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Opioid Agonist Therapy in Australia

A HISTORY

Roger Nicholas

NCETA

The National Centre for Education and Training on Addiction is an internationally recognised research centre that works as a catalyst for change in the alcohol and other drugs (AOD) field.

Our mission is to advance the capacity of organisations and workers to respond to alcohol and drug-related problems. Our core business is the promotion of workforce development (WFD) principles; research and evaluation of effective practices; investigating the prevalence and effects of alcohol and other drug use in society; and the development and evaluation of prevention and intervention programs, policy and resources for workplaces and organisations.

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NCETA respectfully acknowledge the Kaurna people as the Traditional Owners of the land and waters on which our Centre is located. We pay our respects to Kaurna elders past, present and emerging

FOREWORD

A key purpose of this book is to document the contribution that opioid agonist therapy (OAT) has made to public health and to the life of individuals in Australia. As with many fields of endeavour, OAT began from relatively rudimentary beginnings in Australia and has developed as the evidence base concerning effective practice grew. It is noteworthy that Australia made a substantial contribution to the development of this evidence base.

The development of OAT programs has varied significantly between Australian jurisdictions. So too, there are significant variations between jurisdictions in current patterns of OAT provision. The federated nature of Australia's system of government has contributed to these variations, and as such, this system is described in Chapter One. Other contributors to these differences include differing profiles of drug problems, differing funding models and at times, happenstance.

This flexibility in service provision is characteristic of the development of OAT in Australia. One of the great strengths of the Australian approach to OAT has been that no attempt has been made to dictate to prescribers that they must utilise one OAT medicine for all clients. As a result, the OAT system in Australia has developed based on providing flexibility concerning the OAT medicines that best suit the needs of individual clients.

Opioid agonist therapy in Australia faces a number of challenges, including:

- a relatively narrow and diminishing prescribing base
- stigma (both clients and service providers)
- dispensing costs to clients.

These problems notwithstanding, OAT coverage in Australia is relatively good and compares favourably with other countries.

On occasions, throughout the book, the term addict is used. While recognising that this is no longer acceptable terminology, the term is retained in some instances because this was used in historical references that have been cited.

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LIST OF ABBREVIATIONS

ACT	Australian Capital Territory
ADA	(WA) Alcohol and Drug Authority
ADATB	(SA) Alcohol and Drug Addicts Treatment Board
A&DS	Tasmania Alcohol and Drug Services
AMC	Alexander Maconochie Centre
AMSAD	Australian Medical Society on Alcohol and other Drugs
AMPSAD	Australian Medical and Professional Society on Alcohol and Drugs
ANCD	Australian National Council on Drugs
APSAD	Australian Professional Society on Alcohol and other Drugs
APSAD	Australasian Professional Society on Alcohol and other Drugs (after December 2004)
CAC	(NT) Clinical Advisory Committee
CADTH	Canadian Agency for Drugs and Technologies in Health
CDHSH	Commonwealth Department of Human Services & Health,
CDU	(WA) Central Drug Unit
CPOP	(WA) Community Program for Opioid Pharmacotherapy
CRADA	Cooperative Research and Development Agreement
DASC	(SA) Drug and Alcohol Services Council
DASSA	Drug and Alcohol Services SA
DATA	United States Drug Abuse Treatment Act
DHHS	(Victorian) Department of Health and Human Services
DODO	(NSW) Directorate of the Drug Offensive
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
FDA	United States Food and Drug Administration
GP	General Practitioner
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDWA	Health Department of WA
HIV	Human Immunodeficiency Virus
IGCD	Intergovernmental Committee on Drugs
LAAM	Levacetylmethadol
LAI	Long-Acting Injectable (Buprenorphine)
MAT	Medication Assisted Treatment
MATOD	Medication Assisted Treatment for Opioid Dependence
MCDS	Ministerial Council on Drug Strategy
MHS	(WA) Mental Health Services
MTAR	Methadone to Abstinence Residential
NCADA	(Australia's) National Campaign Against Drug Abuse

NCE	New Chemical Entities
NDS	National Drug Strategy
NEACID	National Expert Advisory Committee on Illicit Drugs
NEPOD	National Evaluation of Pharmacotherapies for Opioid Dependence
NGOs	Non-Government Organisations
NHMRC	National Health and Medical Research Council
NMG	National Methadone Guidelines
NSP	Needle Syringe Program
NIDA	The National Institute on Drug Abuse
NOPSAD	National Opioid Pharmacotherapy Statistics Annual Data
NSW	New South Wales
NT	Northern Territory
NZ	New Zealand
OAT	Opioid Agonist Therapy
OBOT	Office Based Opioid Treatment
OPP	(NT) Opioid Pharmacotherapy Program
OTP	(NSW) Opioid Treatment Program
OSTAR®	Opioid Substitution to Abstinence Residential
PABN	Pharmacotherapy Area-Based Networks
PBS	Pharmaceutical Benefits Scheme
RAAM	(Canadian) Rapid Access to Addictions Medicine
R&C	Reckitt & Colman
RDH	Royal Darwin Hospital
RNABD	(Portuguese) Referral Network for Addictive Behaviours and Dependencies
RPBS	Repatriation Pharmaceutical Benefits Scheme
RTOD®	Residential Treatment of Opioid Dependence
SA	South Australia
SAE	Serious Adverse Events
SAMHSA	Substance Abuse and Mental Health Services Administration
SMS	Specialist Methadone Service
SP	Schering-Plough
SPS	Specialist Pharmacotherapy Services
SWAT	State-Wide Advisory Team
Qld	Queensland
TCs	Therapeutic communities
TGA	Australian Therapeutic Goods Administration
US	United States
VIC	Victoria
TAS	Tasmania
UNODC	United Nations Office on Drugs and Crime
WA	Western Australia
WHOS	We Help Ourselves
WSC	William Street Clinic

CHAPTER 1: THE AUSTRALIAN CONTEXT

The implementation of opioid agonist therapy (OAT) programs in Australia has been substantially influenced by the country's socio-economic status and governmental arrangements.

Australia is a stable, multicultural and democratic society with a population of 25.6 million people (Australian Bureau of Statistics, 2020). It is one of the most economically, politically and socially stable nations in the Oceania region. Australia is a culturally diverse society with migrants from over 200 nations, as well as its Indigenous Aboriginal and Torres Strait Islander peoples, contributing to its national identity (Ritter et al., 2011). Most (90%) of the Australian population lives in urban areas (Australian Bureau of Statistics, 2016). Australia has a strong, competitive economy and is the world's 10th richest nation in per capita terms (FocusEconomics, 2019). It has a highly trained labour force of approximately 13 million, with almost half of this workforce having a university, trade or diploma qualification. The education system within Australia is also well developed, with attendance rates among the highest in the world (Australian Bureau of Statistics, 2016).

Government in Australia

The Government of Australia (also called the Australian Government, the Commonwealth Government, the Federal Government, the National Government, or simply the Commonwealth) is a federal parliamentary constitutional monarchy. Australia is a federation of six States. Each of the States, New South Wales (NSW), Victoria, Queensland, WA (WA), South Australia (SA) and Tasmania, were, until 1901, separate British colonies. There are also two self-governing Territories: the Australian Capital Territory (ACT) and the Northern Territory (NT). The Federal Government has no power to override the decisions of State governments except in accordance with Australia's Constitution, but it can, and does, exercise that power over the territories.

Australia has three levels of government, federal, state and local. The federal decision-making body is the Federal Parliament, led by the Prime Minister. Federal government responsibilities include foreign affairs, social security, industrial relations, trade, immigration, customs, income taxation, currency and defence. The decision-making body of State / Territory governments is the State parliament/legislative assembly (the lower and upper houses) and are led by State Premiers or Chief Ministers. State and Territory government responsibilities include justice, consumer affairs, health, education, forestry, public transport, and main roads. The decision-making body of local government is usually called the city council, shire council or local council. Councils are established by State governments to meet the needs of a city or local community. Local government responsibilities include local road maintenance, garbage collection, building regulations and land subdivisions, and public health and recreation facilities such as swimming pools.

In the Australian political system, power and responsibility are fragmented. Governments often have differing perspectives on national approaches to problem-solving, particularly when States perceive that the Commonwealth is seeking to exert undue influence on States' activities. In situations where the States have exclusive powers, the Federal Government can use financial inducements to obtain support for national programs. Examples of this kind of approach include the joint State-Commonwealth hospital cost-sharing agreements and public housing programs (Swensen, 1990).

This governance structure has a range of implications for illicit drug policy in general, and approaches to OAT in particular. For example, States and Territories, as primary funders of health services, are largely free to structure health services as they see fit, just so long as they do not contravene areas of Commonwealth control as outlined in the Australian Constitution. This partially explains the considerable historical, and current, variations in approaches to the provision of OAT across different Australian jurisdictions.

The division of powers between the States/Territories and the Federal Government means that although the Federal Government meets the cost of OAT medicines (and the cost of testing urine samples associated with treatment programs at pathology laboratories), it has no powers to regulate the running of OAT programs. For instance, if a State or Territory did not establish an OAT program it is unlikely the Federal Government would have any power to establish one. Since crucial components of OAT policy and practice are exclusively the remit of the States and Territories (for example, providing authorisation to doctors to prescribe OAT, and prescribing and dispensing procedures), the Federal Government's power is at best persuasive and must be reliant on cooperative joint arrangements with all the States and Territories (Swensen, 1990).

Although the States and Territories are primarily responsible for the provision of health services, Australia also has a federally funded universal healthcare program, Medicare.

Medicare gives Australians access to:

- free or subsidised treatment by health professionals such as general practitioners, specialists, optometrists, dentists and other allied health practitioners (in special circumstances only)
- free treatment and accommodation as a public patient in a public hospital
- 75% of the Medicare Schedule fee for services and procedures for private patients in a public or private hospital.

Through the Medicare Benefits Scheme, the Commonwealth Government pays for fees it has scheduled for a list of health services that it deems to attract a Medicare Benefit. This only occurs if the service is provided by a health service provider registered with Medicare. Relevant health service providers include private general practitioners (GPs), psychiatrists and psychologists. General practitioners' role in Australia's OAT program (prescribing methadone and buprenorphine) is funded through Medicare.

Medicines are also subsidised in Australia by the Pharmaceutical Benefits Scheme (PBS) or the Repatriation Pharmaceutical Benefits Scheme (RPBS). The Australian Government fully funds the cost of OAT drugs buprenorphine, buprenorphine/naloxone and methadone supplied through clinics and pharmacies approved by State and Territory governments. The provision of OAT (and a range of other specialised) drugs occurs under Section 100 of the National Health Act, 1953. While these Section 100 OAT drugs are provided free of charge to consumers, they are generally subject to dispensing fees charged by pharmacies. This cost is generally borne by consumers.

Over the past decade there has been an increasing trend in most States and Territories to provide OAT services via general practitioners and community pharmacies, rather than though specialist State/Territory alcohol and drug services. While this better utilises primary health care services, it also means that the prescribing costs are borne by the Commonwealth (via Medicare) and the dispensing costs are largely borne by consumers. Consequently, as OAT prescribing has moved from State/Territory run clinics to private prescribers, the costs of OAT prescribing has shifted from States and Territories to the Commonwealth.

A further example of the impact on Australian OAT programs of the interplay between Federal Government and State/Territory jurisdictions, involved the proposal to conduct a trial of heroin for OAT in the Australian Capital Territory (ACT) in the late 1990s. The objective of the trial was to examine whether the provision of heroin to heroin-dependent people, in a controlled manner, would benefit the users themselves and the broader community. The trial was intended to replicate an earlier Swiss trial which had found significant improvements in the social and health status of participants (Uchtenhagen, Gutzwiller, Dobler-Mikola, & Steffen, 1997). The ACT trial was endorsed by a majority of Australian States and Territories, and the then Federal Health Minister, Dr Michael Wooldridge (Mendes, 2001). Soon after, however, the Prime Minister of the day, Mr John Howard, was able to block the proposal by refusing to amend relevant Federal legislation that would have allowed the importation of heroin for the trial, and by refusing funding for the trial (Macintosh, 2006). This is an example of a drug policy proposal that was endorsed by most States and Territories which could be blocked by the use of Commonwealth powers.

At a general level, however, there is a considerable degree of cooperation between the Commonwealth and the States and Territories in drug policy development and implementation. Australia's National Drug Strategy is developed jointly by the Commonwealth and the States and Territories, and then implemented by jurisdictions in accordance with local circumstances.

CHAPTER 2: THE DISCOVERY AND DEVELOPMENT OF METHADONE

Methadone is the first medicine that was widely used to treat opioid dependence. That said, shorter acting opioids (such as morphine) were also commonly prescribed in the United States (US) to treat opioid dependence in the early part of the 20th century (Courtwright, 2001), and anecdotally the same occurred here in Australia.

Methadone is an opioid agonist which was long thought to have been developed in Germany in response to a shortage of opium (and therefore morphine) during the later stages of World War II. For some time, it was believed that Adolf Hitler instructed his scientists to quickly develop an oral substitute for morphine. In reality, however, it appears that methadone was discovered in the course of work on unrelated spasmolytic compounds to treat asthma and renal and biliary colics (Defalque & Wright, 2007; Gerlach, 2004; Lenz et al.,1986, as cited in Payte, 1991).

There is also strong evidence that Germany did not experience a shortage of morphine during World War II. The extensive World War II German medical records clearly show that morphine was the main analgesic used in military as well as in civilian practices and that large stockpiles of morphine still existed in Germany as late as the beginning of 1945. The medical records also indicate that Germany did not use methadone during the war. Further, Turkish opium (Papaverum somniferum) remained available to the European pharmaceutical industry throughout the war. Even if Turkish opium became difficult to source, 20% of the morphine produced on the Continent at the time was derived from opium straw, made out of the milled dried capsules and stems of Papaverum setigerum, the wild poppy growing throughout the Mediterranean regions (Defalque & Wright, 2007). From this perspective, there was no need for the German leadership to order its scientists to develop an oral morphine substitute.

The process that resulted in the discovery of methadone began with the discovery of pethidine (then known as Dolantin) in 1937. Dolantin was first synthesised by two scientists, Eisleb and Schaumann, who worked for the German chemicals conglomerate IG Farbenindustrie at Hoechst-Am-Main in Germany. Close colleagues Bockmuhl and Ehrhart began working on compounds based on the structure of pethidine. In 1938, they created the compound now known as methadone. It was given the serial number Hoechst 10820 and named Amidon in 1941. The scientists conducted cursory trials on Hoechst 10820 (which revealed that it was an analgesic) and applied for a patent on September 25,1945. No attempt was made to bring Hoechst 10820 into commercial production during the war (Defalque & Wright, 2007; Preston & Bennett, 1996).

After the war, all German patents and trade names were requisitioned by the allies. The formulae for 10820 and all the other Hoechst products were distributed around the world and produced commercially by many companies that were free to choose their own trade names. The US Department of Commerce sold the patents and records to the US pharmaceutical firms for $1, and in the late 1940s, methadone was sold in the US under various trade names such as Adanon® (Winthrop), Methadone® (Upjohn, Abbott, Mallinckrodt, Merck-Sharp-Dome) as an oral or parenteral analgesic, and Methajade® as an oral cough depressant (Defalque & Wright, 2007).

The American pharmaceutical giant Eli-Lilly was the only US firm to conduct extensive laboratory and clinical studies into the drug. It was Eli-Lilly, and not the Germans, which gave 10820 the trade name Dolophine. Rather than being a derivation of Adolf, as is commonly believed, Dolophine was probably derived from a combination of the French words *dolor* (pain) and *fin* (end) (Defalque & Wright, 2007; Preston & Bennett, 1996).

On August 27 1947, the drug was given the generic name 'methadon' by the Council on Pharmacy and Chemistry of the American Medical Association (Gerlach, 2004). The generic name of Methadon was an abbreviation of diphenyl METHAmino- DiphenylheptanONE. The reason why the final 'E' of heptanone was dropped, and how it later reappeared, is unknown (Defalque & Wright, 2007).

In that year, a group of researchers led by Dr Harris Isbell published a review of their experimental and clinical work with the drug. They gave volunteers incredible doses of up to 200mg four times a day[1]. Unsurprisingly, the volunteers rapidly developed tolerance and euphoria. The researchers had to reduce the doses given to the volunteers because of signs of toxicity (Preston & Bennett, 1996).

Initial research showed that although methadone was a powerful analgesic, it had few advantages over other analgesics and all the disadvantages - nausea, respiratory depression and a potential for dependence. Consequently, it remained just another, relatively unused drug in the analgesic repertoire until 1964, when Drs Vincent Dole and Marie Nyswander rediscovered it (Preston & Bennett, 1996).

The history of the use of methadone in the United States

The current OAT situation in the US is discussed in Chapter 26, but a brief outline of the history of US methadone use is included here because it provides an insight into the early influences on methadone programs in Australia.

Following World War II, the US was experiencing escalating problems with intravenous heroin use. In New York City in particular, during the 1950s and1960s, heroin use reached epidemic proportions. Between 1950 and 1961, the death rate associated with heroin injection increased from 7.2 per 10,000 deaths to 35.8 per 10,000 deaths, with 75% of the deaths in the 15 to 35 years age group. During this period, heroin injection became the leading cause of death in New York City for young adults. The average age of death from heroin-related use was 29 years for both sexes (Halpern & Rho, as cited in Joseph et al., 2000).

Previously in 1949, Isbell and Vogel had reported that methadone was the most effective medication for withdrawing addicts[2] from heroin. This involved prescribing decreasing doses of methadone to heroin addicts over seven to 10 days or more (Isbell & Vogel, 1949). This protocol was subsequently followed in many US clinics. Methadone was used as an office-based addiction treatment by a handful of physicians who prescribed it in the 1950s. In addition, the New York State Department of Mental Health ran an informal methadone maintenance program in 1959. However, the strongly anti-maintenance Federal Bureau of Narcotics (FBN) harassed physicians who prescribed methadone or other opioids at the time (Campbell & Lovell, 2012). Follow-up studies in the 1950s and 1960s showed relapse rates of more than 90% after patients left this short-term treatment (Payte, 1991).

The impetus for longer-term methadone treatment for heroin dependence emanated from the work of husband-and-wife researchers Drs Vincent Dole and Marie Nyswander in the United States in the 1960s. As noted above, methadone was already being used as a medication to

1 Contemporary practice is to commence clients on methadone doses of 20-30 mg daily with dose increments of five to 10 mg every three to five days (Gowing, Ali, Dunlop, Farrell, & Lintzeris, 2014)

2 The term heroin addict is not one which is currently widely used, but it is the term used in older journals, and it is used in this context.

withdraw addicts from heroin (albeit with poor results). But instead of discontinuing methadone treatment, these researchers maintained their patients on the drug so that its effects could be studied. In 1965, Dole and Nyswander described how a group of 22 heroin addicts when given daily doses of methadone and a comprehensive program of rehabilitation:

- stopped their 'narcotic hunger'
- experienced sufficient tolerance to block the euphoric effects of heroin
- improved their behaviour and appearance
- returned to school or obtained jobs
- reconciled with their families (Dole & Nyswander, 1965).

After entering the program, the addicts were admitted to hospital for six weeks, during which time they undertook careful medical and social examinations and were gradually stabilised on a blockade dose of methadone. Methadone was commenced on a low dosage (10 to 20 mg/day in divided portions) and increased slowly over a period of four to six weeks to avoid adverse effects such as respiratory depression. After the addicts had reached the stabilisation level (80 to 120 mg/day) they were maintained on a single, daily, oral dose. At the end of the six weeks of hospitalisation, they were discharged to outpatient clinics where they received their daily methadone and gave urine specimens for illicit drug analysis. The clinics were established either in the outpatient area of a hospital or in rented offices located in the community (Dole & Nyswander, 1967). In the mid-1960s Dole and Nyswander were visited by a Sydney psychiatrist Dr Stella Dalton. This visit was to profoundly impact the course of OAT in Australia.

Dole and Nyswander's inpatient methadone program was conducted on the metabolic ward of the Rockefeller University Hospital. The venue provides an insight into the way in which Dole and Nyswander viewed heroin addiction. Dole, who had previously studied the metabolic factors involved in obesity, speculated that the craving reported by addicts and the effects of the abstinence syndrome were symptomatic of a metabolic alteration within the central nervous system. Dole and Nyswander argued that addiction was a metabolic deficiency, much like diabetes. Dole had previously undertaken research into obesity in the 1950s and had found metabolic differences between obese and non-obese patients. He had also discovered that that there were similarities in the craving of obese patients, heroin users and cigarette smokers and that relapse was common among these groups (Joseph et al., 2000).

Therefore, Dole believed that the stabilisation of this metabolic deficit using methadone should be the key treatment priority, rather than abstinence from drugs. This represented not only a major shift in thinking about the treatment of heroin dependence, but also fundamentally questioned existing paradigms regarding the aetiology of drug dependence itself (Joseph et al., 2000).

Up to this point, heroin dependence had been viewed as stemming from moral or character weaknesses. Dole and Nyswander argued that the traits commonly seen in addicts (such as chaotic, drug-focused behaviour) were a consequence, rather than a cause, of addiction. From this perspective, addiction ultimately stemmed from differences in the ways in which addicts metabolised opioids, and they could therefore be rehabilitated on a medical program which addressed their metabolic difficulties. In addition, by providing a legal, longer-acting opioid substitute, individuals had an opportunity to improve their social situation and take advantage of the psychotherapeutic and rehabilitative services that were an integral part of the Program (Dole & Nyswander, 1967).

Dole and Nyswander's early research involved shorter-acting opioids such as morphine and oxymorphone, but they ultimately concluded that these shorter-acting opioids were unsuitable.

Eventually, they decided that methadone treatment was most effective in reducing heroin use and also in reducing criminal activity (Dole & Nyswander, 1965).

The powerful US Committee on Problems of Drug Dependence gave Dole and Nyswander a lukewarm reception concerning the findings of their methadone maintenance pilot program and grudging acceptance of its social benefits. This was no surprise. The Committee had never favoured agonist maintenance. The Committee had long aligned itself with the drug control apparatus in viewing methadone maintenance with scepticism. Similarly, the World Health Organization Expert Committee on Drug Dependence at the time considered methadone maintenance a research approach, but not an established treatment. Dole and Nyswander characterised such attitudes as those of a stodgy addiction research establishment opposed to methadone maintenance on political grounds (Campbell & Lovell, 2012).

Paradoxically, the continued use of methadone resulted in physiological adaptation to methadone (i.e., the user became physically dependent on methadone), which became the cornerstone of methadone's success. The addictive nature of methadone retained, or 'captured,' heroin users in the treatment program so that both primary benefits accrued to the individual (e.g., daily opiate intoxication and freedom from the rigours of illicit heroin use), and secondary social benefits accrued to the individual's family and the community (Swensen, 1990).

By the early 1970s, a fundamental shift in social attitudes was occurring in the US in which heroin use was increasingly regarded as a medical, not a criminal problem. This led to climate of high expectations that a solution for a complex social problem was possible by the use of a medicine (Swensen, 1990).

Nevertheless, there was a range of criticisms of the use of methadone to treat heroin problems in the US in the 1970s. These included that:

- the positive results obtained by Dole and Nyswander could have stemmed from therapeutic and vocational supports offered in their program, rather than from the methadone
- Dole and Nyswander's program had selective admission criteria which meant that participants were not typical of street heroin users
- participation in Dole and Nyswander's program could have protected clients involved in crime from arrest (thereby falsely indicating reduced criminal involvement)
- methadone represented a source of social control over addicts by providing a State-sanctioned drug to people with a preoccupation with intoxication
- leakage of methadone onto the black market was a major problem
- methadone was simply one of a number of substances that the pharmaceutical industry was marketing to policy makers and the medical profession as a panacea for a range of social ills (Swensen, 1990).

Nevertheless, methadone programs expanded rapidly in the US because of pressure from the Nixon White House to reduce crime. There was also a concern that soldiers returning from the Vietnam War would worsen the nation's heroin problem. As a result, President Nixon ordered the first Federal program to treat opiate addiction using methadone in 1971. This was coupled with an abundance of poorly qualified but eager, or opportunistic, practitioners anxious to solve the heroin problem. By the early 1970s, 100,000 addicts were receiving methadone in the United States as a treatment for their drug dependency (Payte, 1991).

In 1971, President Nixon created the Special Action Office for Drug Abuse Prevention and appointed Jerome Jaffe as Director. Despite concerns about methadone's limitations, including

the frequency of dosing, refusal and refractory cases, Jaffe played a crucial role in expanding methadone maintenance as a treatment modality in the United States (Campbell & Lovell, 2012).

In the 1970s, the Committee on Problems of Drug Dependence also shifted its position towards supporting agonist maintenance and assisted the development of the first practice guidelines governing methadone maintenance. The guidelines Narcotics and Medical Practice, were issued by the American Medical Association Council on Mental Health and the National Research Council in 1971 (Campbell & Lovell, 2012).

The Guidelines stated that:

1. *Methadone maintenance programs should include:*
    - *adequate facilities for the supervised collection of urine and for frequent and accurate urine testing for the presence of morphine and other drugs*
    - *general medical and psychiatric services*
    - *hospital facilities as needed*
    - *adequate staff*
    - *rigid controls of methods of dispensing methadone to prevent diversion to illicit sale or to possible intravenous use.*
2. *Care should be exercised in the selection of patients to prevent the possibility of causing people who were not dependent on heroin to become dependent on methadone.*
3. *There should be continued evaluation of the long-term effectiveness of methadone programs for stabilised persons.*
4. *Where feasible, staff members of new methadone maintenance programs should be trained in an established effective program.*
5. *Continuing research was required regarding:*
    - *the care of those patients whose needs for allied services were minimal*
    - *the role of methadone maintenance in the treatment of heroin dependent patients under age 18 years*
    - *the use of methadone maintenance in combination with other approaches to the treatment of morphine-type dependence (American Medical Association Council on Mental Health, 1971).*

A key aspect of the Guidelines was that methadone maintenance was not feasible in the office practices of private physicians, because they could not meet all the therapeutic needs of such patients. Concerns about methadone diversion also played a major part in the decision not to allow office-based methadone prescription (Campbell & Lovell, 2012).

CHAPTER 3: THE DISCOVERY AND DEVELOPMENT OF BUPRENORPHINE

The author is indebted to Dr Chris Chapleo from Indivior, who provided a considerable degree of the detail concerning the history and development of buprenorphine. Unless otherwise referenced, this Chapter is based on information provided by Dr Chapleo.

Buprenorphine is a synthetic opioid derived from thebaine, an alkaloid that is extracted from the opium poppy. It was discovered in 1966 by researchers at Reckitt & Colman (R&C, which became Reckitt Benckiser in 1999) in Hull, England. This was at the time when pharmaceutical research was focused on the identification of a 'perfect morphine' for treating severe pain which was free from, or had substantially reduced, typical morphine-like side effects such as respiratory depression, opioid dependency liability, constipation and emetic effects.

The research effort was led by Dr John Lewis with the chemist Dr Ken Bentley who proposed that to achieve such an end-point, a more complicated chemical structure than morphine was required to improve its selectivity for the morphine (mu) receptor. Consequently, an extra ring system was introduced into the morphine skeleton which ultimately led to a series of compounds with unique opioid receptor selectiveness. This included buprenorphine, etorphine and diprenorphine. The latter two products were launched as veterinary products in 1970 as Immobilon® and Revivon® (mu receptor agonist as the tranquiliser and mu receptor antagonist as the reversal agent). Buprenorphine is a mu receptor partial agonist with kappa receptor antagonist properties. This results in a ceiling to its effects on respiratory depression and a lower opioid dependence liability than morphine. These represent two important safety benefits over morphine.

Injectable buprenorphine was launched in the United Kingdom in 1978 for the treatment of severe pain (especially post-operative pain) and the sublingual format was subsequently launched in 1982. By 1985, injectable buprenorphine had been marketed as an analgesic in 29 countries and the sublingual format in 16 countries. Although R&C Pharmaceuticals had no global pharmaceutical infrastructure in Europe, the US and parts of Asia, marketing of the analgesic products was achieved through the appointment of distributors at the country or regional level. This resulted in 10 distribution agreements which were difficult to manage because the distributors chose how to promote the products. Consequently, there was no global analgesic positioning of the brands.

In 1972, Lewis first disclosed buprenorphine's pharmacological profile at the annual meeting of the US Committee on Problems of Drug Dependence, which resulted in much interest in the US research community in their drive to identify new treatments for opioid dependency. Lewis appointed Dr Donald Jasinski as the company's consultant covering both analgesia and opioid dependency, and in 1978, Jasinski and colleagues described the therapeutic potential of buprenorphine in a landmark paper (Jasinski, Pevnick, & Griffith, 1978). They reported that buprenorphine was 25 to 50 times more potent than morphine, with a longer duration of action, and importantly, produced little if any physical dependence. It was also noted that the effects of 120 mg doses of morphine were blocked by buprenorphine, a blockade that persisted for more than 29 hours.

The key finding was that buprenorphine had potential for treating opioid dependence since it:

- was acceptable to patients
- was long acting
- produced a low level of physical dependence such that patients could be easily detoxified
- was less toxic than drugs used for maintenance therapy and blocked the effects of opioids (Jasinski et al., 1978).

By the late 1980s, the misuse and diversion of buprenorphine and its' 'off-label' use to treat opioid addiction (stimulated by the positive research results being reported in the US on its effectiveness in treating drug addiction) was becoming an increasing problem for Reckitt & Coleman. Ultimately, buprenorphine was rescheduled in 1989, resulting in a significant reduction in the analgesic component of the business. There was a reluctance within the company to enter the addiction therapeutics arena, reflecting a more general attitude among pharmaceutical companies that analgesics might be tainted in the eyes of prescribers and pain patients if also used for treating addiction. Methadone, for example, had found little use as a pain medication (Campbell & Lovell, 2012).

The rescheduling of buprenorphine, the poorer than expected performance of the analgesics business, coupled with the failure of two new chemical entities (NCEs) (potential antihypertensive and non-steroidal anti-inflammatory medications) in very late-stage development, resulted in the Company rethinking its pharmaceutical strategy. In-house research on NCEs was terminated, with future research focussing on their self-purchase medications such as Gaviscon®, Fybogel® and Lemsip®. Reckitt and Coleman then determined buprenorphine was 'off-strategy' and consequently put it up for sale.

Although methadone maintenance had been adopted internationally as a standard treatment of opioid dependence, concerns over diversion and misuse in the US resulted in it being delivered in a clinical and/or supervised dosing environment. This generally set the scene for future 'agonist' medications for opioid dependence treatment. The National Institute on Drug Abuse (NIDA) had been established to identify new treatments for opioid dependence and the first medication to come through their research was levacetylmethadol (LAAM) which was first approved in the US by the Food and Drug Administration (FDA) in 1993.

The Jasinski et al. (1978) paper on buprenorphine led to a flurry of research in the US funded by NIDA which all provided support for Jasinski's findings. This resulted in NIDA approaching R&C in the early 1990s seeking the Company's involvement in the development of buprenorphine under the auspices of a Cooperative Research and Development Agreement (CRADA). Reckitt and Coleman provided NIDA with buprenorphine to enable the agency to conduct its research, as well as providing NIDA with access to all the available safety data. Although R&C's Pharmaceutical Division was reluctant to enter a CRADA with NIDA, especially as buprenorphine was for sale, Vernon Sankey, the Chief Executive took the decision that the Company should enter a collaboration with NIDA. The CRADA was finally signed in 1994 (Federal Register notice of intent published May 1993). As a result, Reckitt and Coleman's buprenorphine business was no longer for sale.

France was the first country to approve sublingual buprenorphine for the treatment of opioid dependence. The President of the French Narcotics Agency, George Lagier, asked R&C and their French analgesic Distributor, Schering-Plough (SP) to provide an update on the US developments at a meeting in Paris in October 1994. Lagier had spent a sabbatical period with NIDA in the US and was aware of the safety advantages of buprenorphine over methadone. It is important to note that this was occurring at a time when the human immunodeficiency virus (HIV) epidemic was occurring across Europe. There was a significant increase in HIV incidence in France, predominantly associated with injecting drug users.

Following a review of the research data with the relevant French authorities, Lagier requested that R&C submit its Regulatory Dossier[3] by the end of 1994, because of the 'HIV emergency'. In July 1995, Subutex® was approved for the treatment of opioid dependence in general practice and was launched in February 1996. Reckitt and Coleman's and Schering-Plough's sales data suggested that approximately 25,000 patients were in treatment by the end of 1996. This had the effect of normalising addiction problems in France and allowed general practitioners to prescribe Subutex®, as they would any other treatment (Campbell & Lovell, 2012). In contrast, methadone was restricted to authorised clinics where dosing was supervised. France referred to the introduction of buprenorphine approach as a harm reduction initiative (Lovell, 2006).

The use of buprenorphine for opioid dependence treatment in France was subsequently associated with a dramatic decrease in deaths due to overdose. This, along with the implementation of methadone treatment and needle and syringe programs, contributed to a reduction in HIV infection prevalence in France among injecting drug users between 1996 and 2003 (from 40% to 20%). Nevertheless, buprenorphine diversion did occur in France, but this was largely associated with inadequate dosages, social vulnerability and obtaining prescriptions from multiple providers (Carrieri et al., 2006).

The success of Subutex® in France and the demise of the analgesic business with its complicated distributor agreements resulted in R&C terminating all existing agreements and appointing Schering-Plough as its global distributor in 1997. This was amended a year later because the SP Australian business determined that the provision of buprenorphine in Australia for opioid dependence treatment was commercially non-viable. This resulted in R&C retaining responsibility for buprenorphine in both Australia and New Zealand. Surprisingly, in the US SP was reluctant to have any involvement in the opioid dependence therapeutics. Even though the company was aware of the FDA's imminent approval of buprenorphine, SP had not made any preparations to launch the products, nor had it engaged with any of the key stakeholders. Therefore, (the by then) Reckitt Benckiser acquired back the rights for the US buprenorphine business from SP. This was concluded the week prior to receiving the FDA approval.

Subutex® (buprenorphine) and Suboxone® (4:1 ratio buprenorphine/naloxone) were both approved in October 2002 by the FDA and launched in 2003. The US FDA delayed the approval of Subutex® until the development of Suboxone® was completed, because of concerns over misuse and diversion of the buprenorphine product. National field evaluations revealed no significant safety issues emerging with the combination product which was comparable to Subutex® (Campbell & Lovell, 2012).

Thus, the US became the first country to approve Suboxone®. Key to the success in the US was the Drug Abuse Treatment Act (DATA) in 2000. This legislative landmark was signed by President Clinton in 2000 during his final week in office. The legislation allowed office-based physicians who met registration requirements to prescribe buprenorphine products. Thus, buprenorphine become the first agonist substitution treatment in US history to be available for use under this office-based treatment paradigm. The DATA (2000) required that prescribing doctors seek Federal permission to do so, attend eight hours of training, accept a 30-patient limit (amended in 2006 to 100 patients after a year of prescribing) and attest to their ability to make counselling referrals (Drug Enforcement Administration, 2019; Sontag, 2013).

3 A Regulatory Dossier is a package of documents, which includes all required information regarding newly developed drug products. It is required to grant marketing authorisation approvals.

The Act resulted in new profiles of patients being attracted into treatment. Patients were more likely to:

- be white and employed
- have some postsecondary education
- have fewer years of opioid dependence
- have no history of methadone treatment and to be addicted to prescription analgesics (Carrieri et al., 2006).

Suboxone® sublingual film replaced the sublingual tablets following FDA approval in 2010, and the once-a-month sustained release product Sublocade® was approved in 2017, providing an alternative treatment option to sublingual tablets.

Sustained release buprenorphine

Following its approval for clinical use, there was a desire among clinicians to develop sustained-release formulations of buprenorphine that could greatly reduce, or eliminate, the need to have large quantities of medications taken away from clinics or pharmacies. A sustained release formulation was also seen as desirable because it was more likely to lead to steady-state blood levels and to reduce the risk of withdrawal (Ling, Shoptaw, & Goodman-Meza, 2019).

Probuphine was the first attempt at sustained release buprenorphine, and it was in subcutaneous implant form. Each implant, a rod 2.5 mm in diameter and 26 mm in length, contained 80 mg of buprenorphine hydrochloride blended and extruded with an ethylene vinyl acetate polymer. Four implants were inserted sub-dermally under local anaesthesia into the inner side of the upper arm, in a brief office procedure. This provided a sustained non-fluctuating buprenorphine blood level over six months. Probuphine was not a commercial success. The major problem concerned the need for a surgical procedure, something most addiction medicine specialists had no inclination for (Ling et al., 2019).

Indivior (demerged from Reckitt Benckiser in December 2014) developed a sustained-release injectable formulation (Sublocade®) as an alternative treatment option to Suboxone® sublingual film. Sublocade® consists of buprenorphine base in an ATRIGEL® delivery system, designed to be subcutaneously injected monthly into the abdominal area. Formulations available are 100 mg and 300 mg once monthly injections. Sublocade® injections were initially required to be stored refrigerated at two to eight degrees Celsius. Subsequently, it was determined that Sublocade® could be stored in its original packaging at room temperature (below 25°C) for up to 28 days prior to injection. The US FDA approved Sublocade® in November 2017, for the treatment of moderate to severe opioid use disorder in patients who had initiated treatment with a transmucosal buprenorphine-containing product followed by dose adjustment for a minimum of seven days (Ling et al., 2019).

In December 2018, the US FDA approved a second injectable buprenorphine product, CAM 2038, now named Brixadi® (or Buvidal® in Australia) (Braeburn Pharmaceuticals and Camurus). Buvidal® is once weekly or once monthly extended-release, prefilled small volume, injectable buprenorphine. Buvidal® uses the FluidCrystal® injection depot technology which comprises a low volume lipid-based liquid with a dissolved active ingredient. The buprenorphine is subsequently released from the depot at a controlled and steady rate over the one-week or one-month period as the depot slowly biodegrades in the subcutaneous tissue. Buvidal® is delivered with a thin 23-gauge needle and administered in the buttock, thigh, abdomen or upper arm. Buvidal® does not require refrigeration and therefore has fewer logistical issues regarding storage (Ling et al., 2019; Lintzeris, Dunlop, & Masters, 2019).

There is a growing international body of literature that points to depot buprenorphine being an efficacious treatment for opioid dependence (Albayaty et al., 2017; Frost et al., 2019; Haasen, Linden, & Tiberg, 2017; Haight et al., 2019; Ling et al., 2020; Ling et al., 2019; Liu & Gobburu, 2018; Lofwall et al., 2018; Walsh et al., 2017). Yet despite this, the uptake has lagged in the US, potentially as a result of a range of systemic issues (Ling et al., 2019).

CHAPTER 4: AUSTRALIA'S POLICY AND LEGAL APPROACHES TO OPIOID DRUG PROBLEMS. COLONIAL SETTLEMENT UP UNTIL THE MID-1960s

Australia's opioid-related policy approaches were slow to develop and evolved in response to three main stimuli:

- anti-Chinese sentiment in the late 19th century
- international treaties and the influence of Australia's allies such as the United States
- the growth of recreational and dependent use of illicit drugs in the 1960s and 1970s (Norberry, 1997).

An examination of the development of opioid-related drug policies in Australia can conveniently be divided into three parts:

- colonial settlement up until the mid-1960s
- the mid-1960s to mid-1980s
- the mid 1980s to the present.

Colonial settlement up until the mid-1960s

Australia's struggle with substance use problems can be traced back to its early European settlement. Since that time, and throughout the decades which followed, Australians consumed large quantities of alcohol. In the early days of colonial settlement, alcohol fulfilled many functions. Both convicts and gaolers lived in a harsh environment, far from home. Alcohol provided both entertainment and escape. Since hard currency was scarce, rum even became an alternative form of payment in the country (United Nations Office on Drugs and Crime, UNODC, 2008). From this perspective, post-colonial Australia has a long history of being an intoxicated society.

There was also early concern about opium use, mainly linked to some pockets of Chinese people who had settled in the country as indentured labourers, or in response to a gold rush that occurred in the 1850s and 1860s. Most of the colonies/States and Territories subsequently introduced legislation prohibiting the smoking of opium towards the end of the 1800s and early 1900s, in order to prevent the spread of opium smoking from the Chinese minority to the broader population (Norberry, 1997). The Commonwealth Opium Proclamation, 1905 (made under the Customs Act 1901) was passed to prohibit the importation of opium for non-medical purposes. The racial basis of the prohibition was made explicit by General Order 956 of the Department of Trade and Customs, which referred to illegal possession of opium by Chinese or others (Manderson, 1987).

Victoria was among the first States to pass complementary legislation, outlawing the sale, manufacture, possession and use of smoking opium in 1905. A speaker in a Victorian parliamentary debate at the time suggested that it would be preferable not to ban opium, because it would result in the Chinese continuing to smoke the drug until they were wiped out of existence. Likewise, Victorian parliamentarian, John Wood, declared that although he would not be inconsolable if, through opium, they [the Chinese] suffered this fate, he was more concerned at the rapid increase of the use of opium amongst the white population, more especially among young girls who were systematically decoyed into dens occupied by 'filthy Chinese' (Rowe, 2001).

Ironically, the use of opium by some Chinese immigrants was, in large part, due to the actions of British colonial authorities. Throughout the 19th century, the colonial British government in India derived significant revenue through the sale of massive quantities of Indian opium to China. This led to the threat of mass addiction, and as a result, the Chinese government sought to halt the trade. The British, unwilling to relinquish its lucrative enterprise, responded aggressively, and fought China in the Opium Wars of 1839-1843, a consequence of which was China's forced acceptance of opium imports. Not until 1906 did a British government come to power that was sympathetic to China's attempts to reduce the growing social devastation wrought by opium. In 1909, the relevant nations met in Shanghai and signed a resolution, which in turn led to the signing of the first multilateral drug control treaty at The Hague in 1912. From this point on, the drug policies of individual nations were linked to broader issues of international cooperation (Rowe, 2001).

In 1898, the Friedrich Bayer Pharmaceutical Company in Germany patented a product it subsequently launched as a new cough suppressant: diacetylmorphine, or heroin. Heroin was so called because the German term heros referred to an ancient Greek hero who was honoured as a demigod on account of his good deeds. Heroin was developed by the same research team that introduced aspirin. These researchers were convinced that heroin would make a valuable contribution to medicine as a cough suppressant, to assist breathing in patients with severe lung disease (Sneader, 1998).

Although a limited number of proprietary medicines had been available in Sydney since the 1820s, it was not until the 1870s that the Australian market became a target of patent medicine companies. These companies derived large profits from 'secret remedies' that generally had a high opium or alcohol content, and often both (Gibson et al., 2003). In the late 19th century, Australia drug consumption might justifiably have been described as a national trait. By the end of the 19th century, Australia had the world's highest per capita consumption of proprietary medicines (Manderson, 1993). Colonial authorities saw little reason to impose controls on this thriving patent medicine industry (Rowe, 2001).

At this time, the consumption of opioids in Australia was largely a matter of personal choice. Drugs, including opioids, were available from a wide variety of sources, including medical practitioners, pharmacists, homoeopaths, sellers of patent medicines, and grocers. The medical profession had not yet come to dominate the provision of health services. Self-treatment was common, and dependence on opium (or cocaine) was generally therapeutically-induced (Manderson, 1992). Ironically, heavy use of these patent opium-containing remedies among the European population was regarded as medicinal use, while opium smoking was regarded deviant and offensive (Swift, Maher, Sunjic, & Doan, 1997).

The profile of drug dependence in Australia at the turn of the twentieth century was similar to that of many other nations. The typical dependent user was a middle-class, middle-aged woman or health professional using legally purchased medicines. This 'user' profile remained largely unchanged until the 1960s (Manderson, 1992). In the late 19th and early 20th century, ingredients then used in proprietary medicines included:

- opium and morphine in Bonnington's Irish Moss
- morphine in Cherry Pectoral, Kay's Essence of Linseed and Winslow's Soothing Syrup
- opium in Perry Davis' Painkiller, Atkinson's Royal Infant Preservative and Ayer's Sarsaparilla Mixture (Norberry, 1997).

Concern about the role of these proprietary medicines in poisonings, murders and suicides led to the restriction of their sale to registered pharmacists in the early 1900s. In 1901, the Federation of the Australian colonies empowered the Commonwealth to ban the importation of opium suitable for smoking, which it did in 1905. This was a move which may have been inspired by anti-Chinese sentiments, although it is noteworthy that a substantial proportion of the Chinese community was also opposed to opium smoking. These laws also heralded the emergence of the medical profession as a powerful pressure group. The decline of the proprietary medicine industry was part of a broader movement away from laissez-faire government towards increased regulation of citizens. In 1910, the Commonwealth made it an offence to be in possession of opium without reasonable excuse, and placed the burden of proving a reasonable excuse with the defendant (Manderson, 1992; Norberry, 1997).

The early regulation of drugs such as opioids occurred by way of poisons laws which imposed requirements on the sale and labelling of certain drugs. In 1908, a Royal Commission was established by the Commonwealth Government to inquire into Secret Drugs, Cures and Foods. The Royal Commission criticised the lack of controls on the composition and availability of proprietary medicines, advertising claims, and the use of preparations containing cocaine and opioids to pacify infants and to treat alcohol problems. Their free availability to adolescents and adults alike also drew criticism from the Commission (Norberry, 1997).

Although Australian authorities had commenced drug control efforts at the State/Territory level in the 19th century and at the Federal level at the beginning of the 20th century, the subsequent development of illicit drug laws and policies and opioid drug treatment programs were strongly influenced by the emergence of the international drug conventions (MacKay, 2001).

The control of opioids had been a global concern since the International Opium Commission, (known as the Shanghai Conference) of 1909. An Opium Conference at the Hague in 1911 drafted the first treaty which attempted to control opium (and cocaine) through worldwide agreement, by means of the Hague Convention, 1912. The parties to this Convention agreed to:

- limit the manufacture, trade and use of opioid products to medical use
- cooperate to restrict use and to enforce restrictions efficiently
- penalise possession
- prohibit selling to unauthorised persons (MacKay, 2001).

From 1920, the Hague Convention, 1912 was the responsibility of the League of Nations and since 1946 it has been administered by the United Nations (MacKay, 2001).

Australian drug laws, like those of many other countries, closely followed the development of these international drug treaties. The Australian Government was among the first countries to ratify the Hague Convention, 1912 (in 1914) and used it to extend import controls on a range of drugs, including opium, various other opioids, and cocaine (Norberry, 1997).

Regulation of the use, sale, possession or manufacture of previously uncontrolled drugs such as morphine, heroin, cocaine and medicinal opium was introduced at State/Territory level between 1913 and 1930. The possession of these drugs became legal only if obtained with a medical prescription, or if the possessor was an authorised person such as a doctor or chemist. A system of licences, record-keeping requirements and authorisations was established, and penalties were introduced for unauthorised possession. The medical use of heroin was phased out in Australia as the 20th century progressed, in response to international conventions and pressure, particularly from the United States. In 1953, the Commonwealth Government introduced an absolute prohibition on the importation of heroin and urged the States to prohibit its manufacture. This occurred despite strong opposition from the medical profession (Norberry, 1997).

In 1935, the NT Chief Medical Officer Dr Cecil Cook expressed concern about increasing opium smoking in the NT. A group of Chinese who were addicted to opium were financing their dependency by introducing and selling the smuggled opium to the Aboriginal labourers on the railway and in agriculture. Dr Cook proposed a system whereby the government would purchase opium and supply it to registered addicts. This, he argued, would enable some control of the situation. Similar proposals had previously been contemplated for such problems in Queensland and WA. The Commonwealth firmly rejected the proposal after consultation with the League of Nations, which reinforced Australia's commitment to the 1912 Hague International Convention for the Prohibition of Opium (Chalmers, 1993).

World War II changed Australia's international relations. There was a move away from Britain towards reliance upon the United States (US) to guarantee Australia's security. The US was, and had always been, less tolerant of drug use than Britain. For example, Britain offered heroin as an OAT for heroin dependence, something which would never have been countenanced in the US. Consequently, Australia began to take a harder legislative stance towards drug use. As a wider range of drugs were developed and promoted, many, including pethidine, were added to the list of restricted drugs. Throughout the 1950s, the United States no longer pursued an isolationist foreign policy and its officials increasingly dominated international organisations involved in drug control. These attitudes also influenced Australian policies towards drugs, international control measures and drug treatment approaches (Gibson et al., 2003).

It appears likely that Australia's first formalised OAT program commenced in Queensland after the end of the World War II. This was initiated by the Queensland Department of Health, primarily to cater for the needs of an ageing cohort of people of Chinese descent who were opium smokers. Since possession of smoking opium was illegal, the Department provided these individuals with tincture of opium (laudanum) as a substitute. In 1955, there were 34 Australians of European descent receiving morphine, pethidine or in some cases methadone, under the control of the Queensland Government, and 68 older Chinese people receiving laudanum. As recently as 1960, 47 people of Chinese descent remained on this maintenance program (Manderson, 1993).

CHAPTER 5: AUSTRALIA'S POLICY AND LEGAL APPROACHES TO OPIOID DRUG PROBLEMS. THE MID-1960s TO THE EARLY 1980s.

Up until the late 1960s, few resources were devoted to illicit drug use issues in Australia, since there was little unsanctioned use of drugs (MacKay, 2001). Until the 1960s, drug dependence was not viewed as a major social problem in Australia (Norberry, 1997). Dependent users whose addiction was therapeutically induced were maintained on heroin (prior to its banning), pethidine, morphine and opium. However, recreational and dependent use of illicit drugs grew in the 1960s and 1970s in Australia and other Western nations. The participation of Australia in the Vietnam war exposed young Australian soldiers to readily available heroin. Importantly, many young US soldiers who served in Vietnam came to Australia for rest and recreation, and brought with them newly acquired drug habits (UNODC, 2008).

Records from the US Department of Defence revealed that 45% of enlisted US servicemen in Vietnam had used narcotics during 1970-1971. It could be expected that a number of those servicemen on leave in Australia were users of heroin and brought it into the country. Once these supplies were depleted, a system of importation developed to provide for the US troops and their numerous local counterparts. Heroin from Hong Kong replaced opium as the drug of choice amongst eastern Australia's Chinese community in the 1950s, and by the mid-1960s their distribution networks were able to simply divert supplies to Kings Cross in Sydney and its growing clientele (Rowe, 2001). In the 1960s, and for decades thereafter, Kings Cross was Australia's premier illicit drug market (Gibson et al., 2003). The growth of the heroin market in Kings Cross eventually spilled over to the broader population as well (UNODC, 2008).

Ironically, the ending of the war in Vietnam indirectly expanded the heroin trade. The withdrawal of troops from South East Asia deprived the area's illicit economies of a major market. This compelled heroin syndicates to seek out alternative markets. Australia, a middle-class country with an emerging youth movement and little cultural resistance to heroin use, was a prime target. It also offered the added advantage of being close to production bases, and its vast coastline made effective policing virtually impossible. Until the 1970s, heroin importation had consisted primarily of traders making small-scale purchases of the drug in South East Asia and arranging its importation into Australia by enterprising young users. However, such methods were soon superseded by organised large-scale operations, ironically because of a major drug enforcement effort in the late 1970s (Rowe, 2001).

Internationally, there was renewed interest in treaties to control illicit drug use at this time, and consequently penalties for illicit drug use were increased in Australia throughout the 1960s and 70s (Norberry, 1997). During this period, Australian policy-makers were faced with a choice of approaches to deal with the emerging heroin problem. They could either lean towards the British system, which emphasised the controlled provision of drugs (including heroin) to addicts, or the US model, which emphasised prohibition (McArthur, 1999b).

Ultimately, throughout the 1970s and early 1980s, Australian governments continued to pursue a deterrent-based drug control strategy, following more closely the approach adopted in the US. This approach was centred on giving law enforcement agencies a legal basis for illicit drug control and on providing more resources to these agencies. Policies generally focused on raising maximum penalties, creating additional offences, making offences easier to prove, and establishing new investigative bodies such as the National Crime Authority. This significantly increased the powers and the technology available to law enforcement agencies to detect drug offences. Civil asset forfeiture were also implemented to confiscate illicit drug profits (UNODC, 2008).

According to the 1980 Williams Royal Commission of Inquiry into Drug Trafficking, between 900 and 1300 kilograms of heroin would have been needed to supply Australia's addict population annually. The Commission estimated that there were between 14,200 and 20,300 addicts in Australia in 1978. By the late 1970s, large and relatively sophisticated criminal syndicates were making regular runs between Thailand and Australia to import heroin. Despite large-scale seizures becoming commonplace throughout the 1980s, police had little impact on the expanding trade, partially because of corruption (Williams, 1980).

In June 1983, the Stewart Royal Commission found evidence of criminal conduct on the part of police, including falsifying evidence in return for payment, stealing drugs and money from offenders, supplying heroin in exchange for information, and selling confiscated drugs (Rowe, 2001).

Drug Treatment Services

In the early 1960s, specialist drug and alcohol services were very under-developed. People with addiction problems tended to be seen by psychiatrists within mental health services or by non-government, charitable organisations (McArthur, 1999b).

Apart from the post-war program in Queensland, the first well documented use of methadone in Australia as a treatment for heroin users was by Dr Stella Dalton, a private psychiatrist, in Sydney in 1969 (see Chapter 12 for more details). In the early 1970s, methadone treatment expanded rapidly and by the end of 1976 about 1,980 people had participated in public and private methadone programs in NSW (Swensen, 1990).

Methadone treatment was also introduced in the early 1970s in Victoria, Queensland, SA and WA. Several methadone policy options were available to Australian States and Territories at the time. They could:

- not permit methadone treatment at all, the approach adopted by Tasmania and the NT
- establish a fully State-run methadone program, an approach adopted, for example, in SA in 1973 and WA after 1977
- permit a completely privately-run program
- adopt a mixture of public and privately run programs, the approach adopted in NSW, Victoria and Queensland (Swensen, 1990).

The main features of this phase were the introduction of tight governmental controls over the activities of private prescribers and restricted provision of methadone treatment by State health authorities. In some jurisdictions, particularly NSW, the major emphasis of drug treatment policy was to fund drug-free rehabilitation programs run by non-government welfare organisations, and there was still significant disquiet regarding non-abstinence-based treatment approaches.

There was also an emerging belief in the mid-1970s that methadone was not regarded by its target population as a treatment, but simply as an avenue to obtain opioids legally. The capacity of methadone programs at the time to attract large numbers of heroin users, compared to detoxification and drug-free programs, was not interpreted as a measure of treatment demand or its success. Rather, this was seen as evidence of over-prescribing (Swensen, 1990).

The development of the Australian Medical Society on Alcohol and Drugs

In the late 1970s, Dr Les Drew and Professor James Rankin discussed the needs, feasibility and value of establishing an Australian medical group in the drug and alcohol field. Dr Rankin was the Director of the Drug and Alcohol Division within the Health Commission of NSW. Dr Drew was the Senior Advisor on Drug Dependence for the Commonwealth Government. They believed that at that time, no suitable national professional and scientific organisation had developed in Australia within which medical scientists and practitioners could effectively meet to discuss, pursue and promote matters of mutual interest in the field (Australasian Professional Society on Alcohol and other Drugs, APSAD, 2020; Drew, 2014).

In 1981, Dr Drew and Professor Rankin and a group of medical colleagues established the Australian Medical Society on Alcohol and other Drugs (AMSAD) and became members of its first Board of Directors. Their intention was that the Society should be primarily a medically-oriented organisation established to meet the needs of medical scientists and practitioners. The Society also endeavoured to attract a broad medical membership from individuals who had a scientific or professional interest in alcohol and drug-related problems, their prevention, diagnosis and treatment. The First Annual Meeting of the Society was held at the Australian National University, Canberra, on July 31 and August 1, 1981 (APSAD, 2020).

A major change in focus occurred during the first 10 years of the Society's existence, following its acceptance of non-medical professionals as full members. In recognition of this, the Society's name was changed to the Australian Medical and Professional Society on Alcohol and Drugs (AMPSAD). The name was subsequently changed again in November 1993 to the Australian Professional Society on Alcohol and other Drugs (APSAD), and again on December 1, 2004 to the Australasian Professional Society on Alcohol and Other Drugs (APSAD) to encompass New Zealand colleagues (APSAD, 2020).

The Society also worked with the NSW Drug and Alcohol Directorate to develop the NSW Methadone Prescribers Accreditation Course, which was subsequently replicated in other States and Territories, and was internationally recognised. The Society also became involved with the National Methadone Conference in 1994, and this Conference was held in association with the annual APSAD conference until 2002 (APSAD, 2020). Over the years, the Society has made a substantial contribution to enhancing the quality of OAT provision in Australia.

CHAPTER 6: AUSTRALIA'S POLICY AND LEGAL APPROACHES TO OPIOID DRUG PROBLEMS. THE MID 1980s.

The beginning of the National Campaign Against Drug Abuse

By the mid-1980s, the advent of HIV caused Australia to evaluate and re-direct its approaches to drug policy, to increase the emphasis placed on prevention and treatment. This followed the realisation that HIV could be transmitted via intravenous injection. In November 1982, the then Leader of the Opposition, Bob Hawke, in his election policy statement, made a passing commitment to educate young Australians about the dangers of illicit drugs and to rehabilitate those with drug-related problems. During the election campaign, a proposal for a Drug Summit originated as the result of a talk-back interview. Incidental as these events might appear, they reflected the future Prime Minister's long-standing personal concern regarding illicit drugs. It was from these commitments to action that the Australia's National Campaign Against Drug Abuse (NCADA), developed (Blewett, 1988).

On April 2, 1985, the by then Prime Minister, Bob Hawke, convened a meeting in Canberra with all six State Premiers and the Chief Minister of the NT.[4] The special Premier's Conference, usually referred to as the Drug Summit, was said to be the first meeting of the Prime Minister and Premiers since World War II to discuss anything other than finance. One of the items raised at the Drug Summit, along with a raft of other issues, was a proposal to adopt harm minimisation as Australia's official national drug policy. This meeting was to have far-reaching repercussions, including the establishment of the NCADA (Wodak, 2015). In addition, the Drug Summit also resolved to increase the availability of methadone treatment for heroin dependence (Commonwealth Department of Human Services & Health, [CDHSH] 1995). In many ways, the Drug Summit laid the foundation for the expansion of methadone and other treatment programs that followed in Australia.

The attendees at the Drug Summit represented a broad range of perspectives on the future direction of Australia's drug policies. There were the 'drug war warriors' who were prepared for some collateral damage in their pursuit of the drug dealers. There were also 'harm minimisers' whose focus was chiefly on the victims of drug use. While these groups tended to fall into two hostile camps there was a considerable degree of fluidity in the positions of the key players. The Queensland Premier, Joh Bjelke-Petersen, was perhaps the most ferocious drug war warrior at the Summit, yet he was a strong advocate of the expansion of methadone programs. The NSW Premier, Neville Wran, was the leading advocate of supplying heroin to addicts, but sought to outflank Bjelke-Petersen with the ferocity of his supply side proposals. Although attendees were divided on many key issues, there was a broad consensus that the drug problem was primarily a medical or health one, rather than primarily a criminal law and police problem (Blewett, 2009).

4 The Australian Capital Territory Legislative Assembly was not established until 1988, first meeting was in 1989.

The Official Communique from the Drug Summit read:

> *... existing methadone maintenance programs should be expanded and new ones established; the existing guidelines for the use of methadone will be reviewed. The Conference was opposed to the provision of heroin as a treatment for drug addiction.*
>
> *It was also agreed that a range of special treatment and rehabilitation services for drug abusers be established in teaching hospitals and other major hospitals. Treatment and rehabilitation services are to be made available to drug dependent prisoners. Regular evaluation of programs by community agencies will be a condition of continued government funding of services (Department of Prime Minister and Cabinet, 1985).*

Commonwealth Health bureaucrats were subsequently given the responsibility for developing the NCADA Strategy Paper. They used this opportunity to subtly shift the emphases of the Ministerial Communiqué to more clearly reflect the concerns of the public health community, which had sought to place more emphasis on minimising the harmful effects of drugs on Australian society. Yet the terms 'minimising harm', 'harm minimisation' or 'harm reduction' occur nowhere in the 6-page Ministerial Communiqué. Consequently, what has been described as 'the cornerstone of the Australian approach to drugs' was an inspired, but bureaucratic intervention, rather than one that wholly emanated from the Drug Summit (Blewett, 2009).

The NCADA, launched in 1985, codified the new policy orientation by stressing that drug use should be treated primarily as a health issue and that a key aim should be to minimise the harm associated with drug use. This approach addressed both licit and illicit drugs (Wodak et al., 2012). The rationale for this was that by minimising the harmful effects of the supply and demand for illicit and licit drugs, Government policy could have a positive impact on the country's overall level of social and economic wellbeing and health. Licit and illicit drug supply, demand and reduction strategies formed an integral part of this approach. The Campaign was coordinated and overseen by the Ministerial Council on Drug Strategy which reported to the Premiers' Conference (UNODC, 2008). The Australian approach sought to minimise drug harm through a balance of supply, demand, and harm reduction strategies.

A core feature of the new approach was the perception that drug use was a complex phenomenon that would never be eliminated, but that useful gains could be made by minimising associated harms. Australia was one of the first countries to adopt harm reduction as its official national drug policy. Few countries have been as explicit as Australia when adopting harm reduction (Wodak et al., 2012). As the then Federal Health Minister Dr Neal Blewitt noted, NCADA was...

> *... the first national attempt of all the governments of Australia to reduce the harm associated with drug use in our community. That national quality is itself worth pondering. Federation is one of the great log jams to effective national action in this country, but for once, the States and Commonwealth have put aside most of their usual bickering to join, for the first time, in a co-operative National Campaign Against Drug Abuse (Blewett, 1988).*

The harm minimisation approach to drug issues in Australia has not been without criticism. There was confusion over the meaning of term itself, which diminished the shared ownership of NCADA and its subsequent iterations. There was also debate about the underlying principles that underpinned harm minimisation. Despite the fact that reducing levels of drug use was a key plank in reducing drug harm, some commentators argued that focussing on minimising the harm from drugs use could diminish efforts to reduce drug use overall (Ritter et al., 2011).

From a strategic point of view, this policy approach focused on the harm caused to individuals and society stemming from the use and supply of heroin and other drugs. Abstinence from illicit drugs was still seen as an objective, but it was not necessarily the primary goal of drug policy. This significant change opened the door for wider acceptance of methadone treatment for heroin problems.

One of the most tangible signs of this new approach to drug policy was movement of the political authority for drug policy from the Federal Attorney General's Department to the Federal Department of Health (UNODC, 2008). This shift of responsibility stemmed from a greater understanding that heroin use was a health, rather than a legal, issue. This in turn changed the balance of policy emphasis from law enforcement sector approaches towards health sector approaches. Methadone treatment for opioid dependence was prominent in this regard.

Several measures were also implemented to improve drug policy coordination, including the creation of partnerships between the Commonwealth and the States and Territories, and between the health care and the law enforcement sectors. The latter also reflected the Government's new commitment to a comprehensive and integrated approach to drug problems (UNODC, 2008). The National Drug Strategy Committee (NDSC) was established to lead policy development in conjunction with the Ministerial Council on Drug Strategy (MCDS) (Ritter et al., 2011).

Until the NCADA, the Federal government had not directly provided money for drug programs to the States, except through hospital cost-sharing agreements (Swensen, 1990). A major reason why there was such a major expansion in treatment services following the Drug Summit was that the Summit secured the involvement of the Commonwealth government, the wealthiest of Australian governments, for the first time in a significant way in drug issues (Blewett, 2009).

Dr Robert Ali

In the same year as the Drug Summit and the launch of NCADA, Dr Robert Ali commenced work in the Drug and Alcohol Services Council (DASC) in South Australia. Dr Ali had no prior experience in working with alcohol and other drug clients and began working in DASC's detoxification facilities. He ultimately moved to DASC's methadone program. This occurred at the same time as a large injection of funding began flowing to DASC from NCADA.

The DASC methadone program at this time was characterised by naloxone assessments to determine opioid dependence, low dosage shorter-term treatment.

In 1987 Dr Ali attended his first meeting of the National Methadone Guidelines Working Party. This began a long and distinguished career in OAT. Dr Ali went on to chair the National Expert Advisory Committee on Illicit Drugs. Dr Ali played a very prominent role in OAT policy documents and clinical guidelines for almost three decades.

CHAPTER 7: AUSTRALIA'S POLICY AND LEGAL APPROACHES TO OPIOID DRUG PROBLEMS. THE MID 1980s TO MID 1990s

Given that the provision of methadone produces some form of dependence, historically there was understandably a serious clinical concern about providing methadone to non-dependent drug users. However, in the mid to late 1980s, such concerns were substantially suspended because of HIV. Increasingly, individuals did not have to be 'physically' dependent on opioids to be administered methadone if he, or she, was a risk to public health (Bennett, 2011).

Likewise, in an attempt to reduce the harm associated with the spread of blood-borne diseases, Australia's first needle syringe program (NSP) opened in Darlinghurst in November 1986 (Hughes, 2020) as an act of civil disobedience (Wodak et al., 2012). Soon afterwards, all State governments accepted the need for NSPs and the necessary legislation was adopted. By the end of the 1980s, sterile needles and syringes were readily available throughout most of Australia. The fact that harm minimisation was the cornerstone of official national drug policy facilitated the early adoption and vigorous expansion of NSPs and methadone programs. Nevertheless, this expansion still required major ongoing advocacy efforts (Wodak et al., 2012).

When considering this period of OAT in Australia, as in the rest of the world, it is important to be mindful that the evidence base informing OAT practice was sparse. Consequently, between 1985 and 1995, there was a worldwide active research program investigating the effectiveness of methadone maintenance treatment and the factors influencing that effectiveness. Four comprehensive reviews of the accumulated methadone literature were conducted, two in Australia (Ward, Mattick, & Hall, 1992; Mattick & Hall, 1993) and two in the United States (Gerstein & Lewin, 1990; Sisk, 1990). These reviews all found sufficient evidence to conclude that methadone maintenance treatment led to substantial reductions in heroin use, crime and opioid-related deaths. They also concluded that it was highly likely that methadone treatment would also contribute significantly to preventing the spread of HIV among injecting opioid users. These reviews supported the endorsement of methadone maintenance as part of NCADA and the subsequent expansion that took place in methadone services around Australia (Ward, 1995).

Despite this expansion, there were very few doctors, nurses and psychologists with any experience in delivering methadone treatment. The treatment expansion saw some new clinics being staffed by people with no knowledge of or experience in methadone treatment. Some came from services providing abstinence-based treatments, often assuming a paradigm of treatment based on 'curing' clients. Others had no background in treatment of addiction and had negative assumptions about people who used illicit drugs, which hampered the establishment of therapeutic relationships. A proliferation of different models of treatment occurred as a result of untrained staff bringing a diverse set of assumptions to an unfamiliar treatment modality (Bell, 2000).

A lack of clinical consensus was particularly apparent in the mid-1980s. Methadone maintenance was widely seen as a treatment of last resort and it was considered important to place barriers in the way of people entering treatment (Bell, 1996). Similar problems of inexperienced staff and proliferating competing models of treatment were observed in the US during the earlier expansion of treatment there (D'Amanda, 1983; Dole & Nyswander, 1973).

Rosenbaum (1985) described significant variations in approaches adopted by providers of methadone services the United States at the time. Three types of methadone clinics were evident in the US. This typology, which was highly relevant to Australia at the time, and to some extent currently, is described below.

1. The medical model clinic

The medical model clinic was philosophically based upon the metabolic theory of addiction and later endorphin research.[5] Addicts were seen as having a chronic illness that needed to be treated, perhaps for the duration of their lives. From this perspective, it was fruitless and potentially dangerous for addicts to try to live without some opioid substitute after being addicted for an extended period.

2. The reformist clinics

Clinics which espoused a reformist philosophy posited that methadone was a tool for an ultimately drug-free existence. Methadone maintenance was seen as a relatively short- term treatment that gave heroin addicts time to get their lives in order. After treatment, addicts should detoxify from methadone and stop using drugs altogether. Some reformist clinics had time limits of two to three years, after which the client was automatically detoxed off the program. Above all, the addict was seen as an individual with a behavioural problem which needed to be remedied or at least controlled.

3. The libertarian clinics

These clinics maintained that individual freedom in all realms was crucial and people should be free to do what they please to and for themselves. Furthermore, the libertarian perspective held that heroin addicts have been singled out as the target of unfair discrimination. From this perspective, although society is obsessed with drug taking (e.g., nicotine, alcohol, and caffeine), only certain groups are persecuted (and prosecuted). Therefore, the belief was that the purpose of a methadone clinic was to provide addicts with what they needed but could not acquire legally. These clinics saw their role, within appropriate regulations, to right an injustice (Rosenbaum, 1985).

It is perhaps overly simplistic to suggest that all Australian methadone treatment providers at the time fitted neatly into Rosenbaum's typology. For example, one type of methadone clinic missing from Rosenbaum's typology was those private clinics present in Australia over the years whose raison d'être was to generate substantial income for their owners and the providers of associated pathology services. Nevertheless, the typology highlights some of the tensions faced by those responsible for providing direction to methadone services in Australia.

5 This research suggested that some individuals may endorphin abnormalities. In this way, individuals with an endorphin deficiency find opioids such as heroin to be an instant relief, which would help to explain their attraction and subsequent addiction to heroin. Perhaps more pertinent to treatment issues was the suggestion that even in individuals with 'normal' endorphin levels, prolonged opioid use renders the body's own endorphin system inadequate (e.g., Goldstein, 1979).

The prevailing view among most clinicians in the mid-late 1980s was that methadone programs should adopt a psychotherapeutic approach to methadone treatment, with an emphasis on counselling, use of low-dose methadone, and time-limited treatment. The use of methadone in short-term withdrawal programs was common. Assessment of treatment suitability was seen as particularly important, and lengthy and detailed assessment procedures were often employed to guard against entry of non-dependent drug users (Bell, 2000). This included the use of naloxone testing.

Unfortunately, these intake procedures adversely impacted program effectiveness. A study undertaken in Sydney found that not only did prolonged assessment procedures deter more than half the initial applicants from entering methadone maintenance, but they also did not improve in-treatment outcomes. Prolonged assessment was associated with significantly increased in-treatment heroin use and an increased likelihood of expulsion and premature discharge from treatment (Bell, Caplehorn, & McNeil, 1994).

There were also some less-than-flattering evaluations of methadone treatment occurring at this time. For example, in a study of 63 admissions to a methadone maintenance program at the Royal Newcastle Hospital:

- thirteen clients remained on the program for less than two weeks.
- of the remaining 50 such admissions, 35 were terminated because of absenteeism, drug abuse, violence or drug-dealing.
- twelve patients did not take intravenously administered drugs during the time that they were receiving methadone, but in 25 of the 50 admissions that lasted for more than two weeks, such drugs were used at least fortnightly.
- eight patients achieved a stable state without drugs that lasted at least three months.
- no improvements were noted in patients' social situations, relationships, health or criminal activity, but compliant patients did improve their employment status.

This study concluded that a significant minority of patients benefited from methadone maintenance therapy, but most continued their drug misuse and drug-related life-styles (Foy, Drinkwater, & White, 1989).

In the late 1980s and early 1990s, policy-makers and treatment practitioners sought to return methadone treatment to the harm reduction framework from which it originally arose. This was to ensure that there was sufficient treatment available to meet demand and to ensure that treatment remained effective. Several key changes took place in methadone treatment policy and practice during this period including:

- a move away from short-term treatment aimed at abstinence to an approach that accepted that individuals should be maintained on methadone for as long as was necessary
- reducing therapeutic demands placed on clients, reflecting the view that it was more important for drug users to reduce risk behaviours and be in touch with health services, than to unrealistically demand that they eliminate their drug use altogether
- reducing the number and range of services provided by methadone programs
- liberalising entry criteria, which resulted in a change in the population being treated, with less motivated and less compliant individuals being accepted for, and retained in, treatment
- moving away from specialist clinics as the preferred mode of treatment delivery and instead adopting a range of options aimed at 'mainstreaming' or 'normalising' methadone treatment. This included the management of prescribing by general practitioners, dispensing in community pharmacies and the integration of methadone services into the activities of primary health care centres and hospitals (Ward, 1995).

The progressive broadening of the admission criteria for methadone programs and their increased accessibility resulted in a large increase in younger people and women in Australian methadone programs (Gaughwin et al., 1993).

Many of these changes were formalised in the National Methadone Policy published in 1993 (Commonwealth of Australia, 1993). The National Policy was based on National Methadone Guidelines which had been operational since 1987. The policy reflected a national position on the role of methadone and provided core operational procedures to guide the provision of services. The Policy was endorsed by the Ministerial Council on Drug Strategy in 1993 and was distributed widely throughout Australia (CDHSH, 1995).

The initial growth in the number of people in methadone treatment in the post NCADA era was a result of government-funded clinics providing free treatment. Demand for treatment remained strong, but funding for treatment did not keep pace with continued growth. As a result of the continued brisk demand and limited public funding, two new forms of service delivery funded by patient fees were introduced. These were private methadone clinics, and office-based methadone treatment, in which clients saw a doctor, usually a general practitioner, who prescribed methadone, which was dispensed daily from a retail pharmacy. These new approaches were underpinned by the development of training programs designed to recruit and equip practitioners to treat people with heroin problems with methadone (Bell, 2000).

Arguably, this change in the approach to providing methadone was driven more by economic than clinical imperatives. One of the problems with office-based methadone was that it was more cost effective for dispensers to provide clients with take-away doses of methadone, compared with providing supervised doses (since fewer staff were needed for supervised administration). At the same time, this increased the costs to clients because they were responsible for meeting the pharmacies' dispensing costs. As a result, clients could be tempted to sell a portion of their take-away dose to meet the high dispensing fees. A further issue was that, as medical practitioners became increasingly prominent providers of methadone treatment, many of the wrap-around support services that had been provided in State Government-funded clinics fell away. In many cases, the doctors just provided methadone prescriptions (Bell, 2000).

Despite the move towards private methadone prescribing in several jurisdictions, public clinics (or those operated by the private sector under contract to State Governments) continued to play an important role. The public clinics tended to specialise in the initial treatment of clients and the continued treatment of more complex cases. Once stabilised, clients were generally referred to the private sector. While this public/private sector delineation of roles in the provision of services seemed logical, this tended to have an adverse effect on morale of staff working in the public clinics. Continually treating complex clients in the public sector could become demoralising over time. By not being involved in the treatment of more stable clients, who generally had a greater chance of a successful outcome, at least in the short-term, staff of public clinics often did not have balanced workloads (CDHSH, 1995).

The increasing shift towards the involvement of the private sector in the provision of methadone treatment saw this treatment increasingly being funded by the Commonwealth, through Medicare. Between 1986 and 1994 the methadone program participation rate in Australia tripled from 5.9 persons per 10,000 in the target population group to 18.2 persons per 10,000 in the

target population. Public sector participation rates increased from 3.6 persons per 10,000 to 7.9 persons per 10,000, while private sector participation rates increased from 2.3 persons per 10,000 to 10.2 persons per 10,000 in 1994. This was largely due to the growth in the private sector in NSW and Victoria. This led to concern in the Commonwealth Department of Human Services and Health about the increasing costs being incurred by the Commonwealth, and a perceived imbalance in the agreed methadone program cost-sharing arrangements with the States. In 1989, an inquiry into funding arrangements for methadone maintenance treatment recommended a new funding formula for public and private services, but this failed to gain national agreement (CDHSH, 1995).

A comparison of public and private methadone clinics in NSW at the time found that the two treatment settings differed substantially. Private clinics charged dispensing fees, had frequent, usually brief medical consultations, no other formal counselling, had lower staff-patient ratios and provided many more take-away doses of methadone. In all private clinics the availability of take-away doses of methadone appeared a matter of policy, rather than being based on patients' stability in treatment. Consequently, selling and injecting take-away doses was not uncommon. No private clinics had written policies, procedures or job descriptions and stated policies were frequently not enforced. There was also a lack of staff training and supervision. There were also substantial differences between clinics in each of the public and private sectors, and overall, differences in outcomes between clinics within the public and private sectors were greater than differences between the sectors (Bell et al., 1995).

In the late 1980s and early 1990s, the Queensland (Qld) methadone program was receiving criticism from other jurisdictions about liberal nature of its program. In the late 1980s and early 1990s, Qld had the highest per-capita level of methadone prescribing in Australia. This pattern was attributable to the fact that in the early 1980s, Qld was the only State without limitations on the prescribing of methadone for opioid dependence (Gaughwin et al., 1993). Dr Michael Bolton from Qld noted:

> *I mean I'm not saying we got it right but I think we got it less wrong than a lot of people. In those early days in opioid related deaths we were the only State that went down. Everyone else went up. I remember using that at MCDS6 meetings to argue the toss. At that stage we were under siege. (Bolton, 1994, as cited in McArthur, 1999)*

The doses of methadone prescribed in Queensland over this period were generally higher than in other jurisdictions. However, as McArthur (1999) reported, prescribing in Queensland was more consistent with the recommendations contained in the National Methadone Guidelines, compared with other jurisdictions.

This high level of prescribing in Queensland remained relatively stable over the next several years, during which time there was a dramatic increase in methadone prescribing in New South Wales (NSW) and more gradual increases in other jurisdictions (Gaughwin et al., 1993).

In 1988, an independent evaluation of the NCADA was undertaken and the MCDS agreed that NCADA should continue for a further three years. The evaluation concluded that there had been considerable progress, including the expansion of treatment services, community awareness and better monitoring and evaluation (Ritter et al., 2011).

Between the publishing of the 1985 National Methadone Guidelines and the revised 1993 National Methadone Policy, a relatively new concept, referred to as 'opioid dependence syndrome', was increasingly adopted. The problem was that neither 'physical dependence',

6 The Ministerial Council on Drug Strategy which consisted of law enforcement, health and related Ministers from states and territories and the Commonwealth.

nor the more precise term 'neuroadaptation' (the adaptation of neurones to the effects of drugs) adequately characterised the range of problems that individuals seeking treatment presented with. The term 'opioid dependence syndrome' was an attempt to reconceptualise the phenomenon of dependence in a form that more adequately reflected both the problem and the solution (Bennett, 2011).

The term 'opioid dependence syndrome' encompassed a range of other issues beyond physical dependence such as:

- a continued desire to use opioids despite persistent and recurrent problems associated with their use
- a narrowed repertoire of behaviours associated with opioid use
- repeated unsuccessful attempts to reduce or stop opioid use
- the prioritisation of opioid use over other life activities (Bennett, 2011).

One of the cornerstones of Australian's approach to drug policy in the post NCADA period was the level of cooperation between the law enforcement and health sectors. Nevertheless, in the early days of the expansion of methadone programs in Australia, over-zealous police officers would park outside a clinic if they were looking for someone who had outstanding warrants or was wanted for questioning regarding criminal activities. Generally, (but not always) these problems were quickly addressed by high-level liaison (Ward, 1995).

In February 1992, the second NCADA evaluation No Quick Fix was released. The evaluation was positive, particularly regarding the emphasis on harm minimisation. It made 66 recommendations, with one of these proposing the relaunch of the NCADA as the National Drug Strategy (NDS) based on a new National Drug Strategic Plan. The National Drug Strategic Plan 1993-97 was released in 1993 (Intergovernmental Committee on Drugs, 2000).

A key component of the new NDS was appropriate training for workers in the drug treatment field. The importance of this issue for methadone prescribers was reinforced by several deaths due to methadone poisoning in Victoria in 1989-89. A coronial investigation identified a lack of training and understanding about the basic pharmacodynamics of methadone as contributing to these deaths. Other jurisdictions with methadone programs responded with the development and/or implementation of training programs and treatment manuals which provided information for medical practitioners about the management of methadone (Ward, 1995).

In the 10 years after the commencement of NCADA, which established the centrality of methadone to the management of heroin dependence in Australia, there was a dramatic growth in methadone programs. In 1995, almost 15,000 Australians were receiving methadone treatment, up from 2,200 10 years earlier. By 1995, all States and the ACT had methadone programs. The NT did not, and its preferred approach was to provide heroin dependent people with a one-way bus ticket to enable them to seek treatment in another jurisdiction (Ward, 1995).

By the mid-1990s, Australia, along with Switzerland, had the highest per capita participation in methadone treatment in the world. This participation rate was 2.5 times higher than the United Kingdom, and nearly twice that of the US (Berbatis, Sunderland, Bulsara, & Lintzeris, 2000). Despite this, in the mid to late 1990s, only 36% of the estimated 74,000 dependent heroin users in Australia were in OAT (Hall et al., 2000). However, there were increasing concerns about the quality of methadone treatment being provided by some private providers, particularly in NSW. An independent study of three low-intervention, private methadone clinics in Sydney identified several issues influencing the quality and effectiveness of methadone treatment. These included poor clinical record-keeping, a lack of treatment ethos, poor staff training, and lack of staff role clarity. It was also evident that clients were required to attend for too many, very brief medical

consultations. This seemed to be based more on the financial return to the doctor than the welfare of the patient. There was also poor compliance with clinical guidelines concerning the use of take-away doses and consistent, significant differences between the clinics in terms of client satisfaction (Bell et al., 1995).

The availability of take-away doses declined markedly over the 1990s, particularly in NSW. Early take-away dose guidelines meant that take-away doses were provided in both public and private clinics, and to people receiving office-based treatment. Problems rapidly arose, principally that public clinics rapidly filled with patients, who had no wish to transfer to paying fees at private clinics. As a result, public clinics began restricting, then abolishing, the availability of take-home doses. The rationale for this was that stabilised patients eligible for take-aways should transfer to private treatment (usually GP/pharmacy), allowing public clinics to take on new and non-stabilised patients (Bell, 2000).

A further issue led to reduction in take-away doses. In the mid-1990s, needle and syringe programs in NSW were distributing mostly 20ml syringes, the key purpose of which was to inject methadone. The response of the State government was to ban the distribution of 20ml syringes. This began a series of policy changes to reduce inappropriate prescribing of take-aways. Initially, NSW Health announced that take-aways were to be restricted to four per week, but this rule was widely ignored. New South Wales Health then began an audit of prescribers, asking all registered prescribers to self-complete a questionnaire about the number of take-aways being prescribed. As a result of this, a few doctors were asked to explain why their practice deviated (in terms of more take-aways) from that of their peers (Bell, 2000).

There were substantial differences between the level of methadone diversion for injection between jurisdictions in the mid-1990s. A study conducted among 312 heroin users and methadone clients in Sydney found that 29% reported having injected methadone within the last six months (23% of heroin users not in methadone treatment, and 34% of current methadone clients). Of those who had injected methadone, 40% reported injecting methadone at least weekly (Darke, Ross, & Hall, 1996). Similarly, Hando et al. (1998) found that 30% of Sydney injecting drug users reported having injected methadone within the last six months. In addition, almost half (49%) of individuals enrolled in methadone programs reported injecting methadone during this period.

Yet the situation was entirely different in Melbourne. A survey of injecting drug users in Melbourne (Rumbold & Fry, 1998) revealed that only 2% of injecting drug users and 6% of those enrolled in methadone programmes reported injecting methadone within the past six months. In a further study of Melbourne methadone clients (Lintzeris, Lenne, & Ritter, 1999), only one % reported having injected methadone within the preceding 6-month period. Lintzeris et al. (1999) concluded that the lower prevalence of methadone injecting in Melbourne (compared to Sydney) was likely to be a result of the less liberal take-away policy, and the mandatory dilution of methadone take-aways to 200ml of liquid.

This is another example of the diversity of approaches to methadone treatment that were evident at the time.

There was a very uneven uptake of methadone programs throughout Australia. Between 1985 and 1991, there were large increases in methadone prescribing by private practitioners in NSW and Victoria in particular. Private prescribing of methadone may not have been the sole explanation for increased rates of uptake nationally. In SA, where there were no private clinics, the sharp rise in the rate of prescription after June 1990 was attributed to the end of practices which had hindered patients from receiving methadone. These practices included offering only alternative treatments at assessments for methadone, using naloxone to diagnose opioid dependence, and discharging patients from the OAT if they used other opioids (Gaughwin et al., 1993).

At this time in Australia, as in other parts of the world, patterns of service provision to the public, including drug treatment services, were changing. Governments were moving away from primarily providing services to the public in favour of being the funders of services. As a result, traditionally government-run services were increasingly being privatised (including not-for-profit organisations within this definition). For illicit drugs policy, this included the provision of treatment, prevention, and even policing services. This led an increased reliance and focus on the role and function of non-government organisations (NGOs). Placing NGOs as the primary service providers also empowered them to have a stronger voice at the policy table (Ritter et al., 2011). This was particularly the case in Victoria, where as a result of policies implemented by the Kennett government, the overwhelming majority of OAT services were transferred to the private sector.

Parallel with these changes in the way treatment was delivered was a change in the prevailing paradigm of treatment, which shifted from a primarily psychotherapeutic model to a more 'metabolic' model of OAT. This was in response to several factors, including client preferences and recognition of the importance of methadone dosages in improving client treatment retention (for example, Caplehorn & Bell, 1991; Ward, Mattick & Hall, 1994).

Linked to this new treatment approach was a shift in emphasis away from keeping people out of treatment towards improving treatment access. The ability to access adequate daily doses of methadone was a key component of this change of approach. The shift away from the psychotherapeutic model may have occurred as a result of increasing confidence among practitioners and the integration of research findings into practice. However, it was also influenced by the pragmatic issue of trying to expand treatment with limited resources (Bell, 2000).

The 1995 National Review of Methadone Programs

In 1995, a national review of Australian methadone programs found that, while there were many areas of commonality among the States and Territories regarding their philosophy of treatment, there were also considerable differences across jurisdictions. These differences related to their histories of methadone program development and the mechanisms by which those services were provided. There were differences in the:

- extent of centralised versus decentralised control
- differing roles of the public and private sectors
- extent to which methadone services were provided by large specialist clinics or medical practitioners as part of their general practice (CDHSH, 1995).

The Review found that despite systematic differences between the sectors in the treatment delivered, when taken as a whole, outcomes achieved across the public clinics and private clinics were very similar. Importantly, within both the public and private sectors, there were large differences in the quality and effectiveness of treatment delivered in different clinics. While clients in public clinics reported greater satisfaction with counselling services, there was no evidence that the greater emphasis on formal counselling contributed to less heroin use or greater psychological stability among clients of public clinics. Similarly, the considerable difference in take-away availability did not seem to affect clinical outcomes, although there were clearly other disadvantages associated with their greater availability in private clinics (CDHSH, 1995).

The Review reinforced the need for the implementation of quality assurance mechanisms aimed at raising the standard of services provided in both sectors. Common to all practice settings

was the need for service providers to be suitably qualified in the first instance, and to maintain those skills over time. By the mid-1990s, all jurisdictions with methadone programs offered training courses to medical practitioners, but the courses varied in their content and duration, and participation was not universally compulsory. The Review found that the involvement of the private sector, particularly GPs, had the greatest potential to improve access to services by clients, particularly in more remote areas, and to reduce the stigma associated with attendance at specialist methadone clinics. The major difficulty with this approach was attracting medical practitioners and pharmacists to methadone programs, and the need to ensure that they were appropriately qualified and trained (CDHSH, 1995).

The Review found that nationally the direct costs per client treated in the public treatment system were reasonably consistent. The exceptions to this were in Tasmania and Victoria, where relatively few public clients were treated, and concerns were held about the reliability of the costs reported. If these two States were excluded from the analysis, the average direct cost per client per annum of methadone treatment in the public sector was approximately $2,100, while the total cost (including program administration etc.) was $2,250 per client per annum (CDHSH, 1995).

In the private sector, the Review found considerable variation in treatment costs, depending on the intensity of treatment and the nature of the service provider (that is, whether it was a GP or a specialist). Services provided by psychiatrists cost approximately three times those of GP services in all stages of treatment. These differences were reflective of considerable differences in treatment patterns between the two groups, and the higher fees charged by psychiatrists. It was doubtful that the differences in fees charged between these groups could be justified in terms of the nature of the service provided. The costs of services provided by psychiatrists were comparable to the costs incurred in the public sector.

However, the costs quoted for the private sector excluded the cost of dispensing methadone, as this was usually met by the client. Costs in the public sector generally included the dispensing costs of public clinics. When taken into account, this difference in reporting largely negated the difference in the quoted costs for the two sectors (CDHSH, 1995).

The review found that in combination, these factors demonstrated that the delivery of methadone programs on a national basis operated in a complex environment. There were also differences regarding methadone dosages provided. Some programs routinely used blockade dosages (>100 mg) while others regarded the provision of minimum possible dosages as being most desirable. In addition, some programs aimed to maintain clients on OAT while other aimed for gradual or more rapid dose reductions. There were also differing approaches to the provision of take-away doses (CDHSH, 1995).

CHAPTER 8: AUSTRALIA'S POLICY AND LEGAL APPROACHES TO OPIOID DRUG PROBLEMS. THE MID 1990s TO EARLY 2000s

The increase in heroin use and related deaths

During the mid to late 1990s in Australia, the prevalence of heroin use increased dramatically. This was associated with a steep rise in overdose deaths. In 1994, there were 425 accidental deaths due to opioid (predominantly heroin) use among those aged 15 to 54 years, but by 1999 this had grown to 1,116 (Roxburgh & Burns, 2012). These deaths accounted for one in eight deaths among young Australians aged 15 to 24 years at that time (Degenhardt, Roxburgh, & Black, 2003). There were also substantial rises in the number of people treated for heroin dependence and in the number of those arrested for heroin offences (Hall et al., 1999; Hall et al., 2000).

The heroin treatment trial proposal

Between 1992 and 1996, a major initiative had important impacts on Australian drug policy. A 4-year feasibility study into the prescription of heroin to opioid-dependent persons was conducted (Bammer & Douglas, 1996). The feasibility study, undertaken after encouragement from a national seminar of drug treatment and policy experts, resulted in a proposal for a trial (comprising two pilot studies and a full-scale clinical trial) of prescribed heroin to dependent users in one Australian city. Support for the trial was sought and received from the Ministerial Council on Drug Strategy (MCDS). However, the trial was vetoed at Federal Cabinet level by Prime Minister John Howard. The Prime Minister was vehemently opposed to the heroin trial, arguing that it sent an 'adverse signal' about the use of heroin and that his decision reflected the community's opposition to the trial. Mr Howard announced the establishment of a Commonwealth Task Force to develop an alternative policy response. Mr Howard's actions were also in response to a concerted campaign by certain sectors of the media that maintained the trial was contentious, morally indefensible and profoundly evil (Fitzgerald, 2005; McArthur, 1999b).

Tough on Drugs and the Australian National Council on Drugs

In 1997, under a raft of new measures entitled the Tough on Drugs package, Prime Minister Howard established a new policy advisory body, the Australian National Council on Drugs (ANCD) in an attempt to change the policy-making environment (Fitzgerald, 2005). The ANCD was also intended to be a means through which increasingly important NGO organisations could have a voice in illicit drug policy (Ritter et al., 2011).

From its earliest beginnings, the ANCD was of particular interest to Prime Minister Howard and a means by which he could more directly influence the drug policy arena. This interest involved

not only the strategic placement of the ANCD in the complex web of advisory structures, but also the tight control of the composition of the Council and substantial increases in specific project funding in the States and Territories. Members of the ANCD were appointed by the Prime Minister (Fitzgerald, 2005).

> *The Prime Minister was able to get agreement for the establishment of the Council because he was prepared to put significant additional funds into an area that all jurisdictions recognised as critical (Moore, 2002, as cited in Fitzgerald, 2005).*

The original Council membership was intended to include a 'broad church' of drug policy experts. It was headed by abstinence advocate Salvation Army Major Brian Watters, but it also included harm reductionists such as Professor Margaret Hamilton, Professor Wayne Hall, and Mr Tony Trimmingham (Fitzgerald, 2005). In describing his reasons for choosing Major Watters, Prime Minister Howard said:

> *I deliberately hand-picked and chose Major Watters to chair the Australian National Council on Drugs... It is no secret that Major Watters was a critic of the heroin trial in the ACT... It is no secret that Major Watters adopts the view, as do many others, including myself, that the policy of zero tolerance of drug taking in this country is a highly credible policy and a policy that ought to be pursued more vigorously... I make it very clear that I do not apologise for a moment for the appointment of Major Brian Watters as Chairman of this council. I think it was an excellent appointment. I cannot think of a better man or woman in Australia to do the job...(Parliament of Australia, 1998)*

The broad church of the first Council was not, however, reflected in the composition of the second Council, appointed in 2001. The second Council was more heavily weighted toward abstinence-oriented members, including representatives from Narcotics Anonymous, Drug Arm, and Drug Beat. Through the positioning of abstinence-based service providers on a key national advisory body, the Prime Minister's Office was able to shift the direction of debate concerning appropriate responses to drug problems in Australia (Fitzgerald, 2005).

The Tough on Drugs campaign provided $87 million over three years to be split equally between law enforcement, education and treatment, rehabilitation and counselling. A second instalment of $100 million over four years was also announced in March 1998 (Mendes, 2001). The Tough on Drugs strategy did not replace the existing National Drug Strategy but signalled a renewed commitment to funding initiatives that tackled both the use of, and harms associated with, illicit drugs. The Tough on Drugs Federal strategy also signalled a number of new initiatives including research into pharmacotherapies for heroin dependence (in lieu of the heroin trial which was blocked by Prime Minister Howard) (Ritter et al., 2011).

Almost in parallel with the implementation of the Tough on Drugs strategy, the Australian Federal, State and Territory Governments drafted and adopted a National Drug Strategic Framework (1998/99 – 2002/03). This Framework maintained the policy principles of the previous phases of the National Drug Strategy (NDS) and adopted the recommendations of Mapping the Future: An Evaluation of the National Drug Strategy 1993-97. The focus remained on harm minimisation (Ritter et al., 2011).

The National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD) project

In 1997, Tough on Drugs funding was made available for research into heroin dependence pharmacotherapies. The Ministerial Council on Drug Strategy decided that a coordinated approach should be taken to better understand the nature and potential role of these pharmacotherapies. Thus, the National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD) project was commenced. This 3-year collaboration between Australian researchers and clinicians began in mid-1998 and was coordinated by the National Drug and Alcohol Research Centre (Digiusto et al., 2001). The NEPOD and the associated 13 associated treatment outcome trials received more than $7 million in direct funding, plus several million dollars more in overhead support contributed by the facilities that conducted the research. This was the largest ever effort to provide a foundation for the delivery of evidence-based drug and alcohol treatment in Australia (Digiusto et al., 2001), and in many parts of the world. The NEPOD project built on an existing body of work in this area that had been undertaken in other jurisdictions such as Victoria and SA.

The treatment approaches that NEPOD examined were:

- methadone maintenance
- buprenorphine maintenance
- levo-alpha-acetylmethadol (LAAM) maintenance
- naltrexone treatment
- rapid opioid detoxification with anaesthesia or sedation
- outpatient detoxification using buprenorphine
- conventional inpatient detoxification
- conventional outpatient detoxification (Mattick et al., 2001).

The NEPOD research demonstrated that all the pharmacotherapies were successful in achieving some positive outcomes, but the extent to which patients were retained in the treatment program was the key determinant of success. The overall rate of serious adverse events (SAE) was low while patients were in treatment but was somewhat higher in naltrexone treatment (56 per 100 patient-years) than in methadone, buprenorphine or LAAM treatment (10 to 20 per 100 patient-years). Rates of SAEs generally increased after patients left treatment. Heroin overdose rates were higher among patients who entered naltrexone treatment in comparison with other treatments. The heroin overdose rate increased from 11 per 100 patient-years while patients were in naltrexone treatment, to 35 per 100 patient-years after they left naltrexone treatment (Mattick et al., 2001).

A number of recommendations arose from the research, including:

- promoting a diversity of treatment options
- continuing to support methadone maintenance treatment as the most cost-effective treatment available in Australia
- improving retention in treatment to improve outcomes
- encouraging general practitioner involvement in shared-care models
- linking detoxification to continuing treatment
- encouraging the use of buprenorphine for outpatient detoxification
- making rapid detoxification under sedation available for heroin users seeking induction into naltrexone
- all jurisdictions reviewing their clinical guidelines, policy documents and systems of service delivery relating to opioid detoxification and maintenance treatment in the light of the NEPOD findings (Mattick et al., 2001).

One of the great strengths of the approach to OAT adopted in Australia was not to dictate to prescribers that they must utilise one OAT medicine for all clients. As a result, the OAT system in Australia has developed on the basis of providing the OAT agent that best suits the needs of individual clients.

From a national perspective, the growth in methadone treatment was greatest in NSW. In 1985, there were about 1,000 people on methadone in NSW, and by September, 2003 there were 16,200 on methadone or buprenorphine, of whom about 1,000 were receiving treatment in the prison system (Bell, Burrell, Indig, & Gilmour, 2006).

In conjunction with the NEPOD project, the Intergovernmental Committee on Drugs (IGCD) established the National Expert Advisory Committee on Illicit Drugs (NEACID), chaired by Dr Robert Ali. The NEACID was one of 11 expert advisory committees and subcommittees the purpose of which was to provide advice to the Ministerial Council on Drug Strategy, Australian National Council on Drugs and the IGCD.

Opioid agonist therapy in therapeutic communities

Therapeutic communities (TCs) had their origins in the late 1940s when Dr Maxwell Jones, a psychiatrist working in London, established a residential community as an alternative to medical treatment for young people with behavioural problems. In 1958, the first drug-free TC, Synanon, was established in California to rehabilitate people with drug problems. Therapeutic communities are non-medical, residential settings that encourage personal growth by changing the lifestyle of individuals with social problems, including criminal behaviour. People in a TC are community members, not patients, and they play a part in the management of the community. The main emphasis is on the resocialisation of an individual within this community prior to moving back into society. Therapeutic communities have clear rules that govern the behaviour of all members, focus on developing problem-solving skills and use encounter groups. Historically therapeutic communities supporting people with drug problems were drug-free (Hall et al., 1993).

The proposal to integrate pharmacotherapies into residential treatment was initially considered antithetical to the methods adopted by TCs, in which abstinence was historically the primary treatment objective. The abstinence-based perspective was often deeply imbedded in organisational philosophies, treatment approaches and goals (Campbell et al., 2011)

In the late 1990s, the charitable organisation We Help Ourselves (WHOS) was running TCs which integrated a harm minimisation philosophy. The WHOS TCs provided their community members with knowledge on safer drug use practises and linked them in with networks that aimed to reduce harmful drug use practices.

In 1999, WHOS developed the Methadone to Abstinence Residential (MTAR) program to offer support to individuals wanting to withdraw from OAT whilst undertaking TC program. The MTAR was developed to target OAT clients who were relatively stable. The MTAR program was subsequently retitled OSTAR® (Opioid Substitution to Abstinence Residential), in light of the availability of OAT medicines other than methadone.

The WHOS Residential Treatment of Opioid Dependence (RTOD®) stabilisation program also commenced in 2009 and targeted clients who were less stable, or had chosen to remain on OAT treatment, or had been unable to successfully complete an OAT reduction program for various reasons (including mental and physical health issues). The WHOS RTOD® stabilisation clients are seen as having multiple complex needs, including polydrug use, psychosocial issues, physical and mental health issues.

Opioid agonist therapy is now more widely accepted in TC settings in Australia.

The heroin shortage

In January 2001, there were reports of an unpredicted and unprecedented reduction in heroin supply with an abrupt onset in all Australian jurisdictions. The shortage was most marked in NSW, the State with the largest heroin market, which saw increases in price, dramatic decreases in purity at the street level, and a reduction in the ease with which injecting drug users reported being able to obtain the drug (Degenhardt, Day, Gilmour, & Hall, 2006).

This became known as the Australian heroin shortage, although there was some debate at the time about whether the period prior to the heroin supply contraction represented a supply glut. In other words, the reduced level of supply that occurred in 2001 may simply have been a reversion to normal Australian supply levels (Dietze & Fitzgerald, 2002). The shortage was probably due to the increased success of high-level Australian drug law enforcement operations conducted nationally and internationally by the Australian Federal Police and Customs (in cooperation with other agencies internationally). These operations removed key individuals directing a small number of highly centralised drug trafficking networks that had supplied large amounts of heroin to Australia, and seized over 1,000 kg of heroin in 2000 (Degenhardt et al., 2006).

Australia was fortunate that this reduction in heroin supply occurred against a backdrop of a range of harm and demand reduction initiatives, particularly OAT. This probably reduced the severity of some of the negative consequences of reduced heroin supply (such as drug substitution and higher risk injecting) (Degenhardt et al., 2006).

Somewhat surprisingly, the contraction in heroin supply did not have a major impact on demand for OAT, but there was a dramatic decrease in the number of people entering heroin withdrawal, or assessment only, treatment episodes. The demand for heroin dependence treatment decreased among younger users, as did their entry into OAT. This was, perhaps in part, because they switched to the use of psychostimulant drugs. The shortage had no observable impact upon the treatment entry among persons who had previously engaged in OAT (Degenhardt, Conroy, Day, Gilmour, & Hall, 2005).

This suggests that changes in heroin supply did not affect active heroin users who had been previously engaged in OAT for heroin dependence. Interestingly, the availability of OAT treatment places increased around the time of the reduction in heroin supply, so the increase in new cases did not reflect treatment availability. Older heroin users were marginally more likely to re-engage with opioid maintenance treatment and more likely to comply with that treatment. Those who did not re-engage with treatment may have been more likely to engage in polydrug use and riskier forms of injecting drug use. Overall, heroin supply reduction did not greatly affect retention in treatment either (Degenhardt et al., 2005).

Opioid Agonist Therapy 1990s to early 2000s

A study of pharmacotherapy services in Australia published in 2009 (Ritter & Chalmers, 2009) found that while the services were better than in many other countries, there were aspects that warranted improvement. These related to the three key issues of:

- accessibility (access)
- affordability (cost)
- availability (number of treatment places).

Nationally in 2007, the vast majority of pharmacotherapy maintenance prescribing was being provided within the private sector through general practice and through specialist clinic services,

while the medicines were mostly provided through community pharmacies. Nationally, OAT services cost approximately $11.73 million per month. This came predominantly from State and Territory governments (43%) and, to a lesser extent, from the Australian Government. Consumers contributed 33% of the amount, an average of $142 per month per client. This was a significant barrier to service access. Close to 80% of Australian pharmacotherapy clients paid fees and the OAT system did not shield clients on low incomes from the financial impost of dispensing fees (Ritter & Chalmers, 2009). As Chalmers et al. (2009) highlighted, it was unusual in Australia for patient co-payments for medicines used to treat chronic relapsing medical conditions to be so high.

A further issue during this period was that if clients had a choice between free dispensing in public clinics and fee-for-service dispensing in community pharmacies, there was a financial incentive for the client to remain with the public clinic. There were other client costs associated with treatment in the private sector, including general practitioner consultation fees and ancillary medication and counselling costs. With limited places in public clinics, this restricted new entrants to public clinics. Accessibility problems existed in relation to both access to prescribers and dispensers, with between 10,000 and 30,000 Australians who would access treatment if they were able to access services that met their needs. New entrants to treatment from regional areas also often had to wait long periods to gain access to treatment (Ritter & Chalmers, 2009).

Chalmers et al. (2009) undertook a range of scenario modelling regarding the potential changes to the Australian OAT system. Key findings included the following:

- while it would be costly for the Federal Government to subsidise the cost of methadone dispensing, these costs would be outweighed by the economic benefits accruing to the community through reductions in health care utilisation and crime
- accessibility of treatment was examined through changing the source of demand for treatment. The modelling suggested that it would take a 50% increase in the rate of new client entry into treatment to match the impact on in-treatment numbers of a 20% decrease in the length of stay between treatment
- when comparing the benefits of quality individually focused care versus a low-threshold program, it was estimated that in a low threshold model, a 25% increase in the individual goal attainment of all opioid-dependent people (in- and between-treatment) could be achieved with a small cost-saving to the government (prescribing costs alone), while in a high-threshold model, it would take a 31% increase in such costs to achieve a 50% increase in overall individual goal attainment
- a 20% reduction in treatment places would lead to a reduction in treatment numbers of over 25% and would expose opioid dependent people to a greater risk of injecting drug use, overdose and other harms associated with heroin use.

Learning objectives for methadone prescribers

In 1997, at the request of the National Expert Advisory Committee on Illicit Drugs, Professor Steve Allsop developed learning objectives for methadone prescribers (Allsop, 1997). This was the first international attempt to document the key knowledge, skills and attitudes required to prescribe methadone. The objectives were described in terms of units (distinct roles or functions carried out by a medical practitioner). These, in turn, were subdivided into elements (demonstrable or assessable processes or activities that a medical practitioner carries out in prescribing methadone). The learning objectives were developed through consultation with a group of methadone prescribers and trainers. The facilitators guided descriptions of methadone prescribing, to identify the variety of functions, activities and contexts in which prescribing is undertaken.

CHAPTER 9: THE ARRIVAL AND DEVELOPMENT OF BUPRENORPHINE PROGRAMS IN AUSTRALIA

In 1997, there were an estimated 74,000 heroin dependent users in Australia, a number that had doubled over the preceding 15 years (Hall et al., 2000). This increase was accompanied by an increase in fatal heroin overdoses (Hall et al., 1999). In addition, the cost of heroin-related crime in Australia was estimated to be between $535 million and $1.6 billion (Maher, Dixon, Hall, & Lynskey, 2002). One possible response that was under consideration at that time was to undertake a clinical trial to assess the possible role of treatment with diacetylmorphine (heroin) but this approach was stopped by the then Prime Minister, John Howard.

However, Prime Minister Howard did recognise the need to increase treatment options and therefore provided funding to the National Drug and Alcohol Research Centre to coordinate 13 studies which were selected to evaluate methadone, LAAM, buprenorphine and naltrexone in the NEPOD program (Mattick et al., 2001). The data from this program ultimately resulted in the development of new clinical guidelines for methadone (Henry-Edwards et al., 2003), naltrexone (Bell et al., 2003) and buprenorphine (Lintzeris et al., 2006). LAAM was never widely introduced into Australia.

Data from Australian studies confirmed that buprenorphine greatly reduced the risk of overdose and had a shorter and less severe withdrawal syndrome than methadone and LAAM. The studies confirmed that buprenorphine also exhibited ceiling effects on respiratory depression and had a long duration of action, so it could be administered on alternate days while maintaining its effects over the 48-hour period (Ward et al., 1999).

Other Australian research found that buprenorphine could also be used for heroin withdrawal. This research compared buprenorphine with symptomatic drugs for outpatient heroin withdrawal, found that buprenorphine use led to greater client retention, less heroin use, and less discomfort during withdrawal. Therefore, buprenorphine came to be viewed as a gateway treatment drug in Australia. Heroin-dependent treatment seekers could be easily inducted onto buprenorphine, for the commencement of a withdrawal episode. For those patients not able to sustain the withdrawal, they could be easily transferred to maintenance buprenorphine or other maintenance options. Those completing the withdrawal were also more likely to link into appropriate post-withdrawal counselling options (Lintzeris, Bell, Bammer, Jolley, & Rushworth, 2002)

Buprenorphine (Subutex®) was registered by the Australian Therapeutic Goods Administration (TGA) in November 2000 and became widely available in 2001.

In March 2001, the Intergovernmental Committee on Drugs (IGCD) published the National Buprenorphine Policy, to provide a broad policy context and a framework for State and Territory policies and guidelines. Buprenorphine was subsequently listed as a treatment for opioid dependence under the Pharmaceutical Benefits Scheme from August 1, 2001. Doing so facilitated access to, and enhanced affordability of, the drug as a treatment option for opioid dependent people (Green, 2001).

In 2006, the Commonwealth Department of Health and Aged Care also published the National Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Dependence (Lintzeris et al., 2006) to assist in the safe and effective implementation of buprenorphine treatment in Australia.

A randomised buprenorphine implementation trial was conducted, comparing buprenorphine and methadone treatment under routine clinical conditions in 139 subjects across 19 Victorian sites. The implementation trial found that:

- general practitioners and pharmacists experienced in delivering methadone treatment could become competent to provide buprenorphine without intensive training
- the clinical guidelines developed were appropriate for community settings, with high levels of adherence
- buprenorphine treatment could become an effective treatment alternative to methadone for heroin users and those transferring from low or medium doses of methadone (Lintzeris et al., 2004).

Several issues were identified as important in the future uptake of buprenorphine treatment in Australia, namely to:

- develop and evaluate clinical guidelines appropriate for community-based settings
- develop and evaluate training programs for service providers
- compare the effectiveness (and cost effectiveness) of buprenorphine treatment in the Australian community (Lintzeris et al., 2004).

The service system initially established for buprenorphine treatment in Australia paralleled that for methadone. That is, the same prescribers and dispensers were trained and able to provide buprenorphine treatment (Ritter & Chalmers, 2009). For detoxification services, this meant examining the use of buprenorphine in inpatient settings, specialist outpatient clinic settings and in outpatient general practice and pharmacy primary care settings. In relation to maintenance treatment, there had been limited international experience with using buprenorphine outside of specialist clinic settings. The French approach, which involved the widespread prescribing of buprenorphine by general practitioners, was not readily replicable in Australia, because in Australia clients were linked to a particular treatment program staffed by trained service providers and with a predominantly pharmacy-based system of supervised dispensing (Lintzeris et al., 2004)

Buprenorphine-naloxone in sublingual tablets (marketed as Suboxone®) was available from 2006. When buprenorphine/naloxone film (Suboxone®) for opioid dependence treatment was introduced in Australia in 2011, there were key differences in State policy approaches. For example, transfer from buprenorphine/naloxone tablets to buprenorphine/naloxone film was mandated in SA, with NSW and Victoria having less stringent policies. Subsequently, more SA clients were found to be unhappy with their transfer (compared with clients in comparison sites in NSW and Victoria). Clients in SA reported a larger number of adverse effects compared with clients in the other jurisdictions. Arguably the perception of restricted choice in medication undermined initial acceptance in SA (Larance et al., 2015).

A subsequent study was undertaken of the relative merits of buprenorphine versus methadone among first-time OAT entrants in NSW between August 2001 and December 2010. Several key findings emerged. Fewer clients on buprenorphine, relative to methadone, were retained in OAT but there were improvements in buprenorphine retention over time. The reasons behind improvements associated with buprenorphine treatment retention over time were unclear but it is possible that more accurate titration occurred as clients and clinicians became more familiar with the medicine. Clients on buprenorphine were more likely to leave their first treatment episode at an earlier point, have multiple treatment episodes and switch medications more often than those who commenced on methadone (Burns et al., 2015)

Following the introduction of buprenorphine/naloxone sublingual film in 2011 a study was undertaken to compare tablet and sublingual formulations on subjective dose effects and equivalence, trough plasma levels, adverse events, patient satisfaction, supervised dosing time, and impact upon treatment outcomes (substance use, psychosocial functioning). The study demonstrated dose equivalence and comparable clinical outcomes between the buprenorphine/naloxone film and tablet preparations, while showing improved dispensing times and patient ratings of satisfaction with the film (Lintzeris et al., 2013).

Post-marketing surveillance of buprenorphine/naloxone in Australia found that among regular injecting drug users, levels of injection were lower for buprenorphine/naloxone relative to buprenorphine, but comparable to those for methadone, adjusting for background availability. Both sublingual medications were diverted more frequently than liquid methadone (Larance et al., 2011). Two years post-introduction, the level of buprenorphine/naloxone film diversion and injection remained comparable with that of methadone and buprenorphine/naloxone tablets and lower than mono-buprenorphine. Buprenorphine/naloxone film had lower non-adherence and diversion than the tablet formulation (Larance et al., 2016).

Long acting depot buprenorphine was listed on the Pharmaceutical Benefits Scheme (PBS) on September 1, 2019 as an S100 drug, making it free for people with an opioid dependency (Lintzeris et al., 2019). The first long-acting depot buprenorphine formulation to be registered by the TGA for the treatment of opioid dependence was Buvidal® Weekly and Monthly. This occurred in November 2018. A further long acting depot buprenorphine formulation Sublocade® was registered by the TGA in Australia in July 2019 (Lintzeris et al., 2019).

Between 2017 and 2018, studies were undertaken to investigate perceptions of the depot buprenorphine products among Australians using illicit/extra-medical opioids regularly and/or receiving treatment for opioid use disorder. Perceptions were generally positive with between 53% and 68% believing it would be a good treatment option for them if it were available. A range of reasons from this were cited, including:

- less frequent contact with treatment services
- reducing the burden of attendance for supervised dosing
- increasing privacy for OAT clients and reducing stigma (Larance et al., 2020; Nielsen et al., 2020).

An Australian study exploring long-acting buprenorphine in custodial settings showed treatment retention, substance use and safety outcomes comparable with those observed in community settings and for other OAT used in custodial settings, without increased risk of diversion. Long-acting buprenorphine was found to be a more efficient and less costly OAT delivery method, requiring fewer health and custodial staff resources to administer. The authors recommended that consideration be given to enhancing access to depot buprenorphine in custodial settings worldwide (Dunlop et al., 2021).

Nevertheless, the uptake of long-acting buprenorphine treatment, at least up to March 2020, was largely concentrated in services that had been involved in clinical trials, or a handful of 'early adopter' individual private practitioners. The COVID-19 pandemic subsequently interrupted many of the usual innovation translational activities, and renewed efforts will be required to ensure widespread uptake of long-acting buprenorphine. The extent to which treatment services revert

to the predominately pre-COVID-19 supervised consumption model of treatment for methadone and sublingual buprenorphine in a post COVID-19 environment, is unclear. If this occurs, it will likely propel more patients toward the convenience of long-acting buprenorphine treatment. The COVID-19 pandemic has brought about circumstances that have demonstrated the potential utility of depot buprenorphine from both patients' and providers' perspectives (Arunogiri & Lintzeris, 2020).

CHAPTER 10: NATIONAL METHADONE / MATOD POLICIES

In 1977, the Commonwealth Government produced a National Policy on Methadone treatment for the first time. The Policy, which was developed by the Mental Health Standing Committee of the National Health and Medical Research Council (NHMRC), regarded abstinence from all drugs as only one of many goals of treatment. It was the view, however, that methadone should only be used in a limited way for a small group of the most hardened and chronic addicts. The guidelines also indicated that relatively high doses of methadone be prescribed (between 80 and120 mg per day), as this had been found to be more effective in limiting or reducing illicit drug use. While the policy document clearly stated that higher doses should be given to patients on maintenance, in practice, low dosages came to be prescribed because the maintenance goal was not widely accepted. The guidelines were not widely adhered to apart from in Queensland (McArthur, 1999a).

The National Policy on Methadone may have been intended to resolve some of the disagreements that had arisen between and within jurisdictions over various issues. These included high versus low dosages, withdrawal (short-term) versus maintenance (long-term) treatment aims, minimum standards of patient conduct, use of sanctions for the use of non-prescribed drugs, methods of detection of non-prescribed drug use, and admission criteria. The authority of the NHMRC was a major factor in developing what amounted to a voluntary code of conservative practice for doctors involved in the prescription of methadone. A key aspect of the NHMRC document was the need for careful selection and screening prior to admission, preferably by a demonstrable physical addiction to heroin, such as naloxone testing. It could also be verified by a requirement of prior unsuccessful treatment attempts or a minimum period of opioid use. This was 12 months in the case of short-term treatment and two years in the case of long-term treatment. It was expressly stated that methadone should not be prescribed to persons under 18 years of age. There were a number of omissions from the report, for instance, procedures for individuals with special health needs, such as chronic liver disease, or a protocol for the management of pregnant women (Swensen, 1990).

The next phase in the development of a national methadone policy was under the sponsorship of the Federal Government. The NHMRC policy of 1977, which had become obsolete, was revised in 1985 by the Department of Community Services and Health as the National Methadone Guidelines (NMG) (Commonwealth of Australia, 1985) (Swensen, 1990).

Following concerns that further liberalisation of the 1985 NMG was necessary, at a meeting of the Australian Health Ministers' Conference in April 1987, it was resolved that the Guidelines would be further revised. After consultations between State representatives in 1987, the next iteration of the Guidelines was produced and endorsed by the Ministerial Council on Drug Strategy in November 1987. The 1987 Guidelines advised prescribers that some long-term medical conditions which cause particular risk to clients and others should result in the relaxation of normal acceptance criteria. These were pregnancy, chronic hepatitis, persistent hepatitis B antigenaemia, and clinical evidence of AIDS. An important addition to the 1987 NMG was a policy for methadone use in prisons. Methadone was then introduced into prisons in NSW and Victoria as an HIV preventive strategy (CDHSH, 1995; Swensen, 1990).

In 1993, a National Methadone Policy was adopted, based on the 1987 NMG. The Policy reflected a national position on the role of methadone, and provided core operational procedures to guide the provision of services (CDHSH, 1995).

In 1997 the National Policy on Methadone Treatment was subsequently developed under the auspices of the National Drug Strategy (National Drug Strategy, 1997).

In 2001, in recognition of the increasing uptake of buprenorphine for OAT in Australia, the National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Opioid Dependence were developed. These Guidelines were subsequently revised in 2006 (Lintzeris et al., 2006).

In 2003, the Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence were prepared under the auspices of the National Expert Advisory Committee on Illicit Drugs (NEACID) (Henry-Edwards et al., 2003). In 2003, Clinical Guidelines and Procedures for the Use of Naltrexone in the Management of Opioid Dependence were also developed (Bell et al., 2003).

In 2007, the National Pharmacotherapy Policy for People Dependent on Opioids was developed at the request of the Intergovernmental Committee on Drugs. This Policy aimed to provide a broad policy context and a framework for State and Territory policies, and guidelines concerned with the treatment of opioid dependence with methadone, buprenorphine and naltrexone (Department of Health and Ageing, 2007).

In 2014, guidelines were produced which represented a consolidation of the most recent four opioid treatment guidelines (Gowing et al., 2014). The 2014 guidelines also reflected the experience which had, by then, accrued with the use of buprenorphine. The guidelines were titled Medication-Assisted Treatment of Opioid Dependence because this title was more encompassing term than 'pharmacotherapy'. The guidelines aimed to provide a broad policy context and framework while retaining flexibility to accommodate different jurisdictional approaches. These guidelines are the most up-to-date resource available in Australia at present, but they do not contain information concerning the use of depot buprenorphine products.

The OAT guidelines that were developed in Australia over the years have played a pivotally important role in defining approaches to treatment. They have been gradually adapted as the evidence base has grown and as clinical experience with newer forms of OAT has developed.

CHAPTER 11: CURRENT ISSUES FACING OPIOID AGONIST THERAPY IN AUSTRALIA

There are a number of issues facing the ongoing provision of OAT in Australia. These include:

- the stigma associated with being on and providing OAT
- OAT dispensing costs
- having insufficient OAT prescribers and dispensers
- complex regulatory arrangements associated with OAT provision.

Stigma

The stigma associated with OAT is one of the key barriers to uptake of the therapy. The attitude of health professionals towards people with opioid dependence and people receiving OAT can have significant impacts on, and consequences for, the delivery and accessibility of services for those seeking treatment. Stigma can have a pervasive effect in the lives of OAT consumers. The stigma associated with opioid dependence impacts on a diverse range of issues from treatment retention through to the willingness of healthcare professionals to provide services to clients (Carlisle, 2021; Harm Reduction Australia & ScriptWise, 2018).

As Carlisle (2021) reported, OAT clients can experience stigma from a range of sources, including family and friends, healthcare professionals and members of the wider community. Stigmatising OAT service users can make their community re-integration challenging and can lead to individuals returning to drug using networks, as these networks are somewhere they feel a sense of belonging. The ultimate impact of being repeatedly exposed to stigma is an internalisation of these judgements, resulting in feelings of shame and worthlessness which impact individuals' ability to seek help and develop supportive new relationships with others.

Carlisle (2021) described this stigma as a situation whereby an individual's entire identity is defined by a single, apparently negative attribute. In the case of OAT, individuals may possess overlapping stigmatised identities of 'OAT service user', 'drug user' and 'injecting drug user'. Some will be further stigmatised because they may be experiencing homelessness, be HIV or Hepatitis C positive, or are involved in sex-work.

Community pharmacies are one environment in which service users report experiencing a great deal of stigma. Unlike customers collecting other prescriptions, many OAT service users receive their medications (methadone/buprenorphine) via supervised dosing. This means they must be observed taking their medication by a pharmacist to ensure that it is not diverted to others. This is often conducted in full view of other customers. This leaves OAT service users open to the scrutiny of the 'public gaze' (Carlisle, 2021; Harm Reduction Australia & ScriptWise, 2018).

The 2017 National Pharmacotherapy Summit called for the implementation of a range of measures to address the stigma associated with OAT and its clients. These included:

- improved training to reduce stigma among health professionals, including incorporation of such training into OAT credentialling processes
- enhancing consumer engagement and participation in OAT policy development and in a national campaign addressing OAT-related stigma
- ensuring that police services follow standard operating procedures and policies regarding OAT treatment by not conducting unwarranted patrols, surveillance, or person checks in the vicinity of OAT premises
- all jurisdictions reviewing their current approaches to ensure that all policies and practices are consistent with OAT goals and evidence and basic human rights principles and practices (Harm Reduction Australia & ScriptWise, 2018).

Dispensing costs for people on OAT

Research both within Australia and internationally has confirmed that personal affordability is a significant determinant not only to OAT accessibility, but also retention (Ezard et al., 1999). Opioid Agonist Therapy clients in Australia are usually bulk billed through Medicare for visits to their prescriber, but they are charged a program/dispensing fee by their pharmacist. This co-payment varies and can range from $1 to $10 daily. This amount has remained relatively stable for the past 20 years. In addition, OAT clients' co-payment per dose might be $5, regardless of whether the person has take-away doses (hence making fewer visits to pharmacy), or attends the pharmacy each day (Penington Institute, 2015).

Pharmacists in most jurisdictions receive no other payment for the provision of OAT, although there are subsidy schemes in Tasmania and the ACT, and an inducement scheme in NSW. Even though consumer co-payments do not necessarily cover the costs of OAT provision, co-payments have remained relatively stable, presumably because of the difficulties OAT clients have in paying existing fees. The fact that consumer co-payments may not necessarily cover the costs of provision is likely to be acting as a disincentive to more pharmacies becoming involved in OAT, which is another factor limiting access to OAT (Penington Institute, 2015).

Opioid Agonist Therapy co-payments are charged to incorporate:

- the pharmacist's time (they are required to prepare and provide the consumer's dose, and complete all documentation)
- consumables (cups, bottles, labels and cordial in some States)
- general business costs (Penington Institute, 2015).

Fees tend to be higher when OAT is provided through private clinics (mostly NSW) where OAT is their sole business. Public clinics may also charge dispensing fees. However, these are heavily or completely subsidised by relevant State/Territory governments. Public clinics tend to only treat patients for a limited time before they are referred to a GP and a community pharmacy (Penington Institute, 2015).

The cost of OAT dispensing means that many clients need to sacrifice life necessities to fund their drug treatment, miss doses, or even stop treatment. The inability to make regular dispensing fee payments frequently contributes to a break-down in the relationship between pharmacist and consumer, and can influence the client's untimely exit from treatment (Chalmers & Ritter, 2012).

A 2012 examination of OAT dispensing fees found that while providing dispensing fee relief for clients would be costly, these additional costs would be offset by the social and health gains achieved from the OAT program (Chalmers & Ritter, 2012).

A 2017 National Pharmacotherapy Summit called for the implementation of a range of measures to address the impact of dispensing fees on OAT and its clients. These included:

- the development of a nationally subsidised scheme, whereby the costs associated with the provision and dispensing of OAT medications are funded by the Federal Government
- the potential to view opioid use disorder within a chronic disease framework/model to increase funding and the quality of treatment.

Insufficient OAT prescribers and dispensers

One of the key issues facing the provision of OAT is an insufficient number of prescribers and dispensers, and their geographical location. One NSW study which examined the retention of OAT prescribers between 2001 and 2018 found that the rate of prescribers ceasing OAT prescribing has been increasing over time. For example, prescribers who commenced providing OAT between 2016 and 2017 had over four times the risk of cessation compared with those who initiated before 2001. The highest prescriber cessation rate was in prescribers who had prescribed for shorter time periods. By 2017, more prescribers were discontinuing prescribing than new prescribers were starting. This meant that approximately 87% of OAT clients were under the care of 20% of OAT prescribers. The research concluded that OAT prescribing is increasingly concentrated in a small group of mature prescribers, and new prescribers are not being retained (Jones et al., 2021).

Complex regulatory arrangements for OAT provision

Jurisdiction-based restrictions and regulations represent significant barriers to OAT prescribing in Australia. Complex approval processes, additional provider training, and the burden of regular updates all serve as administrative barriers. In addition, these restrictions give the impression to potential prescribers that OAT is difficult, dangerous and to be avoided. This perpetuates a professional fear that OAT is too risky to prescribe, and increases concerns about medico-legal consequences of patient harms, including mortality (Prathivadi & Sturgiss, 2021).

It is important to maintain a balance between regulating access to OAT medicines to maintain safety, and ensuring that regulation does not become unduly burdensome and an impediment to OAT access. However, for most patients, OAT is protocol-driven and relatively simple to prescribe. General practitioners already prescribe a substantial proportion of non-OAT opioids and prescribe a range of medicines that are protocol-driven and can be dangerous if protocols are not followed. These factors have led to calls for OAT to become a normalised part of comprehensive health care provided by general practitioners and other healthcare providers (Prathivadi & Sturgiss, 2021).

CHAPTER 12: THE HISTORY OF OPIOID AGONIST THERAPY IN VICTORIA

Methadone treatment was introduced in Victoria in 1972 and rapidly gained popularity. Initially, services were funded and provided by government clinics and hospitals. The number of patients rose to approximately 300 in the late 1970s. By 1981, however, the number of patients admitted to programs fell significantly. This reduction was associated with:

- indiscriminate patient selection criteria
- failure of the treatment to satisfy the initial expectations of it being 'the new cure' for opioid dependency
- diversion of methadone into the black market
- poor regulation of 'take-away' doses, which was associated with a number of cases of accidental overdose by children (Burgess, Gill, Pead, & Holman, 1990).

From 1981 up until the National Drug Summit of April, 1985, the number of patients commenced on methadone in Victorian programs was negligible (Burgess et al., 1990). Prior to the commencement of the NCADA in 1985, there were just 155 people receiving methadone for the treatment of heroin dependence in Victoria. By January 1987, this had grown to 329. Of these, 135 were in programs under the care of private practitioners linked in with community alcohol and other drug agencies and local pharmacies. The remaining 194 attended the five major inner and outer metropolitan clinics, Pleasant View Centre, Smith Street Clinic, Heatherton Hospital, the Austin Hospital and Moreland Hall. At this time, there was only one methadone program, based at the Austin Hospital, where clients could receive methadone treatment for longer than two years. In 1987, the Austin Hospital had 41 clients on methadone and three-quarters of them had been on methadone for more than two years (Hulse, 1987).

There were distinct differences between clinic-based programs and those provided by private practitioners. Clinic-based treatment was provided by a team of practitioners (for example, medical officers, pharmacists and counsellors) located in the one setting, who worked exclusively with drug-dependent people. Private practitioner programs typically operated on a 'fee-for-service' basis and were characterised by general practitioners (and, to a lesser extent, private psychiatrists), pharmacists and counsellors who treated the patient at independent locations (Burgess et al., 1990).

By 1990, many Victorian clinicians were very concerned about the rapid expansion of methadone program places, particularly in general medical practice. Concerns were expressed at the time that methadone programs in Victoria could once again become discredited as they had been in the late 1970s and early 1980s (Burgess et al., 1990).

During 1989 and 1990, there was a series of 10 methadone overdose deaths in Victoria. Overdose deaths among methadone clients were not unheard of prior to this, but the previous deaths usually resulted from the ingestion of a larger than prescribed methadone dosage, or from ingestion by a person for whom the treatment was not prescribed. However, this particular series of 10 deaths resulted from clients taking the prescribed quantity of methadone, and occurred within a few days of commencing methadone treatment in programs managed by general practitioners. The coronial inquests that were held into three of these deaths found several contributing factors, including a lack of client supervision and counselling; the failure of prescribers and pharmacists to differentiate between methadone toxicity and opioid withdrawal effects; and the relatively high starting doses (Drummer, Opeskin, Syrjanen, & Cordner, 1992). These findings provided an added impetus for clinical standards in Victoria to be enhanced.

In the early 1990s, starting methadone doses in Victoria were in the 20 to 40 mg range. Maximum doses in 1991 were usually in the range of 30 to 50 mg, but subsequently rose significantly. There was no limit to treatment duration but duration averaged 18 months (CDHSH, 1995; Harrison, 1994).

In 1992, the Kennett government came to power in Victoria and the privatisation of the public sector was high on its agenda. Prisons, electricity, public transport and health services were privatised and public assets sold. The public sector was reduced by over 25%, or 70,000 staff, through a combination of outsourcing, privatisation and downsizing. In the health sector, as elsewhere, policy development was separated from service provision through purchaser/provider arrangements. Services were contracted out to a mix of public and private agencies through compulsory competitive tendering. Funding was allocated on the basis of accountability for outputs, and efficiency was measured in terms of cost reduction (Fraser & Valentine, 2008).

As well as the financial drivers for this change, this was a deliberate strategy to normalise and de-stigmatise opioid dependence and make it a much more accessible treatment option. In addition, this approach aimed to better integrate the treatment of opioid dependence with general medical care. This was regarded as important, because many opioid-dependent people experience serious illness or injury as a result of their years of injecting drug use and dependence. Community-based programs were also seen as valuable because they avoided the congregation of large numbers of clients and made it easier for patients to retain their anonymity (Drugs and Poisons Unit Victorian Department of Human Services, 2000).

The key to this model was the provision of services primarily through general practitioners and community pharmacies. The other critical component of the model was the development of specialist services to treat the most serious and complex opioid dependence problems and provide the necessary supports to community-based OAT providers (King, Berends, & Ritter, 2011).

In 1992, the Victorian Department of Health and Community Services developed a comprehensive manual of procedures and rules for prescribing practitioners (Gill et al., 1992). This was part of an on-going program of GP support called the Methadone Information Network. The manual included information on the objectives of methadone treatment and clinical information related to the potency, dose, long-term effects, side effects and withdrawal symptoms (CDHSH, 1995).

By 1993, the number of methadone clients had increased dramatically, averaging an increase of 15% per annum. This increase occurred almost entirely in community-based programs. Clients could enter the service via general health and welfare services, be referred into the specialist system from the general health provider, or enter at the specialist level independently. Over 85% of the 2,270 clients receiving methadone at that time were under the care of private general practitioners and collected their daily oral dose at a local retail pharmacy. Some public methadone programs remained, but these were utilised primarily by clients with complex needs, and provided backup, support and training to community-based providers. In 1993, there were approximately 40 places in public methadone programs to manage clients with complex needs. This Specialist Methadone Service (SMS) was subsequently expanded across four metropolitan regions, giving access to a total of 240 places for this group of clients (Harrison, 1994).

By the mid-1990s, all Victorian government-run alcohol and drug services had closed and services were provided (through tendering processes) by an array of non-government organisation providers (Ritter et al., 2014). One of the implications of this was that community pharmacies rather than specialist clinics were routinely used for methadone induction and stabilisation. This meant that new, or returning-to-treatment, clients were likely to be less stable and potentially more vulnerable in the early stages of treatment, compared with clients who had already been stabilised in a specialist clinic (Winstock, Lea, & Sheridan, 2010). A further implication of the closure of Government services was that several of Victoria's addiction medicine specialist moved interstate.

Between 1994 and 1997, the four SMSs were established in metropolitan Melbourne and one further SMS was established subsequently. In 1999, an evaluation of the SMSs found that they were providing high quality and valuable services to their target population. Nevertheless, there were some barriers evident. Foremost among these was the dearth of community-based prescribers and pharmacists. In addition, the level of secondary consultation and health practitioner training and education was less than expected. Overall, clients and referral agents indicated a high level of satisfaction with the model of service delivery, the intensity of services available, and the staff employed by the SMS (Hales & Cox, 2000).

In the mid-1990s in Victoria, one take-away dose per week and an additional three take-away doses per month were permitted for stable clients who had been on the program for at least three months. Random urine drug screening was required as part of the program. In reality, the rationale for urine testing, and its frequency, varied between practitioners (Ezard et al., 1999).

A 1996 evaluation of community-based methadone services in Victoria indicated that the average daily methadone dose was 41 mg, ranging from seven mg to 140 mg. Most clients were satisfied with the program and the services delivered by dispensing pharmacies and prescribing doctors. Most clients had reduced their heroin use and criminal activity since commencing methadone. Several concerns about the program were also identified. These included the high proportion of weekly income which clients spent on methadone-related activities, and the level of use of tranquillisers by clients on higher methadone doses. The evaluation did not survey rural methadone clients and heroin-dependent people who not in treatment. In general, however, the community-based methadone program was found to be an acceptable method of service delivery to metropolitan clients in Victoria (Ezard et al., 1999).

By 2007, 95% of OAT in Victoria was being prescribed by community prescribers and dispensed in community pharmacies. Nationwide, there was a dearth of prescribers available to provide this service to the community, but this issue was particularly problematic in Victoria which relied so heavily on community prescribing. In the early 2000s, Victoria placed significant emphasis on training GPs to prescribe OAT. The numbers of Victorian GPs who received approval to prescribe between 2001 and 2004 were as follows: 65 in 2001, 57 in 2002, 34 in 2003, and 12 in 2004. By the end of 2004, almost half (46%) of these authorised GPs had never obtained a permit to prescribe for a patient. In addition, at any one time, approximately two-thirds of authorised GPs (ranging from 60% to 72%) did not hold a patient prescribing permit, and the vast majority of active prescribers treated fewer than 10 patients. Meanwhile, a small percentage of GPs (12.5% of the 168 GPs) prescribed to more than 50 clients (King et al., 2011).

Between 2006 and 2010 the number of people receiving OAT in Victoria rose 15% to more than 13,000. Over the same period, the number of GP prescribers declined by the same percentage, to approximately 400 active prescribers. This decline should be viewed in the context of an already low base, with fewer than 10% of GPs involved in OAT provision in Victoria in any given year. This led to a lack of treatment places which made the OAT service system difficult to access, particularly in some rural areas. Over 90% of OAT clients had their medications dispensed in community pharmacies. Although the number of pharmacies involved in the OAT program had increased by 5% over the preceding four years, only about 40% of all pharmacies were involved in the OAT program (King et al., 2011).

In 2010, the SMSs (by now called specialist pharmacotherapy services [SPSs]) were acknowledged as providing good quality clinical services but catered for less than 5% of the total OAT client group, and only to those residing in close proximity to the Melbourne-based services. Access to these services was difficult and virtually impossible for those in rural and remote areas. The original intent of the SPSs was that they would engage with community OAT providers in shared-care arrangements and provide secondary consultation and training. However, these aims were largely unrealised (King et al., 2011).

In 2010, OAT system challenges, such as increasing demand and reducing capacity, led to a review of Victorian OAT services (King et al., 2011). The review found that the SPSs were almost irrelevant to OAT clients and community-based service providers located in outer metropolitan suburbs, and most particularly, in rural areas. The OAT system was originally conceptualised as a partnership between the specialist system and community or primary care providers. The aim was to develop client care pathways using various formal and informal agreements to ensure that there was good capacity to match the intensity of the services with the complexity of the issues confronting clients (recognising that these change over time) (King et al., 2011).

By 2010, the Victorian rates for the buprenorphine/naloxone combination product (Suboxone®) had risen to 30.1% of all OAT prescriptions, up from 13.6% in 2006. This rapid increase reflected the better safety profile and reduced diversion potential associated with buprenorphine-naloxone. Client dispensing fees were a major issue highlighted in the 2010 review. The fees were viewed as inequitable, discriminatory and a critical problem for Victorian OAT clients. The difficulties associated with meeting the financial obligations of OAT were identified as a major contributing factor to the deterioration of relationships between dispensing pharmacists and clients which, in turn, was leading to involuntary treatment termination (King et al., 2011).

A further issue identified was the need to develop workforce capacity in the specialist system to respond to clients with serious and complex needs, including pain management and pharmaceutical opioid dependence. Particularly important in this regard, was the training of, and recruitment to, Addiction Medicine Specialist positions. In addition, the review identified the need for further training and support to be provided for GPs and pharmacists, and a need to enhance administrative systems to manage permits and monitor OAT prescriptions (King et al., 2011).

Finally, the Review identified a range of quality-of-care concerns. This included some long-standing issues such as inadequate dosing, particularly of methadone. Some of the quality-of-care concerns related to a lack of initial training and on-going professional development, while others were attributable to the lack of specialist support that could be addressed by the development and effective dissemination of clinical guidelines. The review also found that some GPs were unfamiliar with complex Medicare care items that had the potential to adequately remunerate them for providing more comprehensive care (King et al., 2011).

Likewise, a 2013 Victoria Department of Health future directions paper discussed a number of shortcomings with the OAT system in that State. These included:

- insufficient treatment places due to limited number of GP prescribers and pharmacy dispensers
- poor referral and support pathways between specialist and primary care
- limited workforce development opportunities and support
- varied quality of care, depending on the provider

- limited access to the specialist system
- limited options to consider reduction regimes
- limited mentoring and support available for community-based OAT providers
- cumbersome administrative systems for managing data and permits
- the large increase in the use of Schedule three, four and eight opioids because of ill-informed prescribing practices, potentially increasing the number of people who are medically dependent on opioids (Victoria Department of Health, 2013).

A key approach outlined in the 2013 future directions paper was the establishment of pharmacotherapy area-based networks (PABNs). As part of the 2011-12 State Budget, the Victorian Government announced funding of $11 million over four years for additional support to service providers to improve client access to OAT treatment. Subsequently in 2014, five PABNs were established in Victoria to facilitate localised approaches in connecting care, driving best practice and improving health and wellbeing outcomes for opioid dependent patients. Each of the PABNs was designed to support health professionals (general practitioners, pharmacists and allied health clinicians) to prevent, identify and treat opioid dependence throughout the State. The networks were established to identify and provide local solutions to service needs in their area, work with other services to form partnerships and referral pathways, facilitate ongoing training for pharmacotherapy providers, and provide access for complex clients to addiction medicine specialists (Department of Health and Human Services, 2020).

Since their inception, the PABNs have achieved significant increases in primary care OAT practitioner numbers in Victoria. In the 12 months from December 2015 to December 2016 alone, net prescriber numbers increased by 114 (or 22%), and net dispenser numbers by 48 (or nine %), across the State. The prescriber/dispenser figures since the PABNs began operation are even higher, with GP numbers increasing by up to 100% in some regions, and dispensers by up to 25%. By December 2016, over 10% of Victorian GPs were active prescribers (Statewide Pharmacotherapy Network, 2017).

In 2016, following coronial recommendations emanating from a series of Victorian pharmacotherapy deaths, the State's pharmacotherapy guidelines were revised. These changes reduced the number of take-away doses allowed for OAT, with the following results:

- the maximum number of methadone take-away doses per week was reduced from five to four
- no single methadone supply should exceed three consecutive take-away doses (down from 5)
- the minimum period of stability in treatment before take-away methadone doses may be permitted is three months
- reiteration that unsupervised take-away pharmacotherapy doses are highly dangerous, and should be restricted to very stable and continuous dosing clients
- time in treatment should not be the only consideration when it comes to assessing eligibility for a client to receive unsupervised take-away (Victoria Department of Health, 2020).

A 2017 Opioid Treatment Forum identified a range of issues related to the provision of OAT in Victoria. Foremost among these was that Victoria did not have the capacity to properly meet current levels of demand for OAT, with GP prescribers being in particularly short supply, and overloaded. The forum heard that the Victorian OAT program was largely reliant on a small number of prescribers with high caseloads who are nearing retirement age. The stigmatisation of clients was a major reason for the reluctance of many GPs to engage with the OAT program. The strict regulations and guidelines around OAT prescribing and the professional risks, whether perceived or real, of stepping outside the guidelines was raised as another reason that GPs were hesitant to participate in the OAT program in Victoria (Harm Reduction Australia, 2017c).

A further issue was the lack of dispensing pharmacies, particularly in rural areas. As was the case with GP prescribers, stakeholders also identified that stigma and discrimination toward OAT consumers were barriers to recruiting pharmacies to the program. A further key disincentive for pharmacies was the risk of accruing bad debt from OAT consumers. Many pharmacists were also aware that OAT dispensing fees were not affordable for the vast majority of OAT consumers living on government benefits (Harm Reduction Australia, 2017c).

Other issues identified at the Opioid Treatment Forum included the following:

- the lack of addiction training in undergraduate courses
- the need to improve relationships between OAT prescribers, GPs and pain specialists
- the need to expand specialist OAT services and services in rural areas
- the need to enhance consumer participation in OAT planning (Harm Reduction Australia, 2017c).

In a 2017 submission to a Victorian Parliamentary Inquiry, the Turning Point Alcohol and Drug Centre expressed significant concerns regarding pharmacotherapy policy in that State. The submission described pharmacotherapy governance as "unchecked" because there was no statutory body overseeing pharmacotherapy in Victoria, other than the Department of Health and Human Services (DHHS) Drugs and Poisons Division. By contrast, unlike other States which had dedicated governmental bodies, the submission noted that there was no clear approach to pharmacotherapy governance in Victoria. The submission highlighted a particular governance issue regarding client prescribing permits which are required before a doctor starts prescribing. These permits last in perpetuity unless actively cancelled by the prescriber. In 2017 there were far more permits than active patients (20,000 permits and about 13,500 active patients) and there was no active oversight of these permits, or review of their continued relevance (Turning Point, 2017).

The submission also noted that a large proportion of pharmacotherapy management was in the hands of a diminishing number of GPs, and that there were no limits to the number of patients allowed in prescribers' caseloads, or limits on dosage levels. This meant that there was a small number of prescribers who held hundreds of prescribing permits, and OAT medicines could be prescribed at doses well above current clinical guidelines. Concern was also expressed that there was no active oversight of these practices, which potentially left the community at risk of iatrogenic harm and ran counter to existing evidence concerning best practice (Turning Point, 2017).

Turning Point (2017) also called for increased funding for pharmacotherapy support services. A key area of need identified was insufficient training places for addiction medicine specialists and addiction psychiatrists. This lack of a career pathway meant that Victoria would be facing a future without this expertise, as a result of the exodus of addiction specialists to funded positions interstate in recent years, and many of the remaining cohort of specialists nearing retirement. It was suggested that this lack of expertise would become most evident in areas of clinical complexity, such as pain and addiction and pharmaceutical drug misuse.

A further submission to the Parliamentary Inquiry from the Australian Medical Association, Victoria, indicated that there was a need for the Victorian Government to improve information sharing between medical practitioners and pharmacists involved in pharmacotherapy. While the Victorian pharmacotherapy policy highlighted the importance of strong collaboration at all stages of treatment, the Victorian Branch of the Australian Medical Association indicated that coordination did not often occur in practice, and improved information sharing in a confidential manner was required (Parliament of Victoria Law Reform Road and Community Safety Committee, 2018).

On a snapshot day in 2015, there were 14,122 people receiving OAT in Victoria. Of these, 13,193 had a private prescriber, and 929 had a correctional prescriber. Of these OAT clients, 9,303 were receiving methadone, 452 buprenorphine; and 4,367 buprenorphine/naloxone. The majority (13,120) were dosed at community pharmacies, 929 in correctional facilities, and 73 at other facilities (Australian Institute of Health and Welfare, 2016).

Current situation in Victoria

In 2020, there were 14,968 people receiving opioid pharmacotherapy in Victoria, up from 13,755 in 2011. This represents a population rate of 22 per 10,000, compared with 25 per 10,000 in 2011. Methadone was the most common opioid pharmacotherapy in use in Victoria in 2020 (62.3%), followed by buprenorphine/naloxone (30.4%), buprenorphine long- acting injectable (4.3%) and buprenorphine (2.9%). Ongoing clients represented 58.2% of OAT participants, while 21.1% were readmitted clients and 20.6% were new clients (Australian Institute of Health and Welfare, 2021).

In 2020 there were 1,585 OAT prescribers, comprising 1,572 private prescribers and 13 based in correctional facilities. The State had no public prescribers. In that year, there were 9.4 clients per prescriber, compared with 15.6 per prescriber nationally. There were 734 dosing sites in Victoria, comprising 663 in pharmacies, 12 in correctional facilities and 59 in other sites such as hospitals, mobile dosing sites, community health clinics, non-government organisations, and doctors' surgeries. Victoria had 20.4 clients per dosing site, compared with 17.3 nationally and 26.7 in the ACT (Australian Institute of Health and Welfare, 2021).

CHAPTER 13: THE HISTORY OF OPIOID AGONIST THERAPY IN NEW SOUTH WALES

Unlike other jurisdictions, opioid agonist programs in NSW developed from a model which was hospital based and was predominantly led by medical specialists.

As Norberry (1997) reported, unofficial OAT programs using medicines such as morphine had been occurring for some time, but in 1966, Dr Stella Dalton started treating opioid dependent people in NSW, and commenced a methadone program in 1968. Dr Dalton was a British psychiatrist who had previously been involved in prescribing heroin for heroin dependence the United Kingdom. In 1970, she established Wisteria House, a specialist residential drug and alcohol unit in Western Sydney (Caplehorn & Batey, 1992). A key factor which enabled Dr Dalton to obtain funding to establish and run Wisteria House was that heroin-related arrest rates doubled in NSW in 1969, and methadone treatment was seen as a means of addressing this problem (Davies, 1986).

At the time, Wisteria House was the sole specialised addiction treatment unit of the NSW Health Commission. Wisteria House was modelled on Dole and Nyswander's program in that it had an initial 6-week inpatient component, used high (blockade) doses of methadone, and patients were involved in running the program and were often employed as counsellors (Caplehorn & Batey, 1992).

A key difference between Dr Dalton's approach and that of Dole and Nyswander was that the former initially sought to induce total abstinence from opioids after two or three years. However, by 1980, Dr Dalton had changed her expectations and was treating many patients on the assumption that they might require methadone indefinitely (Dalton, 1980, as cited in Caplehorn & Batey, 1992).

In the early 1970s, the average opioid dependent person in treatment at Wisteria house was a 24-year-old single male who had been taking drugs for five years. Those seeking treatment preferentially used opioids when available, but generally used other drugs as well. After full history taking and careful assessment to ensure that potential clients had an established opioid addiction, increasing dosages of methadone were administered over a period of six weeks, up to a daily total of approximately 120 mg. A key aim of the program was to avoid treating non-addicted patients with methadone. This was a possibility that caused great concern to those who administered the treatment, and to the Health Commission of NSW. Before blockade doses were reached, a range of individual and group therapy techniques were employed to develop interpersonal relationships, and simultaneously, to assess the individual potential for recovery. After the blockade dosage was reached, patients were encouraged to seek employment and leave the unit, but were asked to keep in touch with the staff members (which was unavoidable in the early days, as all methadone was issued daily and only at Wisteria House) (Dalton & Duncan, 1979).

By early 1972, 82 heroin users had received methadone maintenance in NSW (Reynolds et al., 1976, as cited in Caplehorn & Batey, 1992). In mid-1972, the NSW Health Commission decided to expand methadone treatment services and opened the Brisbane Street Drug Dependence Service, ironically adjacent to the NSW Police Drug Squad offices. The approaches adopted by

the new clinic differed markedly from those adopted by Dr Dalton. Specifically, the clinic was abstinence-focused, and the treatment aim was to withdraw methadone treatment after about six months.

The clinic encountered a range of difficulties including:

- insufficient medical oversight of clinical services
- a lack of tertiary educated or experienced staff
- no peer review processes
- little staff training
- no library, or access to research literature
- lack of clear lines of authority or clinical guidelines provided by the NSW Health Commission
- high levels of staff burnout and turnover (Caplehorn & Batey, 1992).

Unfortunately, the difficulties experienced at the clinic contributed to a growing professional rejection of methadone treatment in other medical and community health arenas (Caplehorn & Batey, 1992).

The period from 1973 to 1976 in NSW has been described as the first period of expansion of methadone programs in that State (Caplehorn & Batey, 1992). During this period in NSW, smaller non-specialist methadone programs were established in community health clinics. Many of these clinics were modelled on the Brisbane Street Clinic, in that they were abstinence-oriented with most patients receiving methadone withdrawal or low-dose, short- term maintenance. However, there was also very limited availability of methadone programs in regional areas (O'Neill, Reilly, & Sinclair, 1985).

In 1975, 43% of those admitted into methadone programs in NSW had a dose of less than 40mg, while only 14% received a dose of at least 80 mg. An independent evaluation of the Brisbane Street Clinic undertaken in that year indicated that it was failing to achieve its principle aim of abstinence from all opioid drugs. Nevertheless, the evaluation also demonstrated that being on methadone conveyed several benefits for program participants and that being on a higher methadone dose was significantly associated with decreased use of illicit opioids. Despite this, there was little widespread support for methadone maintenance from within or outside of most treatment agencies (Caplehorn & Batey, 1992).

A 1976 survey of nine public addiction treatment clinics in NSW (excluding Dr Dalton's program) found that two refused to offer any methadone treatment, while another offered methadone withdrawal treatment only. The survey found that nine of the 10 major methadone prescribers (which were representative of six of the nine clinics) were opposed to the continuation of the NSW methadone program (Reynolds et al., 1976, as cited in Caplehorn & Batey, 1992).

Overall, in the mid-1970s the methadone program in NSW was poorly resourced, poorly administered and ideologically unpopular, with little perceived legitimacy as a form of treatment. The failure to reach consensus about the objectives of methadone treatment almost led to its demise. The problems that arose from inadequate management of the program, such as poor supervision of clients while on methadone, and the diversion of methadone onto the black market, appeared to legitimise the ideological position of its opponents. These problems were used as ammunition to argue against methadone programs (McArthur, 1999a).

A 1976 review of the performance of these programs by the NSW Health Commission urged restrictions on methadone treatment because of concerns about the administration of programs and because it was believed methadone treatment undermined alternative drug-free programs (Swensen, 1990).

In addition, a report from the Joint Committee of the NSW Parliament which investigated drug use and treatment approaches in that State, delivered a scathing review of methadone treatment, claiming that:

- it become an alternative means of drug dependence to many
- it had lent itself to abuse by both users and prescribers
- it had not been matched by back-up vocational rehabilitation programs
- it stifled initiative in exploring alternative means of treatment to meet the needs of the individual (Swensen, 1990).

The Committee wanted to see methadone programs phased out altogether because it could not endorse an approach which sought to replace one form of drug dependence with another (Swensen, 1990).

In NSW, up until 1975, the methadone treatment policy was one of a limited regulation of prescribers. From 1976 to the early 1980s, methadone treatment was severely restricted by the Wran Labor government, which preferentially funded detoxification facilities, drug-free rehabilitation programs, and self-help groups. There was also limited support for methadone treatment outside of NSW, because other States had smaller heroin problems. As such, there was a limited opportunity for a national approach. The other States also adopted measures to restrict the growth in methadone programs. Compared to other modalities there were few supporters of methadone. It was a treatment that was only begrudgingly tolerated (Swensen, 1990).

The arrival of Dr Jim Rankine

In 1978, Dr Jim Rankine, a pioneer in alcohol and other drug treatment in NSW, returned to Sydney after spending nine years as Director and Physician-in-Chief of the Clinical Institute of the Addiction Research Foundation of Ontario and Associate Professor of the Department of Medicine at the University of Toronto. Dr Rankine become the Director of the Drug and Alcohol Division within the Health Commission of NSW. Dr Rankine's role was to advise the Commission on alcohol and drug issues, develop new services and improve existing ones (Mellor, 2008).

Dr Rankine's arrival was associated with a tightening up of methadone programs in NSW (other than the program run by Dr Dalton which was already apparently tightly managed). New State guidelines were developed, clearer criteria were established, and the programs became more accountable. New units were established which were still abstinence orientated, where patients received methadone withdrawal or low short-term, relatively low dose maintenance. Methadone treatment became a tight and restrictive approach to heroin problems that was used primarily as a 'last resort'. Nevertheless, insufficient controls over the dispensing of methadone still saw the drug finding its way onto the black market in substantial quantities. Since low dose methadone treatment was the norm, many addicts supplemented their therapy with street heroin (McArthur, 1999a).

One of the key arguments in favour of methadone programs at that time was their ability to reduce crime and other community problems (rather than their ability to support addicts and their families). When it became apparent that methadone treatment would not provide a quick solution to property crime or to the spread of heroin addiction in NSW, the NSW Government

moved to abandon methadone maintenance. Methadone was ceasing to be regarded by the NSW Government, as elsewhere, as a legitimate long-term treatment (McArthur, 1999a) and the broader community had failed to accept methadone as a viable and helpful option in the treatment of people with heroin problems. This resulted in a sense of despair among many clinicians who wanted to use methadone in the management of this group of clients (Caplehorn & Batey, 1992).

In 1978, the NSW Government placed a freeze on the recruitment and replacement of community health staff which, as a result of the high levels of staff turnover, caused the rapid deterioration of services (Baldwin, 1983, as cited in Caplehorn & Batey, 1992). This resulted in a substantial loss of methadone treatment places during a time of increasing heroin problems and increasing demand for methadone treatment. The number of people receiving methadone treatment in NSW fell from 700 in 1976 to under 500 in 1981, with many of the patients expelled from NSW programs being absorbed into Dr Dalton's Western Sydney program (Caplehorn & Batey, 1992).

In response to burgeoning heroin-related crime rates in NSW, the Rankin Committee of Inquiry (Rankin Committee, 1981) was established in 1981 to examine the alternatives for dealing with drug-related crime. This included the possibility of legalising heroin. The Committee's Report also recommended that the methadone program should be expanded and be made more available throughout NSW, but that only doctors working in designated clinics should be authorised to prescribe methadone. The exclusion of the broader medical profession from prescribing methadone was controversial. The report also recommended that methadone program staff receive specialised training, and stressed the need for group decision-making regarding the use of methadone. These recommendations were largely ignored at the time (Caplehorn & Batey, 1992; McArthur, 1999b).

Capelhorn and Batey (1992) argued that the reasons for the delay in implementing the Rankin Committee's advice related to concerns about the exclusion of the broader medical profession from prescribing methadone. A further issue was continuing strong negative views about methadone treatment held by the NSW Department of Health and some workers in the addiction field. These factors delayed the implementation of the Committee's recommendations for four years.

The delay in implementing the Rankin Committee's recommendations also ultimately led to the development of a large private sector methadone program. In May, 1984, for the first time since the early 1970s, private practitioners were authorised to prescribe methadone in maintenance programs. In mid-1985, NSW Health Department officials authorised private doctors to prescribe methadone to up to 120 people (although most were limited to 20 to 25 patients) (Caplehorn & Batey, 1992).

Caplehorn & Batey (1992) suggested that private prescribers were permitted to provide these services primarily because of the inability of local health authorities to establish and staff publicly funded facilities. Indeed, the funds that the Commonwealth Government provided to NSW for methadone services in 1984-85 were not fully spent.

In the early 1980s, media attention was increasingly being given not only to the links between heroin use and crime, but also to calling for solutions. White (1985, as cited in McArthur, 1999), in an analysis of 1984 Sydney media, found that there had been a move away from a focus on the drugs/crime link towards a drug/political 'solution' paradigm. The media, having discovered the link between crime and drug use some time before, endorsed methadone treatment as the solution. This gave a voice to the campaign carried out by some groups in the community for an expansion of the methadone program.

Significant expansion occurred in methadone programs in NSW after 1985. There were three reasons for this:

- increasing recognition of the links between heroin use and crime (e.g., Dobinson & Ward, 1985) and the effectiveness of methadone in reducing criminal behaviour
- a substantial demand from addicts for methadone treatment
- the emergence of a national approach to drug policy, and recognition of the role methadone treatment could play in reducing the risk of HIV/AIDS infection (McArthur, 1999a).

By the mid-1980s, the newly developed National Campaign Against Drug Abuse coupled with increasing concerns about HIV/AIDS and other blood-borne diseases led the Commonwealth Department of Health to press the NSW Department of Health to expand its methadone services. By September 1985, the NSW Health Minister promised 1,000 more treatment places in public clinics. At the beginning of 1986, of the 980 patients receiving treatment from public methadone clinics, 225 were attending new facilities (Caplehorn & Batey, 1992).

Caplehorn & Batey (1992) highlighted the paradoxical way in which HIV/AIDS improved the services provided for people who injected drugs.

> *As they lack even the limited political and organisational power of other disadvantaged Australians, intravenous drug users have generally received a very poor standard of health care. Paradoxically, the HIV has improved the situation. As the principal vector for the spread of the virus into the heterosexual population, intravenous drug users have suddenly found themselves the centre of public, political and professional attention. P 673.*

Difficulties with uniform approaches between clinical services remained however, which Caplehorn & Batey (1992) suggested were due to NSW Health directives and procedures failing to identify appropriate clinical objectives or standards. As a result, the differences in policy and procedures within the units were nearly as great as the differences between units.

By the early 1990s, research examining the impact of methadone treatment on crime was showing positive results. A 12-month study of clients attending three low-intervention private methadone clinics found that self-reported, as well as officially recorded, crime dropped promptly and substantially on entry to treatment. Acquisitive crime fell to approximately one-eighth of that reported during out-of-treatment levels. Treatment factors were also independently predictive of continued involvement in crime. Treatment at one of the clinics was associated with greater involvement in crime compared with the other two. This clinic operated in a chaotic and poorly organised way. The researchers concluded that involvement in crime during methadone treatment is substantially lower than during street addiction, although the extent of reduction depends on the quality of treatment being delivered (Bell, Mattick, Hay, Chan, & Hall, 1997). This also serves to highlight the highly variable nature of treatment provision in NSW at the time.

In 1992, the NSW Health Department approached the Australian Professional Society for Alcohol and Drugs (APSAD) to develop a training and accreditation system for medical practitioners wishing to become authorised methadone prescribers in that State. Funding was provided to develop, pilot and evaluate the training program. This involved defining the core skills and knowledge required to treat opioid-dependent patients with methadone, and these definitions were converted into a training manual. A one-day training program was developed which aimed to give trainees an opportunity to integrate the material contained in the manual, and to address many of the individual anxieties and beliefs about addiction which can make for difficulties in delivering methadone treatment. The third component of the program was a clinical placement, in which the trainees spent half a day interviewing patients, then discussing the issues raised, with an experienced prescriber (Bell, 1996).

The program had mixed success. On the one hand, it attracted numbers of doctors to prescribe, particularly from remote areas. However, in terms of the need for safety, and for more empirically based treatment to be delivered, the training program was not effective in producing sustained change in behaviour. Subsequent Health Department data indicated that trainees provided methadone doses that increased too rapidly, resulting in one patient dying during the first week of treatment. In addition, despite an emphasis on the importance of higher methadone doses as an important factor in reducing heroin use, trainees were prescribing a mean maintenance dose of approximately 60 mg. This was the State average at the time, which suggests that a significant proportion of patients were being maintained on sub-optimal doses. Thus, there was no evidence that the training program brought about beneficial changes in prescribing behaviour, and some evidence that it failed to do so (Bell, 1996).

The mid to late 1990s saw increasing community opposition to methadone treatment. For some time in NSW, there had been local community opposition to the operation of methadone clinics in particular neighbourhoods. In the late 1990s, there was also increasing criticism of methadone treatment and questioning of its legitimacy. This occurred in the context of increasing heroin availability and use, and increasing heroin overdose deaths. It was clear that expanding methadone treatment had not stemmed the increase in heroin addiction. Politicians began to be concerned about the cost of keeping more and more people in indefinite treatment (Bell, 2000).

Several commentators lamented that Australia had been 'losing the war against drugs' and needed to take a harder anti-drug line. Methadone treatment was being seen as a 'soft option' and less satisfactory than abstinence-based treatment. These concerns were reinforced by the perception that many methadone clinics were poorly managed, particularly in relation to giving excessive take-away methadone doses (Bell, 2000). This perception was reinforced by research conducted in 1995, which found that among heroin users in Sydney, methadone injecting was widespread. Fifty-two per cent of 312 respondents reported having injected methadone syrup, with 29% having done so in the preceding six months. Forty per cent of current methadone injectors reported weekly or more frequent methadone injecting over the preceding six months (Darke et al., 1996). Similar research conducted in Victoria found that only 1.2% of 168 clients (n=2) reported having injected methadone within the last six months. Ironically, the two clients who reported having injected methadone had done so in NSW before coming to Victoria. The researchers suggested that the lower prevalence of methadone injecting in Melbourne, compared to Sydney, was a result of the less liberal take-away policy, and the mandatory dilution of methadone take-aways to 200 ml of liquid (Lintzeris et al., 1999).

The Royal Commission into the NSW Police Service, also known as the Wood Royal Commission, occurred between 1995 and 1997. The Terms of Reference were to determine the existence and extent of corruption within the NSW Police. Specifically, it sought to determine whether corruption and misconduct were systemic and entrenched within the service, and to advise on the process to address such a problem. The Wood Royal Commission's report concluded that a 'war on drugs' approach contributed towards police corruption. The Commission recommended increased attention to alternate approaches to drug law enforcement in NSW, including increased focus on harm minimisation strategies, increasing public education, expanding methadone availability and establishing a supervised injecting facility (Wood, 1997).

The most serious consequence of the growing public concern was that methadone treatment became politicised. This occurred during a State election in 1999, when one political leader proposed a policy of reducing the number of people receiving methadone treatment (Bell, 2000).

The Drug Summit

In late 1998 there was a widespread perception that the problem of illicit drugs was not being adequately addressed through existing resources and policies. The Premier of NSW, Bob Carr, made the commitment that, if re-elected in the March 1999 election, there would be a Summit on the drug problem (Champion & Gray, 2003).

On January 31, 1999, a photograph of a teenage boy engaged in injecting drug use in a laneway in Redfern appeared on the front page of a Sydney newspaper. This acted as the catalyst leading to the establishment of the Drug Summit. The article alluded to the apparent contradiction of governments spending millions of dollars on the 'war against drugs', yet at the same time funding clean needle programs where injecting equipment and advice were handed out. The then Minister for Health, Andrew Refshauge, reacted by immediately closing down the needle exchange outlet, and ordering a review of the $9 million State-wide needle exchange program (Swain, 1999).

The NSW Drug Summit was held in May, 1999. All NSW State Government politicians were invited, as were approximately 100 members of the public who were selected to represent the widest possible range of expertise and experience. The Summit's agenda covered many aspects of the illicit drug problem, including education, prevention, treatment, young people, regional and rural NSW, and the role of the police and the criminal justice system. The Summit resulted in agreement among participants regarding 20 general principles and 172 resolutions, covering a wide range of issues. These resolutions formed the framework of the NSW Government Plan of Action on drugs and was supported with a financial commitment of $176 million over four years (Champion & Gray, 2003).

The Summit made several recommendations that impacted on the provision of OAT in NSW, including the following:

- service delivery for substance use problems should operate within an integrated framework supported by a comprehensive range of services (including OAT) which were readily accessible within all metropolitan, regional and rural geographic areas and indigenous communities
- general practitioners and pharmacists should be encouraged to assist with the methadone program
- measures to improve service standards in alcohol and drug treatment, including OAT, should be introduced (Champion & Gray, 2003).

One of the key initiatives to arise from the Summit was the Pharmacy Incentive Scheme which paid individual pharmacists to dispense OAT medications. Under the Scheme:

- an initial payment of $1,000 was offered to each pharmacy practice to enrol in providing treatment or dispensing services for OAT medication
- a further payment of $100 per patient (up to a maximum of 20 patients) was paid for each OAT enrolment. Patients needed to be dosed continuously for two months, with payments made twice each year
- pharmacies could dose up to a maximum of 50 patients at any one time (although patients who were dosed only once each week were excluded from the cap).
- pharmacists were free to charge a 'dispensing' fee to OTP patients, with this fee being set at the determination of the individual pharmacy (Puplick, 2014).

At the time, the Summit was seen as a significant national event, an achievement in public problem-solving, and a lesson for ways in which public problems could be addressed in the future (Webster, 2000). It formed the basis for the NSW Government's NSW Drug Summit 1999: Government Plan of Action (NSW Government, 1999).

The Summit resulted in a number of initiatives which were intended to:

- enhance access to OAT, particularly in regional areas
- accredit services and improve training for OAT prescribers
- monitor the quality of service provision, including the prescribing of take-away doses of methadone
- increase proactive activities carried out by the Pharmacotherapy Credentialling Subcommittee (Champion & Gray, 2003).

Between 1999 and 2002, access to pharmacotherapy treatment improved significantly and this was accompanied by a rapid decline in suspected opioid overdose deaths (Champion & Gray, 2003).

In 2005, the State-Wide Advisory Team (SWAT): Drug Health Streamed Shared Care was established in 2005 by Drug Health Services, Sydney South-West Area Health Service and NSW Department of Health. The purpose of the SWAT was to map, consult with and support opioid pharmacotherapy services, including treatment provision at community pharmacies across NSW. Specifically, SWAT had the objective of building capacity within existing specialist and community resources for the management of those with drug and alcohol problems, initially for those with opioid dependence (Winstock, Lea, & Molan, 2008a).

By 2007, OAT programs in NSW were conducted through both the private and public sectors. Public sector programs were commonly run as clinics, while private sector programs comprised both clinics and arrangements combining general practitioners and pharmacy-based dispensing. There was some crossover between public and private sectors, in which, for instance, private practitioners prescribed methadone from public clinics (Fraser, Valentine, Treloar, & Macmillan, 2007).

Public and private treatment differed in a range of ways, particularly in the provision of take-away doses. Fewer restrictions were placed on take-aways in the private sector than in the public sector. More clients in private clinics than in public programs obtained their doses through pharmacies, which were often less rigorously controlled than public facilities. In general, private clinics had more autonomy than public programs (Fraser et al., 2007).

A study of public OAT clinics in NSW undertaken in 2006 (Winstock, Lea, & Molan, 2008b) identified wide variations in culture, priorities, staffing levels, resources and operational practices. These variations resulted in unequal and incomplete access to treatment and inconsistencies in service delivery across the State. The researchers also found that there were insufficient on-site medical and psychosocial services provided to clients attending public OAT clinics and wide variation in clinical staffing ratios. This impacted upon the frequency of review by both prescribers and case managers. There were also wide variations between clinics in terms of their relationships with local Divisions of General Practice. In general, clinics placed little emphasis on accessing GPs in the community to become either primary care providers or prescribers for stable patients.

Winstock et al., (2008b) reported that there was wide variation in the utilisation of community pharmacy dosing by public clinics. Among the community pharmacies providing dosing in NSW, there were approximately 2,800 unfilled dosing places. Of note, 5% of pharmacies providing methadone and 19% of pharmacies providing buprenorphine reported having no clients currently on that medication type.

Although pharmacy dosing places were not always available where they were most required, in many areas this was not the case. There were several barriers to clients being dosed at pharmacies. These included clinic culture and priorities, the reluctance of clients to pay, and the absence of standardised assessment and selection criteria. Other barriers included the absence of sufficient incentives to leave the clinic, such as the provision of take-aways at almost half of public clinics in NSW (Winstock et al., 2008b).

At that time, almost all pharmacies involved in OAT provided take-away doses of methadone. Thirty-seven per cent of 407 responding pharmacies dispensed methadone take-aways within the existing NSW guidelines, being a maximum of two consecutive take-aways and no more than four take-away doses per week. The remaining 63% of pharmacies dispensed methadone take-aways to at least some clients outside of these guidelines. Thirty-six per cent provided a maximum of three consecutive take-away doses, and 27% provided or more consecutive take-aways. Remoteness and difficulty of access to the pharmacy were not major contributing factors associated with these pharmacies dispensing take-away methadone doses outside of NSW guidelines (Winstock et al., 2008a).

At this time, there was increasing recognition that a proactive approach was required to move stable clients out to community dosing, to allow public clinics to provide increased access for non-priority groups. There was also a high level of support for adopting a standardised approach to assessment of client stability (Winstock et al., 2008b).

In 2006, the majority of pharmacies (92%), in NSW charged a flat weekly methadone dispensing fee (mean=$31.90) regardless of the number of take-away doses provided. For buprenorphine, 75% of pharmacies charged a flat weekly dispensing fee regardless of the dosing schedule (mean=$31.00). Seventy-one per cent of pharmacies reported that they provided credit to clients, with approximately one-quarter of pharmacies stating they currently had clients in debt (Winstock et al., 2008a).

A study of OAT in NSW from 1985 to 2006 examined client characteristics and patterns and predictors of treatment retention. The study found clear evidence of an ageing cohort of opioid-dependent people over this period, which was consistent with fewer younger people initiating heroin use since the heroin shortage of 2001. Retention in methadone treatment did not change dramatically over time, but it was lower and was dependent on heroin availability. That is, lower heroin availability increased retention in treatment. In addition, the first treatment episode was shorter on average for those who commenced treatment on buprenorphine compared with methadone. Buprenorphine clients were also more likely to switch subsequently to methadone than were methadone clients to switch to buprenorphine. Overall, younger individuals were significantly more likely to leave their first treatment episode than older individuals (Burns et al., 2009).

The Puplick Review

In January 2014, the Minister for Health and Medical Research, the Jillian Skinner, directed that there would be a review of the NSW Opioid Treatment Program to ensure the most effective and cost-effective operation of the program, with consistency State-wide. The aim of the review was to guide program change to better support clients to recovery (Puplick, 2014). The review was undertaken by Mr Chris Puplick, a former Liberal Party senator.

At that time there were almost 20,000 people on OAT throughout NSW, including up to 1,400 being managed by Justice Health. Justice Health set an arbitrary limit of 1,400 on the number of OAT places which it provided in 21 of its facilities (Puplick, 2014).

Puplick (2014) reported that was considerable dispute as to the extent of the unmet need for places in the NSW OAT program, which highlighted the paucity of poor quality of data which surrounded this program.

The Puplick Review revealed a range of concerns regarding the NSW OAT program. These were:

- stigma and discrimination: No issue figured more prominently in the responses of patients, families, carers and their organisations than the enormous extent of stigma and discrimination experienced, directly and indirectly, overtly and subtly, by patients in OAT
- pharmacy-related issues: including the requirement for dispensing to occur only in retail pharmacies; limiting pharmacies' OAT client base to 50; lack of flexibility regarding written prescriptions; and dispensing fees
- general practitioner issues: including stigma and discrimination, negative attitudes about or towards patients, reluctance to participate in the provision of OAT services, and concerns about financial remuneration
- the interface between the provision of public and private health services: including restrictions placed on the expansion of private clinics; and a lack of clarity regarding whether public clinics would act as a safety net for clients who could not be managed in the private sector
- concerns over the appropriateness of the 'one-size-fits-all' approach: Was this an appropriate model for OAT services, given the changing nature of the OAT population, or did this offend the principle of equity in the provision of health services? With increasing numbers of OAT clients developing pharmaceutical (as opposed to illicit) opioid dependency, the issue arose as to whether these two groups should be treated differently. Puplick concluded that OAT clients should be managed on the basis of their level of stability and behaviour rather than the aetiology of their opioid dependence
- the role of the NSW Ministry of Health as policy maker and regulator: including over-regulation, data availability and quality, integration with other health policies and departments, co-morbidity issues, and obsolete treatment guidelines
- the opportunities for NGOs to play a more active role in the provision of and support for OAT: including whether the NGO sector should become further involved in the care of clients with complex needs, and the associated funding issues
- exit strategies and possibilities for exiting being more proactively promoted as an integral part of the OAT: including the extent to which exiting from OAT should be promoted and facilitated, and the ways in which this should occur
- issues of workforce and personal development, training and education, together with access to professional and peer support: including limited workforce development opportunities, and the ageing of the OAT workforce
- a lack of access in rural and remote areas, which was a significant barrier, as was the fact that many services were full, and simply could not provide more places, particularly within the correctional environment
- Issues related to national policy responsibility in this area, national policy coordination and changes in structural and financial arrangements related to the OAT: including the Medicare Item Number schedule for addiction medicine services and national uniformity or co-ordination in the regulation of OAT (Puplick, 2014).

Puplick (2014) also reported that while OAT enjoyed a considerable level of support among those members of the community, including the health professions, who knew that it existed, it had few if any public champions. It was still regarded by many as a politically-charged and sensitive issue and one best avoided in terms of public discussion. In other words, it should continue to fly under the radar.

The Puplick Review concluded that any significant expansion of the OAT program in NSW should be predicated on building a wider and deeper constituency for its growth by having:

- clearer statements of the aims and objectives of OAT, focusing on the goals of OAT and expressed in an entirely patient-centred fashion (rather than being expressed in terms of process issues concerning OAT programs)
- greater public exposure of the successes of OAT as a major public health initiative
- more direct involvement of both existing and former patients/clients and their organisations/representatives in the development of a State-wide strategy for OAT (Puplick, 2014).

On a snapshot day in 2015, there were 19,563 people receiving OAT in NSW. Of these 6,317 had a public prescriber, 11,432 had a private prescriber; 210 had a public/private prescriber and 1,604 had a correctional prescriber. Of these OAT clients, 14,355 were receiving methadone, 5,208 buprenorphine or buprenorphine/naloxone. The majority (10,268) were dosed at community pharmacies; 3,214 were dosed at public clinics; 2,910 were dosed at private clinics and 1,693 in correctional facilities; 336 at other facilities (and 1,142 not stated) (Australian Institute of Health and Welfare, 2016).

A 2017 key stakeholder forum focused on the provision of OAT services in NSW. The key issue identified was that that the OAT Program in NSW had struggled to effectively and consistently implement consumer engagement and participation programs. Even where this engagement did occur, it was described as tokenistic, with little power or influence, and at times operating in a hostile environment. Forum participants reported that staff working in the NSW OAT program had limited knowledge of the value and potential of consumer engagement and participation, both in terms of consumer outcomes and the operational benefits to a service (Harm Reduction Australia, 2017a).

Forum participants also noted the need to increase the number of GP prescribers and OAT dispensing pharmacists. However, the most concerning and overarching OAT workforce issue identified by forum participants was deeply embedded stigma against opioid dependent people and people who inject drugs (Harm Reduction Australia, 2017a) .

There was consensus among forum participants that models of OAT delivery in NSW were inflexible and over-regulated, placing a great deal of constraint on the lives of consumers. The program was described as analogous to being on parole, due to the very high levels of monitoring and surveillance. Further, the inherent inflexibilities within the system frequently worked to undermine rather than actively support consumers to make positive changes in their lives, such as gaining employment (Harm Reduction Australia, 2017a).

Reducing the cost of the NSW Opioid Treatment Program (OTP) to consumers was regarded by forum participants as a crucial but complicated issue in NSW. The participants agreed that community pharmacists needed to be compensated for their time and for the administrative burden of dispensing OAT medications. However, many also noted that it was not fair or sustainable to expect consumers, some of the most financially disadvantaged members of the Australian community, to be burdened with this cost – reportedly between $3 and $12 per day (Harm Reduction Australia, 2017a).

Other issues identified by the participants included the need to:

- support and enhance specialist OAT programs, such as those in prisons
- provide the opioid antagonist naloxone to OAT clients to prevent fatal overdoses
- adapt the OAT Program to meet the needs of clients who also use stimulants
- adapt the OAT Program to meet the needs of clients who are ageing (Harm Reduction Australia, 2017a).

Current situation

Treatment for clients under the NSW OTP must be initiated by an accredited OAT prescriber. A NSW medical practitioner who has not received accreditation as a NSW OTP prescriber may be authorised by the Ministry of Health to prescribe methadone for up to 10 low-risk patients who are being transferred from an accredited prescriber. Unaccredited medical practitioners cannot initiate patients on methadone. With buprenorphine or buprenorphine-naloxone, unaccredited medical practitioners may be authorised to initiate up to 20 buprenorphine or buprenorphine-naloxone patients. The total number of patients that an unaccredited prescriber may obtain authority to prescribe for at any one time is 30, with a maximum of 10 of these patients being prescribed methadone (Australian Institute of Health and Welfare, 2021).

To participate in the NSW OAT Program, community pharmacies must register with the Ministry of Health and comply with the protocol for community pharmacy dosing points issued by the Ministry (Australian Institute of Health and Welfare, 2021).

On a snapshot day in 2020, there were 22,949 clients receiving pharmacotherapy in NSW, up from 18,831 in 2011. This represented 28 per 10,000 of the NSW population receiving opioid pharmacotherapy, up from 26 in 2011, and compared with 21 nationally. The population rate of NSW opioid pharmacotherapy clients remained stable at 26 people per 10,000 between 2011 and 2019, before rising to 28 in 2020. In 2020, 62.4% of NSW pharmacotherapy clients received methadone, with the remaining 37.6% receiving buprenorphine. NSW pharmacotherapy data do not distinguish between buprenorphine, buprenorphine/naloxone and long-acting injectable buprenorphine. Among NSW pharmacotherapy clients in 2020, 82% were ongoing clients, 14.6%t were new clients and 3.2% were readmitted clients (Australian Institute of Health and Welfare, 2021).

In 2020, there were 1,027 OAT prescribers in NSW. This comprised 243 public prescribers, 731 private prescribers and 53 correctional prescribers. In 2020, NSW prescribers had on average 22.3 clients per prescriber, down slightly from 24 clients in 2016. This compares with 15.6 clients per prescriber nationally. Public prescribers had 33.2 clients per prescriber, compared with 17 for private prescribers and 46.1 for correctional prescribers. There were 1,022 dosing point sites in NSW, comprising 36 public clinics, 12 private clinics, 868 pharmacies, two in correctional facilities and 101 other dosing sites (including hospitals, mobile dosing sites, community health clinics, non-government organisations, and doctors' surgeries). There were 22.5 clients per dosing site in NSW, compared with 17.3 nationally (Australian Institute of Health and Welfare, 2021).

Medication Assisted Treatment for Opioid Dependence (MATOD) continues to be delivered in NSW through specialist clinics, community pharmacies, general practitioners, nurse practitioners, public hospitals, and in prisons and juvenile detention centres. Outpatient clinics, community pharmacies and local hospitals are the most common dispensing sites. Specialist clinics have a far more prominent role in OAT in NSW compared with other jurisdictions. These clinics, both public and private, are usually multidisciplinary and may include nurses, medical practitioners and allied health professionals. Some general practitioners who are also authorised prescribers may also share case management with staff from drug and alcohol services or, in some cases, perform this role themselves. Since 2006, nurse practitioners in NSW may also be authorised prescribers, with this role performed principally in the public sector (Furnival & McGovern, 2018).

The Director-General of the Department of Health is responsible for approving prescribers for OAT. To be approved, prescribers must complete the Pharmacotherapy Accreditation Course, either in person or on-line; successfully sit an exam; and undertake a clinical placement or have a written clinical case successfully assessed. An authority to prescribe is required for each patient and approval is required from the Pharmaceutical Service Branch (PSB) before treatment can be initiated. The authority to prescribe is valid for a maximum of one year. Prescribers in NSW are initially limited to treating no more than 25 patients although after six months, they can apply to increase this number (Furnival & McGovern, 2018).

CHAPTER 14: THE HISTORY OF OPIOID AGONIST THERAPY IN QUEENSLAND

Queensland has had a long history of therapeutic and bureaucratic, rather than legalistic and punitive, approaches to dealing with opioid dependence. Since the late 1930s, the Queensland Department of Health had carriage of illicit drug-related matters, in contrast to other Australian jurisdictions in which other departments dealt with this issue. The exclusive authority of the Queensland Department of Health in this area led to the triumph of the medical model of addiction in Queensland and the institutionalisation of a system of opioid maintenance. Since the Queensland Department of Health was exclusively responsible for illicit drug matters that did not involve trafficking or illegal possession, there was no scope for policy counter arguments to this absolute medical authority (Manderson, 1993).

Even more remarkably, the medical 'ownership' of illicit drug issues extended beyond so-called 'therapeutic addicts'. After the end of World War II, the Queensland Department of Health decided that management of the few ageing Chinese opium smokers remaining in the State should be incorporated within the framework of legal opioid use. Opium for smoking was illegal to possess, use or import at the time. Consequently, these Chinese users were legally supplied with tincture of opium (laudanum) as a substitute. By 1955, there were 34 Australians of European descent receiving morphine, pethidine, or, in a few cases methadone under the care of the Queensland Health department and 68 Chinese, all over the age of 50 (Manderson, 1993).

In addition to this long-term approach to opioid dependence, the other critically important factor that shaped the development of the methadone program in Queensland was the influence of first Dr Alan Freed and later Dr Michael Bolton (who argues he was persuaded by Freed's views). Dr Freed was a psychiatrist and neurologist who had been employed as the Director of Drug and Alcohol services in Queensland. He had been the director of a therapeutic community in Newcastle on Tyne in the north of England (Foley, 2013; McArthur, 1999a), before becoming the Director of the Queensland public methadone program in the late 1970s. Dr Bolton graduated from the University of Queensland in 1963, spent more than a decade as a rural GP in Chinchilla, and followed Dr Freed in the role of Director.

Methadone maintenance treatment for opioid dependence was initiated in Queensland by a small number of private psychiatrists in the early 1970s. The first public methadone program was established at a Brisbane Psychiatric Outpatient Clinic in approximately 1975 (CDHSH, 1995).

There were several similarities between the beginnings of the Queensland methadone program and the NSW program. Dr David Jenkins, the psychiatrist who commenced the program in Brisbane, like Dr. Dalton, had worked in England. Although Dr Dalton and Dr Jenkins both brought their experience to Australia, there were substantial differences between the Queensland and NSW programs (McArthur, 1999a). The first was that Queensland doctors initially prescribed intravenous methadone to their clients. Secondly, the major objective of the early Queensland prescribers was to enhance their clients' stability, which allowed the clients to resume normal lives again. In contrast to the NSW program, abstinence from drugs was not necessarily an objective in the Queensland program (McArthur, 1999a).

In the early days, Queensland had what was regarded as the most liberal program in Australia because of its use of intravenous methadone, its relatively low threshold for entry, and its use of generally higher doses, compared with other jurisdictions.

The Queensland program seemed largely unaffected by the debate that was occurring in other jurisdictions regarding the purposes of methadone treatment. Dr Freed was clear in his views concerning the purpose of methadone treatment.

> *I see [methadone] treatment as the lesser of two evils. They (addicts) are either going to be enslaved by a criminal system which includes the police, prisons - enslaved by that circle, criminal to court to prison back to criminal to court. Or a medical system. The difference being in the order of seven times $400 a day. And they have to get up to much fewer tricks to survive on a methadone program than on a heroin scene (Freed, 1994, as cited in McArthur, 1999, p.7).*

The Queensland methadone prescribers discretely grew the methadone program. Dr Ian Curtis, an early Queensland prescriber commented:

> *The incredible thing was that it crept up on them. Basically we created a de facto intravenous drug program here...So that a de facto program just crept up on them and kicked them in the head and then they really couldn't get rid of it (Curtis, 1994, as cited in McArthur, 1999, p.6).*

As a result of the influence of these Queensland opinion leaders, the liberal approach to methadone programs was accepted without a backlash. The Queensland program throughout the 1970s and into the 1980s embraced the wider social objectives of methadone treatment, as opposed to abstinence-based approaches which were more prominent in other jurisdictions.

The stated aims of the Queensland methadone program were:

- to prevent the spread of narcotic dependence and of associated criminal activity by people dependent on narcotics
- to improve the physical health, social functioning, prospects of rehabilitation and the overall quality of life of people dependent on narcotics (Bolton, 1984).

Bolton (1984) noted that if...

> *...dependent persons wish to continue on methadone, they are significantly "better off" than in the "street" scene. They are not breaking the law, they have an opportunity to work, they are likely to be physically healthier and they have an opportunity to reaffiliate with normative society (p.41).*
>
> *The use of methadone enables the dependent person to extricate himself from "the drug scene" and the multiple associated cues for illegal drug taking (settings, withdrawal, needle use etc). The relatively diminished effect, that illegally used heroin will provide when used in a higher dose methadone program will also promote lack of reinforcement of drug taking behaviour. (p.42)*

It is important to reflect for a moment that this liberal and socially aware approach to methadone prescribing occurred during the premiership of Joh Bjelke-Peterson. Bjelke-Peterson was the longest-serving Premier of Queensland, holding office from 1968 to 1987. He was regarded as an uncompromisingly conservative politician, and yet the Queensland methadone program thrived under his period of government. The Queensland Minister of Health between 1974 and 1978 was Dr Llew Edwards, a medical practitioner. Dr Edwards apparently persuaded his political colleagues that medical practitioners were best placed to make decisions regarding the treatment of heroin problems, and that provided the methadone program did not attract adverse media attention, it should be free of interference from politicians.

The conservative political climate of Queensland, with a Premier who strongly espoused values of law and order, still accepted the important role methadone could play in ensuring control over drug addicts (McArthur, 1999a).

In the 1970s, doctors registered to prescribe methadone to illicit drug dependent people in Queensland were usually:

- attached to the Drug Dependence Clinic in Brisbane
- private psychiatrists in Brisbane or country areas
- country hospital superintendents.

On occasions, appropriate general practitioners in Brisbane or country areas were also authorised to prescribe methadone for this purpose (Bolton, 1984).

The Queensland program was also broadly based and aimed to meet a range of client needs. Bolton (1984) noted:

> *The use of methadone is, of course, only one component of a well-run methadone program. Attention must also be paid to individual social needs such as employment and individual psychological needs such as the presence for depression or other psychopathology (p.41).*

Naloxone testing was not favoured in Queensland. Queensland prescribers originally opposed introduction of naloxone testing[7] as a prerequisite to the institution of methadone, but by 1983, naloxone testing protocols had been developed for use when indicated.

In explaining why naloxone testing was not the preferred approach Bolton (1984) noted:

> *One needs to come to terms with the fact that people present to a methadone program because they need and wish help. It is our responsibility to guide them towards appropriate help for their problem. Should one wish to manipulate for methadone (or indeed for other opiate or non-opiate drugs) this can be achieved far more efficiently to general practitioners and other doctors with concocted stories than by presenting to a drug clinic where staff are more aware of such a possibility (p.41).*

With the expansion of the public program in 1977, and a decision by the Commonwealth government that it was no longer prepared to fund intravenous methadone programs, this part of the program was closed to new entrants in 1978 (Reynolds, 1987). The doctors prescribing intravenous methadone argued that it was unfair to immediately stop providing this treatment to clients overnight. The decision was made to allow no more authorisations for intravenous methadone, but to permit those clients who were receiving it to continue until they were transferred to the syrup formulation or withdrawn from all drugs. In 1999, there was still one client receiving methadone intravenously in Queensland (McArthur, 1999a).

The Queensland program even provided places for interstate clients who came to Brisbane seeking treatment:

> *Those numbers escalated dramatically in the early 1980s and the majority of the people we were getting on the program were from New South Wales. We were getting them from other States but we were getting huge numbers coming up from New South Wales saying*

7 Naloxone testing refers to the injection of the opioid antagonist naloxone to assess physical opioid dependence.

they couldn't get onto methadone down there. We literally had people arriving on trains and buses with suitcases and children and dogs coming straight in to get onto the methadone program (Biggs, 1994, as cited in McArthur, 1999).

In contrast to NSW, the staff at the Brisbane clinic believed that there should be no ceiling placed on the numbers in treatment. Consequently, a decision was made to simply provide methadone only. Providing counselling and other services as well as methadone would have meant that less treatment places were available (McArthur, 1999a).

A review of the Queensland methadone program undertaken in 1984 revealed that it was, at least modestly, realising the stated aims listed above. The review also found that there had been a dramatic increase in service utilisation over time, and an ageing of the client population. A further finding was that other health services were only making a limited contribution to treating opioid dependence. A final conclusion was that while there was a need for meticulous supervision of clients on the program to avoid adverse outcomes such as deaths, clients on the program were safer than those who remained in or returned to the illicit drug scene (Bolton, personal communication, October 8, 2018) .

The review also made several recommendations, including:

- improved staffing and facilities
- improved supervision of methadone prescribers and pharmacists
- tightening of methadone policy guidelines (including a restriction of the use of methadone in general practice settings)
- judicious introduction of naloxone administration to test for opioid dependence
- development of standardised assessment protocols
- broadening the base of agencies involved in the assessment and treatment of opioid dependence to include hospitals and other health services (Bolton, personal communication, October 8, 2018).

In 1985, Queensland had the highest rate of methadone prescribing in Australia, and in July that year, the Queensland Drugs of Dependence Clinics in Brisbane recorded their first HIV- positive client. By 1987, this had grown to eight clients (Reynolds, 1987).

By 1987, the Queensland Alcohol and Drug Dependence Services had 940 people on the methadone program, 163 of whom had been on the program for two years or more. There was no waiting list for entry and if clients were assessed as appropriate, they were usually placed on methadone on the day of presentation. At that time, there were only two clients remaining in the intravenous methadone program. There was also a loosening of the criteria regarding who could receive methadone treatment. Regardless of the level of opioid neuroadaptation, if a client was considered at risk of spreading HIV through continued needle sharing, methadone treatment could be offered (Reynolds, 1987).

By 1994, there were 1,952 clients registered on the methadone program in Queensland. Sixty percent were male (average age, 35 years) and 40% were female (average age, 33 years); 48% were aged 35 years or over. The private sector participation rate was relatively stable in Queensland, ranging from 2.3 persons per 10,000 in 1986 to 3.2 persons per 10,000 in 1994. Over the same period, public sector participation rates increased from 4.4 to 9.9 persons per 10,000. Overall participation rates nearly doubled from 6.7 persons per 10,000 population to 13.1 persons per 10,000 in 1994, with most of the increase occurring in the years 1990 to 1994. As at June 1994, there were seven GPs and 24 psychiatrists registered to prescribe methadone. General practitioners treated only 7% of the private clients in the State, with the remaining 93% being treated by psychiatrists. As at September 21, 1994, there were a total of 347 outlets authorised to dispense methadone syrup in Queensland. This comprised:

- 3 public clinics
- 54 hospital pharmacies
- 289 community pharmacies (CDHSH, 1995).

In 2017, a forum addressing OAT issues in Queensland reported that access to OAT in Queensland was not currently meeting community demand, with a particular need to increase the number of prescribers and dispensing pharmacies. Key barriers to GPs prescribing OAT identified included the stigmatised views held by GPs regarding clients, and the perception that practising in this area requires highly specialised knowledge and carries a great deal of risk. The lack of support for prescribers and pharmacies was identified by forum participants as a major factor affecting the quality of OAT in Queensland (Harm Reduction Australia, 2017b).

The actions of Queensland Police in proximity to OAT dispensing pharmacies was identified as a key reason for consumers discontinuing treatment. The inappropriate confiscation of take-away doses by police was leading to unnecessary and costly court cases which were almost always dismissed. Dispensing pharmacies were also being used by the police to conduct stop and search operations, check people for outstanding warrants and create registers of the car licence plate numbers of OTP consumers (Harm Reduction Australia, 2017b).

Forum participants also noted that the general rigidity of the OAT program in relation to take-away doses was a major impediment to client treatment. Other issues identified in the forum included:

- the need to adapt the OAT Program to meet the needs of ageing OAT clients
- the need to reduce dispensing fees for clients
- unnecessary use of expensive urine drug screening
- the need to enhance consumer engagement and participation
- the need to enhance specialist services to prisons, Aboriginal and Torres Strait Islander peoples and during natural disasters and emergency situations (which occur frequently in Queensland and can leave clients cut off from OAT) (Harm Reduction Australia, 2017b)

On a snapshot day in 2015, there were 6,418 people receiving OAT in Queensland. Of these 3,480 had a public prescriber, 2,860 had a private prescriber and 78 had a correctional prescriber. Of these OAT clients, 3,061 were receiving methadone, 760 buprenorphine and 2,597 buprenorphine/naloxone. The majority (4,380) were dosed at community pharmacies; 67 were dosed at public clinics; 703 at private clinics; and 53 in correctional facilities; 254 at other facilities (and 961 not stated) (Australian Institute of Health and Welfare, 2016).

Current situation

The Queensland Opioid Treatment Program is essentially community based, other than for inpatients in hospitals and correctional facilities. Prescribers undertake training provided by Queensland Health, and the Department provides approval to commence prescribing on successful completion of the training program. Prescriber training is provided for all pharmacotherapies currently available (Australian Institute of Health and Welfare, 2021).

No approval is required for community pharmacies to supply opioid treatment drugs, as this is within the endorsement of registered pharmacists (Australian Institute of Health and Welfare, 2021).

On a snapshot day in 2020 there were 7,014 clients receiving pharmacotherapy in Queensland, up from 5,702 in 2011. This represented a rate of 14 per 10,000 of the Queensland population (compared to 21 nationally) and up from 13 per 10,000 in 2011. In 2020, 38.9% of pharmacotherapy clients received methadone; 46.2% received buprenorphine/naloxone; 4.5% received long-acting injectable buprenorphine, and 10.4% received buprenorphine (Australian Institute of Health and Welfare, 2021).

In in Queensland in 2020, there were 292 OAT prescribers, comprising 118 public prescribers, 120 private prescribers and 18 correctional prescribers. Prescribers in Queensland had on average 24 clients each, down from 26.6 in 2016, compared with 15.6 clients per prescriber nationally. In this year there were 658 dosing point sites, comprising 13 public clinics, four private clinics, 566 pharmacies, 10 correctional facility sites and 65 other sites (including hospitals, mobile dosing sites, community health clinics, non-government organisations, doctors' surgeries). There were 10.7 clients per dosing site on average, down from 11.1 in 2016, and compared with 17.3 nationally (Australian Institute of Health and Welfare, 2021).

All Queensland OAT prescribers need to be approved by the Chief Executive of Queensland Health prior to initiating treatment. To gain approval, prescribers need to complete the Prescriber's Accreditation Course. This course includes a formal training program, a knowledge test and a supervised clinical attachment within two months of the training program. This is facilitated by the Drugs of Dependence Unit within Queensland Health, and authorisation to prescribe is granted following successful completion. Prescribers are then required to get approval to prescribe to each individual they treat (Furnival & McGovern, 2018).

In Queensland, dosing sites may include opioid treatment clinics or community or hospital pharmacies, with community pharmacies being the most common. More than a third of pharmacies in Queensland are approved as a dispensing pharmacy for MATOD. To begin dispensing, the pharmacy must be provided with a letter of introduction from a patient's prescriber or clinic. This letter requires a photograph to be attached to ensure that the person presenting the letter is the person for whom MATOD has been prescribed (Furnival & McGovern, 2018).

As with other States, patients need to be assessed as stable before being provided with take-away doses. Criteria for stability include, but are not limited to, regular presentation for dosing; compliance with any care plan; secure and stable accommodation; regular contact with their prescriber or care manager; and no evidence of hazardous substance use. Limits for take-away doses range from 0 to four a week for patients being treated with methadone and between 0 and 31 for patients taking buprenorphine-naloxone. A stepped approach is recommended for take-away doses (Furnival & McGovern, 2018).

CHAPTER 15: THE HISTORY OF OPIOID AGONIST THERAPY IN THE AUSTRALIAN CAPITAL TERRITORY

Methadone was first provided in the ACT in the early 1970s by several private practitioners. The first regulated and coordinated methadone program began in early 1979 when the Drugs of Dependence Unit (DDU) of Woden Valley Hospital was established under Dr Keith Powell. There were four clients on the program in 1979 (Tedeschi, 1987). The estimate of the number of regular heroin users within the ACT at that time ranged from 300 to 600 (Powell, Mench, Smith, & O'Malley, 1984). By 1983, a total of 35 patients had been placed on the program and there were 17 people on the program at that time. By 1987, there were 58 patients on the Maintenance Program (Tedeschi, 1987).

In the early 1980s, an ad-hoc committee of experts experienced in the field of alcohol/drugs/counselling was established by the DDU team to review each application for admission to the methadone program. In the early stages of the program clients were seen once a week, but it soon became apparent that this was excessive and the pendulum swung the other way. Reviews were then conducted too infrequently. Ultimately clients were reviewed approximately every six months and crisis situations were dealt with independent of any review (Powell et al., 1984).

Among the 35 people who had been admitted to the ACT Program by 1983:

- 16 had completed the program, five of whom were opioid free, and 11 had made no improvement (by the standards of the time)
- 17 remained on the program, four of whom were reducing with the aim of ceasing, and 13 were continuing on maintenance doses
- Two had transferred interstate (Powell et al., 1984).

The program was originally based on an abstinence model, and admission to maintenance was offered only after two unsuccessful attempts at withdrawal. Subsequently, two distinct programs were offered. Firstly, there was a methadone reduction program which had an upper limit of 20 clients at any one time. The reduction program lasted approximately 28 days, with starting doses of around 30 to 40 mg. No take-away doses were available on the reduction program. While the reduction program was seldom useful for achieving a drug-free status, it served to bring clients into contact with the Unit and facilitated blood-borne disease testing and medical assessment (Tedeschi, 1987).

Secondly there was a Methadone Maintenance Program, which by 1987 had 58 patients. This was a relatively high intervention program with on-site methadone dosing undertaken daily and take-away doses rarely allowed. The methadone team consisted of a registered nurse, a team secretary, a social worker and a physician. The methadone was dispensed daily by the nurse and rapid referrals to a social worker or physician were available if required. The small size of the program meant that team members knew their clients very well. Supervised urine checks were undertaken regularly on a random basis, averaging one to two per week per person, with no exceptions (Tedeschi, 1987).

New clients were required to attend at the hospital and were seen by a counsellor and medical practitioner. Clients were required to show signs of withdrawal before being considered for the program and a naloxone challenge could be used to achieve this. Decisions regarding admitting clients to methadone maintenance were made by a multidisciplinary group of staff based on:

- time on the waiting list
- whether children were involved
- blood-borne disease status
- pregnancy
- previous methadone reduction/detoxification (Tedeschi, 1987).

Patients were encouraged to stay on the program for no longer than two years but were not removed from the program just because the 2-year period was up. By 1987, in the maintenance program there were:

- 14 clients who had received treatment for six months or less
- 17 clients who had received treatment for six to 12 months
- 15 clients who had received treatment for 12 to 24 months
- 12 clients who had received treatment for more than two years (Tedeschi, 1987).

Maintenance doses were generally between 60 to 80 mg, with doses of greater than 80 mgs rarely allowed. Clinic workers accepted that during the settling-in period, some illicit drug use was to be expected, but clients could be removed from the program if this continued. Antibody testing for HIV was encouraged, but not compulsory. By 1987, there were three HIV-positive tests from 222 tests undertaken (Tedeschi, 1987).

In the early 1990s, a low threshold methadone program was introduced in the methadone clinic for dependent opioid users who were not ready or willing to have major involvement in treatment (Legislative Assembly for the Australian Capital Territory: Select Committee on Drugs, 1992 [Select Committee on Drugs 1992]).

By 1991, there were 85 places for methadone maintenance and 15 for reduction. In late 1992, the maintenance program was expanded to 350 places, and until these were filled in May, 1996, it was easy to re-enter the program after dropping out. Both before 1992 and after May, 1996, there was generally a waiting list, even though the number of places for methadone maintenance was further increased to 400 later in 1996. The policy was to gradually reduce places on the public program to 200 by June 1999 and to transfer 200 stable clients to private medical practitioners and pharmacies (Bammer, Battisson, Ward, & Wilson, 2000).

In 1992, there was a review into the methadone program conducted by the ACT Legislative Assembly Select Committee on Drugs. At that time there were 115 clients on the maintenance program and five clients on the reduction program. The review expressed several concerns regarding the program, including the following:

- the restricted number of people who could be on the program
- program waiting lists of 2-3 months
- the single site location at Woden Hospital which was not conducive to client normalisation
- the fact that the program was primarily based upon abstinence objectives
- the use of urine drug testing
- difficulties associated with clients accessing OAT on interstate trips
- excessive risk aversion to the threat posed by methadone diversion (Select Committee on Drugs, 1992).

The ACT also had a strong methadone consumer lobby group at the time. In addition, approximately every four to six weeks a Methadone Program Development Advisory met to discuss problems and potential changes to the program. Three consumer lobby groups were represented at this meeting. A number of changes were made to the ACT methadone program in response to the Select Committee's findings and the work of the consumer lobby groups (CDHSH, 1995).

Subsequently, the number of clients in the ACT private sector increased from 23 in November 1996 to around 150 as of April 30, 1998. There were 22 doctors and 15 pharmacies participating in the program at that time. In 1992, there was also an increase in the availability of take-away doses. A policy was also introduced in November 1996 whereby private patients and those receiving take-away doses at the public clinic were required to pay $A15 per week. Nevertheless, the first two full years of the take-away dose expansion (1993 and 1994) were also associated with an increase in program dropouts at three and six months and at one and two years. The temporary increase in dropouts at one1 two years suggested that the expansion initially destabilised some people who had already been in treatment for a considerable time. It is possible that as it was relatively easy for people to return to the program, they may have been less concerned about leaving treatment for a range of reasons (Bammer et al., 2000).

In December 2003, the ACT Government implemented the ACT Alcohol and Other Drug Strategy, which outlined the actions that the Government would work to implement over the 4-year period 2004 to 2008, in partnership with the community and nongovernment organisations. It covered key areas of harm minimisation: supply reduction, demand reduction and harm reduction. One of these actions was the creation of 100 additional subsidised places in the methadone and buprenorphine program (Healthcare Management Advisors, 2007).

The ACT also implemented an OAT dispensing subsidy payment to community pharmacists of $15 per week per patient (Chalmers et al., 2009). There were also a number of tiers of charges payable by clients:

- Tier I, where OAT was prescribed by ACT Community Health's Medical Officers and dispensed by the ACT Community Health's Alcohol and Drug Program (ADP). The OAT was free for six months and thereafter all clients paid $15 per week.
- Tier II, where OAT was prescribed by ATC Community Health's Medical Officers, dispensed by a community pharmacy, and the clients paid $15 to the pharmacist per week, with the ADP paying the pharmacy a $15 weekly subsidy.
- Tier III, where OAT was prescribed by a community prescriber and dispensed by a community pharmacy, and clients paid $30 per week to the community pharmacy.
- Tier VI, used for interstate transfers, and the clients paid $35 per week to ACT Health (Healthcare Management Advisors, 2007).

On a snapshot day in 2015, there were 978 people receiving OAT in the ACT. Of these, 567 had a public prescriber, 308 had a private prescriber, and 103 had a correctional prescriber. Of these OAT clients, 382 were receiving methadone, 57 buprenorphine and 318 buprenorphine/naloxone. The majority (706) were dosed at community pharmacies; 169 were dosed at public clinics; and 103 were dosed in correctional facilities (Australian Institute of Health and Welfare, 2016).

Current situation

In the ACT, a prescriber may prescribe a controlled medicine (methadone or buprenorphine) for opioid maintenance treatment. Prescribers are required to prescribe methadone or buprenorphine in accordance with the National Guidelines for Medication Assisted Treatment of Opioid Dependence (2014). Prescribers should also endeavour to comply with the Opioid

Maintenance Treatment in the ACT: Local Policies and Procedures wherever possible (Australian Institute of Health and Welfare, 2021).

Prescribers need to be approved by the Chief Health Officer before prescribing OAT, as well as hold an endorsement if they wish to prescribe for more than five patients or initiate patients onto treatment. The requirement for endorsement is waived if the prescribers work in specific ACT institutions, such as prisons or hospitals. To gain endorsement, prescribers need to undergo training, be examined and also undertake a practical placement (Furnival & McGovern, 2018).

Community pharmacies require a licence to dispense OAT. They are licensed as Opioid Dependency Treatment Centres for up to three years, and the holders of these licences need to ensure that all pharmacists and pharmacy staff involved in OAT have completed the required training course and examination for dispensers in the ACT. Refresher training for both prescribers and pharmacists is required every five years (Furnival & McGovern, 2018).

Most clients commence dosing at either the Alcohol and Drug Service or a community pharmacy. The prescriber must confirm arrangements with the pharmacy that the client wishes to attend for supervised dosing. This confirmation will involve a client visit to the pharmacy to allow the client and pharmacist to agree on dosing arrangements (Australian Institute of Health and Welfare, 2021).

All pharmacists are required to attend training in 'Treatment of Opioid Dependence for General Practitioners, Pharmacists and Health Professionals' before they start dosing clients. Canberra Health Services Pharmacy conducts this training in collaboration with Alcohol & Drug Services (Australian Institute of Health and Welfare, 2021).

On a snapshot day in 2020, there were 1,120 clients receiving pharmacotherapy in the ACT, up from 825 in 2011. This represented a rate of 26 per 10,000 of the ACT population (compared to 21 per 10,000 nationally) and up from 22 in 2011. In 2020, 69% of pharmacotherapy clients received methadone; 20% received buprenorphine/naloxone; 10% received long-acting injectable buprenorphine; and 1% used buprenorphine. Of these clients, 69% were ongoing; 12% were new clients; 19% were readmitted clients: and 0.1% were interstate clients (Australian Institute of Health and Welfare, 2021).

In 2020 in the ACT, there were 69 OAT prescribers, comprising 11 public prescribers, 49 private prescribers, one public/private prescriber, and eight correctional prescribers. Prescribers in the ACT had on average 11.2 clients each, compared with 15.6 clients per prescriber nationally, and down from 18.7 per prescriber in 2016. In this year, there were 42 dosing point sites in the ACT, comprising one public clinic, 40 pharmacies and one correctional facility site. There were 26.7 clients per dosing site on average, compared with 17.3 nationally and down from 31.3 in 2016 (Australian Institute of Health and Welfare, 2021).

To be eligible for take-away doses, patients need to be clinically assessed as stable. Prescribers then need to detail the authorisation of take-away doses, and these must also be maintained on the patient's record. Limits on the number of take-away doses are determined by how long a patient has been in treatment. These vary from 0 to four doses per week for patients taking methadone and from 0 to 27 out of 28 days for patients on buprenorphine-naloxone. Significant processes exist for patients transferring in or out of the ACT, with four weeks' notice recommended for patients seeking a permanent transfer either to or from the Territory (Furnival & McGovern, 2018).

CHAPTER 16: THE HISTORY OF OPIOID AGONIST THERAPY IN SOUTH AUSTRALIA

The methadone program began in SA in 1973 at Hillcrest Psychiatric Hospital approximately 10 km north-east of the Adelaide Central Business District, and as such, the program was incorporated within the overall mental health system. Dr Bill Salter, a psychiatrist, was Medical Superintendent at Hillcrest Hospital at the time. Dr Salter had a strong interest in treating patients with alcohol-related problems, and treatment of people who were heroin dependent was a logical extension of this (South Australian Royal Commission into the Non-Medical Use of Drugs, [Sackville Royal Commission],1979).

The establishment of the methadone program at Hillcrest Hospital was triggered by the discovery by the SA Central Board of Health that an SA general practitioner was providing an unsanctioned methadone program to a small number of heroin-dependent people. There were also some other medical practitioners who were providing methadone prescriptions for local and interstate patients, and this was becoming a small but increasing source of illicit methadone. This was particularly concerning because methadone prescriptions were being provided to interstate patients in the absence of adequate monitoring and supervision (Sackville Royal Commission, 1979).

Consequently, in the early 1970s the South Australian Central Board of Health asked Dr Salter to establish the program at Hillcrest Hospital and to take over management of the general practitioner's six patients and others who sought help. The program was staffed by a nurse and various medical officers. As the program grew in the mid to late 1970s, they were joined by a pharmacist, a nurse and a social worker.

In 1975, the Hillcrest Hospital methadone program was providing services to fewer than 20 individuals. By the end of 1978, this number had increased to approximately 120, but this number fluctuated significantly, mainly because Adelaide was towards the end of Australia's heroin distribution chain at that time. Heroin was predominantly imported into Sydney and then came to Adelaide via Melbourne. This lengthy distribution chain often led to a disrupted supply to the Adelaide market. During periods of heroin shortage, clients were attracted into the program, only to leave once supplies resumed (Sackville Royal Commission, 1979).

The methadone program expansion during the mid to late 1970s was in large part due to increased resources being provided to the program at the time, as well as the closure of other types of treatment facilities. There was also a gradual increase in the availability and use of heroin in SA throughout the 1970s and a corresponding increase in problems of drug dependence (Sackville Royal Commission, 1979).

In the early days, the Hillcrest program was a short-term methadone maintenance program aimed at abstinence. After stabilisation on the program, most clients were taking 40 to 60 mgs of methadone daily. Doses above 80 mg were not used. The usual practice was to keep the clients stable at 40 to 60 mg for two months, before reducing their doses by five to 10 mg a fortnight to bring them off the program. The rationale for this approach was to give clients a period of approximately two months of stability to resolve lifestyle issues before beginning the withdrawal process. If clients used heroin while on the program, they would be rapidly withdrawn from methadone and removed from the program.

As with other jurisdictions, the methadone program in SA attracted a great deal of stigma for both clients and staff. The program was not a particularly welcome addition to psychiatric services at Hillcrest and was viewed with considerable disquiet by psychiatric treatment providers. This view was in keeping with the perceptions of most of the health care providers throughout the State. The notion of giving another opioid to heroin-dependent people, rather than trying to stop them using the drug, was regarded by many at the time as quite bizarre.

For more than 20 years up until the end of 1984, alcohol and other drug services in South Australia had been delivered under the framework of the Alcohol and Drug Addicts' Treatment Act, 1961. The Alcohol and Drug Addicts Treatment Board (ADATB) was a statutory authority created under the Act and was primarily responsible for treatment services provided in SA at that time (Cornwall, 1989).

In the 1970s in SA, there was major disagreement among service providers concerning the most effective treatment approaches for people with heroin-related problems. On the one hand, the Hillcrest Program (under the auspices of the mental health system and not the ADATB) used methadone stabilisation and withdrawal treatment. On the other hand, the ADATB was supportive of abstinence-based programs and was therefore opposed to Hillcrest Hospital's approach. This difference of perspective led to a fundamental lack of coordination in the treatment of heroin-dependent people in SA at the time (Sackville Royal Commission, 1979).

In early 1979, the Sackville Royal Commission's final report was published. This was one of the most comprehensive examinations of illicit drug use ever undertaken in Australia. It was commenced while reforming SA Premier Don Dunstan was in power and was completed just before his resignation in February 1979 (Cornwall, 1989).

The Royal Commission's report was critical of the Hillcrest methadone program being a component of the mental health system. Specifically, the Commission was concerned that the program was physically located in a large psychiatric hospital for the treatment of long-term mental illness and was therefore not well suited to the needs of people with drug or alcohol problems. Hillcrest Hospital was also located in a relatively inaccessible part of Adelaide, which presented major logistical difficulties for the clients who were required to pick up their doses daily. In its report, the Royal Commission also expressed concern regarding the dangers inherent in prescribing methadone too freely to patients who claimed to be addicted. It concluded that the prescribing policies of Hillcrest Hospital should be more restrictive and the program itself should become the responsibility of the ADATB (Sackville Royal Commission,1979; Cornwall, 1989).

In considering the operation of the Hillcrest methadone program, it is important to be mindful that many of the practitioners involved were still 'feeling their way'. There was no substantial body of research concerning how to provide methadone services and consequently no State or national guidelines to follow.

Dr John Cornwall was the SA Health Minister between 1982 and 1988. He oversaw an era of major reform in health care, including the implementation of the Royal Commission's findings in relation to methadone services in that State.

Dr Cornwall was a key critic of the Alcohol and Drug Addicts' Treatment Act, 1961. According to Dr Cornwall, this legislation reflected an authoritarian and institutional approach to treating people with alcohol and other drug problems. In addition, he noted that although the ADATB, as a statutory authority, reported directly to the Minister of Health, in practice this meant that many of the services were organised at arm's length from the central health bureaucracy. As a result, this bureaucracy had little influence over the ADATB's activities (Cornwall, 1989). Consequently, the Board was dissolved in 1984 and was replaced by the Drug and Alcohol Services Council (DASC), which was incorporated under the South Australian Health Commission Act, 1976. The Chief Executive Officer of DASC was able to convince Dr Cornwall that DASC would be in a position to take over methadone provision. Subsequently methadone services in SA then became the responsibility of DASC.

The implementation of the recommendations of the Sackville Royal Commission were not popular with clients and resulted in a decrease in clients in the early 1980s. Methadone continued to be regarded as a treatment of last resort in SA, to be deployed only after clients had unsuccessfully attempted other approaches. Naloxone testing was routinely used to establish physical dependence on opioids. Clients would be removed from the program if their urine drug screening demonstrated heroin use on three occasions. Take-away doses were relatively inaccessible. As a result of these approaches, many heroin users found it easier to get heroin than to be on the methadone program.

In response to the findings of the Sackville Royal Commission, a new methadone clinic was established at the Osmond Terrace Clinic Warinilla in Norwood in the early 1980s. This was a State-funded clinic run under the auspices of DASC. There were approximately 120 clients on methadone treatment when it transferred from Hillcrest to the Warinilla Clinic. Brian Stothard, the social worker, and (subsequently) his wife Kate Stothard transferred from the Hillcrest Methadone Program and became key influences on the SA Methadone Program in the future.

As with programs in other parts of Australia, the SA methadone program during the 1980s tended to be relatively punitive, because clinicians at the time did not regard opioid dependence as a brain disease. Rather, it was more often seen as a moral issue, or a failure of personal commitment. During the early 1980s, clients were generally commenced on 10 tot 20 mg of methadone, aiming for a maintenance dose of 40 to 60 mg. The rationale for providing what would now be considered generally inadequate doses was that keeping clients on as low a dose as possible would make it easier for them to reduce and come off the program as soon as possible.

During the early 1980s there were approximately 40 people receiving methadone at Warinilla, with very little availability in other parts of the State. This increased to 313 in May, 1986, before declining to 275 in March 1987 (Williamson, 1987).

The emergence of HIV in the early to mid-1980s, the establishment of the National campaign Against Drug Abuse (NCADA) in 1985, and the resultant increase in Commonwealth funding for drug treatment services, substantially changed the provision of methadone services in SA. During the initial years of NCADA, SA funding for drug and alcohol programs increased by 50% (Cornwall, 1989). New purpose-built methadone facilities were established at Warinilla.

Warinilla became DASC's fully integrated drug treatment campus, and alcohol treatment was moved elsewhere. There was a large increase in social work, medical and nursing staff and considerable effort was directed to staff education. By 1987, screening for and education about HIV were well integrated into clinical practice at Warinilla. However, at that time there was increasing concern that some HIV-positive clients were refusing to tell their partners about their diagnosis, which was placing their partners at great risk of infection. At that time in SA, only the fully developed clinical condition AIDS was a notifiable disease. This meant that for reasons related to client confidentiality, clinic staff were unable to inform clients' partners of their clients' HIV-positive status. Warinilla staff then brought this to the attention of the SA Health Commission and the Health Minister (Williamson, 1987).

The Warinilla methadone program was substantially 'opened up' to a broader cross-section of people who used heroin. Heroin dependence was no longer a prerequisite for admission to the methadone program, and as a result, naloxone testing ceased because it was no longer relevant. At the time, having HIV was regarded as a death sentence, and consequently a key aim of methadone treatment became to limit the spread of HIV, rather than solely focusing on the treatment of heroin dependence.

In the late 1980s, it was noted that clients would often leave the program after approximately one month, and SA research was beginning to demonstrate that program retention was closely related to methadone dosage (Gaughwin, Solomon, & Ali, 1998). This led to increases in both initial and maintenance dosages.

Pharmacists play an important role in the provision of OAT. In 1988, DASC appointed a new methadone pharmacist, Kevin Foreman. Mr Foreman developed a considerably improved approach to tracking and reconciling clinic daily methadone usage, which was subsequently computerised and is still widely used throughout Australia.

In the early 1990s, a second clinic was also established at Elizabeth, to cater for the needs of clients in the northern suburbs.

In 1992, a streaming process was introduced, which resulted in more stable methadone clients receiving increased take-away doses. DASC also modified clinical policies to allow clients greater control over methadone dose levels (White, Ryan, & Ali, 1996).

The DASC methadone program was aimed at and adapted for three specific client groups:

- **Stream A**

  These were clients with minimal treatment goals and/or no demonstrated stability in treatment (that is, clients who did not wish to engage in formal counselling regarding their unsanctioned opioid use). These clients were provided with a 'low intervention/ high supervision' methadone program. This was essentially a drug substitution program where it was expected that participation in the program would result in associated improvements in health and social functioning and decreased risk of morbidity, mortality and of HIV risk-taking. Clients received no take-away doses of methadone and did not qualify for community pharmacy collection of their methadone.

- **Stream B**

  These were clients who wished to engage in formal efforts to reduce their unsanctioned opioid use and were endeavouring to attain stable treatment progress. These clients were provided with a 'high intervention' methadone program which offered a comprehensive range of services to clients. Total abstinence from unsanctioned opioid use was only one of a range of acceptable treatment goals in this program. However, a higher level of intervention was used to promote and facilitate change in many life areas, so that improved health and social functioning could enable clients to 'normalise' their general lifestyle. Services included a high level of medical and clinical casework intervention, welfare advice and support, social skills training and after-care.

- **Stream C**

  These were clients who had demonstrated good treatment progress in a 'high intervention' methadone program and were stable. This group required little support other than the prescription, administration and medical supervision of their methadone medication. Accordingly, they were offered a 'low intervention/low supervision' methadone program but had access to counselling should they feel they require it (CDHSH, 1995).

By late 1994, there were:

- 265 clients in Stream A
- 358 clients in Stream B
- 182 clients in Stream C (CDHSH, 1995).

A subsequent evaluation of the streaming initiative demonstrated that it resulted in a significant increase in retention rates, as a result of giving clients greater control over their treatment. The demographic and heroin-usage histories of clients admitted into the streaming program did not change, but the program attracted a greater proportion of clients with no previous history of methadone maintenance treatment. Mean clinic doses also increased from 45 mg to 63 mg when clients were allowed to exert control over dosage (White et al., 1996).

An Obstetric Unit was also established, aimed at minimising the adverse effects of opioid use and promoting the physical and psychological health mothers and infants. The Unit provided counselling, support and referral services; medical assessment and review; a methadone maintenance program, where appropriate; and formal education programs, information and advice to service providers and women (CDHSH, 1995).

It was at this time that the SA Prisons Drug Unit was also established. Subsequent negotiations with the Prison Medical Service resulted in HIV-positive methadone clients being able to continue methadone treatment while in prison. Soon, all methadone clients who were on remand as well as those sentenced to less than one month's imprisonment were able to continue their treatment while in custody. Clients sentenced for longer periods were gradually reduced down to 30 mg before cessation and treatment with a clonidine withdrawal regime (Williamson, 1987).

The DASC methadone program reached a critical point in 1994. Due to a lack of resources, DASC introduced a ceiling of 850 people on the Public Methadone Program. Applicants beyond this number were placed on a waiting list and assessed as numbers dropped below this ceiling. As of September 1994, there were 77 people on the waiting list, a position that was unsustainable and inconsistent with efforts to reduce the spread of HIV. This led to a move to increase the number of clients being managed by GPs and dosed at community pharmacies (CDHSH, 1995).

While the move towards private prescribing and dispensing was clearly necessary, there was also a keenness to avoid the overt level of separation between public and private programs that was evident in other Australian jurisdictions. At this time there was also emerging interstate evidence of deaths associated with the privately run methadone programs. Many of these deaths occurred during the induction phase. This evidence emanated from Victoria, (Drummer et al., 1992; Drummer, Syrjanen, Opeskin, & Cordner, 1990) and NSW (Caplehorn, 1998) [describing deaths which actually occurred in 1994]). South Australian clinicians and administrators also wanted to ensure that this did not occur in SA.

A private methadone program was developed which was aimed at medical practitioners who wanted to become methadone prescribers. It was designed for clients who either:

- wanted to engage in formal efforts to reduce their unsanctioned opioid use but who had yet to demonstrate stable treatment progress (i.e., Stream B)
- had demonstrated good treatment progress and were stable (i.e., Stream C).

It was recognised early on that adequate training and support were essential if medical practitioners were to perform this role. The first training program for these medical practitioners was conducted in March 1994.

The aims of the private prescribing program were to:

- enable methadone to be provided to more of the target group by accessing members of the heroin-using population who had not previously been reached
- enhance regional services, particularly in country areas where the public methadone program did not provide a service
- stabilise client numbers on the public methadone program.

The public program continued to play a major role in the initial stabilisation of clients and in receiving referrals of clients with complex needs from the private program (CDHSH, 1995).

At that time in SA, there were approximately 1,100 community pharmacists. Drug and Alcohol Services SA (DASSA) pharmacist Kevin Foreman made considerable efforts to recruit pharmacists, and ultimately trained 190 of them to dispense methadone from community pharmacies. Having 17% of the SA pharmacists trained in this way substantially increased the accessibility of methadone services in the State.

The public/private model continued to grow throughout the 1990s in SA, but in order to avoid the risk of exploitative private clinics, limits were placed on numbers of clients under the care of each prescriber. This resulted in a large number of prescribers each with a small number of clients.

By 1995, the SA Public Methadone Program operated from two main clinics as well as the dedicated Obstetric Unit (Le, 2014).

In the mid-1990s the partial mu-opioid agonist buprenorphine was proposed as an alternative OAT medicine to methadone. Between 1996 and 1999, the SA public methadone program was involved in an important double-blind, double-dummy trial to determine the effectiveness of this new drug (Mattick et al., 2003). The research found that buprenorphine did not differ from methadone in its ability to suppress heroin use but retained approximately 10% fewer program participants. This poorer retention rate was potentially due to a too-slow induction onto buprenorphine. The research also found that for the majority of patients, buprenorphine could be administered on alternate days, resulting in more efficient dosing processes and with less burden on clients. As a result, the use of buprenorphine for OAT grew in SA throughout the early 2000s.

In 2011, SA, as with most jurisdictions, was having difficulties attracting general practitioner OAT prescribers. In 2011, there were only 58 accredited active community OAT prescribers who were prescribing for approximately half of the State's OAT clients. None had vacancies for metropolitan or rural clients. In addition, DASSA's four OAT clinics were at full capacity. As a result, the SA Suboxone® Expansion Policy was implemented in April 2011. This permitted prescribers to treat up to a maximum of five (subsequently 10) patients with Suboxone® without having to undertake accreditation. The policy had the effect of increasing unaccredited GP participation, but as a result of reducing demand on accredited GP providers, did not increase the State's total capacity to service OAT clients. In April 2011, there were 1,783 clients on the SA Community OAT Program but by June this had fallen to 1,632 (Le, 2014).

On a snapshot day in 2014, there were 3,086 people receiving OAT in SA. Of these, 987 had a public prescriber, 1,851 had a private prescriber and 257 had a correctional prescriber. Of these OAT clients, 1,747 were receiving methadone, 21 buprenorphine and 1,318 buprenorphine/naloxone. The majority (2,593) were dosed at community pharmacies; 63 were dosed at public clinics; 235 in correctional facilities; and one was dosed at other facilities (and 194 not stated) (Australian Institute of Health and Welfare, 2015)

Current situation

The OAT program in SA is delivered by medical or nurse practitioners (within their scope of practice) and there are also four public clinics operated by Drug and Alcohol Services SA. The Drugs of Dependence Unit within SA Health is responsible for overseeing OAT authorisation and approvals in SA. Authorisation under the Controlled Substances Act, 1984 must be obtained before prescription of any pharmacotherapy to treat opioid drug dependence (Australian Institute of Health and Welfare, 2021).

Training is offered to SA pharmacists and pharmacy interns, and there are guidelines to assist them in delivering OAT. Patient/pharmacist template contracts are provided as part of the guidelines and the pharmacy is required to keep a signed copy (Furnival & McGovern, 2018).

On a snapshot day in 2020, there were 3,037 clients receiving pharmacotherapy in SA, a number that has remained virtually unchanged since 2011. This represented a rate of 17 per 10,000 of the SA population (compared to 21 per 10,000 nationally) and down from 19 per 10,000 in SA in 2011. In 2020, 52.7% of SA pharmacotherapy clients received methadone; 45.2% received buprenorphine/naloxone; 1.3% received long-acting injectable buprenorphine; and 0.8% received buprenorphine (Australian Institute of Health and Welfare, 2021).

In 2020, there were 261 OAT prescribers in SA, comprising 31 public prescribers, 223 private prescribers, and seven correctional facility prescribers. In 2020, SA OAT prescribers had on average 11.6 clients each, down from 13.4 each in 2016. Public prescribers had 30.6 clients per prescriber, compared with 8.2 for private prescribers and 35.9 for correctional prescribers. This compares with 15.6 clients for all prescribers nationally (Australian Institute of Health and Welfare, 2021).

In 2020, there were 244 dosing points in SA, comprising three public clinics, 229 pharmacies, eight correctional facilities and four others (including hospitals, mobile dosing sites, community health clinics, non-government organisations, and doctors' surgeries). There were 12.4 clients per dosing site compared with 17.3 nationally (Australian Institute of Health and Welfare, 2021).

CHAPTER 17: THE HISTORY OF OPIOID AGONIST THERAPY IN TASMANIA

Historically, heroin has not been readily available in Tasmania. Consequently, local illicit opioid consumers have generally used pharmaceutical opioids at higher rates than their counterparts in other jurisdictions. In Tasmania, the prevalence of the illicit use of opioids other than heroin has traditionally been similar to that of heroin use nationally. This suggests that the illicit opioid using population in Tasmania may have simply substituted pharmaceutical opioids for heroin (Bruno, Ong, & de Graaff, 2007).

In the 1980s, methadone was provided at the John Edis Hospital in Hobart. Despite the availability of funds emanating from the National Campaign Against Drug Abuse which could have funded a methadone program, there was political resistance to the establishment of a State-wide program up until 1992.

The State-wide Tasmanian Methadone Maintenance Program was established by the Director of Tasmanian Alcohol and Drug Services (A&DS), Dr Jacob George, in December 1992, as a pilot program in Hobart. Methadone was initially dispensed through the State government-funded alcohol and drug centre, which consisted of a detoxification and rehabilitation unit as well as an outpatient clinic (CDHSH, 1995). Dr George also established a methadone training program for prescribers and pharmacists in 1992, and clients were subsequently transferred out to private prescribers/dispensers. This led to issues with some clients with more complex needs who exhibited behavioural problems and were unsuitable for private care. As a result, these clients with more complex needs were ultimately brought back to the A&DS.

By the early 1990s, program participants in the southern and northern regions could attend private general practitioners or the A&DS; however, most services were provided directly by the A&DS. There were no full-time A&DS medical officers in north-west region. Consequently, clients in this region only had access to general practitioners for prescribing, with dosing undertaken via community pharmacies. The program's capacity in the north-west area was determined by the number of GPs and the community pharmacies participating in the program. At this time, program participants were eligible for take-away doses, provided they met specific criteria (CDHSH, 1995).

By December 1993, there were 52 pharmacies participating in the program, most of which were in southern Tasmania. By June 1994, there were 90 clients participating in methadone programs across Tasmania, up from 81 in September of the previous year (CDHSH, 1995).

In 1995, the Department of Health and Human Services (DHHS) adopted a policy to more broadly implement a community-based pharmacotherapy treatment model to increase access to clients in need of treatment outside of central Hobart. Pharmacists were provided with a financial incentive to dispense methadone, and clients' dispensing fees were subsidised so that they were only paying approximately $1 per dose (CDHSH, 1995).

There was a steady growth in the number of clients on Tasmania's OAT Program between 1995 and 2006. By 2006, there were more than 500 clients on the program, more than three times the number in 1995. However, this was predominantly because the Program gradually accumulated long-term clients rather than there being a large, rapid influx of new clients. Between 1996/97 and 2000/01, there were approximately 200 new admissions to the program annually, which declined to 78 in 2005/06 (Bruno, 2007).

As with most jurisdictions, buprenorphine was introduced to OAT in 2001, and by 2006 there were approximately 80 clients receiving buprenorphine in Tasmania. It has been suggested that there was a significant level of unmet demand for OAT in Tasmania at the time (Bruno, 2007).

On a snapshot day in 2015, there were 757 people receiving OAT in Tasmania. Of these, 354 had a public prescriber, 399 had a private prescriber and four had a correctional prescriber. Of these OAT clients, 382 were receiving methadone, 57 buprenorphine and 318 buprenorphine/naloxone. The majority (664) were dosed at community pharmacies; 60 were dosed at public clinics; 28 in correctional facilities; and five were dosed at other facilities (Australian Institute of Health and Welfare, 2016).

Current situation

On a snapshot day in 2020, there were 679 clients receiving pharmacotherapy in Tasmania, virtually unchanged since 2011. This represented a rate of 13 per 10,000 of the Tasmanian population (compared to 21 per 10,000 nationally) and up slightly from 12 per 10,000 in 2011. In 2020, 42.4% of pharmacotherapy clients received methadone; 45.7% received buprenorphine/naloxone; 3% received long-acting injectable buprenorphine; and nine% received buprenorphine. Of these clients, 98.4% were ongoing clients; 0.6% were new clients; and 1% were readmitted clients (Australian Institute of Health and Welfare, 2021).

In 2020 in Tasmania, there were 40 OAT prescribers which comprised 14 public prescribers, 23 private prescribers, two public/private prescribers, and one correctional prescriber. Public prescribers had 10.4 clients per prescriber, compared with 16 per prescriber for private prescribers, and 31 per prescriber for correctional prescribers. Tasmanian prescribers had on average 17 clients each, compared with 15.6 clients per prescriber nationally and down slightly from 16.4 per prescriber in Tasmania in 2016. In 2016, there were 74 dosing point sites in Tasmania, comprising one public clinic; 72 pharmacies; and one correctional facility site. There were 9.2 clients per dosing site on average, down from 11.1 in 2016, compared with 17.3 per dosing site nationally (Australian Institute of Health and Welfare, 2021).

Tasmania delivers OAT through both specialist public clinics and community-based medical practitioners, with both hospital and community pharmacies involved in dispensing. Given the challenges facing its population, nearly half of whom live in rural and remote areas, multipurpose health centres or community hospital pharmacies are critical to dispensing (Furnival & McGovern, 2018).

Alcohol and Drug Services (A&DS) is responsible for accrediting doctors and pharmacists to prescribe and dispense MATOD. A&DS is also responsible for the initial assessment and induction of patients; for managing the care of complex, non-compliant or moderate to high-risk patients; for supporting primary care and dosing pharmacies; and for providing access to other services (Furnival & McGovern, 2018).

The A&DS transfers patients to community-based medical practitioners when appropriate and/or possible. These practitioners can assess, induct, and stabilise patients if they are approved by the A&DS. They have an appropriate prescribing authority for each patient and are experienced in OAT. A 12-month probationary authorisation is issued initially, which also involves peer support, review and advice sessions. Ongoing authorisation involves annual renewal through completion of a competency-based e-learning package. Authorities are issued for each patient commencing OAT and there are limits on each medical practitioner's caseload. A full-time general practitioner can prescribe OAT to a maximum of 20 patients, but applications can be made to the Clinical Director of the A&DS to increase this number (Furnival & McGovern, 2018).

For pharmacies to become a dosing site for OAT, the A&DS must approve the pharmacy and each pharmacist involved in dosing also requires accreditation. This accreditation requires the pharmacist to participate in a professional development program and an examination. It is recommended that each patient is interviewed by a pharmacy before they are accepted as a new patient. Detailed instructions are provided regarding dosing procedures for all OAT medications, and take-away doses can be issued to patients who are considered stable in treatment (Furnival & McGovern, 2018).

CHAPTER 18: THE HISTORY OF OPIOID AGONIST THERAPY IN WESTERN AUSTRALIA

The history of methadone treatment in WA draws heavily on work conducted by Mr Greg Swensen. Mr Swensen fastidiously documented the history of the methadone treatment program in WA as partial fulfilment of the requirements for the course-work degree of Master of Arts (Public Policy) at Murdoch University in December 1990 (Swensen, 1990). The author is extremely grateful to Greg for allowing access to this comprehensive piece of work. Unless otherwise stated, the following description of methadone programs in WA up until 1990 is drawn from Greg's work.

In 1971, the Director of the Mental Health Services (MHS) in WA visited nine countries, inspected treatment facilities, and consulted with a wide range of authorities concerning best approaches to alcohol and other drug use problems. This included a visit to Dr Stella Dalton's Wisteria House program in Sydney.

Methadone was first prescribed for heroin dependence in WA in the latter part of 1973. This occurred in psychiatric inpatient settings and aimed to aid the detoxification of dependent heroin users. Soon after, methadone was used by a small number of private psychiatrists and medical practitioners as an outpatient treatment.

In November 1974, the Alcohol and Drug Authority (ADA) was established as a statutory organisation directly responsible to the Minister of Health. It was expressly created as a body separate from the Health Department of WA (HDWA). In the 12 months before the ADA's establishment, methadone had been prescribed by private prescribers to about 30 individuals in Perth.

Swensen (1990) described seven phases of methadone treatment between 1973 and 1989. These are outlined below

Phase 1: 1973 to May 1977 - Maximum Liberality

It is unclear how many individuals received methadone treatment in WA before 1978, as there were difficulties with record-keeping at the time. Before 1978, most of the methadone in WA was prescribed by private prescribers and dispensed by retail pharmacies.

This phase had the following characteristics:

- No maximum daily dosage
- Minimal admission criteria (essentially based on individual medical practitioners' judgement as to whether an individual had a pre-existing opioid dependence)
- Unsupervised consumption of daily doses, (i.e., clients were able to collect take-away doses of methadone for an extended period), with the result that there was a likelihood of intravenous self-administration and/or sale and supply to others
- Multiple dispensing locations, enabling the use of aliases to collect multiple doses
- Multiple prescribers, facilitating the selection of prescribers to avoid sanctions
- Methadone dispensed in tablet form.

During this phase, individuals could attend any private medical practitioner, whether a GP or a psychiatrist, who could at his/her discretion prescribe any S8 drug, for any number of reasons, including to medically manage opioid-related withdrawal sickness, as a substitute for illicit heroin use, or in conjunction with a therapeutic program, (for example, acupuncture or psychotherapy). Attendance at private practitioners did not require clients to bear the cost of the consultation if the doctor bulk billed, a practice that was apparently widespread. Privately prescribed methadone was dispensed at retail pharmacies, meaning that recipients obtained large quantities of methadone in tablet form, even perhaps a week's supply at one time.

From November 1974, an outpatient clinic operated by the ADA started to provide methadone to heroin-dependent people. Many of the medical and nursing staff of the ADA had transferred from the Mental Health Service (MHS), and the inaugural Medical Director, Dr John Pougher, was previously a psychiatrist with the MHS. It is likely that through their prior experience in psychiatric institutions, these staff were conversant with the use of a mood-altering medication like methadone as the basis of treatment.

The ADA provided methadone without financial cost but required more frequent attendance than private prescribers and dispensed smaller quantities of take-away methadone doses. This dual system of private and public prescribers apparently functioned without difficulty until August 1976, when a new Medical Director of the ADA, Dr Scott, was appointed. He too had previously worked as a psychiatrist with the MHS, and before 1975 had worked in the United Kingdom.

From November 1974 to June 1976, the ADA prescribed methadone and other oral and injectable opioid drugs, such as morphine and pethidine, for the treatment of heroin- dependent people.

In August 1976, the ADA changed its methadone policy to a much more conservative one. Dr Scott introduced a two to three week-long detoxification program in place of the previous maintenance policy. After this, the ADA became only peripherally involved in the management of heroin users and prescribed very little methadone. Clientele excluded from the ADA program instead attended private GPs who continued to have much more liberal prescribing approaches. Within a short time, there was a substantial increase in the supply of methadone to addicts in Perth by private prescribers.

As a result of its cautious approach to the use of methadone, the ADA's credibility became tarnished. Its approach to the treatment of heroin-dependent people was the subject of strong and widespread criticism in the media and the political spheres. In addition, at this time a large quantity of methadone was being diverted into the illicit drug market in Perth, which was ironically increasing the prevalence of opioid dependence. Methadone-related deaths also increased, peaking with seven deaths in 1977. At this time, Dr Scott alleged that private doctors were facilitating the recreational use of methadone by overprescribing, by not complying with the requirement for prior Health Department of WA (HDWA) authorisation, and by prescribing methadone in tablet rather than linctus form, which he argued facilitated intravenous use.

Dr Scott's criticism that doctors were failing to obtain prior authorisation from the HDWA was more of a criticism of the HDWA because it had failed neither to enforce the provisions of the Poisons Act, 1964 nor to develop an efficient administrative procedure to process authorisations. The HDWA through its powers under the Poisons Act 1964 was responsible for the regulation of pharmaceutical drugs and for ensuring compliance with laws on dispensing and prescribing of drugs by pharmacists and medical practitioners. The HDWA was in a position of potential conflict of interest, because as both regulator and policy-maker, it could promote policies and enforce regulations that affected interests of several groups.

The HDWA was technically responsible for deciding who should be authorised to prescribe methadone. As there was no legislative basis to deny authorisations to private practitioners, it could have been seen as favouring one form of medical practice over another if it granted the ADA a monopoly over prescribing rights.

There was a fundamental polarisation of views regarding the aims of methadone treatment in WA at this time. On the one hand, the ADA sought to control and limit the use of methadone, aiming for client abstinence. On the other hand, the private prescribers aimed to enhance the use of methadone to improve patients' health and social functioning. As a result of their more liberal approach to treatment, private prescribers essentially became responsible for running the State's methadone program in the mid to late 1970s.

This presented a dilemma for the WA Government concerning whether it should intervene in what appeared to be a difference of opinion between medical practitioners. On the one hand, if the government was seen to be directing private doctors on how they should prescribe methadone, it could have been accused of interfering in doctor-patient relationships. On the other hand, the status quo was resulting in an untenable public/private polarisation of heroin-dependence treatment.

There were other aspects to the Government's dilemma. Heroin-related crime was becoming an increasing problem, including armed robberies of pharmacies, with suggestions that the restrictive nature of the ADA's approach to heroin-dependence treatment was contributing to this. At the same time, the HDWA and the police were becoming involved in sensitive investigations into private sector over-prescribing, falsification of prescriptions, and organised diversion of prescribed methadone.

In addition, the then Chairman of the ADA belonged to the same political party as the government of the day. Any change to methadone policies that placed restrictions on private prescribing would have meant that the ADA needed further resources to treat the large number of clients who had been under the care of private prescribers. This would have included the need to establish further clinics in the metropolitan area to match the access to treatment that private prescribers were providing. This had substantial resource implications for the Government.

In late 1976, the HDWA advised the ADA that it must accept responsibility for the treatment of drug addicts. The Department also indicated that after the end of January 1977, stronger legal action would be taken against doctors who prescribed methadone without an authority. In February 1977, it was reported that Dr Scott's contract would not be renewed. However, in spite of his departure, it was apparent that it was necessary for a formal methadone policy to be developed.

An ingenious means of restricting private prescribing was achieved by an agreement between the HDWA and the Commonwealth Health Department. It was decided that the Commonwealth would provide only methadone linctus, rather than the tablet form of methadone, under the Pharmaceutical Benefits Scheme (PBS), and that the ADA would be the only source of the linctus in WA. Under this arrangement, private prescribers could continue to prescribe methadone, but only in tablet form, meaning that clients would have to pay the full cost of their doses.

In April 1977, the HDWA convened a Working Party consisting of representatives of the ADA and HDWA to investigate the future use of methadone as a treatment for heroin dependence in the State. Its principal recommendation was that treatment should become the exclusive prerogative of the ADA. Importantly, the Working Party reported that the central purpose of methadone treatment was as a public health measure to prevent the spread of heroin addiction in the community.

The first phase ended in May 1977, when many of the Working Group's recommendations were implemented, including the re-establishment of maintenance treatment at the ADA.

Phase 2: June 1977 to August 1978 - Moderate liberality

This phase had the following characteristics:

- there was no maximum daily dosage
- there were minimal admission criteria, on the basis of an individual medical practitioner's judgement as to whether an individual had a pre-existing opioid addiction. However, from October 1977, the ADA started to test naloxone testing as a pre-condition to admission
- there was unsupervised consumption of daily doses, with clients able to have take-away doses)
- the majority of clientele attended a centralised facility in Perth
- only linctus methadone was used
- an identification photo was required.

In July 1977, there were 16 participants in the ADA methadone program, but by the end of the next month the number had increased to 141. By December 1977, there were 206 people in treatment, and by August 1978, this had risen to 305. This was a period of sustained growth in the numbers in methadone treatment and the ADA was becoming overwhelmed by clientele.

There were two key changes made in the ADA's administrative structure during this phase which led to closer ties between the ADA and the HDWA. These changes also supported the public health model, which emphasised disease control, rather than the emphasis on therapeutic change that was emphasised in the former psychiatric model. The HDWA withdrew methadone prescribing authorisations from private prescribers, which led to a small number increasing their prescribing of tablets of another Schedule Eight (S8) drug, Palfium (dextromoramide), a short-acting synthetic opioid. Then in May 1978, the Government announced it would be amending the Poisons Act, 1964 to provide greater powers to restrict private prescribers of S8 drugs. The reluctance of Government to expand the use of methadone may have been well-founded, given the amount of controversy and disruptive behaviour that had been associated with the ADA's West Perth clinic.

Phase 3: September 1978 to June 1979 - Moderate conservatism

This phase had the following characteristics:

- the maximum daily dose used was 80 mg
- objective testing of opioid dependence using an opioid antagonist (naloxone) was a pre-condition to admission
- all doses had to be taken on a daily basis, under supervision, at ADA premises
- punitive sanctions were introduced for non-compliance with daily supervised consumption, by withholding alternate daily doses
- all clientele attended a centralised facility in Perth
- only linctus methadone was used (no tablets)
- photographic ID was required.

In late August 1978, after the passage of the amendments to the Poisons Act, 1964, an express power was given to the Commissioner for Public Health to regulate the prescribing and dispensing of drugs of addiction. As a result, private practitioners ceased to prescribe S8 drugs to treat drug-dependent people in the State. The ADA was given the responsibility of methadone prescribing for the treatment of registered drug addicts.

During this phase, the ADA adopted key principles from the NHMRC's National Policy on Methadone, such as:

- that daily doses should be in the range of 100 to 120 mg
- that treatment goals were to reduce mortality, ill-health, crime and the contagion of illegal drug use, to increase productivity, and to assist the individual addicted person in coping
- that the goal of a drug-free existence was, at least temporarily, deferred.

With its clientele unable to obtain methadone or other S8 drugs from private prescribers, the ADA was able to increase the number of controls over client behaviour to reduce both diversion of methadone and its intravenous use. The strategy adopted to reduce the non-oral consumption of methadone relied on a punitive approach, namely, that if a client did not swallow a dose of methadone under the supervision of dispensary staff, the next day's dose was withheld as a de-facto punishment.

This approach towards obtaining compliance engendered conflict between the ADA and its clientele, and resulted in the formation of a small pressure group of methadone clientele who unsuccessfully attempted to reclaim their 'citizens' rights.'

The ADA ultimately accepted that withholding doses from clients who did not comply with supervised daily methadone consumption was a difficult policy to justify publicly.

Phase 4: July 1979 to October 1980 - Moderate liberality

This phase had the following characteristics:

- the maximum daily dose of methadone was 80 mg
- for the first two weeks on methadone treatment, clients had to consume methadone as supervised doses on ADA premises
- after the two-week period no sanctions would be applied if any client refused to consume methadone under supervision
- objective testing of opioid dependence using an opioid antagonist (naloxone) was a pre-condition to program admission
- all clientele attended a centralised facility in Perth
- only linctus methadone was used (no tablets)
- photographic ID was required.

Phase four consisted of a mixture of both liberal and conservative elements. The program admission policy remained conservative, requiring objective testing of opioid dependence using naloxone. Likewise, there was a conservative prescribing policy, with the maximum dosage remaining at 80 mg per day. On the other hand, the dispensing policy was more liberal in that it did not require supervised daily consumption at ADA premises after the first two weeks of treatment. Ultimately, the influence of the conservative elements outweighed the liberal elements, and the number of people in treatment declined from 232 in July 1979 to 176 in October 1980.

In 1980, two NGOs established drug-free residential treatment programs in WA. These were the Drug Research and Rehabilitation Association (now known as Palmerston Centre) and Cyrenian House. Both agencies were strongly opposed to methadone treatment. The establishment of these two NGOs increased the range of treatment options for drug users in Perth. However, both organisations were largely reliant on funding from the ADA. The ADA was in a difficult position because while it supported the State's methadone program, it also heavily funded two agencies that were philosophically opposed to methadone treatment.

These NGOs maintained high public profiles and were the subject of several highly favourable newspaper articles that promoted their philosophy and activities. Therefore, funds that may have otherwise been used to improve the effectiveness of the methadone programs, (for example, establishing 24-hour multi-site operations) were instead used to establish drug-free programs.

Phase 5: November 1980 to March 1985 - Maximum conservatism

This phase had the following characteristics:

- daily supervised oral consumption of all doses
- denial of methadone for non-compliance with the previous requirement, by automatic detoxification regime by five mg per day
- strict proof of prior opioid use as evidenced by rigorous use of naloxone testing and urine drug testing
- delayed assessment processes, including submission of written reports to a separate decision-making panel
- linctus methadone only (no tablets)
- Photographic ID was required.

In October 1980, several amendments were made to the Regulations of the Poisons Act 1964, which became the first legislative powers dealing with the use of methadone for the treatment of addicts. These amendments did not have any particular policy orientation but were more focused on providing the machinery for prescription authorisations.

The enforcement of strictly supervised dispensing conditions, whereby clients were required to consume methadone under close surveillance, was regarded by clientele as being too onerous, and by September 1981, only 87 people remained in methadone treatment in the State. The size of the methadone treatment population started to increase in mid-1984 and by March 1985, there were 249 people in treatment.

In March 1983, another NGO, Jesus People Incorporated, expanded its services into the drug rehabilitation field, by opening its short-term detoxification service, The Bridge. The three NGO drug-free rehabilitation agencies tended to compete with one another and provided similar services to small numbers of clients. This may have contributed to a decline in numbers of people on the methadone program. In addition, in early 1983, private GPs in Perth started to prescribe ampoules of buprenorphine to addicts, contributing to the decline in numbers on the methadone program.

Following pressure from methadone clients, in 1983 changes were made to the methadone program, such that clients were able to obtain methadone from metropolitan hospitals, so that they would not be required to attend the ADA's William Street Clinic. Take-away doses remained unavailable. The ADA also established small dispensing units at Fremantle and Osborne Park Hospitals, but these were expensive to run as they were fully operated by ADA staff and, as they only operated for three hours a day Monday to Friday, were not popular with clients. These units were not administered by the hospitals (which were not enthusiastic about the service), were difficult for the ADA to support, and were eventually closed.

In late 1983, a new opioid substitution drug, buprenorphine was reported as being overprescribed by private GPs to addicts in Perth, and in 1984, the HDWA prohibited the prescription of buprenorphine to addicts. In that year, there were a number of deaths of addicts that were attributed to the restrictions being placed on buprenorphine and the restrictions enforced by the ADA methadone program. By early 1985, it was apparent that heroin use had again become linked with crime, and that there was considerable pressure to liberalise methadone policy.

Phase 6: April 1985 to July1989 - Moderate liberality

This phase had the following characteristics:

- daily supervised oral consumption of all doses
- after two or three months of daily attendance at the ADA, all clients could have methadone dispensed from retail pharmacies at their own cost for up to six days per week and also attend ADA one day per week. This was subject to ADA veto if the client was considered unstable or unsuitable
- admission to the methadone program was based on medical and social factors, evidence of intravenous opioid use verified by physical examination and drug use history, with naloxone testing rarely used
- the client was admitted on the same day of presentation if they were in opioid withdrawal, otherwise methadone was provided the next day
- if the client was HIV-positive, was a hepatitis B carrier, pregnant, or had a serious medical condition, they were admitted on presentation
- linctus methadone was provided (no tablets)
- photographic ID was required.

In early April 1985, NCADA was launched and was a major catalyst for the liberalisation of access to methadone treatment in those Australian jurisdictions with methadone programs. In April 1985, consistent with the recommendations of the National Methadone Guidelines, the ADA liberalised admission criteria by giving more weight to social factors in determining admission to the program. Naloxone testing was virtually abandoned as a method to determine eligibility, as was urine testing for program compliance. The heightened awareness of HIV risk factors in the client population meant that high rates of admission to methadone treatment were achieved.

Program participants peaked at 358 and then declined to 269 at the end of the June 1987 quarter, possibly because undocumented restrictions were applied after December 1985, to reduce the number of persons in treatment because of overcrowding. Between October 1987 and February 1988, the ADA's methadone program was temporarily transferred to another location, while William Street Clinic was remodelled to increase the amount of office space.

In 1987, a later version of the National Methadone Guidelines was produced which aimed to further liberalise access to methadone. By July 1989, 503 clients were participating in treatment, the highest number ever in the history of the WA methadone program to that point.

In 1987, the William Street Clinic (WSC) had 23 staff members, consisting of four doctors, three social workers, 10 nursing staff and four domestic/clerical staff. There was no waiting time for program admission at the time and treatment was usually commenced the day after assessment. In prisons, methadone was only available to pregnant women (Quigley, 1987).

The ADA program then changed to a low threshold methadone program, the object of which was to attract more heroin users into treatment, thereby reducing the risk of HIV transmission. One impact of this new approach in WA was to sharpen the dichotomy between the methadone program and the drug-free programs. Prior to this change, methadone treatment was seen as providing a link between heroin use and drug-free programs. Increasingly, however, methadone came to be regarded as a stand-alone treatment.

Compared with the drug-free treatment options, it was reported to be much easier and more cost effective for the methadone program to ramp up its services in response to the need to reduce the risk of spread of blood-borne diseases.

In July 1989, the ADA placed restrictions on the number of people who could be admitted to the methadone program, which led to conflict between the Authority and heroin users wanting to be admitted to the methadone program.

Phase 7: August 1989 to December 1989 - Moderate conservatism

This phase had the following characteristics:

- daily supervised oral consumption of all doses
- after two to three months of daily attendance at the ADA, clients were able to have methadone dispensed from retail pharmacies for up to six days per week, and attend ADA only one day per week, with the pharmacist able to charge a daily fee). This system was subject to ADA veto if the client was considered unstable or disruptive.
- program admission was based on medical and social factors, evidence of intravenous opioid use verified by physical examination and drug use history, with naloxone testing rarely used
- a waiting list was created by only allowing up to three bookings for methadone assessment per day, and all assessments were transferred from WSC (methadone clinic) to the Central Drug Unit (CDU), a drug detoxification hospital
- program admission occurred on the same day of presentation if the client was in opioid withdrawal, HIV-positive, a hepatitis B carrier, pregnant, or had a serious medical condition. Otherwise, methadone was provided the next day.
- linctus methadone was used, no tablets
- photographic ID was required.

The introduction of a waiting list and a transfer of assessments from WSC, where methadone was dispensed, to the CDU were the principal measures adopted to restrict the rate of admissions into methadone treatment. These measures were apparently successful, as at the end of December 1989, there were 429 persons in methadone treatment, a drop of 46 from the June quarter. While this policy was successful in reducing numbers, it conflicted with the public health objective of reducing the untreated population of heroin users.

By 1994, all methadone treatment in WA was coordinated by the WSC, and the National Methadone Guidelines provided the basis for the Authority's policies and procedures. The WSC also assessed clients' suitability for methadone treatment, administered methadone, supervised and monitored clients' progress and provided a range of medical, nursing, social work and psychological casework. The Clinic's staff consisted of a manager, medical officers, social workers, nurses, a clinical psychologist, dispensary and pharmacy staff, a phlebotomist/specimen collector, clerical staff and a general attendant (CDHSH, 1995).

In the mid-1990s, the majority of clients presenting for assessment were in their mid to late 20s, with a history of heroin use for five or more years. Following assessment over 90% of the clients were considered eligible for methadone treatment. The remainder were encouraged to engage in counselling, to undergo outpatient detoxification, or seek admission to either a residential detoxification unit or a therapeutic community. Clients were encouraged to book an appointment and there was a four to five day wait before assessment. Treatment was usually commenced the day after assessment (CDHSH, 1995).

Methadone consumption was closely supervised, and over 55% of all doses were administered at the WSC. Community pharmacists administered 36% and the remainder were dispensed through the CDU, country hospitals and nursing posts. Most clients were expected to attend the WSC at least one day a week for methadone dosing. Clients attending community pharmacies during the week returned to the WSC if their pharmacy was closed on Saturdays or Sundays. Take-away methadone was only provided to clients in exceptional circumstances. Urine specimens were randomly collected, and the frequency of specimen collection varied from three times a week, for a client undergoing intensive monitoring, to three times a month for a client who had been receiving methadone for a year or more. Clients were generally encouraged to stay in treatment for at least two years and then gradually detoxify. Some clients elected to have a shorter period of treatment. Treatment could be terminated if clients failed to take their prescribed methadone under supervision (CDHSH, 1995).

The Department of Health, WA, established the Community Based Methadone Program in 1997, which was renamed the Community Program for Opioid Pharmacotherapy (CPOP), when buprenorphine became available for the treatment of opioid dependence in 2001. The key government agencies involved in CPOP were the Drug and Alcohol Office through its clinical services directorate, Next Step Drug and Alcohol Services, and the Department of Health Pharmaceutical Services Branch. Community Clinical Programs (CCP) at Next Step provided coordination, referral, advice and support to clients, general practitioners, pharmacists and other health professionals involved in CPOP. The services at Next Step also included the Clinical Advisory Service (CAS), which provided a 24-hour telephone support and advice service to health professionals across WA on the management of community-based methadone and buprenorphine patients. Services were also provided by a Next Step on-call doctor. The Department of Health Pharmaceutical Services Branch had the regulatory responsibility for all S8 OAT medicines through the Poisons Act, 1964 and coordinated program management and policy development. The Pharmaceutical Services Branch was also responsible for the authorisation of medical practitioners and pharmacies to be part of CPOP (Western Australia Drug and Alcohol Office, 2009).

In 2001, the CPOP sought to recruit and train a further 50 general practitioners and 150 community pharmacists to expand the WA pharmacotherapy program. The recruitment of 12 rural-based prescribers helped to expand services in non-metropolitan regions. A Methadone Review Committee, which included representatives from the Australian Medical Association, the Royal Australian College of General Practitioners, the Health Department and the Pharmacy Guild, was established to assess the ongoing competence and clinical practice of individual prescribers (Next Step Drug and Alcohol Services, 2001).

By 2009, CPOP provided services to over 3,600 authorised OAT clients, with 3,027 receiving dosing on any one day throughout the metropolitan and regional centres of WA. Of these clients, 68.6% received methadone, 25.2% buprenorphine/naloxone and 6.2% buprenorphine. There were 130 medical practitioners authorised to prescribe pharmacotherapies in WA, and 82 of these had authorised patients. There were over 281 community pharmacies authorised to dispense opioid pharmacotherapy, and 219 had patients dosing in January 2009 (Western Australia Drug and Alcohol Office, 2009).

To become an authorised prescriber, medical practitioners had to successfully complete the approved training program provided by Next Step and pass the assessment examination. They also had to agree to comply with the program's clinical policies and procedures of the CPOP. To become an authorised pharmacy, the pharmacy proprietor had to ensure that all pharmacists involved in the dispensing of methadone and buprenorphine had successfully completed approved training, and had to comply with the clinical policies and procedures of CPOP (Western Australia Drug and Alcohol Office, 2009).

The availability of treatment in regional areas varied, largely depending on the willingness of local GPs and pharmacies to provide treatment. WA Country Health Service supported treatment in two regions where GPs elected not to be involved. There were 11 prison services in WA and all prisons provided OAT services. Some prisons provided buprenorphine for withdrawal treatment only and did not offer ongoing opioid replacement maintenance programs (Western Australia Drug and Alcohol Office, 2009).

In 2009, the opioid pharmacotherapy program in prison services was supported by medical and nursing Prison Addiction Service (PAS) teams. The PAS teams facilitated and supported the program, commenced clients on treatment and managed clients' movement into and out of the prison service. Within the prison services, pharmacotherapy costs, including dosing, were paid for by the State Government. There were 240 OAT clients in WA prisons at the time, of whom 225 were on methadone and 15 on buprenorphine. On release of offenders, the PAS team forwarded a referral to the Next Step's Community Clinical Program. This program organised client appointments with either a Next Step doctor or a community prescriber (if one was available) and with a pharmacy for the continuation of the program in the community (Western Australia Drug and Alcohol Office, 2009).

On a snapshot day in 2015, there were 3,441 people receiving OAT in WA. Of these 1,397 had a public prescriber, 1,697 had a private prescriber, and 347 had a correctional prescriber. Of these OAT clients, 2,214 were receiving methadone, 107 buprenorphine and 1,120 buprenorphine/naloxone. The majority (3,080) were dosed at community pharmacies; nine were dosed at public clinics; 345 in correctional facilities and seven were dosed at other facilities (Australian Institute of Health and Welfare, 2016).

Naltrexone treatment

The WA opioid pharmacotherapy treatment landscape varies from that of other jurisdictions because of the prominent role played by naltrexone, an opioid antagonist, particularly in the form of naltrexone implants. A WA addiction medicine specialist, Dr George O'Neil, began using naltrexone in 1996 and subsequently provided a pharmacotherapy service that utilised naltrexone implants. In WA between January 2001 and December 2002, 437 heroin-dependent persons received naltrexone implants from Dr O'Neil's company, Australian Medical Procedures Research Foundation Limited, and between 2001 and 2008 there were 4,505 such procedures (Western Australia Drug and Alcohol Office, 2009).

Current situation

The WA pharmacotherapy program is community-based, other than for hospital inpatients, prisons and the public clinic. Prescribers attend training provided by the Mental Health Commission (MHC), and the Chief Executive Officer of Health provides prescribing authorisation under the Medicines and Poisons Regulations, 2016, the legislative instrument. Prescriber training is provided for all pharmacotherapies currently available and now includes prescriber training for practitioners wishing to prescribe Suboxone® to up to five patients (Australian Institute of Health and Welfare, 2021).

Community pharmacies are authorised to participate in the Community Program for Opioid Pharmacotherapy (CPOP). The pharmacist with overall responsibility is required to ensure that all pharmacists who dose clients have completed the pharmacist online training module on the MHC website (Australian Institute of Health and Welfare, 2021).

On a snapshot day in 2020, there were 3,392 clients receiving pharmacotherapy in WA, virtually unchanged since 2011. This represented a rate of 17 clients per 10,000 of the WA population (compared to 21 per 10,000 nationally). In that year, 59.6% of pharmacotherapy clients received methadone; 33.7% received buprenorphine-naloxone; 5% received long-acting injectable buprenorphine; and 1.7% received buprenorphine. Of these clients, 71.7% were ongoing clients; 5.7% were new clients; and 22.6% were readmitted clients (Australian Institute of Health and Welfare, 2021).

In 2020 in WA, there were 134 OAT prescribers, comprising 29 public prescribers, 81 private prescribers and 24 correctional prescribers. Public prescribers had 47.8 clients per prescriber, compared with 21.8 per prescriber for private prescribers and 10.1 per prescriber for correctional prescribers. WA prescribers had, on average, 25.3 clients each, down from 31.2 in 2016. In 2020, WA OAT prescribers had the highest average number of clients in Australia compared with 15.6 clients per prescriber nationally. In this year, there were 286 dosing point sites in WA, comprising one public clinic; 281 pharmacies; two correctional facility sites; and other sites (including hospitals, mobile dosing sites, community health clinics, non-government organisations and doctors' surgeries). There were 11.9 clients per dosing site on average compared with 17.3 nationally (Australian Institute of Health and Welfare, 2021).

To become a prescriber under the CPOP program, a medical practitioner must first apply, then undertake a training program, do the relevant assessment, and agree to comply with the relevant policies and procedures for OAT. The Department of Health then provides the prescriber with authorisation to participate in the program. To maintain authorisation, prescribers need to treat a minimum of two patients in a 12-month period. In the event that a prescriber fails to do this, refresher training may be required, or an extension granted. Further, a prescriber needs to provide evidence of undertaking continuing professional development activity every three years (Furnival & McGovern, 2018).

Once authorised, prescribers require a client authority for each patient. These are issued by the Department of Health and are usually issued for two years. Sole medical practitioners are generally allowed to treat a maximum of 50 OAT patients, with sole regional prescribers being limited to 25. These numbers may be exceeded where specific approvals are granted (Furnival & McGovern, 2018).

Pharmacies must also be authorised by the Department of Health and must also comply with all relevant policies and procedures. All pharmacists participating in the program must complete an online training program, and the individual holding the pharmacy licence must ensure that all associated pharmacists have done so. In addition, participating pharmacists must undertake continuing professional development and engage with the online training updates provided. Participating pharmacies can dispense to a maximum of 50 patients per day or seek an authorisation for additional patients (Furnival & McGovern, 2018).

Take-away doses may be prescribed for patients deemed stable in treatment. An application and agreement must be completed for all patients requesting take-away doses and the patient must sign the agreement. No take-away doses are provided to patients who have been in treatment for less than six months, no more than three take-away doses of methadone will be permitted in a week, and no more than four doses of Suboxone® where the patient is receiving dosing daily. Prescribers can apply to prescribe more take-away on a regular basis where there are exceptional circumstances. These circumstances are usually work-or health-related and are approved on a case-by-case basis (Furnival & McGovern, 2018).

CHAPTER 19: THE HISTORY OF OPIOID AGONIST THERAPY IN NORTHERN TERRITORY

The provision of OAT programs in the NT faces a range of logistical issues. The NT is a vast, sparsely populated jurisdiction. This presents major challenges in terms of the practicalities associated with service provision in small towns that may be hundreds of kilometres apart. It also presents difficulties associated with protecting the privacy of clients receiving OAT in these locations, and even in Darwin.

Like Tasmania, the NT historically had little heroin use, with pharmaceutical opioids being the major source of opioid dependence. Up until April 2003, the NT was in the unique situation of being the only Australian jurisdiction without a legislated requirement that doctors obtain a permit before prescribing any S8 substance on a long-term basis. In the NT, a doctor could prescribe S8 drugs such as morphine to anyone, if it was for the treatment of a medical condition other than addiction. If a doctor wished to prescribe morphine for the treatment of dependency, an application had to be made to the Chief Health Officer. After the introduction of a new system in 200 three , all S8 substances were subject to a base level of regulatory control (O'Reilly, Leibrick, Huxtable, & Chenhall, 2007).

A methadone program was initially established in Darwin in the 1970s. The program is not well described, but apparently oral methadone in tablet form was dispensed, and in some cases, doses could be taken away. The program was conducted by the Psychiatric Service at Darwin Hospital, and by 1977 catered for up to 45 individuals. The aim of the program appeared to be withdrawal rather than maintenance. There were apparently abuses of the program involving the diversion of methadone for sale. As program criteria became stricter and methadone was dispensed in liquid rather than tablet form, use of the program diminished and it was disbanded altogether in 1978 (Chalmers, 1993).

The supply of S8 drugs such as methadone was controlled under the NT Poisons and Dangerous Drugs Act, 1983. This was amended in 1983 in accordance with other State legislation to prohibit the supply of S8 drugs to treat addiction. There was no provision to prescribe on a discretional basis to clients who had therapeutic opioid dependence, or who were HIV- positive or pregnant. This created a situation whereby some medical practitioners, albeit in good faith, were prescribing outside the law. No action was taken unless flagrant, wrongful prescribing occurred, but several medical practitioners had their right to prescribe S8 drugs revoked by the Chief Medical Officer (Chalmers, 1993). During this time the NT had a very direct way of dealing with opioid dependent people. The government would give addicts a free one-way bus ticket to another jurisdiction if they wanted access to a methadone program (Ward, 1995).

In 1996, the *Poisons and Dangerous Drugs Act*, 1983 made provision for methadone to be prescribed for opioid dependent injecting drug users who were:

- HIV-positive
- pregnant at the time, and for up to six months after delivery
- hospitalised for a serious medical illness which may or may not have been related to intravenous drug use
- on a planned reduction schedule for up to three months (Northern Territory. Taskforce on Illicit Drugs, 2002).

With the expansion of methadone maintenance in all other Australian States and Territories, and more particularly because of concern about the relationship between injecting drug use and HIV infection, a review was undertaken by the NT Taskforce on Illicit Drugs to determine whether a methadone maintenance program should be reintroduced. Up until September 2002, methadone treatment was available for withdrawal, but not for maintenance (Chalmers, 1993).

Following recommendations of the NT Taskforce on Illicit Drugs, OAT maintenance programs recommenced in the NT in September 2002. The Taskforce also recommended the establishment of a Clinical Advisory Committee (CAC) to advise the Chief Health Officer on the provision of S8 drugs to drug-dependent people (Health Outcomes International, 2013).

Given the long period during which the provision of maintenance OAT in the NT was prohibited, significant resistance remained to the OAT program once it was re-established. It has been suggested that this resistance had a significant impact on shaping the program into the future. That is, while the OAT Program was accepted as a necessary part of a broader harm minimisation approach, a risk-averse approach was subsequently adopted in its delivery (Health Outcomes International, 2013).

Under the new system, implemented in September 2002, S8 pharmacotherapies could only be prescribed by accredited prescribers. In 2002, there were 21 people receiving OAT in the NT, but by 2007, this had grown to 114. Given that the NT OAT Program recommenced after the introduction of buprenorphine in Australia for the treatment of opioid dependence in 2001, the NT had a higher proportion of clients receiving buprenorphine OAT compared with other jurisdictions. In addition, the provision of buprenorphine, being a safer drug than methadone, was consistent with the broader risk-averse approach adopted in the Territory. In 2006, 47% of OAT clients in the NT received buprenorphine/buprenorphine-naloxone, compared with 28.7% nationally. By 2006-07 there were 14 OAT prescribers in the NT and 12 dosing points, comprising two public clinics, eight pharmacies and two correctional settings (Australian Institute of Health and Welfare, 2008).

Prior to and since the inception of OAT prescribing, the NT has had insufficient addiction medicine coverage The NT has always relied on support from SA addiction medicine specialists, in particular Dr Paul Williamson.

By 2010, there were 108 clients receiving OAT in the NT, comprising 34 receiving methadone, 15 receiving buprenorphine and 59 receiving buprenorphine/naloxone. In this year, there were 10 prescribers in the NT, comprising five public, four private and one correctional prescriber. The NT had 12 dosing sites, comprising three public clinics, seven pharmacies and two correctional facilities (Australian Institute of Health and Welfare, 2011).

In 2013, the Department of Health NT commissioned a review into the NT Opioid Pharmacotherapy Program (OPP) (Health Outcomes International, 2013). Broadly, the review found that all the structural components were in place in the NT to support the delivery of a harm reduction and client-centred OPP. Nevertheless, the reviewers found that there was a relatively broad perception (rightly or wrongly) that the service tended to be inflexible and punitive. They found that this perception might to some extent be related to the risk averse nature of the service and a lack of appropriate mechanisms for information exchange and clarification with key partners. A paucity of experienced staff was identified as another factor that could have led to this

perception. Ironically, the OPP's policy approach to the provision of take-away OAT doses was not conservative compared with most Australian jurisdictions (Health Outcomes International, 2013).

The review found that the governance and service model of the OPP was in keeping with better practice but made several recommendations for improvement including:

- enhancing the program quality and pursuing formal accreditation
- improving policies
- encouraging greater involvement of GPs and community pharmacists
- ensuring continuous policy review and staff training (Health Outcomes International, 2013).

The review also called for the establishment of improved partnerships with key stakeholders including GPs, community pharmacies, NGOs and other government partners. In addition the review noted that there was a lack of experienced staff, particularly in the Alice Springs Alcohol and Drug Services Central Australia Service (Health Outcomes International, 2013).

When the review was undertaken, dosing was only available at the OPP Clinic at the Royal Darwin Hospital (RDH) and at some community pharmacies. Access to the RDH clinic was difficult for many clients, and often required the use of public transport involving multiple changes. In addition, dosing was only available between 10 am and 12 noon. This resulted in a number of clients meeting, travelling on public transport together and waiting together, a situation which many clients were keen to avoid (Health Outcomes International, 2013).

As a result of historical relationship factors, Alice Springs had two pharmacotherapy services, ADSCA and the Alice Springs Hospital Service. The reviewers saw this as a result of fractured relationships and differing ethos and service models, rather than a logic-driven process. A further issue in Alice Springs was that there was only one community pharmacist dispensing OAT. As a result, if any client issues arose with the pharmacy, the option of community dispensing could be removed for that client. Dosing was also occurring in Katherine and there was capacity for dosing in Nhulunbuy (Health Outcomes International, 2013).

In 2014, there were six OAT prescribers in the NT, comprising five public prescribers and one correctional prescriber. There were 12 dosing points, comprising two public clinics, nine pharmacies and one correctional facility (Australian Institute of Health and Welfare, 2015) .

In 2014, the NT had the highest proportion clients receiving OAT in the form of buprenorphine/naloxone (62%) in Australia (Australian Institute of Health and Welfare, 2015).

On a snapshot day in 2015, there were 157 people receiving OAT in the NT. Of these, 149 had a public prescriber and eight had a correctional prescriber. Of these OAT clients, 48 were receiving methadone, 13 buprenorphine and 96 buprenorphine/naloxone. The majority (139) were dosed at community pharmacies; 10 were dosed at public clinics; and eight in correctional facilities (Australian Institute of Health and Welfare, 2016).

Current situation

On a snapshot day in 2020 there were 157 clients receiving pharmacotherapy in the NT, up slightly from 123 in 2011. This represented a rate of six per 10,000 of the NT population (compared to 21 per 10,000 nationally) and up slightly from five per 10,000 in 2011. In 2020, 19.1% of pharmacotherapy clients received methadone; 45.7% received buprenorphine/naloxone; and 14% received buprenorphine. Of these clients, 82.2% were ongoing; 11.5% were new clients; 5.7% were readmitted clients; and 0.6% were interstate clients (Australian Institute of Health and Welfare, 2021).

In 2020 in the NT, there were 14 OAT prescribers, comprising 10 public prescribers, two private prescribers and two correctional prescribers. Public prescribers had 14.4 clients per prescriber, compared with 1.5 per prescriber for private prescribers and five per prescriber for correctional prescribers. NT prescribers had on average 11.2 clients each, up slightly from 9.9 per prescriber in 2016, and compared with 15.6 clients per prescriber nationally. In this year there were 24 dosing point sites in the NT, comprising two public clinics, 20 pharmacies, and two correctional facility sites. There were 6.5 clients per dosing site on average, down from 8.2 per dosing site in 2016, and compared with 17.3 per dosing site nationally. (Australian Institute of Health and Welfare, 2021).

Opioid agonist therapy prescribers need to complete approved training before providing MATOD in the NT, and further, show ongoing clinical involvement and undertake refresher training in order to continue doing so. For accredited prescribers to prescribe opioid pharmacotherapy for an individual patient, they must apply to the Department of Health, Medicines and Poisons Control, and provide a photograph of the client. The authorisation must be signed and returned to the prescriber before treatment can be initiated. A contract is also drawn up between the prescriber, the patient and the supplying pharmacy for all maintenance treatment, and this information is stored in the Drug Monitoring System database. Prescriptions must include the name of the dispensing pharmacy; the dosage regime including specific dosing days; and any take-aways allowed. The prescription is valid for three days from the prescribing date or the start date if they are different. If a prescription is not presented within three days of prescribing, it becomes invalid. Prescriptions can only cover a supply period of three months. In terms of unsupervised or take-away doses, these may be prescribed to patients who are defined as stable; have reduced or stopped using illicit substances; and have provided urine samples clear of illicit substances. The maximum number of doses is one per week for people on alternate day dosing or per week for people on daily dosing, unless otherwise authorised by the Chief Health Officer. There are requirements for the labelling and storage of these doses (Furnival & McGovern, 2018).

CHAPTER 20: OPIOID AGONIST THERAPY IN AUSTRALIAN PRISONS

The provision of OAT in prisons has a controversial history in some Australian jurisdictions. Arguments in favour of providing OAT in prisons include:

- strong evidence regarding the high prevalence of heroin dependency among prisoners (Degenhardt, Larney, Gisev, et al., 2014) and of ongoing injection while incarcerated, albeit at a lower level than before imprisonment (Cunningham et al., 2018)
- equivalence of care: Under multiple international covenants and legal instruments, incarcerated people are entitled to health services equivalent to those available to the general community outside the prison. Consequently, countries which provide OAT in community settings are obliged to make this treatment available to prisoners (Larney & Dolan, 2009)
- reducing blood-borne disease transmission: Just as providing OAT in community settings reduces injecting-related risk behaviours (for example, Lawrinson et al., 2008), this is also the case in correctional settings (Dolan et al., 2003)
- reduced all-cause mortality while in prison: Mortality of opioid-dependent prisoners is significantly lower while in receipt of OAT during and after imprisonment (Larney et al., 2014)
- reductions in post-release mortality (Degenhardt, Larney, Kimber, et al., 2014).
- reductions in post-release crime and re-incarceration (particularly when treatment continues beyond release) (Larney, Toson, Burns, & Dolan, 2012)
- being on OAT in prison significantly increases the probability that individuals will enter OAT in the days after release (Kinlock, Gordon, Schwartz, Fitzgerald, & O'Grady, 2009).

Arguments against the provision of OAT in prisons, as cited by Larney et al. (2011) include:

- a philosophical position that methadone and buprenorphine are no different to illicit heroin, and that abstinence from all opioids is the only legitimate aim of treatment for heroin dependence
- logistical issues concerning escorting prisoners from their cells to prison medical clinics for dosing
- OAT is conceptualised as 'facilitating addiction', whereas prisons are perceived as sites of opportunity to achieve abstinence
- potential safety concerns associated with the provision of OAT in prisons, particularly the potential for violent 'standover' tactics to force inmates receiving OAT to relinquish their medications
- the voluntary diversion of medication to other inmates in exchange for money or other goods.

There is now strong evidence from Australian studies (e.g., Larney et al., 2014) and international research (for example, Marsden et al., 2017; Moore et al., 2019) that the provision of OAT in prisons is efficacious.

One of the major initial obstacles to introducing OAT into prisons in Australia was that it was tantamount to an admission by prison authorities that injectable drugs could not be completely kept out of correctional facilities (Dolan & Wodak 1996).

In the mid-1980s, it was becoming increasingly apparent to leaders in the field, such as Dr Ron Penny, Dr Alex Wodak and Dr Kate Dolan, that prisons represented a major threat in relation to the spread of HIV (for example, Dolan et al., 1990). There were also emerging concerns regarding the risk of death from overdose following release from prison, although the full extent of this risk did not become apparent until later studies (e.g., Darke et al., 2000; Seaman et al., 1998).

Methadone treatment in Australian prisons commenced in NSW in 1987 as a pilot pre-release program (Byrne & Dolan, 1998). The major aim of the pilot was to reduce criminal recidivism. As the program expanded, its goals broadened to include the continuation of community-based OAT treatment and the reduction of the spread of blood-borne diseases in prison. Gradually, emphasis shifted to the achievement of the latter goal, as it was with OAT programs in the broader community (McLeod, 1992).

The early 1980s was a time of change for the NSW correctional system. This period followed the findings of the Nagle Royal Commission into NSW Prisons which reported in 1978. The Royal Commission highlighted a range of brutal practices and blatant maladministration which characterised the NSW correctional system at the time. The Commission found that the Department of Corrective Services;

- was responsible for gross and illegal use of force directed towards inmates
- had unsuitable and badly trained leaders and staff
- had poor morale
- enforced rules and restrictions in an arrogant and unfair manner
- had an unsympathetic and incompetent Commissioner (Parliament of New South Wales, 1978).

The Nagle Royal Commission highlighted that prisoners in NSW needed to be treated as incarcerated citizens, rather as individuals with no rights (Vinson, Cunneen, Baldry, Collins, & Brown, 2004). Prison reformers such as subsequent commissioner, Mr Tony Vinson, were pivotal in laying the groundwork for a range of reforms, including the provision of methadone in prisons.

There was considerable resistance to the prescribing of methadone in prisons from within and outside the NSW prison system. This dissipated to some extent once there was a greater appreciation of the threat that prisons posed as means through which HIV infection could spread into the general community (McLeod, 1992).

The pre-release (3 months to release) methadone program in NSW soon proved to be numerically too small to be effective in reducing recidivism. It also created tension as prisoners competed for the limited number of places on the program. As a result of the threat of HIV, experience and knowledge gained from overseas, and the difficulties associated with keeping NSW prisons drug-free, the program was eventually funded by the Commonwealth, through the NSW Directorate of the Drug Offensive (DODO). Corrective Services staff were responsible for the assessment and counselling of methadone clients, while Prison Medical Service (PMS) personnel prescribed and dispensed the drug. This separation of functions and difficulties concerning the financing of the program, were both problematic (McLeod, 1992).

The system initially involved the Department of Corrective Services being funded by DODO, and then reimbursing the PMS for its costs. Corrective Services and the PMS had difficulties agreeing on what was a fair and just allocation of costs. Eventually, after escalating financial and philosophical problems, the earlier arrangement was disbanded, and the PMS was directly funded by DODO to run the program independently of corrective services (McLeod, 1992).

The level of opposition to providing methadone treatment in NSW prisons prompted a range of policies and procedures which were likely to impair its effectiveness. Prison regulations provided powerful disincentives to participation in methadone treatment. Prisoners on methadone were not allowed into low-security prisons and were denied access to work in prisons and to work-release programs. The apparent justification for the restrictions on access to prison work and work release was that prisoners on methadone were intoxicated and at increased risk of accidental injury. In addition, prisoners on methadone did not have access to drug and alcohol counselling services within the prison. This was partly because of competition for scarce counselling resources between the Health Department-funded methadone program and the Corrective Services-funded drug and alcohol counselling program, and partly because of an ideological incompatibility between methadone treatment and the abstinence orientation of many counselling staff (Hall et al., 1993).

By 1990 in Australia, methadone was relatively freely available in NSW prisons; available with significant restrictions in Victoria, Queensland, SA and WA; and not available in the NT or Tasmania (Gaughwin, 1992). The programs offered at the time were not necessarily maintenance programs, however. Many of the default methadone programs offered at the time were 10 to 12 week detoxification programs, with maintenance programs offered for clients who were HIV-positive, pregnant or serving short sentences. This was broadly in keeping with the OAT regimes offered in the minority of other countries offering prison OAT programs at that time (Dolan and Wodak, 1996).

By 2000, methadone treatment was available in Queensland and Tasmania if prisoners were already on methadone. It was available only to remandees and those who were pregnant in Victoria and WA, and not available in the ACT or the NT (Dolan, 2000).

By the early 2000s a robust body of evidence was developing concerning the importance of providing methadone in prisons (for example, Dolan et al., 2003). By 2009 OAT was available in prisons in all Australian States and Territories. Approximately 3,328 people were receiving OAT in Australian correctional facilities in that year, representing approximately 11% of all people in prison and around eight % of all people in OAT (Larney et al., 2011)

Opioid Agonist Therapy in Australian Prisons: The situation in 2009 (Rodas, Bode, & Dolan, 2011)

NSW

Both methadone and buprenorphine were offered in 27 NSW prisons, but for maintenance only and not for detoxification. Prison inmates could remain on OAT upon reception to prison, or could commence treatment in prison. In 2009, there were 1,325 inmates on methadone treatment and 264 inmates on buprenorphine treatment. In 2009, Justice Health commenced a total of 1,318 inmates on OAT.

Queensland

Inmates withdrawing from heroin in Queensland prisons were not offered methadone or buprenorphine, nor could they commence OAT in prison. Female receptions to Queensland prisons were able to remain on OAT if they were sentenced to less than 12 months, or were on remand. The policy for continuation of OAT in prison was the same for male receptions. However, males generally did not continue treatment in prison. This was because the availability of services to male prisoners was severely limited by a lack of resources allocated to OAT, and by the Correctional Services eligibility criteria.

Victoria

Prisoners could continue their community OAT or commence treatment for the length of their prison sentence, but methadone and buprenorphine could not to be used for detoxification. Methadone in a liquid form was the most commonly used OAT agent and there were approximately 640 treatment places available.

WA

Prison receptions were permitted to remain on methadone and buprenorphine OAT, but female prisoners had to meet special criteria to remain on buprenorphine. In 2009, both men and women were also able to commence OAT in WA prisons. Inmates were able to commence on methadone only or buprenorphine/naloxone, but could not generally commence on buprenorphine only.

South Australia

Inmates were able to commence or continue methadone or buprenorphine treatment in prisons. In 2009, 4% of male and 9% of female prison receptions were on methadone maintenance treatment, with 2% of male and 4% of female receptions on buprenorphne. Post-release OAT was a particular focus of the program, an approach which substantially reduced post-release mortality. The SA prisons OAT program was also associated with a substantial reduction in opioid overdose or intoxication incidents requiring resuscitation as well as blood-borne disease infections acquired in prison. However, the level of diversion of OAT medication for illicit use in prison was problematic.

Tasmania

Both methadone and buprenorphine treatment was available to inmates wishing to commence treatment in prison, but only for limited numbers. Prison receptions could remain on both methadone/buprenorphine maintenance if they were on a community program immediately before entering prison.

The Northern Territory

Methadone and/or buprenorphine were available for withdrawal in NT prisons. Inmates could also commence methadone and buprenorphine maintenance treatment in prison, and prison receptions could remain on the treatment upon entering prison. In 2009, only one inmate was on OAT in NT prisons.

Australian Capital Territory

In 2009, ACT Corrections Health Program staff were responsible for providing methadone maintenance treatment at the ACT's only full-time correctional facility, the Alexander Maconochie Centre (AMC). Prison receptions who had been on methadone maintenance treatment in the community were able to remain on methadone maintenance treatment in prison. Inmates at the AMC were also able to commence methadone maintenance treatment. In 2009, Australian Capital Territory Health policy was that buprenorphine was not to be offered to individuals in custody, except in exceptional circumstances. Exceptional circumstances included the inmate being a stable client in the community and/or the inmate having been sentenced to a very short period in custody. Buprenorphine was not available at AMC because of the incidence of diversion, even under supervision.

Opioid Agonist Therapy in Australian Prisons: The current situation (Australian Institute of Health and Welfare, 2021)

In 2020, there were 3,959 people receiving OAT in correctional facilities in Australia, representing 7.4% of all people receiving OAT in the country. Of these 2,590 were receiving methadone, 1,144 buprenorphine, 147 buprenorphine/naloxone and 78 long-acting injectable buprenorphine.

In NSW correctional facilities:

- 2,411 people were receiving OAT, representing 10.5% of all OAT recipients in the State
- 1,273 people were receiving methadone
- 1,138 people were receiving buprenorphine or buprenorphine/naloxone (NSW data do not differentiate between short-acting or long-acting buprenorphine or buprenorphine/naloxone).

In Victorian correctional facilities:

- 842 people were receiving OAT, representing 5.6% of all OAT recipients in the State
- 800 were receiving methadone
- three were receiving buprenorphine
- 37 were receiving buprenorphine/naloxone
- two were receiving long-acting buprenorphine.

In Queensland correctional facilities:

- 76 people were receiving OAT, representing 1.1% of all OAT recipients in the State
- six were receiving methadone
- three were receiving buprenorphine
- 67 were receiving buprenorphine/naloxone.

In West Australian correctional facilities:

- 228 people were receiving OAT, representing 6.7% of all OAT recipients in the State
- all were receiving methadone.

In SA correctional facilities:

- 244 people were receiving OAT, representing eight % of all OAT recipients in the State
- 233 were receiving methadone
- 10 were receiving buprenorphine/naloxone
- one was receiving long-acting buprenorphine.

In Tasmanian correctional facilities:

- 20 people were receiving OAT, representing 2.9% of all OAT recipients in the State
- three were receiving methadone
- 17 were receiving buprenorphine/naloxone.

In the single ACT correctional facility:

- 128 people were receiving OAT, representing 11.4% of all OAT recipients in the Territory
- 47 were receiving methadone
- six were receiving buprenorphine/naloxone
- 75 were receiving long-acting buprenorphine.

In the NT's correctional facilities:

- 10 people were receiving OAT, representing 6.4% of all OAT recipients in the Territory
- all were receiving buprenorphine/naloxone.

As is evident in 2020, there were substantial differences in the pattern of OAT services provided to inmates in Australian correctional facilities. For example, in WA, all inmates received methadone, whereas in the NT all received buprenorphine/naloxone. Similarly, in the ACT, most inmates were receiving long-acting injectable buprenorphine, while the uptake of this form of OAT was much lower in other jurisdictions.

There were also major differences in the proportion of jurisdictions' OAT population who were incarcerated. This ranged from 1.1% in Queensland to 11.4% in the ACT. This is consistent with other differences in patterns of OAT provision between jurisdictions.

Long-Acting Injectable Buprenorphine in Prisons

There is growing evidence that long-acting injectable (LAI) buprenorphine can have an important role in custodial settings. Australian researchers (Dunlop et al., 2021) reported that LAI buprenorphine had similar substance use and safety outcomes to those observed in community settings and for other OAT modes used in custodial settings, without increased risk of diversion. The researchers also reported that LAI buprenorphine is a more efficient and less costly OAT delivery method, requiring fewer health and custodial staff to administer. They suggested that enhanced access to LAI buprenorphine (also known as depot buprenorphine) should be considered for custodial settings worldwide.

In conclusion, prison settings provide an important opportunity to engage people in OAT. There is very strong evidence that OAT treatment in prison and immediately post-release is highly protective against the spread of blood-borne diseases and against mortality, both during incarceration and after release.

CHAPTER 21: NATIONAL OVERVIEW OF OPIOID AGONIST THERAPY IN AUSTRALIA, 2020

The National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) collection is a dataset held by the Australian Institute of Health and Welfare. It includes information derived from a snapshot day each year in all Australian jurisdictions concerning:

- clients accessing pharmacotherapy for the treatment of opioid dependence
- prescribers participating in the delivery of pharmacotherapy treatment
- dosing sites providing pharmacotherapy drugs to clients.

The following material is drawn from the 2021 NOPSAD collection report (Australian Institute of Health and Welfare, 2021) which refers to data drawn from a snapshot day in June 2020.[8]

Number and profile of OAT clients

In 2020, 53,316 people in Australia were engaged in OAT. This represented a 4.7% increase in clients since 2019, and the largest yearly increase over the last decade. This increase was largely driven by increases in NSW and Victoria. Changes in client numbers can be influenced by system changes, coding practices, changes in treatment policies, and capacity within jurisdictions. For Victoria, the increase in the number of clients may have been influenced by the implementation of the Victorian Government's SafeScript opioid monitoring initiative. SafeScript has identified previously undetected people with risky prescription opioid use and may have encouraged them to move into OAT. For NSW, the increase in client numbers in 2020 could be attributed to the introduction of the LAI buprenorphine. LAI buprenorphine was reported in the NOPSAD collection for the first time in 2020. Some additional prescribing of LAI buprenorphine occurred in correctional facilities in NSW, which enhanced access to OAT in those facilities. Some NSW Local Health Districts also reported having capacity to increase the number of new patients due to the introduction of LAI buprenorphine.

In the 10-year period to 2020, national OAT client numbers have increased by 15% (46,446 clients in 2011 to 53,316 clients in 2020), However, the rate (the number of clients per 10,000 of the population) receiving OAT has remained relatively stable since 2011, at 21 clients per 10,000 of the Australian population. In 2020, approximately two-thirds (67%, or nearly 35,500) of clients receiving pharmacotherapy on the snapshot day were male.

Opioid agonist therapy clients in Australia are ageing. In 2020, the median age of clients across all pharmacotherapy types was 44 years. This was an increase from 43 years in 2019 and from 38 years in 2011. The highest proportion of clients lay within the 40-to-49-year age group (36%), followed by those aged 30 to 39 (25%) and 50 to 59 (22%). Since 2011, the proportion of clients aged under 30 and between 30 and 39 decreased from 15% and 40% in 2011, to 7.0% and 25% in 2020, respectively). In contrast, the proportions of clients in the older age groups (40 to 49, 50 to 59, and 60 and over) have all increased since 2011.

In June 2020, there were 5,693 clients receiving OAT who identified as Indigenous Australians. This was a rate of 66 clients per 10,000 Indigenous Australians compared with 21 clients per 10,000 of the total Australian population. Of those Indigenous Australian clients to whom pharmacotherapy was provided, over half (53%) were treated with methadone. The remaining Indigenous clients were treated with buprenorphine (32%), buprenorphine/naloxone (13%) or LAI buprenorphine (1%).

Of the 62% of clients for whom data was available concerning the opioid drug which was associated with their dependence, heroin was the most reported drug (59%), followed by oxycodone (9.2%) and buprenorphine (8.0%). These proportions exclude 'not stated/not reported'. High rates of 'not reported' were recorded in NSW (64%), Victoria (33%) and Tasmania (19%).

Opioid agonist therapy medicines

In 2020, methadone was the most frequently utilised OAT medicine in Australia. Fifty-eight percent (or 31,093 clients) were treated with methadone, 21% (10,950 clients) received buprenorphine/naloxone, 19% (9,970 clients) received buprenorphine, and 2% (1,303) received LAI buprenorphine.[9]

Over the past decade there have been significant changes in national patterns of OAT medicines in use. From 2011 to 2020:

- treatment with methadone fell from 69% of clients to 58%
- treatment with buprenorphine/naloxone increased from 18% of clients to 21%,
- treatment with buprenorphine increased from 14% of clients to 19%.

In 2020, a higher proportion of clients in correctional facilities were prescribed methadone (63% of clients) when compared with clients of private prescribers (60%) and public prescribers (53%). Clients of private prescribers were more likely to be prescribed buprenorphine/naloxone (23%) than those with public prescribers (19%) or those with correctional facility prescribers (8%). Given that clients prescribed buprenorphine/naloxone in NSW are reported only as receiving buprenorphine, the proportion of clients receiving buprenorphine/naloxone nationally is likely to be an underestimate.

Opioid agonist therapy prescribers

In 2020, there were 3,422 authorised prescribers of OAT medicines, a 15% increase since 2016. Of these prescribers, around three in five (61% were authorised to prescribe more than one type of drug. A further 19% were authorised to prescribe methadone only and buprenorphine only (9.4% and 9.7% respectively). The remaining 20% were authorised to prescribe buprenorphine/naloxone only.

Most prescribers worked in the private sector (82%) with the remainder working in the public sector (13%), correctional facilities (3.7%), or a combination of sectors (less than 1%). Sixty- four percent of OAT clients received treatment from a private prescriber, 28% from a public prescriber and eight % from a correctional facility prescriber. Private prescribers treated most clients in NSW, Victoria, WA, SA and Tasmania. Public prescribers treated the majority of clients in Queensland, the ACT and the NT.

8 Data collected for a snapshot day are likely to result in an underestimate of total clients receiving pharmacotherapy within a year because clients go onto and come off OAT. In general, all clients receiving their pharmacotherapy dose in person on the snapshot day are counted.

9 New South Wales does not separately report clients receiving buprenorphine, buprenorphine-naloxone or LAI buprenorphine. These clients are included in the number of clients receiving buprenorphine in NSW.

Between 2016 and 2020, the ratio of clients per prescriber decreased in all jurisdictions except the ACT and the NT. WA had the largest decrease (from 31 to 25 clients per prescriber). In 2020, WA had the highest number of clients per prescriber (25), while Victoria had the lowest (9).

Opioid Agonist Therapy dosing facilities

In 2019-20, there were 3,084 OAT dosing points across Australia, a 40% increase over the last 10 years. Nearly nine in 10 (89%) were in pharmacies, which were the most common dosing point sites in all States and Territories. These proportions are similar to previous years. Pharmacies were the most common dosing points for clients receiving methadone (71%), followed by public clinics (9.8%) and correctional facilities (7.4%). For clients who received buprenorphine, 53% dosed at a pharmacy and 20% dosed at a public clinic. For clients whose pharmacotherapy treatment was buprenorphine/naloxone, pharmacies were the most common dosing point (86% of clients). The proportion of clients dosed with buprenorphine/naloxone may be higher than reported, as clients receiving this treatment in NSW are reported only as receiving buprenorphine. Clients receiving LAI buprenorphine were reported for the first time in 2020, but not all jurisdictions report this as a discrete category.

There was substantial variation in the number of OAT clients dosed at different types of dosing facilities. Private clinics in NSW and Queensland dosed 198 clients per dosing point. Nationally, correctional facilities dosed an average of 104 clients per dosing site[10]; public clinics dosed 91 clients per dosing point, pharmacies 14 clients per dosing point, hospital sites four clients per dosing point, and other sites 10 clients per dosing point.

The majority of dosing points were located in major cities (1,889 or 61% of dosing point sites), followed by inner regional (726 or 24%) and outer regional areas (380 or 12%). When taking the size of the population into account, remote areas had the highest rate of dosing point sites (19 dosing points per 100,000 population), followed by outer regional areas (18 dosing points per 100,000 population) and inner regional areas (16 dosing points per 100,000 population). There were 15 dosing points per 100,000 population in very remote areas, and 10 dosing points per 100,000 population in major cities.

10 This number is inflated as New South Wales and WA report all correctional dosing points as being under two sites each rather than counting individual correctional dosing points. When New South Wales and WA data are excluded, correctional facilities dosed an average of 41 clients across the remaining jurisdictions that supplied data.

CHAPTER 22: A COMPARISON OF OPIOID AGONIST THERAPY BETWEEN AUSTRALIAN JURISDICTIONS

As a result of a range of factors, there are significant differences in the way that OAT programs operate in different Australian jurisdictions.

The following information is drawn from the 2021 National Opioid Pharmacotherapy Statistics Annual Data collection report (Australian Institute of Health and Welfare, 2021), which refers to data drawn from a snapshot day in June 2020.[11]

Rates and patterns of opioid agonist treatment

The rates of OAT utilisation vary substantially between Australian jurisdictions. NSW, followed closely by the ACT, has the highest rates of OAT utilisation, with 28/10,000 of the population and 26/10,000 of the population respectively. This compares with Victoria (22/10,000), SA (17/10,000), Queensland (14/10,000), WA/Tasmania (13/10,000) and the NT (6/10,000). As is evident, NSW has more than 4.5 times the rate of OAT utilisation compared with the NT.

Table 1 shows the numbers of pharmacotherapy recipients, and Table 2 shows population rates of OAT jurisdictions

Table 1. Clients receiving pharmacotherapy treatment on a snapshot day, States and Territories, 2020 (Australian Institute of Health and Welfare, 2021)

NSW	VIC	Qld	WA	SA	Tas	ACT	NT	Australia
22,949	14,968	7,014	3,392	3,037	679	1,120	157	50,597

Table 2. Population rates for clients receiving pharmacotherapy treatment on a snapshot day, 2020, per 10,000 population (Australian Institute of Health and Welfare, 2021)

NSW	VIC	Qld	WA	SA	Tas	ACT	NT	Australia
28	22	14	13	17	13	26	6	21

11 Data collected for a snapshot day are likely to result in an underestimate of total clients receiving pharmacotherapy within a year. In general, all clients receiving their pharmacotherapy dose in person on the snapshot day are counted, but since clients come on to and go off OAT the snapshot measurement would underestimate the total number who received OAT in the year.

There were very substantial variations in patterns of OAT medicine utilisation between jurisdictions.

- methadone administration varied between 68.9% in the ACT and 19.1% in the NT
- buprenorphine administration varied between 37.6% in NSW (which includes buprenorphine and LAI buprenorphine) and 0.8% in SA.
- buprenorphine/naloxone administration varied between 66.9% in the NT and 19.8% in the ACT12
- LAI buprenorphine administration varied between 10.3% in the ACT and 1.3% in SA13.

Client profile

Among the States and Territories, the ACT had the highest rate of Indigenous clients receiving OAT (144 clients per 10,000 Indigenous Australians), followed by Victoria (124/100,000 Indigenous Australians) and New South Wales (122/100,000 Indigenous Australians). The NT had the lowest rate of Indigenous clients, with just four clients per 10,000 Indigenous Australians.

There was little difference in the median age of OAT clients between jurisdictions, ranging from 45 years (SA) and 42 years (Tasmania).

Opioid agonist therapy dosing

There were substantial differences between jurisdictions in the type of sites at which OAT dosing occurred: Public clinics varied between 20.3 percent in NSW and nil in Victoria (national average 9.8 percent)

- dosing at private clinics varied between 11.7% in Queensland and 10.2% in NSW, with nil in all other jurisdictions (national average, 5.9%)
- dosing at pharmacies varied between 93% in the NT and 51% in NSW (national average, 70.8%)
- dosing at correctional facilities varied between 11.4% in the ACT and 1.1% in Queensland (national average, 7.4 percent)
- dosing at other varied between 4.8% Queensland and nil in Tasmania, the ACT and the NT.14

12 This excludes NSW data
13 This excludes NSW and NT data.
14 12.4% of dosing sites in Queensland and 4.8% of sites in NSW were listed as 'not stated'.

CHAPTER 23: OPIOID AGONIST THERAPY IN NEW ZEALAND

In New Zealand (NZ), opioid dependence primarily stems from the use of pharmaceutically sourced products, such as morphine, codeine-based products and methadone, and home- bake heroin. Although heroin is the illicit opioid used most commonly internationally, it has not been widely available in NZ since the 1980s (National Association of Opioid Treatment Providers, NAOTP, 2010).

The key principle underpinning OAT in NZ is the promotion of a tripartite partnership approach between the client, the specialist service or primary care team, and the client's nominated support people (advisors, representatives, peer-support workers, family and whanau [extended family]) (New Zealand Ministry of Health, 2014).

The key to these partnerships are:

- the provision of person-centred and recovery-orientated care
- the need for services to recognise and be influenced by cultural and clinical factors and processes that support positive attitudes aimed at improving tangata whaiora (health and wellbeing)
- the need for services, policies and procedures to reflect the requirements of the various relevant sector standards and to satisfy the provisions of the Health and Disability Services (Safety) Act (2001) and the Code of Health and Disability Services Consumer's Rights (1996) (New Zealand Ministry of Health, 2014)

Opioid agonist therapy programs in NZ aim to assist clients to:

- reduce or cease illicit opioid use
- reduce or cease injecting and the associated risk of blood-borne virus transmission
- reduce overdose risk
- reduce substance-related criminal activity (New Zealand Ministry of Health, 2014)

The programs also aim to provide support to initiate and promote client, family and whānau recovery journeys and access to recovery support systems and networks (New Zealand Ministry of Health, 2014).

The concept of 'recovery' is also influential in shaping OAT in NZ, reflecting trends in the United States and the United Kingdom (Deering, Sellman, & Adamson, 2014). Recovery-oriented OAT has been described as:

> *....an approach to the treatment of opioid dependence that combines methadone pharmacotherapy and a sustained menu of professional and peer-based recovery support services to assist patients and families in initiating and maintaining long-term addiction recovery (White and Mojer-Torres, 2010, as cited in New Zealand Ministry of Health, 2014).*

In NZ, OAT is initially prescribed by addiction services' authorised prescribers, but clients may be transferred to primary care prescribers following a period of stability. Although there is no current

estimate of NZ's opioid dependent population, 5,538 people were receiving OAT in December 2017. Clients usually consume OAT medicines (primarily methadone or buprenorphine/naloxone) at a community pharmacy most days of the week under the supervision of a pharmacist. In 2018, there were 1,000 community pharmacies in NZ, and 60% had a contract to provide opioid substitution treatment (Lukey, Gray, & Morris, 2020). Opioid agonist therapy is publicly funded in NZ and is available in NZ prisons (New Zealand Ministry of Health, 2019).

PHARMAC, the NZ pharmaceutical benefits scheme, has funded Suboxone® for OAT since July 2012, and there was a steady increase in the number of people prescribed this medicine after that time (New Zealand Ministry of Health, 2019).

Opioid agonist therapy clients in NZ are ageing. In 2017, 61.1% of clients were over 45 years, with only two services nationally with fewer than 50% of clients over 45 years of age (New Zealand Ministry of Health, 2019)

Opioid agonist therapy is provided in NZ in accordance with the Misuse of Drugs Act 1975. Specialist OAT services, or gazetted primary health care teams, are specified by the Minister of Health under Section 24 of the Misuse of Drugs Act 1975 and notified in the New Zealand Gazette. The Director of Mental Health is responsible for approving qualified practitioners to prescribe controlled drugs for the treatment of drug dependence under Section 24 of the Misuse of Drugs Act 1975 (New Zealand Ministry of Health, 2014).

In NZ, the roles of specialist opioid agonist services include (but are not limited to):

- comprehensive assessment for substance use and related issues
- individualised treatment planning within an integrated recovery and wellbeing focused model
- stabilisation on an adequate individualised dose of OAT medication
- provision of specialist interventions to minimise the harms associated with continued opioid and other substance use
- recovery planning and provision of appropriate psychosocial support to assist clients and their families and whānau to build and maintain recovery capital
- facilitating the transfer of stabilised clients to the care of their primary care provider
- screening, advice and treatment, or referral for treatment, for clients with co-existing medical problems
- assessment and treatment or referral for treatment of clients with co-existing mental health problems
- consultation with and referral to health care and social service providers, including peer support and advocacy services
- assisting clients to withdraw from OAT medication as appropriate (New Zealand Ministry of Health, 2014).

Authorised general practitioners (GPs) must prescribe the OAT medication in accordance with written terms and conditions defined by the specialist service in relation to the specified clients. The GPs are expected to undertake training in managing clients receiving OAT. At a minimum, this involves attendance at training provided by the local specialist service, and completion of the National Opioid Substitution Treatment Providers' Training Programme. There are formalised, agreed relationships in place between authorised GPs and specialist services, and specialist services have protocols for providing advice and consultation to these GPs (Ministry of Health. 2014; National. Association of Opioid Treatment Providers, 2010).

All pharmacy staff regularly involved in the provision of OAT must undergo training. At a minimum, this should involve completion of the *Training Programme for Opioid Substitution Treatment Providers*.

CHAPTER 24: OPIOID AGONIST THERAPY IN CANADA

Opioid use disorder is one of the most challenging forms of substance misuse problems facing the Canadian health care system, with marked rises in opioid-related mortality, particularly since the first half of 2018. The evolving landscape of non-medical opioid use has become increasingly dominated by prescription opioids diverted from the medical system, and more recently, by highly potent, illicitly manufactured synthetic opioids such as fentanyl and its analogues, including carfentanyl. The most recent estimate available of seized controlled substances in Canada (July to September 2020) ranked fentanyl as the most commonly detected opioid seized (Government of Canada, 2021).

Canada faces several key challenges in addressing opioid-related substance use problems, including:

- accessibility to treatment in rural and remote areas
- the rate of hospital admissions related to prescribed opioid poisonings
- a rise in injection of prescription opioids
- the rising rate of apparent opioid-related overdose deaths
- the lack of implementation of evidence-based interventions for treatment of opioid use disorder (Bruneau et al., 2018; Eibl, Morin, Leinonen, & Marsh, 2017).

In May 2018, Canada made significant changes to OAT to more effectively meet these challenges (Bruneau et al., 2018).

The Canadian Clinical Practice Guideline for the management of opioid use disorders recognises that opioid use disorder is often a chronic relapsing condition associated with increased morbidity and death. Nevertheless, the Guideline highlights that with appropriate treatment and follow-up, individuals can achieve sustained long-term remission. This can be achieved by providing:

- collaborative patient-centred care that accommodates patient preferences
- opioid agonist treatment with buprenorphine as the preferred first-line treatment for opioid dependence
- a stepped and integrated care approach, in which treatment intensity is continually adjusted to accommodate individual patient needs and circumstances over time, and recognises that many individuals may benefit from the ability to move between treatments (Bruneau et al., 2018).

Health Canada, the Federal Health Department, primarily controlled methadone regulation until the mid-1990s. Since this time, Health Canada has been transferring OAT oversight to provincial regulatory bodies in order to free up access to the therapy (Canadian Agency for Drugs and Technologies in Health, (CADTH) 2019; Eibl et al., 2017; Priest et al., 2019). At present, these regulatory bodies oversee and control OAT practice for most of the population. Health Canada has retained control and oversight of delivery for First Nations people living on reserves and for people who are incarcerated in Federal correctional facilities (CADTH, 2019).

Each Canadian Province and Territory has individual OAT programs with different policies and practices. As a result, there is considerable variation in opioid dependence treatment across the country. In recent years, Canada has experienced increases in opioid dependence treatment capacity, especially in British Columbia and Ontario. Treatment options have also expanded, with buprenorphine/naloxone and heroin- and hydromorphone-assisted treatment becoming available, in addition to methadone (CADTH, 2019).

Diacetylmorphine, or pharmaceutical-grade heroin and injectable hydromorphone can also be prescribed in Canada when a patient with an opioid use disorder which has not responded to other forms of treatment, such as methadone, or buprenorphine/naloxone. Before May 2018, the dispensing and administration of diacetylmorphine was restricted to hospital settings. Therefore, clients who were receiving diacetylmorphine treatment were required go to a hospital to receive it, even if that meant returning to the hospital multiple times a day. Health care providers can now offer this treatment outside a hospital setting, which greatly improves accessibility. Nurse practitioners are also authorised to prescribe diacetylmorphine if this is permitted under the laws of their Province or Territory (Health Canada, 2018).

In May 2019, Health Canada announced changes to increase the accessibility of diacetylmorphine and hydromorphone, and in September 2019, a national clinical guideline for diacetylmorphine and hydromorphone use was released. Diacetylmorphine provision is highly regulated in Canada, with rules for importation, compounding, storage, and dispensing (Centre for Addiction and Mental Health, (CAMH), 2021, CADTH, 2019; Eibl et al., 2017; Priest et al., 2019).

Provision of diacetylmorphine and hydromorphone in Canada is largely limited to individual providers, with a small number of clinicians providing access in Vancouver, Surrey, Calgary, London, Toronto, Ottawa, and selected other settings. Significant financial, structural and practical barriers impede access to diacetylmorphine and hydromorphone for the majority of opioid users who would most benefit from them (Maghsoudi, Bowles, & Werb, 2020).

Extended-release monthly injections or 6-month subdermal buprenorphine implants are also available for clients who are clinically stable. These approaches are particularly used for clients who:

- would benefit from less frequent medication administration
- are comfortable with an invasive procedure or device
- do not want to administer medications sublingually
- have drug private health coverage if the medication is not covered by public health insurance (CAMH, 2021).

Family physicians and psychiatrists provide the majority of OAT in Canada. Opioid agonist therapy is generally provided in:

- provincially funded addiction program clinics, with comprehensive services provided by a variety of disciplines
- a physician's office, subsidised by a Provincial funding stream
- federal or provincial correctional facilities (CADT, 2019).

Dispensing usually occurs at a clinic, a physician's office, or at a pharmacy (CADT, 2019).

Practitioners and pharmacists are required to meet all applicable provisions of the Narcotic Control Regulations, as well as the requirements established by their Province or Territory or

licensing authority governing their practice when dealing with controlled substances. - Examples of such requirements include additional courses or training (CADT, 2019).

Indigenous Services Canada provides OAT for First Nation, Métis, and Inuit patients for whom the preferred first-line medication is buprenorphine/naloxone (Bruneau et al., 2018).

Opioid agonist therapy is not widely available in Canadian prisons (Bodkin, Bonn, & Wildeman, 2020).

Opioid agonist therapy in Canada is usually multidisciplinary in nature, often combining both pharmacotherapy and psychosocial therapy. Some Canadian jurisdictions have developed Rapid Access to Addictions Medicine (RAAM) clinics, which are low-barrier, walk-in clinics that can help guide patients though substance use treatment and connect them with other services. Some jurisdictions use a hub-and-spoke model of care. In this model, a centralised 'hub' is a specialised clinic that carries out induction and stabilisation and manages clients with complex needs. After stabilisation, patients are then referred to primary care clinics (the 'spokes') to continue treatment. Following stabilisation, patients are generally eligible to receive take-away doses (Eibl et al., 2017).

Telehealth is also used for patients with opioid dependence, as it facilitates connections both between providers and patients, and between providers and other providers, for opioid treatment programs. Appointments for initiation and maintenance of treatment are conducted via teleconference and an individualised treatment plan is then developed. Medication is provided at a pharmacy in the patients' communities. This is particularly useful approach in remote areas, because the demand for treatment has increased far beyond the capacity of the treatment system in these areas (Bruneau et al., 2018; Eibl et al., 2017).

CHAPTER 25: OPIOID AGONIST THERAPY IN PORTUGAL

Since 2014 in Portugal, healthcare for people with drug problems has been provided by the Referral Network for Addictive Behaviours and Dependencies (RNABD). The Network encompasses public specialised treatment services for illicit substance dependence, under the authority of Regional Health Administrations of the Ministry of Health, NGOs and other public or private treatment services. The RNABD ensures ready access to quality-controlled services and integrates with other non-health agencies, to support this vulnerable population. These services are provided free of charge and are accessible to all those who seek treatment for drug problems. The network has three levels of care:

- primary healthcare services
- specialised care, mainly in outpatient settings
- differentiated care, mainly in inpatient settings (detoxification units, therapeutic communities, day centres and/or specialised mental or somatic healthcare).

Although the model accepts that clients can enter treatment at any of these levels, most clients enter treatment through first-level services, that is, primary healthcare (European Monitoring Centre for Drugs and Drug Addiction [EMCDDA], 2019).

The underpinning principles of OAT in Portugal are that:

- a comprehensive diagnosis of each citizen's full biopsychosocial needs is required
- services should be accessible and adaptable
- services should be based on scientific evidence in terms of effectiveness, efficiency and quality, and be underpinned by guidelines (EMCCDA, 2019)

Opioid agonist treatment is widely available in Portugal, through public services such as specialised treatment centres, health centres, hospitals and pharmacies, as well as non-government organisations and non-profit organisations. Methadone has been available for OAT since 1977 and buprenorphine since 1999. Methadone treatment can be initiated in treatment centres and buprenorphine treatment can be initiated by any generalist or specialist medical doctor or treatment centre. Methadone is available free of charge to clients, while buprenorphine-based medications are available in pharmacies, with the National Health Service covering 40 % of the market price (EMCCDA, 2019).

In 2019, 16,867 persons were receiving OAT in Portugal. The number of OAT clients decreased between 2010 and 2013 and has been relatively stable since. Clients are treated in prisons, outpatient services and, less commonly, inpatient services. Sixty-six per cent of OAT clients receive methadone and 34% buprenorphine (EMCCDA, 2021).

Lisbon also has a mobile methadone program. This program is staffed by a doctor who consults with patients and administers medication, a nurse, and two other workers who provide education on such topics as safer drug consumption and safe sex. The two mobile units, which are accessed by self-referral, visit five sites across Lisbon, providing methadone to 1,200 people daily. New patients undertake a urine drug screen and simple interview process to access the program and are generally started on a 30 mg dose of methadone. This dosage can be increased up to 50

mg and then up to 120 mg over time. There is no requirement for daily attendance or abstinence from heroin, although if two doses are missed, the protocol is to drop the dose by one-third. As well as providing methadone, the staff also screen for infectious diseases, exchange needles, offer condoms and distribute medication for mental disorders, HIV and hepatitis. The program describes itself as low-threshold, meaning that individuals are not required to abstain from drugs to use its services (Clay, 2018; Queensland Mental Health Commission, 2018).

Prisoner healthcare is managed by health services under the responsibility of the Ministry of Justice, in partnership with the National Health System. Medication assisted treatment programs (with opioid agonists and antagonists) can be provided in each prison by internal clinical staff, or by the appropriate regional health administrations. At the end of 2017, approximately 1,000 prisoners were enrolled in pharmacological treatment programs in Portuguese prisons. In the past five years, there has been a downward trend in the number of inmates participating in drug treatment programs (both abstinence oriented and those providing pharmacological treatment). This may be related to a reduction in the number of opioid users in general, as evidenced by the recent national prison survey (EMCDDA, 2019).

CHAPTER 26: OPIOID AGONIST THERAPY IN THE UNITED KINGDOM (UK) (ENGLAND, WALES, SCOTLAND & NORTHERN IRELAND)

Substance misuse services are commissioned by local authorities in England, by local health boards in Scotland, by community safety partnerships in Wales and by drug and alcohol coordination teams in Northern Ireland. Contracts to deliver drug treatment services are often held by third-sector organisations such as registered charities. Local agencies across the UK are expected to provide a wide range of services, including provision of information and advice, screening, care planning, psychosocial interventions, community prescribing, inpatient drug treatment, and residential rehabilitation. In addition, people seeking treatment for drug problems are offered aftercare and relapse prevention programmes, HBV vaccination, testing for HBV, HCV and HIV, and access to hepatitis and HIV treatment (European Monitoring Centre for Drugs and Drug Addiction, EMCDDA, 2019).

Opioid agonist therapy in the UK is intended to be:

- well-delivered and evidence-based
- locally delivered and needs-based (as a result of devolution of responsibility to local areas)
- delivered in partnership, working across health and social care and between hospitals, prisons, primary care and community drug services
- delivered by staff with a range of competencies
- involve both patient and carer (Independent Expert Working Group: Drug misuse and dependence, [IEWG], 2017)

Opioid agonist therapy remains the most common treatment for opioid dependence in the UK. It is mainly offered through specialist outpatient drug services, commonly in shared care arrangements with general practitioners. It is also widely available through public services such as specialised treatment centres, health centres, hospitals, pharmacies, NGOs and non-profit organisations, and prisons (EMCCDA, 2019).

In 2017, approximately 150,000 patients were receiving OAT in England and Wales. Since 2010, the number of OAT clients has decreased, but remains above 2006 levels. Oral methadone is the most commonly prescribed OAT drug (66%), although the use of buprenorphine (34%) has been steadily increasing since it became available in 1999. Prescribed injectable methadone and diacetylmorphine are also available in England, but are rarely provided (EMCCDA, 2019). In 2017-18 there were only 280 people in the UK receiving pharmaceutical heroin (Gregory, 2019).

In the UK there are two types of OAT prescribers, medical prescribers and non-medical prescribers (Independent Expert Working Group, 2017). Medical prescribers have three levels of competency:

- generalists who are able to provide OAT in uncomplicated cases
- generalists with additional qualifications, skills and experience in prescribing OAT who care for more challenging patients
- specialists in addiction medicine who undertake complex prescribing, such as injectable OAT (Royal College of Psychiatrists and Royal College of General Practitioners, 2012).

Non-medical prescribers (NMP) are usually nurses and pharmacists who can assess, diagnose and independently prescribe opioids for the treatment of drug dependence, with the exception of diamorphine. There are two categories of non-medical prescribing:

- *Independent prescribing*
  - Carried out by clinicians who are responsible and accountable for assessing patients with both undiagnosed or diagnosed conditions, and for deciding the clinical management required, including prescribing. Independent prescribers can prescribe licensed or unlicensed medicines within their clinical competence. Independent NMPs have the same responsibilities and accountabilities as medical prescribers.
- *Supplementary prescribing*
  - Involves a partnership between an independent prescriber and a supplementary prescriber (nurse, midwife or pharmacist) to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement.
  - The independent prescriber makes the initial diagnosis, then both prescribers prepare and agree the individualised CMP. Non-medical prescribers can then prescribe within the parameters set out in the CMP.
  - Since legislative changes in June 2012, supplementary prescribing is being superseded by independent prescribing (Independent Expert Working Group, 2017).

CHAPTER 27: OPIOID AGONIST THERAPY IN THE UNITED STATES OF AMERICA

In the United States of America (USA) OAT is known as 'medication assisted treatment' (MAT). The FDA approved medications for use in treating opioid use disorder are methadone, buprenorphine (buprenorphine with naloxone) and naltrexone (Alderks, 2017).

The Substance Abuse and Mental Health Services Administration (SAMHSA) has oversight of MAT in the USA. There are two settings in which OAT may be prescribed, opioid treatment programs (OTP) and office-based independent prescribers (office based opioid treatment, OBOT). Methadone for opioid dependence can only be provided from OTPs that have been certified by SAMHSA. Federal law requires that patients who obtain treatment in an OTP receive medical, counselling, vocational, educational and other assessment and treatment services, in addition to prescribed medication. Treatment protocols require that a client take the medication at the clinic where it is dispensed daily. Take-home dosages generally are allowed only for clients who have been on a program for an extended period of time (Alderks, 2017).

The use of take-home methadone must meet explicit Federal requirements. In addition, correctional facilities providing methadone must be a Federally licensed OTP or work in partnership with an OTP. Further, OTP regulations require physicians to be the medical director and mandate that a licensed professional (pharmacist, registered nurse, licensed practical nurse, or any other healthcare professional authorised to administer pharmaceuticals) dispense the medication (Priest et al., 2019). Additional layers of regulations are imposed by the Drug Enforcement Administration (a Federal agency that has authority to conduct on-site visits of OTPs) and by the respective State opioid treatment authority (McElrath, 2018).

The number of OTPs in the US increased from approximately 1,100 in 2003 to almost 1,500 by the end of 2016. The number of clients receiving methadone increased from about 227,000 in 2003 to 356,843 in 2015 (Alderks, 2017).

Office-Based Independent Opioid Treatment providers are practitioners with a 'buprenorphine waiver' who can prescribe buprenorphine in office-based settings, only for detoxification and/or maintenance therapy purposes. Qualified practitioners include physicians, nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anaesthetists, and certified nurse-midwives. Qualified practitioners can treat up to 100 patients in the first year if they possess a waiver. Although the majority of buprenorphine providers are office-based practitioners, OTPs can also provide buprenorphine treatment (Substance Abuse and Mental Health Services Administration, 2021).

The number of OTPs offering buprenorphine increased from 121 OTPs (11%) in 2003, to 779 OTPs (58%) in 2015. In 2003, among non-OTP facilities about 5% (620 facilities) offered buprenorphine services, but by 2015, this had increased to 21% (2,625 facilities) (Alderks, 2017).

Opioid agonist therapy in the US has been described as a 'high threshold, low tolerance' model. High threshold refers to a range of structural and programmatic barriers that can impede peoples' access to OAT. These structural barriers include rigid criteria and long wait times for admission,

high fees and limited treatment availability. Low tolerance denotes the various programmatic and regulatory policies that hinder patients' progress after they initiate MAT. The low tolerance component of the model is often tied to MAT attrition (McElrath, 2018).

The USA has significant gaps between treatment need and capacity at the State and national levels (Jones et al., 2015). Of the approximately 2.1 to 2.4 million individuals with opioid use disorder in the USA, only about 20% receive any treatment for their disorder. Of those, only one-third receive medications during a given care episode and retention is only 30% to 50% in most settings. As a result of these challenges, only about 50,000 (2%) of individuals with opioid use disorder in the USA achieve long-term remission (Blanco & Volkow, 2019).

Opioid agonist treatment is restricted to people who have had an opioid use disorder for at least one year. Most programs are located in urban areas, with 26% of patients travelling 15 miles or more to access OAT, and eight % travelling from another State (McElrath, 2018). The cost to clients varies between States. Out-of-pocket payments are between $42 and $166 a week for methadone, and higher for buprenorphine/naloxone treatment (Peddicord et al., 2015, as cited in McElrath, 2018). Patients requiring ancillary support services can be required to pay additional fees. Several States, as well as programs within States, do not permit Medicaid payments for OAT. Several health insurance companies do not cover the cost of treatment provided by an OTP (McElrath, 2018).

CHAPTER 28: CONCLUSION

Opioid agonist therapy has made, and continues to make, a substantial contribution to the lives of many individuals and to public health in Australia. The evidence base regarding the efficacy of OAT is substantial. The evidence spans the domains of: treatment effectiveness for opioid use disorder (Mattick, Breen, Kimber, & Davoli, 2009); blood-borne disease prevention (Lawrinson et al., 2008); overdose death and all-cause mortality (Shanahan, Hetherington, Mattick, & Weatherburn, 2007); and reincarceration (Larney et al., 2012).

The development of OAT programs has varied significantly between Australian jurisdictions, and so too do current practices associated with the provision of OAT vary between jurisdictions. These differences include: the OAT medications predominantly used; the population prevalence of OAT provision; regulatory arrangements; and the division of prescribing and dispensing activities between the public and private sectors. The federated nature of Australia's governments has contributed to these variations, as have differing profiles of drug problems and differing funding models.

In response to these differences, *Australia's National Guidelines for Medication-Assisted Treatment of Opioid Dependence* (MATOD) (Gowing et al., 2014) provides a broad policy context and a framework for MATOD in this country. The guidelines seek to establish national consistency in approach, while acknowledging different jurisdictional responsibilities for health care, and legislative requirements relating to controlled substances.

This flexibility in OAT is characteristic of the development of OAT in Australia. One of the great strengths of the Australian approach to OAT has been that that there was no attempt to dictate to prescribers that they must utilise one OAT medicine for all clients. As a result, the OAT system in Australia has developed based on providing the OAT agent that best suits the needs of individual clients.

General practice is an ideal setting for the safe and effective provision of OAT to most patients. Potential benefits include improved patient capacity, accessibility, cost effectiveness, reintegration, and the ability to provide comprehensive care for patients with medical and psychiatric co-morbidities (Holliday et al., 2012).

Yet despite evidence of efficacy and its suitability to general practice, OAT is not widely adopted by Australian medical practitioners. In 2020, there were 3,422 registered opioid pharmacotherapy prescribers in Australia (Australian Institute of Health and Welfare, 2021). In 2021, there were 128,003 medical practitioners in Australia[15] and 42,941 general practitioners (Medical Board Australian Health Practitioner Regulation Agency, 2021). In other words, only 2.7% of Australian medical practitioners are registered opioid pharmacotherapy prescribers. By contrast, in France for example, most cases of opioid use disorder are treated with buprenorphine by general practitioners in private practice, with the medication dispensed exclusively in community (Dupouy et al., 2017). In 2015 in France, 58% of private general practitioners prescribed OAT (Dupouy, Maumus-Robert, Mansiaux, Pariente, & Lapeyre-Mestre, 2020).[16]

There is a range of reasons why there is not a broader base of OAT prescribing in Australia. Prominent among these are jurisdiction-based restrictions and regulations. These include lengthy approval and administrative processes, the requirement for additional provider training, and the

15 This includes 3,940 medical practitioners on the Pandemic Response Sub-Registers.

16 However, there has been a decrease in the number of GPs initiating OAT over recent years, leading to concentration of OAT patient management among a limited number of prescribers.

burden of regular training updates. In addition, these restrictions signal to potential prescribers that OAT is difficult, dangerous and to be avoided. This perpetuates a professional fear that OAT is too risky to prescribe, as a result of concerns about medico-legal consequences or patient harms (Prathivadi & Sturgiss, 2021).

Yet OAT is relatively simple to prescribe and generally involves use of protocol-driven regimes involving pharmacist and prescriber collaboration. Therefore, key priorities to increase OAT prescribing are addressing physician fears and reducing the administrative burden without compromising the quality of patient care (Prathivadi & Sturgiss, 2021).

A possible reason for this negative view of OAT is that buprenorphine was initially, at least, introduced into Australia using the same service delivery systems as methadone. This is despite the fact that as a partial agonist, buprenorphine is a safer opioid than methadone, with less potential for over-sedation, respiratory depression and overdose. As a result, there is a risk that buprenorphine, including buprenorphine/naloxone and LAI buprenorphine, is being viewed through a 'methadone lens'.

Optimising the benefits of OAT requires a balance between access and quality. Making a drug widely available improves access, but may compromise the quality and safety of treatment, in the absence of appropriate quality control measures. Restricting a drug to use only in specialist settings limits its usefulness as an intervention. In general, the balance between accessibility and quality is best maintained when general practitioners are trained to prescribe pharmacotherapies and can refer patients to, or consult with, specialist drug and alcohol services. Access will be optimal when the model of service delivery involves general practitioners and other health service providers, supported by specialist drug and alcohol services, with jurisdictional monitoring and regulation (Gowing et al., 2014).

Basic upskilling could sufficiently equip Australian GPs and pharmacists to confidently follow OAT protocols, particularly those associated with the buprenorphine products. This training could be delivered through existing accredited online continuing professional development webinars, conferences or weekend workshops, and GP training. There have been calls for the treatment of opioid use disorder to be an essential skill for GPs, analogous to contraceptive implant insertion, asthma prevention, and treatment and management of diabetes (Prathivadi & Sturgiss, 2021).

Opioid agonist therapy in Australia faces a number of challenges, in addition to the need to increase the number of prescribers.

Stigma remains a major impediment both to clients accessing (Hall et al., 2021) and to practitioners providing the treatment (Longman, Temple-Smith, Gilchrist, & Lintzeris, 2012). The stigma associated with being on OAT, particularly when coupled with other stigmatising client characteristics, is a major factor that stands in the way of normalising OAT in primary health care. It is a key issue to be addressed in the Australian context.

A further challenge is the dispensing costs to clients. Opioid use disorder is a chronic relapsing condition. Yet consumers with other such conditions, such as diabetes, hypertension and smoking-related illness, are not required to pay dispensing costs for their medicines, nor are recipients of other opioids used in the treatment of pain. These patients may have to pay for, or make a contribution towards the cost of their medicines, but they do not have to pay for dispensing. A person with a health care card may pay only a few dollars per month for their prescription of an opioid such as oxycodone, yet a person with a health care card on OAT may pay up to $70 per week for their medication. This is clearly inequitable and a significant impediment to engagement and retention in OAT (Ezard et al., 1999; Penington Institute, 2015).

These problems notwithstanding, OAT coverage in Australia is compares favourably with many other countries (Larney et al., 2017; Uba, Onwuchekwa, & Kofi Park, 2020). Nevertheless, unmet opioid treatment demand remains a problem in Australia (Ritter et al., 2019).

In Australia, as in other parts of the world, OAT has come from relatively basic beginnings as small innovative programs and has evolved over time in various ways across jurisdictions. Factors impacting OAT dissemination and uptake have included increased evidence of clinical efficacy over time, public health threats such as blood-borne diseases, influential policy-makers and clinicians, and serendipitous events.

The developing evidence base concerning effective approaches to OAT has been a major influence on shaping OAT in Australia. Australian researchers have made a major contribution to the development of this evidence base. So too, it is important to recognise the contribution made by the pioneers of OAT in Australia, who persevered with OAT during its darkest hours.

Without the efforts of these pioneers, and those who followed, the harms associated with illicit drug use in Australia would have been very much greater.

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