patient and to do so in a timely manner. Brushwood (2003) also suggested that it would be useful to include in this record a history of patients' responses to different medications. This would not only enable the health practitioner to have ready information about patients' medication history but it would facilitate a better understanding of the impacts of medication on, for example, levels of pain.

4. Clear standards

Health care providers need to be very clear about the standards of practice against which they will be judged by regulatory authorities. Otherwise there is a likelihood of increasing risk-averse health practitioner practices. These clear standards should lead to both decreased prescribing for patients who have received too many prescription drugs in the past and increased prescribing for patients who have received too few. Patient reports transmitted to pharmacists and doctors from electronic PMPs could also include relevant clinical and regulatory guidelines for the use of the drugs, as well as the legal requirements associated with their use. Health practitioners could then compare the actual level of use by their patients with the prescribing/dispensing requirements/guidelines.

5. Periodic program review

Given that the goal of PMPs is to reduce problematic substance misuse without adversely affecting the appropriate use of those substances, then they should be continuously evaluated against this goal.

However, as Manchikanti (2007) pointed out, PMPs can only ever be part of the response to problematic pharmaceutical misuse and need to be implemented in concert with a range of other measures, in particular education programs for doctors and other prescribers, pharmacists and the public.

In summary, the evidence appears to suggest that merely monitoring the prescription of controlled drugs does reduce their prescription. Early generation PMPs risk leading to a 'chilling effect' on appropriate prescribing, or a 'substitution effect' where prescribers use alternative and potentially less appropriate medications. This is because prescription practices are monitored without being given the tools to gain a comprehensive picture of the medications their patients are taking. Coordinated medication management schemes, on the other hand, monitor the prescription practices of prescribers while providing them with real-time information on the medication use of their patients.

The implication of this for Australian jurisdictions with generation one and two PMPs is that there is little advantage to be gained in upgrading their systems to generation three PMPs. In short, the major advantages stem from upgrading to a CMMS.

There may also be some benefit in incorporating the International Statistical Classification of Diseases and Related Health Problems into the CMMS to classify the diseases and the wide range of symptoms for which these drugs are prescribed. This information could be stored in the CMMS and protected by security access and could form the basis of important research into many conditions.

Australia's capacity to monitor the prescription and supply of controlled and other medications could be enhanced by the implementation of a CMMS which is based

around the need to enhance the QUM. Such a system needs to be purpose built, provide a national perspective and be accessible on-line in real time by regulators, prescribers and pharmacists across the country. There may also be grounds for certain prescription data to be provided to law enforcement agencies in particular cases. There is also a need to ensure that the establishment of such a system does not lead to ‘chilling’ or ‘substitution’ effects and that it does not lead to the stigmatisation of patients legitimately prescribed opioids and other medications.

Prescribers’ decisions about prescribing need to be made in the context of understanding patients’ medication history, behavioural patterns and any concerns in relation to the potential for dependency problems. This substantially reduces the risks of inappropriate prescribing. It is also important to note, however, that the implementation of a national CMMS in Australia will not address all of the difficulties associated with the misuse of pharmaceutical drugs. A CMMS would need to be implemented as part of a suite of measures to address this problem.

7.2.2 Data collection and sharing processes

Accurate, reliable and comprehensive data is required to facilitate a better understanding of, and informed responses to, pharmaceutical drug misuse in Australia. Also important is data interpretation and the ability to share data among relevant agencies such as health and regulatory agencies and, where appropriate, law enforcement agencies.

7.2.3 Focussed research

Areas of research which may inform discussion regarding a number of aspects of pharmaceutical misuse in Australia include:

- the extent and nature of pharmaceutical misuse, particularly among those who do not inject their medications

- investigating the dynamics behind existing prescribing patterns to determine where prescribers could be better supported (for example in situations where prescribers may be intimidated by patients demanding medication)
- examining the extent to which the dynamics of regulatory and monitoring systems (see section 7.2 above) impact on pharmaceutical drug misuse and how this could be addressed
- examining the characteristics and needs of new cohorts of illicit pharmaceutical drug misusers and the extent to which drug treatment facilities in Australia cater for the needs of clients who primarily misuse pharmaceutical medications;
- examining the impact of the diversion of pharmaceutical drugs on illicit drug markets and on crime
- examining emerging illicit pharmaceutical drug markets, and
- examining the extent of 'off label' prescribing²⁶ and potential measures to address this.

As noted above, addressing many of these questions will require access to relevant data sources.

7.3 Potential clinical responses

An increasingly wide array of clinicians has a role to play in the safe and effective use of pharmaceuticals. Moreover, these groups also play a pivotal role in minimising the misuse of pharmaceuticals which have this potential. The scope for various professional groups to provide optimal care and safety in this area are outlined below.

Of central importance to enhancing clinical responses is, where possible, the early and clear diagnosis of conditions. An accurate and early differential diagnosis forms the

²⁶ This refers to the prescription of medications under the PBS for conditions for which they are not approved. This, again, is not in keeping with the quality use of medicines.

basis of determining appropriate clinical responses (for example, pharmacotherapy, psychological treatments, physiotherapy etc.).

The role of medical practitioners is considered in the present context first in terms of addressing what is commonly referred to as doctor shopping, or more correctly, medication shopping. It is then addressed in the context of the broader role of the medical practitioner, and, most particularly, the general practitioner, in relation to the management of a range of conditions that may involve or warrant prescription medicines with a propensity for misuse. The latter includes a wide range of conditions but most notably chronic non-malignant pain, together with other conditions such as stress, anxiety and depression.

7.3.1 The role of general practitioners

General practitioners play a crucial role in addressing the misuse of pharmaceutical medications. Reportedly, the majority of prescriptions for medication shoppers in Australia are provided by a small minority of doctors (e.g. White & Tavener, 1997). This suggests that most general practitioners prescribe appropriately. Kamien (2004) reported data from the Health Insurance Commission that indicated that half the prescriptions for doctor shoppers in Australia were written by 7.5% of GPs, the majority of whom were located within one of 10 residential postcodes. However, these data are more than seven years old and more recent data do not appear to have been published.

It has been the NSW experience, for example, that prescribers who are sole practitioners, not affiliated with any Professional College (i.e. not actively engaged in ongoing professional development programs) and who are treating opioid dependent patients over a long period of time are a group most at risk of inappropriate prescribing. Older male doctors are over represented in this at-risk group. There are a number of GPs who find it difficult to set boundaries for patients, and so are at risk of being pressured for drugs. Others have the belief that they are 'helping' or using a harm

minimisation approach by giving drug- seeking patients what they ask for. Some overlook the importance of taking a drug history and conducting a physical examination, which is necessary to establish or verify a diagnosis. Similarly, many doctors do not ask if patients have had these drugs prescribed for them before, and if so, when. These groups may benefit from continuing audit, clinical review and educative support (Lawrance, personal communication, February 9, 2011).

Ensuring a clear understanding of the regulations around prescribing of benzodiazepines and opioid medications is clearly important and mechanisms to ensure all prescribers are well informed of changes to legislation or policy are essential (Monheit, 2010). It is equally important to understand changes in the evidence base and the clinical implications particularly for high-risk drugs. As noted above, Medicare Australia monitors and responds to doctors who are over prescribing or have been unsuspectingly involved in medication shopping activities.

As well as needing to be aware of their own prescribing practices, GPs have a crucial therapeutic role in responding to patients who are medication shoppers. Early identification of medication shoppers is one important function, together with restricting the supply of prescriptions. A comprehensive assessment of, and response to, the reasons behind medication shopping is also essential. The development of appropriate responses could include:

- establishing a plan for appropriate pain management
- dependence treatment including withdrawal or
- engaging pharmacists to monitor medication diversion problems.

There are a number of guidelines that address these management issues, but skills in responding to ‘complex’ patients, particularly those who may be perceived as demanding or manipulative, is also crucial. Many chronic pain patients, for example, have personality features that may make it more difficult for them to manage their pain

(Tragesser, Bruns, & Disorbio, 2010) and cooperation of a mental health professional may also be useful (Monheit, 2010). In addition, Monheit (2010) suggests that local clinic policies that address suspected or identified medication shopping can help reduce the difficulty of saying 'no' to a potential prescription shopper and engaging them in treatment.

As discussed earlier, Monheit (2010) also suggests GPs take a 'universal precautions' approach, especially in regard to chronic pain medication prescribing.

7.3.2 The role of other prescribers

Apart from registered medical practitioners, there are a number of other professionals that have prescribing rights for S4 and S8 drugs. These include dentists, optometrists, podiatrists, nurse practitioners and most recently midwives. There has also been ongoing discussion about prescribing rights for pharmacists and psychologists but these two professions are not at present able to prescribe S4 and S8 medications.

Although 2010 saw the introduction of national health professionals' registration boards to replace state-based boards, prescribing continues to be regulated at the state level. Some of these professionals need to undertake a professional development course to upgrade their qualifications to enable them to prescribe. Some of these professionals can also apply to become PBS prescribers with specific items for that profession. Dentists have been able to prescribe specific medications for some time and are generally considered as medical prescribers. They currently prescribe a number of PBS medications, including adrenalin, high dose aspirin, some antifungals, antibiotics and analgesics such as tramadol, codeine, morphine, and oxycodone.

Nurse practitioners have had prescribing rights in many states for some time and were recently granted access to the PBS medication system, including prescription of morphine, fentanyl, buprenorphine, methadone and diazepam. Since late 2010,

midwives have been able to apply for a limited number of PBS items rights, including morphine. Podiatrists in some states have approval to prescribe a range of drugs including adrenalin, benzodiazepines, codeine and a range of anaesthetics.

Recent changes to the PBS system, and authority to prescribe more generally, are part of a wider reform of the national health care system by the current Labor government.

There has been both support of and opposition to non-medical prescribing. Concerns have been raised about reduced regulation and experience of non-medical prescribers to deal with complex health issues, prescription shoppers and aggressive patients, as well as the fragmentation of the health system.²⁷ For example, the AMA Victoria has raised concerns that Victorian podiatrists can now prescribe a number of S8 drugs without the requirement for shared care arrangements with a medical practitioner.

On the other hand, the health system is strained and the expansion of prescribing rights to professionals other than doctors may help alleviate the pressure on the system. This may be especially the case for those, like nurse practitioners, who work closely with medical practitioners and are required by Commonwealth regulation to maintain shared care arrangements with medical practitioners when prescribing PBS medications. This may potentially address some of the concerns that have been raised for other professionals.

7.3.3 The role of pharmacists

The evidence for pharmacy responses to pharmaceutical drug misuse is relatively limited. Very few documented studies or evaluations have been undertaken that address this issue. Yet, as the dispensing point for pharmaceuticals of concern, both prescription

²⁷

http://www.amavic.com.au/page/Media/Media_Releases/2009/Podiatrist_prescribing_is_a_dangerous_step_Medical_Observer_opinion_editorial/

and OTC, pharmacists have an important role in monitoring, early identification and harm reduction.

Nkansah et al. (2010) reviewed studies of the non-dispensing role of outpatient pharmacists on health outcomes and prescribing practices. They found pharmacist services reduced the incidence of therapeutic duplication and decreased the total number of medications prescribed. Most of the studies supported the role of pharmacists in medication management, counselling and health professional education and suggested that educational outreach visits by pharmacists impacted positively on physician prescribing patterns. Pharmacist interventions resulted in improvements in most clinical outcomes for patients, although not all of these were statistically significant.

However, Thompson et al. (2008), in a qualitative study of benzodiazepine treatment for illicit drug users, noted that many illicit drug users had little understanding of the therapeutic role of pharmacists and often perceived the pharmacist as merely a gatekeeper to dispensing medicines. They also identified a perceived conflict of interest between advertising 'cheap' prescriptions and the pharmacists' therapeutic role in preventing dependence. The authors noted that this perception of pharmacists among illicit drug users may serve to reduce their potential therapeutic impact with this group. Strategies to investigate and address this perception may be needed.

That said, it is also important to note that pharmacists involved in supervised dispensing play a very valuable role in safety and quality assurance. This includes observing the client actually taking the medication and ensuring that doses are not given to patients who are inebriated or otherwise affected by drugs.

There are apparent difficulties concerning the role of pharmacists in preventing medication shopping which relate to professional hierarchies. Some prescribers may not always respond positively to contact from pharmacists concerning medication shopping patients. These professional issues are also apparent in the slow uptake of the Home

Medication Review (HMR) and Domiciliary Medication Management Review (DMMR) programs. These programs, instigated by the Australian Government, facilitate specially trained and accredited pharmacists providing a written medication review for patients living at home or in residential aged care. These reviews are required to be instigated by the general practitioner and there may be some reluctance to do so. (Lawrance, personal communication, February 9, 2011).

The Doctor Shopping Project, which was managed through the Health Insurance Commission (HIC) was funded to June 2002. This involved the employment of pharmacists to counsel identified prescription shoppers. It led to a reduction in the number of doctor shoppers identified over a three year period, but no other data is available. The Doctor Shopping Project focused on a limited number of medications. It was later replaced by the Prescription Shopping Project, which encompasses all medicines on the Pharmaceutical Benefits Scheme (PBS). At that time the Australian Government was becoming increasingly concerned at the rapidly expanding costs of the PBS, especially in relation to the price of some of the new drugs coming onto the PBS. (Lawrance, personal communication, February 9, 2011).

7.3.4 The role of the specialist AOD sector

Some substance use treatment clients misuse pharmaceutical medications. Therefore both addiction medicine specialists and other drug treatment professionals have a role in monitoring and responding to those people in their care who are at risk of this misuse. There is important evidence, for example, that among illicit opioid users, medication shopping may indicate increasing risk of overdose. Martyres, Clode and Burns et al. (2004), found that among 245 people aged 15-24 years old who died from heroin overdose in Australia, there was evidence of escalating medication shopping with an increase in both number of prescriptions and number of prescribers, peaking in the year before they died. They suggested that escalating medication-seeking behaviours may operate as a clinical indicator of increasing risk among young heroin users. Therefore it

is critically important that the opportunity is taken to address pharmaceutical drug misuse problems among younger heroin users engaged with the treatment system.

However, many medication shoppers are not clients of the specialist drug and alcohol treatment system. Nonetheless, the specialist alcohol and other drug (AOD) sector has an important role to play in both the treatment of these people and to support of the GPs and others who treat them.

Bruno (2010) presented an overview of the National Survey of Drug Treatment Centres and found that pharmaceutical misusers were not significantly different in characteristics to 'traditional' illicit drug users. He suggested that drug treatment services were not currently engaging those who may have developed a dependence on their prescribed medication. As discussed earlier, it is not clear whether Australia's drug treatment services are appropriately oriented to meet the needs of misusers of pharmaceutical drugs who are not also injecting drugs users.

In addition, Dunlop (2010) noted that drug treatment services in Australia were typically designed to treat injecting drug users, or focused on specific services or drugs and suggested an important link between pain management and addiction services. He also called for potential paradigm changes to respond more effectively to patients with opioid dependence but no history of injecting.

The AOD sector are specialists in the management of dependence and have an important role to play in direct intervention and in supporting prescribers to manage dependence and withdrawal to reduce the potential for medication shopping. Reynolds (personal communication, January 19, 2011) notes that when problems arise, such as dependence, a new treatment plan is indicated. Advice from, or referral to, addiction medicine specialists for review and assistance with management may be appropriate.

7.3.5 The role of psychological therapies

Many people who eventually experience problems with pharmaceuticals of concern have been prescribed these medications for a physical or mental health issue. The use of pharmaceuticals as a first line treatment may not be warranted in many cases where effective and appropriate therapies exist.

There is substantial evidence that anxiety, depression, sleep and chronic pain problems, including headache and migraine, can be effectively treated with cognitive behaviour therapy (CBT) and other psychological approaches (Butler, Chapman, Forman, & Beck, 2006). Indeed, there is some evidence that in many cases psychological therapies are at least equivalent and sometimes superior to the use of medicines to address these issues (Butler et al., 2006) and the effects are sustained for longer (Hollin et al., 2005).

In addition, in cases where medicines are indicated, the use of psychological therapies in conjunction with medication is typically superior to either alone (e.g., Morin et al., 2009). In cases where a patient has become dependent on their prescribed medication that needs to be addressed, psychological support during withdrawal can also be beneficial. Parr, Kavanagh, Cahill, Mitchell and Young (2008), for example, in a meta-analytic review, showed that combining psychological treatment with gradual dose reduction was superior to gradual dose reduction alone.

For less severe problems, brief psychological therapies delivered by a medical practitioner are effective. For moderate to severe problems, longer therapy by a medical or psychological practitioners may be needed (National Institute for Health and Clinical Excellence [NICE], 2009).

The widespread use of psychological therapies is hampered by a number of issues including:

- lack of access to suitable therapists – many specialist psychologists have long waiting lists
- the cost of the therapist – the rebate from Medicare for psychological practice does not usually cover practice costs, especially for metropolitan practitioners where room costs can be high so many practitioners are not able to bulk bill (O'Kelly, 2009)
- Medicare allows up to 12 psychological sessions in blocks of six and under certain circumstances up to 18 consultations per calendar year (Department of Health and Ageing, 2009)
- a lack of time in general practice to both undertake a thorough assessment of complex issues or deliver brief interventions, and
- the stigma associated with mental health issues and the negative beliefs about help seeking (Schomerus & Angermeyer, 2008; Wilson, Rickwood, Ciarrochi, & Deane, 2002).

The availability of referral options is crucial if medical practitioners are expected to make referrals and encourage patients to use psychological interventions. Lack of resources and long waiting lists prevent effective early intervention, with services inevitably providing services for the most complex and chronic conditions.

With the recent changes to Medicare to improve access to psychologists and other health professionals for mental health issues, as well as recent increases in the number of nurse practitioners, there is a greater opportunity to access psychological intervention. Nevertheless, the services are not well coordinated with both doctors and the referral agencies generally operating as independent small businesses.

In addition, patients may be unwilling to go to the effort required to make and keep an appointment when medication is perceived as a faster solution to the problem. Motivation for treatment can fluctuate markedly and many patients drop out of the system between getting a referral from the GP and attending the psychological therapy.

General practitioners can be very influential in advising patients about their options and may be able to use this influence to encourage them to view psychological intervention as the first line or additional treatment to medication.

7.3.6 Collaborative care models

Although various attempts have been made in Australia to establish formalised collaborative and shared care models to-date these appear to operate in an ad hoc and sporadic fashion. In spite of the evidence base supporting and indicating the value of shared care arrangements, many factors act as impediments. To achieve any significant progress in this area, this issue will need to be addressed and appropriate and logistically feasible models of multidisciplinary care developed.

7.3.7 Impediments to multidisciplinary care

It has been noted that strong forces operate to discourage the thorough assessment, multi-disciplinary care and biopsychosocial framework needed for optimal management of patients with chronic pain (Wodak, Cohen, Dobbin, Hallinan, & Osborn, 2010). Factors that operate as impediments include the traditional biomedical model, Medicare funding arrangements that favour brief consultations while requiring complex and frustrating paperwork to be completed to facilitate patient access to even minimal allied health services (Wodak et al., 2010).

7.4 Workforce development responses, including guidelines

The National Drug Strategy 2010–2015 places considerable emphasis on the development and maintenance of an appropriately skilled and qualified workforce to prevent and respond to alcohol and other drug use problems. The Strategy is committed to addressing a range of factors affecting the ability of the workforce to function with maximum effectiveness. A number of these factors have already been identified (see

Roche & Pidd, 2010). As was discussed earlier, the current iteration of the Strategy also places increased emphasis on responding to pharmaceutical drug misuse problems. Consequently, enhancing the ability of human service providers to respond to problems associated with the misuse of pharmaceutical drugs may be a priority area for activity in the future.

7.4.1 Diffusion of innovation

Given that there appears to be a significant evidence/practice gap in the prescription of drugs such as opioids and benzodiazepines, this gives rise to consideration of what measures could be introduced to enhance the quality use of these medications.

A large literature exists concerning factors which influence the diffusion of innovation in clinical settings. In seminal work in this area, Greenhalgh, Robert, MacFarlane, Bate and Kyriakidou (2004) developed two models of a range of factors which influence change in this area. The first describes different conceptual and theoretical bases for the spread of innovation particularly among human service providers.

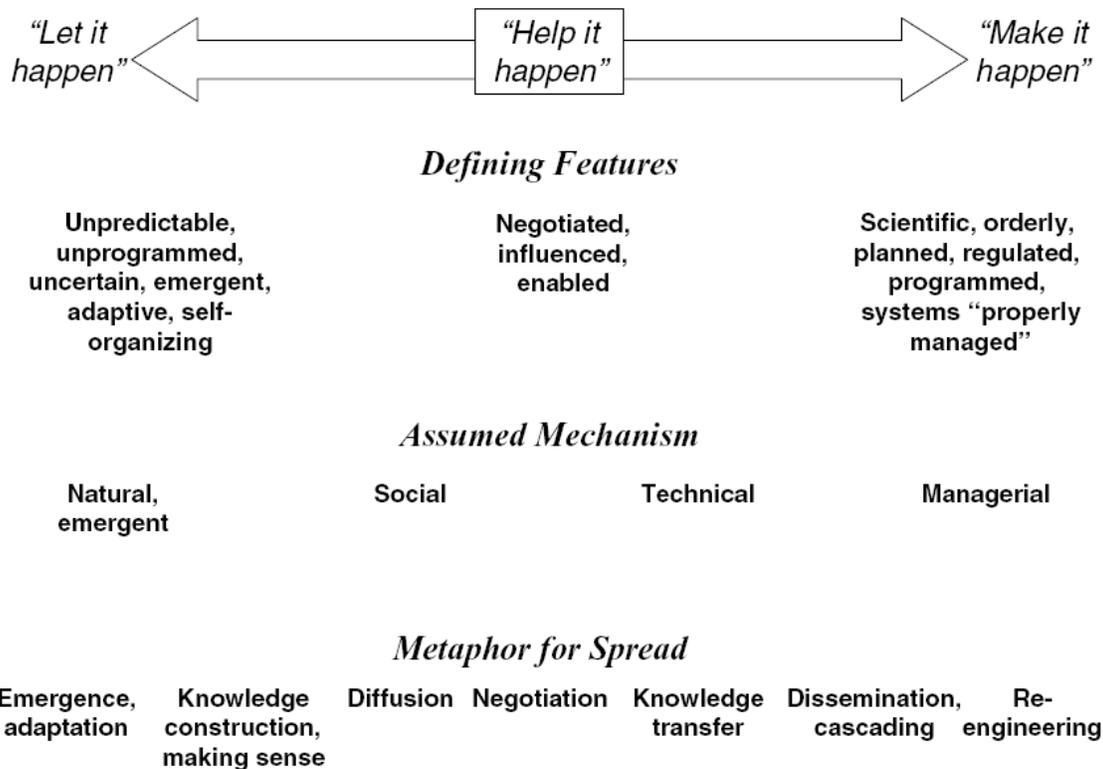


Figure 15. Different conceptual and theoretical bases for the spread of innovation among human service providers

Source: Greenhalgh et al. (2004, p. 593)

As Figure 15 suggests, innovation occurs on a continuum between ‘letting it happen’ ‘helping it happen’ and ‘making it happen’. Each point on this continuum has its own defining features, assumed mechanism and metaphor for spreading innovation.

Following their extensive literature review, Greenhalgh et al. (2004) proposed a complex model for considering the determinants of diffusion, dissemination and implementation of innovations in health service delivery (see Figure 16). The model takes into consideration a wide range of factors that impact upon these processes. Some of the more important issues are discussed below.

Innovations are more likely to be diffused, disseminated and implemented if they:

- have clear, unambiguous effectiveness, or cost effectiveness, advantages over existing practice
- are compatible with the intended adopters' values, norms and perceived norms
- are perceived by key players as being simple to use
- can be trialled before full implementation
- have clearly observable benefits (such as the use of demonstrations)
- can be adapted, refined or otherwise modified to suit the users' specific needs
- have 'fuzzy boundaries' surrounding a 'hard core' of innovation²⁸
- have a required knowledge base that can be codified and transferred from one context to another, and
- have technologies that come with customisation, training and a help desk.

Innovations are more likely to be implemented and routinised if:

- organisations have structured and processes that support devolved decision making
- they have leadership support which supports and advocates for the implementation process
- practitioners have a sufficient level of motivation, capacity and competence
- there is dedicated and ongoing funding for their implementation
- there is effective communication across structural boundaries
- there are strong networks in place within organisations or practice settings
- there is accurate and timely feedback about the impact of the implementation process, and
- if they are adapted to the local environment.

²⁸ This refers to innovations which have a hard core (or the irreducible elements of the innovation itself) accompanied by a fuzzy boundary (which is the adaptability of the organisational structures and systems required to implement them).

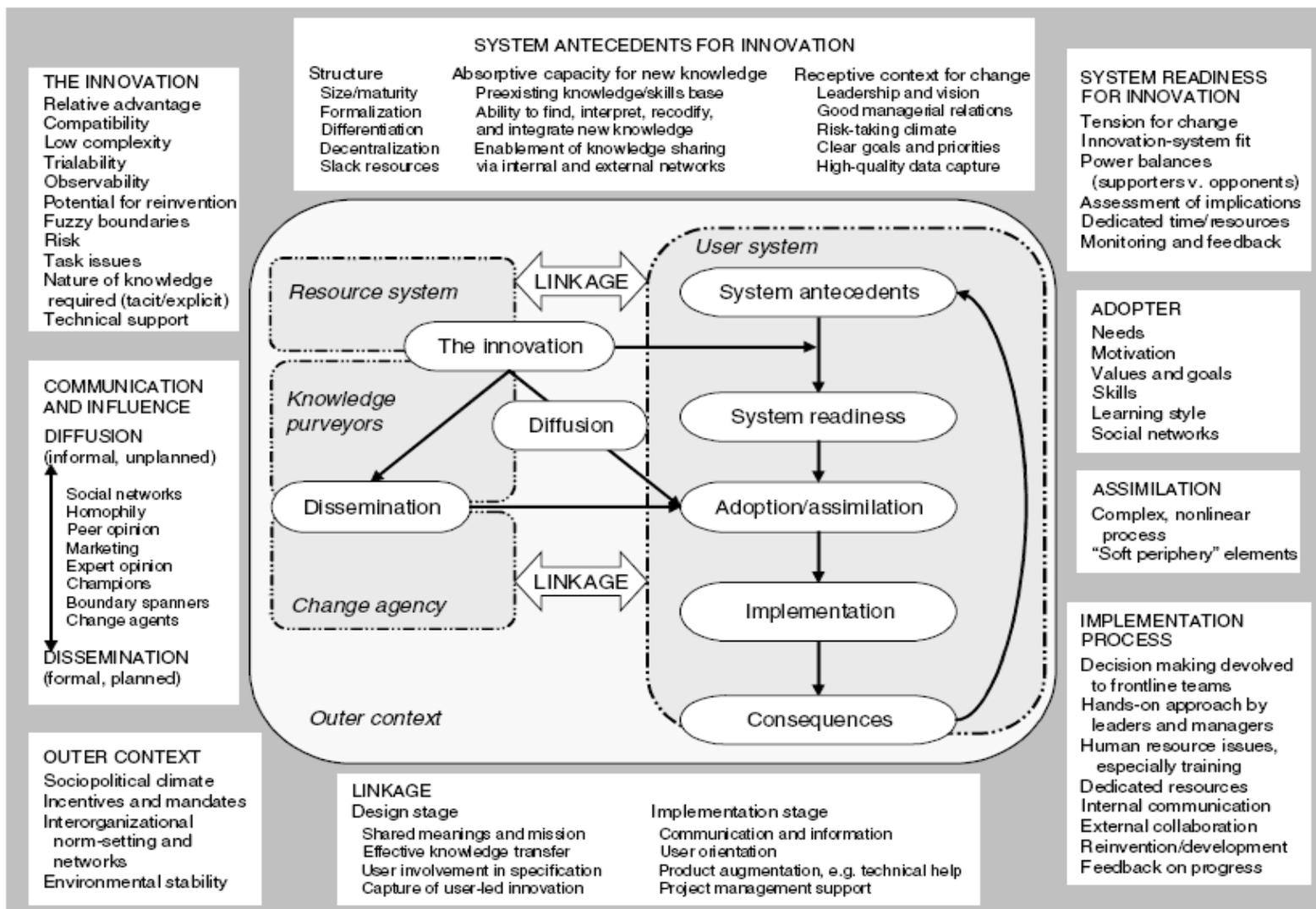


Figure 16: Conceptual model for considering the determinants of diffusion, dissemination, and implementation of innovations in health service delivery and organization, based on a systematic review of empirical research studies

Source: Greenhalgh et al. (2004, p.593)

7.4.2 Workforce development responses to improve prescribing practices

There is a range of workforce development measures that could be implemented to improve prescribing practices. These include education and training programs, clinical mentoring and supervision and systems-based approaches focussing on:

- the need for the adoption of universal precautions in the prescription of opioids and benzodiazepines
- the potentially (but not necessarily) inter-related problems of drug dependence and pain management
- the availability of, and referral pathways into, specialist pain and drug treatment facilities
- the current evidence base concerning the use of pharmacotherapy for conditions such as anxiety, insomnia and CNMP and ways to enhance the use of non-pharmacological approaches
- good practice in managing pain among opioid dependent individuals and those with a history of illicit drug use, and
- responding appropriately to difficult medication-demanding patients.

A range of workforce development strategies was examined to ascertain approaches that demonstrated efficacy and potential applicability in this area. A selection of strategies with proven evidence is outlined below.

There have been a number of Cochrane Reviews examining the effectiveness of various methods of increasing the uptake of evidence-based medicine among medical practitioners and others. In general, the quality of the studies included in the reviews was variable and few had resulted in large changes in practitioner behaviour. Nonetheless, there were some strategies that may be useful in modifying prescribing behaviours, showing small to moderate practitioner change.

To achieve this, changes are required in professional education and training but also in mentoring systems, service delivery systems, referral pathways and reimbursement regimes. Also important is the development, dissemination and application of clinical guidelines. Appropriate guidelines need to be developed with cognisance of the complexity and levels of demands associated with the working environment of the practitioners.

7.4.2.1 Audit and feedback

The use of audit and feedback is a common tool for medical practitioner professional development and appears to improve good practice, especially when baseline adherence is low (Bywood, Lunnay, & Roche, 2008; Jamtvedt, Young, Kristofferson, O'Brien, & Oxman, 2010), offering a potentially effective intervention for those small number of practitioners who have been identified as prescribing inappropriately. Hysong et al. (2006) found that audit and feedback outcomes (i.e. changes to practice) are enhanced when the feedback is actionable, timely, individualised, non-punitive and customised to the person undergoing audit. Audit and feedback could be used as a 'remedial' solution to identify over-prescribing among medical and non-medical prescribers as well as a preventative option.

7.4.2.2 Educational outreach

Educational outreach visits, another common tool in medical practitioner development, alone or with other interventions, shows consistent, although small, improvements, particularly in prescribing practices. Interventions that include educational outreach visits appear to be superior to audit and feedback (O'Brien et al., 2008) and offer another avenue to change practitioner behaviour among those who have been identified as prescribing to medication shoppers.

7.4.2.3 Educational meetings

Educational meetings (such as workshops, grand rounds and seminars) appear to have a small effect on changing professional practice. These were equivalent to those effects seen for audit and feedback or educational outreach visits. Educational meetings did not appear to be effective for complex behaviours compared with less complex behaviours or for clinical practices which could have less serious outcomes for patients, compared with those that could have more serious outcomes (Forsetlund et al., 2009).

7.4.2.4 Clinical guidelines

The first issue in relation to clinical guidelines concerns their development. It is essential that clinical guidelines are evidence-based. Consequently, there are international standards available to assist with their development. Perhaps the most well known and widely utilised of these is the Scottish Intercollegiate Guidelines Network (SIGN). The *SIGN50 Guideline Development Handbook* (SIGN, 2008) contains a detailed description of the processes to be used in the development of clinical guidelines. It includes such factors as:

- the selection of guideline topics
- the involvement of patients
- the composition and responsibilities of the guideline development group
- the processes for conducting literature reviews
- forming guideline recommendations
- consultation and peer review, and
- guideline presentation, dissemination and implementation.

Likewise, the Appraisal of Guidelines, Research and Evaluation (AGREE) Collaboration (with which the *SIGN50 Guideline Development Handbook* is entirely consistent) is also a useful tool to develop clinical guidelines. The AGREE collaboration is an international

group of researchers from 13 countries which developed and validated a generic instrument that can be used to appraise the quality of clinical guidelines. The AGREE instrument is designed to assess the process of guideline development and how well this process is reported. It does, however, not assess the clinical content of the guideline nor the quality of evidence that underpins the recommendations (The AGREE Collaboration, 2003).

Over the past two years a number of guidelines regarding good practice in the use of opioids for CNMP and benzodiazepines for anxiety and insomnia have been developed by professional organisations and other groups worldwide. Many of these have been outlined earlier in this literature review.²⁹

The RACP (2009) noted that historically guidelines of this type have only had limited influence in clinical practice. Wodak et al. (2010) came to similar conclusions. Similarly, while a number of guidelines exist, none was designed for practical use in the busy front line of general practice. It is increasingly argued that guidelines are only one component of a comprehensive strategy to reduce the risks associated with opioid prescribing (Wodak et al., 2010).

Cabana et al. (1999) examined barriers to uptake of guidelines by practitioners in 76 articles on the topic. They grouped barriers into: lack of awareness, lack of familiarity,

²⁹ There are a number of existing guidelines to assist prescribers to manage prescriptions of pharmaceutical medicines such as benzodiazepines and opioids, and the treatment of dependence, including:

- Royal Australian College of General Practitioners (RACGP) web-based guidelines www.racgp.org.au/guidelines/benzodiazepines
- The National Health and Medical Research Council (NHMRC) Guidelines for the Prevention and Management of Benzodiazepine Dependence (NHRMC, 1991)
- Reconnexion guidelines (www.reconnexion.org.au). Step by Step Guide to Reducing from Benzodiazepines and Recovery from Withdrawal (for service users), and Benzodiazepine Reduction Guidelines for General Practitioners
- Turning Point Alcohol and Drug Centre's Clinical Treatment Guidelines for Alcohol and Drug Clinicians, Prescribing for Withdrawal (Murray, Lintzeris, Gijsbers, & Dunlop, 2002)
- UK Maudsley guidelines (Taylor, Paton, & Kerwin, 2005), for service providers
- British Association for Psychopharmacology's evidence-based guidelines for the pharmacological management of substance misuse (Lingford-Hughes, Welch, & Nutt, 2004).

lack of agreement, lack of self efficacy, lack of outcome expectancy, inertia of previous practice, external barriers (e.g. time, patient preference).

Lack of familiarity was more common than lack of awareness although in 78% of cases more than 10% of practitioners were unaware that guidelines existed. The authors did not consider lack of agreement to be a common barrier but lack of self-efficacy and lack of outcome expectancy in changing behaviour was a common reason for lack of uptake of guidelines. Self-efficacy and outcome expectancies have also been investigated more generally in behaviour change, including among practitioners and patients and are highly correlated with change. Among prescribers responding to medication shoppers, self efficacy may be insufficiently developed for those not trained or experienced in managing complex behaviours (Cabana et al., 1999).

The existence of established patterns of practice was a very common reason for not implementing guidelines. In a study of cancer screening, Cabana et al. (1999) applied the Prochaska and Di Clemente stages of change model. Nearly 50% of practitioners were identified as being in the pre-contemplation stage and not ready to change practices. This suggests that merely disseminating prescribing guidelines, with the assumption that all prescribers are ready to take up those changes, is unlikely to be successful and may need to be combined with other strategies, such as tailored education visits to enhance uptake.

Even when internal barriers such as self efficacy and inertia are not barriers to the uptake of guidelines, there may be a number of other barriers outside the direct control of the practitioner. External barriers include those which are: guideline related (such as guidelines not being easy to use or understand); patient related (e.g. resistance); and environmental (such as time, availability of other essential personnel).

The examination of barriers is crucial in the uptake of change in practice, and needs to be tailored to each individual case. Baker et al. (2010) found that tailoring interventions

to the practitioner and prospectively addressing barriers to behaviour change, was more successful than no intervention or dissemination of guidelines only.

It may also be beneficial to target prescribers who have been identified as prescribing 'outliers'. They could benefit from tailored and intensive change strategies including: an examination of their barriers to change; the dissemination of guidelines; education and training; and audit and feedback.

7.4.2.5 Other educational options

In hospital settings, clinical pathways³⁰ are associated with reduced in-hospital complications related to wound infections, bleeding and pneumonia, and improved documentation without negatively impacting on length of stay and hospital costs (Rotter et al., 2010), but their impact on prescribing in community or hospital settings is unknown.

Two Cochrane Reviews also found that opinion leaders alone or in combination with other interventions may be an effective method to disseminate evidence-based practices among practitioners (Flodgren et al., 2010) and that mass media campaigns may also have a role in influencing the use of health care interventions (Grilli, Ramsay, & Minozzi, 2002).

Using computer technology, Shojania et al. (2010) found that pop-up reminders resulted in small to modest improvements in prescribing behaviour of GPs. For example, when prescribing for pain medication a reminder might pop up to prompt them about the appropriate dose or an alternative treatment. The median improvement in practices was 4% and the authors suggested that further research is required to identify which type of reminders work best and when. In another review, computerised advice for drug dosage

³⁰ These are document-based tools that provide recommendations, processes and time-frames for the management of specific medical conditions.

resulted in significant benefits, including increasing the initial dose, increasing serum concentrations, reducing the time to therapeutic stabilisation, reducing the risk of toxic drug level and reducing the length of hospital stay (Durieux et al., 2008).

The use of mental health workers in primary care to deliver psychological and psychosocial interventions showed a significant reduction in primary care practitioner behaviour such as numbers of consultations, prescribing, and referrals to specialist care (Harkness & Bower, 2011). This is an important development in mental health and pain management that may achieve more intensive patient management and reduce over-prescribing. The use of psychologists, nurses and mental health workers to undertake effective psychological pain, sleep or anxiety management strategies and to provide ongoing support to patients who are prescribed medications can potentially increase the amount of monitoring available to the patient and aid in early detection of problems and issues with medication.

7.4.2.6 Summary

Together these studies suggest that, in general, only modest returns are available from common practices such as audit and feedback, educational outreach visits, educational meetings and provision of educational materials such as guidelines. Nonetheless these may have some clinically beneficial effect on improving the quality of prescribing, especially if messages are tailored to those practitioners identified as over-prescribing and address individual barriers to change. The use of other methods, such as mental health workers and computer reminders, as well as opinion leaders and mass media, may also impact on prescribing practices of general practitioners.

7.5 Harm reduction responses

The implementation of measures to enhance the quality use of these medications will not prevent all unsanctioned use. The use of these drugs by individuals other than those to

whom they were prescribed, or at dosages or by routes of administration that were unintended by prescribers or manufacturers, can be very harmful. These harms include overdose and vascular, organ, limb, or digit damage. It will be important that measures are put in place to minimise these harms. Potential responses that warrant consideration include a range of established harm reduction strategies such as:

- peer education programs concerning the risks associated with using these medications in this way and strategies to avoid harms; and
- ready accessibility of consumables, such as appropriate needles and syringes, winged infusions, syringe driven filters and peer naloxone distribution.

The introduction of measures such as these will ensure that the NPDMS adopts a balanced approach to pharmaceutical drug misuse and balances the three pillars of the National Drug Strategy, namely supply, demand and harm reduction.

7.6 Potential consumer responses

The first of the five key principles which underpins Australia's National Strategy for the Quality Use of Medicines (NSQUM) is the primacy of consumers. The NSQUM recognises both the central role consumers play in attaining QUM and the wisdom of their experience. Consequently consumers must be involved in the NPDMS at a range of levels. The NPDMS will need to include strategies that:

- address expectations that consumers have about the efficacy of medicines
- ensure that that consumers understand current best practice in the quality use of medicines and understand their rights and responsibilities in relation to their health care

- enhance levels of health literacy³¹ among the population
- enhance and standardise medication labelling and
- involve awareness raising programs among the general public about the risks of exceeding therapeutic doses of OTC medications.

A population of consumers that understands health care information as well as their rights and responsibilities in relation to their health care are potentially less likely to inadvertently misuse pharmaceuticals and are in a better position to ask questions of their health care professional and make confident decisions about their health.

In Australia, health literacy generally increases between the ages of 15 and 39 years and then decreases from 40 years on (ABS, 2008); the decrease coinciding at a time when health care use and potentially use of medications such as opioid pain medication is increasing. Health literacy is not necessarily equivalent to general literacy, with more people scoring poorly on health domains of a literacy assessment than on prose, documentation and numeracy domains (ABS, 2008).

Studies have shown that people with low health literacy not only have less knowledge of illness management but have less input into their own health care decisions, lower adherence to medication (Coulter & Ellins, 2007; Nutbeam, 2008) and poorer health outcomes (Wolf, Gazmararian, & Barker, 2005).

US Pharmacopeia is the official public authority for setting standards for prescription and over the counter medicines and other health care products manufactured or sold in the United States (US Pharmacopeia, 2011). It has established several recommendations for pharmaceutical labelling of preparations to improve the quality use of medicines by consumers, including:

³¹ Health literacy includes the ability to understand instructions on prescription drug bottles, appointment slips, medical education brochures, prescribers' directions and consent forms, and the ability to negotiate complex health care systems.

- organising the prescription label in a patient-centred manner
- simplifying the language
- using explicit text to describe dosage/interval instructions
- including purpose for use
- improving readability and format
- providing labelling in patient's preferred language
- including supplemental information, and
- standardising directions to patients.

Labelling can improve patient understanding of the good use of medicines (Wolf, Feinglass, Thompson, & Baker, 2010). In a US study, Goldsworthy et al. (Goldsworthy, Schwartz, & Mayhorn, 2008) found that around 49.8% of participants in their study had either 'lent' or 'borrowed' prescription medications, including pain medication, although those with higher health literacy were more likely to share medication than those with lower health literacy, suggesting a need to emphasise the quality use of medicines among the general public.

Nielsen et al. (2010) recommend raising awareness among the general public about the risks of exceeding therapeutic doses of over the counter medications and ways to support pharmacists to respond effectively to those over-using their OTC medicines. They found around a third of respondents to an online survey, who were relatively well educated and socio-economically stable, exceeded the recommended dose on the last use occasion and over 45% had used codeine for non-medical purposes at some time. Many of these respondents started with legitimate pain levels and failed to get appropriate medical treatment as the pain levels increased.

7.7 Potential technological responses

Technology could contribute to a reduction of pharmaceutical drug misuse via the implementation of a CMMS. There are, however, other potential contributions that

technology could make. It will be important that these technological approaches do not inadvertently make unsanctioned use more harmful.

7.7.1 Tamper-resistant technologies

One such aid is the development of tamper-resistant technologies. These seek to reduce the opportunities available for the misuse of relevant medications. Broadly there are two approaches to this. The first of these is abuse resistant formulations (ARFs). The ARF formulations use a barrier that make it difficult to tamper with, or extract, the core medication, or renders the tampered tablets unsuitable for injecting or snorting (Webster & Fine, 2010).

This could include:

- the use of hard plastic polymers which make the tablet difficult to crush or dissolve
- using a highly viscous liquid which is intended to resist crushing, dissolution, injection or inhalation
- using a waxy medication carrier which is resistant to crushing and boiling (Webster & Fine, 2010)
- using pro-drugs which are then transformed into the active drugs once inside the body, and
- bio-activated dosage forms which require exposure to specific gastro-intestinal conditions to release their active agents (Wright, Kramer, Zalman, Smith, & Haddox, 2006).

Abuse deterrent formulations (ADFs) deter misuse by pharmacologically modifying the formulation, such as adding another compound that decreases or prevents reward or induces an aversive effect. This could include:

- adding sequestered naltrexone (an opioid antagonist) to opioid medications which is released when the tablet is crushed in order to blunt the effects of the opioid, and
- adding an aversive agent (such as niacin) that causes unpleasant effects when injected, inhaled or taken orally in high doses (Webster & Fine, 2010).

It is also possible to combine both ARF and ADF based approaches in the one medication (Webster & Fine, 2010) but as Wright et al. (2006) pointed out, these measures can only be expected to reduce, not eliminate, the misuse of these substances.

7.7.2 Pharmaceutical pedigrees

A further way in which technology can assist in reducing pharmaceutical misuse is by the implementation of pharmaceutical pedigrees. A pharmaceutical pedigree is an audit trail that follows a drug from the time it is manufactured through the distribution system to a pharmacy and even to the patient level (Howe, Goldner, & Fennig, 2007).

Pharmaceutical pedigrees have benefits as far as preventing counterfeit medications from entering the supply stream and in terms of monitoring of medications. Although simple in concept, the practicalities of this process are complex. There are three potential ways to create a pedigree system. The first is simple paper recording of records, and the second is bar-coding. Neither of these approaches is likely to be sufficient because of the large amount of data that would need to be manipulated to enable traceability down to the individual item level. The primary packaging of drugs is also problematic as they get aggregated up into cartons, pallets and shipping containers. Since paper records and bar codes rely on line-of-site methods for verification, this means that their use is impractical for this purpose (Howe et al., 2007).

The third form of pharmaceutical pedigrees involves the use of radio frequency identification (RFID). These are tags attached to medication packets which can then be automatically read through the outer layers of packaging (Howe, et al. 2007).

The US Food and Drug Administration is soon to mandate the use of drug pedigrees in that country.

7.7.3 Measures to reduce tampering with or forgery of prescriptions

A further important potential contribution of technology relates to the use of prescriptions which are unable to be easily forged or altered. There is a range of technological safeguards that can be included in a secure prescription form to reduce the likelihood of tampering. Both procedural and technological safeguards can be combined to create secure prescription forms that balance fraud protection with accessibility, ease of use, and affordability for practitioners. This balance can mutually serve the needs of government and practitioners providing appropriate pain treatment to their patients (Fishman et al. 2004).

7.8 The marketing and promotion of pharmaceutical drugs in Australia

The marketing and promotion of pharmaceutical drugs in Australia occurs under a self regulatory code of conduct administered by Medicines Australia (MA), the peak body for the pharmaceutical industry. It sets the standards for the conduct of companies when engaged in the promotion of prescription products used under medical supervision as permitted by Australian legislation. The Code complements the legislative requirements of the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations. Reviews of the code are conducted on a triennial basis (Medicines Australia, 2009). The Code is subsequently approved by the Australian Competition and Consumer Commission (ACCC).

There is a strong incentive for pharmaceutical companies to market their drugs aggressively. Pharmaceutical companies hold patents over medicines for up to 25 years before generic versions of the same drug can be manufactured by other producers and offered to consumers at a lower price. During the patent period their ability to generate sales without price competition from generic versions is greatest, because they have a monopoly on manufacture and distribution. The marketing of pharmaceuticals is an important way in which companies stimulate demand and generate high turnover (Choice, 2008).

Doctors are the key targets of pharmaceutical marketing in Australia because direct-to-consumer advertising is prohibited and because doctors have the power to prescribe drugs. Pharmaceutical companies market their products to doctors through sales representatives that regularly visit doctors to promote medicines and by advertising in doctors' publications and within medical prescribing software. They also conduct educational seminars for medical professionals (Choice, 2008).

In 2009, the 16th Edition of the Code of Conduct was approved by the ACCC. The Code prohibits pharmaceutical companies from providing entertainment and extravagant hospitality to healthcare professionals, with the requirement that all benefits provided by companies successfully withstand public and professional scrutiny. Pharmaceutical companies are now required to publicly disclose any hospitality provided to healthcare professionals (Medicines Australia, 2009).

Nevertheless there are still concerns that the self-regulatory approach may be insufficient and that current advertising and promotion practices may be unduly affecting prescribing practices (Choice, 2008).

The development of the NPDMS provides a good opportunity to consider the marketing of pharmaceuticals and how approaches such as self-regulation can contribute to minimising the misuse of pharmaceuticals.

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